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Abstract

Contrast-enhanced ultrasound and/or colour duplex ultrasound for surveillance after endovascular abdominal aortic aneurysm repair: a systematic review and economic evaluation

Miriam Brazzelli,[1]* Rodolfo Hernández,[2] Pawana Sharma,[1] Clare Robertson,[1] Michal Shimonovich,[1] Graeme MacLennan,[1] Cynthia Fraser,[1] Russell Jamieson[3] and Srinivasa Rao Vallabhaneni[4]

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Background: Endovascular abdominal aortic aneurysm repair (EVAR) of abdominal aortic aneurysm (AAA) is less invasive than open surgery, but may be associated with important complications. Patients receiving EVAR require long-term surveillance to detect abnormalities and direct treatments. Computed tomography angiography (CTA) has been the most common imaging modality adopted for EVAR surveillance, but it is associated with repeated radiation exposure and the risk of contrast-related nephropathy. Colour duplex ultrasound (CDU) and, more recently, contrast-enhanced ultrasound (CEU) have been suggested as possible, safer, alternatives to CTA.

Objectives: To assess the clinical effectiveness and cost-effectiveness of imaging strategies, using either CDU or CEU alone or in conjunction with plain radiography, compared with CTA for EVAR surveillance.

Data sources: Major electronic databases were searched, including MEDLINE, EMBASE, Science Citation Index, Scopus' Articles-in-Press, Cochrane Central Register of Controlled Trials (CENTRAL), Database of Abstracts of Reviews of Effects (DARE) and NHS Economic Evaluation Database from 1996 onwards. We also searched for relevant ongoing studies and conference proceedings. The final searches were undertaken in September 2016.

Methods: We conducted a systematic review of randomised controlled trials and cohort studies of patients with AAAs who were receiving surveillance using CTA, CDU and CEU with or without plain radiography. Three reviewers were involved in the study selection, data extraction and risk-of-bias assessment. We developed a Markov model based on five surveillance strategies: (1) annual CTA; (2) annual CDU; (3) annual CEU; (4) CDU together with CTA at 1 year, followed by CDU on an annual basis; and (5) CEU together with CTA at 1 year, followed by CEU on an annual basis. All of these strategies also considered plain radiography on an annual basis.

Results: We identified two non-randomised comparative studies and 25 cohort studies of interventions, and nine systematic reviews of diagnostic accuracy. Overall, the proportion of patients who required reintervention ranged from 1.1% (mean follow-up of 24 months) to 23.8% (mean follow-up of 32 months). Reintervention was mainly required for patients with thrombosis and types I–III endoleaks. All-cause mortality ranged from 2.7% (mean follow-up of 24 months) to 42% (mean follow-up of 54.8 months). Aneurysm-related mortality

occurred in < 1% of the participants. Strategies based on early and mid-term CTA and/or CDU and long-term CDU surveillance were broadly comparable with those based on a combination of CTA and CDU throughout the follow-up period in terms of clinical complications, reinterventions and mortality. The economic evaluation showed that a CDU-based strategy generated lower expected costs and higher quality-adjusted life-year (QALYs) than a CTA-based strategy and has a 63% probability of being cost-effective at a £30,000 willingness-to-pay-per-QALY threshold. A CEU-based strategy generated more QALYs, but at higher costs, and became cost-effective only for high-risk patient groups.

Limitations: Most studies were rated as being at a high or moderate risk of bias. No studies compared CDU with CEU. Substantial clinical heterogeneity precluded a formal synthesis of results. The economic model was hindered by a lack of suitable data.

Conclusions: Current surveillance practice is very heterogeneous. CDU may be a safe and cost-effective alternative to CTA, with CTA being reserved for abnormal/inconclusive CDU cases.

Future work: Research is needed to validate the safety of modified, more-targeted surveillance protocols based on the use of CDU and CEU. The role of radiography for surveillance after EVAR requires clarification.

Study registration: This study is registered as PROSPERO CRD42016036475.

Funding: The National Institute for Health Research Health Technology Assessment programme.

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AAA	abdominal aortic aneurysm
AMSTAR	Assessment of Multiple Systematic Reviews
ASERNIP-S	Australian Safety and Efficacy Register of New Interventional Procedures – Surgical
BSIR	British Society of Interventional Radiologists
CDSR	Cochrane Database of Systematic Reviews
CDU	colour duplex ultrasound
CEAC	cost-effectiveness acceptability curve
CENTRAL	Cochrane Central Register of Controlled Trials
CEU	contrast-enhanced ultrasound
CI	confidence interval
CRD	Centre for Reviews and Dissemination
CT	computerised tomography
CTA	computed tomography angiography
DARE	Database of Abstracts of Reviews of Effects
ENGAGE	Endurant Stent Graft Natural Selection Global Postmarket Registry
EQ-5D	EuroQol-5 Dimensions
EUROSTAR	The EUROpean collaborators on Stent–graft Techniques for abdominal aortic Aneurysm Repair
EVAR	endovascular abdominal aortic aneurysm repair
HTA	Health Technology Assessment
ICER	incremental cost-effectiveness ratio
ICTRP	International Clinical Trials Registry Platform
IQR	interquartile range
ITT	intention to treat
KPNC	Kaiser Permanente Northern California
KPSGR	Kaiser Permanente Endovascular Stent Graft Registry
MeSH	medical subject heading
NHS EED	NHS Economic Evaluation Database
NICE	National Institute for Health and Care Excellence
NVR	National Vascular Registry
PSV	peak systolic velocity
QALY	quality-adjusted life-year
RCT	randomised controlled trial
ReBIP	Review Body for Interventional Procedures
SD	standard deviation

Plain English summary

An abdominal aortic aneurysm is a swelling of the lower part of the major blood vessel that supplies blood to the body. A type of keyhole surgery (called endovascular abdominal aortic aneurysm repair) can be used to repair the aneurysm, but it can cause some complications to the patient. People are, therefore, followed up (surveillance) for a very long time after surgery so that complications can be identified and treated appropriately. Follow-up includes taking images of the abdomen with technologies like computed tomography angiography (CTA) or ultrasound – either colour duplex ultrasound (CDU) or contrast-enhanced ultrasound (CEU) – or a combination of these techniques. CTA is considered to be accurate, but it carries the risk of repeated exposure to radiation and a potentially unpleasant contrast agent. Ultrasound has been suggested as a possible, safer, alternative, but it is currently not used in all hospitals. It is therefore unclear which type of imaging technique is best. How frequently imaging tests should be carried out is also unclear. We assessed the current evidence on the use and costs of the two types of ultrasound (CDU and CEU) compared with CTA. We identified 27 studies, mainly of poor or moderate quality, that reported different types of follow-up after aneurysm surgery. Because the studies were very different, we could not combine data or draw firm conclusions. The economic evaluation showed that CDU was the best value for money for the NHS for people at a normal level of risk of developing complications. CTA was the next-best value and CEU was the least-best value for money. CDU might therefore be an appropriate alternative to CTA for the long-term follow-up of some patients after aneurysm surgery, but there is a need to identify how often imaging should occur, taking a person's individual risk of developing complications into consideration.

Scientific summary

Background

Endovascular abdominal aortic aneurysm repair (EVAR) consists of placing a stent–graft within the aneurysm via the femoral arteries. The purpose of the stent–graft is to reduce the risk of rupture by excluding the aneurysm from the influences of blood flow and blood pressure. Failure to obtain, or maintain, aneurysm exclusion, such that blood leaks into the aneurysm sac, is seen as a failure of the technique and is called 'endoleak'. Although less invasive than open surgery, with a lower perioperative mortality rate, EVAR is associated with important complications, such as different types of endoleaks, stent–graft migration, distortion or kinking of the stent–graft, structural disintegration of the stent–graft and stent–graft thrombosis. Any complication leading to a loss of aneurysm exclusion risks the failure of treatment in the form of aneurysm rupture, whereas any complication leading to stent–graft thrombosis risks the failure of supplying blood to the patient's legs. Post-EVAR surveillance is performed to detect complications and direct treatments with adequate surveillance relying on appropriate imaging strategies. Since the development of EVAR, computed tomography angiography (CTA) has been the most common modality adopted for surveillance; however, its use is associated with repeated radiation exposure and with the risk of contrast nephropathy. Modified surveillance protocols have recently been proposed as a way to minimise radiation exposure by eliminating unnecessary CTA examinations. Colour duplex ultrasound (CDU) and, more recently, contrast-enhanced ultrasound (CEU) have been suggested as possible, safer, alternatives to CTA.

Objective

To assess the current evidence for the clinical effectiveness and cost-effectiveness of strategies using either CDU or CEU alone or in conjunction with plain radiography compared with CTA for surveillance after EVAR.

Methods

Clinical effectiveness

Ovid MEDLINE Epub Ahead of Print, MEDLINE In-Process & Other Non-Indexed Citations, Daily and Ovid MEDLINE, EMBASE, Science Citation Index, Scopus' Articles-In-Press, Cochrane Central Register of Controlled Trials (CENTRAL), Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects and the Health Technology Assessment (HTA) database were searched from 1996 onwards to identify reports of studies of interventions and systematic reviews of diagnostic studies.

The World Health Organization's International Clinical Trials Registry Platform, Current Controlled Trials, and Clinical Trials.gov were also searched for ongoing studies, clinical experts and relevant websites were consulted and reference lists were perused.

Clinical effectiveness evidence was considered from randomised controlled trials, non-randomised comparative studies and/or prospective and retrospective cohort studies of different imaging modalities and follow-up strategies. In particular, we assessed the relative effectiveness of CEU or CDU, used alone or in conjunction with plain radiography, for the long-term surveillance following EVAR. The comparator modality was CTA. The population considered were adults undergoing surveillance following EVAR for abdominal aortic aneurysm (AAA).

Two reviewers independently selected studies for inclusion. One reviewer completed data extraction and assessed the risk of bias of included studies, and two reviewers independently cross-checked the details extracted by the first reviewer. A formal meta-analysis and metaregression of outcome data proved to be unfeasible, owing to the dearth of relevant comparative studies. Outcome data are summarised descriptively.

Cost-effectiveness

The evidence on cost-effectiveness was explored using a two-step approach: (1) a systematic review of economic evaluations, followed by (2) a de novo decision-analytic model.

The NHS Economic Evaluations Database, the HTA database, MEDLINE In-Process & Other Non-Indexed Citations, Epub Ahead of Print, EMBASE and Research Papers in Economics were searched from 1996 onwards for relevant economic evaluations. Clinical experts and relevant websites were consulted and reference lists were scanned. The titles and abstracts of all of the identified citations were screened by one reviewer. The full-text papers of potentially relevant studies were retrieved and assessed for inclusion.

A Markov model was developed to include five surveillance strategies:

1. annual CTA plus plain radiography
2. annual CDU plus plain radiography
3. annual CEU plus plain radiography
4. colour duplex ultrasound together with CTA and plain radiography at 1 year, followed by CDU and plain radiography on an annual basis
5. contrast-enhanced ultrasound together with CTA and plain radiography at 1 year, followed by CEU and plain radiography on an annual basis.

The parameter estimates were derived from the systematic review of clinical effectiveness, expert opinions and other UK-based sources. The model considered a cohort of 74-year-old men, a lifetime time horizon, a 6-month cycle length, a 3.5% discount rate and a NHS and Personal Social Services perspective. The costs were expressed in 2015–16 Great British pounds and the effectiveness was expressed in quality-adjusted life-years (QALYs) and incremental cost per QALY.

Adverse events and complications during surveillance were generically named as ‘abnormalities’. These were divided into those conditions that would trigger an elective intervention (abnormal I) and those that, on clinical assessment, would require a closer follow-up (abnormal II – e.g. type II endoleaks with sac expansion of < 5 mm in 6 months or with limbs with kinking or partial thrombosis). The first category was further subdivided into two: abnormal Ia includes non-endoleak-triggered interventions (e.g. limb occlusions, graft infections) and abnormal Ib accounts for the endoleak-prompted interventions (e.g. types I, III and IV, type II or endotension with sac expansion of > 5 mm).

Results

Clinical effectiveness

The evidence for this assessment is derived from two non-randomised comparative studies (including 750 participants, 694 participants in one study and 56 participants in the other), 25 cohort studies (including 7196 participants) and nine systematic reviews of diagnostic test accuracy (including 174 primary studies). Surveillance protocols based on a combination of CTA and CDU or CEU were assessed.

The study duration ranged from 3 years to 16 years. The mean duration of follow-up ranged from 14 months (interquartile range 7–27 months; range 1–46 months) to 54.8 months (standard deviation 35.9 months). Patient characteristics and the type of aneurysm varied between studies.

The two non-randomised comparative studies compared a surveillance protocol based on a combination of CTA and CDU, with a simplified protocol based on CDU for long-term surveillance. In the largest comparative study (694 participants), no significant differences between the two surveillance strategies were observed during the 3-year follow-up in terms of reinterventions, clinical complications, mortality and adverse effects, including renal impairment.

All studies included CDU as part of their surveillance protocols, apart from one study that followed up patients using CEU and/or CTA. Studies that used CDU for annual long-term surveillance were published more recently than those that used a combination of CTA and CDU for long-term surveillance. In the majority of the included cohort studies ($n = 10$), surveillance was based on a combination of CTA and CDU throughout follow-up. Eight studies used CTA and/or CDU for early and mid-term assessments and CDU for long-term surveillance. Two studies used CTA for long-term surveillance (i.e. CTA at discharge, CDU at 6 months and then CTA at 12 months and annually thereafter). Three studies adopted a protocol based exclusively on CDU after EVAR and two studies included CEU together with CTA as part of their surveillance strategy.

Overall, the proportion of participants requiring reintervention after EVAR ranged from 1.1% during a mean follow-up of 24 months to 23.8% in a cohort that included high-risk patients with hostile neck anatomy who underwent a secondary procedure after a mean follow-up period of 32 months. Reintervention was required mainly for the treatment of limb occlusion (< 1% to 7.2% of participants), thrombosis/stenosis (< 1% to 5.6% of participants), type I endoleaks (<1% to 8.3% of participants), type II endoleaks (< 1% to 3.6% of participants) and type III endoleaks (< 1% to 1.6%). Across the studies, all-cause mortality ranged from 2.7% (mean follow-up period of 24 months) to 42% among a cohort that included a proportion of high-risk patients with hostile neck anatomy (mean follow-up period of 54.8 months). In the four cohort studies that reported it, aneurysm-related mortality occurred in < 1% of the participants.

The studies that used a combination of CTA and CDU throughout follow-up reported the highest all-cause mortality (42%) and the highest proportion of participants who required reinterventions for complications after EVAR (23.8%). However, it is worth noting that the study that reported the highest all-cause mortality (42% of patients) and the highest proportion of patients requiring reinterventions (23.8%) focused on high-risk patients, some of whom presented with features of hostile neck anatomy. Apart from this study, the remaining studies based on early and mid-term CTA and/or CDU and long-term CDU surveillance were broadly comparable with those based on a combination of CTA and CDU throughout follow-up in terms of clinical complications, reinterventions and mortality.

The findings of the nine systematic reviews of diagnostic accuracy show that for CDU the pooled sensitivity for detection of all types of endoleaks ranged from 65% to 96% and the pooled specificity ranged from 90% to 97%, whereas for CEU the pooled sensitivity ranged from 81% to 98% and the pooled specificity ranged from 78% to 88%. CEU accuracy improved when only studies that utilised the second generation of contrast agents were considered.

Cost-effectiveness

Five economic studies were identified. All of the studies were cohort studies and they compared a surveillance strategy based on the use of CDU or CEU with a strategy based on CTA and assessed the reduction in costs as a result of fewer CTA scans in accordance with a modified surveillance protocol. Although all of the studies fairly agree on the clinical outcomes of interest (i.e. endoleaks, AAA size and the need for secondary interventions), the reporting of costs and cost methods was disparate. None of the studies used a preference-based measure of effectiveness and the time horizon chosen was not long enough to allow for all relevant costs and consequences. Consequently, as a result of insufficient information for decision-making, a decision-analytic model was developed.

The Markov model base-case analysis results shows that annual follow-up with CDU only is the strategy with the lowest expected cost (£3791), followed by CTA only (£3828) and CEU only (£4709). The strategies with higher expected costs are those that use CDU (£4732) or CEU (£5644) in conjunction with CTA at the start

of follow-up. A CTA-only strategy produces the lowest expected QALYs (6.552) and is dominated by CDU only (6.553). Moreover, adding CTA to CDU or CEU at the start of follow-up results in more QALYs than using only one imaging modality, but these strategies are either dominated or the incremental cost for an additional QALY is well above the accepted cost-effectiveness threshold (i.e. £30,000). CEU-based strategies result in higher expected QALYs (i.e. 6.559 and 6.560) than all of the other strategies, although the incremental cost-effectiveness ratios to adopt any of these are well above the £30,000 threshold.

The probabilistic analyses show that, for willingness-to-pay (for an extra QALY) values of up to £50,000, annual follow-up with CDU only has a > 58% probability of being cost-effective, with CTA having a probability of between only 32% and 42% and CEU having a probability of between only 0.1% and 4.1%. CTA added to CDU or CEU has zero probability of being cost-effective.

The sensitivity analyses showed that a CEU-only strategy became cost-effective at very high rates of test sensitivity and specificity (e.g. when it was assumed to produce perfect information – sensitivity and specificity of 100% and no indeterminate results) and for a cost difference between CDU and CEU of < £55. A further sensitivity analysis explored the effect of surveillance in a very high-risk group. At an annual incidence rate of 7% for the abnormal Ib group (e.g. type I and III endoleaks, together with type II endoleaks with a > 5-mm sac expansion and other conditions commonly detected by non-X-ray modalities), CEU-based surveillance becomes cost-effective. Although in clinical practice it is unlikely to observe an incidence of 7% for type I or type III endoleaks, an incidence of 7% for type II endoleaks with sac expansion is, perhaps, possible.

Limitations

The majority of the studies were rated as being at a high or moderate risk of bias.

There was considerable heterogeneity in terms of imaging modality and the frequency of imaging, the duration of follow-up, outcome measures, definition of the outcomes (e.g. the definition of decreased aneurysm size) and the time points at which the outcomes were assessed. Owing to the observed clinical heterogeneity, a statistical synthesis of the relevant outcomes was considered to be inappropriate.

Studies comparing protocols based on CDU with those based on CEU were not found. The majority of surveillance protocols were based on a combination of CTA and CDU. Data from studies that exclusively used a CDU-based surveillance (three studies) and from studies that used CEU as part of their imaging protocol (two studies) were scarce.

The economic model was hindered by a lack of suitable data. The identification and selection of input data were particularly challenging, with key model parameter values being based on expert opinions.

Conclusions

The current evidence assessing the effects of surveillance after EVAR is very heterogeneous, with protocols being based on different imaging modalities, frequency of imaging and length of follow-up. No firm conclusion can be drawn with regard to the optimal surveillance strategy after EVAR. There is a need to improve current protocols to reduce radiation exposure, the risk of contrast nephropathy and costs, while ensuring that patients are adequately followed up to minimise their risk of secondary complications, especially aneurysm rupture. CDU may be a safe alternative to CTA, with CTA being reserved for abnormal or inconclusive CDU cases that require further investigation. Further research is required, however, to validate the safety of modified protocols based on the use of CDU and/or CEU. Access to modern equipment and highly experienced operators remains a crucial requirement for the adoption of CDU surveillance. The economic evaluation shows that CDU is the most cost-effective option, with a 63% probability of being cost-effective at a £30,000 willingness-to-pay-per-QALY threshold. Strategies based on CEU produce more QALYs, but are also more expensive and might be cost-effective for only higher-risk patients.

Suggested research priorities

- Further research is needed to assess the value of targeted surveillance (i.e. patients with a greater risk of complications may receive more frequent surveillance, whereas those with uncomplicated EVAR may undergo less-frequent assessments or be discharged from surveillance).
- If surveillance is to be targeted, is CDU and/or CEU surveillance satisfactory for all patient groups or are there groups for which CTA is required to avoid excessive risk?
- The criteria used for identifying patients at high risk of complications (e.g. use of validated score systems, risk prediction models) require further investigation.
- The role of plain radiography as part of EVAR surveillance needs to be clarified. If CTA is to be performed less frequently or avoided, should plain radiography be mandatory or reserved for patients with abnormalities on ultrasound imaging?
- Future research should explore the effects of the information generated by the imaging modalities used for surveillance and incorporate this within economic analyses.

Study registration

This study is registered as PROSPERO CRD42016036475.

Funding

Funding for this study was provided by the HTA programme of the National Institute for Health Research.

Chapter 1 Background

Description of the health problems

Brief statement describing the health problem

Endovascular abdominal aortic aneurysm repair (EVAR) was undertaken for the first time by a Ukrainian surgeon, Nicholas Volodos, in 1987[1] and introduced into wider clinical practice by Juan Parodi in 1991.[2] Since then, EVAR has become the preferred treatment option for abdominal aortic aneurysm (AAA).[3] A typical EVAR device consists of a stent covered with graft material to prevent the leakage of blood out of the device.[4] Although it is less invasive than open surgery, and has a lower perioperative mortality rate, EVAR is associated with complications in the follow-up period, such as different types of endoleaks, stent–graft migration, distortion or kinking of the stent–graft, structural disintegration of the stent–graft and aneurysm expansion, all of which could potentially lead to failure of treatment in the form of an aneurysm rupture.[5–8] Therefore, all patients receiving EVAR are placed on surveillance with a view to identifying complications in time to allow for remedial secondary interventions.

Data from The EUROpean collaborators on Stent–graft Techniques for abdominal aortic Aneurysm Repair (EUROSTAR) registry of 2846 patients treated with EVAR from December 1999 to December 2004 showed a cumulative incidence of secondary interventions of 6.0%, 8.7%, 12% and 14% at 1, 2, 3 and 4 years, respectively.[9,10] It is therefore necessary that patients receive lifelong surveillance following EVAR. The main purpose of surveillance is to detect clinically significant complications, which are often asymptomatic, and to prevent aneurysm rupture.[11] Endoleaks are the most common complications that occur after EVAR.[12–14]

Classification of endoleaks

An endoleak, which can be defined as a persistent blood flow within the aneurysm but outside the stent–graft, is the most frequent complication after EVAR, and is noted in approximately 20% of patients at some point during follow-up. Endoleaks vary in size, direction and the rate of blood flow, and they have variable origins.[15] Five categories of endoleaks have been described in the literature in accordance with the source of blood flow (*Table 1*).

Treatment and prognosis depends on the type of endoleak. Type I endoleaks, which have been reported to occur in as many as 10% of patients after EVAR,[17] have blood flow from the stent–graft attachment site as a result of sealing failure and are associated with increased pressure in the aneurysm sac. Type I endoleaks are usually treated at the time of the index operation and require urgent treatment if they present later. The risk of intraoperative as well as a secondary late type I endoleak is higher in anatomically difficult situation.[17,18] Type II endoleaks, which are characterised by retrograde blood flow into the aneurysm, are the most common type of endoleaks after abdominal EVAR and could be noted in as many as 20–30% of patients at 30 days, 18.9% of patients at 1 year and 10% of patients after 1 year.[17] Most of the type II endoleaks run a benign course and hence are dealt with a 'wait and see' follow-up approach. In some patients, surveillance monitoring may be increased. Treatment is required if the aneurysm increases in size; often a > 5 mm increase is deemed to be clinically significant.[15,18] Type III endoleaks result from structural defects arising in the stent–graft or modular disconnection, and always require immediate treatment. Structural failure of the device is more likely to happen over time as arterial pulsations and other factors cause repetitive stress on the device. Tears or holes in the fabric of the graft can be hard to detect, but modular disconnections are usually well seen with computed tomography angiography (CTA) and on plain radiography (stent–grafts have radio-opaque markers to allow for the diagnosis of modular distraction or dissociation on radiological examinations). The incidence of type III endoleaks is usually low (with an estimated incidence of 4% beyond 1 year).[17] Type IV endoleaks occur perioperatively or in the early postoperative phase (defined as being within 30 days) as a result of graft fabric porosity. However, with the advent of low-porosity graft fabrics, this type of endoleak is now observed less frequently. An endoleak

TABLE 1 Classification of endoleaks[8,16]

Endoleak	Origin of blood flow
Type I	Attachment site leaks
A	Proximal
B	Distal
C	Iliac occluder
Type II	Branch leaks
A	Simple (one patent branch)
B	Complex (two or more patent branches)
Type III	Graft defect
A	Junctional leak or modular defect
B	Fabric disruption (midgraft hole)
Type IV	Fabric porosity (within 30 days of procedure)
Type V	Endotension
A	With no endoleak
B	With sealed endoleak
C	With type I or III endoleak discovered at the time of open redo surgery
D	With type II endoleak discovered at the time of open redo surgery

detected on follow-up imaging should not be considered a type IV endoleak. Type IV endoleaks usually resolve once the coagulation profile returns to normal after the EVAR procedure. Treatment of type IV endoleaks is not usually required, but care should be taken to exclude other types of endoleaks at the point of diagnosis.[15,18–20] Type V endoleaks are a diagnosis of exclusion when no endoleak is actually demonstrable. This refers to the phenomenon of endotension, defined as the persistent or recurrent pressurisation of an aneurysm, which is identified by the continued expansion of the aneurysm sac. Although the exact cause of endotension is not always elucidated, possible causes include slow blood flow that is not visible on current imaging techniques, ultrafiltration of blood through the stent–graft, seroma, infection and the transmission of pressure through the thrombus in seal zones. Type V endoleaks are managed on an individual basis.[15,18]

Epidemiology of abdominal aortic aneurysm

Abdominal aortic aneurysm represents a significant health risk in the older population. Studies conducted in the 1990s in Europe and the USA indicated an overall prevalence of 2–4% for men and 1–2% for women.[10,21,22] A prospective population-based study conducted in Oxfordshire, UK, between 2002 and 2014 showed an annual incidence rate per 100,000 population of 55 in men aged 65–74 years; the incidence increased to 112 in men aged 75–84 years and to 298 in those aged ≥ 85 years.[23] Similarly, a systematic literature review published in 2014, which estimated the global and regional incidence and prevalence of AAA in 21 world regions, reported that in 2010 the age-specific annual incidence rate per 100,000 population ranged from 0.83 [95% confidence interval (CI) 0.61 to 1.11] in the 40–44 years age group to 165 (95% CI 152.20 to 178.78) in the 75–79 years age group.[24]

In the USA, even though the total number of AAAs remains stable at 45,000 cases per year, the overall use of EVAR has risen sharply in the past 10 years (from 5.2% to 74% of the total number of AAA repairs).[25] In the UK, the 2016 report of the National Vascular Registry (NVR), which was based on information on AAA repairs from 98 NHS organisations (82 in England, five in Wales, nine in Scotland and two in Northern Ireland), showed an increasing trend in the proportion of EVAR procedures, growing from 54% in 2009 to

66% in 2013. This trend appears to have stabilised over the last few years, with EVAR procedures accounting for 69% of the elective AAA repairs in 2015. The total number of elective EVAR repairs submitted to the NVR in 2015 was 2882. The majority of the EVAR procedures performed were in men (89%) and in people aged > 65 years (86%). Similarly, the UK 2015–16 record of the Hospital Episode Statistics indicates that there were 2975 hospital admissions for endovascular insertion of a stent–graft for AAA in England. Of these, 2650 were admissions of male patients and 382 were emergency admissions. The mean age of admitted patients was 76 years.

Current post-endovascular abdominal aortic aneurysm repair surveillance: variation in services and uncertainty about best practice

Surveillance following EVAR is now universally accepted and recommended, even though there are currently no standard regimens.[26] Post-EVAR surveillance should include a measurement of the aortic aneurysm, the identification and classification of endoleaks and the detection of stent–graft deformation and thrombus build-up within the graft.[27,28] The ideal frequency of surveillance is not defined and heterogeneous strategies exist between centres.[8,15,29] A web-based survey of UK surveillance practice conducted among the members of the British Society of Interventional Radiologists (BSIR) in 2011 indicated that imaging protocols comprise routine CTA imaging at 1 month, 6 months, 12 months and annually thereafter.[29] CTA is still considered to be the current reference standard for monitoring aneurysm size and migration and for the detection of endoleaks.[26] CTA scanning, however, does not provide information on the direction of blood flow associated with an endoleak and its frequent use has the disadvantage of exposing the patient to cumulative doses of ionising radiation with a potential lifetime cancer risk, as well as exposing the patient to contrast medium-induced nephrotoxicity.[30–32] The risks associated with the repeated use of CTA have led some investigators to consider revising the current surveillance protocols in order to minimise the radiation dose and to eliminate unnecessary CTA examinations.[12,33–35] The results of the 5-year follow-up of the US Zenith (Cook Inc., Bloomington, IN, USA) trial suggest, for example, that, in patients without an early endoleak, the 6-month surveillance can be safely omitted from the surveillance schedule.[36] Moreover, it has been observed that only 1.4–9% of patients require reintervention as a result of surveillance-detected abnormalities, whereas the majority of reinterventions occur in symptomatic patients with previously normal surveillance assessments.[11,26,37–39] Colour duplex ultrasound (CDU) and, more recently, contrast-enhanced ultrasound (CEU) have been proposed as possible safer alternatives to CTA.[40–43] Some investigators have suggested that CDU/CEU might have a role in situations when CTA is equivocal or when endotension is suspected.[44] It has also been suggested that CDU/CEU could replace CTA for annual surveillance for patients who have not experienced endoleaks or an increase in aneurysmal sac size in the first year after EVAR.[19,36,45,46] It is debatable whether or not CDU or CEU can currently replace CTA in the immediate post-EVAR surveillance period, as complications are more likely in the early postoperative period and CTA provides more precise evaluation of aneurysm morphologic changes, sac diameter, graft anchorage and integrity.[18] A significant increase in aneurysm size, the detection of a new endoleak or cases in which CDU is non-diagnostic because of obesity, gas or the lack of a suitable window, may also prompt further imaging with CTA for clarification.[3,12,36]

A survey conducted in 2010 among the 41 clinical centres enrolled in the UK EVAR trial 1[47] showed that 12 out of 41 centres used CTA as the primary surveillance modality, 14 out of 41 centres used CDU as the primary surveillance modality and 15 out of 41 centres used a combination of CTA and CDU. Similarly, the recently published 15-year follow-up of the UK EVAR trial 1[48] demonstrated a shift in contemporary practice towards CDU.

Although the original EVAR trial 1 protocol was for annual follow-up using CTA, which was used in the early stages of the trial, in the later stages, many EVAR patients were followed up with CDU.[48] The change from CTA to CDU was partly influenced by the growing concern about the risks associated with radiation exposure.[49]

Relevant clinical guidelines

Although there is currently no consensus on the best place for CDU/CEU in the care pathway of surveillance after EVAR, some clinical guidelines allude to a possible role of CDU/CEU within the existing imaging care pathway. In the USA, the Society for Vascular Surgery practice guidelines, published in 2009,[19] recommend contrast-enhanced computerised tomography (CT) imaging at 1 month and 12 months during the first year after EVAR. If at 1 month the CT imaging identifies an endoleak or other abnormalities of concern, postoperative imaging at 6 months should be considered to further evaluate the proper exclusion of an aneurysm. If neither an endoleak nor an aneurysm enlargement is detected during the first year of surveillance after EVAR, colour duplex ultrasound may be regarded as a reasonable alternative to CT imaging for postoperative surveillance. The presence of a type II endoleak should initially prompt continued CT surveillance to ascertain whether or not the aneurysm is increasing in size. However, if the aneurysm is shrinking in size or is stable, follow-up with CDU may be an option.

Despite some existing algorithms and guidelines,[19,29] there is currently no consensus on the optimal surveillance strategy after EVAR. Current surveillance paradigms in the UK are considerably heterogeneous, with each centre performing its own protocol, which varies in both the timing and the modality of imaging.

Description of technology under assessment

Summary of interventions

Computed tomography angiography

Computed tomography angiography is widely used as an imaging modality for surveillance after EVAR and is considered to be the reference standard imaging test.[11] Multiple-phase CTA is recommended initially, because of the variable flow rates of endoleaks after contrast injection. With multiple-phase CTA, imaging is conducted before the administration of an intravenous iodinated contrast medium, after administration in the arterial phase of contrast circulation as determined by bolus chasing, and in a delayed phase, usually in the portal venous phase of contrast circulation.[15] CTA is quick, widely available and less operator dependent. CTA offers clear vascular and non-vascular imaging, and enables differentiation between true endoleaks and areas of calcification or high attenuation that may mimic an endoleak.

The disadvantages of CTA include the cost of follow-up imaging, radiation exposure (15–31 mSv per study[11] compared with 0.014 mSv for a chest radiography),[50] the nephrotoxic properties of the contrast medium and occasional allergic reactions to the contrast material. The incidence of contrast-induced nephropathy is estimated to range from 7% to 12%.[32,45,47,51] CTA imaging is therefore unsuitable for use in patients with, or at risk of, significant renal impairment.

Plain radiography

Despite the availability of advanced imaging modalities, plain radiography is still used in many centres in Europe and North America for a general assessment of stent–graft position and integrity,[12,52] as well as for evaluating device migration, wire frame fracture, kinking or distortion.[53,54] The European Society for Vascular Surgery recommends using plain radiography in conjunction with CTA for the first 12 months of surveillance and, if no endoleaks are detected, in conjunction with CDU or CEU thereafter.[31] The BSIR survey showed that 20 out of 37 respondents (54%) performed plain films in addition to CTA at the 1-year postoperative follow-up.[29] Contrary to CTA, CDU and CEU, plain radiography has little to no role in surveillance for sac enlargement and the detection of endoleaks.[12] For this reason, plain radiography must be used in conjunction with other imaging modalities and cannot be used as the sole surveillance modality after EVAR.[11]

Colour duplex ultrasound

Colour duplex ultrasound offers high levels of endoleak characterisation by delivering information regarding the direction of endoleaks and velocity of blood flow, which is not provided by CTA. CDU can also be used to guide the endovascular treatment of endoleaks, is inexpensive and portable, and avoids exposing the patient to radiation and potentially nephrotoxic contrast agents. The imaging quality of CDU is, however, operator-dependent, and scanning and reporting protocols can vary considerably between institutions.[55] CDU imaging is also affected by patient body habitus and bowel gas and is less able to detect stent–graft defects or migration than CTA.

Contrast-enhanced ultrasound

Contrast-enhanced ultrasound is an evolving imaging modality that provides dynamic examination through the administration of an intravenous contrast agent, which can be followed in real time as it appears within the graft, with endoleaks appearing as a contrast outside the stent–graft, but within the aneurysm.[11]

During the last decade, the technique of CEU has changed and the developments include more stable microbubble contrast material, as well as the introduction of a fundamentally different method of generating ultrasound images utilising harmonics, compared with the earlier version of Doppler imaging with contrast material.[56] The contrast agents used in contemporary CEU are stabilised microspheres consisting of sulphur hexafluoride or perfluorocarbon encapsulated by a phospholipid shell.[20,57]

Unlike CTA, CEU is safe to use in patients with renal impairment. Like CDU, CEU imaging is operator dependent and, because of its technical requirements and the need to administer a contrast agent, should be conducted by specialist sonographers trained in EVAR surveillance, rather than general sonographers. Obesity and bowel gas can interfere with ultrasound scanning.[29,56] Ultrasound equipment needs to be of adequate standard and equipped with the relevant capabilities, which is often missing in dated equipment.

Purpose of this assessment

The purpose of this appraisal is to assess the current evidence for the clinical effectiveness and cost-effectiveness of imaging strategies using either CDU or CEU alone or in conjunction with plain radiography compared with CTA for the surveillance of EVAR.

Chapter 2 Clinical effectiveness and diagnostic accuracy of endovascular abdominal aortic aneurysm repair surveillance imaging modalities

This chapter reports the assessment of the clinical effectiveness and diagnostic accuracy of imaging strategies using either CDU or CEU alone or in conjunction with plain radiography compared with CTA for the surveillance of EVAR. The methods were prespecified in a research protocol (PROSPERO database CRD42016036475).

Clinical effectiveness

Methods for assessing the outcomes arising from the use of the intervention

We conducted an objective synthesis of the evidence for the clinical effectiveness of imaging strategies using either CDU or CEU alone or in conjunction with plain film X-ray compared with CTA for the surveillance of EVAR. The evidence synthesis was carried out in accordance with the general principles of the Centre for Reviews and Dissemination (CRD)'s guidance for undertaking reviews in health care,[58] the recommendations of the *Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0*.[59] and the National Institute for Health and Care Excellence (NICE)'s guidance on the methods of technology appraisal,[60] and it is reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA).[61]

Identification of studies

Comprehensive electronic searches were conducted to identify reports of published randomised trials and cohort studies. Highly sensitive search strategies were designed, including appropriate subject headings and text-word terms, to combine the search facets for endovascular aneurysm repair, the imaging modalities under consideration and the study design. The searches were initially undertaken on 25 January 2015 and updated on 5 September 2016, and these included studies published from 1996 in order to reflect the introduction of CEU into clinical practice. There were no language restrictions, but non-English-language reports were excluded because the evidence base containing English-language reports was sufficiently large. Full details of the search strategies are reported in *Appendix 1*. The databases searched were Ovid MEDLINE Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Daily and Ovid MEDLINE (1946 to 5 September 2016), EMBASE (1996 to week 36 2016), Science Citation Index (1997 to 5 September 2016), Scopus' Articles-in-Press (inception to 5 September 2016), Cochrane Central Register of Controlled Trials [(CENTRAL) issue 3 2016], Cochrane Database of Systematic Reviews [(CDSR) issue 3 2016], Database of Abstracts of Reviews of Effects [(DARE) inception to 25 January 2016] and the Health Technology Assessment (HTA) database (inception to 25 January 2016). The reference lists of all of the included studies were perused for further evidence. Members of the advisory group were contacted for details of additional reports.

Identification of other relevant information, including unpublished data

The World Health Organization's International Clinical Trials Registry Platform (ICTRP), Current Controlled Trials and Clinical Trials.gov were searched on 27 January 2016 for evidence of ongoing studies.

Eligibility criteria

Studies fulfilling the following criteria were included in this assessment.

Population
Adults undergoing surveillance following EVAR for AAAs.

Setting
Secondary or tertiary care settings.

Interventions
Contrast-enhanced ultrasound or CDU, used either alone or in conjunction with plain radiography for long-term surveillance following EVAR.

Colour duplex ultrasound
Colour duplex ultrasound is inexpensive, portable and avoids exposing the patient to radiation and potentially nephrotoxic contrast agents; however, the imaging quality of CDU is dependent on the quality of the machine and the thoroughness of the examination. Similarly, CDU image reporting is operator dependent and scanning protocols can vary considerably between institutions.[55] CDU imaging is also affected by patient habitus and bowel gas and is less able to detect graft defects or migration than CTA.

Contrast-enhanced ultrasound
There is evidence that the use of contrast enhancement increases the sensitivity of ultrasound surveillance.[62] The main advantage of CEU is better classification of endoleaks as a result of dynamic visualisation of the direction of blood into the aneurysm sac.[43,52] As with CDU, CEU is operator dependent, with scan quality and scanning protocols varying considerably between centres. Unlike CTA, CEU is safe to use in patients with renal impairment. The use of an intravenous contrast agent and the presence of a clinician for its administration make CEU more expensive than CDU. At present in the UK, CEU is not as widely available as CDU.[29]

Plain radiography
The European Society for Vascular Surgery recommends using plain radiography in conjunction with CTA for the first 12 months of surveillance, and, if no endoleaks are detected, in conjunction with CDU or CEU thereafter.[29,31] In contrast to CTA, CDU and CEU, plain radiography has little to no role in surveillance for sac enlargement and the detection of endoleaks.[12]

Comparator

Computed tomography angiography
Computed tomography angiography is the most widely used imaging modality for surveillance after EVAR and is considered to be the reference standard imaging test.[11] CTA is quick, widely available and less operator dependent, and it is not affected by body habitus. CTA offers clear vascular and non-vascular imaging and enables differentiation between true endoleaks and areas of calcification or high attenuation that may mimic an endoleak. Disadvantages include the cost of CTA follow-up, radiation exposure[11] and nephrotoxic properties of the contrast medium.[32,45,47,51]

Outcomes
Studies providing data on any of the following outcomes (using any measure) were considered to be suitable for inclusion:

- Clinical and surgical outcomes –
    - incidence and type of complications (e.g. all types of endoleaks, migration, kinking and fracture), as defined by the authors of the relevant selected studies
    - reintervention rate
    - incidence and type of secondary interventions.

Adverse effects and harms associated with a specific mode of surveillance (imaging modality) were also taken into consideration (e.g. contrast-induced nephropathy).

Study design

We considered randomised controlled trials (RCTs), non-randomised comparative studies and/or prospective and retrospective cohort studies of different surveillance imaging modalities, regimens and follow-up strategies.

Exclusion criteria

Studies not fulfilling the prespecified criteria and the following types of reports were excluded:

- preclinical and biological studies
- case reports
- reports investigating technical aspects of the imaging modalities used for surveillance after EVAR
- editorials and opinions.

Data extraction and management

Two reviewers (PS and MS or CR and MS) independently screened the titles and abstracts of all citations identified by the search strategies. Full-text copies of all of the potentially relevant studies were retrieved and assessed independently by the two reviewers for eligibility using a screening form developed ad hoc for the purpose of this assessment (see *Appendix 2*). Any disagreements during study selection were resolved by discussion or in consultation with a third reviewer (MB).

A data extraction form was specifically designed and piloted for the purpose of this assessment (see *Appendix 2*). Detailed information on study design, characteristics of the participants, settings, characteristics of the interventions and outcome measures was extracted. Data extraction was carried out by three reviewers (PS, CR and MS). One reviewer completed the data extraction and a second reviewer cross-checked the extracted data for errors or inaccuracies. There were no disagreements between reviewers.

Quality assessment strategy

The methodological quality of the included studies was independently assessed by two reviewers (PS, CR or MS). Disagreements were resolved by consensus or arbitration with a third reviewer (MB). Studies were not excluded on the basis of their methodological quality. We assessed the risk of bias of non-randomised studies using a 17-item checklist that we developed for NICE through the Review Body for Interventional Procedures [(ReBIP) see *Appendix 3*]. The ReBIP checklist was adapted from several sources, including the NHS CRD guidance for conducting or commissioning systematic reviews,[58] Verhagen *et al.*,[63] Downs and Black[64] and the Generic Appraisal Tool for Epidemiology (GATE).[65] The four italicised questions of the checklist used to evaluate the risk of bias of comparative studies were disregarded for all but the two included comparative studies.[66,67] Individual items within the checklist were rated as 'yes', 'no' or 'unclear' so that a rating of 'yes' denoted the optimal rating for methodological quality. We did not assess the quality of abstracts, as the word limit for abstracts is usually insufficient to make informed judgements about the potential risk of bias of the reported study.

Method of analysis/synthesis

The summary results and baseline characteristics from eligible studies have been described, tabulated and demonstrated by graphs using methods that are appropriate for the types of measurements reported by the included studies. We had planned a formal meta-analysis and metaregression of outcome data from the included studies; however, this was not possible, owing to the lack of comparative studies. The outcome data have been summarised descriptively.

Results of the evidence synthesis

Quantity and source of the evidence

The original primary searches and subsequent updates retrieved a total of 3249 records after deduplication. After reviewing the titles and abstracts, 456 records were subsequently excluded. Full-text copies of 483 potentially relevant reports were obtained and screened for inclusion, of which 27 were deemed to be eligible for inclusion. This comprised 24 full-text papers (two non-randomised comparative studies and 22 cohort studies) and three abstracts (all cohort studies). *Figure 1* shows the flow diagram of the study selection process. *Appendix 4* lists all of the studies included in this assessment, and *Appendix 5* lists the studies excluded after full-text scrutiny together with the reasons for their exclusion. Studies were excluded if they failed to meet one or more of the specified inclusion criteria with regard to study design, participants, intervention or outcomes.

Quality assessment of included studies

Non-randomised comparative cohort studies

The results of the methodological quality assessment for the two non-randomised comparative cohort studies[66,67] indicated that the Chisci *et al.*[66] study was of moderate methodological quality, whereas the Nyheim *et al.*[67] study was of poor methodological quality, mainly because over half of the ReBIP checklist items were rated as having an 'unclear' risk of bias.[67] In particular, it was unclear if the patients were taken from a representative sample – at a similar point in their disease progression – or selected consecutively, and if the study groups were comparable.[67] The study groups in the Chisci *et al.*[66] study were comparable, but we noted that the length of the follow-up period was not similar between the study groups. In both studies, it was unclear whether or not the outcomes were assessed blindly or if the authors had adjusted for confounding factors. *Figure 2* summarises the results of the methodological assessment of the two non-randomised comparative studies.

Cohort studies

The 22 cohort studies published in full were of mixed quality (*Figure 3*).[40,41,68–87] The individual study-level results are detailed in *Appendix 6*. For the majority of studies, over half or more of the ReBIP criteria were not met, or the information provided in the studies was insufficient to determine if the criteria were met, and were, therefore, judged as being of low or moderate quality. Three cohort studies were deemed to be

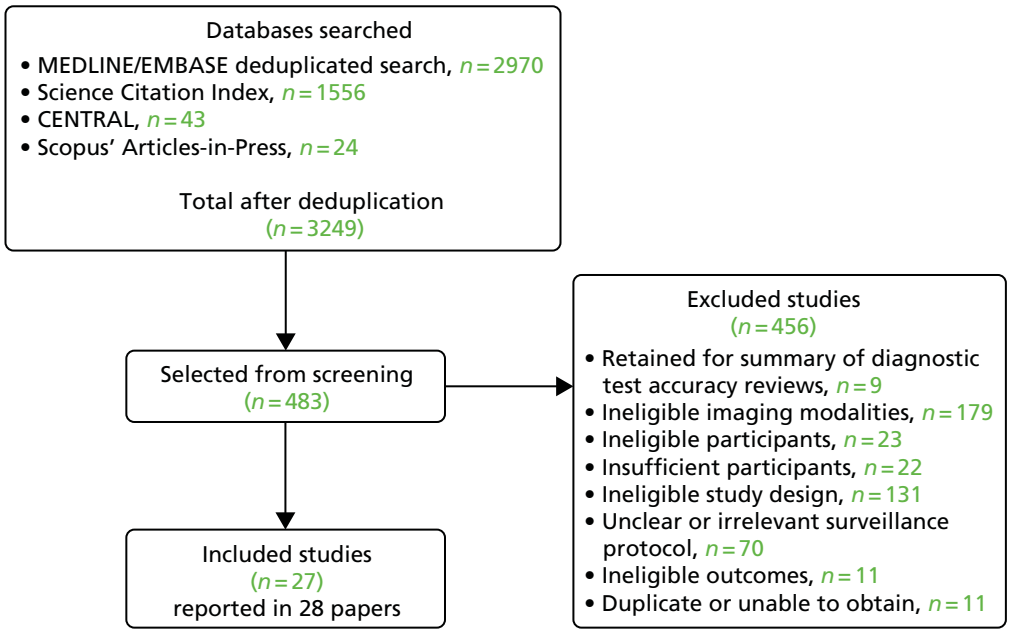

FIGURE 1 Flow diagram of the study selection process.

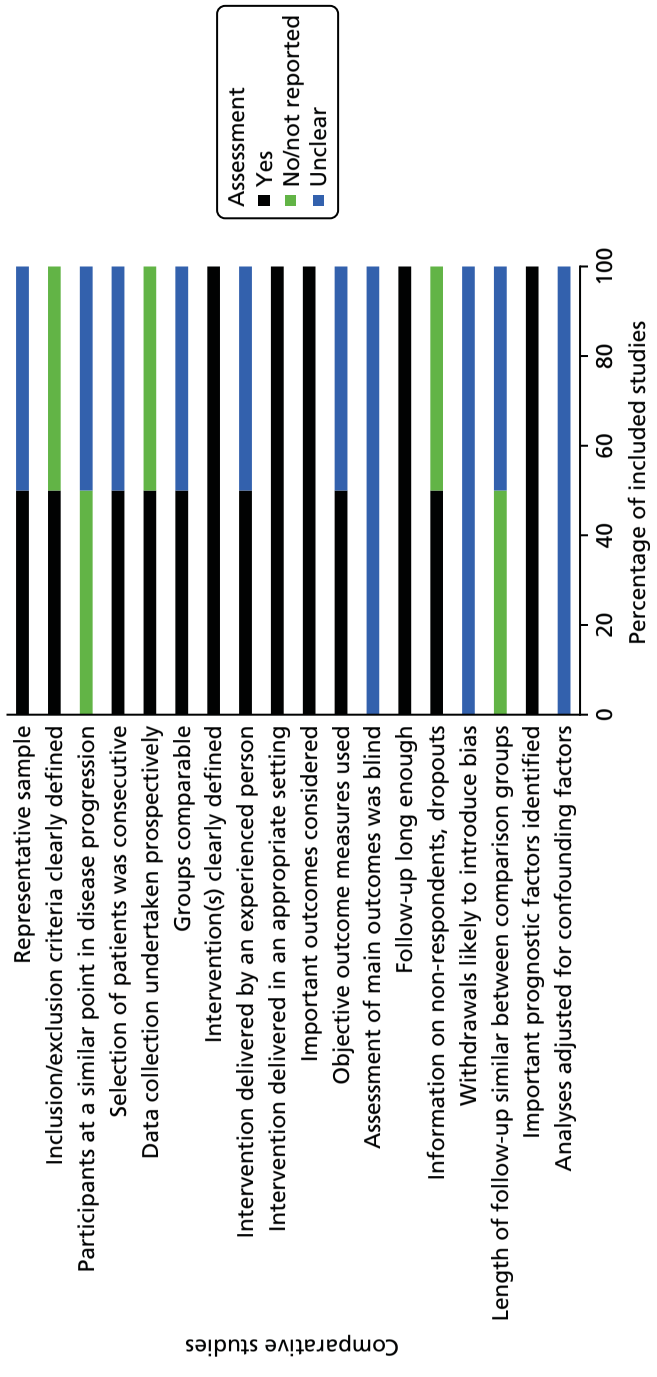

FIGURE 2 Risk-of-bias assessment of the two non-randomised comparative studies.[66,67]

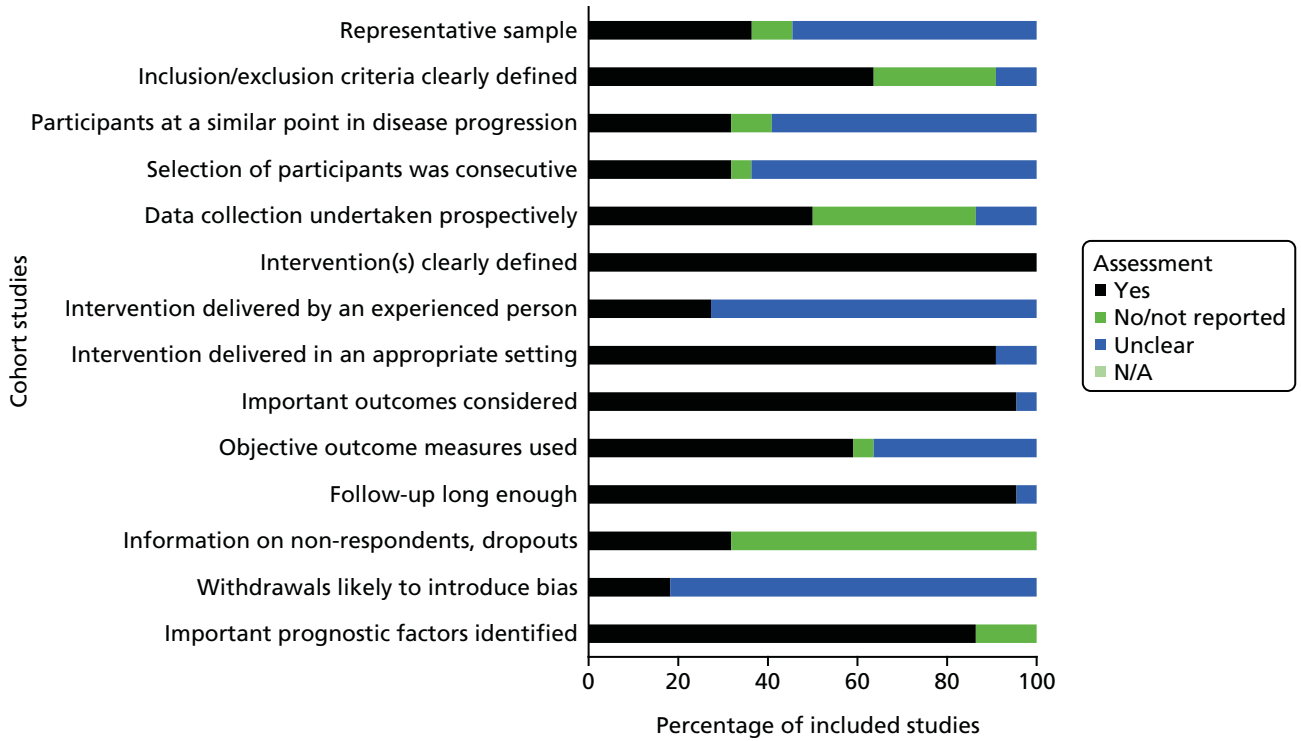

FIGURE 3 Quality assessment for non-comparative cohort studies. N/A, not applicable.

of higher quality as they met all the ReBIP criteria.[76,84,87] Three of the included cohort studies were published only as abstracts[88–90] and therefore were not quality assessed.

Participants were selected consecutively and were a representative sample in just over one-third of the 22 cohort studies. Similarly, the majority of studies undertook prospective data collection (see *Appendix 6*), clearly defined the intervention and clinical setting and considered long-term outcomes. The majority of the cohort studies (85%) were not clear in their reporting of participant dropouts and withdrawals and over one-third did not clearly report their inclusion/exclusion criteria.

Study characteristics of all included studies

Details of all of the included studies, including baseline characteristics of participants, description of the adopted surveillance strategy (imaging modality and frequency) and clinical outcomes, are described in the subsequent text and *Table 2*, and are presented in *Appendix 8*.

TABLE 2 Participant characteristics in the included studies

Participants' characteristics	Total	Studies	
		Comparative	Cohort
Total enrolled, *n*	9596	1282	8314
Total analysed, *n*	7946	750	7196
Number lost to follow-up, *n* (%)[a]	1650 (17.2)	532 (41.5)	1118 (13.4)
Number of men, *n* (%)[b]	5399 (67.9)	663 (88.4)	4856 (86.0)
Range of mean age (years)	68.7–77.5	74–77.5	68.7–76.6
Range of aneurysm diameter (mm)[c]	51.6–64	61–64	51.6–59
***Comorbidities*, n *(%)*[d]**	**N = *5918***	**N = *1613***	**N = *4225***
Hypertension	1602 (27.4)	523 (32.4)	1079 (25.5)
Cardiovascular disease[e]	1468 (25.1)	449 (27.8)	1019 (24.1)
Cerebrovascular disease	181 (3.1)	NR	181 (4.3)
Hyperlipidaemia	988 (16.9)	417 (25.9)	571 (13.5)
Respiratory disease[f]	169 (2.9)	NR	169 (4.0)
Diabetes	649 (11.1)	224 (13.9)	425 (10.1)
Smoking	773 (13.2)	NR	773 (18.3)
Other	8 (0.1)	NR	8 (0.2)
Type/terminology of AAA*, n *(%)			
AAA (no additional description supplied)	6770 (85.2)	514 (68.5)	6256 (86.9)
Infrarenal AAA	842 (11.3)	0 (0)	842 (11.7)
Iliac artery aneurysm[g]	295 (3.7)	236 (31.5)	59 (0.8)
Ruptured AAA	39 (0.5)	0 (0)	39 (0.5)

NR, not reported.
a Per cent of total studies that provided data. Information was not available from six studies.[69,71,78,81,82,89]
b Per cent of total studies that provided data. Seven studies did not provide data.[69–71,73,81,87,89]
c Information not available from 15 trials.[41,67,69,71–74,79,80,82,84,88–90]
d Per cent of total studies that provided data. Information was not available from 14 studies.[41,67,69,71–73,78,81–83,86,88–90]
e Includes congestive heart failure, myocardial infarction, heart disease, coronary heart disease, hypercholesterolaemia, coronary artery bypass.
f Includes chronic obstructive pulmonary disease.
g Includes iliac artery aneurysms and bilateral iliac aneurysms.

Country

Nine of the included studies were conducted in the USA,[40,69–71,73,80,81,87,88] six studies were conducted in Italy,[66,75,76,83,86,89] three studies were conducted in Germany,[68,77,84] three studies were conducted in the UK,[41,78,82] two studies were conducted in France,[72,85] one study was conducted in the Czech Republic,[79] one study was conducted in Norway[67] and one study was conducted throughout Europe.[74] The location was not reported in one study.[90]

Setting

Surveillance following EVAR took place largely at hospitals, vascular centres and tertiary referral centres. Two studies were conducted in two centres each,[68,74] one study involved 33 centres[81] and the remaining 24 studies were conducted in a single centre.

Length of follow-up

The study duration ranged from 3[40,68,76,84,86] to 16 years.[89] The longest median length of follow-up was 68 months (range 1–144 months),[90] whereas the shortest median length of follow-up was 23.4 months.[72] Mean follow-up ranged between 14 months [interquartile range (IQR) 7–27 months; range 1–46 months][83] and 55 months [standard deviation (SD) 36 months].[85] Seven studies had mean or median follow-up assessment periods that were > 36 months.[41,66–68,78,85,90]

Participants

A total of 7946 participants were assessed among the 27 included studies. The characteristics of the patients' aneurysm type varied. The majority of studies (17/27 studies with a total of 6770 participants) did not specify the type of AAA or reported only that participants had 'abdominal aortic aneurysm'.[40,41,67,69,72–74,76–82,86–90] In four studies, participants (total of 898) were reported to have infrarenal AAAs;[70,71,84,85] in two studies participants (total of 295) were reported to have iliac artery aneurysms;[66,83] in two other studies, participants (total of 195) were reported to have asymptomatic aneurysms;[77,79] in three studies, participants (total of 45) were reported to have symptomatic aneurysms;[75,77,79] and, in two studies, participants (total of 39) were reported to have ruptured AAAs.[68,75]

Surveillance imaging and frequency

We did not identify any studies that compared a surveillance protocol based on CEU with one based on CDU.

Non-randomised comparative cohort studies

Of the two included non-randomised comparative studies, the study by Chisci *et al.*[66] compared a surveillance strategy based on CDU and CTA 1 month after EVAR and every 6 months thereafter, with a strategy based on CDU and CTA 1 month after EVAR and CDU and radiography every 6 months thereafter. The study by Nyheim *et al.*[67] compared a conventional surveillance protocol consisting of CTA, CDU and plain radiography at 1, 6 and 12 months and annually thereafter with a simplified surveillance protocol based on CDU and plain radiography at 6–8 weeks, CTA/CDU/plain radiography at 1 year and CDU and plain radiography annually thereafter.

Cohort studies

Among the included 25 cohort studies, the majority (22/25 studies) reported surveillance protocols based on mixed CDU and CTA imaging. Only three studies included CEU with or without CDU as a part of their surveillance strategy.[75,76,86] Of these, one study included CEU used alone at 6 months and in combination with CTA annually thereafter,[75] one study used CEU along with CTA and CDU at 1, 3, 6 and 12 months and annually thereafter[86] and, in the remaining study, the use of CEU instead of CDU was restricted to selective cases only.[76] Two of the three studies did not report the technique,[76,86] and one reported the use of SonoVue [sulphur hexafluoride microbubbles (Bracco UK, High Wycombe, UK)].[75]

There was significant heterogeneity with regard to the modality of imaging, the timing of imaging and the duration of surveillance among the included cohort studies (*Table 3*). Depending on the type and frequency of imaging, the included cohort studies were broadly categorised into the following six surveillance protocols:

1. Early and mid-term CTA and/or CDU and long-term CDU surveillance – eight studies (CTA and/or CDU then CDU).

    i. The eight studies varied in their early and medium-term surveillance; however, all studies used CDU for the annual long-term surveillance after EVAR. Six studies used a combination of CTA and CDU for early surveillance after EVAR (1-month or 3-month follow-up).[41,77,80,82,89,90] Four studies assessed patients at 6 months.[76,80,89,90] Two of these studies used CDU for the 6-month follow-up,[76,89] whereas two studies used both CTA and CDU.[79,90] Of the two studies that used CDU at 6 months, one study reported the use of CEU alongside CDU for selective cases only.[76] One study assessed patients using CTA at 1 and 12 months and CDU annually thereafter.[40]
    ii. Computed tomography angiography scans were performed in case of abnormalities in three studies[40,41,82] and plain abdominal radiography was used as a part of the surveillance protocols in two studies.[41,82]

2. Early CTA, mid-term CDU and long-term CTA surveillance – two studies (CTA then CDU then CTA).

    i. In two studies, CTA was used immediately after EVAR (at discharge), CDU was used at 6 months and CTA was used for long-term surveillance (12 months and annually thereafter).[68,74]

3. Combination of CTA and CDU throughout surveillance – 10 studies (CTA and CDU).

    i. Ten studies used CTA and/or CDU for both short- and long-term surveillance after EVAR. The frequency of imaging was broadly similar between the surveillance protocols, with most of the studies using imaging at 1 month, 6 months, 12 months and annually thereafter (see *Table 3*).[70–72,79,81,83–85,87,88] Six of these studies included the use of radiography alongside CTA and CDU for the surveillance examinations following EVAR.[70,72,81,83,85,87]

4. Colour duplex ultrasound-based surveillance – three studies.

    i. Two studies used CDU exclusively as the imaging modality for surveillance after EVAR.[69,78] Another study used CDU at 1 month, 6 months and thereafter, and CTA was used only in selective cases.[73]

5. Combination of CTA and CEU/CDU throughout surveillance – one study (CTA and CDU and CEU).

    i. In one study, participants underwent CTA, CEU and CDU surveillance at 1, 3, 6 and 12 months after EVAR and annually thereafter.[86]

6. Early CTA, mid-term CEU and long-term CTA or CEU surveillance – one study (CTA then CEU then CTA or CEU).

    i. In one study, the surveillance protocol after EVAR included CTA at 1 month, CEU at 6 months and yearly examinations with either CTA or CEU thereafter.[75]

TABLE 3 The imaging modality and frequency of imaging in included cohort studies

Study, first author (year of publication)	Surveillance frequency									
	< 1 month	1 month	3 months	6 months	Every 6 months	12 months	Annually thereafter	18 months	24 months	Annually thereafter
Early and mid-term CTA and/or CDU and long-term CDU surveillance										
Chaer (2009)[40]		CTA				CTA	CDU (CTA selectively)			
Fargion (2016)[89]			CTA and CDU	CDU						
Freyrie (2014)[76]	CDU	CTA		CDU (CEU selectively)		CTA	CDU			
Ghotbi (2010)[77]		CDU	CTA and CDU			CTA and CDU	CDU			
Harrison (2011)[41]		CTA and CDU				CDU and AXR (CTA selectively)	CDU and AXR (CTA selectively)			
Kray (2015)[80]		CTA and CDU		CTA and CDU		CTA and duplex ultrasound	CDU			
Mazzaccaro (2011)[90]			CTA and CDU	CTA and CDU		CDU	CDU			
Oshin (2010)[82]		CTA and CDU and AXR					CDU and AXR (CTA selectively)			
Early CTA, mid-term CDU and long-term CTA surveillance										
Bisdas (2014)[68]	CTA			CDU		CTA	CTA			
Donas (2016)[74]	CTA			CDU		CTA	CTA			
Combination of CTA and CDU throughout surveillance										
Bush (2001)[70]		CTA		CTA and CDU and radiography		CTA and CDU and radiography	CTA and CDU and radiography			
Carroccio (2002)[71]		CTA and CDU	CTA and CDU	CTA and CDU		CTA and CDU	CTA and CDU			
Cochennec (2007)[72]		CTA and CDU and radiography		CTA and CDU and radiography		CTA and CDU and radiography	CTA and CDU and radiography			
Dominguez (2010)[88]		CTA and CDU		CTA and CDU			CTA and CDU			
Köcher (2004)[79]			CTA and CDU	CTA and CDU		CTA and CDU	CTA and CDU			
Meier (2001)[81]			CTA and CDU and radiography	CTA and CDU and radiography		CTA and CDU and radiography	CTA and CDU and radiography			
Parlani (2002)[83]		CTA and CDU and AXR		CDU and AXR	CDU and AXR	CDU and AXR	CTA			

Study, first author (year of publication)	Surveillance frequency									
	< 1 month	1 month	3 months	6 months	Every 6 months	12 months	Annually thereafter	18 months	24 months	Annually thereafter
Schunn (2000)[84]					CTA and/or CDU (every 6 to 12 months)					
Soler (2015)[85]				CTA and CDU and AXR		CTA and CDU and AXR		CTA and CDU and AXR	CTA and CDU and AXR	CTA and CDU and AXR
Wolf (2002)[87]				CTA and CDU and AXR		CTA and CDU and AXR	CTA and CDU and AXR			
CDU-only surveillance										
Blom (2012)[69]	CDU			CDU			CDU			
Collins (2007)[73]	CDU			CDU (CTA selectively)	CDU (CTA selectively)					
Karthikesalingam (2012)[78]		CDU	CDU	CDU	CDU (at 9 months)	CDU		CDU annually thereafter		
Combination of CTA and CEU/CDU throughout surveillance										
Stella (2009)[86]		CTA and CDU and CEU	CTA and CDU and CEU	CTA and CDU and CEU		CTA and CDU and CEU	CTA and CDU and CEU			
Early CTA, midterm CEU and long term CTA or CEU surveillance										
Fossaceca (2013)[75]		CTA		CEU			CTA/CEU			

AXR, abdominal radiography.

Assessment of outcomes and follow-up

Of the 27 included studies, > 90% reported data on reinterventions and on the incidence and type of clinical complications, 85% reported mortality data and 37% reported changes in aneurysm diameter. In total, 20 studies reported the incidence of type I endoleaks,[40,41,66–68,73–77,79,82–85,87–91] 18 studies reported the incidence of type II endoleaks,[40,41,66–68,73,75–77,79,80,82–85,88–90] 10 studies reported the incidence of type III endoleaks,[66–68,74–76,79,83,85,86] 10 studies reported the incidence of limb occlusion[40,41,66,69,72,74,78,82,84,85] and 12 studies reported the rate of aneurysm rupture[41,66,74,76,77,80,82,83,85–87,90] (see *Appendix 9*). Other complications reported in the included studies were thrombosis (seven studies[68,71,75,76,79,86,90]), infection (seven studies[66–68,70,74,79,85]), stenosis (five studies[41,74–76,79]), migration (six studies[66,67,72,76,77,79]), ischaemia (five studies[66,68,72,88,92]) and kinking (three studies[41,72,78]). All of the outcomes were measured at different time points after EVAR and during surveillance using various imaging modalities. When reported, the definitions of complications varied among the included studies.

Results of individual studies

The results of the included studies in terms of type and rate of EVAR-related clinical complications, reintervention rates and types of secondary procedure performed, changes in aneurysm diameter and mortality rates are presented in *Appendices 10–13*.

Results of non-randomised comparative cohort studies

The two non-randomised comparative studies included a total of 750 participants. Both studies used CTA along with CDU, but the timing of imaging varied between the two studies. The results from two comparative studies are shown in *Table 4* and described in the text below.

The study by Chisci *et al.*[66] compared CTA and CDU surveillance at 1 month after EVAR and every 6 months thereafter (protocol I; 376 participants) with CTA and CDU at 1 month after EVAR and CDU and radiography every 6 months thereafter (protocol II; 341 participants) and reported outcomes on reintervention rates, clinical complications, mortality and aneurysm diameter. The proportion of participants who required reintervention was similar between the two protocols (18.1% vs. 16.4%; $p = 0.625$). There was no evidence of a difference between the two protocols with regard to early reintervention and late reintervention rates. Similarly, the incidence of type Ia and Ib endoleak, type II endoleak, type III endoleak, graft migration, limb occlusion, limb ischaemia, aneurysm rupture, graft infection and bowel ischaemia was similar between the two protocols (*Table 5*). A higher proportion of graft kinking was picked up by protocol II compared with protocol I (3.0% vs. 1.3%; $p = 0.050$). Mortality was similar between the two protocols (2.1% vs. 1.8%; $p = 0.932$) and there was no evidence of a difference in the proportion of participants with permanent (> 30% over baseline) renal impairment (8.8% vs. 8.5%; $p = 0.997$).

The study by Nyheim *et al.*[67] compared a conventional surveillance protocol consisting of CTA, CDU and plain radiography at 1, 6 and 12 months and annually thereafter (participant numbers not reported), with a simplified surveillance protocol of CDU and plain radiography at 6–8 weeks, CTA/CDU/plain radiography at 1 year and CDU and plain radiography annually thereafter (56 participants), but failed to provide suitable comparative data. Data on reintervention rates, mortality rates and aneurysm diameter were available for the simplified protocol only. The number of participants who died (16%) or required reintervention (25%) was fairly high. In general, the rate of complications picked up by a surveillance protocol based on CDU soon after EVAR, CTA/CDU at 1 year and CDU annually thereafter was higher than that in the study by Chisci *et al.*[66]

Results of cohort studies

Reintervention and complication rates

Eighteen studies reported the number of participants requiring reintervention for various complications (see *Appendix 11*).[40,41,68,70,72,74–80,83,85–88,90] The proportion of participants who required reintervention ranged from 1.1% during a mean follow-up of 24 months[40] to 23.8% in a cohort that included high-risk patients with hostile neck anatomy during a mean follow-up of 32 months.[85] Five studies did not provide a breakdown of the type of reintervention or the type of complication that required reintervention.[69,80,83,88,90] Six studies

TABLE 4 Results from the two non-randomised comparative studies

	Study, first author (year of publication)							
	Chisci (2012)[66]				Nyheim (2013)[67]			
		Protocol				Protocol		
Outcomes	Time point	I: CTA, CDU at 1 month and every 6 months thereafter ($N = 376$)	II: CTA, CDU at 1 month and CDU every 6 months thereafter ($N = 341$)	*p*-value	Time point	I: CTA, CDU at 1, 6 and 12 months and annually thereafter ($N =$ NR)	II: CDU at 6–8 weeks, CT/CDU at 1 year and CDU yearly thereafter ($N = 56$)	*p*-value
Reintervention								
Number (%) of secondary interventions	During 3 years	68 (18.1)	56 (16.4)	0.625	–	–	–	–
	< 30 days	17 (4.5) (two asymptomatic and 15 symptomatic)	11 (3.2) (one asymptomatic and 10 symptomatic)	0.602	–	–	–	–
	> 30 days	51 (13.6) (31 asymptomatic and 20 symptomatic)	45 (13.2) (24 asymptomatic and 21 symptomatic)	0.621	> 30 days	NR	14 (25)	–
Secondary intervention free survival (%)	At 3 years	82	83.5	0.876	–	–	–	–
Conversion to open repair, *n* (%)	Not specified	3 (0.8)	1 (0.3)	0.626	–	–	–	–
Mortality								
Number (%) of participants who died (all cause)	During 3 years	8 (2.1)	6 (1.8)	0.932	< 30 days	NR	0	–
	–	–	–	–	> 30 days	NR	9 (16)	
Number of participants who died (AAA related)	–	–	–	–	> 30 days	NR	0	
Overall survival rate (%)	At 3 years	83	84	0.764	–	–	–	
Freedom from AAA-related mortality (%)	At 3 years	94.9	95.6	0.814	–	–	–	–

continued

TABLE 4 Results from the two non-randomised comparative studies (*continued*)

	Study, first author (year of publication)							
	Chisci (2012)[66]				Nyheim (2013)[67]			
		Protocol				Protocol		
Outcomes	Time point	I: CTA, CDU at 1 month and every 6 months thereafter (*N* = 376)	II: CTA, CDU at 1 month and CDU every 6 months thereafter (*N* = 341)	*p*-value	Time point	I: CTA, CDU at 1, 6 and 12 months and annually thereafter (*N* = NR)	II: CDU at 6–8 weeks, CT/CDU at 1 year and CDU yearly thereafter (*N* = 56)	*p*-value
EVAR-related adverse events (only symptomatic data for Chisci* et al.[66]*), n (%)								
Type I endoleak	During 3 years	7 (1.9)	5 (1.5)	NR	–	–	–	–
A (proximal)	< 30 days	2 (0.5)	1 (0.3)	1.000	< 30 days	NR	2 (3.6)	–
	> 30 days	4 (1.1)	4 (1.2)	1.000	–	–	–	–
B (distal)	During 3 years	1 (0.3)	0	1.00	–	–	–	–
Type II endoleak		57 (15.2)	45 (13.2)	0.519	< 30 days	NR	9 (16)	–
	–	–	–	–	At 6 months	NR	1 (1.8)	–
Type III endoleak	During 3 years	3 (0.8)	3 (0.9)	1.000	–	–	–	–
	< 30 days	0	1 (0.3)	1.000	< 30 days	NR	1 (1.8)	–
	> 30 days	3 (0.8)	2 (0.6)	1.000	–	–	–	–
Graft migration	> 1 cm; during 3 years	2 (0.5)	1 (0.3)	0.565	> 10 mm; > 30 days	NR	4 (7.1)	–
Graft kinking	> 30 days	5 (1.3)	10 (3.0)	0.050	–	–	–	–
Limb occlusion	During 3 years	10 (2.6)	8 (2.3)	0.977	< 30 days	NR	2 (3.6)	–
	–	–	–	–	> 30 days	NR	0	–

Outcomes	Study, first author (year of publication)							
	Chisci (2012)[66]				Nyheim (2013)[67]			
		Protocol				Protocol		
	Time point	I: CTA, CDU at 1 month and every 6 months thereafter ($N = 376$)	II: CTA, CDU at 1 month and CDU every 6 months thereafter ($N = 341$)	*p*-value	Time point	I: CTA, CDU at 1, 6 and 12 months and annually thereafter ($N =$ NR)	II: CDU at 6–8 weeks, CT/CDU at 1 year and CDU yearly thereafter ($N = 56$)	*p*-value
Limb ischaemia	During 3 years	5 (2.7)	2 (0.6)	NR	–	–	–	–
	< 30 days	2 (0.5)	0	0.501	–	–	–	–
	> 30 days	3 (0.8)	2 (0.6)	1.000	–	–	–	–
Aneurysm rupture	> 30 days	2 (0.5)	1 (0.3)	1.00	–	–	–	–
Graft infection	During 3 years	0	0	–	< 30 days	NR	2 (3.6)	–
Bowel ischaemia	During 3 years	2 (0.5)	0	0.501	–	–	–	–
	< 30 days	1 (0.3)	0	1.000	–	–	–	–
	> 30 days	1 (0.3)	0	1.000	–	–	–	–
Aneurysm diameter/sac size	> 5-mm increase during 3 years	54 (14.4)	43 (12.6)	0.565	> 5-mm increase within > 30 days	NR	6 (10.8)	–
Reduction in mean aneurysm diameter	–	–	–	–	During 3 years	9 mm		–

NR, not reported.

TABLE 5 Results of the cohort studies according to the type of surveillance protocol

Study information	Surveillance protocols					
	Early and mid-term CTA and/or CDU and long-term CDU surveillance	Early CTA, mid-term CDU and long-term CTA surveillance	Early CTA and CDU, mid-term CDU and long-term CTA surveillance	CDU-based surveillance	Combination of CTA and CEU and CDU throughout surveillance	Early CTA, mid-term CEU and long-term CTA or CEU surveillance
Number of studies	8	2	10	3	1	1
Total enrolled, *n*	2701	405	4000	886	100	222
Total analysed, *n*	1821	401	3766	886	100	222
Follow-up (months)	Mean 20	Mean 24.6	Mean 14.6	Mean 22.3	Mean 23.2	Mean 29.6
Outcomes, % (number of studies reporting each outcome)						
All-cause mortality	Early: 0–1.2 (3)	17.2–28.6 (2)	Early: 0.5–7.7 (4)	4.4 (1)	6	6.8
	Late: 0–19.7 (3)	Early: 0.8 (1)	Late: 3.9–42 (8)			
Aneurysm-related mortality	0.5–0.8 (2)	0.2 (1)	0.4 (1)	NR	NR	0
Reintervention	1.1–11.5 (6) (NC = 2)[a]	9.5–15.6 (2)	2.9–23.8 (9); NC (1)[a]	10.1 (1)	6	10.8
Clinical complications						
Type I endoleak	0–7.9 (5)	1.8–3.1 (2)	Early: 0.8–8.3 (3)	NC (1)[a]	2	1.8
			Late: 1.8–7.7 (4)			
Type II endoleak	0.5–13 (6)	1.5–24.8 (2)	1–24.8 (5)	NC (1)[a]	26	24.8
Type III endoleak	0 (1)	0.4–1.6 (2)	0–0.8 (4)	NR	0	0.45
Thrombosis	0.6–5.6 (2)	NR	2.5–4.5 (3)	NR	4	4.5
Aneurysm rupture	0–1.3 (5)	0.8 (1)	0–0.6 (3)	NR	0/100	NR
Limb occlusion	0–1.1 (3)	3.1–3.7 (2)	5.3–7.2 (2); NC (1)[a]	0–0.4 (2)	NR	NR

Study information	Surveillance protocols					
	Early and mid-term CTA and/or CDU and long-term CDU surveillance	Early CTA, mid-term CDU and long-term CTA surveillance	Early CTA and CDU, mid-term CDU and long-term CTA surveillance	CDU-based surveillance	Combination of CTA and CEU and CDU throughout surveillance	Early CTA, mid-term CEU and long-term CTA or CEU surveillance
Kinking	0.5 (1)	NR	NR	7.5 (1)	NR	NR
Migration	1 (1)	NR	NR	NR	NR	NR
Infection	NR	0.4–0.8 (2)	0–2 (2)	NR	NR	NR
Ischaemia	NR	0.4 (1)	0.2 (1)	NR	NR	NR
Stenosis	NR	4.7 (1)	0.5 (1)	NR	NR	0.4

NC, not calculable; NR, not reported.

a Fargion *et al.*[89] ($N = 966$) and Oshin *et al.*[82] ($N = 295$) who used CDU and a combination of CTA and CDU for surveillance, Carroccio *et al.*[71] ($N = 351$) who used a combination of CTA and CDU and both Blom *et al.*[69] ($N = 248$) and Collins *et al.*[73] ($N = 160$) who used CDU only, reported the number of events per total procedures and did not provide the number of participants experiencing those events. Therefore, reintervention or complication rates could not be calculated.

reported the total number of reintervention procedures performed during surveillance and are described below in accordance with the type of surveillance protocol.[69,71,73,82,85,89] In particular, three of these studies reported the total number of graft limbs that required an intervention.[69,71,82]

Reintervention after EVAR was mainly indicated for a type I endoleak in < 1%[75] to 8.3% of participants,[79] for a type II endoleak in < 1%[41,79] to 13.1% of participants,[89] for a type III endoleak in < 1%[68,79,85] and 1.6% of participants,[74] for limb occlusion in < 1%[72,78,79] to 7.2% of participants and for thrombosis/stenosis in < 1%[41] to 10.7% of participants.[85] In ≤ 1% of the participants for each report, reintervention was needed for aneurysm rupture, infection, graft angulation, ischaemia, haematoma, false aneurysm, endotension, migration and kinking.[41,68,70,74–76,85,86] In one study, a high proportion of the participants (8.3%) who were detected with primary endoleaks were treated during the early postoperative follow-up.[79] Another study reported that reintervention was required in 13.6% of participants for the repair of any endoleaks during a mean follow-up of 15.8 months (range 1–48 months).[87]

Overall aneurysm diameter

Eleven of the studies reported various data on aneurysm shrinkage/expansion (see *Appendix 12*).[40,41,68,74,76,79,81,83,85–87] The observed average aneurysm size decrease was 4.3 mm[83] to 15 mm.[40] In studies assessing aneurysm shrinkage, > 50% of participants were reported to have aneurysm shrinkage during follow-up.[68,74,76,79,83,85] It is worth noting that the definitions of decreased aneurysm size and the axis of diameter measured varied among the included studies.

Overall mortality

Overall, 19 cohort studies reported the number of deaths during surveillance after EVAR (see *Appendix 13*).[40,41,68,70,72–77,79,80,83–88,90] The all-cause mortality rate ranged from 0% during a 12-month follow-up[80] to 42% during a mean follow-up of 54.8 months.[85] It is worth noting that the study that reported the highest all-cause mortality (42%) focused on high-risk patients, some of whom presented with features of hostile neck anatomy. Two studies reported that no deaths occurred during follow-up.[77,80] Early mortality rate (< 30 postoperative days) ranged from 0.5%[74] to 7.6%.[75] With regard to the study that reported the highest postoperative mortality rate (7.6%; 17 patients), it is worth noting that 13 out of the 17 patients underwent EVAR as an urgent procedure, whereas 4 out of the 17 patients underwent EVAR as an elective procedure.[75] Aneurysm-related deaths occurred in < 1% of the participants in four studies.[40,41,68,83] Three studies reported no aneurysm-related deaths.[70,75,87]

Results in accordance with the type of surveillance protocols

The 25 included cohort studies (22 published in full[40,41,68–87] and three abstracts[88–90]) assessed a total of 7196 participants. There was considerable heterogeneity among the included cohort studies in terms of imaging modalities, frequency of imaging, length of follow-up and outcome measures.

The outcomes from the included cohort studies are presented according to the six broad surveillance protocols we described before (see *Study characteristics of all included studies*). *Table 5* presents a summary of the results of the included cohort studies in terms of mortality, reintervention and complication rates.

1. Early and mid-term computed tomography angiography and/or colour duplex ultrasound and long-term colour duplex ultrasound surveillance = eight studies (computed tomography angiography and/or colour duplex ultrasound then colour duplex ultrasound)

Table 6 details the results of the eight cohort studies, with a total of 1821 patients, that used CTA and CDU for the short- and mid-term surveillance and CDU for the long-term surveillance following EVAR.

Reintervention Among studies that used CDU and/or CTA for the short- and mid-term surveillance and CDU for the long-term surveillance after EVAR, reintervention was initiated in 1.1% of participants at a mean follow-up length of 24 months[40] to ≈11% of participants at a median follow-up length of 68 months.[76,90] Only four studies provided a breakdown of the type of reintervention or reported the proportion of participants

TABLE 6 Results of studies that used early and mid-term CTA and/or CDU and long-term CDU surveillance (CTA and/or CDU then CDU)

Characteristic	Study, first author (year of publication)							
	[a]Chaer (2009)[40]	Fargion (2016)[89]	Freyrie (2014)[76]	Ghotbi (2010)[77]	Harrison (2011)[41]	Kray (2015)[80]	Mazzaccaro (2011)[90]	Oshin (2010)[82]
Follow-up, months (range)	Mean 24 (1–48)	Median 30 (1–168)	Mean 32.9 ± 23.3 (1–77)	Mean 20 (NR)	Median 36 (12–57)	Up to 12 months' follow-up	Median 68 (1–144)	Median 24 (NR)
All-cause mortality, *n/N* (%)	5/184 (2.7)	NR	2/177 (1.1) at 30 days	0/100 (0) at 30 days	25/219 (11.7) at 12 months AAA related: 1/194 (0.5)	0/191 (0) at 12 months	6/488 (1.2) at 30 days 77/391 (19.7) at > 30 days AAA related: 3/391 (0.8)	NR
Reintervention rate, *n/N* (%)	2/184 (1.1)	47/289 (16.3) procedures	20/177 (11.3) at 45 months	6/100 (6)	9/194 (4.6) at 12 months	13/191 (6.8) at > 6 months	45/391 (11.5)	11/583 (1.8) limbs
Clinical complications *n/N* (%)								
Type I endoleak	2/184 (1.1)	9/289 (3.1) procedures	2/177 (1.1)	0/100 (0) at 3 months 0/100 (0) at 12 months	1/194 (0.5)	NR	31/391 (7.9)	NR
Type II endoleak	1/184 (0.5)	38/289 (13.1) procedures	23/177 (13.0)	15/100 (15) at 3 months 7/100 (7) at 12 months	4/194 (2.1)	17/191 (8.9) at 1 month 18/191 (9.4) at 6 months	3/391 (0.8)	NR
Type III endoleak	NR	NR	0/177 (0)	NR	NR	NR	NR	NR
Thrombosis	NR	NR	10/177 (5.6)	NR	NR	NR	3/488 (0.6) at 30 days 8/391 (2.0)	NR
Limb occlusion	0/184[b] (0)	NR	2/177[c] (1.1)	NR	2/194 (1.0)	NR	NR	11/583 (1.8) procedures
Kinking	NR	NR	NR	NR	1/194 (0.5)	NR	NR	NR

continued

TABLE 6 Results of studies that used early and mid-term CTA and/or CDU and long-term CDU surveillance (CTA and/or CDU then CDU) (*continued*)

Characteristic	Study, first author (year of publication)							
	[a]Chaer (2009)[40]	Fargion (2016)[89]	Freyrie (2014)[76]	Ghotbi (2010)[77]	Harrison (2011)[41]	Kray (2015)[80]	Mazzaccaro (2011)[90]	Oshin (2010)[82]
Aneurysm rupture	0/184 (0)	NR	2/177 (1.1)	NR	1/194 (0.5)	0/191 (0) at 6 months	5/391 (1.3)	NR
Migration	NR	NR	0/177 (0)	1/100 (1.0) at 24 months	NR	NR	NR	NR
Stenosis	NR	NR	1/177 (0.6)	NR	1/194 (0.5)	NR	NR	NR

NR, not reported.
a This study utilised CTA at 1 and 12 months and CDU annually thereafter.
b Graft occlusion.
c Renal artery occlusion.

with complications who required reintervention. Reinterventions were performed for type Ia endoleaks in 0.6%[76] to 1% of participants,[77] for type Ib endoleaks in ≈2% of participants,[40,76] for type II endoleaks in 1.1% of participants,[41,76] for thrombosis in 5.6% of participants,[76] for stenosis, haematoma and kinking in 0.5% of participants,[41,76] for aortic rupture in 1.1% of participants,[76] for occlusion in 1% of participants[77] and for migration in 1.5% of participants.[41] Two studies[82,89] provided information on the total number of reinterventions. In one study, among 289 participants who were followed up for a median of 30 months, a total of 47 reinterventions were required for the treatment of nine type I endoleaks and 38 type II endoleaks.[89] In another study, among a total of 583 limbs at risk in 295 patients treated with EVAR, 11 stent–graft limb occlusions (1.8%) were identified over a median follow-up length of 24 months, and eight of these required secondary intervention.[82]

Clinical incidence/complications The proportion of participants with type I endoleaks ranged from 0%[77] to 7.9%[90] in five studies that reported this information,[40,41,76,77,90] although the proportion of participants with type II endoleaks ranged from 0.5%[40] to 13%[76] in six studies.[40,41,76,77,80,90] No incidence of type III endoleaks was reported. Two studies[76,90] reported the proportion of participants with thrombosis and the rate was fairly high in one study (5.6% at a median follow-up length of 32 months)[76] compared with the other study (2.0% at a median follow-up length of 68 months).[90] Data from five studies showed that aneurysm rupture occurred in up to 1.3% of participants.[40,41,76,80,90] Less than 1% of participants experienced limb occlusion (≈1%),[41,76] kinking (0.5%),[41] stenosis (0.5–0.6%)[41,76] and migration (1%).[77]

Aneurysm diameter Three of the studies that used CDU for the long-term surveillance after EVAR reported data on aneurysm shrinkage/expansion.[40,41,76] Two studies observed an average decrease in aneurysm size of 10 mm[76] and 15 mm,[40] respectively. One study reported that around 73% of participants showed an aneurysm shrinkage of > 5 mm.[76] Another study reported an aneurysm expansion of ≈1%.[41]

Mortality Of the eight studies that used CDU and CTA short- and mid-term surveillance after EVAR and then CDU for the following examinations, six studies reported data on mortality. Of these, three studies reported data on early mortality (< 30 days)[76,77,90] and three studies reported data on late mortality (> 30 days).[40,41,80] With regard to early mortality, no deaths occurred in one study[77] and the proportions of participants who died were similar in the other two studies (1.1%[76] and 1.2%,[90] respectively). Mortality rates of > 30 days ranged from 0% at 1 year[80] to 19.7% during a median follow-up length of 68 months.[90]

Data from two studies indicate that < 1% of participants died as a result of aneurysm-related complications.[41,90] The overall survival rate was 86.2% at 3 years in one study[76] and 32% at 12 years in another study.[90]

2. Early computed tomography angiography, mid-term colour duplex ultrasound and long-term computed tomography angiography surveillance – two studies (computed tomography angiography then colour duplex ultrasound then computed tomography angiography)

The results from the two studies that used CTA immediately after EVAR, CDU at 6 months and CTA at 12 months and annually thereafter are presented in *Table 7*. The studies included a total of 401 patients.

Reintervention The proportion of participants who required reintervention was 9.5% in one study (median follow-up length of 42 months)[68] and 15.6% in the other study (mean follow-up length of 24.6 months).[74] In both studies, secondary procedures were undertaken mainly for treating limb occlusion (≈4% of participants),[68,74] stenosis (4.7% of participants)[74] and type I endoleak (1.8% of participants).[68]

Clinical complications Data from the two studies indicate that the presence of a type I endoleak was observed in 1.8%[68] and 3.1%[74] of participants and the presence of a type III endoleak was observed in 0.3%[68] and 1.6% of participants.[74] In one study, the proportion of participants with a type II endoleak was 1.5%.[68] In both studies, a similar proportion of participants had limb occlusion (3.7% in one study[68] and 3.1% in the other study[74]). Other complications, such as infection[68,74] and ischaemia,[68] were observed in

TABLE 7 Results of studies that used early CTA, mid-term CDU and long-term CTA surveillance (CTA then CDU then CTA)

Characteristic	Study, first author (year of publication)	
	Bisdas (2014)[68]	Donas (2016)[74]
Follow-up (months)	Median 42 (IQR 31–50)	Mean 24.6 (SD 17.4) range 0–61
All-cause mortality, *n/N* (%)	78/273 (28.6)	22/128 (17.2) at mean follow-up
		1/128 (0.8) at 30 days
Aneurysm-related mortality, *n/N* (%)	1/273 (0.4)	NR
Reintervention rate, *n/N* (%)	26/273 (9.5)	20/128 (15.6)
Clinical complications, *n/N* (%)		
Type I endoleak	5/273 (1.8)	4/128 (3.1)
Type II endoleak	4/273 (1.5)	NR
Type III endoleak	1/273 (0.4) at 10 months	2/128 (1.6)
Limb occlusion	10/273 (3.7)	4/128 (3.1)
Aneurysm rupture	NR	1/128 (0.8)
Infection	1/273[a] (0.4)	1/128 (0.8)
Ischaemia	1/273 (0.4)	NR
Stenosis	NR	6/128 (4.7)

NR, not reported.
a Groin infection.

< 1% of participants across the studies. One study reported aneurysm rupture in 0.8% of participants and stenosis in 4.7% of participants.[74]

Aneurysm shrinkage Aneurysm shrinkage was observed in > 50% of participants in both studies. The definitions of aneurysm shrinkage varied between studies despite the availability of reporting standards. The average decrease in aneurysm size was 9 mm (IQR 3–15 mm) at a median follow-up length of 42 months in one study[68] and ≈4 mm at a mean follow-up length of 24.6 months in the other.[74]

Mortality The proportion of deaths was 17.2% (mean follow-up length of 24.6 months) in one study[74] and 28.6% in the other study (median follow-up length of 42 months).[68] One study reported an early mortality rate (< 30 days) of 0.8%.[74] The rate of aneurysm-related death was 0.4% in one study.[68] The overall survival rate at 5 years was 67% in one study.[68]

3. Combination of computed tomography angiography and colour duplex ultrasound throughout surveillance after endovascular abdominal aortic aneurysm repair = 10 studies (computed tomography angiography and colour duplex ultrasound)

Table 8 shows the results from the 10 cohort studies, with a total of 3766 patients, that used a combination of CTA and CDU for surveillance after EVAR.[70–72,79,81,83–85,87,88] All but one study[81] reported data that could be tabulated. The frequency of imaging was broadly similar between the studies with follow-up imaging carried out at 1 month, 6 months, 12 months and annually thereafter in most of them.

Reintervention All but one study[84] provided information on the proportion of participants requiring reintervention. This ranged from 2.9% (mean follow-up length of 14 months)[70] to 23.8% of participants (mean follow-up length of 31.9 months).[85] Reinterventions (see *Appendix 11*) for type I endoleaks occurred in 1%[86] to 8.3% of participants,[79] for type II endoleaks in 1.7% of participants,[79] for any type of endoleak

TABLE 8 Results of studies that used a combination of CTA and CDU throughout surveillance after EVAR (CTA and CDU)

Characteristic	Study, first author (year of publication)									
	Bush (2001)[70]	Carroccio (2002)[71]	Cochennec (2007)[72]	Dominguez (2010)[88]	Köcher (2004)[79]	Meier (2001)[81]	Parlani (2002)[83]	[a]Schunn (2000)[84]	Soler (2015)[85]	Wolf (2002)[87]
Mean follow-up (months)	14.6 ± 12.4	20 ± 9 (range 2–54)	28 (NR)	NR	20.7 (range 2–60)	23.2 (range 2.0–78.8)	14 (IQR 7–27, range 1–46)	18 (length of follow-up 46)	54.8 ± 35.9	15.8 ± 11.3 (range 1–48)
Mortality, *n/N* (%)	12/104 (11.5)	NR	18/460 (3.9)	22/1378 (1.6) at 30 days	13/120 (10.8)	NR	Late mortality: 21/336 (6.3)	1/190 (0.5) at 30 days	83/197 (42)	< 30 days: 2/154 (1.3)
							AAA related: 1/336 (0.4)			> 30 days: 25/154 (16.2)
Reintervention rate, *n/N* (%)	3/104 (2.9)	26/702 (3.7) procedures	33/460 (7.2)	273/1378 (19.8)	16/120 (13.3)	NR	19/336 (5.6)	31/190 (16.3)	47/197 (23.8)	23/154 (15.0)
Clinical complications, *n/N* (%)										
Any endoleak										21/154 (13.7)
Type I	18/104 (17.3) at 1 month	NR	NR	106/1378 (7.7)	Total early: 10/120 (8.3) [A 7/120 (5.8); B 3/120 (2.5)]	NR	4/366 (1.1) at 30 days	32/190 (16.8)	Reintervention for 21 endoleaks	1/154 (0.6)
Type II				329/1378 (5.7)	9/120 (7.5)	NR	22/366 (6.0) at 30 days	32/190 (16.8)		
Type III					Early: 1/120 (0.8)	NR	1/366 (0.3) at 30 days			
Thrombosis		26/702 limbs			3/120 (2.5)	NR				
Limb occlusion			33/460 (7.2) at follow-up			NR		10/190 (5.3)		
			9/460 (2.0) at week 1; 14/360 (3.9) at 1 month; 23/460 (5.0) at 6 months; 30/460 (6.5) at 36 months					at 30 days		
Aneurysm rupture						NR	1/366 (0.3) at 30 days			Late: 1/154 (0.6)
Infection	1/104 (≈1) at 3 months				0/120					
	2/104 (≈2) at 26 months									
Stenosis										

NR, not reported.

a Schunn *et al.*[84] used either CTA or CDU for long-term surveillance.

in approximately 14% of participants,[87] for limb occlusion in 7.2% of participants,[72] for thrombosis in 2% of participants,[79,86] for infection in 1% of participants,[70] for hook fracture in 2% of participants,[70] for migration in 0.6% of participants[87] and for ischaemia in 1% of participants.[86] One study reported that endoleaks (any type of endoleak) were observed at 1 month in approximately 17% of participants, but they did not seem to require reintervention throughout the follow-up period.[70]

Two studies provided information on the type of secondary procedures undertaken.[71,85] In one of these studies, which assessed a total of 351 participants, secondary procedures were performed for 26 limb occlusions out of 702 limbs evaluated.[71] In the other study, which assessed a total of 197 participants, 70 secondary procedures were performed to repair 12 type Ia endoleaks, nine type Ib endoleaks, 29 type II endoleaks, two type III endoleaks, one endotension, 29 stenosis/occlusions, three infections and three ruptures.[85]

Clinical complications Surveillance strategies based on the use of CTA and CDU picked up a type I endoleak in 1.1%[83] to 8.3% of participants[79] 1 month after EVAR. Type III endoleaks were identified in < 1% of participants[75,79,83] and type II endoleaks were detected in 5.7%[88] to 7.5%[79] of participants at 30 days. One per cent of these type II endoleaks were detected immediately after EVAR (< 30 days).[83] In one study, thrombosis was detected in 2.5% of participants during a mean follow-up length of ≈20 months,[79] whereas in another study, the proportion of participants with limb occlusion was reported to increase during the follow-up period (by 2% in the first week after EVAR, 3.9% at 1 month, 5% at 6 months and 6.5% within 3 years).[72] Infection was reported in 2% of participants in one study.[70] The results of two studies indicate that aneurysm rupture occurred in <1% of participants.[83,87]

Aneurysm diameter Five studies reported information on the aneurysm diameter.[79,81,83,85,87] A decrease in aneurysm diameter was detected in > 50% of participants after EVAR.[79,83,85] It is worth noting, however, that the definitions of aneurysm size shrinkage and the duration of the follow-up period varied among studies. In one study,[79] the proportion of participants with shrinkage (i.e. a decrease in aneurysm diameter) increased as the length of follow-up doubled (58.6% at > 12 months' follow-up and 67.4% at > 24 months' follow-up). One study reported a mean aneurysm shrinkage of 7.3 mm during a mean follow-up length of 23 months.[81] In another study, there was no change in orthogonal and transverse aneurysm diameter during a mean follow-up length of 15.8 months.[87]

Mortality All but one study[71] reported information on mortality. The late mortality rate (> 30 postoperative days) ranged from 3.9%[72] during a mean follow-up length of 28 months to 42% during a mean follow-up length of 54.8 months.[85] The mortality rate assessed within 30 days of EVAR ranged from 0.5%[84] to 7.7%.[83] One study reported a proportion of aneurysm-related deaths of 0.4% at a mean follow-up length of 14 months.[83]

4. Colour duplex ultrasound-based surveillance (three studies)

Three studies with a total of 886 patients used exclusively CDU-based imaging for surveillance after EVAR. One of these three studies also used CTA, but for selective cases only.[73]

Reintervention/complications In one study, 10% of participants required a secondary intervention for the treatment of limb occlusion (0.4%) and limb outflow impairment (7.5%).[78] Kinking was observed in 7.5% of participants, but no reintervention was required.

Across the three studies, the rate of reinterventions ranged from 2%[69] to 9% (type I endoleaks = 2%; type II endoleaks = 7%).[73]

Aneurysm shrinkage None of the studies reported on aneurysm shrinkage.

Mortality One study reported a mortality rate of 4.4% during a 5-year follow-up period.[73]

5. Combination of computed tomography angiography and contrast-enhanced ultrasound/colour duplex ultrasound throughout surveillance = one study (computed tomography angiography and colour duplex ultrasound and contrast-enhanced ultrasound)

In one study with a total of 100 participants, CTA, CEU and CDU were used at 1, 3, 6 and 12 months after EVAR and annually thereafter. The mean duration of the follow-up period was 23.2 months.[86]

Reintervention Reinterventions were needed for participants with iliac limb thrombosis (2%), type I endoleaks (1%), external artery iliac occlusion (2%) and spinal cord ischaemia (1%). The two reinterventions for the external iliac artery occlusion occurred at 1 month and 8 months.

Clinical complications A type I endoleak was detected in three patients (3%): one on 2 days postoperatively, one at 4 months and one at 6 months. Within 24 months, type II endoleaks were detected in 26 patients (26%). At 6 months, four patients (4%) showed signs of thrombosis. No patients had aneurysm ruptures at any point during the follow-up period.

Aneurysm diameter The mean baseline aneurysm diameter was 55.2 mm and ranged from 45 to 99 mm. During the follow-up period, an increase in aneurysm diameter (of 6 mm) was observed in two patients (2%). The diameter of the aneurysm was unchanged in 98 patients (98%).

Mortality Six patients died of all-cause mortality during the follow-up period (mean 23.3 months).

6. Early computed tomography angiography, mid-term contrast-enhanced ultrasound and long-term computed tomography angiography or contrast-enhanced ultrasound surveillance = one study (computed tomography angiography then contrast-enhanced ultrasound then computed tomography angiography or contrast-enhanced ultrasound)

In one study with a total of 222 patients, surveillance after EVAR was based on CTA at 1 month, CEU at 6 months and yearly examinations with either CTA or CEU thereafter. The mean duration of the follow-up period was 29.6 months.[75]

Reinterventions A total of 24 participants (10.8%) required interventions during the follow-up period and three participants required interventions within 30 days. The majority of the interventions were required because of thrombosis (10 participants) and type II endoleaks (eight participants). The rest of the reinterventions were for the treatment of type Ia and type III endoleaks combined (three participants), type Ib endoleaks (two participants) and infection (one participant). Details of the reinterventions for the three patients who suffered complications within the first 30 days were not reported.

Clinical complications Type I endoleaks occurred in four participants (1.8%), type II endoleaks occurred in 55 participants (24.8%) and type III endoleaks occurred in one participant (0.45%). Of the 55 type II endoleaks, eight were treated and 47 were managed conservatively with CEU follow-up. Stenosis occurred in one participant (0.4%) and thrombosis occurred in 10 participants (4.5%).

Aneurysm diameter The study did not report on aneurysm diameter.

Mortality Within 30 days postoperatively, 17 people (7.7%) died. During the follow-up period (mean 29.6 months), 14 of the remaining 205 participants (6.8%) died.

Summary of clinical effectiveness

The evidence for this assessment derives from two non-randomised comparative studies and 25 cohort studies assessing various surveillance protocols after EVAR based on a combination of CTA and CDU or CEU. Of the two included non-randomised comparative studies, one was judged to be of moderate

methodological quality, whereas the other study was considered to be of poor quality. The majority of the cohort studies were judged to be of low or moderate methodological quality.

The study duration ranged from 3 years to 16 years among the included studies and the mean length of follow-up ranged from 14 months (IQR 7–27 months; range 1–46 months) to 54.8 months (SD 35.9 months). The characteristics of the participants and the type of aneurysm varied between the studies.

The majority of the included studies assessed EVAR surveillance protocol based on a combination of CTA and CDU imaging throughout the follow-up period. Only two studies included CEU as the main imaging modality and one other study used CEU, but only in selective cases. We did not identify any studies comparing surveillance protocols based on CEU with those based on CDU.

Non-randomised comparative studies

The two non-randomised comparative studies assessed a total of 750 participants (694 participants in one study and 56 participants in the other), and compared a CTA and CDU surveillance protocol with a simplified protocol based on the use of CDU for long-term surveillance after EVAR. The timing of imaging varied between studies, and one of these did not provide suitable data for statistical comparisons. It is worth noting that the largest comparative study, which assessed a total of 694 participants, reported that there was no evidence of a difference between the two surveillance groups in terms of reintervention rate, clinical incidences, mortality and adverse effects, including renal impairment.

Cohort studies

Twenty-five cohort studies assessed a total of 7196 participants. There was considerable heterogeneity in terms of frequency of imaging modalities, duration of the follow-up period, outcome measures, definition of outcomes used (e.g. the definition of decreased aneurysm size) and the time points at which the outcomes were assessed. Owing to the observed heterogeneity between studies, it was not deemed to be appropriate to provide a statistical summary of the outcomes considered. We decided to group the studies according to their similarity in terms of type and frequency of imaging modalities for surveillance after EVAR and created six different surveillance categories (see *Table 5*). We tabulated and narratively summarised the results for each of these categories.

All but one of the included studies included CDU as part of their surveillance protocols. The remaining study followed up patients using CEU and/or CTA. In the majority of the studies ($n = 10$), surveillance after EVAR was based on the use of CTA and CDU throughout the follow-up period. Eight studies used CDU for long-term surveillance after EVAR and CTA and/or CDU for early and mid-term surveillance. Two studies used CTA for the long-term surveillance after EVAR (CTA at discharge, CDU at 6 months and then CTA at 12 months and annually thereafter). Two studies included CEU, together with CTA, as part of their surveillance strategies, and three studies adopted a surveillance protocol based exclusively on the use of CDU.

Overall, in the assessed cohort studies, the proportion of participants requiring reintervention after EVAR ranged from 1.1% during a mean follow-up period of 24 months to 23.8% in a cohort that included high-risk patients with hostile neck anatomy who were followed up for a mean length of 32 months. For the cohort studies that provided information on the type of complications requiring treatment, a reintervention was required mainly for the treatment of limb occlusion (< 1–7.2% of participants), thrombosis/stenosis (< 1–5.6% of participants), type II endoleaks (< 1–3.6% of participants), type I endoleaks (< 1–3.1% of participants) and type III endoleaks (< 1–1.6%). The studies that used a protocol based on assessments with CTA and/or CDU throughout the follow-up period showed the highest proportion of participants (range 2.9–23.8%) who required reintervention for complications after EVAR, including type I endoleaks, type II endoleaks, type III endoleaks, thrombosis, limb occlusion, infection and aneurysm rupture. It is worth noting that the study that reported the highest proportion of participants requiring reinterventions (23.8%) focused on high-risk patients, some of whom presented with features of hostile neck anatomy and had the longest follow-up period (mean length 54.8 months). Only limited data were available from studies using CEU as part of their surveillance protocol or studies based exclusively on CDU.

Across the included studies, all-cause mortality ranged from 2.7% (during a mean follow-up length of 24 months) to 42% in a cohort that included a proportion of high-risk patients with hostile neck anatomy (during a mean follow-up length of 54.8 months). Aneurysm-related deaths occurred in < 1% of the participants in four studies. All-cause mortality was generally higher among surveillance strategies that used CTA for early and long-term surveillance after EVAR. One study based on long-term CDU surveillance (median follow-up length of 68 months; range 1–144 months) reported a higher mortality rate and a higher proportion of participants who required reintervention.

The current evidence from the literature assessing the effect of surveillance after EVAR does not show a consistent paradigm. The type of imaging modalities, frequency of imaging and length of follow-up vary considerably between surveillance protocols. Therefore, no firm conclusions can be drawn with regard to the optimal surveillance strategy after EVAR.

Summary of published endovascular abdominal aortic aneurysm repair registries data

Data from relevant registries are summarised in *Table 9* and the results are described in the following text. It is worth pointing out that data from existing clinical registries and databases are not organised in accordance with the imaging modalities used for post-EVAR surveillance.

The Endurant Stent Graft Natural Selection Global Postmarket Registry

The Endurant Stent Graft Natural Selection Global Postmarket Registry (ENGAGE) is a prospective, multinational, long-term post-market study of the real-world use of the Endurant stent–graft system (Medtronic, Santa Rosa, CA, USA) for infrarenal AAA repair. The registry, which used only minimal selection criteria to obtain a more realistic representation of the current clinical practice, commenced in March 2009 and ended in January 2017. Patients with unruptured infrarenal AAAs who underwent elective EVAR were recruited from 79 clinical centres in 30 different countries. A minimum of five consecutive patients were enrolled from each centre. An EVAR surveillance protocol was carried out in accordance with the standard practice at each clinical site, with the exception of the requirement for 30-day and 1-year imaging.

Five publications reporting data from the ENGAGE registry were identified in the literature[93–97] (*Table 10*). The study by Tang *et al.*,[93] which compared the 12 outcomes after repair of AAA with bifurcated versus aorto-uni-iliac configuration of the Endurant stent–graft, used data collected in the ENGAGE registry from March 2009 to August 2010. Among the total of 1172 participants in this study, 1089 (92.9%) received bifurcated device stent–graft repair and 83 (7.1%) were treated with an aorto-uni-iliac femorofemoral bypass. The study by Stokmans *et al.*[94] reported data from 1266 participants from March 2008 to April 2011. Both of these studies reported similar proportions of participants requiring secondary intervention at 1 month (1.5%[94] and 0.9%[93]) and at 12 months (4.6%[94] and 4.9%[93]). Reinterventions were needed for the repair of type I and type III endoleaks in 1.2% of participants in the Stokmans *et al.* study[94] and in 0.6% of participants at 12 months in the Tang *et al.* study.[93] In the Stokmans *et al.* study,[94] at 12 months, secondary procedures were performed in 2.0% of participants for occlusion/stenosis/kinking and in 0.6% of participants for persistent type II endoleaks. Overall, at 1 month, the detection rates of type I endoleaks, type II endoleaks, type III endoleaks, type IV endoleaks, graft occlusion, graft kinking and graft stenosis were similar in both of these studies (see *Table 10*). The occurrence of other complications, including bowel ischaemia, myocardial infarction, renal failure and stroke, was similar in both studies. In both studies, the all-cause mortality rate was 1.3% at 1 month and ≈8.5% at 1 year. In the Tang *et al.* study,[93] the proportion of participants who died from aneurysm-related causes was 1.2% at 1 month and 1.5% at 1 year.[93] In the Stokmans *et al.* study,[94] the 1-year assessment showed an overall survival rate of 91.6% (SD 1.4%) and an aneurysm-related survival rate of 98.8% (SD 0.5%).

The study by Karthikesalingam *et al.*[95] used data from the ENGAGE registry on reintervention and engraft complications at 3 years to predict whether patients would be at a low risk or a high risk of complications after EVAR based on the international validated St George's Vascular Institute score.[95] Overall, there were

TABLE 9 Characteristics of the identified EVAR registries

	Registry							
Characteristic	ENGAGE	EUROSTAR	KPSGR	ASERNIP-S	Vascunet database	The west of Scotland Anaconda Registry	RETA	Lifeline Registry of Endovascular Aneurysm Repair
Number of publications	5	16	5	4	1	4	2	4
Study dates	March 2009–January 2017	1996–2006	Since 2000 and ongoing	Between November 1999 and May 2001; January 2009 and May 2013; ongoing	2005–2009	June 2005–September 2009	January 1996–March 2000	1999–2004
Study centres	Multinational, 79 centres in 30 countries	European countries	17 Kaiser Permanente Northern California medical centres, USA	Australia	Nine countries (Denmark, Hungary, Italy, Norway, Sweden, UK, Australia, Finland and Switzerland)	Three hospitals in the west of Scotland, UK	UK	USA
Surveillance protocol	In accordance with standard practice at each clinical site, with the exception of the requirement for 30-day and 1-year imaging	Post-EVAR protocol varied within the centres. Most frequently, CT examinations were used during follow-up at 1, 6, 12, 18 and 24 months and annually thereafter	Post-EVAR protocol varied within the centres. Patients generally received a CT scan at 1 month and then usually every 6–12 months, depending on the clinical scenario	No standard protocol. Postoperatively up to 30 days, at 3 months, 6 months, 12 months and then on an annual basis	Varied depending on country	CT and abdominal radiography at discharge, 1 month, 6, 12 months and annually thereafter	Not specified	Not specified; follow-up up to 5 years

ASERNIP-S, Australian Safety and Efficacy Register of New Interventional Procedures – Surgical; KPSGR, Kaiser Permanente Endovascular Stent Graft Registry; RETA, Registry of Endovascular Treatment of Abdominal Aortic Aneurysms.

TABLE 10 Results of studies that analysed data from the ENGAGE registry

Characteristic	Study, first author (year of publication)						
	Stokmans (2012)[94]			Tang (2013)[93]		Karthikesalingam (2015);[95] and Bastos Goncalves (2015)[97]	Faure (2015)[96]
Study dates	March 2008–April 2011			March 2009–August 2010		March 2009–April 2011	March 2009–April 2011
Mean length of follow-up (months)				12		29.9 (range 24.0–36.8)	18
Mean (SD) aneurysm diameter (mm)	60.3 (11.7)					Median 58 (IQR 54–65)	
Mean age (years)	73.1 (SD 8.1; range 43–93)			73.1 (SD 8.1; range 43–93)		Median 74 (IQR 79–68)	
Total number of participants	1266			1172		1263	1143
Outcomes	***At 1 month,* N = *1151***	***At 1 month,* N = *1262 (ITT)***	***At 1 year,* N = *500***	***1 month,* N = *1089***	***1 year,* N = *325***		
Stent–graft kinking, *n* (%)	20 (1.7)			18 (1.6)	0		
Stent–graft occlusion, *n* (%)	23 (2)			19 (1.7)	1 (0.3)		39 [(92.9) 42 in total]; 13 (31.0) within 30 days and 30 (71.4) within 6 months
Stent–graft stenosis, *n* (%)	16 (1.4)			13 (1.2)	3 (0.9)		
Stent–graft migration, *n*	0					0	
Endoleak, *n* (%)	138 (12)						
Type I	16 (1.4)			10 (0.9)	0	18 [(1.4) Bastos Goncalves *et al.*[97]]	
Type II	114 (10)			102 (9.3)	19 (5.8)		
Type III	2 (0.2)			2 (0.2)	1 (0.3)		
Type IV	1 (0.09)			0	0		
Type I and/or III	17 (1.5)			12 (1.1)	1 (0.3)		
Undetermined	7 (0.6)			7 (0.6)	0		

continued

TABLE 10 Results of studies that analysed data from the ENGAGE registry (*continued*)

Characteristic	Study, first author (year of publication)					
	Stokmans (2012)[94]		Tang (2013)[93]		Karthikesalingam (2015);[95] and Bastos Goncalves (2015)[97]	Faure (2015)[96]
All-cause mortality, *n* (%)	16 (1.3)	42 (8.4)	14 (1.3)	28 (8.6)		
Procedure-related mortality (up to 30 days)			3/325 (0.9)	4/325 (1.2)		
Aneurysm-related mortality (up to 30 days)	–	1 (0.2)	4/325 (1.2)	5/325 (1.5)		
Bowel ischaemia, *n* (%)	3 (0.2)	2 (0.4)	2 (0.2)	0		
Myocardial infarction, *n* (%)	14 (1.1)	9 (1.8)	12 (1.1)	7 (2.2)		
Renal failure, *n* (%)	4 (0.3)	5 (1.0)	3 (0.3)	5 (1.5)		
Stroke, *n* (%)	2 (0.1)	2 (0.4)	2 (0.2)	2 (0.6)		
Respiratory failure, *n* (%)	–	1 (0.2)				
Conversion to open repair, *n* (%)	3 (0.2)	–				
Secondary interventions, *n* (%)	19 (1.5)	23 (4.6)	3/325 (0.9)	16/325 (4.9)	12 [(1%) for type I endoleaks]	
Endovascular (occlusion, stenosis or kinking)	8 (0.6)	10 (2.0)				
Endovascular (type I/III endoleak)	4 (0.3)	6 (1.2)	0/325	2/325 (0.6)		
Open bypass procedure	6 (0.5)	5 (1.0)				
Other	1 (0.07)					
Endovascular (persistent type II endoleak)	–	3 (0.6)				

Characteristic	Study, first author (year of publication)					
	Stokmans (2012)[94]		Tang (2013)[93]		Karthikesalingam (2015);[95] and Bastos Goncalves (2015)[97]	Faure (2015)[96]
Aneurysm rupture	–	0	0/325	1/325 (0.3%)		
Overall survival rate, % (SD)	91.6 (1.4) at 1 year					
Aneurysm-related survival rate, % (SD)	98.8 (0.5) at 1 year					
Aneurysm size	Increased by ≥ 5 mm (2.8%); stable (55.9%); decreased by ≥ 5 mm (41.3%) at 1 year					
Freedom from limb occlusion, % (SD)						97.9 (0.3) at 2 years

ITT, intention to treat.

Notes

Tang *et al.*:[93] 92.9% ($n = 1089$) received bifurcated device stent–graft repair. Therefore, only outcomes after repair of AAA with bifurcated device are considered here.

Karthikesalingam *et al.*:[95] outcomes in accordance with risk stratification (St George's Vascular Institute score) for predicted low-risk vs. high-risk group, including freedom from reintervention and freedom from endograft complications ($n = 1207$ analysed).

Bastos Goncalves *et al.*:[97] secondary intervention 12 out of 18 [corrected by remodelling the stent–graft, $n = 2$; with extension cuffs (proximal or distal), $n = 6$; others, $n = 4$].

107.6 type I endoleaks, 209.8 type II endoleaks and 86.3 type III endoleaks per 100 patient-years of follow-up (affecting 4.5%, 19.6% and 0.4% of participants, respectively). Aneurysm expansion that was greater than 5 mm was observed in 90.1 participants per 100 patient-years of follow-up (affecting 14.8% of participants). The study by Faure *et al.*[96] reported 97.9% freedom from limb occlusion at 2 years.

The EUROpean collaborators on Stent–graft Techniques for abdominal aortic Aneurysm Repair registry

The EUROSTAR registry was established in 1996 to collate and analyse data from patients who underwent endovascular treatment for AAAs. The EUROSTAR standardised case record forms were used to collect data. Information on patients with AAA enlargements but without detectable endoleaks (known as endotension), patients who had an elective treatment for AAAs and patients with suitable vascular anatomy for implantation of a stent–graft were collected from various centres in different European countries. The EUROSTAR registry is no longer active (patient enrolment was closed in November 2006).

Sixteen publications reporting data from the EUROSTAR registry were identified in the literature.[5,9,91,98–110] Post-EVAR protocols varied considerably between centres. In most centres, CTA examinations were used at 1, 6, 12, 18 and 24 months after EVAR and annually thereafter. Other imaging modalities used for EVAR surveillance were CDU, CEU and magnetic resonance imaging. It is worth noting, however, that these publications were based on data collected from 1996 to 2006, when CDU and CEU were not in much use in clinical practice. The results from each EUROSTAR report are outlined in *Table 11*.

The Kaiser Permanente Endovascular Stent Graft Registry

The Kaiser Permanente Endovascular Stent Graft Registry (KPSGR) is a prospective registry that makes use of electronic medical records to track device utilisation and to appraise short- and long-term EVAR outcomes. The data collection started in 2000 and is ongoing. Patients with endovascular repair of AAAs were identified from a retrospective review of EVARs performed at 17 Kaiser Permanente Northern California medical centres in the USA.

Five publications reported data from the KPSGR.[111–116] No standardised post-EVAR surveillance protocol existed during the data collection period. In general, patients received CTA at the 1-month follow-up and then every 6–12 months depending on the clinical scenario.

In three studies, the proportion of participants requiring reintervention was 10.3%,[115] 10.8%[112] and 15% (median of 32.2 months' follow-up), respectively.[116] The study by Hye *et al.*[112] reported an overall reintervention rate of 10.8%. Of the reinterventions, 4.6% were for endoleaks, 1.7% were for stenosis, 1.5% were for thrombosis, 1.3% were for occlusion, 1.6% were for device malfunction, 1.3% were for haematoma/seroma, 0.6% were for pseudoaneurysm, 0.6% were for abdominal compartment syndrome, 0.5% were for infection and 0.4% were for rupture. In the study by Walker *et al.*,[114] aneurysm rupture occurred in 1.2% of participants during a median follow-up length of 32.2 months (IQR 14.2–52.8 months). Aneurysm-related mortality was 0.6% at 1 month and 0.8% at 1 year, whereas all-cause mortality was 14.3% at 1 year. In the study by Anthony *et al.*,[115] all-cause mortality was 1.2% at the 1-month follow-up.

Australian Safety and Efficacy Register of New Interventional Procedures – Surgical

The Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S) is a national collection of data for the evaluation of EVAR. An audit containing information on patients who had a Zenith graft repair for AAA between November 1999 and May 2001 was managed and published by the ASERNIP-S.

No standardised EVAR surveillance protocols were specified. Postoperative follow-up was carried out at 30 days, 3 months, 6 months, 12 months and annually thereafter.

The 787 Zenith graft patients enrolled in the audit were followed up until 2008. Technical success was 93.5% at 30 days. During the 7-year follow-up period, reinterventions were required in 13.5% of

TABLE 11 Results of studies that analysed data from the EUROSTAR registry (1996–2006)

Study, first author (year of publication)	Study dates	Total number of participants	Mean length of follow-up	Summary of the major findings that are relevant to the review
Buth (2003)[91]	1996–NR	2272	NR	In total, 297 (12%) participants had type I or type III endoleaks Overall 2-year survival was 90% in the entire cohort A total of 0.6% ($n = 15$) of the participants had a rupture of their aneurysm at a mean of 16 months' follow-up, and 5.4% of participants reported an increase in the size of the aneurysm Secondary intervention was needed in 54% ($n = 160$) of those with type I and III endoleaks compared with 6% ($n = 118$) of those without endoleaks Type I and type III endoleaks were associated with an increased frequency of open conversion (11% vs. 0.8%) or risk of rupture of the aneurysm (3.4% vs. 0.25%) compared with those without endoleaks
Cuypers [(2011)[99] reprinted article]; Cuypers [(1999)[110] original article]	1994–98	899	Median 6.2 months (range 0–48 months)	At 18 months, cumulative patient survival was 88% and persistent endoleak-free survival was 79% During follow-up, procedure- or device-related complications occurred in 7–14% of patients, 0.7% of patients ($n = 6$) had aneurysm rupture and reintervention was needed in 4–4.7% of patients in each 3-month follow-up interval
Harris (2000)[5]	1996–2000	2464	12.19 months (SD 12.3 months)	There were 0.6% of patients ($n = 14$) with a confirmed rupture of their aneurysms. The cumulative rate of rupture was ≈1% per year The death rate at 30 days was 3.2% ($n = 79$) At 1 month, an endoleak was identified in 8.3% of patients ($n = 140/1688$) Significant risk factors for rupture included proximal type I endoleak, type III endoleak, graft migration and kinking. Significant risk factors for late conversion were proximal or distal type I endoleak, type III endoleak, type II endoleak, graft migration and kinking
Hobo (2006)[9]	1999–2004	2864	23 months (SD 12 months, range 1–60 months)	Secondary intervention was required in 8.7% of patients ($n = 247$) at a mean of 12 months after EVAR. The cumulative incidence of secondary intervention was 6.0%, 8.7%, 12% and 14% at 1, 2, 3 and 4 years, respectively. The most frequent reasons for secondary procedures were type I endoleak ($n = 144$), type II endoleak ($n = 370$), type III endoleak ($n = 101$), thrombosis/stenosis ($n = 100$) and migration/kinking ($n = 113$)

continued

TABLE 11 Results of studies that analysed data from the EUROSTAR registry (1996–2006) (*continued*)

Study, first author (year of publication)	Study dates	Total number of participants	Mean length of follow-up	Summary of the major findings that are relevant to the review
Koole (2011)[98]	1996–2006	6337	24.6 months (range 1–120 months)	Aneurysm rupture and aneurysm-related mortality occurred in 0.4% of patients ($n = 26$) and 2.5% of patients ($n = 162$), respectively. At 7 years, 95.9% of patients had freedom from rupture. A total of 1.3% ($n = 83$) had conversion to open AAA repair
Laheij (2000)[100]	1996–99	1023	20 months	In total, 18% of participants ($n = 186$) needed secondary intervention, occurring at a mean of 14 months after initial EVAR. The rates of freedom from intervention at 1, 3 and 4 years were 89%, 67% and 62%, respectively The 3-year cumulative survival rate of patients was 90% ($n = 41$) in those without a secondary intervention and 85% ($n = 13$) in those who had secondary intervention
Leurs (2004)[103]	1996–2004	676	13.5 months (range 1–60 months)	Results were presented for those with an aneurysm diameter that was < 5.5 cm [($n = 300$) group A] and > 5.5 cm [($n = 376$) group B] Device migration (0% vs. 2%), type I and type III endoleak (2% vs. 4%) occurred more frequently in those with a larger aneurysm The overall death rate after 3 years of follow-up was significantly higher in group B participants (4% vs. 14%; $p = 0.0025$). Aneurysm-related mortality at 3 years was significantly higher in group B (0.3% vs. 3%; $p = 0.02$)
Leurs (2005)[105]	1996–2004	4433		Evaluation of the determinants and consequences of surveillance completeness. Results were presented based on patients who attended all scheduled visits compared with those who came infrequently
Leurs (2006)[104]	1999–2005	3499		Analysis of clinical outcomes was based on infrarenal neck length. Overall results not presented
Leurs (2007)[102]	1998–2005	213	18 months (SD 16.1 months, range 1–60 months)	In total, 12% of participants ($n = 25$) needed secondary intervention occurring at a mean of 8 months after initial EVAR. The rates of freedom from intervention at 1 and 2 years were 86% and 83%, respectively The 2-year cumulative survival rate was 85% in participants without secondary intervention and 58% in those who had secondary procedures Complications, including migration, occlusion/stenosis and type I and type III endoleak, occurred more frequently in those who needed a secondary intervention

TABLE 11 Results of studies that analysed data from the EUROSTAR registry (1996–2006) (*continued*)

Study, first author (year of publication)	Study dates	Total number of participants	Mean length of follow-up	Summary of the major findings that are relevant to the review
Leurs (2007)[101]	1994–99	1190	3820 person-years of follow-up	Overall, all-cause death and aneurysm-related death occurred in 19.9% and 3.0% of the participants, respectively. In total, 7.1% of participants had conversion to open repair and 2.4% of participants had aneurysm rupture during the follow-up period. The most frequently occurring procedure-related complications were endoleak (13 cases per 100 patient-years), stenosis/thrombosis (4.6 cases per 100 patient-years), and stent migration (4.3 cases per 100 patient-years)
Peppelenbosch (2004)[106]	1998–2002	4392		Outcomes were presented for three groups defined by the preoperative diameter of the aneurysm. Overall results not presented
Szmidt (2007)[107]	1998–2006	445		Case studies of three patients
van Marrewijk (2004)[108]	1996–2002	3595	15 months (range 0–72 months)	Analysis of risk factors for type II endoleak and adverse events Overall, 55% of participants with type II endoleak had reintervention after EVAR along with aneurysmal growth compared with 15% of patients without any endoleak ($p < 0.0001$)
Vallabhaneni (2001)[109]	1996–2000	2862	Median 12 month (range 0–72 months)	The mortality rate at 30 days was 2.9% ($n = 85$). The cumulative survival rate at 48 months was 77.1% Late rupture of the aneurysm occurred in 14 out of 2464 participants for an annual cumulative rate of 1% Late conversion to open repair occurred in 41 out of 2862 participants for an annual cumulative rate of 2.1%

NR, not reported.

participants. Overall, 4.2% of participants developed type I endoleaks, 14% developed type II endoleaks, < 2% experienced kinking, stenosis, migration or thrombosis and < 1% developed type III endoleaks or infection.

All-cause mortality was 0.5% at 1 month, 32% at 5 years and 44% at 7 years. During the follow-up period (7 years after EVAR) 4.4% of participants (35/787) died from aneurysm-related causes. Ten of these deaths (1.5%) were due to ruptured aneurysms.

A recent publication by Fitridge *et al.*,[117] which combined data from a total of 1647 patients from two ASERNIP-S audits of EVAR (from 1999 to 2001 and from 2009 to 2013), reported a 1-year survival rate of 93.7% (1544/1647) and a 30-day survival rate of 98.4% (1620/1647).

Vascunet database

The Vascunet registry collected data from national and regional vascular registries in Australia, Denmark, Finland, Hungary, Italy, Norway, Sweden, Switzerland and the UK on primary AAA repairs performed between 2005 and 2009.

A total of 31,427 intact AAA repairs were assessed. The overall perioperative mortality rate (in-hospital or within 30 days) was 2.8% and was stable over time. The perioperative mortality rate varied from 1.6% (95% CI 1.3% to 1.8%) in Italy to 4.1% (95% CI 2.4% to 7.0%) in Finland. A total of 7040 ruptured AAA repairs were identified. The overall perioperative mortality rate was 31.6% (95% CI 30.6% to 32.8%), which decreased over time.[118]

Registry of Endovascular Treatment of Abdominal Aortic Aneurysms

The Registry of Endovascular Treatment of Abdominal Aortic Aneurysms was established in January 1996 to collect data from 41 centres that initially undertook EVAR in the UK.[119,120] The data for the first 1000 cases submitted to the registry were published in 2005 by Thomas *et al.*[119] Overall, the mortality rate was 11% at 1 year and 8% at 5 years. The cumulative risk of rupture was 2% at 5 years. Complications related to the aneurysm or device occurred in 13% of participants at 1 year and in 16% of participants at 5 years. The most common complications were endoleaks or graft migration during a mean follow-up length of 3.1 years (range 30 days to 5 years). The cumulative freedom from endoleak was 88% at 1 year and 68% at 5 years. The cumulative freedom from secondary procedures was 87% at 1 year and 62% at 5 years.

Lifeline Registry of Endovascular Aneurysm Repair

The Lifeline Registry of Endovascular Aneurysm Repair was established in 1998 to evaluate the long-term outcomes of endovascular treatment for patients with AAAs. Four publications have reported outcomes of EVAR based on the data submitted to the Lifeline Registry of Endovascular Aneurysm Repair from 1999 to 2004.[121–124] Outcome data from 2664 endograft patients were published in 2005.[124] The overall survival rate was 74% at 4 years, 66% at 5 years and 52% at 6 years. A survival analysis conducted using 6-year data revealed freedom from aneurysm rupture in 99% of patients who had undergone EVAR, freedom from aneurysm-related death in 98% of patients and freedom from surgical conversion in 95% of patients. Most secondary interventions (85%) were performed < 30 days after EVAR. Freedom from secondary interventions was 84% at 1 year and 78% at 5 years.

Anaconda Registry

The Anaconda Registry was a prospective database of clinical outcomes of 106 consecutive patients who underwent endoluminal repair of AAAs using the Anaconda endograft (Vascunet, Inchinnan, UK) in three hospitals in the west of Scotland between 2005 and 2009. Four publications based on data from the Anaconda Registry were identified in the literature.[76,86,92,125] Three of these publications were included in the review of clinical effectiveness evidence.[76,86,92] During a mean follow-up period of 2 years, 9.4% of participants died from causes other than aneurysm. There were no aneurysm-related deaths. Type II endoleaks were detected through CTA scanning at 1, 6, 12, 24, 36 and 48 months in 8.4%, 4.8%, 7.2%, 7.8%, 11.1% and 0% of patients, respectively. There were no type I, III or IV endoleaks. Five cases of endograft limb thrombosis were observed during follow-up. Four of these cases were treated by femorofemoral crossover grafting without any further complications. Follow-up CTA detected hypogastric artery occlusion in three other patients. All three patients remained asymptomatic with no further intervention required.[125]

Diagnostic performance of imaging modalities for surveillance after endovascular abdominal aortic aneurysm repair

The scoping literature searches identified a number of published systematic reviews assessing the diagnostic test accuracy of the imaging modalities considered for the purpose of this assessment. Therefore, we adopted a pragmatic approach and conducted an overview of reviews[126] in order to obtain appropriate estimates of diagnostic test accuracy to populate the economic model. The reviews included in the overview were used as a source of existing evidence, but were not formally updated.

Methods for assessing the diagnostic test accuracy of colour duplex ultrasound and contrast-enhanced ultrasound versus computed tomography angiography

Identification of studies

The literature searches for the clinical effectiveness review were sufficiently broad that they retrieved nine relevant diagnostic test accuracy reviews.[3,62,127–133] Therefore, specific searching to identify additional reviews was more focused but included appropriate subject headings and text word terms. To combine the search facets for endovascular aneurysm repair, the imaging modalities under consideration and diagnostic reviews, MEDLINE and EMBASE were searched from 1996 until March 2016, whereas the CDSR and DARE were searched on 29 March 2016 without date restrictions. The search strategies are reproduced in *Appendix 1*.

Eligibility criteria

We included systematic reviews of diagnostic test accuracy that compared imaging surveillance with CDU and/or CEU in participants who have undergone EVAR for AAA. CTA, despite not demonstrating perfect accuracy, is generally considered to be the reference standard for surveillance imaging after EVAR. To be eligible for inclusion, reviews had to report on the sensitivity and specificity of CDU and/or CDU for the detection of endoleaks and/or other relevant clinical complications.

Data extraction and management

Two reviewers (PS and CR) independently screened the titles and abstracts of all citations identified by the search strategies. Full-text copies of all potentially relevant studies were retrieved and assessed for eligibility independently by the two reviewers. Any disagreements during study selection were resolved by discussion or in consultation with a third reviewer (MB). A data extraction form was specifically designed and piloted for the purpose of this assessment (see *Appendix 2*). Detailed information on study design, participant characteristics, study settings, characteristics of the index tests and reference standard and estimates of accuracy was extracted. One reviewer completed the data extraction form (CR) and a second reviewer (MS) cross-checked the extracted data for possible errors or inaccuracies. There was no disagreement between the reviewers.

Quality assessment strategy

The risk of bias of included reviews was assessed using both the Assessment of Multiple Systematic Reviews (AMSTAR) tool for the assessment of the methodological quality of systematic reviews[134] and the recommendations of the York CRD.[58] The included reviews were independently assessed by two reviewers (PS, CR or MS). Disagreements were resolved by consensus or arbitration with a third reviewer (MB). We did not assess the quality of the abstracts, as the word limit for abstracts is usually insufficient to make informed judgements about the potential risk of bias of reported reviews.

Quantity and quality of the evidence

Characteristics of the included reviews

The literature searches retrieved a total of 48 records, and, after deduplication, 45 reports were available for full-text screening. Nine reviews met the inclusion criteria and were included in this assessment. No additional reviews were identified. *Table 12* shows the characteristics of the identified reviews. Eight of the included reviews were published in full, but one[131] was available as an abstract and was consequently excluded from the risk-of-bias assessment. The number of studies included in the reviews ranged from 8 to 35, the number of participants ranged from 259 to 4654, and the number of paired scans ranged from 639 to 5343. The review by Cantisani *et al.*[129] included two literature reviews, which are also included in this overview,[62,132] and the review by Howard *et al.*[131] included one literature review, but did not provide its bibliographic details. Three reviews assessed both CDU and CEU versus CTA,[62,132,133] two reviews[130,131] assessed CEU versus CTA and one review[130] provided sensitivity and specificity estimates for CEU.

Quality assessment of the diagnostic test performance reviews

The eight reviews of diagnostic test accuracy published in full were of mixed methodological quality.[3,62,127–130,132,133] The majority of the included reviews were considered to have searched major relevant bibliographic data sources, conducted hand-searching of references and provided example of key text words,[3,62,127,128,130,132] specified their inclusion/exclusion criteria[62,127,128,130,132,133] and provided sufficient information on the characteristics of included studies.[3,62,127,130,132,133] However, only one study provided information on the inclusion of grey literature and on a priori design,[127] two reported on duplicated selection and extraction,[62,127] two provided a list of excluded studies,[130,133] one assessed the presence of publication bias[62] and only two used the results of the risk-of-bias assessment to draw conclusions.[62,132] A potential conflict of interest was assessed in half of the included reviews.[62,130,132,133] Of the eight reviews published in full, one, by Cantisani *et al.*,[129] was rated as being at a high risk of bias because, for the majority of the AMSTAR and CRD criteria, the information was unclear or not reported (*Figures 4* and *5*). Four reviews were considered to be of good methodological quality.[62,127,130,132] The three remaining reviews were considered to be of moderate quality.[3,128,133]

Assessment of diagnostic test performance

All of the included reviews assessed the diagnostic test accuracy of CDU and/or CEU versus CTA for the identification of endoleaks during post-EVAR surveillance. Sun *et al.*[133] also assessed the accuracy of CDU for aneurysm sac measurements. Six reviews provided pooled estimates of accuracy for CDU,[62,127–129,132,133] five reviews provided these for CEU,[62,130–133] and two reviews reported the same accuracy estimates for CTA.[129,132] The systematic review by Ashoke *et al*.[127] provided estimates of accuracy for CDU based on eight published data sources and also combined the results of the published data with two unpublished data sources. The review by Karanikola *et al*.[3] did not combine estimates of test accuracy because of the heterogeneity observed between the included studies.

The pooled estimates of test accuracy for detecting all types of endoleaks are presented in *Table 13*. The lowest reported sensitivity estimate for CDU was 62%[128] and the highest was 96%;[127] the lowest specificity estimate was 90%[129] and the highest was 97%.[129] The lowest reported sensitivity estimate for CEU was 81%[133] and the highest was 98%;[62,131] the lowest specificity estimate for CEU was 78%[130] and the highest was 88%.[62] Two reviews[128,132] also reported the test accuracy estimates categorised by type of endoleak (*Table 14* provides further details). The review conducted by Chung *et al.*[130] also presented a narrative summary of the results of the included studies, indicating that the majority of endoleaks detected or missed by CEU were characterised as type II endoleaks.

Of the three reviews assessing the diagnostic test accuracy of both CDU and CEU,[62,132,133] two[62,132] were rated as being at a low risk of bias.[62,132] In particular, the results of the review by Karthikesalingam *et al.*,[132] which included more recent literature searches and provided estimates of accuracy by type of endoleak, were used to populate the economic model.

TABLE 12 Characteristics of the systematic reviews of diagnostic test accuracy

Study, first author (year of publication)	Aim	Databases searched	Number of included studies	Total number of participants/ paired scans	Surveillance imaging modality
Ashoke (2005)[127]	To synthesise available evidence regarding the diagnostic accuracy of CDU vs. CTA for the detection and classification of endoleaks after aortic endografting	MEDLINE, EMBASE, PubMed, BioMed, CENTRAL, Business Information Database System and Ingenta from 1991 to 2004	10	711 participants 1355 paired scans	CDU and CTA
Bevis (2012)[128]	To review the accuracy of CDU compared with CTA for endoleak detection	MEDLINE, Google Scholar (Google Inc., Mountain View, CA, USA) and the Current Controlled Trials register from 1998 to 2011	29	5343 paired scans	CDU and CTA
Cantisani (2015)[129]	To present a comprehensive overview of the use of CEU for post-EVAR surveillance	MEDLINE, EMBASE and The Cochrane Library from 1998 to 2015	8	> 259 patients > 1191 paired scans	CDU, CEU and CTA
Chung (2015)[130]	To assess the accuracy of CEU vs. CTA for the detection of endoleaks during post-EVAR surveillance	PubMed, EMBASE and The Cochrane Library from 1997 to 2013	8	454 patients 639 paired scans	CEU and CTA
Howard (2011)[131]	To assess the role of CEU for EVAR surveillance and endoleak detection	NR	11	NR	CEU and CTA
Karanikola (2014)[3]	To review the current literature for the effectiveness and safety of CDU compared with CTA for post-EVAR surveillance	PubMed, MEDLINE, Ovid, EMBASE and The Cochrane Library from 1995 to 2013	35	4525 patients	CDU and CTA
Karthikesalingam (2012)[132]	To review the diagnostic accuracy of CEU and CDU, focusing on the detection of clinically relevant type I and type III endoleaks	EMBASE, MEDLINE, the Current Controlled Trials register, DARE and The Cochrane Library from 1996 until 2012	31	4654 paired scans	CDU, CEU and CTA
Mirza (2010)[62]	To determine the diagnostic accuracy of CDU and CEU vs. CTA for endoleak detection	EMBASE, MEDLINE, Current Controlled Trials register, DARE and the Cochrane Controlled Trials Register from 1996 to 2009	21	2886 patients 2895 paired scans	CDU, CEU and CTA
Sun (2006)[133]	To investigate the diagnostic accuracy of CDU vs. CTA for the detection of endoleaks and aneurysm sac measurements	PubMed and MEDLINE from 1991 to 2005	21	1534 patients	CDU, CEU and CTA

NR, not reported.

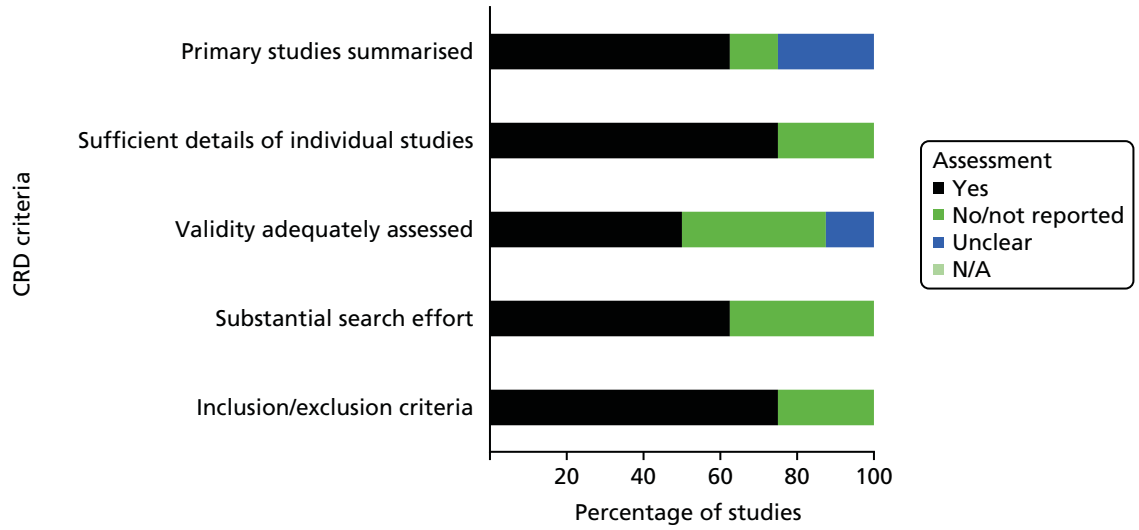

FIGURE 4 Risk-of-bias assessment using the CRD criteria. N/A, not applicable.

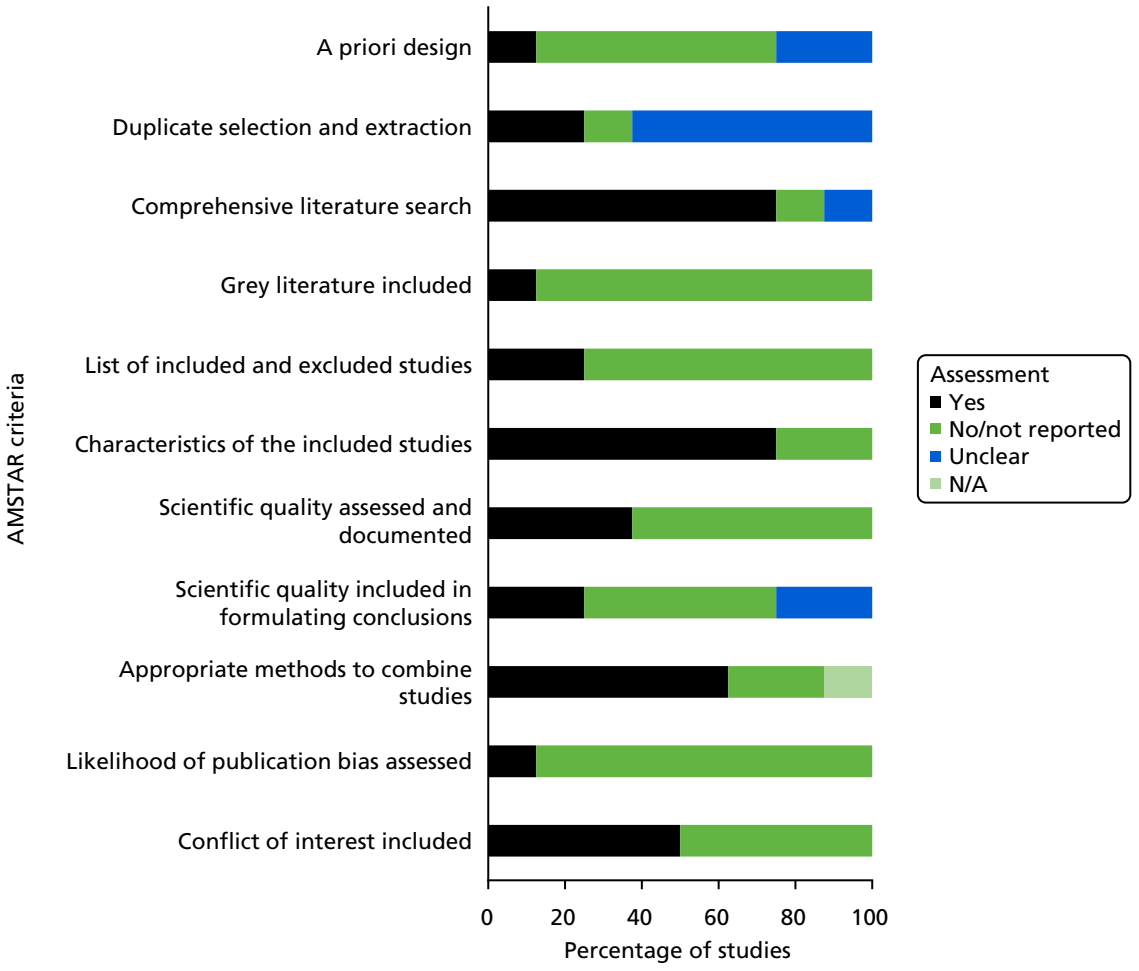

FIGURE 5 Risk-of-bias assessment using the AMSTAR criteria. N/A, not applicable.

TABLE 13 Pooled sensitivity and specificity estimates with 95% CIs from included systematic reviews of diagnostic test accuracy for endoleak detection (all endoleaks)

Study, first author (year of publication)	Imaging modality, % (95% CI)						Number of studies included in the review
	CTA		CDU		CEU		
	Sensitivity	Specificity	Sensitivity	Specificity	Sensitivity	Specificity	
Ashoke (2005)[127]			96 (52 to 87)	91 (87 to 95)			10 (eight published and two unpublished)
			67.4 (47.5 to 87.3)	92.2 (88.3 to 96.1)			Eight published
Bevis (2012)[128]			62 (58 to 65)	94 (93 to 94)			29
Cantisani (2015)[129]	Reports pooled data from Karthikesalingam *et al.*[132]		62–83 (NR)	90–97 (NR)	Reports pooled data from Mirza *et al.*[62]		8
Chung (2015)[130]					91 (87 to 95)	78 (74 to 82)	8
Howard [(2011)[131] abstract]					98 (95% CI NR)		11
Karanikola (2014)[3]	Pooled estimates not reported because of the observed heterogeneity between studies						35
Karthikesalingam (2012)[132]	70 (53 to 82)	98 (94 to 100)	74 (62 to 83)	94 (90 to 97)	96 (85 to 99)	85 (76 to 92)	31
Mirza (2010)[62]			77 (64 to 86)	94 (88 to 97)	98 (90 to 99)	88 (78 to 94)	21
Sun (2006)[133]			66* (52 to 81)	93 (89 to 97)	81* (52 to 100)	82 (68 to 97)	21

*$p < 0.05$.
NR, not reported.

TABLE 14 Reported pooled sensitivity, specificity and 95% CIs of the included diagnostic test performance systematic reviews (categorised by type of endoleak)

Study, first author (year of publication)	Imaging modality, % (95% CI)						Number of studies providing data
	CTA		CDU		CEU		
	Sensitivity	Specificity	Sensitivity	Specificity	Sensitivity	Specificity	
Karthikesalingam (2012)[132]							
Types I and III endoleaks			83 (40 to 97)	100 (97 to 100)	99 (25 to 100)	100 (98 to 100)	13 on CDU Eight on CEU
Accuracy*, n/N *(%)							
Bevis (2012)[128]							29
Type I endoleaks			43/51 (84)				
Type II endoleaks			126/228 (55)				
Type III endoleaks			6/10 (60)				
Type IV endoleaks			1/2 (50)				

Despite its limitations, CTA is still considered to be the best current imaging modality for the detection of endoleaks and clinical complications after EVAR. However, it is worth pointing out that the technique of ultrasound, and in particular of CEU, has fundamentally changed during the last decade. Many studies included in the identified reviews predate the most recent technical improvements. A mixture of early- and late-generation ultrasound machines and different CTA phases were used in the primary studies included in the identified systematic reviews. The impact of this 'technological heterogeneity' on the reported pooled estimates of accuracy is unclear. Two reviews attempted to address this issue. Mirza *et al.*[62] conducted a sensitivity analysis in which studies published prior to 2003 were excluded in order to assess the potential confounding effect of CEU equipment being more modern than CDU equipment. Similar sensitivity and specificity estimates were obtained for CDU and CEU. Chung *et al.*[130] reported that CEU studies that utilised second-generation contrast agents [i.e. SonoVue and Optison (Amersham Health, Princeton, NJ, USA)] had excellent sensitivity estimates compared with CEU studies that utilised first-generation contrast agents. They also observed that two studies that used both generations of contrast agents demonstrated good sensitivity for the detection of type II endoleaks. References for these two studies were, however, not given. The authors concluded that CEU was as accurate as CTA in detecting endoleaks when studies that utilised first-generation contrast agents were omitted from the analyses.[130] These results are in line with the claim of some investigators that more recent data seem to suggest that the specificity of CEU is higher than that of CTA (Professor Srinivasa Rao Vallabhaneni, Royal Liverpool University Hospital, 2017, personal communication). It is therefore possible that the performance of single-phase CTA as the current accepted reference test was not good enough to assess the accuracy of modern CEU. To take this into account in the economic model, we have conducted sensitivity analyses using different sensitivity and specificity estimates to reflect the recent technological improvements of imaging modalities for surveillance after EVAR.

Chapter 3 Assessment of cost-effectiveness

The evidence of the cost-effectiveness of using CDU or CEU alone or in conjunction with CTA for the surveillance of adults after EVAR was explored in the health economic component of this assessment. A two-step approach was used: (1) a systematic review of economic evaluations to retrieve any readily available evidence on cost-effectiveness, followed by (2) a de novo decision-analytic model to synthesise the available evidence on effectiveness, health-care resources used and costs. *Review of the cost-effectiveness studies* reports the systematic review of cost-effectiveness studies and *Economic analysis with a newly developed decision model* focuses on the economic model exercise.

Review of the cost-effectiveness studies

In order to summarise the available evidence on cost-effectiveness, we conducted a systematic literature review to identify studies that reported an economic evaluation of surveillance strategies for adult individuals after an EVAR intervention that included CDU and/or CEU compared with CTA.

Methods for review of the cost-effectiveness studies

Search strategy

Comprehensive search strategies were designed to identify economic evaluations of surveillance after EVAR (see *Appendix 1*). Searches were undertaken on 29 March 2016 and updated on 5 September 2016. The following databases were searched: NHS Economic Evaluation Database (from inception to 31 March 2015), the HTA Database (from inception to 5 September 2016) and MEDLINE In-Process and Epub Ahead of Print (from 1946 to 5 September 2016), EMBASE (from 1947 to week 36 2016) and Research Papers in Economics (from inception to 5 September 2016). The websites of HTA organisations were consulted for additional reports. The reference lists of all included studies were scanned, and appropriate experts were contacted for details of additional reports of cost-effectiveness.

The titles and abstracts of all citations identified by the search strategies for economic evaluations were screened for inclusion by a health economist (RH). The full-text papers of potentially relevant studies were retrieved and formally assessed for inclusion. Any uncertainty regarding study selection was discussed with the review team.

Inclusion and exclusion criteria

The inclusion criteria required the studies to be full economic evaluations (i.e. to consider the costs and effects of more than one strategy) in order to be included in the review. No restrictions were imposed on the way in which costs and/or effects were calculated. In addition, the study should compare post-EVAR surveillance strategies with at least one of the relevant diagnostic tests (e.g. CDU, CEU and CTA).

Either RCTs or decision-model economic evaluations were included. Studies that did not meet the inclusion criteria but reported relevant data that could inform the de novo economic model (e.g. costs, quality of life, model structure, probabilities) were retained for further consultation.

Data extraction

Data were extracted from the included studies using a prespecified data extraction form. The following information was sought:

- Background information, such as the research question, study design, intervention and comparator details.
- Characteristics of the study population (e.g. age, setting, inclusion criteria, exclusion criteria).
- Costing methodology, in particular the perspective, year, currency and the discount rate applied.

- Methodology used for the analysis of costs, effectiveness and uncertainty.
- Mean costs and outcomes, incremental costs and outcomes for the differences between groups and incremental cost-effectiveness ratios (ICERs). The results were reported when uncertainty was explored (e.g. 95% CI from the bootstrap analysis).
- Study strengths and limitations, as reported by the study authors.
- Conclusions and suggestions for further research, as reported by the study authors.

Quality assessment of the included studies

Cohort-based studies were assessed for quality against the *British Medical Journal* checklist for referees of economic evaluations.[135] When possible, the results were assessed from the NHS perspective. No decision-modelling studies matching the inclusion criteria were identified and therefore no studies were appraised against the NICE reference case.[60,136]

Data synthesis

No data synthesis was attempted, and a summary of the study characteristics, the costing methods used and the quality assessment of each study is provided.

Results of the review of cost-effectiveness studies

After deduplication of the records, 278 abstracts were screened for suitability. Seven studies were selected for full-text assessment, with only five of these studies meeting the inclusion criteria.[41,45,66,137,138] Two studies were conducted in the USA[45,137] and three studies were conducted in Europe (in Italy,[66] Ireland[138] and the UK[41]). All of these studies considered the effects of crossing from CTA to CDU plus plain radiography as first-line surveillance test. The studies estimated the difference in the number of CTAs required by the new surveillance strategy and the replaced strategy.

Beeman *et al.*[45] attempted to determine the cost savings and outcome differences of moving from both CTA and CDU imaging at 2 weeks, 6 months and 12 months after discharge and yearly thereafter (group 1 – before 1 July 2004) to CDU imaging as the sole surveillance test after the 2-week scans (group 2 – after 1 July 2004), with CTA being conducted only if any problem was detected by CDU. The authors analysed data on 82 patients for group 1 and on 117 patients for group 2. The clinical outcomes included the number of endoleaks detected and the measurement of the AAA sac diameter. The average length of the follow-up period was 3.5 years (range 0–9 years) and 1.6 years (range 6 months–4 years) for groups 1 and 2, respectively. The authors used hospital charges for CTA and CDU and noted that the decreased charges of US$1595 per patient per year (2008 prices) or US$198 per patient per year using Medicare reimbursements were realised by eliminating CTA surveillance in group 2. Moreover, the sensitivity of CDU for detecting endoleaks was 0.71 and the specificity was 0.99, whereas the sensitivity of CTA was 0.731 and the specificity was 0.991. The authors could not find any difference in aneurysm sac diameters measured by CDU and CTA when these scans were performed within 1 month of each other in group 1. Although the authors do not advocate eliminating CTA from the surveillance protocols, they state that its use should be limited to those circumstances in which it could provide other details about problems first detected by the ultrasound examination.

Bendick *et al.*[137] evaluated the use of an ultrasound contrast agent to enhance imaging for stent–graft surveillance and compared the costs of this technique with those of CTA. Data on the first 40 patients received in their vascular laboratory were analysed. The follow-up examinations ranged from 1 to 24 months after graft placement, with a mean follow-up time of 13.7 $\pm$ 6.1 months. Clinical outcomes included type I or type II endoleaks and costs were calculated using hospital charges with average costs per study that were equal to US$2779 for CTA, US$525 for CDU (including contrast) and US$147 for plain film abdominal radiography. No details of the price year were stated. The authors reported a sensitivity to the presence of any endoleaks of 53% (8/15) for CDU, 93% (14/15) for CEU and 73% (11/15) for CTA. The average 3-year charges per patient were US$22,232 and US$5376 for CTA-based surveillance and surveillance using CDU (including contrast) plus radiography, respectively (a saving of US$16,856 per patient over 3 years). The authors concluded that the technique of duplex ultrasound with an ultrasound contrast agent should

become the method of choice for stent–graft surveillance if the promising early results shown in their present series can be demonstrated in a larger patient population.

Chisci *et al.*[66] evaluated whether or not the imaging modality of surveillance influenced the detection of these conditions affecting the rate of asymptomatic secondary interventions (i.e. endoleaks, AAA expansion, migration, graft infection, graft thrombosis, conversion to open repair, postoperative renal impairment, bowel ischaemia and myocardial infarction). The authors followed a cohort of individuals for whom the follow-up protocol was changed at a given date. Protocol I, performed from January 2003 to December 2006, consisted of CDU plus CTA at 1 month after the procedure and every 6 months thereafter. Protocol II, performed from January 2007 to June 2010, included CDU plus CTA at 1 month after operation, CDU plus plain radiography every 6 months thereafter and CTA carried out during follow-up only for specific conditions. The authors analysed data for 376 individuals in protocol I and 341 individuals in protocol II with a mean follow-up of 1148 days (range 1–3204 days) and 942 days (range 1–1512 days), respectively ($p < 0.001$). On the 3-year analysis, the authors reported that protocol I cost approximately €3000, whereas protocol II cost approximately €1000; this was a threefold reduction in overall costs for protocol II ($p < 0.0001$). However, there were no details of the costing method used or the cost categories included in this analysis. The authors concluded that the detection rate of asymptomatic secondary interventions following EVAR is not affected by the type of surveillance imaging and that a surveillance schedule based primarily on CDU and radiography appears to be justified.

Gray *et al.*[138] retrospectively reviewed the CDU and CTA scans of all 145 patients who underwent EVAR at the Mater Misericordiae University Hospital, Ireland, from 1 June 2003 to 1 July 2010 and compared their results for endoleak detection and determination of residual sac size. The authors' aim was to assess the cost savings obtained if CDU was employed as a first-line surveillance tool following EVAR and to compare CDU and CTA in terms of efficacy. A total of 484 scans (68%) from 114 patients (78.6%) were available for comparison. The hospital protocol for patients after EVAR included CDU and CTA scans of the aorta within 7 days of surgery. After discharge, all patients underwent CDU at 1 month and then CDU and CTA at 6 months, 12 months and annually thereafter, provided that there was no documented endoleak on either the CDU or CTA. The costs of CTA (€500 per scan) and of radiography (€85) were considered in the costing calculations (expressed in 2010 prices). However, no details of the unit cost sources were reported. The authors found that CDU was 100% sensitive and 95.7% specific in the detection of endoleaks, with a positive predictive value of 28.7% and a negative predictive value of 100%. Furthermore, no statistically significant difference between the two imaging modalities was detected for the determination of residual AAA sac diameter. The authors hypothesised that a reduction in costs resulted from a change in protocol for the year 2010. Adopting a protocol with CDU and abdominal radiography as the first-line surveillance tool would result in a reduction in the number of postoperative CTA scans from 235 to 36. This would equate to a reduction in expenditure from €117,500 to €34,915 (a saving of €82,585). The authors concluded that CDU combined with plain abdominal radiography could safely replace CTA as the primary long-term imaging modality, resulting in a significant cost saving without the loss of scan accuracy.

The only study conducted in the UK[41] was a retrospective review of a prospectively maintained database of all patients undergoing elective, standard EVAR at a large tertiary referral centre (Royal Liverpool University Hospital). As with the other studies, the authors assessed the efficacy of a modified post-EVAR surveillance protocol based, primarily, on CDU and radiography, with CTA triggered only by significant findings on the CDU scan or radiography. The study included patients who had their EVAR operation between 1 August 2005 and April 2009, for whom at least 1 year's post-surgical follow-up data were available. The primary outcome measure considered was aneurysm rupture, whereas the secondary outcome measures included the requirement for secondary intervention and the number of CTA scans avoided, from which the radiation dose reduction and cost savings were calculated. The costs were expressed in 2010–11 prices and NHS tariffs were used to cost the tests (radiography, €35.71; CDU, €187.47; CTA, €269.61; exchange rate: £1 = €1.18).[41] The authors analysed data on 194 patients who underwent a total of 606 sets of surveillance imaging: 194 sets at 1 month (radiography, CDU and CTA) and 412 per protocol sets thereafter (radiography and CDU). No patient presented with ruptures or aneurysm-related complications that were not identified by the modified

surveillance protocol. The authors obtained the number of tests performed in the modified protocol and compared this with those that would have been performed for the same group had the protocol not been modified: 412 tests would have been conducted for the follow-up period that would have costed €14,711 for radiography, €77,326 for CDU and €111,078 for CTA. With the modified protocol, the number of tests and costs for radiography and CDU remained the same. However, only 71 CTA scans were conducted, with a cost of €19,142, which was a saving of €91,936. The authors concluded that follow-up after EVAR primarily based on CDU and radiography was feasible and safe, and reduced the use of CTA substantially, with consequent reductions in exposure to ionising radiation or an intravascular contrast medium, and costs.

Summary

Five studies met the inclusion criteria. All of these compared a surveillance strategy based on CDU or CEU with a CTA-based strategy. All of the studies assessed the reduction in costs as a result of the smaller number of CTA scans performed in the modified protocol. Only cohort studies were identified in the searches. However, the studies by Beeman *et al.*[45] and Chisci *et al.*[66] compared cohorts before and after the protocol changes took place. In the other studies, an economic analysis was conducted on the basis of the resources required (i.e. the number of CTA scans performed) if a hypothetical alternative protocol were to be used. Although all of the studies[41,45,66,137,138] fairly agree on the clinical outcomes of interest (i.e. endoleaks, AAA size and the need for secondary interventions), the reporting of costs and the cost method was disparate; although one study gave details of the cost categories, the unit cost used, the sources and the price year used, another study reported only the final cost calculations.

The only study from the UK that could inform NHS policy was the study conducted by Harrison *et al.*[41] However, neither this nor any of the non-UK studies used a preference-based measure of effectiveness. Moreover, judging from the number of scans used in the authors' cost calculations, the follow-up period considered was just over 2 years. This time horizon might not be long enough to consider all of the costs and consequences that are relevant for the question posed. As such, a new economic model was developed to assess the relative efficiency of CDU or CEU in the surveillance of individuals after EVAR. This is reported in the next section.

Economic analysis with a newly developed decision model

None of the available economic evaluations from the systematic review provided a definite answer on the cost-effectiveness of the use of CDU or CEU compared with that of CTA from the NHS perspective. Therefore, a de novo economic model was developed. The aim of the economic model was to assess the relative efficiency of surveillance strategies that used CEU or CDU alone or in combination with CTA.

Methods

Care pathways

Care pathways were discussed and developed within the project management group and the project advisory group meetings. It was agreed that surveillance involves the search for information about abnormalities that are relevant to the disease. It was also agreed that, once there is any indication of an abnormality, the patient status changes and the surveillance stops. After this, the following steps are then part of diagnostic investigations and/or eventual treatment. Hence, surveillance applies only to those individuals who are deemed to have no detected EVAR-related abnormalities and, as such, the model considers those patients who were regarded as not having an EVAR-related complication (e.g. at 6 months post surgery).

Five surveillance strategies were agreed:

1. annual CTA scan plus plain radiography
2. annual CDU scan plus plain radiography
3. annual CEU scan plus plain radiography

4. colour duplex ultrasound scan together with CTA scan and plain radiography at 1 year, followed by CDU scan and plain radiography on an annual basis
5. contrast-enhanced ultrasound scan together with CTA scan and plain radiography at 1 year, followed by CEU scan and plain radiography on an annual basis.

A positive test result in any of the surveillance strategies would trigger either further diagnostic investigations or treatment. This part of the decision model was identical for all of the strategies.

The economic model

A Markov model approach was selected for the decision-analytic model exercise.[135] Markov models have Markov states in which individuals spend a period of time, which is named a 'cycle'. At the end of each cycle, the individuals can remain in their current Markov state or move to another state. The probabilities of moving to other Markov states or remaining in the current state are named 'transition probabilities'. Individuals in the model would accrue costs and benefits (e.g. life-years) depending on the time spent in each Markov state and the interventions and/or events modelled within each Markov state. Markov models are particularly suitable to model recurrent issues and chronic diseases. They allow the incorporation of health states to reflect the movement of patients during surveillance, further diagnosis and treatment. In the current study, model states reflect the underlying condition (e.g. post-EVAR state with known or unknown complications), together with the decision on treatment (e.g. reintervention after EVAR). In all of these models, an absorbing state is included, in which all individuals would end up if the model was run for a sufficiently long period of time (e.g. Markov death state).

Description of the Markov model and the model structure

The model overall state-transition diagram is reported in *Appendix 14*. A simpler, schematic representation of the Markov model is shown in *Figures 6–9*. In these figures, circles represent the Markov states, whereas squares represent an event that occurs within a Markov state (e.g. an emergency procedure). Arrows show the direction of the possible transitions in the model. Unless specified, individuals can remain in a Markov state for more than one cycle. Eight Markov states are considered in the model:

1. normal (no residual EVAR complication)
2. abnormal Ia (intervention required)
3. abnormal Ib (intervention required – endoleak)
4. abnormal II (no intervention required)
5. enhanced follow-up (normal)
6. elective surgery (one cycle, temporary state)
7. enhanced follow-up (abnormal II)
8. death.

Figure 6 shows the four Markov states that reflect the underlying condition but are yet to be detected ('undiagnosed' states 2–4 above). *Figures 7–9* show one of these four Markov states representing the underlying condition together with the Markov states that individuals can move to (e.g. those states that result from a diagnosis – the 'diagnosed' side of the figure – correctly or not). The performance of a surveillance strategy in this model is given by the correct identification of those individuals with an abnormal condition and the corresponding transfer of those individuals into the true-positive states on the right sides of *Figures 7–9*.

All individuals start in the 'normal (no residual EVAR complication)' health state and can develop abnormalities as the model runs (see *Figure 6*). The surveillance strategies aimed to detect a variety of conditions and complications . These were generically described as 'abnormalities' and were divided into two categories: conditions that trigger an elective intervention and conditions that, on clinical assessment, necessitate closer follow-up (e.g. additional 6-month CTA scans). The first category was subdivided into two: abnormal 1a includes non-endoleak-triggered interventions (e.g. limb occlusions, graft infections) and abnormal 1b counts for the endoleak-prompted interventions (e.g. type I, III and IV, type II or endotension

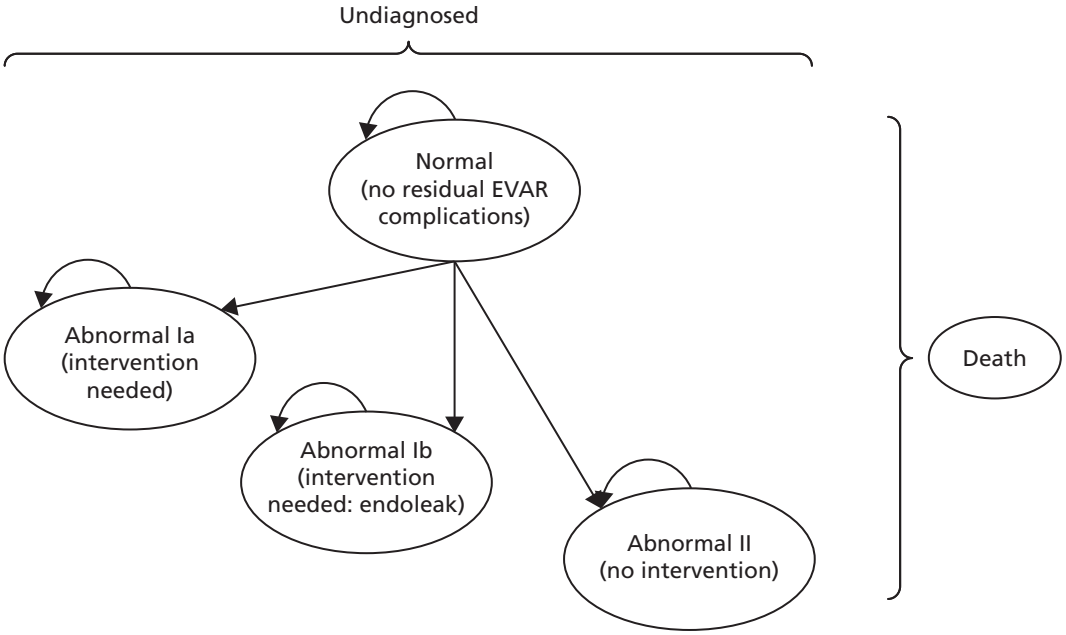

FIGURE 6 Schematic diagram of the surveillance for EVAR Markov model; underlying condition.

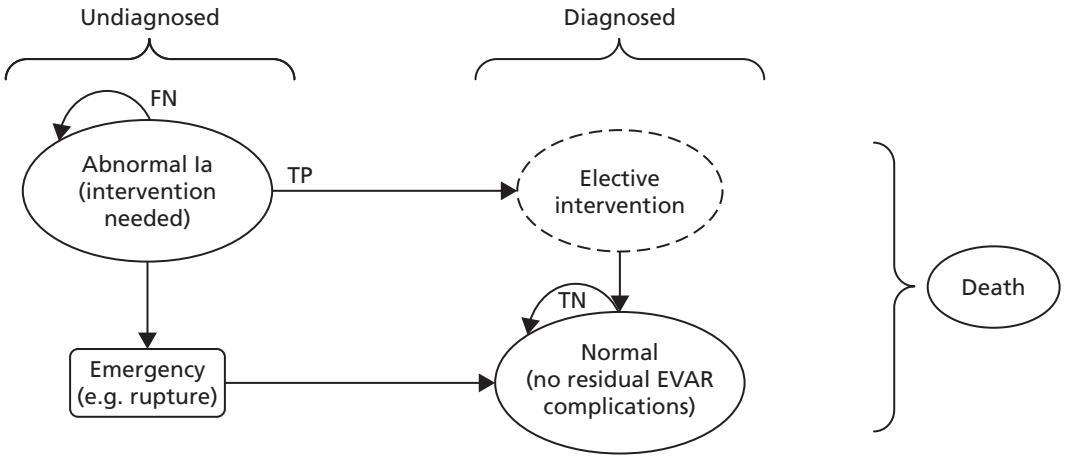

FIGURE 7 Schematic diagram of the surveillance for EVAR Markov model (from abnormal Ia, intervention needed Markov state). FN, false negative; TN, true negative; TP, true positive.

with sac expansion > 5 mm). Examples of patients with conditions within the close follow-up group (abnormal II) are those with type II endoleaks with a sac expansion of < 5 mm in 6 months or with limbs with kinking or partial thrombosis.

These abnormal Markov states are tunnel states. In tunnel states, individuals go through the health states in a defined sequence. The rationale behind these tunnel states for individuals with an abnormality is to count the length of time for which the individuals have had the abnormality. Thus, the probability of experiencing a rupture as a result of, for instance, a type I or III endoleak will increase as length of time for which the individual has had the endoleak increases (i.e. the length of time that the individual remains in the undetected health state). Finally, individuals can move from any health state to the absorbing death state (presented, for simplicity, at the side of the figures).

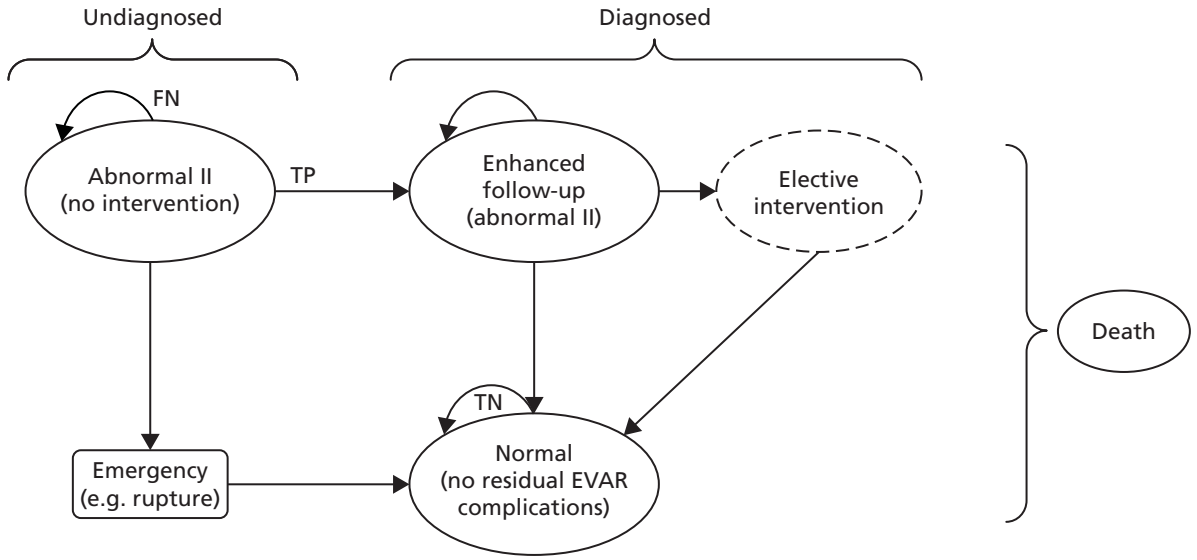

FIGURE 8 Schematic diagram of the surveillance for EVAR Markov model (from abnormal II, no intervention needed Markov state). FN, false negative; TN, true negative; TP, true positive.

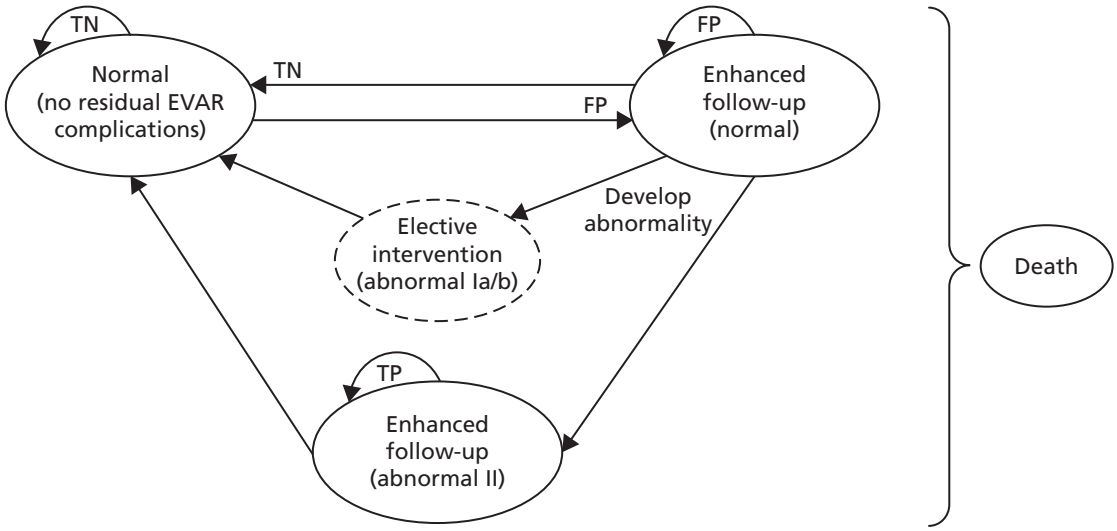

FIGURE 9 Schematic diagram of the surveillance for EVAR Markov model (from normal, no residual EVAR complications Markov state). FP, false positive; TN, true negative; TP, true positive.

Abnormal Ia Once an abnormal condition has been identified, individuals move to another Markov state, in which they can be treated (see *Figure 7*) or followed up more closely (see *Figure 8*). *Figure 7* shows the pathway of individuals who developed a non-endoleak abnormality that would require elective surgery. If the condition is undetected through surveillance (a false-negative result), the person remains in the abnormal Ia state. This person can experience an event and, as a result, go through an emergency intervention. If the situation is resolved, the person would move back to the original normal state. If the underlying condition is detected through surveillance (a true-positive result), the individual would move to the elective surgery state. This is a temporary state and individuals can remain within this state only for one cycle (to have surgery and subsequently move on to another health state). Again, once the surgical intervention is successful, the individual moves back to the original normal state. Moreover, individuals can move to the absorbing death state from any of the other health states as a result of an emergency (e.g. rupture), surgery (e.g. hospital mortality) or other comorbidities (general population mortality). A similar structure was followed for individuals who developed an endoleak abnormality that required an elective intervention (abnormal Ib Markov health state).

Figure 8 shows the pathway for the abnormal II health state. Undetected individuals (a false-negative result) will remain in this state (i.e. represented by the back arrow from the state). These people have the risk of experiencing an event that would trigger an emergency intervention. If the abnormality is detected (a true-positive result), the individuals will move to enhanced follow-up, which is defined as 6-month visits at which a CTA-based assessment is conducted. If the patient is stable and no further interventions (e.g. elective surgery) are decided after 2 years (four model cycles), the patient returns to the surveillance pathway (e.g. annual check-ups based on the original surveillance test – CDU, CEU or CTA).

Abnormal II The model also includes a false-positive state for those individuals without an abnormal condition (see *Figure 9*) but with a positive test result [e.g. enhanced follow-up (normal)]. If the individual developed an abnormality while under enhanced follow-up, they would either move straight to elective intervention (e.g. for abnormal Ia or Ib) or remain under enhanced follow-up but within a different Markov state (e.g. for abnormal II).

Normal state Individuals can suffer an event between surveillance visits. This is considered in the model to be an event within a Markov state and is shown in *Figures 6–9* as a square (e.g. emergency procedure). The model assumes that individuals who survive an unsuccessful second intervention could undergo a third intervention. However, a pragmatic assumption based on small probabilities was made and individuals can either have a successful third intervention or die.

Parameter estimates used in the economic model

The parameter estimates required to populate the economic model were obtained from the results of the clinical effectiveness search, which was supplemented by structured and focused searches (e.g. of EVAR trials with a longer follow-up period). When no suitable data resulted from these searches, expert opinion was sought. *Probabilities* gives details of the probabilities, unit costs and utility weights used in the model. Also provided within this section are details of the probability distributions used for the probabilistic sensitivity analysis.

Probabilities

The model starts with the whole cohort in the normal state, and therefore no prevalence data were necessary. The annual incidence of abnormalities was developed from data reported by Tang *et al.*,[93] based on ENGAGE (*Table 15*). The authors report 1-year data, excluding the first 31 days after EVAR. From a total of 325 patients, 25 abnormalities were reported (20 endoleaks, one stent–graft occlusion, three stent–graft stenoses and one other event related to the stent–graft). These data were initially used to obtain the proportions of cases within each of the model abnormal subgroups (graft occlusion for abnormal Ia, types I and III endoleaks for abnormal Ib, and type II endoleak for abnormal II). However, in consultation with the experts in the project advisory group, these figures were revised, as it was believed that a higher proportion of abnormalities Ia and Ib are currently seen in UK practice (Professor Srinivasa Rao Vallabhaneni, and Dr Russell Jamieson, NHS Grampian, 2017, personal communication). Beta distributions were used to assess the uncertainty around the central point estimates.

TABLE 15 Incidence and mortality

Variable	Value	Probability distribution	Source
Annual incidence of abnormal cases	0.04	Beta(13,312)	Tang *et al.*[93]
Proportion of abnormal Ia subgroup from all abnormal individuals	0.15	Beta(15,85)	Based on expert opinion
Proportion of abnormal Ib subgroup from all abnormal individuals	0.15	Beta(15,85)	Based on expert opinion
Proportion of abnormal II subgroup from all abnormal individuals	0.70	Beta(70,30)	Based on expert opinion

Unfortunately, the systematic review of clinical effectiveness could not identify any studies that directly compared the performance of alternative CDU and CEU surveillance strategies. Therefore, test performance data were used to feed the model. Test sensitivity and specificity (*Table 16*) were obtained from the systematic review by Karthikesalingam *et al.*[132] Alternative data were available (see *Diagnostic performance of imaging modalities for surveillance after endovascular abdominal aortic aneurysm repair* in *Chapter 2*). However, Karthikesalingam *et al.*[132] is the only review reporting sensitivity and specificity for all three tests (CDU, CEU and CTA), and the quality assessment of all of these diagnostic review studies resulted in the Karthikesalingam *et al.*[132] review being deemed to be of higher quality. Beta distributions were used to address uncertainty around the central parameter values.

The probability of having a reintervention and the risk of rupture and mortality are reported in *Table 17*. The probability of having a reintervention was developed from Tang *et al.*[93] Disregarding the first month post EVAR, 13 individuals out of 319 had a secondary procedure. The proportion of successful secondary procedures was based on the proportion of individuals free of a secondary intervention in the EVAR 1 trial – 15-year follow-up data.[48] The model allows for individuals with an unsuccessful surgery to go to a third procedure. We found no data to inform the model parameters related to the third intervention (e.g. the probability of having a third intervention and the proportion of successful interventions) and therefore the data as for the second intervention were applied.

The risk of rupture for undetected endoleaks was based on an analysis of early data from the EUROSTAR registry. Buth *et al.*[91] conducted two cohort analyses comparing a cohort of people with type I and type III endoleaks ($n = 297$) with those who had never experienced an endoleak ($n = 1975$), and a cohort of people with type II endoleaks ($n = 320$) with those who had never experienced an endoleak ($n = 3275$). The authors state that the cumulative rate of rupture from type I and type III endoleaks was 4% at 2 years compared with 0.7% for those who had never experienced an endoleak. Moreover, the number of late ruptures in patients with type II endoleaks was not significantly different from the number of late ruptures in those who had never experienced an endoleak. The risk of rupture for individuals with type I and type III endoleaks after 1 year was adjusted based on data reported by Moll *et al.*[31] The authors report the risk of rupture according to aneurysm size, based on population studies. To calculate the risk in the model, an aneurysm size of 55 mm at baseline was assumed, together with a growth rate of 5 mm per cycle. These rupture risks were applied to the undetected abnormal Ib group in the model only.

Table 17 also reports the mortality data assumed in the model. Age- and gender-specific general population mortality rates were applied to the cohort. The risk of surgical death in an elective setting was based on expert opinion (Professor Srinivasa Rao Vallabhaneni and Dr Russell Jamieson, personal communication). The main event that surveillance is trying to avoid is the aneurysm rupture and its associated high mortality rate. The risk of death from a rupture was calculated based on the systematic review and meta-analysis of late

TABLE 16 Test sensitivity and specificity

Variable	Value	Probability distribution	Source
CDU sensitivity	0.74	Beta(48.8,17.2)	Karthikesalingam *et al.*[132]
CDU specificity	0.94	Beta(164.5,10.5)	Karthikesalingam *et al.*[132]
CEU sensitivity	0.96	Beta(28,1.2)	Karthikesalingam *et al.*[132]
CEU specificity	0.85	Beta(64.3,11.3)	Karthikesalingam *et al.*[132]
CTA sensitivity	0.70	Beta(26.1,11.2)	Karthikesalingam *et al.*[132]
CTA specificity	0.98	Beta(81.1,1.7)	Karthikesalingam *et al.*[132]
Proportion of individuals adhering to surveillance visits	0.93	Uniform(0.5,1)	Assumption based on expert opinion

TABLE 17 Reintervention, rupture and mortality

Variable	Value	Probability distribution	Source
Probability of having a reintervention	0.020	Beta(13,312)	Tang *et al.*[93]
Probability of not having a third intervention	0.860	Beta(541,85)	Patel *et al.*[48]
Probability of rupture (type I or III endoleak)	0.0102	Beta(3,294)	Developed from Buth *et al.*[91]
Probability of rupture (type I or III endoleak) after 1 year	0.1	Uniform(0.1,0.2)	Moll *et al.*[31]
Probability of rupture (type I or III endoleak) after 2 years	0.3	Uniform(0.3,0.3)	Moll *et al.*[31]
Probability of rupture (type II endoleak)	0.0018	Beta(3.5,1971.5)	Developed from Buth *et al.*[91]
Probability of rupture (no endoleaks)	0.0018	Beta(3.5,1971.5)	Developed from Buth *et al.*[91]
Mortality			
Elective surgery	0.007	Beta(12,598)	Based on expert opinion[a]
Emergency surgical intervention (rupture)	0.32	Beta(36.6,77.9)	Antoniou *et al.*[139]
Rupture	0.16	Beta(30,160)	Antoniou *et al.*[139]
Age- and gender-specific general population mortality for the UK	Various	Not applicable	*National Life Tables, UK*[146] 2013–2015. Office for National Statistics

a Professor Srinivasa Rao Vallabhaneni and Dr Russell Jamieson, personal communication.

ruptures by Antoniou *et al.*[139] The authors identified 11 studies (case series) that reported a total of 190 ruptures: 30 patients were managed with palliative care or died before surgery. Moreover, the authors reported a perioperative mortality rate of 32% (95% CI 24% to 41%).

Costs

Unit costs were obtained from *NHS Reference Costs 2015 to 2016*[140] (*Table 18*). The unit costs for ultrasound tests (with and without contrast) of < 20 minutes' duration reported in the NHS reference costs are surprisingly similar. Moreover, the stated average unit cost for an ultrasound with contrast was lower than an ultrasound without contrast. Therefore, the unit cost for a vascular ultrasound scan was used to cost CDU and CEU tests. The clinical experts noted that clinical staff (i.e. a consultant radiologist) should be present to administer the contrast agent for CEU. In addition, CEU includes a contrast agent [i.e. sulfur hexafluoride or perfluorocarbon encapsulated by a phospholipid shell (SonoVue)] with an associated cost of £46 for a 10-vial box (Mr Craig Rore, Grampian Medicines Information Centre, 2017, personal communication). Therefore, the unit cost of CEU was adjusted to add the cost of 30 minutes (Professor Srinivasa Rao Vallabhaneni, personal communication) of a medical consultation (based on a cost per hour of £135)[141] plus £4.60 for the cost of the contrast. Furthermore, the cost of a CT scan of one area, with pre and post contrast, was used for CTA. Notably, *NHS Reference Costs 2015 to 2016*[140] does not report the unit cost for a plain radiography. The cost of a plain radiography is absorbed within other cost categories (e.g. outpatient visit) because of its relatively high volume and low cost. As plain radiography was considered in all of the strategies in a similar manner (on an annual basis), an executive decision was made and the unit cost of plain radiography was not incorporated in the model. If a surveillance test outcome was indeterminate, a further assessment was assumed (i.e. with CTA) and the cost of a visit was added to the cost of the subsequent test (i.e. non-admitted face-to-face attendance, follow-up – vascular surgery).

Endovascular AAA repair reintervention was costed as a weighted average of the unit costs for elective EVAR repair (complex and non-complex). The cost of percutaneous transluminal embolectomy or thrombolysis was used as the cost of other procedures for the abnormal Ia group. Emergency procedures were costed assuming non-elective categories plus the cost of emergency medicine (i.e. any investigation with category 5 treatment) and ambulance service (i.e. see and treat and convey).

TABLE 18 Unit costs

Variable	Cost (£)	Probability distribution	Source
CDU	57.53	Gamma(6.23,0.11)	RD47Z – vascular ultrasound scan – *NHS Reference Costs 2015 to 2016* (main schedule)[140]
CEU	57.53	Gamma(6.23,0.11)	RD47Z – vascular ultrasound scan – *NHS Reference Costs 2015 to 2016* (main schedule)[140]
CTA	118.53	Gamma(13.67,0.12)	RD22Z – CT scan of one area, with pre and post contrast – *NHS Reference Costs 2015 to 2016* (main schedule)[140]
Additional cost of CEU	72.10	Uniform(49.6,94.6)	30 minutes of medical consultation (based on an hourly cost of £135 – PSSRU hospital-based doctors with qualifications) plus contrast agent at £46 for 10 vials (one vial used per test per person). Probability distribution based on assumption[141]
Further assessment visit	140.21	Gamma(8.38,0.06)	WF01A – non-admitted face-to-face attendance, follow-up – vascular surgery – *NHS Reference Costs 2015 to 2016*[140]
EVAR intervention (elective)	11,925.16	Gamma(5.99,0)	Weighted average codes YR04Z and YR03Z (AAA endovascular and complex endovascular elective repair) – *NHS Reference Costs 2015 to 2016*[140]
Other surgical procedures (elective)	12,707.99	Gamma(4.03,0)	Percutaneous transluminal embolectomy or thrombolysis (weighted average codes YR23A and YQ11B plus YR12Z – percutaneous and open procedures plus stent) – elective inpatient – *NHS Reference Costs 2015 to 2016*[140]
EVAR intervention (emergency)	20,675.86	Gamma(4.3,0.0002)	AAA endovascular and complex endovascular repair (weighted average categories YR04Z and YR03Z – non-elective) and VB01Z (emergency medicine) and ASS02 (ambulance) – *NHS Reference Costs 2015 to 2016*[140]
Other surgical procedures (emergency)	18,681.87	Gamma(3.65,0.0002)	Percutaneous transluminal embolectomy or thrombolysis (weighted average for codes YR23A and YQ11B plus YR12Z – percutaneous and open procedures plus stent) – non-elective inpatient and VB01Z (emergency medicine) and ASS02 (ambulance) – *NHS Reference Costs 2015 to 2016*[140]

PSSRU, Personal Social Services Research Unit.

Utility weights

Population-based utility weights for patients aged ≥ 74 years were assumed for individuals after EVAR (*Table 19*). These utility weights were calculated using the equation provided by Ara and Brazier[142] [i.e. EuroQol-5 Dimensions (EQ-5D) = 0.9508566 + 0.0212126 × (1, if males, or 0, if females) – 0.0002587 × age – 0.0000332 × age^2].[142] The rationale behind this is that the condition is mostly asymptomatic and, as such, would have no effect on the individual's quality of life. Interestingly, this utility weight is of a similar value to the one reported by Brown *et al.*[143] on the EVAR 1 RCT for baseline EQ-5D score [mean 0.75 (SD 0.22); mean age 74 years]. The utility decrement for those going into any reintervention was developed from the EVAR 1 trial.[143] This decrement was calculated as a proportional reduction from baseline until the first year post EVAR, when patients are assumed to be back to the population-based utility weight.

TABLE 19 Quality-of-life weights

Variable	Value	Probability distribution	Source
All health states – at the start (74-year-old male cohort)	0.77	Not applicable	Age- and gender-specific general population EQ-5D score[142]
Surgery QALY weight decrement	2.22	Beta(4.7,209.4)	Developed from Brown *et al.*[143] (EVAR 1 RCT) as difference from baseline

QALY, quality-adjusted life-year.

Base-case analyses

The model base-case analysis was run for a cohort of 74-year-old men for a lifetime time horizon. A 6-month cycle length was defined. The analysis was conducted from the NHS and Personal Social Services perspective. Costs were expressed in 2015–16 Great British pounds and effectiveness was expressed in quality-adjusted life-years (QALYs). Costs and QALYs were discounted at an annual rate of 3.5%.[60] The cost-effectiveness analysis results are reported using ICERs.[60] ICERs are calculated as the ratio of the difference in expected costs between two alternative strategies to the difference in expected QALYs. This ratio measures the additional costs that would have to be paid in order to obtain an extra unit of effectiveness (i.e. an extra QALY). A probabilistic sensitivity analysis was conducted, in which 10,000 iterations were run. The stability of results was verified by examining the probabilistic results for a lower number of iterations (e.g. 1000). The probabilistic analysis results are reported using cost-effectiveness acceptability curves (CEACs).[144,145] These curves show the probability that a particular strategy is cost-effective at alternative values of willingness to pay for an extra QALY.

Assessment of uncertainty (sensitivity analysis)

A number of sensitivity analyses were conducted to address the uncertainty in this economic evaluation (one-way, two-way, threshold, scenario and probabilistic sensitivity analyses).

Approximately 90% of EVAR procedures in the UK are conducted in males (see *Epidemiology of abdominal aortic aneurysm*). Therefore, the base-case analysis was run for a male cohort. Gender-specific data were not available and the only differing data for men and women were general population mortality rates and utility weight. Female utility weight for 74-year-olds is lower (0.75) than that for males (mean 0.77), but mortality data show a longer life expectancy that could result in a longer time for benefits, but also costs. Therefore, a further analysis was conducted using these data, to observe the effect of longer life expectancy in the model results. In addition, one-way sensitivity analyses were conducted on all cost categories (e.g. cost of tests, visits and surgery), test diagnosis sensitivity and specificity, incidence of abnormalities, adherence to surveillance and mortality as a result of an unexpected event (rupture) and emergency intervention. Ranges to run these analyses were informed by the lower- and upper-unit cost quartiles published in *NHS Reference Costs 2015 to 2016*[140] (cost variables), the 95% CI reported by Karthikesalingam *et al.*[132] (sensitivity and specificity) and, for those variables for which there were no published data available, by expert opinion (e.g. adherence to surveillance).

Given the base-case and sensitivity analyses results, a threshold analysis was conducted for the cost of CEU, which explored the value that would make CEU cost-effective. Two scenario analyses were developed; the first assumes that the information from the CEU test is perfect, that is, sensitivity and specificity are equal to 1, plus no indeterminate or inconclusive results. This scenario corresponds to the notion that CEU could be the present reference standard.

A further scenario analysis was implemented, which assumed a cohort with a higher proportion (50%) of individuals belonging to abnormal Ib group together with a higher overall incidence for any abnormality (up to 10% per 6-month cycle). This scenario explored the effects of monitoring only those individuals at high risk of developing abnormalities.

The base-case and selected sensitivity analyses results are presented in *Results*. The full sensitivity analysis results are reported in *Appendix 15*.

Results

In *Table 20*, the base-case analysis results are reported. Annual follow-up with CDU only is the strategy with the lowest expected cost, followed by CTA only and CEU only. The strategies with higher expected costs are those that use CDU or CEU in conjunction with CTA at the start. In *Table 21*, the strategy expected costs are disaggregated into three cost categories: costs of surgical procedures, costs of surveillance visits and costs of tests. Consistently throughout the alternative strategies, surgical costs represent a higher proportion of the total costs. For the strategies involving CTA, the costs of the test represent over 30% of the total costs. The costs of visits were considered only in the case of a reassessment, and therefore these represent the lowest proportion in all of the surveillance strategies (i.e. between 6% and 13%).

The CTA-only strategy produces the lowest number of expected QALYs (see *Table 20*). This can be explained by the relatively low sensitivity of CTA that was assumed in the model. As such, the CDU-only strategy dominates the CTA-only strategy (i.e. CDU has lower expected costs and a higher number of expected QALYs than CTA only). Moreover, adding CTA to CDU or CEU at the start results in more QALYs than using only one imaging modality. However, either these strategies are dominated (i.e. CDU and CTA, then CDU) or the incremental cost for an additional QALY is well above the often-accepted cost-effectiveness threshold [£30,000[60] (i.e. CEU and CTA, then CEU)]. Furthermore, CEU-based strategies result in a higher number of expected QALYs than all of the other strategies, although the ICER to adopt any of the CEU-based strategies is well above the £30,000 threshold.[60]

Figure 10 shows the cost-effectiveness plane for the base-case analysis. For ease of interpretation, square data markers were used for CDU-based strategies, triangle data markers were used for CEU-based strategies and dots were used for CTA-only strategies. It can be clearly observed that the CEU-based strategies produce more QALYs, but at higher expected costs, than the CDU-based strategies. Furthermore, it is of note that the CDU plus CTA and then annual CDU strategy is dominated by the CEU-only strategy. However, the ICERs to

TABLE 20 Base-case cost-effectiveness results: men

Strategy	Cost (£)	Incremental cost (£)	QALYs	Incremental QALYs	ICER (£)
CDU	3791		6.5532		
CTA	3828	37	6.5517	–0.00150	Dominated
CEU	4709	919	6.5594	0.00622	147,626
CDU and CTA, then CDU	4732	22	6.5543	–0.00510	Dominated
CEU and CTA, then CEU	5644	935	6.5598	0.00032	2,912,177

TABLE 21 Base-case cost results: disaggregated

Strategy	Cost of, £ (%)			Total cost, £ (%)
	Surgery only	Visits only	Test only	
CDU	2423 (64)	477 (13)	890 (23)	3791 (100)
CTA	2400 (63)	229 (6)	1198 (31)	3828 (100)
CEU	3146 (67)	585 (12)	978 (21)	4709 (100)
CDU and CTA, then CDU	2430 (51)	441 (9)	1861 (39)	4732 (100)
CEU and CTA, then CEU	3148 (56)	550 (10)	1945 (34)	5644 (100)

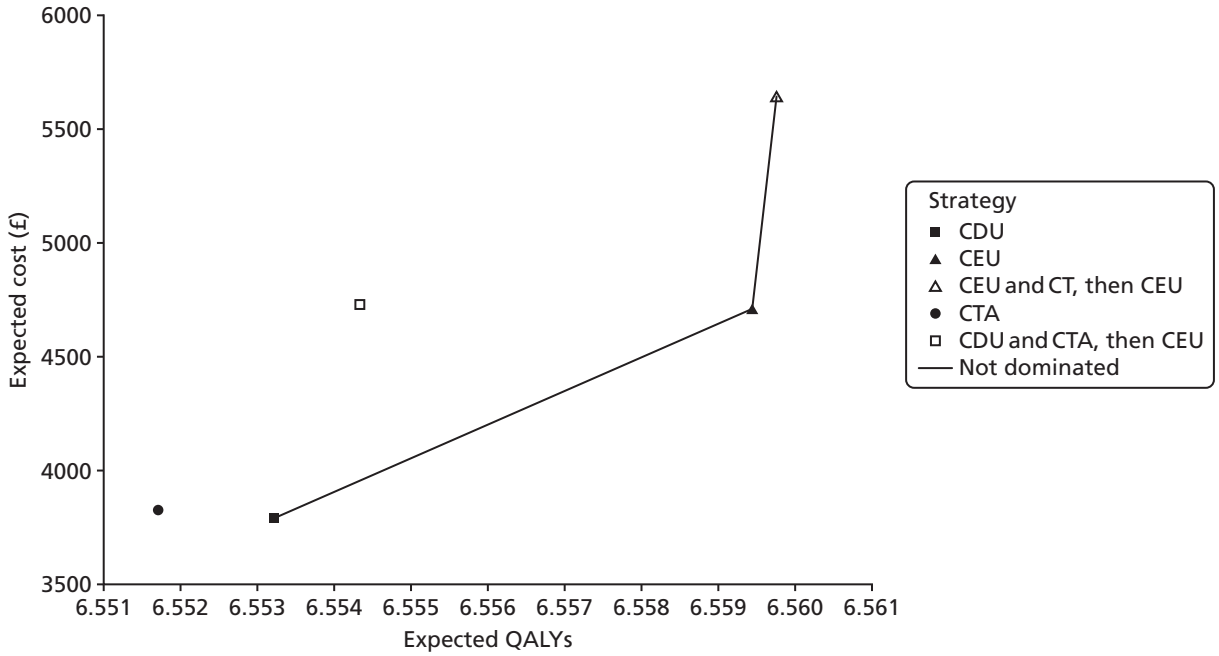

FIGURE 10 Base-case cost-effectiveness results: men.

move to any of these strategies (either CDU and CTA, then CDU or CEU only) from CDU only are well above the usual cost-effectiveness threshold.

Table 22 shows the probabilistic sensitivity analysis results for the base case. Annual follow-up with CDU only has the highest probability of being cost-effective for any value of willingness to pay for an extra QALY below £50,000 (i.e. a probability of > 58%). Surveillance with CTA only has a probability of between 32% and 42% of being cost-effective at values of willingness to pay for an extra QALY of between £10,000 and £50,000. Adding CTA to CDU or CEU has a zero probability of being cost-effective at any willingness-to-pay values. Finally, as surveillance with CEU only produces more expected QALYs, this strategy has a growing probability of being cost-effective at increasing willingness-to-pay values. However, at £50,000, its chance of being cost-effective is just 4.1%. *Figure 11* presents the CEACs. It is worth noting that the probability of CDU being cost-effective stabilises at around 60% for high values of willingness to pay for a QALY. At higher values than those reported in the figure, surveillance with CEU increases its chances of being cost-effective compared with CDU- and CTA-only strategies (i.e. 27% at £100,000 – data not shown). Finally, the ICERs calculated with the probabilistic analysis were lower than the deterministic base-case analysis reported in *Table 20* (i.e. ICER for CEU with respect to CDU: £129,700 and for CEU and CTA; then CEU strategy with respect to CEU only: £2,479,000). However, these ICERs are all well above the usual threshold used in the UK (e.g. £30,000).

TABLE 22 Probabilistic analysis results

	Proportion cost-effective at alternative willingness-to-pay for a QALY threshold (%)				
Strategy	£10,000	£20,000	£30,000	£40,000	£50,000
CDU	58.0	60.5	62.6	63.5	63.8
CTA	42.0	39.2	36.6	34.6	32.1
CEU	0.1	0.2	0.8	1.9	4.1
CDU and CTA, then CDU	0.0	0.0	0.0	0.0	0.0
CEU and CTA, then CEU	0.0	0.0	0.0	0.0	0.0

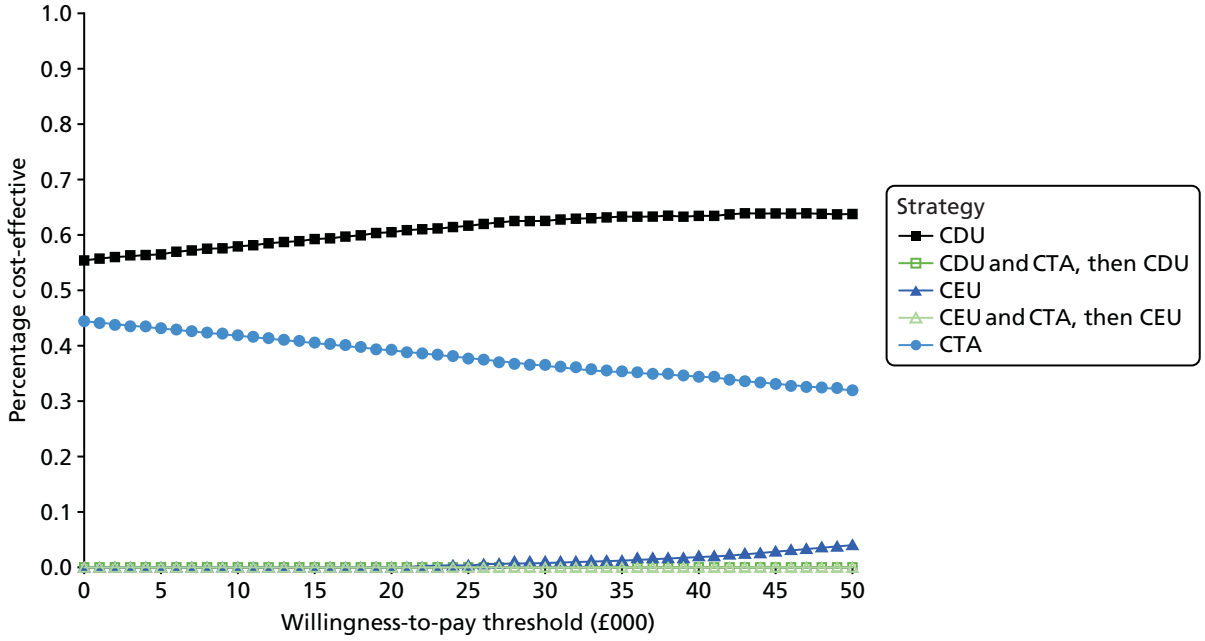

FIGURE 11 Cost-effectiveness acceptability curves, base case: men.

Sensitivity analysis results

Base-case analysis for women

Table 23 shows the results of the base-case analysis for women. General population mortality data[146] for women were used for this analysis, as well as the utility weight for women > 74 years of age (i.e. mean 0.75), using the methods provided by Ara and Brazier 2010.[142] Expected costs and QALYs for women are generally higher than for males, reflecting the longer life expectancy of women. Overall, the results are very similar to those of the base-case analysis for men, with CDU having the lowest expected cost, followed by CTA only and surveillance with CTA only being dominated by surveillance with CDU only. CEU-based strategies have ICERs that are well above the often-used willingness to pay for an extra QALY threshold.[60] Owing to the similarity of these results to those for the males model run, all other sensitivity analyses were conducted using data for only males.

One-way sensitivity analysis results for the unit cost of the CDU test are reported in *Table 24*. The upper quartile for a vascular ultrasound in *NHS Reference Costs 2015–16*[140] is £70. For this reason, a range up to £80 was used in an attempt to include other plausible values. The base-case unit cost for a CDU test was £58; thus, for any values below this, the base-case results hold. At a CDU unit cost of £80, CDU is more costly than CTA, and, therefore, CTA becomes cost-effective. CEU only improves its cost-effectiveness compared with CDU as the unit cost for CDU increases. However, the ICERs for CEU-based strategies are still above the £30,000 threshold, at a unit cost of £80 for a CDU test.

TABLE 23 Base-case analysis: women

Strategy	Cost (£)	Incremental cost (£)	QALYs	Incremental QALYs	ICER
CDU	4327		7.1460		–
CTA	4367	40	7.1442	–0.0018	Dominated
CEU	5372	1046	7.1536	0.0075	138,707
CDU and CTA, then CDU	5393	20	7.1473	–0.0063	Dominated
CEU and CTA, then CEU	6431	1059	7.1539	0.0004	2,926,141

TABLE 24 One-way sensitivity analysis for the unit cost of a CDU test

Value (£)	Strategy	Cost (£)	Incremental costs (£)	QALYs	Incremental QALYs	ICER (£)
55	CDU	3769		6.5532		
	CTA	3828	58	6.5517	–0.0015	Dominated
	CEU	4709	940	6.5594	0.0062	151,067
	CDU and CTA, then CDU	4710	1	6.5543	–0.0051	Dominated
	CEU and CTA, then CEU	5644	935	6.5598	0.0003	2,912,177
60	CDU	3812		6.5532		
	CTA	3828	16	6.5517	–0.0015	Dominated
	CEU	4709	898	6.5594	0.0062	144,267
	CDU and CTA, then CDU	4753	43	6.5543	–0.0051	Dominated
	CEU and CTA, then CEU	5644	935	6.5598	0.0003	2,912,177
70	CTA	3828		6.5517		
	CDU	3896	69	6.5532	0.0015	45,611
	CEU	4709	813	6.5594	0.0062	130,667
	CDU and CTA, then CDU	4837	128	6.5543	–0.0051	Dominated
	CEU and CTA, then CEU	5644	935	6.5598	0.0003	2,912,177
75	CTA	3828		6.5517		
	CDU	3939	111	6.5532	0.0015	73,755
	CEU	4709	771	6.5594	0.0062	123,867
	CDU and CTA, then CDU	4879	170	6.5543	–0.0051	Dominated
	CEU and CTA, then CEU	5644	935	6.5598	0.0003	2,912,177
80	CTA	3828		6.5517		
	CDU	3981	153	6.5532	0.0015	101,899
	CEU	4709	728	6.5594	0.0062	117,067
	CDU and CTA, then CDU	4922	212	6.5543	–0.0051	Dominated
	CEU and CTA, then CEU	5644	935	6.5598	0.0003	2,912,177

Table 25 presents the results for the one-way sensitivity analysis for the unit cost of CEU. The lower quartile reported in *NHS Reference Costs 2015 to 2016*[140] for a vascular ultrasound was £39; thus, a lower value was used in order to consider other lower plausible values. In addition to the £72.10 for the contrast agent and the extra staff involved (who remained unchanged for the present one-way sensitivity analysis), the ultrasound cost for the CEU base-case analysis was £58, so any values above this would result in CEU being less cost-effective. The base-case results are robust to changes in the cost of the CEU test. A threshold analysis was conducted, and, owing to CEU being more sensitive but less specific, CEU needs to be slightly cheaper than CDU in order to become cost-effective.

Test performance

Two-way sensitivity analyses were conducted for sensitivity and specificity for each compared test. *Figure 12* presentd the results for CDU. The figure shows the strategy with the highest net benefit at £30,000 per QALY according to alternative values of sensitivity and specificity for CDU. The value ranges used were broader than the 95% CIs reported by Karthikesalingam *et al.*[132] (i.e. sensitivity, 95% CI 0.62 to 0.83; specificity,

TABLE 25 One-way sensitivity analysis for the unit cost of a CEU test

Value (£)	Strategy	Cost (£)	Incremental costs (£)	QALYs	Incremental QALYs	ICER (£)
20	CDU	3791		6.5532		
	CTA	3828	37	6.5517	–0.0015	Dominated
	CEU	4394	603	6.5594	0.0062	96,889
	CDU and CTA, then CDU	4732	338	6.5543	–0.0051	Dominated
	CEU and CTA, then CEU	5328	935	6.5598	0.0003	2,912,607
30	CDU	3791		6.5532		
	CTA	3828	37	6.5517	–0.0015	Dominated
	CEU	4478	687	6.5594	0.0062	110,408
	CDU and CTA, then CDU	4732	254	6.5543	–0.0051	Dominated
	CEU and CTA, then CEU	5412	935	6.5598	0.0003	2,912,493
40	CDU	3791		6.5532		
	CTA	3828	37	6.5517	–0.0015	Dominated
	CEU	4562	771	6.5594	0.0062	123,927
	CDU and CTA, then CDU	4732	170	6.5543	–0.0051	Dominated
	CEU and CTA, then CEU	5496	935	6.5598	0.0003	2,912,378
50	CDU	3791		6.5532		
	CTA	3828	37	6.5517	–0.0015	Dominated
	CEU	4646	855	6.5594	0.0062	137,446
	CDU and CTA, then CDU	4732	86	6.5543	–0.0051	Dominated
	CEU and CTA, then CEU	5581	935	6.5598	0.0003	2,912,264

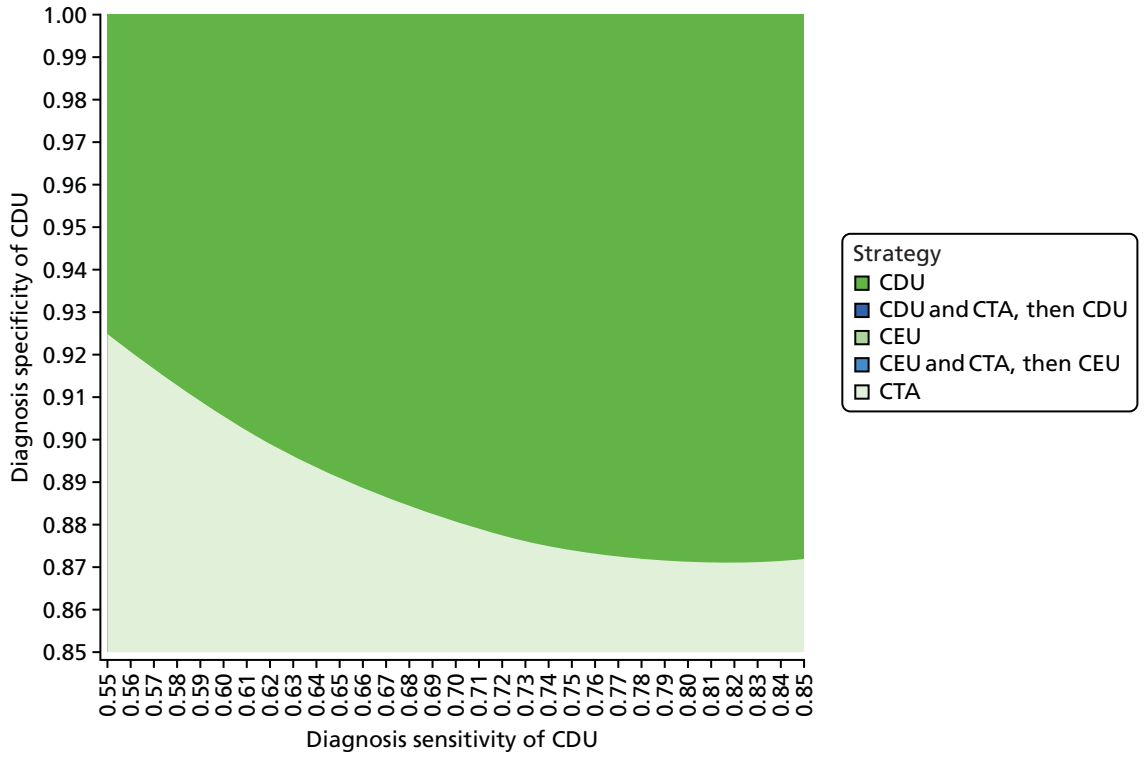

FIGURE 12 Two-way sensitivity analysis: CDU test sensitivity and specificity (net benefit, willingness-to-pay threshold of 30,000).

95% CI 0.90 to 0.97), in order to explore the effects of alternative plausible figures. At low levels of sensitivity and specificity for CDU, the imaging strategy that has the highest net benefit is CTA. Surveillance with CDU only has the highest net benefit at 93% specificity (or higher), regardless of the CDU sensitivity.

Perfect information from contrast-enhanced ultrasound

There was an indication from the clinical experts that the CEU test might have become the reference standard. A scenario analysis was conducted, assuming perfect information from CEU. That is, it was assumed that sensitivity and specificity were equal to 100% and that no indeterminate or inconclusive results were possible. Moreover, a threshold analysis was conducted to explore the difference in cost between CEU and CDU that would make CEU cost-effective. The results of this analysis are reported in *Table 26* and show that, if the test performance from CEU is assumed to be perfect, a cost difference of up to £55 between CEU and CDU could make CEU cost-effective at a threshold value of willingness to pay for a QALY of £30,000. Larger cost differences would shift the ICER above the frequently used cost-effectiveness threshold (i.e. £30,000).

TABLE 26 Scenario analysis assuming perfect information from CEU. Value refers to the cost difference between CEU and CDU

Value (£)	Strategy	Cost (£)	Incremental costs (£)	QALYs	Incremental QALYs	ICER (£)
40	CDU	3791		6.5532		
	CTA	3828	37	6.5517	–0.0015	Dominated
	CEU	3943	152	6.5614	0.0082	18,682
	CDU and CTA, then CDU	4732	788	6.5543	–0.0070	Dominated
	CEU and CTA, then CEU	4947	1004	6.5614	0.0000	> 29 million
50	CDU	3791		6.5532		
	CTA	3828	37	6.5517	–0.0015	Dominated
	CEU	4027	237	6.5614	0.0082	28,978
	CDU and CTA, then CDU	4732	704	6.5543	–0.0070	Dominated
	CEU and CTA, then CEU	5032	1004	6.5614	0.0000	> 29 million
55	CDU	3791		6.5532		
	CTA	3828	37	6.5517	–0.0015	Dominated
	CEU	4069	279	6.5614	0.0082	34,126
	CDU and CTA, then CDU	4732	662	6.5543	–0.0070	Dominated
	CEU and CTA, then CEU	5074	1004	6.5614	0.0000	> 29 million
60	CDU	3791		6.5532		
	CTA	3828	37	6.5517	–0.0015	Dominated
	CEU	4111	321	6.5614	0.0082	39,274
	CDU and CTA, then CDU	4732	620	6.5543	–0.0070	Dominated
	CEU and CTA, then CEU	5116	1004	6.5614	0.0000	> 29 million
70	CDU	3791		6.5532		
	CTA	3828	37	6.5517	–0.0015	Dominated
	CEU	4195	405	6.5614	0.0082	49,569
	CDU and CTA, then CDU	4732	536	6.5543	–0.0070	Dominated
	CEU and CTA, then CEU	5200	1004	6.5614	0.0000	> 29 million

Note
'Value' refers to the cost difference between CEU and CDU.

High-risk patient group

A relatively more sensitive test can be beneficial when a higher proportion of individuals have the condition under study. A scenario analysis was considered in which half of the abnormal individuals belonged to the abnormal Ib group (e.g. types I and III endoleaks, plus other conditions necessitating elective intervention). *Table 27* presents the results from a one-way sensitivity analysis for the incidence of any abnormality. The base-case analysis assumed circa 4% incidence per 6-month cycle. In the present analysis, this incidence of abnormalities implies that 2% of abnormalities are type Ib. Alternatively, the percentages in *Table 27* could be broadly interpreted as the annual incidence of Ib abnormalities. To facilitate the comparison between CDU- and CEU-only strategies, in *Table 27* the ICER for the CEU-only strategy has been calculated with respect to the CDU-only strategy and not the strategy with an immediately lower cost (i.e. CDU and CTA, then CDU). The results show that CEU is more cost-effective than CDU when the incidence of group Ib abnormalites is > 6% per year (3% incidence per 6-month cycle, which corresponds to 6% in *Table 27*).

Summary of cost-effectiveness

This chapter reported on a systematic review of economic evaluations and a model-based economic evaluation of alternative strategies to monitor individuals after an EVAR intervention. Similarly to the systematic review of clinical effectiveness, only cohort studies were identified in the systematic review of economic evaluations. Five studies met the inclusion criteria. Although two studies[45,66] compared outcomes before and after a surveillance protocol took place, the three remaining studies hypothesised the resource use implications (i.e. the number of CTA scans performed) of moving to surveillance strategies, using ultrasound as first-line test. Only one study gave full details of the cost calculations. Moreover, none of the studies assessed the relative efficiency of CDU and CEU, which is addressed by the current assessment. As such, the studies identified were unsuitable to fully inform the study question posed and therefore unlikely to help decision-making in the UK. Thus, a new model was developed following UK methodological guidelines.[60]

The developed model included five strategies. Three of these were CTA, CDU or CEU used on an annual basis, and the two other strategies considered CTA in addition to CDU or CEU for the first surveillance visit, with CTA scans being conducted afterwards only if further investigations were needed. Plain radiography was included in all of the strategies as part of the surveillance assessment.

The model base-case results show that, once the primary EVAR surgical complications have been discarded, surveillance with CDU as a first-line test becomes the less expensive option. This strategy is less expensive and produces more expected QALYs than a strategy that uses CTA only. Adding CTA to CDU in the first surveillance visits is not worthwhile. Moreover, surveillance strategies based on CEU result in more expected QALYs, but are also more expensive, and the ICERs are well above the usual threshold used in the UK (i.e. £30,000). The our base-case probabilistic analyses show that the CDU-only strategy has a probability of being cost-effective of between 57% and 64%, depending on the cost-effectiveness threshold (e.g. 62% at £30,000).

Extensive sensitivity analyses were conducted (see *Appendix 15*), with the base-case results being robust for the great majority of these. The sensitivity analysis showed that a CEU-only strategy could become cost-effective at very high rates of test sensitivity and specificity (e.g. when it was assumed to produce perfect information – sensitivity and specificity of 100% and no indeterminate results). Even in this case, the cost difference between CDU and CEU should not be above £55 for CEU to be cost-effective at a £30,000 threshold of willingness to pay for an additional QALY.

As risk stratification of patients might become a feasible option, a further sensitivity analysis was conducted to explore the effect of using these surveillance strategies in a very high-risk group only. Incidence rates of > 2% per 6-month cycle were considered for the abnormal Ib group (i.e. types I and III endoleaks, together with type II endoleaks with sac expansion > 5 mm and other conditions commonly detected by non-radiography imaging modalities). At an annual incidence rate of 7% for this group, CEU-only surveillance becomes cost-effective with an ICER of £29,756 with respect to CDU-only

TABLE 27 Scenario analysis assuming that 50% of abnormalities are Ib (e.g. types I and III endoleaks)

Value	Strategy	Cost (£)	Incremental costs (£)	QALYs	Incremental QALYs	ICER (£)
4%	CDU	5966		6.5018		
	CTA	5991	25	6.4961	–0.0057	Dominated
	CDU and CTA, then CDU	6918	952	6.5057	0.0038	248,084
	CEU	6929	963	6.5258	0.0240	40,126
	CEU and CTA, then CEU	7875	946	6.5270	0.0011	849,127
5%	CDU	6902		6.4818		
	CTA	6919	17	6.4751	–0.0068	Dominated
	CDU and CTA, then CDU	7854	952	6.4866	0.0047	200,797
	CEU	7910	1008	6.5105	0.0287	35,167
	CEU and CTA, then CEU	8852	942	6.5119	0.0014	683,732
6%	CDU	7748		6.4635		
	CTA	7757	9	6.4557	–0.0078	Dominated
	CDU and CTA, then CDU	8701	953	6.4691	0.0056	169,359
	CEU	8801	1053	6.4964	0.0329	31,965
	CEU and CTA, then CEU	9740	939	6.4980	0.0016	573,576
7%	CDU	8516		6.4465		
	CTA	8517	2	6.4378	–0.0087	Dominated
	CDU and CTA, then CDU	9470	954	6.4530	0.0065	146,967
	CEU	9612	1096	6.4833	0.0368	29,756
	CEU and CTA, then CEU	10,548	936	6.4852	0.0019	494,974
8%	CTA	9209		6.4212		
	CDU	9215	6	6.4308	0.0095	642
	CDU and CTA, then CDU	10,172	957	6.4381	0.0073	130,221
	CEU	10,353	1138	6.4712	0.0404	28,159
	CEU and CTA, then CEU	11,287	934	6.4733	0.0021	436,083
9%	CTA	9840		6.4059		
	CDU	9853	14	6.4162	0.0103	1316
	CDU and CTA, then CDU	10,813	959	6.4244	0.0082	117,233
	CEU	11,031	1178	6.4599	0.0437	26,964
	CEU and CTA, then CEU	11,964	932	6.4623	0.0024	390,326
10%	CTA	10,417		6.3916		
	CDU	10,437	21	6.4026	0.0110	1884
	CDU and CTA, then CDU	11,400	963	6.4116	0.0090	106,873
	CEU	11,655	1217	6.4494	0.0467	26,045
	CEU and CTA, then CEU	12,586	931	6.4520	0.0026	353,758

Note
CEU only Incremental cost and QALYs and ICER are calculated with respect to CDU only strategy.

surveillance. It is worth noting that, although an incidence of 7% for type I or type III endoleaks is unlikely to be observed in clinical practice, an incidence of 6% for type II endoleaks with sac expansion is perhaps possible.

We can conclude that the use of CDU as a first-line test for the surveillance of individuals after EVAR is cost-effective, with a probability of > 58% at the usual cost-effectiveness threshold used in the UK.[60] The analysis results are driven by the interplay of the test performance data (i.e. sensitivity and specificity) and the cost of the test. Lower unit costs together with higher specificity are needed for CEU to become cost-effective.

Chapter 4 Discussion and conclusions

Statement of principal findings

Clinical effectiveness

To our knowledge, this is the first assessment that considers the effectiveness and cost-effectiveness of CTA, CDU and CEU for surveillance after EVAR. The clinical evidence base for this assessment consists of two non-randomised comparative studies (with a total of 750 participants) and 25 observational cohort studies (with a total of 7196 participants), assessing various surveillance protocols after EVAR. The surveillance protocols were based on the use of either CDU and/or CEU in combination with CTA.

The majority of the included studies assessed EVAR surveillance protocols based on a combination of CDU and CTA. Three studies used CDU as the main imaging modality for surveillance after EVAR, two studies used CEU as the main imaging modality and one study used CEU in selected cases only. There were no studies that compared CDU surveillance with CEU surveillance.

The risk of bias was rated as being high or moderate for the majority of the included studies, with only three cohort studies rated as being at a low risk of bias according to the prespecified criteria for the risk-of-bias assessment (ReBIP checklist).[76,84,87]

There was considerable heterogeneity among the included studies in terms of the surveillance protocols (imaging modality, frequency of imaging, duration of follow-up, reported outcomes, definition of clinical outcomes – for example, the definition of decreased aneurysm size, the axis of the diameter measured and the time points at which outcomes were assessed). Owing to the observed clinical heterogeneity, it was deemed to be inappropriate to perform a statistical synthesis of the reported outcomes.

We conducted a narrative synthesis of the main clinical findings and grouped studies according to their similarities in terms of modality and frequency of imaging. A combination of CTA and CDU was the most commonly implemented surveillance strategy. Studies that used a combination of CTA and CDU for surveillance after EVAR were published between 2001 and 2010. The second most common surveillance strategy involved CTA and/or CDU for early and mid-term assessments and CDU for long-term surveillance after EVAR. Studies assessing this type of strategy were published more recently, between 2009 and 2016.

This may indicate a growing trend towards a CDU-based surveillance. It is worth noting that one study that followed up 494 patients who underwent EVAR using CTA and CDU for early and mid-term imaging assessments and CDU for long-term surveillance reported the highest mortality and reintervention rates.[90] However, any comparisons between cohort studies are tentative, owing to the observed clinical heterogeneity. In this particular case, it is difficult to ascertain whether or not the reported high mortality and reintervention rates were observed because of the length of the follow-up period (12 years), the characteristics of the patient population or the imaging modalities used for surveillance.

Three of the included cohort studies were conducted in the UK.[41,78,82] Evidence from these studies was considered to be of moderate methodological quality, as the studies did not satisfy all of the criteria of the ReBIP checklist. One of these studies used CDU exclusively for surveillance after EVAR,[78] whereas the other two studies used a strategy based on a combination of CDU and CTA.[41,82] In particular, Harrison *et al.*,[41] who followed up a total of 194 patients using a combination of CDU and CTA for early surveillance and CDU for long-term surveillance after EVAR, reported a mortality rate of 13% at 12 months. In contrast, a non-UK-based study that assessed 494 EVAR patients using a similar surveillance strategy reported 19.7%

mortality during a median follow-up of 68 months.[90] In general, the proportion of patients requiring reintervention in the study by Harrison *et al.*[41] was similar to that reported by other non-UK-based studies that used a combination of CTA and CDU for early surveillance and CDU for long-term surveillance. The study by Karthikesalingam *et al.*[78] used CDU at 1.5, 3, 5, 9, 12 and 18 months and annually thereafter to assess the role of peak systolic velocity provided by CDU for the prediction of limb complications in a cohort of 478 EVAR patients. The authors found that serial increases in the peak systolic velocity recorded during CDU surveillance were associated with an increased risk of stent–graft limb complications.[78]

The proportion of patients with type I endoleaks identified by a surveillance strategy based on early and mid-term CTA and/or CDU and long-term CDU was comparable to that identified by a surveillance strategy based on a combination of CTA and CDU throughout the follow-up period (range 0–7.9% vs. 0.8–8.3%). No type III endoleaks were reported in the eight cohort studies that used early and mid-term CTA and/or CDU and long-term CDU for the surveillance after EVAR. It is worth noting that all but one study[76] were rated as being at a high or moderate risk of bias. The study by Freyrie *et al.*,[76] which was the only study that was rated as being at a low risk of bias in this surveillance category, reported two cases (1.1%) of type I endoleak, 23 cases (13%) of type II endoleak and no cases of type III or IV endoleak during a mean follow-up of 33 months.

Detection of limb occlusion was lower among cohort studies that used CDU for long-term surveillance after EVAR (range 0–1.1%) than cohort studies that used either CTA for long-term surveillance (range 3.1–3.7%) or a combination of CTA and CDU throughout surveillance (range 5.3–7.2%). This is, however, only an observation and not a causal association.

The study by Chaer *et al.*[40] evaluated the safety of long-term CDU for surveillance after EVAR. One hundred and eighty-four patients with shrinking or stable aneurysms who received CTA at 1 and 12 months after EVAR were followed up annually with CDU for up to 4 years. Freedom from endoleaks was 96% and freedom from secondary interventions was 95% at 4 years. The authors concluded that CDU-based surveillance after EVAR is safe in patients with stable aneurysms.

Similarly, the comparative study by Chisci *et al.*,[66] which compared CDU and CTA 1 month after EVAR and every 6 months afterwards (protocol I, 367 patients) with CDU and CTA 1 month after EVAR and CDU and radiography every 6 months afterwards (protocol II, 341 participants), reported no significant differences between the two surveillance strategies during the course of the study (3-year follow-up) in terms of reinterventions, clinical complications and mortality. The authors concluded that the current post-EVAR surveillance protocol could be simplified by adopting CDU as the main follow-up imaging modality and restricting the use of CTA to selective cases, when adverse events are suspected.

Cost-effectiveness

This assessment is the first model-based economic evaluation to consider the role of CDU, CEU and CTA for post-EVAR surveillance. Only the study by Bendick *et al.*[137] provided a head-to-head comparison of the three imaging modalities as first-line surveillance using data from a cohort of 40 individuals and considered both costs and clinical outcomes. All of the other economic evaluation studies identified in the systematic review compared the use of CTA as first-line monitoring with CDU only, with CTA being used after CDU for selected cases only, to provide further diagnostic information. Moreover, all of the studies assessed the reduction in costs as a result of the fewer number of CTA scans conducted in the ultrasound-based protocols. The model considered a broader measure of effectiveness based on a preference-based measure of utility in accordance with the UK economic evaluation methodological guidelines,[60] as well as a lifetime time horizon with all relevant consequences from the NHS perspective. None of the retrieved studies attempted an incremental analysis of the costs and clinical outcomes. For this reason, any comparison between the study's results and those of the earlier economic evaluations should be conducted with caution.

The model results show that a surveillance strategy based on CDU as the imaging modality of choice becomes the strategy with the lowest expected costs, in addition to producing more QALYs than a strategy based exclusively on CTA. By comparison, although a surveillance strategy based exclusively on CEU would generate more QALYs, it would be more expensive, and the ICER would be well above the usual threshold used in the UK (i.e. £30,000). In addition, the base-case probabilistic analysis shows that a CDU-only strategy would have a probability of being cost-effective of between 57% and 64%, depending on the cost-effectiveness threshold (e.g. 62% at £30,000). Adding CTA to CDU or CEU in the first annual surveillance visit is not worthwhile, as it generates more QALYs but at a very high cost per QALY.

The base-case results, which show that CDU is the least expensive option, are in general agreement with those of previous economic evaluations that reported savings because fewer CTA tests were conducted in ultrasound-based protocols.[41,45,66,137,138] However, although Bendick *et al.*[137] reported savings for a 3-year cost comparison between CEU- and CTA-based protocols, the model results indicate a higher expected cost for a CEU-only strategy than for a CTA-only strategy. This can be explained by the relatively lower specificity assumed for CEU in the economic model, which generates a higher proportion of false-positive results. These false-positive results will trigger further testing for a period of up to 2 years.

Extensive sensitivity analyses were conducted (see *Appendix 15*), with the base-case results being robust for the great majority of these. The sensitivity analysis showed that a CEU-only strategy could become cost-effective at very high rates of test sensitivity and specificity (e.g. when it was assumed to produce perfect information – sensitivity and specificity of 100% and no indeterminate results) and with a difference in the cost of CEU and CDU of < £55.

A further sensitivity analysis considered higher incidence rates for the abnormal Ib group (e.g. types I and III endoleaks and other abnormalities commonly detected by non-radiography imaging modalities). Annual incidence rates of 4% and above were used in this analysis. Compared with CDU-only surveillance, CEU-only surveillance becomes cost-effective, with an ICER of £29,756, when the annual incidence rate for this group is 7%. Although in clinical practice it is unlikely that an incidence rate of 7% for type I or type III endoleaks would be observed, an incidence rate of 6% for type II endoleaks with sac expansion is perhaps possible.

The interplay of sensitivity, specificity and unit costs of the test drives the results in the study's model. For instance, a lower unit cost for CEU helps to make the CEU-based strategies relatively more cost-effective; however, cost on its own will not make a CEU-only strategy a cost-effective option. A higher specificity is also necessary in order to reduce the expected cost of the strategy as a result of the follow-up of individuals without an abnormality. In addition, a higher sensitivity triggers further interventions (e.g. secondary interventions for the abnormal Ia and Ib groups and further monitoring for the abnormal II group). As such, although these interventions might result in higher expected QALYs, they also add to the expected costs, with an uncertain final effect on cost-effectiveness.

The majority of patients in the cohort considered in the model will have no further need for subsequent interventions. Furthermore, in the base-case analysis, 70% of patients with an abnormality correspond to the abnormal II group. Because a large proportion of patients are elderly with multiple comorbidities, there are instances when a secondary intervention, which is considered to be technically indicated based on surveillance imaging, may not be carried out because the risk associated with the intervention is considered prohibitively high. Furthermore, in the cost–utility analysis, there is no benefit attributed to the reassurance that the abnormality is minor or from any information provided by the test. From the point of view of the economic model, following up individuals for whom no further interventions are possible just adds to the expected cost of the strategy, with no effects on QALYs. Future research should explore more broadly the effects of the information generated by the surveillance strategies and incorporate this within the economic analysis.

Uncertainties from the assessment

Clinical effectiveness

The clinical evidence identified for this assessment demonstrates that surveillance practice after EVAR is currently heterogeneous and the most effective method for surveillance has yet to be established.

Since the advent of EVAR, CTA has been the main imaging modality for long-term surveillance. A survey of current clinical practice after EVAR published by Uthoff *et al.*[147] in 2012, which involved 674 respondents from 52 countries worldwide, found that CTA was the imaging modality used most often for standard surveillance. A CTA scan at 1 year was scheduled by 64.5% of the respondents.

The use of CTA presents important drawbacks, including exposure to ionising radiation, which may result in an increased risk of cancer.[30] Moreover, the intravenous iodinated contrast medium used in CTA may damage renal function over time and increase the risk of contrast nephropathy. A study by Mitchell *et al.*,[148] published in 2010, found that the incidence of contrast-induced nephropathy was 11% among a cohort of 633 patients who received contrast-enhanced CT in the emergency department. Six patients with contrast-induced nephropathy developed severe renal failure and four (0.6%) died.[148] In most EVAR patients, these risks could be eliminated or reduced by modifying the surveillance protocol and limiting the number of CTA scans.[11,26,35,149]

As the main purpose of surveillance is to identify complications and direct treatments, most surveillance protocols involve CTA scans at 1, 6 and 12 months and annually thereafter; however, some investigators have challenged the utility of the 6-month CTA in patients with a normal 1-month CTA.[46] The authors of the 5-year US Zenith multicentre trial have proposed a reduced surveillance protocol, with no 6-month CTA, for patients without early endoleaks.[36] According to the European Society for Vascular Surgery 2010 guideline,[31] CTA and radiography should be used to categorise patients with and without endoleaks. Patients without an endoleak should be followed up with CTA at 12 months and with CDU and plain radiography thereafter, whereas those with a type II endoleak should receive CTA at 6 and 12 months and annual CTA and plain radiography thereafter.[31] Similarly, the Society for Vascular Surgery practice guidelines recommend CTA at 1 and 12 months during the first year after EVAR. CTA at 6 months is added to the surveillance schedule only if the 1-month CTA identifies an endoleak or other abnormalities of concern.[19] In the survey of current clinical practice after EVAR published by Uthoff *et al.*[147] in 2012, 48.6% of the 674 respondents agreed that, in the absence of an endoleak or AAA sac enlargement after initial CTA, no further CTA follow-up at 6 months is required.

Although the current trend is to reduce the frequency of CTA for early surveillance after EVAR or replace it with other imaging modalities, there is limited information on the optimal duration of long-term surveillance and if annual surveillance should continue indefinitely. A systematic review published by Nordon *et al.*[26] in 2010, assessed the rates of secondary interventions in 32 studies (17,987 EVAR patients) and reported the evidence in favour of a modified EVAR practice. The authors have observed a mean time to secondary intervention of approximately 1–1.5 years and have suggested that patients who have completed 3 years of surveillance without detection of endoleaks or sac enlargement can be discharged from standard surveillance.[26]

Some investigators and clinical guidelines now recommend annual post-EVAR surveillance with CDU if the first annual CTA does not demonstrate an endoleak or residual sac enlargement.[12,19,73,150] Compared with CTA, CDU is less invasive, less expensive, easily available and less risky as it does not require the use of a contrast agent and does not expose the patient to repeated radiation. A number of studies and systematic reviews have confirmed the role of CDU in the evaluation of endoleaks.[42,62,73,78,129,151–154] CDU can be regarded as a feasible and safer alternative to CTA, especially in patients with a stable aneurysm. Indeed, the number of centres using CDU seems to be increasing. In the survey by Uthoff *et al.*[147] published in 2012, the use of CDU during surveillance was reported by 36.3% of centres. High-volume, experienced centres were more likely to opt for CDU surveillance after 1 year than less experienced centres with fewer cases.

Moreover, centres with a lot of EVAR experience were more likely to favour ultrasound for the follow-up of type II endoleaks.[147] Similarly, a UK telephone survey administered to 41 centres with 10 years' experience in EVAR showed that 14 out of 41 (34.1%) centres used CDU as the primary surveillance modality.[155]

In general, the evidence identified for this assessment showed no significant differences in terms of reinterventions and clinical complications between strategies based on the use of CDU for long-term surveillance after EVAR and those based on the use of CTA or CTA and CDU; however, the identified studies were clinically heterogeneous and any attempt to compare surveillance strategies should be considered to be tentative.

Current evidence on the use of CEU is limited, and CEU technology has evolved considerably over the past decade. A number of studies in the literature have reported a high accuracy of CEU in comparison with single and biphasic CTA.[57,156,157] A systematic review published in 2015,[130] which assessed the accuracy of CEU versus CTA for the detection of endoleaks during post-EVAR surveillance, concluded that, compared with CTA, CEU that utilises second-generation contrast agents is a highly sensitive modality for the detection of endoleaks and especially for the detection of type II endoleaks. Similarly, a study of 539 patients published by Millen *et al.*[43] in 2013, suggests that CEU may be useful for the resolution of clinical uncertainties that arise from conventional imaging modalities, especially in the classification of endoleaks.

There is growing evidence that the majority of reinterventions post EVAR are triggered by symptoms and are independent of standard surveillance.[39] Among the cohort studies included in this assessment, the proportion of patients requiring reintervention during surveillance ranged from 1.1% during a mean follow-up of 24 months[40] to 23.8% in a cohort of high-risk patients who presented with hostile neck anatomy after a mean follow-up of 32 months,[85] indicating that the risk of reintervention was not homogeneous and was related to patients' characteristics. Karthikesalingam *et al.*,[39] who followed a cohort of 553 patients for a median follow-up period of 31 months (range 1–97 months) and assessed the extent to which surveillance after EVAR triggers reinterventions, found that 5.1% of asymptomatic patients underwent reintervention prompted exclusively by surveillance imaging, whereas 8.3% of patients presented symptomatically. Black *et al.*[37] assessed the number of secondary interventions after EVAR among 417 patients and reported that reinterventions were performed in 31 (7.4%), of whom only six (1.4% (6/417) had abnormalities that were detected by standard surveillance. Similarly, Dias *et al.*[38] found that the majority of follow-up CTA scans post EVAR did not lead to reintervention, and only 9.3% of asymptomatic patients (26/279) underwent a secondary procedure based on imaging findings detected by routine surveillance. The systematic review by Nordon *et al.*,[26] which assessed secondary interventions after EVAR from 32 papers and included a total of 17,987 cases, reported that surveillance practice alone initiated a secondary intervention in only 1.4–9% of cases.

It is possible that current surveillance practice is poorly targeted and that most patients do not benefit from an unstratified surveillance programme that does not take into account the individual risk of developing complications.[11] There is a growing interest in risk-stratified surveillance, whereby the frequency of imaging is directed by the preoperative risk of complications. Risk factors for early and late complications post EVAR have been documented.[158–160] Such an approach would allow more intense surveillance regimes to be targeted to those patients with greater risk, with less frequent surveillance in patients at low risk (Alan Karthikesalingham, St. George's Vascular Institute, St. George's University of London, 2016, personal communication).

Schanzer *et al.*[161] assessed a large population of US Medicare beneficiaries (19,962 patients) who underwent EVAR between 2001 and 2008 and found that 50% of patients were lost to annual imaging follow-up by 5 years post EVAR. For the subset of patients with 8 years of follow-up, substantive declines in imaging follow-up continued, with only 37% undergoing an imaging study between year 6 and year 8.[161] In the UK, Karthikesalingam and Holt,[162] as part of the Multicentre Post-EVAR Surveillance Evaluation Study (EVAR-SCREEN), assessed 1539 patients who underwent EVAR in 10 EVAR-SCREEN collaborator centres. Five years after EVAR, 39.7% of patients remained compliant with the surveillance programme, whereas 21.4% were deliberately removed from surveillance. The authors reported that, compared with 131 compliant patients, non-compliant patients were more likely to undergo reintervention (5-year freedom from reintervention was

76.6% vs. 62.7% in compliant and non-compliant patients, respectively), but demonstrated similar all-cause mortality rates (5-year survival rate of 65.6% vs. 54.7% in compliant and non-compliant patients, respectively).[162] These findings suggest that patients who undergo EVAR should receive appropriate information and counselling about the lifelong risk of complications and the need for annual imaging surveillance. UK centres that have adopted a comprehensive informative approach towards EVAR patients have reported satisfactory compliance rates (Professor Srinivasa Rao Vallabhaneni, 2016, personal communication). These findings also highlight that the current challenge facing EVAR surveillance is the frequency/timing of imaging, which currently is not targeted to patients' risk of developing complications. It is possible that current imaging surveillance is performed too frequently for low-risk patients and not frequently enough for high-risk patients.

Patient perspectives of endovascular abdominal aortic aneurysm repair surveillance

We invited two lay patient representatives to join the advisory group for this assessment. We sought their opinion on receiving surveillance following EVAR to better understand the patient experience of undergoing surveillance. Both representatives were men who had received EVAR between 6 and 3 years prior to joining the advisory group and had received 6-monthly CTA or CDU surveillance. Both men indicated that they had no preference for the type of imaging modality they received; however, they felt that continuity of the professional conducting and interpreting the results of the imaging procedure was important, to give them reassurance that they were receiving adequate monitoring and that their test results were being correctly interpreted. Both men stated that they would welcome more information about the reasons underlying the frequency of their surveillance schedule, with one man stating that he would be willing to undergo more frequent assessments, either for the added reassurance given by a normal surveillance imaging result or for the reassurance that any abnormality would be detected (and treated) early. It is, however, possible that other patients would feel more anxious by the prospect of more intense surveillance regimens. These concerns highlight the potential need to ensure that patients have a greater understanding of the purpose of their surveillance programme after EVAR, as well as of the required frequency of imaging. Travel to surveillance appointments was mentioned as a possible constraint, as the men lived between 8 and 16 miles from their nearest surveillance centre. Both men felt that it would be impossible to attend surveillance appointments solely by public transport and, therefore, relied upon travel by car for all or part of the distance. Practical issues, like travel limitations (especially for elderly people), could explain poor compliance with EVAR surveillance in some cases.

Cost-effectiveness

With regard to the reported economic model and cost-effectiveness analyses, there are a number of limitations that are worth mentioning. Both the identification and the selection of the input data were challenging. In order to identify the relative effect of different surveillance strategies, it was necessary to model a baseline situation (e.g. the cost and consequences of a situation without surveillance). Unfortunately, data to model the natural history of the disease were scarce. For this reason, the attention was turned to studies that analysed registry data. When particular input data were available from more than one source, the newest study was selected in an attempt to capture the technical developments of the modalities under consideration. Moreover, in the economic model, it was assumed that the imaging modalities differentiate the same conditions, that is, the tests identify a proportion of 'abnormalities' according to test sensitivity and specificity data. Once the overall abnormality proportion was defined, this proportion was divided among the abnormal Ia, Ib and II groups in the same proportions, regardless of the original test performed. In addition, the performance data used (i.e. sensitivity and specificity) were based on the detection of endoleaks (all types) that was reported by Karthikesalingam *et al.*[132] Unfortunately, there were no sensitivity and specificity data available by type of abnormality and test, and therefore this is a limitation of the analysis.

A further assumption in the model is the perfect identification of certain abnormalities by plain radiography. In effect, all individuals developing a type Ia abnormality (e.g. non-endoleak needing elective intervention) are assumed to be correctly identified in the next surveillance visits through a plain radiography. Unfortunately, there were no data to inform the test performance for plain radiography in this context. Moreover, although plain radiography shows graft migration and kinking, the abnormal Ia group includes graft infection and limb thrombosis, which will not be seen on plain radiography. In fact, plain radiography in the model is always conducted alongside another imaging test. Therefore, the underlying assumption is that the conditions in the abnormal Ia group are perfectly identified by either plain radiography or the imaging test. A corollary of this is that the differences between the surveillance strategies are a result of the test performances for the abnormal Ib and II subgroups. This is in line with the project brief, as its main interest was related to the detection and management of endoleaks.

There are a number of structural assumptions in the study's model. First, no patients present with symptoms between surveillance visits. Individuals presenting with symptoms make surveillance less worthwhile. Hence, the assumption in the study's model works in favour of surveillance. However, up to 8% of individuals could present with symptoms in a non-emergency situation (Professor Srinivasa Rao Vallabhaneni, 2016, personal communication), and the magnitude of the effect of this assumption on the model results is limited. Second, the model did not include a 'do nothing' alternative. Although this is recommended by a number of economic evaluation methodological guidelines,[60] a no-surveillance strategy was regarded as unacceptable and unrealistic for the UK context. Third, none of the strategies considered a partial use of CEU in a search for further information if the results from the CDU test were inconclusive. This is a limitation of the present analysis and material for further research. Fifth, all strategies considered surveillance on an annual basis. This was agreed with the clinical advisors, as annual surveillance frequency was deemed to be the only acceptable option. Finally, there was no risk stratification of the cohort. An alternative model could consider different surveillance strategies with differing visit frequencies, as well as alternative test arrangements, depending on the patient's risk of developing complications.

The model might overestimate overall survival for this patient group compared with the results of the EVAR 1 trial (EVAR trial arm).[48] A higher overall survival rate would make any surveillance programme relatively more attractive, as people would enjoy the benefits for a longer period of time. The EVAR 1 trial includes individuals who are under surveillance. As a result, the lower mortality rate in the study's model might correspond to events and conditions that cannot be avoided through a surveillance programme. Therefore, our model might overestimate the overall expected costs and QALYs because of a higher overall survival rate; the relative effect of this issue on the modelled strategies is ultimately unclear, although it is believed to be small in magnitude.

Conclusions

The current evidence assessing the effect of surveillance after EVAR is very heterogeneous, with surveillance protocols based on different imaging modalities, frequency of imaging and length of follow-up. Consequently, no firm conclusion can be drawn with regard to the optimal surveillance strategy after EVAR. There is a need to improve current surveillance protocols to reduce radiation exposure, risk of contrast nephropathy and costs, while ensuring that the patients are adequately followed up to minimise their risk of secondary complications, especially aneurysm rupture. CDU may be a safe alternative to CTA, with CTA reserved for abnormal or inconclusive CDU cases that require further investigation. Further research is required, however, to validate the safety of modified surveillance protocols after EVAR based on the use of CDU and/or CEU. Access to modern equipment and highly experienced operators remains a crucial requirement for the adoption of CDU surveillance. The study's economic evaluation shows that CDU is the most cost-effective option for post-EVAR surveillance, with a 63% probability of being cost-effective at a threshold of willingness to pay per QALY of £30,000. Surveillance strategies based on CEU produce more QALYs, but are also more expensive, and might be cost-effective only for higher-risk patient groups.

Suggested research priorities

- Further research is needed to assess the value of targeted surveillance (i.e. patients with a greater risk of complications may receive more frequent surveillance, whereas those with uncomplicated EVAR may undergo less frequent assessments or be discharged from surveillance). A large, multicentre trial with an extended follow-up period (over many years) would be required to answer the question of the optimal surveillance strategy after EVAR; therefore, the identification of high-risk EVAR patients mandating close follow-up may be a more realistic recommendation.
- If surveillance is to be targeted, is ultrasound-based surveillance (CDU and/or CEU) satisfactory for all patient groups, or are there groups for which CTA is required to avoid excessive risk?
- The criteria for identifying patients who are at a high risk of complications (e.g. use of validated score systems, risk prediction models) require further investigation.
- There is a need to clarify the role of plain radiography as part of EVAR surveillance. If CTA is to be performed less frequently or avoided, should plain radiography be mandatory or reserved for patients with abnormalities on ultrasound imaging?
- Future research should explore more broadly the effects of the information generated by the imaging modalities used for surveillance and incorporate this within the economic analyses.

Various aspects of EVAR surveillance may also warrant further consideration, for example it would be useful if:

- some indication of patients' compliance with surveillance could be documented across centres in order to identify best surveillance practice and ensure that surveillance protocols are engaging with patients
- national clinical registries and databases could consider recording data on complications and mortality after EVAR according to the imaging modalities used for surveillance.

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Contributions of authors

Miriam Brazzelli (Senior Research Fellow) oversaw and co-ordinated all aspects of this assessment.

Rodolfo Hernández (Health Economist) reviewed the evidence on the cost-effectiveness of the relevant imaging modalities used for EVAR surveillance, developed the economic model and conducted the cost-effectiveness analyses.

Pawana Sharma and **Clare Robertson** (Research Fellows) reviewed and summarised the current evidence on the clinical effectiveness of imaging strategies for EVAR surveillance.

Michal Shimonovich (Research Assistant) contributed to the data extraction process and to the assessment of the risk of bias of included studies with assistance from **Clare Robertson** and **Miriam Brazzelli**.

Graeme MacLennan (Senior Statistician) provided statistical support.

Cynthia Fraser (Senior Information Specialist) developed and ran the literature searches and provided information support throughout the assessment.

Russell Jamieson (Consultant Vascular Surgeon, NHS Grampian, Aberdeen, UK) and **Srinivasa Rao Vallabhaneni** (Professor of Vascular Surgery, Consultant Vascular and Endovascular Surgeon, Regional Vascular Unit, Royal Liverpool University Hospital, Liverpool, UK) provided expert advice on the clinical aspects of this assessment and clinical guidance.

All authors contributed to the writing of this report and approved its final version.

Data-sharing statement

Most available data are contained within the report. All queries should be submitted to the corresponding author.

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Appendix 1 Search strategy

Clinical effectiveness

Databases

EMBASE (1996 to week 36 2016), Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) (1946 to 5 September 2016).

Last date of search: 5 September 2016.

Search strategy

1. Endoleak/di [Diagnosis]
2. endoleak/ or endoleak?.tw,kw.
3. evar.tw,kw.
4. (endovascular adj5 repair? adj5 abdominal).tw,kw.
5. or/2-4
6. Ultrasonography/ use ppez
7. Echography/ use emef
8. (duplex adj2 (ultrasound or ultrasono$)).tw.
9. Ultrasonography, Doppler, Duplex/ use ppez
10. Doppler echography/ use emef
11. (contrast enhanced adj2 (ultrasound or ultrasono$)).tw
12. (cdu or ceu).tw,kw.
13. Tomography, X-Ray Computed/ use ppez
14. Multidetector Computed Tomography/
15. Computer Tomography Scanner/ use emef
16. (computed adj3 tomograph$).tw.
17. Endoleak/us [Ultrasonography]
18. 5 and (6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16)
19. 1 or 17 or 18
20. Aortic Aneurysm, Abdominal/ use ppez
21. Abdominal Aorta Aneurysm/ use emef
22. endovascular procedures/ use ppez
23. endovascular surgery/ use emef
24. evar.tw,kw.
25. (endovasc$ adj5 repair?).tw.
26. (20 or 21) and (22 or 23 or 24 or 25)
27. 26 or endovascular aneurysm repair/
28. exp Epidemiological Monitoring/ use ppez
29. Patient monitoring/ use emef
30. surveillance.tw,kw.
31. monitor$.tw,kw.
32. 27 and (28 or 29 or 30 or 31)
33. 19 or 32
34. randomized controlled trial.pt.
35. controlled clinical trial.pt.
36. randomi?ed.ab.
37. randomization/ use emef
38. placebo.ab.
39. drug therapy.fs.

40. randomly.ab.
41. trial.ab.
42. groups.ab.
43. (chang$ or evaluat$ or reviewed or baseline).tw.
44. major clinical study/ use emef
45. exp clinical trial/ use emef
46. comparative study/
47. follow-up studies/
48. time factors/
49. (prospective$ or retrospective$).tw.
50. (cohort$ or case series).tw.
51. (compare$ or compara$).tw.
52. (registry or registries or register?).tw.
53. (anaconda or eurostar or karbase or lifeline or renu or swedvasc or uk reta or vascunet).tw.
54. or/34-53
55. 33 and 54
56. 55 not (editorial or letter or comment or case reports).pt.
57. limit 56 to yr=1996-2016
58. remove duplicates from 57

Databases

Science Citation Index (1997 to 5 September 2016).

Web of Knowledge ISI (http://wok.mimas.ac.uk/).

Last date of search: 5 September 2016.

Search strategy

1. TS=endoleak*
2. TS=evar
3. TS=(endovascular N/5 repair* N/5 abdominal)
4. #1 OR #2 OR #3
5. TS=(duplex NEAR/3 (ultrasound OR ultrasono*))
6. TS=('contrast enhanced' NEAR/3 (ultrasound OR ultrasono*))
7. TS=(CDU OR CEU)
8. TS=(Computed NEAR/3 tomograph*)
9. #5 OR #6 OR #7 OR #8
10. #4 AND #9
11. TS=(abdominal NEAR/5 aort* NEAR/5 aneurysm*)
12. TS=evar
13. TS=(endovascular NEAR/5 repair*) Indexes=SCI-EXPANDED, IC Timespan=1997-2016
14. #11 AND (#12 OR #13)
15. TS=monitor*
16. TS=surveillance
17. #16 OR #15
18. #17 AND #14
19. #18 OR #10

Database

The Cochrane Library: Issue 3 2016 [CENTRAL, CDSR, DARE (www3.interscience.wiley.com/)].

Last date of search: 5 September 2016.

Search strategy

1. MeSH (medical subject heading) descriptor: [Endoleak] explode all trees and with qualifier(s): [Diagnosis – DI]
2. MeSH descriptor: [Endoleak] explode all trees
3. endoleak*:ti,ab,kw (Word variations have been searched)
4. (endovascular near/5 repair* near/5 abdominal):ti,ab,kw (Word variations have been searched)
5. #2 or #3 or #4
6. MeSH descriptor: [Ultrasonography] this term only
7. (duplex near/2 (ultrasound or ultrasono*))
8. MeSH descriptor: [Ultrasonography, Doppler, Duplex] this term only
9. (contrast enhanced near/2 (ultrasound or ultrasono*))
10. cdu or ceu:ti,ab,kw (Word variations have been searched)
11. MeSH descriptor: [Tomography, X-Ray Computed] this term only
12. MeSH descriptor: [Multidetector Computed Tomography] this term only
13. MeSH descriptor: [Endoleak] explode all trees and with qualifier(s): [Ultrasonography - US]
14. #5 and (#6 or #7 or #8 or #8 or #9 OT #10 or #11 or #12)
15. #1 or #13 or #14
16. MeSH descriptor: [Aortic Aneurysm, Abdominal] this term only
17. MeSH descriptor: [Endovascular Procedures] this term only
18. evar or (endovasc* near/5 repair*):ti,ab,kw (Word variations have been searched)
19. #16 and (#17 or #18)
20. MeSH descriptor: [Epidemiological Monitoring] explode all trees
21. (surveillance or monitor*):ti,ab,kw (Word variations have been searched)
22. #19 and (#20 or #21)
23. #15 or #22

Database

Scopus' Articles-In-Press (www.scopus.com/).

Last date of search: 5 September 2016.

Search strategy

(TITLE-ABS-KEY (endoleak*) AND DOCTYPE (ip)) OR (TITLE-ABS-KEY (abdominal aortic aneurysm*) AND DOCTYPE (ip))) AND (TITLE-ABS-KEY (surveillance OR monitor* OR ultraso* OR tomograph*) AND DOCTYPE (ip)).

Database

Clinical Trials (http://clinicaltrials.gov/ct/gui/c/r).

Date searched: 27 January 2016.

Search strategy

Abdominal Aortic Aneurysm And endoleak.

Database

EU Clinical Trials Register (www.clinicaltrialsregister.eu/).

Date searched: 27 January 2016.

Search strategy

Abdominal Aortic Aneurysm And endoleak.

Database
The World Health Organization's ICTRP (www.who.int/ictrp/en/).

Date searched: 27 January 2016.

Search strategy
Abdominal Aortic Aneurysm And endoleak.

Diagnostic reviews

Databases
EMBASE (1996 to week 13 2016), Ovid MEDLINE(R) without Revisions (1996 to week 3 2016), Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations (28 March 2016) Ovid multifile search (https://shibboleth.ovid.com/).

Date searched: 29 March 2016.

Search strategy

1. Endoleak/di [Diagnosis]
2. endoleak/ or endoleak?.tw,kw.
3. evar.tw,kw.
4. (endovascular adj5 repair? adj5 abdominal).tw,kw.
5. or/2-4
6. Ultrasonography/ use medf
7. Echography/ use emef
8. (duplex adj2 (ultrasound or ultrasono$)).tw.
9. Ultrasonography, Doppler, Duplex/ use medf
10. Doppler echography/ use emef
11. (contrast enhanced adj2 (ultrasound or ultrasono$)).tw.
12. (cdu or ceu).tw,kw.
13. Tomography, X-Ray Computed/ use medf
14. Multidetector Computed Tomography/
15. Computer Tomography Scanner/ use emef
16. (computed adj3 tomograph$).tw.
17. Endoleak/us [Ultrasonography]
18. 5 and (6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16)
19. 'sensitivity and specificity'/
20. roc curve/
21. receiver operating characteristic/ use emef
22. predictive value of tests/
23. diagnostic errors/ use emef
24. false positive reactions/ use medf
25. false negative reactions/ use medf
26. diagnostic accuracy/ use emef
27. diagnostic value/ use emef
28. du.fs. use medf
29. sensitivity.tw.
30. distinguish$.tw.
31. differentiat$.tw.
32. identif$.tw.
33. detect$.tw.

34. diagnos$.tw.
35. (predictive adj4 value$).tw.
36. accura$.tw.
37. comparison.tw.
38. or/19-37
39. 18 and 38
40. 1 or 17 or 39
41. systematic$ review$.tw.
42. systematic review/ use emef
43. systematic review as topic/ use emef
44. Meta analysis as topic/
45. meta analysis/ use emef
46. meta analysis.tw,pt.
47. metanalysis.tw.
48. metaanalysis.tw.
49. meta synthesis.tw.
50. metasynthesis.tw
51. Meta regression.tw.
52. metaregression.tw.
53. (synthes$ adj3 (literature or evidence)).tw.
54. (systematic study or systematic studies).tw.
55. evidence based review.tw.
56. comprehensive review.tw.
57. or/41-56
58. review.pt,ti.
59. (medline or pubmed or cochrane or embase or cinahl or psyc?lit or psyc?info).ab.
60. (search adj3 (literature or database? or bibliographic or electronic or internet or computeri?ed)).ab.
61. included studies.ab.
62. (inclusion adj3 studies).ab.
63. ((inclusion or selection or predefined or predetermined) adj criteria).ab.
64. (assess$ adj3 (quality or validity)).ab.
65. (select$ adj3 (study or studies)).ab.
66. (data adj3 extract$).ab.
67. extracted data.ab.
68. (data adj2 abstracted).ab.
69. (data adj3 abstraction).ab.
70. or/59-69
71. 58 and 70
72. 57 or 71
73. (letter or editorial or comment).pt.
74. 72 not 73
75. 74 and 40
76. remove duplicates from 75 (36)

Databases

Database of Abstracts of Reviews of Effects and CRD (www.crd.york.ac.uk/CRDWeb/).

Date searched: 29 March 2016.

Search strategy

MeSH DESCRIPTOR Endoleak EXPLODE ALL TREES.

Database

The Cochrane Library Issue 1 2016 [CDSR (www3.interscience.wiley.com/)].

Date searched: 29 March 2016.

Search strategy

1. MeSH descriptor: [Endoleak] explode all trees and with qualifier(s): [Diagnosis – DI]
2. MeSH descriptor: [Endoleak] explode all trees
3. endoleak*:ti,ab,kw (Word variations have been searched)
4. (endovascular near/5 repair* near/5 abdominal):ti,ab,kw (Word variations have been searched)
5. #2 or #3 or #4
6. MeSH descriptor: [Ultrasonography] this term only
7. (duplex near/2 (ultrasound or ultrasono*))
8. MeSH descriptor: [Ultrasonography, Doppler, Duplex] this term only
9. (contrast enhanced near/2 (ultrasound or ultrasono*))
10. cdu or ceu:ti,ab,kw (Word variations have been searched)
11. MeSH descriptor: [Tomography, X-Ray Computed] this term only
12. MeSH descriptor: [Multidetector Computed Tomography] this term only
13. MeSH descriptor: [Endoleak] explode all trees and with qualifier(s): [Ultrasonography - US]
14. #5 and (#6 or #7 or #8 or #8 or #9 OT #10 or #11 or #12)
15. #1 or #13 or #14

Cost-effectiveness

Databases

EMBASE (1996 to week 36 2016), Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) (1946 to 5 September 2016).

Last date of search: 5 September 2016.

Search strategy

1. exp 'costs and cost analysis'/ use mesz
2. exp economic evaluation/ use emcz
3. economics/
4. health economics/ use emcz
5. exp health care cost/ use emcz
6. exp economics,hospital/ use mesz
7. exp economics,medical/ use mesz
8. economics,pharmaceutical/ use mesz
9. pharmacoeconomics/ use emcz
10. exp models, economic/ use mesz
11. exp decision theory/
12. monte carlo method/
13. markov chains/
14. exp technology assessment, biomedical/
15. (cost$ adj2 (effective$ or utilit$ or benefit$ or minimis$)).ab.
16. economics model$.tw.
17. (economic$ or pharmacoeconomic$).tw
18. (price or prices or pricing).tw.
19. budget$.tw.

20. (value adj1 money).tw.
21. (expenditure$ not energy).tw.
22. markov$.tw.
23. monte carlo.tw.
24. (decision$ adj2 (tree? or analy$ or model$)).tw.
25. or/1-24
26. (metabolic adj cost).tw.
27. ((energy or oxygen) adj (cost or expenditure)).tw.
28. 25 not (26 or 27) (1521739)
29. (letter or editorial or note or comment).pt.
30. 28 not 29
31. exp animals/ not humans/ use mesz
32. (animal/ or nonhuman/) not exp human/ use emcz
33. 30 not (31 or 32)
34. Endoleak/di [Diagnosis]
35. endoleak/ or endoleak?.tw,kw
36. evar.tw,kw)
37. (endovascular adj5 repair? adj5 abdominal).tw,kw.
38. or/35-37
39. Ultrasonography/ use mesz
40. Echography/ use emcz
41. (duplex adj2 (ultrasound or ultrasono$)).tw.
42. Ultrasonography, Doppler, Duplex/ use mesz
43. Doppler echography/ use emcz
44. (contrast enhanced adj2 (ultrasound or ultrasono$)).tw.
45. (cdu or ceu).tw,kw.
46. Tomography, X-Ray Computed/ use mesz
47. Multidetector Computed Tomography/
48. Computer Tomography Scanner/ use emcz
49. (computed adj3 tomograph$).tw.
50. Endoleak/us [Ultrasonography]
51. 38 and (39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49)
52. 34 or 50 or 51
53. Aortic Aneurysm, Abdominal/ use mesz
54. Abdominal Aorta Aneurysm/ use emcz
55. endovascular procedures/ use mesz
56. endovascular surgery/ use emcz
57. evar.tw,kw.
58. (endovasc$ adj5 repair?).tw
59. (53 or 54) and (55 or 56 or 57 or 58)
60. 59 or endovascular aneurysm repair/
61. exp Epidemiological Monitoring/ use mesz
62. Patient monitoring/ use emcz
63. surveillance.tw,kw.
64. monitor$.tw,kw.
65. 60 and (61 or 62 or 63 or 64)
66. 52 or 65
67. 33 and 66
68. Aortic Aneurysm, Abdominal/ec use mesz
69. 67 or 68
70. remove duplicates from 69

Databases

NHS Economics Evaluations Database.

Centre for Reviews and Dissemination.

Date of last search: 9 September 2016.

Search strategy

1. MeSH DESCRIPTOR Aortic Aneurysm, Abdominal IN NHSEED
2. MeSH DESCRIPTOR Endoleak IN NHSEED
3. (endoleak*) OR (evar) OR (repair*)
4. (surveillance) OR (monitor*)
5. #2 OR #3 OR #4
6. #1 AND #5

Database

Health Technology Assessment Database [Canadian (www.crd.york.ac.uk/PanHTA/HistoryPage.asp)].

Date of last search: 9 September 2016.

Search strategy

1. MeSH DESCRIPTOR Aortic Aneurysm, Abdominal EXPLODE ALL TREES IN PCHTA 9 Delete
2. MeSH DESCRIPTOR Endoleak EXPLODE ALL TREES IN HTA
3. #1 or #2

Database

Research Papers in Economics (http://repec.org/).

Date of last search: 9 September 2016.

Search strategy

Abdominal aortic aneurysm* or endoleak*.

Appendix 2 Study eligibility and data extraction forms

Full-text screening form

HTA EVAR Surveillance

Study Eligibility Screening Form

Version 3 **April 2016**

Assessor initials: _____	**Date assessed:** _____
Study identifier (surname of first author + year of publication)	
Interventions in the study Q1. Does the study involve EVAR surveillance using CDU, CEU or CTA and CDU/CEU imaging modalities?	Yes ⇩ Go to Q1a Unclear ⇩ No ⇩ **Exclude**
Participants in the study Q2. Are some or all of the participants in the adult men or women who have been previously treated for an abdominal aortic aneurysm with EVAR?	Yes ⇩ Go to Q2a Unclear ⇩ No ⇩ **Exclude**
Q2a. If only some of the participants were treated with EVAR, were these results reported separately from the rest of the study sample?	Yes ⇩ Go to Q3a Unclear ⇩ No ⇩ **Exclude**
Type of study Q3a. Is the study a randomised controlled trial of EVAR surveillance interventions/strategies?	Yes ⇩ Go to Q4 Unclear ⇩ No ⇩ Go to Q3a
Q3b. Is the study a non-randomised comparison including more than one EVAR surveillance intervention/strategy group?	Yes ⇩ Go to Q4 Unclear ⇩ No ⇩ Go to Q3b
Q3c. Is the study a single cohort study reporting details of a surveillance protocol for one or more of the considered imaging modalities with ≥100 participants and ≥1 year follow-up?	Yes ⇩ Go to Q4 Unclear ⇩ No ⇩ **Exclude**
Q3d. Is the study a systematic review of diagnostic accuracy of EVAR surveillance modalities (CTA, CDU and/or CEU)?	Yes ⇩ Go to Q4 Unclear ⇩ No ⇩ **Exclude**
Outcomes in the study *Please highlight which outcomes are reported* Q4. Does the study report one or more of the following outcomes? Incidence and type of EVAR complications (e.g. significant and non-significant endoleaks, migration, kinking and fracture), Re-intervention rate, Incidence and type of secondary interventions, adverse effects/harms associated with the surveillance modality, survival/deaths, aneurysm size	Yes ⇩ **Include** Unclear ⇩ No ⇩ **Exclude**
Final decision (subject to clarification of 'unclear' points)	**Include** **Unclear** **Exclude**

Data extraction form

Reviewer
Date
Administration details
Study ID
Publication status
Study IDs of linked reports
Study aim
Study details
Study design
Setting
Country
Number of centres
Sample identification
Method of recruitment
Allocation method
Study dates
Duration of the study
Length of follow-up
Eligibility criteria
Inclusion criteria
Exclusion criteria

Interventions and comparators						
Details of the intervention	**CDU**	**CEU**	**CDU and CEU**	**With plain radiography**	**Without plain radiography**	**Other (describe)**
Frequency of imaging (frequency and duration – e.g. imaging at 1 month, 6 months, 12 months post EVAR)						
Details of the operator, including experience level if reported						
Details of the comparator	**CTA multiphase**	**CTA single phase**	**CDU/CEU (specify)**	**With plain radiography**	**Without plain radiography**	**Other (describe)**
Frequency of imaging (frequency and duration – e.g. imaging at 1 month, 6 months, 12 months post EVAR)						
Details of the operator, including experience level if reported						
Outcomes						
Primary outcomes reported						
Secondary outcomes reported						
Adverse events reported						
Other information						
Additional information on intervention and comparators						
Data analysis – did the analysis adjust for any confounding factors [if yes, please state the confounding factor(s)]? How was the confounding factor categorised?						
Source of						

Number of participants, *n* (%)	Total			Intervention				Comparator
Enrolled								
Randomised								
Received treatment								
Post-randomisation exclusions								
Discontinued study								
Lost to follow-up								
Analysed								
Reasons for dropouts								
Pre randomisation								
Post randomisation								
Participant baseline characteristics	**Intervention**	***n***	***N***	**Comparator**	***n***	***N***	**Total**	***n***	***N***
Age									
Male/female (%)									
Aneurysm type									
Abdominal aortic (AAA)									
Iliac aortic									
Infrarenal									
Ruptured AAA									
Other (specify)									
BMI									

Renal insufficiency											
None											
Mild											
Moderate											
Severe											
End stage											
Hypertension											
Coronary heart disease											
Ischaemic heart disease											
Cerebrovascular disease											
Hyperlipidaemia											
Diabetes											
Smoking											
Aneurysm diameter/sac size (mm)											
Time since EVAR (months)											
Type of endograph											
Insert name of graft											
Insert name of graft											
Insert name of graft											
Insert name of graft											
Additional information											
Clinical outcomes	**Time point**	**Specify measures (mean %, median %, etc.) and variance (SD, range, 95% CI, etc.)**	**Intervention**			**Control**			**Difference between groups (include type of difference)**	***p*-value**	**Additional information**
			Values	**Variance**	***n***	**Values**	**Variance**	***n***			
Type of reintervention											
Type of secondary intervention											

Mortality	Time point	Specify measures (mean %, median %, etc.) and variance (SD, range, 95% CI, etc.)	Intervention			Control			Difference between groups (include type of difference)	*p*-value	Additional information
			Values	Variance	*n*	Values	Variance	*n*			

Adverse events (EVAR related)	Time point	Specify measures (mean %, median %, etc.) and variance (SD, range, 95% CI, etc.)	Intervention			Control			Difference between groups (include type of difference)	*p*-value	Additional information
			Value	Variance	*n*	Values	Variance	*n*			
Type I endoleak – attachment site											
A (proximal)											
B (distal)											
C (iliac occluder)											
Type II endoleak – branch leak											
A (simple – one branch)											
B (complex – two or more branches)											
Type III endoleak – graft defect											
A (junctional leak or modular defect)											
B (fabric disruption/ graft hole)											
Type IV endoleak – fabric porosity within 30 days											

Type V endoleak – endotension	
	A (no endoleak)
	B (sealed endoleak)
	C (type I or 3 endoleak discovered at the time of open redo surgery)
	D (type II endoleak discovered at the time of open redo surgery)
Graft migration	
Graft kinking	
Graft stenting	
Limb outflow impairment	
Limb occlusion	
Aneurysm rupture	
Aneurysm diameter/sac size	

BMI, body mass index; ID, identification.

Appendix 3 Review Body for Interventional Procedures tool for assessing the quality of non-randomised studies

Checklist for the quality assessment of non-randomised studies (comparative and cohort studies)

Items specific to comparative studies are in italic.

Assessor initial:

Date evaluated:

Study ID:

Criteria	Yes	No	Unclear	Comments
1. Were participants a representative sample selected from a relevant patient population, e.g. randomly selected from those seeking for treatment despite of age, duration of disease, primary or secondary disease and severity of disease?				
2. Were the inclusion/exclusion criteria of participants clearly described?				
3. Were participants entering the study at a similar point in their disease progression, i.e. severity of disease?				
4. Was selection of patients consecutive?				
5. Was data collection undertaken prospectively?				
6. *Were the groups comparable on demographic characteristics and clinical features?*				
7. Was the intervention (and comparison) clearly defined?				
8. Was the intervention undertaken by someone experienced at performing the procedure?[a]				
9. Were the staff, place, and facilities where the patients were treated appropriate for performing the procedure? (e.g. access to back-up facilities in hospital or special clinic)				
10. Were any of the important outcomes considered, i.e. on clinical effectiveness, cost-effectiveness, or learning curves?				
11. Were objective (valid and reliable) outcome measures used, including satisfaction scale?				
12. *Was the assessment of main outcomes blind?*				
13. Was follow-up long enough (≥ 1 year) to detect important effects on outcomes of interest?				
14. Was information provided on non-respondents, dropouts?[b]				
15. Were the withdrawals/dropouts having similar characteristics as those completed the study and therefore unlikely to cause bias?[c]				
16. *Was length of follow-up similar between comparison groups?*				

continued

Criteria	Yes	No	Unclear	Comments
17. Were the important prognostic factors identified, e.g. age, duration of disease, disease severity?[d]				
18. *Were the analyses adjusted for confounding factors?*				

a 'Yes' if the practitioner received training on conducting the procedure before or conducted the same kind of procedure before (i.e. no learning curve).
b 'No' if participants were from those whose follow-up records were available (retrospective).
c 'Yes' if no withdrawal/dropout; 'No' if dropout rate ≥ 30% or differential dropout (e.g. those having the most severe disease died during follow-up, but the death was not because of treatment; no description of those lost).
d 'Yes' if two or more than two factors were identified.

The same form was adapted to assess the quality of the case series after taking out questions 6, 12, 16 and 18.

Appendix 4 Included primary studies

Clinical effectiveness

Comparative

Chisci E, Setacci F, Iacoponi F, de Donato G, Cappelli A, Setacci C. Surveillance imaging modality does not affect detection rate of asymptomatic secondary interventions following EVAR. *Eur J Vascular Endovasc Surg* 2012;**43**:276–81.

Nyheim T, Staxrud LE, Rosen L, Slagsvold CE, Sandbaek G, Jørgensen JJ. Review of postoperative CT and ultrasound for endovascular aneurysm repair using Talent stent graft: can we simplify the surveillance protocol and reduce the number of CT scans? *Acta Radiol* 2013;**54**:54–8.

Cohort

Bisdas T, Weiss K, Eisenack M, Austermann M, Torsello G, Donas KP. Durability of the Endurant stent graft in patients undergoing endovascular abdominal aortic aneurysm repair. *J Vasc Surg* 2014;**60**:1125–31. https://doi.org/10.1016/j.jvs.2014.04.070

Blom AS, Troutman D, Beeman B, Yarchoan M, Dougherty MJ, Calligaro KD. Duplex ultrasound imaging to detect limb stenosis or kinking of endovascular device. *J Vasc Surg* 2012;**55**:1577–80. https://doi.org/10.1016/j.jvs.2011.12.058

Bush RL, Lumsden AB, Dodson TF, Salam AA, Weiss VJ, Smith RB, III, Chaikof EL. Mid-term results after endovascular repair of the abdominal aortic aneurysm. *J Vasc Surg* 2001;**33**(Suppl. 2):70–6.

Chaer RA, Gushchin A, Rhee R, Marone L, Cho JS, Leers S, Makaroun MS. Duplex ultrasound as the sole long-term surveillance method post-endovascular aneurysm repair: a safe alternative for stable aneurysms. *J Vasc Surg* 2009;**49**:845–9. https://doi.org/10.1016/j.jvs.2008.10.073

Carroccio A, Faries PL, Morrissey NJ, Teodorescu V, Burks JA, Gravereaux EC, *et al.* Predicting iliac limb occlusions after bifurcated aortic stent grafting: anatomic and device-related causes. *J Vasc Surg* 2002;**36**:679–84.

Cochennec F, Becquemin JP, Desgranges P, Allaire E, Kobeiter H, Roudot-Thoraval F. Limb graft occlusion following EVAR: clinical pattern, outcomes and predictive factors of occurrence. *Eur J Vasc Endovasc Surg* 2007;**34**:59–65.

Collins JT, Boros MJ, Combs K. Ultrasound surveillance of endovascular aneurysm repair: a safe modality versus computed tomography. *Ann Vasc Surg* 2007;**21**:671–5.

Dominguez I, Mehta M, Roddy SP, Clement Darling R, Sternbach Y, Taggert JB, *et al.* A prospective evaluation of the impact of balloon-expandable palmaz stent placement in aortic neck during EVAR. *J Vasc Surg* 2010;**52**:1123.

Donas KP, Torsello GB, Piccoli G, Pitoulias GA, Torsello GF, Bisdas T, *et al.* The PROTAGORAS study to evaluate the performance of the Endurant stent graft for patients with pararenal pathologic processes treated by the chimney/snorkel endovascular technique. *J Vasc Surg* 2016;**63**:1–7. https://doi.org/10.1016/j.jvs.2015.07.080

Fargion A, Masciello F, Melani A, Pratesi G, Pulli R, Dorigo W, Pratesi C. The influence of the timing of onset of type II endoleak on the late outcomes of endovascular repair of abdominal aortic aneurysms. *J Vasc Surg* 2016;**63**(Suppl. 1):19S.

Fossaceca R, Guzzardi G, Cerini P, Di Terlizzi M, Malatesta E, Filice L, *et al.* [Endovascular treatment of abdominal aortic aneurysms: 6 years of experience at a single centre.] *Radiol Med* 2013;**118**:616–32. https://doi.org/10.1007/s11547-012-0905-8

Freyrie A, Gallitto E, Gargiulo M, Faggioli G, Bianchini Massoni C, Mascoli C, *et al.* Results of the endovascular abdominal aortic aneurysm repair using the Anaconda aortic endograft. *J Vasc Surg* 2014;**60**:1132–9. https://doi.org/10.1016/j.jvs.2014.04.073

Ghotbi R, Sotiriou A, Mansur R. New results with 100 Excluder cases. *J Cardiovasc Surg* 2010;**51**:475–80.

Harrison GJ, Oshin OA, Vallabhaneni SR, Brennan JA, Fisher RK, McWilliams RG. Surveillance after EVAR based on duplex ultrasound and abdominal radiography. *Eur J Vasc Endovasc Surg* 2011;**42**:187–92. https://doi.org/10.1016/j.ejvs.2011.03.027

Karthikesalingam A, Kumar S, Anandarajah JJ, Hinchliffe RJ, Poloniecki JD, Thompson MM, Holt PJ. Predictive value of peak systolic velocity for the development of graft limb complications after endovascular aneurysm repair. *J Endovasc Ther* 2012;**19**:428–33. https://doi.org/10.1583/11-3739MR.1

Köcher M, Utíkal P, Koutná J, Bachleda P, Buriánková E, Herman M, *et al.* Endovascular treatment of abdominal aortic aneurysms – 6 years of experience with Ella stent–graft system. *Eur J Radiol* 2004;**51**:181–8. https://doi.org/10.1016/S0720-048X(03)00165-7

Kray J, Kirk S, Franko J, Chew DK. Role of type II endoleak in sac regression after endovascular repair of infrarenal abdominal aortic aneurysms. *J Vasc Surg* 2015;**61**:869–74. https://doi.org/10.1016/j.jvs.2014.11.003

Mazzaccaro D, Settembrini AM, Malacrida G, Stegher S, Occhiuto MT, Sorba F, *et al.* Endovascular aneurysm repair: experience of 12 years in a single institution. *Interact Cardiovasc Thorac Surg* 2011;**12**:S43.

Meier GH, Parker FM, Godziachvili V, Demasi RJ, Parent FN, Gayle RG. Endotension after endovascular aneurysm repair: the Ancure experience. *J Vasc Surg* 2001;**34**:421–6.

Oshin OA, Fisher RK, Williams LA, Brennan JA, Gilling-Smith GL, Vallabhaneni SR, McWilliams RG. Adjunctive iliac stents reduce the risk of stent–graft limb occlusion following endovascular aneurysm repair with the Zenith stent–graft. *J Endovasc Ther* 2010;**17**:108–14. https://doi.org/10.1583/09-2854.1

Parlani G, Zannetti S, Verzini F, De Rango P, Carlini G, Lenti M, Cao P. Does the presence of an iliac aneurysm affect outcome of endoluminal AAA repair? An analysis of 336 cases. *Eur J Vasc Endovasc Surg* 2002;**24**:134–8.

Schunn CD, Krauss M, Heilberger P, Ritter W, Raithel D. Aortic aneurysm size and graft behavior after endovascular stent–grafting: clinical experiences and observations over 3 years. *J Endovasc Ther* 2000;**7**:167–76. https://doi.org/10.1177/152660280000700301

Soler RJ, Bartoli MA, Mancini J, Lerussi G, Thevenin B, Sarlon-Bartoli G, Magnan PE. Aneurysm sac shrinkage after endovascular repair: predictive factors and long-term follow-up. *Ann Vasc Surg* 2015;**29**:770–9. https://doi.org/10.1016/j.avsg.2014.12.016

Stella A, Freyrie A, Gargiulo M, Faggioli GL. The advantages of Anaconda endograft for AAA. *J Cardiovasc Surg* 2009;**50**:145–52.

Wolf YG, Tillich M, Lee WA, Fogarty TJ, Zarins CK, Rubin GD. Changes in aneurysm volume after endovascular repair of abdominal aortic aneurysm. *J Vasc Surg* 2002;**36**:305–9.

Appendix 5 List of excluded studies with rationale

Diagnostic reviews (*n* = 9)

Ashoke R, Brown LC, Rodway A, Choke E, Thompson MM, Greenhalgh RM, Powell JT. Color duplex ultrasonography is insensitive for the detection of endoleak after aortic endografting: a systematic review. *J Endovasc Ther* 2005;**12**:297–305.

Bevis PM, Cooper DG. [Duplex ultrasound for surveillance after endovascular repair of abdominal aortic aneurysm.] *Ital J Vasc Endovasc Surg* 2012;**19**:237–43.

Cantisani V, Grazhdani H, Clevert DA, Iezzi R, Aiani L, Martegani A, *et al.* EVAR: benefits of CEUS for monitoring stent–graft status. *Eur J Radiol* 2015;**84**:1658–65. https://doi.org/10.1016/j.ejrad.2015.07.001

Chung J, Kordzadeh A, Prionidis I, Panayiotopoulos Y, Browne T. Contrast-enhanced ultrasound (CEUS) versus computed tomography angiography (CTA) in detection of endoleaks in post-EVAR patients. Are delayed type II endoleaks being missed? A systematic review and meta-analysis. *J Ultrasound* 2015;**18**:91–9. https://doi.org/10.1007/s40477-014-0154-x

Howard JM, Ezwawah O, Guiney M, Ryan M, McEniff N. Contrast-enhanced ultrasound versus CT angiography for the detection of endoleak in patients post-EVAR: an evidence based radiology approach. *Cardiovasc Intervent Radiol* 2011;**34**:567–8.

Karanikola E, Dalainas I, Karaolanis G, Zografos G, Filis K. Duplex ultrasound versus computed tomography for the postoperative follow-up of endovascular abdominal aortic aneurysm repair. Where do we stand now? *Int J Angiol* 2014;**23**:155–64. https://doi.org/10.1055/s-0034-1387925

Karthikesalingam A, Al-Jundi W, Jackson D, Boyle JR, Beard JD, Holt PJ, Thompson MM. Systematic review and meta-analysis of duplex ultrasonography, contrast-enhanced ultrasonography or computed tomography for surveillance after endovascular aneurysm repair. *Br J Surg* 2012;**99**:1514–23. https://doi.org/10.1002/bjs.8873

Mirza TA, Karthikesalingam A, Jackson D, Walsh SR, Holt PJ, Hayes PD, Boyle JR. Duplex ultrasound and contrast-enhanced ultrasound versus computed tomography for the detection of endoleak after EVAR: systematic review and bivariate meta-analysis. *Eur J Vasc Endovasc Surg* 2010;**39**:418–28. https://doi.org/10.1016/j.ejvs.2010.01.001

Sun Z. Diagnostic value of color duplex ultrasonography in the follow-up of endovascular repair of abdominal aortic aneurysm. *J Vasc Interv Radiol* 2006;**17**:759–64.

Imaging modalities (*n* = 179)

Abraham CZ, Chuter TA, Reilly LM, Okuhn SP, Pethan LK, Kerlan RB, *et al.* Abdominal aortic aneurysm repair with the Zenith stent graft: short to midterm results. *J Vasc Surg* 2002;**36**:217–24.

Ahanchi SS, Carroll M, Almaroof B, Panneton JM. Anatomic severity grading score predicts technical difficulty, early outcomes, and hospital resource utilization of endovascular aortic aneurysm repair. *J Vasc Surg* 2011;**54**:1266–72. https://doi.org/10.1016/j.jvs.2011.05.019

Albuquerque FC, Tonnessen BH, Noll RE, Cires G, Kim JK, Sternbergh WC. Paradigm shifts in the treatment of abdominal aortic aneurysm: trends in 721 patients between 1996 and 2008. *J Vasc Surg* 2010;**51**:1348–52. https://doi.org/10.1016/j.jvs.2010.01.078

Altaf N, Abisi S, Yong Y, Saunders JH, Braithwaite BD, MacSweeney ST. Mid-term results of endovascular aortic aneurysm repair in the young. *Eur J Vasc Endovasc Surg* 2013;**46**:315–19. https://doi.org/10.1016/j.ejvs.2013.04.027

Arko FR, Filis KA, Hill BB, Fogarty TJ, Zarins CK. Morphologic changes and outcome following endovascular abdominal aortic aneurysm repair as a function of aneurysm size. *Arch Surg* 2003;**138**:651–5. https://doi.org/10.1001/archsurg.138.6.651

Bartoli MA, Thevenin B, Sarlon G, Giorgi R, Albertini JN, Lerussi G, *et al.* Secondary procedures after infrarenal abdominal aortic aneurysms endovascular repair with second-generation endografts. *Ann Vasc Surg* 2012;**26**:166–74. https://doi.org/10.1016/j.avsg.2011.02.047

Becker GJ, Kovacs M, Mathison MN, Katzen BT, Benenati JF, Zemel G, *et al.* Risk stratification and outcomes of transluminal endografting for abdominal aortic aneurysm: 7-year experience and long-term follow-up. *J Vasc Interv Radiol* 2001;**12**:1033–46.

Beckerman WE, Tadros RO, Faries PL, Torres M, Wengerter SP, Vouyouka AG, *et al.* No major difference in outcomes for endovascular aneurysm repair stent grafts placed outside of instructions for use. *J Vasc Surg* 2016;**64**:63–74.e2. https://doi.org/10.1016/j.jvs.2016.01.034

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Appendix 6 Quality assessment result of individual included studies

TABLE 28 Individual study-level quality assessment of the non-randomised comparative studies

Study, first author (year of publication)	Representative sample	Inclusion/ exclusion criteria clearly defined	Participants at a similar point in disease progression	Selection of patients was consecutive	Data collection undertaken prospectively	Groups comparable	Intervention(s) clearly defined	Intervention delivered by an experienced person
Chisci *et al.* (2012)[66]	1	1	2	1	2	1	1	1
Nyheim *et al.* (2013)[67]	0	2	0	0	1	0	1	0

ID, identification.
0 = unclear; 1 = yes; 2 = no/not reported.

TABLE 29 Individual study-level quality assessment of the single cohort studies[a]

Study, first author (year of publication)	Representative sample	Inclusion/exclusion criteria clearly defined	Participants at a similar point in disease progression	Selection of patients was consecutive	Data collection undertaken prospectively
Bisdas *et al.* (2014)[68]	1	2	0	1	1
Blom *et al.* (2012)[69]	0	2	0	0	1
Bush *et al.* (2001)[70]	0	0	2	1	2
Carroccio *et al.* (2002)[71]	0	0	0	0	1
Chaer *et al.* (2009)[40]	0	1	1	0	1
Cochennec *et al.* (2007)[72]	0	2	0	0	1
Collins *et al.* (2007)[73]	0	2	0	0	2
Donas *et al.* (2016)[74]	0	1	1	0	1
Fossaceca *et al.* (2013)[75]	0	1	1	0	2
Freyrie *et al.* (2014)[76]	1	1	0	0	1
Ghotbi *et al.* (2010)[77]	2	1	1	1	0
Harrison *et al.* (2011)[41]	0	1	0	0	2
Karthikesalingam *et al.* (2012)[78]	1	1	0	1	2
Köcher *et al.* (2004)[79]	1	1	1	0	0
Kray *et al.* (2015)[80]	1	2	1	0	2
Meier *et al.* (2001)[81]	0	1	0	0	1
Oshin *et al.* (2010)[82]	1	2	0	0	2
Parlani *et al.* (2002)[83]	0	1	0	1	1
Schunn *et al.* (2000)[84]	1	1	1	2	1
Soler *et al.* (2015)[85]	2	1	2	1	2
Stella *et al.* (2009)[86]	1	1	0	0	1
Wolf *et al.* (2002)[87]	0	1	0	1	0

ID, identification.
0 = unclear; 1 = yes; 2 = no/not reported.
a Only ReBIP items suitable for the assessment of observational cohort studies are tabulated; ReBIP items applicable to comparative studies are not presented in the table.

Intervention delivered in an appropriate setting	Important outcomes considered	Objective outcome measures used	Assessment of main outcomes blind	Follow-up long enough	Information on non-respondents, dropouts	Withdrawals likely to introduce bias	Length of follow-up similar between comparison groups	Important prognostic factors identified	Analyses adjusted for confounding factors
1	1	1	0	1	1	0	2	1	0
1	1	0	0	1	2	0	0	1	0

Intervention(s) clearly defined	Intervention delivered by an experienced person	Intervention delivered in an appropriate setting	Important outcomes considered	Objective outcome measures used	Follow-up long enough	Information on non-respondents, dropouts	Withdrawals likely to introduce bias	Important prognostic factors identified
1	0	0	1	0	1	1	1	1
1	1	1	1	1	1	1	1	2
1	0	1	1	0	1	2	1	1
1	0	0	1	0	1	2	0	2
1	1	1	1	2	1	2	0	1
1	0	1	1	0	1	2	0	1
1	1	1	1	0	1	2	0	2
1	0	1	1	0	1	2	0	1
1	0	1	1	0	1	2	0	1
1	1	1	1	1	1	1	0	1
1	0	1	1	1	1	2	0	1
1	0	1	1	1	1	2	0	1
1	0	1	1	1	1	2	0	1
1	1	1	0	1	0	2	0	1
1	0	1	1	0	1	1	0	1
1	0	1	1	1	1	2	0	1
1	0	1	1	1	1	2	0	1
1	0	1	1	1	1	2	0	1
1	1	1	1	1	1	1	0	1
1	0	1	1	1	1	1	0	1
1	0	1	1	1	1	2	0	1
1	0	1	1	1	1	1	1	1

Appendix 7 Review-level quality assessment of the diagnostic test performance systematic reviews

TABLE 30 Review-level quality assessment of the diagnostic test performance systematic reviews assessed using the CRD criteria

Study, first author (year of publication)	CRD criteria				
	Inclusion/ exclusion criteria	Substantial search effort	Validity adequately assessed	Sufficient details of individual studies	Primary studies summarised
Ashoke *et al.* (2005)[127]	1	1	1	1	1
Bevis and Cooper (2012)[128]	1	2	2	2	0
Cantisani *et al.* (2015)[129]	2	2	2	2	2
Chung *et al.* (2015)[130]	1	1	1	1	1
Karanikola *et al.* (2014)[3]	2	1	2	1	1
Karthikesalingam *et al.* (2012)[132]	1	1	1	1	1
Mirza *et al.* (2010)[62]	1	1	1	1	1
Sun (2006)[133]	1	2	0	1	0

ID, identification.
0 = unclear; 1 = yes; 2 = no/not reported.

TABLE 31 Review-level quality assessment of the diagnostic test performance systematic reviews assessed using the AMSTAR criteria

	AMSTAR criteria										
Study, first author (year of publication)	A priori design	Duplicate selection and extraction	Comprehensive literature search	Grey literature included	List of included and excluded studies	Characteristics of included studies	Scientific quality assessed and documented	Scientific quality included in formulating conclusions	Appropriate methods to combine studies	Likelihood of publication bias assessed	Conflict of interest included
Ashoke *et al.* (2005)[127]	1	1	1	1	2	1	2	0	1	2	2
Bevis and Cooper (2012)[128]	0	0	1	2	2	2	2	2	2	2	2
Cantisani *et al.* (2015)[129]	2	0	0	2	2	2	2	2	2	2	2
Chung *et al.* (2015)[130]	2	0	1	2	1	1	1	2	1	2	1
Karanikola *et al.* (2014)[3]	0	0	1	2	2	1	2	0	3	2	2
Karthikesalingam *et al.* (2012)[132]	2	0	1	2	2	1	1	1	1	2	1
Mirza *et al.* (2010)[62]	2	1	1	2	2	1	1	1	1	1	1
Sun (2006)[133]	2	2	2	2	1	1	2	2	1	2	1

ID, identification.
0 = unclear; 1 = yes; 2 = no/not reported; 3 = not applicable.

Appendix 8 Characteristics of the included primary studies

TABLE 32 Characteristics of the included primary studies

Study, first author (year of publication)	Type of study	Setting	Number of centres	Geographic location	Study duration, mean/median follow-up SD (range unless otherwise noted)	Total analysed	Age (years)	Number of male participants	Frequency	Imaging modality sequence	Aneurysm type (%)	Aneurysm diameter (mm)	Type of endograph
Comparative cohort studies													
Chisci *et al.* (2012)[66]	Retrospective	Tertiary referral centre	1	Italy	Protocol I: 4 years Protocol II: 3.5 years Protocol I mean: 1148 days (1–3204 days) Protocol II mean: 942 days (1–1512 days)	Protocol II: 376 Protocol II: 341	Protocol I: 76.8 (±8.7, range 67–90) Protocol II: 77.7 (±7.0, range 66–92) $p = 0.239$	Protocol 1: 327 (87%) Protocol II: 286 (84%) $p = 0.285$	Protocol I: 1 month post operation, every 6 months thereafter Protocol II: 1 month post operation Every 6 months	Protocol I: CTA, CDU and clinical examination Protocol II: CTA, CDU and plain radiography, clinical examination CDU, plain radiography and clinical examination	Iliac artery aneurysm: • Protocol I: 86 (23) • Protocol II: 61 (18) $p = 0.119$ Bilateral iliac aneurysm: • Protocol I: 41 (11) • Protocol II: 48 (14) $p = 0.241$	Protocol I: 64 (+6) Protocol II: 61 (+8) $p < 0.001$	Talent (Medtronic, Santa Rosa, CA, USA): • Protocol I: 242 (64%) • Protocol II: 144 (43%) $p < 0.0001$ Zenith: • Protocol I: 51 (13%) • Protocol II: 16 (5%) $p < 0.0001$ Endurant: • Protocol I: 168 (49%) Anaconda: • Protocol I: 17 (4%) • Protocol II: 4 (1%) $p < 0.05$ Excluder (W L Gore & Associates, Inc., Flagstaff, AZ, USA): • Protocol I: 64 (19%) • Protocol II: 9 (2%) $p < 0.0001$

Study, first author (year of publication)	Type of study	Setting	Number of centres	Geographic location	Study duration, mean/median follow-up SD (range unless otherwise noted)	Total analysed	Age (years)	Number of male participants	Frequency	Imaging modality sequence	Aneurysm type (%)	Aneurysm diameter (mm)	Type of endograph
Nyheim *et al.* (2013)[67]	Prospective	Vascular centre	1	Norway	5 years Median: 41.5 months (2–94 months)	56	74 (range 55–87)	50 (89.3%)	6–8 weeks 1 year Poor visibility, presence of endoleak, AAA diameter increase on ultrasound or migration on PFA	CDU and plain radiography CTA, CDU and plain radiography CTA	AAA: 56 (100)	Median 60 (range 51–80)	Talent stent–graft
Non-comparative cohort studies													
Bisdas *et al.* (2014)[68]	Prospective	Outpatient department of hospital and university clinic	2	Germany	3 years Median: 42 months (IQR 30.7–50.7 months)	273	73 (±9)	246 (90%)	Before discharge, after 1 year, annually up to 5 years At 6 months	CTA CDU	Ruptured AAA (2) Symptomatic aneurysms: (7) AAA (91)	Maximal AAA: 57 (range 40–87)	Endurant stent–graft (100%)
Blom *et al.* (2012)[69]	Prospective	Hospital	1	USA	12 years Mean: 22.3 months (1–123 months)	248	NR	NR	1 week, 6 months and annually	Duplex ultrasound	AAA (100)	NR	Ancure [(Guidant Cardiac and Vascular Division, Menlo Park, CA, USA) 4.8%] AneuRx [(AneuRx, Inc., Sunnyvale, CA, USA) 41.5%] Excluder (16.5%) Endologix [(Endologix Inc., Irvine, CA, USA) 5.2%] Zenith (31.9%)

continued

TABLE 32 Characteristics of the included primary studies (*continued*)

Study, first author (year of publication)	Type of study	Setting	Number of centres	Geographic location	Study duration, mean/median follow-up SD (range unless otherwise noted)	Total analysed	Age (years)	Number of male participants	Frequency	Imaging modality sequence	Aneurysm type (%)	Aneurysm diameter (mm)	Type of endograph
Bush *et al.* (2001)[70]	Retrospective	University hospital	1	USA	5.5 years High-risk group: Mean 14.6 ± 12.4 months Low-risk group: Mean 17.7 ± 15.0 months	104 High-risk group: 51 Low-risk group: 53	High-risk group: 72.2 (± 7.2) Low-risk group: 73.8 (± 7.1)	NR	1 month 6 months, 12 months, annually thereafter	CEU CTA, CDU and plain radiography	Infrarenal AAA: (100)	High-risk group: 58.2 (± 11.3) Low-risk group: 52.2 (± 11.5)	EVT/Guidant endograft (Guidant Corp, Menlo Park, CA, USA) 71 (68.3%) AneuRx: 16 (15.4%) Excluder: 17 (16.3%)
Carroccio *et al.* (2002)[71]	Prospective	Medical centre	1	USA	4 years Mean: 20 ± 9 months (2–54 months)	351	NR	NR	1, 3, 6, 12 months, annually thereafter	Duplex scan and 3-mm slice CTA	Infrarenal aortic aneurysms: (100)	NR	AneuRx: 35 (10.0%) Ancure: 8 (2.3%) Gore (W L Gore & Associates, Sunnyvale, CA, USA) 25 (7.1%) Talent: 255 (72.6%) TERAMed (TERAMed Inc., Miami, FL, USA): 10 (2.8%) Vanguard (Boston Scientific, Marlborough, MA, USA): 18 (5.1%)
Chaer *et al.* (2009)[40]	Prospective	University medical centre	1	USA	3 years Mean: 24 ± 13 months (12–48 months)	184	73.9 (± 7.1, range 52.6–96.4)	159 (86.4%)	Annually 1 month and 12 months, and only selectively thereafter	CDU Helical CT	AAA: (100)	54 (± 8)	Ancure: 76 (41.3%) Zenith: 58 (31.5%) Excluder: 39 (21.2%) AneuRx: 7 (3.8%) Lifepath (Edwards Lifesciences, Irvine, CA, USA): 4 (2.2%)

Study, first author (year of publication)	Type of study	Setting	Number of centres	Geographic location	Study duration, mean/median follow-up SD (range unless otherwise noted)	Total analysed	Age (years)	Number of male participants	Frequency	Imaging modality sequence	Aneurysm type (%)	Aneurysm diameter (mm)	Type of endograph
Cochennec *et al.* (2007)[72]	Prospective	Department of vascular surgery at hospital	1	France	10 years Mean: 28 months, median: 23.4 months	460	72.3 (±8, range 47–88)	435 (94.6%)	1, 6 and 12 months, annually thereafter Clinical symptoms suggesting endograft thrombosis	Plain radiography, CDU and CTA CT scans or angiography and duplex scan	Bifurcated: 369 Aortomonoiliac: 91	NR	Zenith: 310 Vanguard: 60 Gore: 31 AneuRx: 21 Stenford (Stenford Groupe, Valendos S.A., Nanterre, France): 9 Stentor (MinTec, La Ciotat, France): 8 Talent (World Medical Inc., Medtronic Vascular, Sunrise, FL, USA): 7
Collins *et al.* (2007)[73]	Retrospective	University department of surgery	1	USA	5 years (NR)	160	NR	NR	Every 6 months, first study within 1 month of EVAR Select cases, enlargement of the AAA sac and evidence of an endoleak	Ultrasound CT	AAA: (100)	NR	Ancure: 82 (51.3%) AneuRx: 63 (39.4%) Other: 15 (9.4%)
Dominguez *et al.* (2010)[88] (abstract only)	Unclear	NR	NR	USA	8 years (NR)	1378	NR	EVAR with Palmaz (Cordis Corp, Miami Lakes, Fl, USA) stent: 90 (61.6%) EVAR only: 969 (78.7%)	1 and 6 months, and every 12 months thereafter	CTA and duplex ultrasound	AAA: (100)	NR	NR
Donas *et al.* (2016)[74]	Prospective	Vascular centres	2	Europe	4 years Mean: 24.6 months ± SD 17.4 months (0–61 months)	128	76.6 (±7.7)	113 (88.3%)	6 and 12 months, annually thereafter	CTA	AAA: (100)	64.8 (±14.6, range 48–135)	Endurant stent–graft (100%)

continued

TABLE 32 Characteristics of the included primary studies (*continued*)

Study, first author (year of publication)	Type of study	Setting	Number of centres	Geographic location	Study duration, mean/median follow-up SD (range unless otherwise noted)	Total analysed	Age (years)	Number of male participants	Frequency	Imaging modality sequence	Aneurysm type (%)	Aneurysm diameter (mm)	Type of endograph
Fargion *et al.* (2016)[89] (abstract only)	Retrospective	University hospital	1	Italy	16 years Median: 30 months (1–168 months)	289	NR	NR	Within 3 months post operation Every 6 months	CTA and duplex ultrasound Duplex ultrasound	AAA: (100)	NR	NR
Fossaceca *et al.* (2013)[75]	Retrospective	Hospital	1	Italy	6 years Mean: 29.6 months	222	76 (range 54–97)	213 (95.9%)	1 month, 12 months 6 months Annually thereafter	CT (contrast enhanced) CEU Either CT angiography or CEU	Urgent cases: Ruptured AAA – 34 (15.3) Symptomatic AAA – 20 (9.0%) Elective cases – 168 (75.7)	59 (range 40–100)	Excluder: 85 (38.3%) Zenith: 74 (33.3%) Endurant: 35 (15.8%) Evita (JOTECH GmbH, Hechingen, Germany): 24 (10.8%) Talent: 2 (0.9%0 LeMaitre (LeMaitre Vascular, Inc., Burlington, MA, USA): 1 (0.5%) Aorfix (Lombard Medical, Didcot, UK): 1 (0.5%)
Freyrie *et al.* (2010)[92] [secondary study to Freyrie *et al.* (2014)[76]]	Prospective	Hospital	NR	Italy	2 years	127	73.5 ± 6.9 (range 55–89)	120 (94.4%)	1, 3, 6 and 12 months and annually thereafter	CTA, CEU and CDU	AAA (100)	Group A: 58.9 ± 12.8 Group B: 55.0 ± 8.2	Anaconda: 127 (100%)
Freyrie *et al.* (2014)[76]	Prospective	Hospital	1	Italy	3 years Mean: 32.9 ± 23.3 months (1–77 months)	177	73.3 ± 7.4 (range 47–89)	167 (94.4%)	Discharge, 6 and 12 months, yearly thereafter 1 and 12 months	CDU CTA	NR	55 ± 9.7 (range 45–99)	Anaconda: 177 (100%)
Ghotbi *et al.* (2010)[77]	Unclear	Clinic	1	Germany	4 years Mean: 20 months	100	74.1 (range 44–91)	91 (91%)	1, 3 and 12 months, annually thereafter 3 and 12 months	CDU CTA	Asymptomatic aneurysm: 91 (91) Symptomatic aneurysm: 9 (9)	56.1 (range 45–70)	Excluder: 100 (100%)

Study, first author (year of publication)	Type of study	Setting	Number of centres	Geographic location	Study duration, mean/median follow-up SD (range unless otherwise noted)	Total analysed	Age (years)	Number of male participants	Frequency	Imaging modality sequence	Aneurysm type (%)	Aneurysm diameter (mm)	Type of endograph
Harrison *et al.* (2011)[41]	Retrospective	Tertiary referral centre	1	UK	4 years	194	76 (range 47–93)	165 (85%)	1 month	Abdominal radiography, CDU and CTA	NR	NR	NR
									12 months after EVAR, annually thereafter	Abdominal radiography and CDU			
					Median: 36 months (12–57 months)				Inadequate DUS, abnormality identified	CTA			
Karthikesalingam *et al.* (2012)[78]	Retrospective	NR	NR	UK	6 years	478	75 ± 7	425 (88.9%)	1.5, 3, 6, 9, 12 and 18 months and annually thereafter	CDU	AAA: (100)	65 ± 13	Zenith: 295 (61.7%)
					Median: 43 months (1–92 months)								Talent: 98 (20.5%)
													Other: 85 (17.8%)
Köcher *et al.* (2004)[79]	Unclear	NR	NR	Czech Republic	6 years	120	70.7 (range 49–89)	102 (85.0%)	3, 6 and 12 months, annually thereafter	CTA and CDU	AAA: 120 (100)	< 50: 18 (15%)	Ella stent–graft (Ella-CS Hradec Králové, Czech Republic): 120 (100%)
					Mean: 20.7 months (2–60 months)						Type I AAA: 6 (5)	50–65: 73 (61%)	
											Type II AAA: 105 (87)	> 65: 29 (24%)	
											Type III AAA: 9 (8)		
											Asymptomatic: 104 (86.6)		
											Symptomatic: 16 (13.4)		
Kray *et al.* (2015)[80]	Retrospective	Medical centre	1	USA	4 years	191	74.4 ± 7.4 (range 53–92)	161 (84.3%)	1, 6 and 12 months	CTA and CDU	AAA: 191 (100)	NR	Zenith, Excluder and AneuRx
					Maximum follow-up of 12 months								
Mazzaccaro *et al.* [2011[90] (abstract only)]	Unclear	NR	NR	NR	12 years	391	73 (range 49–91)	363 (92.8%)	2 months, 12 months and annually thereafter	CDU	AAA: 391 (100)	NR	NR
					Median: 68 months (1–144 months)				6 months	CEU			

continued

TABLE 32 Characteristics of the included primary studies (*continued*)

Study, first author (year of publication)	Type of study	Setting	Number of centres	Geographic location	Study duration, mean/median follow-up SD (range unless otherwise noted)	Total analysed	Age (years)	Number of male participants	Frequency	Imaging modality sequence	Aneurysm type (%)	Aneurysm diameter (mm)	Type of endograph
Meier *et al.* (2001)[81]	Prospective	Clinic	33	USA	5.5 years Mean: 23.2 months (2.0–78.8)	476	NR	NR	3, 6 and 12 months, annually thereafter	CTA, CDU and plain radiography	AAA: 476 (100)	Major axis diameter: 57.5 ± 9.9 (range 34.8–92.7) Minor axis diameter: 51.6 ± 9.2 (range 30.9–86.4)	Ancure endograft: 476 (100%)
Oshin *et al.* (2010)[82]	Retrospective	NR	NR	UK	8 years Maximum follow-up: 27 months (median 24 months)	295	75 (± 7)	261 (88.5%)	1 month, annually thereafter	Abdominal radiograph, CEU and CDU Duplex ultrasound and radiography (CT selectively)	AAA: 295 (100)	NR	Zenith: 295 (100%)
Parlani *et al.* (2002)[83]	Prospective	NR	1	Italy	4 years Mean: 14 months (IQR 7–27 months; range 1–46 months)	336	Group A: 70 Group B: 71 $p = NS$	Group A: 260 (94%) Group B: 56 (95%) $p = NS$	1 month, annually thereafter 1, 6 and 12 months, every 6 months thereafter	CTA Clinical evaluation, abdominal radiography and CDU	Concomitant iliac aneurysm: 40 (11.9) Bilateral CIA aneurysm: 19 (5.7) AAA: 277 (82.4)	Group A: 50 (IQR 45 ± 55; range 40 ± 86) Group B: 52 (IQR 48 ± 56; range 40 ± 74) $p = NS$	AneuRx: 228 (68%) Anaconda: 27 (8%) Zenith: 2 (0.6%) Excluder Gore-Tex (W L Gore & Associates, Inc., Flagstaff, AZ, USA): 29 (9%) Endologix: 39 (12%)
Schunn *et al.* (2000)[84]	Prospective	Tertiary care	NR	Germany	3 years Mean:18 months, range to 46	190	68.7 (range 40–87)	176 (92.6%)	3–6 months 6 to 12 months, 1 CTA scan per year in subsequent year	CEU and CDU (if possible), abdominal radiography CTA and/or CDU	Intrarenal AAA: 190 (100)	NR	Stentor system (August 1994 to May 1996): 190 (100%) Vanguard aortic stent–graft (May 1996 to July 1997): 190 (100%)

Study, first author (year of publication)	Type of study	Setting	Number of centres	Geographic location	Study duration, mean/median follow-up SD (range unless otherwise noted)	Total analysed	Age (years)	Number of male participants	Frequency	Imaging modality sequence	Aneurysm type (%)	Aneurysm diameter (mm)	Type of endograph
Soler *et al.* (2015)[85]	Retrospective analysis of prospective registry	Centre	1	France	11 years Mean: 54.8 ± 35.9 months	197	74.8	190 (96.4%)	6, 12, 18 and 24 months, annually thereafter	CTA, plain abdominal radiography, CDU and a standard blood test	Intrarenal AAA: 197 (100). From 2003, EVAR was performed only for the patients who met the high-risk criteria defined by the French Agency for the Safety of Health Products	56.7 ± 9.4 (range 42–110)	Zenith: 124 (62.9%) PowerLink (Endologix, Irvine, CA, USA): 35 (17.8%) AneurX: 15 (7.6%) Talent: 9 (4.6%) Lifepath: 6 (3.0%) Home-made: 6 (3.0%) Excluder: 1 (0.5%) Bard device (Bard, Murray Hill, NJ, USA): 1 (0.5%)
Stella *et al.* (2009)[86]	Prospective	Hospital	1	Italy	3 years Mean: 23.2 ± 11.0 months (1.4–38.6 months)	100	73.9 (range, 55–89)	94 (94%)	1, 3, 6 and 12 months, annually thereafter	CTA, CDU and CEU	AAA: 100 (100)	55.2 ± 3.4 (range 45–99)	NR
Wolf *et al.* (2002)[87]	Unclear	University hospital	1	USA	3.5 years Mean: 15.8 ± 11.3 months (1–48 months)	154	NR	NR	6 months, 12 months, annually thereafter	CTA, CDU, abdominal radiograph and clinical examination	AAA: 154 (100)	57.9 ± 9.4[a]	Bifurcated AneuRx (Medtronic): 154 (100%)

CIA, common iliac artery; ID, identification; NR, not reported; NS, nonsignificant; PFA, plain film abdomen radiography.
a Orthogonal diameter.

Appendix 9 Type of clinical complications reported in the included studies

TABLE 33 Type of clinical complications reported in the included studies

Study, first author (year of publication)	Endoleak				Graft							
	Type I	Type II	Type III	Type IV	Migration	Kinking	Stenosis	Thrombosis	Limb occlusion	Aneurysm rupture	Infection	Ischaemia
Comparative cohort studies												
Chisci *et al.* (2012)[66]	✗	✗	✗		✗				✗	✗	✗	✗
Nyheim *et al.* (2013)[67]	✗	✗	✗		✗						✗	
Non-comparative cohort studies												
Bisdas *et al.* (2014)[68]	✗	✗	✗					✗			✗	✗
Blom *et al.* (2012)[69]									✗			
Bush *et al.* (2001)[70]	✗										✗	
Carrocio *et al.* (2002)[71]								✗				
Chaer *et al.* (2009)[40]	✗	✗							✗			
Cochennec *et al.* (2007)[72]					✗	✗			✗			✗
Collins *et al.* (2007)[73]	✗	✗										
Dominguez *et al.* (2010)[88] (abstract only)	✗	✗										✗
Donas *et al.* (2016)[74]	✗		✗				✗		✗	✗	✗	
Fargion *et al.* (2016)[89] (abstract only)	✗	✗										
Fossaceca *et al.* (2013)[75]	✗	✗	✗				✗	✗				
Freyrie *et al.* (2014)[76] and Freyrie *et al.* (2010)[92]	✗	✗	✗		✗		✗	✗		✗		
Ghotbi *et al.* (2010)[77]	✗	✗			✗					✗		
Harrison *et al.* (2011)[41]	✗	✗				✗	✗		✗	✗		
Karthikesalingam *et al.* (2012)[78]						✗			✗			
Köcher *et al.* (2004)[79]	✗	✗	✗		✗		✗	✗			✗	

Study, first author (year of publication)	Endoleak				Graft		Stenosis	Thrombosis	Limb occlusion	Aneurysm rupture	Infection	Ischaemia
	Type I	Type II	Type III	Type IV	Migration	Kinking						
Kray *et al.* (2015)[80]		✗								✗		
Mazzaccaro *et al.* (2011)[90]	✗	✗						✗		✗		
Oshin *et al.* (2010)[82]									✗	✗		
Parlani *et al.* (2002)[83]	✗	✗	✗							✗		
Schunn *et al.* (2000)[84]	✗	✗							✗			
Soler *et al.* (2015)[85]	✗	✗	✗	✗					✗	✗	✗	
Stella *et al.* (2009)[86]			✗		✗			✗		✗		
Wolf *et al.* (2002)[87]	✗									✗		

ID, identification.

Appendix 10 Endovascular abdominal aortic aneurysm repair-related clinical complications

TABLE 34 Endovascular AAA repair-related clinical complications

Study, first author (year of publication)	Time point (follow-up if time point not reported)	Endoleak (specify subtypes, e.g. proximal, distal), *n*/*N*				Stenosis, *n*/*N*	Thrombosis, *n*/*N*	Aneurysm rupture, *n*/*N*	Limb occlusion, *n*/*N*	Infection, *n*/*N*	Ischaemia, *n*/*N*	Notes
		Type I	Type II	Type III	Type IV							
Comparative cohort studies												
Chisci *et al.* (2012)[66]	Protocol I											
	< 30 days	2/376										Migration (> 1 cm): 2/376
	> 30 days	5/376	57/376	3/376				2/376	10/376	0/376 (graft)	2/376 (bowel)	Conversion to open repair: 3/376
	Protocol II											
	< 30 days	1/341										Migration (> 1 cm): 1/341
	> 30 days	4/341	45/341	3/341				1/341	8/341	0/341 (graft)	0/341 (bowel)	Conversion to open repair: 1/341
Nyheim *et al.* (2013)[67]	< 30 days	2/56 (4%)	9/56 (16%)	1/56 (2%)						2/56		Migration (> 10 mm): 4/56 (7%) (> 30 days)
	6 months		1/56 (2%)									
Non-comparative cohort studies												
Bisdas *et al.* (2014)[68]	NR [median 42 months (IQR 31–50 months)]	5/273 (1.8%)	4/273 (1.5%)				10/273[a] (3.7%)			1/273 [0.4 (groin)]	1/273 [0.4 (bowel ischaemia)]	Renal artery occlusion: 1/273
	10 months			1/273 (0.4%)								False aneurysm: 1/273
												Progression of aneurysmal disease: 1/273
												Distal popliteal artery embolisation: 1/273
Blom *et al.* (2012)[69]	46 months (range 1 month–10 years)								0/248			
Bush *et al.* (2001)[70]	1 month	18/104 (17.3%)										Endoleak detected by CTA
	2 months									1/104 [1.0% (graft)]		
	26 months									2/104 [2.0% (hook fracture)]		Data combined for two groups

Study, first author (year of publication)	Time point (follow-up if time point not reported)	Endoleak (specify subtypes, e.g. proximal, distal), *n/N*				Stenosis, *n/N*	Thrombosis, *n/N*	Aneurysm rupture, *n/N*	Limb occlusion, *n/N*	Infection, *n/N*	Ischaemia, *n/N*	Notes
		Type I	Type II	Type III	Type IV							
Carroccio *et al.* (2002)[71]	Mean time to occlusion 5.2 ± 6.5 months (range 1 day to 23 months)						26/702 limbs (3.7%)					13/26 (50%) identified within 30 days 24/26 (92.3%) identified within 1 year
Chaer *et al.* (2009)[40]	NR [mean: 24 ± 13 months (range 12–48 months)]	2/184 (1.1%)	1/184 (0.5%)					0/184	0/184 (graft occlusion)			Graft occlusion: 0; one type II endoleak with stable sac size could not be identified on the CTA obtained 3 months later
Cochennec *et al.* (2007)[72]	During follow-up (mean: 28 months)								33/460 (7.2%)		9/33 (27%)	
	Intraoperative								2/460 (0.4%)			Graft migration: 9/460 (1.96) Graft limb kink: 13/460 (2.82)
	Within the first week								9/460 (2.0%)			
	Within 1 month								14/460 (3.0%)			
	Within 6 months								23/460 (5.0%)			
	Within 3 years								30/460 (6.5%)			
	NR								Symptomatic: 27			Acute ischaemia: ($n = 9$); rest pain: ($n = 8$); claudication ($n = 10$)
	NR								Asymptomatic: 4			Found on systematic duplex scan

continued

TABLE 34 Endovascular AAA repair-related clinical complications (*continued*)

Study, first author (year of publication)	Time point (follow-up if time point not reported)	Endoleak (specify subtypes, e.g. proximal, distal), *n*/*N*				Stenosis, *n*/*N*	Thrombosis, *n*/*N*	Aneurysm rupture, *n*/*N*	Limb occlusion, *n*/*N*	Infection, *n*/*N*	Ischaemia, *n*/*N*	Notes
		Type I	Type II	Type III	Type IV							
Collins *et al.* (2007)[73]	Ultrasound, NR (scans performed every 6 months until AAA sac resolved)	7/359 scans	26/359									Ultrasound scans: $n = 359$; CTA scans: $n = 35$; Combine types I and II: • Ultrasound – 8/359 • CTA – 4/35 CTA discovered three endoleaks that were not seen with CDU. However, these scans were inadequate because of additional factors Of the 41 endoleaks found on CDU, only 14 were found on CTA
	CTA scans	9/35	9/35									
Dominguez *et al.* (2010)[88]	NR (follow-up NR)	106/1378 (7.7%)	329/1378 (23.9%)								29/1378 [2.1% (ischaemic colitis)]	Data combined for 'EVAR only' and 'EVAR with Palmaz stent' Stent–graft explant: 16/1378
Donas *et al.* (2016)[74]	NR mean: 24.6 (SD 17.4 months; range 0–61 months)	4/128 (3.1%)		2/128 (1.6%)		6/128 [4.7% (high grade)]			8/128 (6.25%)	1/128 (0.8%)		
	27 months							1/128 (0.8%)				Procedure-related late aortic rupture caused by the dislocation of iliac limbs and type III endoleaks; endotension, $n = 1$

Study, first author (year of publication)	Time point (follow-up if time point not reported)	Endoleak (specify subtypes, e.g. proximal, distal), *n*/*N*				Stenosis, *n*/*N*	Thrombosis, *n*/*N*	Aneurysm rupture, *n*/*N*	Limb occlusion, *n*/*N*	Infection, *n*/*N*	Ischaemia, *n*/*N*	Notes
		Type I	Type II	Type III	Type IV							
Fargion *et al.* (2016)[89] (abstract only)	NR [median: 30 months (range 1–168 months)]	9/289	38/289									Total number of procedures, *n* = 289
Fossaceca *et al.* (2013)[75]	> 30 days' follow-up (mean 29.6 months)	4/222 (1.8%)	55/222 (24.8%)	1/222 (0.45%)		1/222 [0.45% (stent–graft explant)]	10/222 (4.5%)					Type II endoleaks: eight treated; 47 managed conservatively with CEU follow-up; thrombosis in seven cases at the 1-month follow-up and in three cases at the 6-month follow-up
Freyrie *et al.* (2010)[92]	Second postoperative day	1/127										
	6 months	1/127										
	9 months						2/127					
	1 year						1/127					
	NR										1/127	
Freyrie *et al.* (2014)[76]	NR [32.9 ± 23.3 months (range 1–77 months)]	2/177 (1.1%)	23/177 (13%)	0/177		1/177 [0.6% (iliac leg)]	10/177 [5.6% (iliac leg, *n* = 8; external iliac artery, *n* = 1; endograft, *n* = 1)]	2/177 (1.1%)				Endoleaks observed at completion angiography Renal artery occlusion: 2/177 (12-month follow-up) Migration: 0/177
Ghotbi *et al.* (2010)[77]	Intraoperative	3/100 (3%)	24/100 (24%)					0/100 (0%)				Migration: 1/100 (after 2 years)
	After 3 months	0/100	15/100 (15%)									
	After 12 months	0/100	7/100 (7%)									
Harrison *et al.* (2011)[41]	During 4 years' follow-up [median: 36 months (range 12–57 months)]	1/194 (0.5%)	4/194 (2.1%)			1/194 (0.5%)		1/194 (0.5%)	2/194 (1.0%)			Kinking: 1/194 (0.5) Indeterminant endoleaks: 3/194 (1.54)
Karthikesalingam *et al.* (2012)[78]	NR [median: 34 months (range 1–92 months)]								2/478 (0.4%)			Kinking: 36/478 (7.5)

continued

TABLE 34 Endovascular AAA repair-related clinical complications (*continued*)

Study, first author (year of publication)	Time point (follow-up if time point not reported)	Endoleak (specify subtypes, e.g. proximal, distal), *n/N*				Stenosis, *n/N*	Thrombosis, *n/N*	Aneurysm rupture, *n/N*	Limb occlusion, *n/N*	Infection, *n/N*	Ischaemia, *n/N*	Notes
		Type I	Type II	Type III	Type IV							
Köcher *et al.* (2004)[79]	Early complications	10/120 (8.3%); A: 7/120 (5.8%); B: 3/120 (2.5%)		1/120 (0.8%)								
	During follow-up [mean 20.7 months (range 2–60 months)]		9/120 (7.5%)			0/120	3/120 (2.5%)			0/120 (graft infection)		Migration: 0/120
Kray *et al.* (2015)[80]	1 month		17/191 (8.9%)									
	6 month		18/191 (9.4%)					0/191				
Meier *et al.* (2001)[81]	23.2 (range 2.0–78.8 months)											
Mazzaccaro *et al.* (2011)[90]	Long-term [median: 68 months (range 1–144 months)]	31/391 (7.9%)	3/391 (0.8%)				8/391 (2.0%)	5 (three fatal)/391 (1.3%)				
	At 30 days						3/488 (0.6%)					
Oshin *et al.* (2010)[82]	27 months								11/583 limbs (1.83%)			Stent–graft limb occlusions
Parlani *et al.* (2002)[83]	At 30 days	4/366 (1.1%)	22/36 (6.0%)	1/366 (0.3%)				1/366 (0.3%)				Data combined for two groups
Schunn *et al.* (2000)[84]	Intraoperatively or at the first postoperative imaging study	32/190 (16.8%)	32/190 (16.8%)									
	30 days								10/190 (5.3)			
Soler *et al.* (2015)[85]	NR (mean: 54.8 ± 35.9 months)	21/197 (10.6%)	29/197 (14.7%)	2/197 (1.0%)	1/197 (0.5%)			4/197 (2.0%)	Limb occlusion and stenosis: 29/197 (14.7%)	3/197 (1.5%)		Data combined for two groups

Study, first author (year of publication)	Time point (follow-up if time point not reported)	Endoleak (specify subtypes, e.g. proximal, distal), *n*/*N*				Stenosis, *n*/*N*	Thrombosis, *n*/*N*	Aneurysm rupture, *n*/*N*	Limb occlusion, *n*/*N*	Infection, *n*/*N*	Ischaemia, *n*/*N*	Notes
		Type I	Type II	Type III	Type IV							
Stella *et al.* (2009)[86]	NR (mean: 23.3 months)			0/100				0/100				
	Postoperative day 2	1/100 (1%)										
	3 months		26/100									
	4 months	1/100 (1%)										
	6 months	1/100 (1%)					4/200 (2%)					
Wolf *et al.* (2002)[87]	Late [mean: 15.8 ± 11.3 months (range 1–48 months)]	1/154 (0.6%)						1/154 (0.6%)				

ID, identification; NR, not reported.

a Iliac limb thrombosis.

Appendix 11 Reintervention and type of secondary procedures performed

TABLE 35 Reintervention and type of secondary procedures performed

Study, first author (year of publication)	Time point (follow-up if time point not reported)	Total reintervention, *n*/*N*		Type of reintervention (specify open, endovascular, revision, secondary/other)	Complication needing reintervention	Number of patients receiving reintervention		Health state (A, B or C)	
Comparative cohort studies									
Chisci *et al.* (2012)[66]	Protocol I Protocol II	Protocol I	Protocol II	Secondary interventions, number of interventions = 124 (Protocol I: *n* = 68; Protocol II: *n* = 56)[a]		Protocol I	Protocol II	Protocol I	Protocol II
	< 30 days (early secondary intervention)	2/68	1/56		Type I endoleak	2	1		
		0/68	1/56		Type III endoleak	0	1		
		3/68	2/56		Limb occlusion	3	2		
		2/68	0/56		Limb ischaemia	2	0		
		1/68	1/56		Stent–graft limb kink	1	1		
		1/68	0/56		Bowel ischaemia	1	0		
		8/68	5/56		Access site-related problems	8	5		
		1/68	0/56		Blue toe syndrome	1	0		
		0/68	1/56		Renal infarction	0	1		
	> 30 days (late secondary intervention)	5/68	4/56		Type I endoleak	5	4		
		21/68	17/56		Type II endoleak	21	17		
		1/68	1/56		Impending rupture, type II endoleak	1	1		
		3/68	2/56		Type III endoleak	3	2		
		2/68	4/56		Limb occlusion	2	4		
		3/68	2/56		Limb ischaemia	3	2		
		5/68	10/56		Stent–graft limb kink	5	10		
		2/68	1/56		Rupture	2	1		
		1/68	0/56		Bowel ischaemia	1	0		
		5/68	4/56		Access site-related problems	5	4		

Study, first author (year of publication)	Time point (follow-up if time point not reported)	Total reintervention, *n*/*N*	Type of reintervention (specify open, endovascular, revision, secondary/other)	Complication needing reintervention	Number of patients receiving reintervention	Health state (A, B or C)
Nyheim 2013[67]	> 30 days	14/56 (25%) patients	Secondary interventions	Endoleaks	7	
				Endotension	5	
				Migration	2	
Non-comparative cohort studies						
Bisdas *et al.* (2014)[68]	NR [median 42 months (IQR 31–50 months)]	26/273 (9.5%) patients	Explanation of the endograft and open repair (open)	Type Ia endoleak	1	A (1)
	NR		Proximal cuff (NR)	Type Ia endoleak	1	A (1)
	NR		Chimney endografting and use of Onyx (Endovascular Inc., Plymouth, MN, USA) (endovascular)	Type Ia endoleak	1	A (1)
	NR		Iliac side branch device (NR)	Type Ib endoleak and progression of aneurysmal disease distal	2	A (1)
	NR		Embolisation of the inferior mesentric artery (NR)	Type II endoleak	3	A (2)
	NR		Open repair (open)	Type II endoleak	1	A (2)
	10 months		Implantation of an additional endurant limb (endovascular)	Type III endoleak	1	A (1)
	NR		Iliac-to-renal bypass [no dialysis (NR)]	Renal artery occlusion	1	A (1)
	NR		Thrombectomy and stenting (NR)	Limb occlusion	6	A (1/2)
	NR		Crossover bypass (NR)	Limb occlusion	4	A (1/2)
	NR		Hemicolectomy (NR)	Bowel ischaemia	1	A (1)
	NR		Overstitch of the common femoral artery (NR)	False aneurysm	1	A (1)

continued

TABLE 35 Reintervention and type of secondary procedures performed (*continued*)

Study, first author (year of publication)	Time point (follow-up if time point not reported)	Total reintervention, *n*/*N*	Type of reintervention (specify open, endovascular, revision, secondary/other)	Complication needing reintervention	Number of patients receiving reintervention	Health state (A, B or C)
	NR		Thrombectomy, distal extension of the iliac limb with Advanta V12 stent–graft (Atrium Europe, Mijdrecht, the Netherlands) (NR)	Distal popliteal artery embolisation	1	A (1)
	NR		Vacuum-assisted closure device (NR)	Groin infection	1	Not a surveillance issue
	NR		Early reintervention (< 1 year) (NR)	NR	13	Inadequate information
	NR		Late secondary procedures [> 4 years (NR)]	NR	4[b]	Inadequate information
Blom *et al.* (2012)[69]	At mean follow-up [46 months (range, 1 month–10 years)]	12/496 limbs (2.4%) required intervention in 248 patients	NR	NR	NR	Inadequate information
Bush *et al.* (2001)[70]	2 months	3/104 (2.9%) patients	Late conversion (NR)	Graft infection	1	A (1/2)
	26 months		Late conversion (NR)	Hook fracture	2	A (1/2)
Carroccio *et al.* (2002)[71]	NR [mean: 20 ± 9 months (range 2–54 months)]	26/702 limbs (3.7%) in 351 patients	Thrombolysis and stent [endovascular (NR)]	Limb occlusion	2	A (1)
			Axillary femoral bypass (NR)		1	A (1/2)
			Femorofemoral bypass (NR)		13	A (1/2)
			Axillary bifemoral bypass (NR)		2	A (1/2)
			Observation (NR)		8	
[c]Chaer *et al.* (2009)[40]	NR [mean: 24 ± 13 months (range 12–48 months)]	2/184 (1.1%) patients	Limb extension (secondary intervention)	Type Ib endoleak	2	A (1/2)

Study, first author (year of publication)	Time point (follow-up if time point not reported)	Total reintervention, *n*/*N*	Type of reintervention (specify open, endovascular, revision, secondary/other)	Complication needing reintervention	Number of patients receiving reintervention	Health state (A, B or C)
Cochennec *et al.* (2007)[72]	NR (mean: 28 months; median: 23.4 months)	33/460 (7.2%) patients	Thrombectomy and stent (endovascular)	Limb occlusion	3	A (1/2)
	NR		Thrombolysis and stent (endovascular)	NR	6	A (1)
	NR		Femorofemoral bypass (NR)	NR	19	A (1/2)
	NR		Axillofemoral bypass (NR)	NR	3	A (1/2)
	NR		Conservative (NR)	NR	2	B
Collins *et al.* (2007)[73]	NR (follow-up NR)	33/359 (9.2%) procedures	NR	Type I endoleak	7	A1
	NR		NR	Type II endoleak	26	A2
Dominguez *et al.* (2010)[88] (abstract)	NR (follow-up NR)	273/1378 (19.8%) patients	Secondary intervention (NR)	NR	NR	Inadequate information
Donas *et al.* (2016)[74]	NR [24.6 ± SD 17.4 months (range 0–61 months)]	20/128 (15.6%) patients	Endovascular management (NR)	High-grade stenosis of renal chimney	6	Not a complication of standard EVAR
	2 months		Endovascular management (NR)	Chimney graft occlusion (majority of the occlusions were identified during the first 2 months)	4	Not a complication of standard EVAR
	45 days post operation		Ileorenal extra-anatomic bypass (NR)	NR	1	A1
	NR		Conservative treatment (NR)	NR	1	B
	NR		Surgical ligation of the aneurysm sac (NR)	Endotension	1	A2
	2.5 and 4 years		Transformation of single to multiple chimneys and tube placement (NR)	Type Ia endoleak	2	A1
	NR		Distal iliac limb extension (NR)	Type Ib endoleak	1	A1

continued

TABLE 35 Reintervention and type of secondary procedures performed (*continued*)

Study, first author (year of publication)	Time point (follow-up if time point not reported)	Total reintervention, *n*/*N*	Type of reintervention (specify open, endovascular, revision, secondary/other)	Complication needing reintervention	Number of patients receiving reintervention	Health state (A, B or C)
	NR		Surgical conversion (NR)	Type Ib endoleak and infection	1	A (1/2)
	27 months		Iliac limb placement (NR)	Type III endoleak	2	A1
	NR		Endovascular management (NR)	Inadvertent coverage of the superior mesentric artery	1	Not a surveillance issue
Fargion *et al.* (2016)[89] (abstract only)	NR [median: 30 months (range 1–168 months)]	47/289 (16.3%) procedures	Reintervention (type NR)	Type II endoleak with significant sac enlargement	38	A2
	Up to 3 months		NR	NR	17	Inadequate information
	> 3 months		NR	NR	21	Inadequate information
	NR		Reintervention, as type I developed after reintervention owing to type II endoleak (NR)	Type I endoleak	9	A1
	Up to 3 months		NR	NR	5	Inadequate information
	More than 3 months		NR	NR	4	Inadequate information
Fossaceca *et al.* (2013)[75]	NR (mean: 29.6 months)	24/222 (10.8%) patients	Fibrinolysis (NR)	Thrombosis	10	A (1)
			Iliac extension (NR)	Type Ib endoleak	2	A (1)
			Cuff (NR)	Type Ia and III endoleaks	3	A (1)
			Thrombin injections (NR)	Type II endoleak	8	A (2)
			Stent–graft removal (NR)	Infection	1	A (1/2)
	Up to 30 days	3/222 (1.4%) patients	Surgical conversion (NR)	NR	3	A (1/2)

Study, first author (year of publication)	Time point (follow-up if time point not reported)	Total reintervention, *n*/*N*	Type of reintervention (specify open, endovascular, revision, secondary/other)	Complication needing reintervention	Number of patients receiving reintervention	Health state (A, B or C)
Freyrie *et al.* (2010)[92]	6 months	3/127 (2.4%) patients	Iliac extension (NR)	Type Ib endoleak	1	A (1)
	9 months		Thrombolytic therapy and percutaneous angioplasty (NR)	Iliac limb thrombosis	1	A (1/2)
	9 months		Surgical conversion (NR)	Iliac limb thrombosis	1	A (1/2)
Freyrie *et al.* (2014)[76]	0, 0, 4, 4, 4, 4, 6, 23 and 31 months	20/177 (11.3%) procedures	Percutaneous balloon angioplasty iliac leg and stenting of external iliac artery or adjunctive urokinase (Urokinase medac, Medac Pharma GmbH, Wedel, Germany) and percutaneous balloon angioplasty stenting of external iliac artery (endovascular)	Iliac leg stenosis/ thrombosis	9	A (2)
	6 months		Renal artery chimney (endovascular)	Type Ia endoleak	1	A (1)
	9 months		Conversion (open repair)	Iliac leg thrombosis	1	A (1/2)
	32 and 36 months		Conversion (open repair)	Contained aortic rupture	2	A (1)
	33 months		Iliac leg surgical repair (open repair)	Type Ib endoleak	1	A (1)
	7, 35 and 45 months		Iliac leg extension (endovascular)	Type Ib endoleak	3	A (1)
	22 and 35 months		Inferior mesentric artery clipping (open repair)	Type II endoleak and AAA sac enlargement	2	A (2)
	0 months		Surgical drainage (open repair)	Retroperitoneal haematoma	1	A (1/2)

continued

TABLE 35 Reintervention and type of secondary procedures performed (*continued*)

Study, first author (year of publication)	Time point (follow-up if time point not reported)	Total reintervention, *n*/*N*	Type of reintervention (specify open, endovascular, revision, secondary/other)	Complication needing reintervention	Number of patients receiving reintervention	Health state (A, B or C)
Ghotbi *et al.* (2010)[77]	NR (mean: 20 months)	6/100 (6%) patients	Stentangioplasty of the iliac artery (NR)	Plication at the distal end of the endoprosthesis	3	A (2)
	NR		Thrombectomy and TEA of the inguinal artery (NR)	Occlusion of iliac artery	1	A (1/2)
	NR		Proximal banding (NR)	NR	1	A (1)
	NR		Proximal cuff implantation (NR)	Migration and type I endoleak	1	A (1)
Harrison *et al.* (2011)[41]	Up to first year of follow-up [median: 36 months (range 12–57 months)]	9/194 (4.6%)	Embolisation (NR)	Type II endoleak	1	A (2)
			Iliac angioplasty (NR)	Stenosis	1	A (2)
			Iliac stent (NR)	Kinked graft	2	A (2)
			Open revision (NR)	Graft migration	3	A (1)
			Bridging stent (NR)	Limb dislocation	1	A (1)
			Stent (NR)	Graft angulation	1	A (2)
Karthikesalingam *et al.* (2012)[78]	NR [median: 34 months (range 1–92 months)]	38/478 patients (7.9%)	NR	Limb outflow impairment	36	B
			NR	Limb occlusion	2	A (1/2)
Köcher *et al.* (2004)[79]	Early reinterventions [mean 20.7 months (range 2–60 months)]	11/120 (9.2%) patients	Additional stent–graft	Type Ia	2	A (1)
			Extra large Palmaz stent	Type Ia	1	A (1)
			Surgical conversion	Type Ia	1	A (1)
			Surgical banding neck	Type Ia	3	A (1/2)
			Spontaneous seal (NR)	Type Ib	1	C
			Additional stent–graft	Type Ib	1	A (1)
			Surgical conversion	Type Ib	1	A (1)
			Endovascular conversion	Type IIIa	1	A (1)
	During follow-up, NR	5/120 (4.2%) patients	Laparoscopic clipping (NR)	Type II endoleaks	2	A (2)
			Femorofemoral crossover bypass	Thrombosis	3	A (1/2)

Study, first author (year of publication)	Time point (follow-up if time point not reported)	Total reintervention, *n*/*N*	Type of reintervention (specify open, endovascular, revision, secondary/other)	Complication needing reintervention	Number of patients receiving reintervention	Health state (A, B or C)
Kray *et al.* (2015)[80]	Up to 6 months (maximum follow-up of 12 months)	0/191 (0%) patients	NR	NR	NR	Inadequate information
	> 6 months	13/191 (6.8%)	NR	NR	NR	Inadequate information
Mazzaccaro *et al.* (2011)[90]	Long-term [median: 68 months (range 1–144 months)]	45/391 (11.5%) patients	NR	NR	NR	Inadequate information
Oshin *et al.* (2010)[82]	27 months	11/583 limbs (1.8%)	Conservative management	Stent–graft limb occlusions	3	C
			Femorofemoral crossover graft		7	A
			Mechanical thrombectomy and secondary adjunctive stenting		1	A
Parlani *et al.* (2002)[83]	NR [mean: 14 months (IQR 7–27 months; range 1–46 months)]	19/336 (5.6%) patients	NR	NR	NR	Inadequate information
Schunn *et al.* (2000)[84]	Early (< 7 days)	14/190 (7.4%)	Conversion to conventional transabdominal repair	Malpositioned graft	4	
				Prosthetic defect	5	
				Endoleak	2	
				Occlusion and endoleak	1	
				Arterial disruption	2	
	Late [mean: 20.9 months (range 1.7–35.6 months)]	17/190 (8.9%)		Prosthetic defect	1	
				Endoleak11		
				Occlusion and endoleak	3	
				Distal secondary aneurysm	2	

continued

TABLE 35 Reintervention and type of secondary procedures performed (*continued*)

Study, first author (year of publication)	Time point (follow-up if time point not reported)	Total reintervention, *n*/*N*	Type of reintervention (specify open, endovascular, revision, secondary/other)	Complication needing reintervention	Number of patients receiving reintervention	Health state (A, B or C)
[d]Soler *et al.* (2015)[85]	During follow-up (mean: 31.9 months)	70 procedures 47/197 patients (23.8%)	NR	Type Ia endoleak	11	A (1)
	NR					
	NR		NR	Type Ib endoleak	7	A (1)
	NR		NR	Type II endoleak	24	A (2)
	NR		NR	Type III endoleak	1	A (1)
	NR		NR	Endotension	1	A (2)
	NR		NR	Stenosis and occlusions	21	A (1/2)
	NR		NR	Infection	2	A (1/2)
	NR[e]		NR	Rupture	3	A (1)
Stella *et al.* (2009)[86]	4 months	6/100 (6%) patients	Iliac extension (NR)	Type I endoleak	1	A (1)
	Up to 6 months		Thrombolytic therapy (unsuccessful) and surgical conversion (NR)	Iliac limb thrombosis	1	A (1/2)
			Thrombolytic therapy and percutaneous angioplasty iliac limbs (NR)	Iliac limb thrombosis	1	A (1)
	1 and 8 months		Thrombectomy (NR)	External iliac artery obstructions	2	A (1/2)
	NR [mean: 23.2 ± 11.0 months (range 1.4–38.6 months)]		Endograft extended to both external iliac arteries and surgical revascularisation of the right hypogastric artery (NR)	Spinal cord ischaemia	1	A (1)

Study, first author (year of publication)	Time point (follow-up if time point not reported)	Total reintervention, *n*/*N*	Type of reintervention (specify open, endovascular, revision, secondary/other)	Complication needing reintervention	Number of patients receiving reintervention	Health state (A, B or C)
Wolf *et al.* (2002)[87]	During follow-up period [mean: 15.8 ± 11.3 months (range 1–48 months)]	23/154 (15.0%) patients	NR	Presence of endoleak with expanding or non-shrinking aneurysm	21	A (2)
	NR		NR	Volume increased without a demonstrable endoleak	1	A (2)
	NR		NR	Migration occurred and proximal fixation appeared to be insecure	1	A (1)

ID, identification; NR, not reported; TEA, thromboendarterectomy.
a Numbers as reported in the report; do not add up.
b Numbers do not add up to 26.
c During CDU-only surveillance.
d Data combined for both groups [Soler *et al.* (2015),[85] group 1: aneurysm was reduced by ≥10 mm; group 2: aneurysm did not reduce. Parlani *et al.* (2002),[83] group 1: without concomitant iliac aneurysm; group 2: with concomitant iliac aneurysm].
e Numbers do not add up to 70.

Appendix 12 Results on aneurysm shrinkage, enlargement and stability, as reported in cohort studies

TABLE 36 Results on aneurysm shrinkage, enlargement and stability as reported in cohort studies

Study, first author (year of publication)	Total number of patients	Mean/median follow-up ± SD (range, unless specified otherwise)	Aneurysm diameter/sac size (mm)		Change	Other indicators
			At baseline	At last follow-up		
Comparative cohort studies						
Nyheim *et al.* (2013)[67]	56	Median: 41.5 months (2–94 months)	57 (range 30–87)	NR	NR	Identified increased diameter (≥ 5 mm) without evidence of an endoleak: 6/56
Non-comparative cohort studies						
Bisdas *et al.* (2014)[68]	273	Median: 42 months (IQR 30.7–50.7 months)	NR	NR	AAA shrinkage Median: 9 mm (IQR 3–15 mm)	Aneurysm shrinkage of > 5 mm: 158/273 (57.8%)
Chaer *et al.* (2009)[40] (CTA-US)	184	Mean: 24 ± 13 months (1–4 years)	Mean: 54 ± 8	Mean: 39 ± 11	Mean AAA diameter decreased by 15 mm	NR
Donas *et al.* (2016)[74]	128	Mean: 24.6 ± 17.4 months (0–61 months)	Mean: 64.8 ± 14.6 (range 48–135)	Mean: 60.1 ± 16.3[a]	NR	Aneurysm shrinkage: 87/128 (68%) Stable aneurysm: 29/128 (23%) Aneurysm enlargement: 12/128 (9%)
Freyrie *et al.* (2014)[76] Ultrasound and CTA-ultrasound	177	Mean: 32.9 ± 23.3 months (1–77 months)	Mean: 55 ± 9.7 (range 45–99)	NR	AAA shrinkage Mean: 10 ± 8.7 (range –10 to 44)	Aneurysm shrinkage: 130/177 (73.4%) Stable aneurysm: 40/177 (22.6%) Aneurysm enlargement of > 5 mm: 7/177 (4%)
Harrison *et al.* (2011)[41] Ultrasound and CTA-ultrasound	194	Median: 36 months (12–57 months)	NR	NR	NR	Aneurysm expansion: 2/194 (≈1%)

Study, first author (year of publication)	Total number of patients	Mean/median follow-up ± SD (range, unless specified otherwise)	Aneurysm diameter/sac size (mm)			
			At baseline	At last follow-up	Change	Other indicators
Köcher *et al.* (2004)[79]	120	Mean: 20.7 months (2–60 months)	NR	NR	NR	Follow-up of > 12 months: • Shrinkage 44/75 (58.6%) • Enlargement 7/75 (9.3%) • No change 24/75 (32%) Follow-up of > 24 months: • Shrinkage 31/46 (67.4%)
Meier *et al.* (2001)[81]	476	Mean: 23.2 months (2–78.8 months)	Major axis diameter: • Mean – 57.5 ± 9.9 (range 34.8–92.7) Minor axis diameter: • Mean – 51.6 ± 9.2 (range 30.9–86.4)	NR	AAA shrinkage: Mean: –7.3 ± 9.2 (range –50.6 to 32.6)	Rate of overall aneurysm contraction: (–3.75 mm/year)
Parlani *et al.* (2002)[83]	366	Mean: 14 months (IQR 7–27; range 1–46 months)	Group A: 50 (IQR 45 ± 55; range 40 ± 86); group B: 52 (IQR 48 ± 56; range 40 ± 74) p = NS	NR	AAA diameter • Group A: –4.3 mm • Group B: 4.5 mm (p = NS)	Decrease of diameter of > 2 mm: 182/366 (56%) Unchanged diameter: 127/366 (39%) Increase of > 2 mm: 21/366 (6%) Of the 77 iliac aneurysms treated without immediate death and/or conversion: • Decrease of diameter of > 2 mm: 46/77 (60%) • Unchanged diameter: 28 (36%) • Increase of > 2 mm: 3 (4%)

continued

TABLE 36 Results on aneurysm shrinkage, enlargement and stability as reported in cohort studies (*continued*)

Study, first author (year of publication)	Total number of patients	Mean/median follow-up ± SD (range, unless specified otherwise)	Aneurysm diameter/sac size (mm)		Change	Other indicators
			At baseline	At last follow-up		
Soler *et al.* (2015)[85]	197	Mean: 54.8 ± 35.9 months	Group A: 55.8 mm Group B: 57.7 mm Population: 56.7 mm	NR	NR	Reduction of ≥ 10 mm of the maximum aneurysmal diameter after EVAR in 51.8% of the patients
Stella *et al.* (2009)[86]	100	Mean: 23.2 ± 11.0 months (1.4–38.6 months)	Mean: 55.2 ± 3.4 (range 45–99)	NR	NR	Diameter of AAA was unchanged: 98/100 (98%) Increase in aneurysmal sack of 6 mm: 2/100 (2%)
Wolf *et al.* (2002)[87]	154	Mean: 15.8 ± 11.3 months (1–48 months)	57.9 ± 9.4[b]	58.3 ± 8.9	Overall change in transverse diameter after endovascular repair: –0.29 mm/month ± 0.73 Absolute changes in transverse diameter during mean follow-up of 7 ± 3 months (range 3–24 months) after endovascular repair No endoleak: –2.7 mm ± 4.5 Endoleak present: 1.0 mm ± 3.9	

ID, identification; NR, not reported; NS, non significant.
a Change is during follow-up, not at last follow-up.
b Orthogonal diameter.

Appendix 13 Mortality rates reported in the included cohort studies

TABLE 37 Mortality rates reported in the included cohort studies

Study, first author (year of publication)	Time point (follow-up if time point not specified)	Mortality, *n/N* (%)		Survival		Notes
		All-cause	AAA-related	Overall rate	Disease-free rate, *n/N* (%)	
Comparative cohort studies						
Chisci *et al.* (2012)[66]	Protocol I					
	30 days	8/376 (2.1)				
	3 years	64/376 (17)	19/376 (5.1)		357/376 (94.9)	
	Protocol II					
	30 days	6/341 (1.8)				
	3 years	55/341 (16.1)	15/341 (4.4)		326/341 (95.6)	
Nyheim *et al.* (2012)[67]	> 30 days	9/56 (16)				All died of other causes
Non-comparative cohort studies						
Bisdas *et al.* (2014)[68]	Median: 42 months (IQR 31–50 months)	78/273 (28.6)	1/273 (0.4)			All-cause mortality (including AAA-related mortality): cardiac ($n = 29$), carcinoma ($n = 13$), pulmonary ($n = 14$), sepsis ($n = 6$), stroke ($n = 4$), suicide ($n = 1$), unknown ($n = 10$) AAA related: technical failure to advance the endograft. The patient was denied open repair because of severe heart insufficiency and the aneurysm ruptured 2 weeks later
	3 years post operation			77%		
	4 years post operation			73%		
	5 years post operation			67%		
Bush *et al.* (2001)[70]	High-risk group: mean 14.6 months (± 12.4 months)	12/104 (11.5)	0/104 (0)	NR	NR	All-cause mortality: conversion from endovascular to open repair ($n = 1$), aborted procedure and severe coronary artery disease ($n = 1$), successful endovascular repair without evidence of postoperative endoleak ($n = 1$), severe heart failure ($n = 1$). None of the reported late deaths were related to the initial endovascular procedure, device failure or late aneurysm rupture
	Low-risk group: mean 17.7 months (± 15.0 months)					
	Up to 30 days post operation	5/104 (4.8)				
Chaer *et al.* (2009)[40]	Mean: 24 months (± 13 months, range 1–4 years)	5/184 (2.7)	1/184 (0.5)			All-cause mortality (including AAA-related mortality): deaths from lung cancer ($n = 2$), acute coronary event with post-infarction heart failure and a prolonged stay in the coronary care unit ($n = 2$); AAA related: ($n = 1$)

Study, first author (year of publication)	Time point (follow-up if time point not specified)	Mortality, *n/N* (%)		Survival		Notes
		All-cause	AAA-related	Overall rate	Disease-free rate, *n/N* (%)	
Cochennec *et al.* (2007)[72]	Mean: 28 months; median: 23.4 months	18/460 (3.9)		NR	NR	
Collins *et al.* (2007)[73]	NR (study duration 5 years)	7/160 (4.4)		NR	NR	
[a]Dominguez *et al.* (2010)[88]	Up to 30 day post operation	22/1378 (1.6)		NR	NR	
Donas *et al.* (2016)[74]	Up to 30 day post operation	1/128 (0.8)		NR	NR	Cause of death: cardiac decompensation
	Mean: 24.6 months, ± SD 17.4 months (range 0–61 months)	22/128 (17.2)		NR	NR	All-cause mortality: cardiac insufficiency and tumour as major causes
Fossaceca *et al.* (2013)[75]	Up to 30 days post operation	17/222 (7.7)		NR	NR	All-cause mortality: heart failure, respiratory failure and aspiration pneumonia[b]
	During follow-up (mean: 29.6 months)	14/205 (6.8)	0/205 (%)	NR	NR	Unrelated to aneurysm
Freyrie *et al.* (2014)[76]	Up to 30 days post operation	2/177 (1.1)		NR	NR	
	3 years			86.2%		
Ghotbi *et al.* (2010)[77]	> 30 days post operation	0/100 (0)				
Harrison *et al.* (2011)[41]	1 year post operation	25/194 (12.9)	1/194 (0.5)			All-cause mortality (includes AAA-related mortality): ischaemic heart disease ($n = 6$), malignancy ($n = 10$), gastrointestinal disease ($n = 2$), respiratory illness ($n = 3$), cerebrovascular accident ($n = 2$), renal failure ($n = 1$) AAA-related mortality: ($n = 1$)
Köcher *et al.* (2004)[79]	Perioperative	4/120 (3.3)				
	During follow-up [mean: 20.7 months (range 2–60 months)]	13/120 (10.8)				All-cause mortality: cardiac, pulmonary or malignancy[c]
Kray *et al.* (2015)[80]	Up to 12 months' follow-up	0/191[d] (0)				

continued

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TABLE 37 Mortality rates reported in the included cohort studies (*continued*)

Study, first author (year of publication)	Time point (follow-up if time point not specified)	Mortality, *n/N* (%)		Survival		Notes
		All-cause	AAA-related	Overall rate	Disease-free rate, *n/N* (%)	
Mazzaccaro *et al.* (2011)[90]	Up to 30 days post operation	6/488 (1.2)				
	> 30 days post operation	77/391 (19.7)				
	144 months			32.80 (± 4.4)		
Parlani *et al.* (2002)[83]	Perioperative	4/336 (1.2)	1/336 (0.4)			All-cause mortality (including AAA-related mortality): congestive heart failure in a patient with severe respiratory and cardiac disease ($n = 1$), pulmonary oedema ($n = 1$), massive haemorrhage from intraprocedural aortic rupture requiring immediate conversion to open repair ($n = 1$), and sepsis in a patient affected by chronic leukaemia and tender AAA ($n = 1$)
	Late mortality	21/336 (6.3)				Not related to the endovascular procedure
Schunn *et al.* (2000)[84]	Up to 30 days post operation	1/190 (0.5)				Succumbed to retroperitoneal haemorrhage attributable to an unrecognised iliac artery puncture
Soler *et al.* (2015)[85]	Mean 54.8 months (± 35.9 months)	83/197 (42)				Group 1 (diameter reduction of ≥ 10 mm during follow-up): 34/102
	5 years post operation			Group 1: 71% Group 2: 58.7% $p < 0.0001$		Group 2 (diameters were increased, stable, or reduced by < 10 mm during follow-up): 49/95 ($p = 0.0144$)
Stella *et al.* (2009)[86]	Mean: 23.3 months	6/100 (6)				Data given for 1–24 months; rates given for clinical success
	24 months follow-up			87.90%		
Wolf *et al.* (2002)[87]	< 30 days post operation	2/154 (1.3)				Both died of myocardial infarction
	> 30 days	25/154 (16.2)	0/154 (0)			None of the deaths were aneurysm related; post-mortem examinations were performed in six cases

ID, identification; NR, not reported.
a Data combined for both groups.
b Number of deaths for each cause not reported.
c Number of deaths for each cause not reported.
d In-hospital deaths.

Appendix 14 State-transition diagram for the surveillance after endovascular abdominal aortic aneurysm repair Markov model

The whole cohort starts at the 'Normal (no residual EVAR complications)' Markov state. The arrows in the model show possible transitions from each state. Arrows from and to the same Markov state have not been drawn for simplicity. Individuals can remain in any of the Markov states for more than one cycle. The exception to this is the 'TP – surgery (elective)' state, as this is a one-cycle tunnel state. Arrows to the 'Death' Markov states have also been omitted for simplicity. Age-adjusted general population mortality has been accounted for, and individuals can move from any Markov state to the 'Death (general population mortality)' state. In addition, individuals with EVAR-related abnormalities can die as a result of EVAR-related complications, moving to the 'Death (EVAR related)' Markov state.

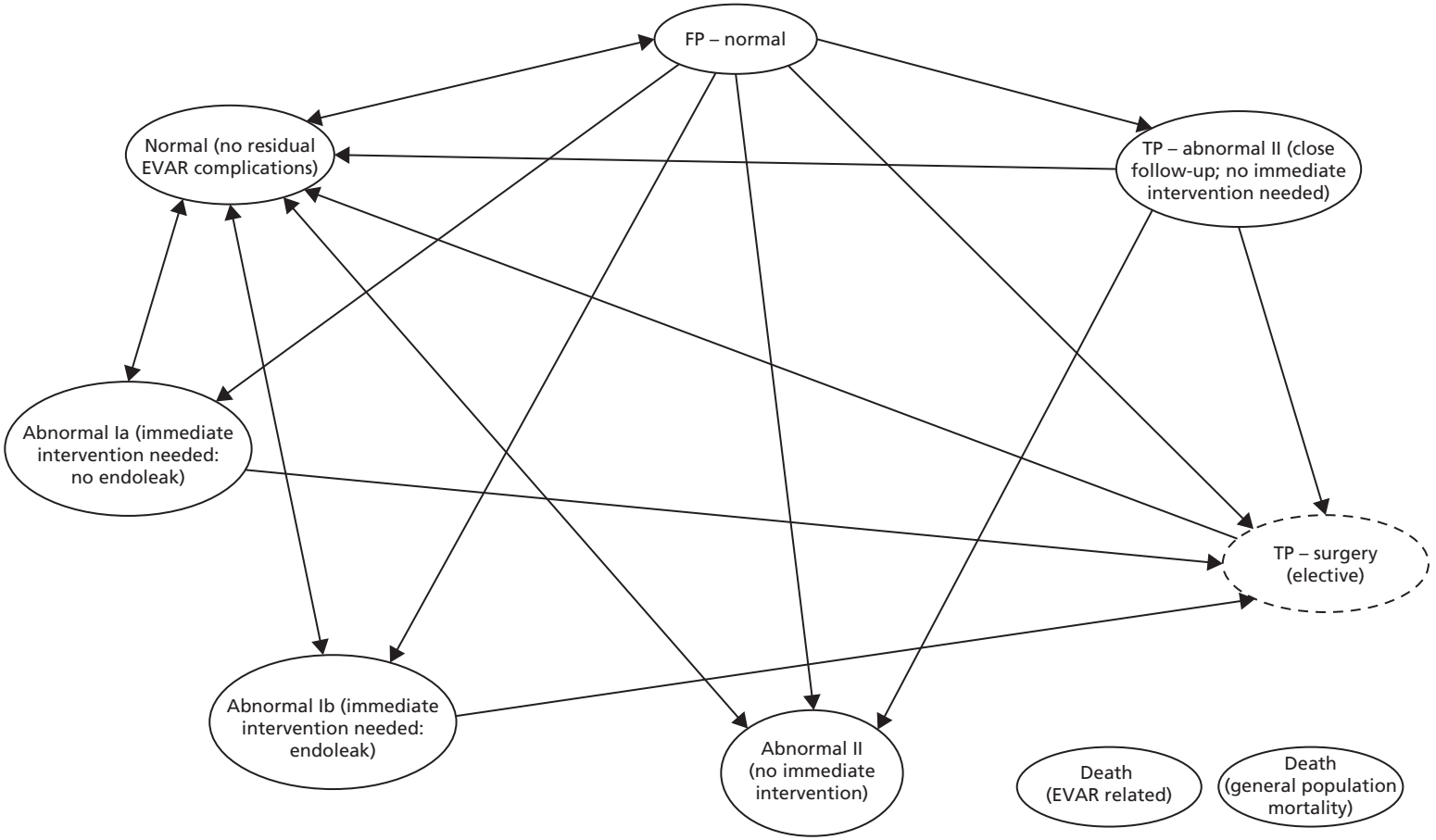

FIGURE 13 State-transition diagram for the surveillance after EVAR Markov model. FP, false positive; TP, true positive.

Appendix 15 Economic evaluation sensitivity analyses results

TABLE 38 One-way sensitivity analysis: cost of a further assessment visit

Value (£)	Strategy	Cost (£)	Incremental costs (£)	QALYs	Incremental QALYs	ICER (£)
50	CDU	3484		6.5532		
	CTA	3680	197	6.5517	–0.0015	Dominated
	CEU	4333	849	6.5594	0.0062	136,513
	CDU and CTA, then CDU	4448	115	6.5543	–0.0051	Dominated
	CEU and CTA, then CEU	5290	957	6.5598	0.0003	2,981,660
100	CDU	3654		6.5532		
	CTA	3762	108	6.5517	–0.0015	Dominated
	CEU	4542	888	6.5594	0.0062	142,673
	CDU and CTA, then CDU	4605	64	6.5543	–0.0051	Dominated
	CEU and CTA, then CEU	5486	945	6.5598	0.0003	2,943,149
150	CDU	3824		6.5532		
	CTA	3844	20	6.5517	–0.0015	Dominated
	CEU	4750	926	6.5594	0.0062	148,832
	CDU and CTA, then CDU	4762	12	6.5543	–0.0051	Dominated
	CEU and CTA, then CEU	5682	932	6.5598	0.0003	2,904,637
200	CTA	3925		6.5517		
	CDU	3994	69	6.5532	0.0015	45,791
	CDU and CTA, then CDU	4920	925	6.5543	0.0011	827,921
	CEU	4959	39	6.5594	0.0051	7666
	CEU and CTA, then CEU	5878	920	6.5598	0.0003	2,866,125
250	CTA	4007		6.5517		
	CDU	4165	157	6.5532	0.0015	104,639
	CDU and CTA, then CDU	5077	912	6.5543	0.0011	816,205
	CEU	5167	91	6.5594	0.0051	17,739
	CEU and CTA, then CEU	6075	907	6.5598	0.0003	2,827,613

TABLE 39 One-way sensitivity analysis: cost of a CTA test

Value (£)	Strategy	Cost (£)	Incremental costs (£)	QALYs	Incremental QALYs	ICER (£)
80	CTA	3438		6.5517		
	CDU	3660	221	6.5532	0.0015	147,221
	CEU	4549	264	6.5594	0.0051	51,682
	CDU and CTA, then CDU	4285	625	6.5543	0.0011	559,439
	CEU and CTA, then CEU	5169	620	6.5598	0.0003	1,932,376
90	CTA	3539		6.5517		
	CDU	3694	154	6.5532	0.0015	102,632
	CEU	4590	190	6.5594	0.0051	37,132
	CDU and CTA, then CDU	4401	707	6.5543	0.0011	632,756
	CEU and CTA, then CEU	5292	702	6.5598	0.0003	2,186,672
100	CTA	3640		6.5517		
	CDU	3728	87	6.5532	0.0015	58,044
	CEU	4632	115	6.5594	0.0051	22,582
	CDU and CTA, then CDU	4517	789	6.5543	0.0011	706,074
	CEU and CTA, then CEU	5415	783	6.5598	0.0003	2,440,968
110	CTA	3741		6.5517		
	CDU	3762	20	6.5532	0.0015	13,455
	CEU	4674	41	6.5594	0.0051	8032
	CDU and CTA, then CDU	4633	871	6.5543	0.0011	779,392
	CEU and CTA, then CEU	5539	865	6.5598	0.0003	2,695,263
120	CDU	3796		6.5532		
	CTA	3843	47	6.5517	–0.0015	Dominated
	CEU	4715	920	6.5594	0.0062	147,807
	CDU and CTA, then CDU	4749	33	6.5543	–0.0051	Dominated
	CEU and CTA, then CEU	5662	947	6.5598	0.0003	2,949,559
130	CDU	3830		6.5532		
	CTA	3944	114	6.5517	–0.0015	Dominated
	CEU	4757	927	6.5594	0.0062	149,039
	CDU and CTA, then CDU	4865	108	6.5543	–0.0051	Dominated
	CEU and CTA, then CEU	5785	1028	6.5598	0.0003	3,203,854
140	CDU	3864		6.5532		
	CTA	4045	181	6.5517	–0.0015	Dominated
	CEU	4799	935	6.5594	0.0062	150,271
	CDU and CTA, then CDU	4981	182	6.5543	–0.0051	Dominated
	CEU and CTA, then CEU	5909	1110	6.5598	0.0003	3,458,150
150	CDU	3898		6.5532		
	CTA	4146	248	6.5517	–0.0015	Dominated
	CEU	4841	943	6.5594	0.0062	151,503
	CDU and CTA, then CDU	5097	256	6.5543	–0.0051	Dominated
	CEU and CTA, then CEU	6032	1191	6.5598	0.0003	3,712,445

TABLE 40 One-way sensitivity analysis: cost of an EVAR procedure

Value (£)	Strategy	Cost (£)	Incremental costs (£)	QALYs	Incremental QALYs	ICER (£)
6000	CDU	3163		6.5532		
	CTA	3217	54	6.5517	–0.0015	Dominated
	CEU	3997	834	6.5594	0.0062	134,071
	CDU and CTA, then CDU	4097	100	6.5543	–0.0051	Dominated
	CEU and CTA, then CEU	4930	932	6.5598	0.0003	2,905,650
8000	CDU	3375		6.5532		
	CTA	3423	48	6.5517	–0.0015	Dominated
	CEU	4238	863	6.5594	0.0062	138,646
	CDU and CTA, then CDU	4311	74	6.5543	–0.0051	Dominated
	CEU and CTA, then CEU	5171	933	6.5598	0.0003	2,907,853
10,000	CDU	3587		6.5532		
	CTA	3629	43	6.5517	–0.0015	Dominated
	CEU	4478	891	6.5594	0.0062	143,222
	CDU and CTA, then CDU	4526	48	6.5543	–0.0051	Dominated
	CEU and CTA, then CEU	5412	934	6.5598	0.0003	2,910,056
12,000	CDU	3799		6.5532		
	CTA	3835	37	6.5517	–0.0015	Dominated
	CEU	4718	920	6.5594	0.0062	147,798
	CDU and CTA, then CDU	4740	21	6.5543	–0.0051	Dominated
	CEU and CTA, then CEU	5653	935	6.5598	0.0003	2,912,260
14,000	CDU	4011		6.5532		
	CTA	4041	31	6.5517	–0.0015	Dominated
	CEU	4959	5	6.5594	0.0051	960
	CDU and CTA, then CDU	4954	943	6.5543	0.0011	843,974
	CEU and CTA, then CEU	5894	935	6.5598	0.0003	2,914,463
16,000	CDU	4222		6.5532		
	CTA	4247	25	6.5517	–0.0015	Dominated
	CEU	5199	31	6.5594	0.0051	6106
	CDU and CTA, then CDU	5168	945	6.5543	0.0011	845,943
	CEU and CTA, then CEU	6135	936	6.5598	0.0003	2,916,666

TABLE 41 One-way sensitivity analysis: cost of other surgical procedures

Value (£)	Strategy	Cost (£)	Incremental costs (£)	QALYs	Incremental QALYs	ICER (£)
2000	CDU	2950		6.5532		
	CTA	2988	38	6.5517	–0.0015	Dominated
	CEU	3864	914	6.5594	0.0062	146,834
	CDU and CTA, then CDU	3891	27	6.5543	–0.0051	Dominated
	CEU and CTA, then CEU	4798	934	6.5598	0.0003	2,911,629
6000	CDU	3264		6.5532		
	CTA	3302	38	6.5517	–0.0015	Dominated
	CEU	4180	915	6.5594	0.0062	147,130
	CDU and CTA, then CDU	4205	25	6.5543	–0.0051	Dominated
	CEU and CTA, then CEU	5114	934	6.5598	0.0003	2,911,834
10,000	CDU	3578		6.5532		
	CTA	3615	37	6.5517	–0.0015	Dominated
	CEU	4495	917	6.5594	0.0062	147,426
	CDU and CTA, then CDU	4519	23	6.5543	–0.0051	Dominated
	CEU and CTA, then CEU	5430	935	6.5598	0.0003	2,912,039
14,000	CDU	3892		6.5532		
	CTA	3929	37	6.5517	–0.0015	Dominated
	CEU	4811	919	6.5594	0.0062	147,722
	CDU and CTA, then CDU	4833	22	6.5543	–0.0051	Dominated
	CEU and CTA, then CEU	5746	935	6.5598	0.0003	2,912,243
18,000	CDU	4206		6.5532		
	CTA	4243	36	6.5517	–0.0015	Dominated
	CEU	5127	921	6.5594	0.0062	148,018
	CDU and CTA, then CDU	5147	20	6.5543	–0.0051	Dominated
	CEU and CTA, then CEU	6062	935	6.5598	0.0003	2,912,448

TABLE 42 One-way sensitivity analysis: utility weight for the normal health state

Value (%)	Strategy	Cost (£)	Incremental costs (£)	QALYs	Incremental QALYs	ICER (£)
0.5	CDU	3791		4.4668		
	CTA	3828	37	4.4657	–0.0011	Dominated
	CEU	4709	919	4.4712	0.0044	208,846
	CDU and CTA, then CDU	4732	22	4.4676	–0.0036	Dominated
	CEU and CTA, then CEU	5644	935	4.4714	0.0002	4,212,790
0.6	CDU	3791		5.3602		
	CTA	3828	37	5.3589	–0.0013	Dominated
	CEU	4709	919	5.3654	0.0053	174,038
	CDU and CTA, then CDU	4732	22	5.3611	–0.0043	Dominated
	CEU and CTA, then CEU	5644	935	5.3657	0.0003	3,510,658
0.7	CDU	3791		6.2535		
	CTA	3828	37	6.2520	–0.0015	Dominated
	CEU	4709	919	6.2597	0.0062	149,176
	CDU and CTA, then CDU	4732	22	6.2546	–0.0051	Dominated
	CEU and CTA, then CEU	5644	935	6.2600	0.0003	3,009,136
0.8	CDU	3791		7.1469		
	CTA	3828	37	7.1452	–0.0017	Dominated
	CEU	4709	919	7.1539	0.0070	130,529
	CDU and CTA, then CDU	4732	22	7.1481	–0.0058	Dominated
	CEU and CTA, then CEU	5644	935	7.1543	0.0004	2,632,994
0.9	CDU	3791		8.0402		
	CTA	3828	37	8.0383	–0.0019	Dominated
	CEU	4709	919	8.0482	0.0079	116,026
	CDU and CTA, then CDU	4732	22	8.0416	–0.0065	Dominated
	CEU and CTA, then CEU	5644	935	8.0486	0.0004	2,340,439

TABLE 43 One-way sensitivity analysis: utility weight reduction for EVAR surgery

Value (%)	Strategy	Cost (£)	Incremental costs (£)	QALYs	Incremental QALYs	ICER (£)
0.0	CDU	3791		6.5541		
	CTA	3828	37	6.5526	–0.0015	Dominated
	CEU	4709	919	6.5604	0.0063	145,617
	CDU and CTA, then CDU	4732	22	6.5552	–0.0052	Dominated
	CEU and CTA, then CEU	5644	935	6.5607	0.0003	2,893,195
0.5	CDU	3791		6.5539		
	CTA	3828	37	6.5524	–0.0015	Dominated
	CEU	4709	919	6.5602	0.0063	146,064
	CDU and CTA, then CDU	4732	22	6.5550	–0.0052	Dominated
	CEU and CTA, then CEU	5644	935	6.5605	0.0003	2,897,445
1.0	CDU	3791		6.5537		
	CTA	3828	37	6.5522	–0.0015	Dominated
	CEU	4709	919	6.5600	0.0063	146,514
	CDU and CTA, then CDU	4732	22	6.5548	–0.0051	Dominated
	CEU and CTA, then CEU	5644	935	6.5603	0.0003	2,901,707
2.0	CDU	3791		6.5533		
	CTA	3828	37	6.5518	–0.0015	Dominated
	CEU	4709	919	6.5595	0.0062	147,423
	CDU and CTA, then CDU	4732	22	6.5544	–0.0051	Dominated
	CEU and CTA, then CEU	5644	935	6.5599	0.0003	2,910,269
4.0	CDU	3791		6.5525		
	CTA	3828	37	6.5510	–0.0015	Dominated
	CEU	4709	919	6.5587	0.0062	149,274
	CDU and CTA, then CDU	4732	22	6.5536	–0.0050	Dominated
	CEU and CTA, then CEU	5644	935	6.5590	0.0003	2,927,545

TABLE 44 One-way sensitivity analysis: utility weight decrement from other surgical procedures

Value (%)	Strategy	Cost (£)	Incremental costs (£)	QALYs	Incremental QALYs	ICER (£)
0	CDU	3791		6.5539		
	CTA	3828	37	6.5524	–0.0015	Dominated
	CEU	4709	919	6.5601	0.0062	147,541
	CDU and CTA, then CDU	4732	22	6.5550	–0.0051	Dominated
	CEU and CTA, then CEU	5644	935	6.5604	0.0003	2,910,951
1	CDU	3791		6.5536		
	CTA	3828	37	6.5521	–0.0015	Dominated
	CEU	4709	919	6.5598	0.0062	147,579
	CDU and CTA, then CDU	4732	22	6.5547	–0.0051	Dominated
	CEU and CTA, then CEU	5644	935	6.5601	0.0003	2,911,503
2	CDU	3791		6.5533		
	CTA	3828	37	6.5518	–0.0015	Dominated
	CEU	4709	919	6.5595	0.0062	147,618
	CDU and CTA, then CDU	4732	22	6.5544	–0.0051	Dominated
	CEU and CTA, then CEU	5644	935	6.5598	0.0003	2,912,055
3	CDU	3791		6.5530		
	CTA	3828	37	6.5515	–0.0015	Dominated
	CEU	4709	919	6.5592	0.0062	147,656
	CDU and CTA, then CDU	4732	22	6.5541	–0.0051	Dominated
	CEU and CTA, then CEU	5644	935	6.5595	0.0003	2,912,607
4	CDU	3791		6.5527		
	CTA	3828	37	6.5512	–0.0015	Dominated
	CEU	4709	919	6.5589	0.0062	147,695
	CDU and CTA, then CDU	4732	22	6.5538	–0.0051	Dominated
	CEU and CTA, then CEU	5644	935	6.5592	0.0003	2,913,159

TABLE 45 One-way sensitivity analysis: mortality risk from an emergency event (e.g. rupture)

Value (%)	Strategy	Cost (£)	Incremental costs (£)	QALYs	Incremental QALYs	ICER (£)
20	CDU	3781		6.5515		
	CTA	3817	36	6.5499	–0.0016	Dominated
	CEU	4702	921	6.5582	0.0067	137,783
	CDU and CTA, then CDU	4722	20	6.5527	–0.0055	Dominated
	CEU and CTA, then CEU	5637	935	6.5585	0.0003	2,718,603
40	CDU	3733		6.5430		
	CTA	3766	33	6.5409	–0.0022	Dominated
	CEU	4668	935	6.5520	0.0090	103,821
	CDU and CTA, then CDU	4675	7	6.5446	–0.0074	Dominated
	CEU and CTA, then CEU	5602	934	6.5525	0.0005	2,040,700
60	CDU	3685		6.5345		
	CTA	3715	30	6.5318	–0.0027	Dominated
	CEU	4633	6	6.5458	0.0093	603
	CDU and CTA, then CDU	4628	942	6.5365	0.0020	477,727
	CEU and CTA, then CEU	5567	934	6.5464	0.0006	1,633,664
80	CDU	3637		6.5260		
	CTA	3664	26	6.5228	–0.0032	Dominated
	CEU	4599	18	6.5396	0.0113	1624
	CDU and CTA, then CDU	4580	943	6.5284	0.0024	399,585
	CEU and CTA, then CEU	5532	934	6.5403	0.0007	1,362,184
100	CDU	3590		6.5176		
	CTA	3613	23	6.5138	–0.0038	Dominated
	CEU	4564	31	6.5335	0.0132	2346
	CDU and CTA, then CDU	4533	944	6.5203	0.0027	343,576
	CEU and CTA, then CEU	5497	933	6.5343	0.0008	1,168,209

TABLE 46 One-way sensitivity analysis: mortality risk from an emergency procedure

Value (%)	Strategy	Cost (£)	Incremental costs (£)	QALYs	Incremental QALYs	ICER (£)
10	CDU	3856		6.5648		
	CTA	3898	42	6.5640	–0.0008	Dominated
	CEU	4756	900	6.5679	0.0031	293,910
	CDU and CTA, then CDU	4796	40	6.5654	–0.0025	Dominated
	CEU and CTA, then CEU	5691	935	6.5680	0.0002	5,644,541
20	CDU	3826		6.5595		
	CTA	3866	39	6.5584	–0.0011	Dominated
	CEU	4735	909	6.5640	0.0045	201,888
	CDU and CTA, then CDU	4767	32	6.5604	–0.0037	Dominated
	CEU and CTA, then CEU	5670	935	6.5643	0.0002	3,956,617
30	CDU	3797		6.5543		
	CTA	3834	37	6.5528	–0.0014	Dominated
	CEU	4714	917	6.5602	0.0059	154,478
	CDU and CTA, then CDU	4737	24	6.5553	–0.0049	Dominated
	CEU and CTA, then CEU	5648	935	6.5605	0.0003	3,046,161
40	CDU	3767		6.5490		
	CTA	3802	35	6.5472	–0.0018	Dominated
	CEU	4692	925	6.5564	0.0074	125,567
	CDU and CTA, then CDU	4708	16	6.5503	–0.0061	Dominated
	CEU and CTA, then CEU	5627	934	6.5568	0.0004	2,476,565
50	CDU	3737		6.5438		
	CTA	3771	33	6.5416	–0.0021	Dominated
	CEU	4671	933	6.5526	0.0088	106,096
	CDU and CTA, then CDU	4679	8	6.5453	–0.0072	Dominated
	CEU and CTA, then CEU	5605	934	6.5530	0.0004	2,086,592

TABLE 47 One-way sensitivity analysis: adherence to surveillance

Value (%)	Strategy	Cost (£)	Incremental costs (£)	QALYs	Incremental QALYs	ICER (£)
40	CDU	2554		6.5240		
	CTA	2568	14	6.5224	–0.0016	Dominated
	CEU	2976	11	6.5319	0.0070	1587
	CDU and CTA, then CDU	2965	410	6.5249	0.0009	449,694
	CEU and CTA, then CEU	3385	409	6.5323	0.0003	1,263,460
50	CDU	2817		6.5316		
	CTA	2835	18	6.5299	–0.0017	Dominated
	CEU	3337	9	6.5399	0.0073	1205
	CDU and CTA, then CDU	3329	512	6.5326	0.0010	503,094
	CEU and CTA, then CEU	3847	510	6.5402	0.0003	1,458,998
60	CDU	3061		6.5381		
	CTA	3083	22	6.5363	–0.0017	Dominated
	CEU	3678	4	6.5463	0.0072	617
	CDU and CTA, then CDU	3674	613	6.5392	0.0011	564,002
	CEU and CTA, then CEU	4288	610	6.5467	0.0004	1,692,335
70	CDU	3293		6.5436		
	CTA	3319	26	6.5419	–0.0017	Dominated
	CEU	4004	711	6.5515	0.0079	90,203
	CDU and CTA, then CDU	4006	2	6.5447	–0.0068	Dominated
	CEU and CTA, then CEU	4713	709	6.5519	0.0004	1,974,710
80	CDU	3515		6.5483		
	CTA	3545	31	6.5466	–0.0017	Dominated
	CEU	4317	803	6.5556	0.0073	110,298
	CDU and CTA, then CDU	4327	10	6.5494	–0.0061	Dominated
	CEU and CTA, then CEU	5125	808	6.5559	0.0003	2,322,223
90	CDU	3728		6.5522		
	CTA	3764	35	6.5506	–0.0015	Dominated
	CEU	4620	892	6.5587	0.0065	137,508
	CDU and CTA, then CDU	4639	19	6.5533	–0.0054	Dominated
	CEU and CTA, then CEU	5526	905	6.5590	0.0003	2,758,785
100	CDU	3935		6.5554		
	CTA	3975	40	6.5540	–0.0014	Dominated
	CEU	4914	979	6.5609	0.0056	176,167
	CDU and CTA, then CDU	4944	30	6.5565	–0.0045	Dominated
	CEU and CTA, then CEU	5916	1002	6.5612	0.0003	3,321,498

TABLE 48 One-way sensitivity analysis: sensitivity of the CDU test

Value (%)	Strategy	Cost (£)	Incremental costs (£)	QALYs	Incremental QALYs	ICER (£)
0.5	CDU	3552		6.5421		
	CTA	3828	276	6.5517	0.0096	28,822
	CEU	4709	882	6.5594	0.0077	114,115
	CDU and CTA, then CDU	4506	678	6.5447	–0.0070	Dominated
	CEU and CTA, then CEU	5644	935	6.5598	0.0003	2,912,177
0.6	CDU	3654		6.5474		
	CTA	3828	173	6.5517	0.0043	40,032
	CEU	4709	882	6.5594	0.0077	114,115
	CDU and CTA, then CDU	4603	775	6.5492	–0.0025	Dominated
	CEU and CTA, then CEU	5644	935	6.5598	0.0003	2,912,177
0.7	CDU	3753		6.5517		
	CTA	3828	75	6.5517	0.0000	Dominated
	CEU	4709	14	6.5594	0.0064	2121
	CDU and CTA, then CDU	4696	943	6.5530	0.0013	720,056
	CEU and CTA, then CEU	5644	935	6.5598	0.0003	2,912,177
0.75	CDU	3800		6.5536		
	CTA	3828	28	6.5517	–0.0019	Dominated
	CEU	4709	909	6.5594	0.0059	154,976
	CDU and CTA, then CDU	4741	31	6.5546	–0.0048	Dominated
	CEU and CTA, then CEU	5644	935	6.5598	0.0003	2,912,177
0.8	CTA	3828		6.5517		
	CDU	3847	19	6.5552	0.0035	5367
	CEU	4709	863	6.5594	0.0042	205,467
	CDU and CTA, then CDU	4784	75	6.5561	–0.0033	Dominated
	CEU and CTA, then CEU	5644	935	6.5598	0.0003	2,912,177
0.85	CTA	3828		6.5517		
	CDU	3892	64	6.5567	0.0050	12,831
	CEU	4709	817	6.5594	0.0027	301,755
	CDU and CTA, then CDU	4827	118	6.5574	–0.0020	Dominated
	CEU and CTA, then CEU	5644	935	6.5598	0.0003	2,912,177
0.9	CTA	3828		6.5517		
	CDU	3937	109	6.5581	0.0063	17,162
	CEU	4709	773	6.5594	0.0014	558,213
	CDU and CTA, then CDU	4869	160	6.5586	–0.0009	Dominated
	CEU and CTA, then CEU	5644	935	6.5598	0.0003	2,912,177
1.0	CTA	3828		6.5517		
	CDU	4023	195	6.5602	0.0085	22,844
	CEU	4709	687	6.5594	–0.0008	Dominated
	CDU and CTA, then CDU	4950	928	6.5605	0.0002	4,263,080
	CEU and CTA, then CEU	5644	693	6.5598	–0.0007	Dominated

TABLE 49 One-way sensitivity analysis: specificity of the CDU test

Value (%)	Strategy	Cost (£)	Incremental costs (£)	QALYs	Incremental QALYs	ICER (£)
0.8	CTA	3828		6.5517		
	CDU	3967	140	6.5532	0.0015	92,448
	CEU	4709	742	6.5594	0.0062	119,382
	CDU and CTA, then CDU	4916	207	6.5543	–0.0051	Dominated
	CEU and CTA, then CEU	5644	935	6.5598	0.0003	2,912,177
0.85	CTA	3828		6.5517		
	CDU	3904	77	6.5532	0.0015	50,833
	CEU	4709	805	6.5594	0.0062	129,466
	CDU and CTA, then CDU	4850	141	6.5543	–0.0051	Dominated
	CEU and CTA, then CEU	5644	935	6.5598	0.0003	2,912,177
0.9	CTA	3828		6.5517		
	CDU	3841	14	6.5532	0.0015	9018
	CEU	4709	868	6.5594	0.0062	139,553
	CDU and CTA, then CDU	4784	75	6.5543	–0.0051	Dominated
	CEU and CTA, then CEU	5644	935	6.5598	0.0003	2,912,177
0.95	CDU	3778		6.5532		
	CTA	3828	50	6.5517	–0.0015	Dominated
	CEU	4709	931	6.5594	0.0062	149,645
	CDU and CTA, then CDU	4718	9	6.5543	–0.0051	Dominated
	CEU and CTA, then CEU	5644	935	6.5598	0.0003	2,912,177
1.0	CDU	3715		6.5532		
	CTA	3828	113	6.5517	–0.0015	Dominated
	CEU	4709	57	6.5594	0.0051	11,152
	CDU and CTA, then CDU	4652	937	6.5543	0.0011	838,696
	CEU and CTA, then CEU	5644	935	6.5598	0.0003	2,912,177

TABLE 50 One-way sensitivity analysis: proportion of CDU indeterminate results

Value (%)	Strategy	Cost (£)	Incremental costs (£)	QALYs	Incremental QALYs	ICER (£)
0	CDU	3419		6.5535		
	CTA	3828	408	6.5517	–0.0018	Dominated
	CEU	4709	270	6.5594	0.0048	55,755
	CDU and CTA, then CDU	4439	1020	6.5546	0.0011	960,112
	CEU and CTA, then CEU	5644	935	6.5598	0.0003	2,912,177
5	CDU	3523		6.5534		
	CTA	3828	305	6.5517	–0.0017	Dominated
	CEU	4709	189	6.5594	0.0049	38,426
	CDU and CTA, then CDU	4520	998	6.5545	0.0011	926,163
	CEU and CTA, then CEU	5644	935	6.5598	0.0003	2,912,177
10	CDU	3626		6.5534		
	CTA	3828	202	6.5517	–0.0016	Dominated
	CEU	4709	108	6.5594	0.0050	21,587
	CDU and CTA, then CDU	4602	976	6.5544	0.0011	893,091
	CEU and CTA, then CEU	5644	935	6.5598	0.0003	2,912,177
15	CDU	3729		6.5533		
	CTA	3828	99	6.5517	–0.0016	Dominated
	CEU	4709	26	6.5594	0.0051	5220
	CDU and CTA, then CDU	4683	954	6.5544	0.0011	860,869
	CEU and CTA, then CEU	5644	935	6.5598	0.0003	2,912,177
20	CTA	3828		6.5517		
	CDU	3832	4	6.5532	0.0015	2939
	CEU	4709	877	6.5594	0.0063	140,201
	CDU and CTA, then CDU	4764	55	6.5543	–0.0051	Dominated
	CEU and CTA, then CEU	5644	935	6.5598	0.0003	2,912,177
25	CTA	3828		6.5517		
	CDU	3935	107	6.5531	0.0014	77,897
	CEU	4709	774	6.5594	0.0063	121,991
	CDU and CTA, then CDU	4845	136	6.5542	–0.0052	Dominated
	CEU and CTA, then CEU	5644	935	6.5598	0.0003	2,912,177
30	CTA	3828		6.5517		
	CDU	4038	211	6.5530	0.0013	163,168
	CEU	4709	671	6.5594	0.0064	104,271
	CDU and CTA, then CDU	4927	217	6.5542	–0.0053	Dominated
	CEU and CTA, then CEU	5644	935	6.5598	0.0003	2,912,177

TABLE 51 One-way sensitivity analysis: sensitivity of the CEU test

Value (%)	Strategy	Cost (£)	Incremental costs (£)	QALYs	Incremental QALYs	ICER (£)
0.8	CDU	3791		6.5532		
	CTA	3828	37	6.5517	–0.0015	Dominated
	CEU	4569	778	6.5552	0.0020	384,006
	CDU and CTA, then CDU	4732	162	6.5543	–0.0009	Dominated
	CEU and CTA, then CEU	5512	942	6.5561	0.0009	1,097,985
0.85	CDU	3791		6.5532		
	CTA	3828	37	6.5517	–0.0015	Dominated
	CEU	4614	823	6.5567	0.0035	234,124
	CDU and CTA, then CDU	4732	118	6.5543	–0.0024	Dominated
	CEU and CTA, then CEU	5554	940	6.5574	0.0007	1,407,843
0.9	CDU	3791		6.5532		
	CTA	3828	37	6.5517	–0.0015	Dominated
	CEU	4658	867	6.5581	0.0048	179,185
	CDU and CTA, then CDU	4732	74	6.5543	–0.0037	Dominated
	CEU and CTA, then CEU	5595	937	6.5586	0.0005	1,881,847
0.95	CDU	3791		6.5532		
	CTA	3828	37	6.5517	–0.0015	Dominated
	CEU	4701	910	6.5592	0.0060	151,514
	CDU and CTA, then CDU	4732	31	6.5543	–0.0049	Dominated
	CEU and CTA, then CEU	5636	935	6.5596	0.0003	2,682,568
1.0	CDU	3791		6.5532		
	CTA	3828	37	6.5517	–0.0015	Dominated
	CEU	4743	11	6.5602	0.0059	1879
	CDU and CTA, then CDU	4732	941	6.5543	0.0011	841,931
	CEU and CTA, then CEU	5675	933	6.5605	0.0002	4,286,486

TABLE 52 One-way sensitivity analysis: specificity CEU test

Value (%)	Strategy	Cost (£)	Incremental costs (£)	QALYs	Incremental QALYs	ICER (£)
0.75	CDU	3791		6.5532		
	CTA	3828	37	6.5517	–0.0015	Dominated
	CEU	4835	104	6.5594	0.0051	20,296
	CDU and CTA, then CDU	4732	941	6.5543	0.0011	841,931
	CEU and CTA, then CEU	5775	940	6.5598	0.0003	2,930,454
0.8	CDU	3791		6.5532		
	CTA	3828	37	6.5517	–0.0015	Dominated
	CDU and CTA, then CDU	4732	941	6.5543	0.0011	841,931
	CEU	4772	41	6.5594	0.0051	7968
	CEU and CTA, then CEU	5710	937	6.5598	0.0003	2,921,324
0.85	CDU	3791		6.5532		
	CTA	3828	37	6.5517	–0.0015	Dominated
	CEU	4709	919	6.5594	0.0062	147,626
	CDU and CTA, then CDU	4732	22	6.5543	–0.0051	Dominated
	CEU and CTA, then CEU	5644	935	6.5598	0.0003	2,912,177
0.9	CDU	3791		6.5532		
	CTA	3828	37	6.5517	–0.0015	Dominated
	CEU	4646	855	6.5594	0.0062	137,498
	CDU and CTA, then CDU	4732	85	6.5543	–0.0051	Dominated
	CEU and CTA, then CEU	5578	932	6.5598	0.0003	2,903,015
0.95	CDU	3791		6.5532		
	CTA	3828	37	6.5517	–0.0015	Dominated
	CEU	4583	792	6.5594	0.0062	127,355
	CDU and CTA, then CDU	4732	149	6.5543	–0.0051	Dominated
	CEU and CTA, then CEU	5512	929	6.5598	0.0003	2,893,836
1.0	CDU	3791		6.5532		
	CTA	3828	37	6.5517	–0.0015	Dominated
	CEU	4520	729	6.5594	0.0062	117,196
	CDU and CTA, then CDU	4732	212	6.5543	–0.0051	Dominated
	CEU and CTA, then CEU	5446	926	6.5598	0.0003	2,884,641

TABLE 53 One-way sensitivity analysis: proportion of CEU indeterminate results

Value (%)	Strategy	Cost (£)	Incremental costs (£)	QALYs	Incremental QALYs	ICER (£)
0	CDU	3791		6.5532		
	CTA	3828	37	6.5517	–0.0015	Dominated
	CEU	4405	614	6.5606	0.0073	83,663
	CDU and CTA, then CDU	4732	327	6.5543	–0.0062	Dominated
	CEU and CTA, then CEU	5409	1003	6.5607	0.0001	9,142,747
5	CDU	3791		6.5532		
	CTA	3828	37	6.5517	–0.0015	Dominated
	CEU	4490	699	6.5603	0.0071	99,125
	CDU and CTA, then CDU	4732	242	6.5543	–0.0059	Dominated
	CEU and CTA, then CEU	5474	984	6.5604	0.0002	5,970,958
10	CDU	3791		6.5532		
	CTA	3828	37	6.5517	–0.0015	Dominated
	CEU	4574	783	6.5600	0.0067	116,170
	CDU and CTA, then CDU	4732	158	6.5543	–0.0056	Dominated
	CEU and CTA, then CEU	5539	965	6.5602	0.0002	4,334,894
15	CDU	3791		6.5532		
	CTA	3828	37	6.5517	–0.0015	Dominated
	CEU	4659	868	6.5596	0.0064	135,141
	CDU and CTA, then CDU	4732	73	6.5543	–0.0053	Dominated
	CEU and CTA, then CEU	5605	946	6.5599	0.0003	3,340,291
20	CDU	3791		6.5532		
	CTA	3828	37	6.5517	–0.0015	Dominated
	CEU	4743	11	6.5593	0.0050	2305
	CDU and CTA, then CDU	4732	941	6.5543	0.0011	841,931
	CEU and CTA, then CEU	5670	927	6.5596	0.0003	2,674,165
25	CDU	3791		6.5532		
	CTA	3828	37	6.5517	–0.0015	Dominated
	CEU	4828	96	6.5590	0.0046	20,782
	CDU and CTA, then CDU	4732	941	6.5543	0.0011	841,931
	CEU and CTA, then CEU	5735	908	6.5594	0.0004	2,198,543
30	CDU	3791		6.5532		
	CTA	3828	37	6.5517	–0.0015	Dominated
	CEU	4912	181	6.5586	0.0043	42,443
	CDU and CTA, then CDU	4732	941	6.5543	0.0011	841,931
	CEU and CTA, then CEU	5801	889	6.5591	0.0005	1,843,151

TABLE 54 One-way sensitivity analysis: sensitivity of the CTA test

Value (%)	Strategy	Cost (£)	Incremental costs (£)	QALYs	Incremental QALYs	ICER (£)
0.5	CTA	3581		6.5395		
	CDU	3749	168	6.5516	0.0121	13,922
	CEU	4672	923	6.5584	0.0069	134,033
	CDU and CTA, then CDU	4690	18	6.5526	–0.0058	Dominated
	CEU and CTA, then CEU	5609	937	6.5589	0.0005	1,986,663
0.6	CTA	3708		6.5463		
	CDU	3770	62	6.5524	0.0061	10,196
	CEU	4691	921	6.5590	0.0065	140,583
	CDU and CTA, then CDU	4711	20	6.5535	–0.0054	Dominated
	CEU and CTA, then CEU	5626	936	6.5594	0.0004	2,374,667
0.7	CDU	3791		6.5532		
	CTA	3828	37	6.5517	–0.0015	Dominated
	CEU	4709	919	6.5594	0.0062	147,626
	CDU and CTA, then CDU	4732	22	6.5543	–0.0051	Dominated
	CEU and CTA, then CEU	5644	935	6.5598	0.0003	2,912,177
0.8	CDU	3811		6.5540		
	CTA	3941	130	6.5559	0.0019	67,435
	CEU	4728	786	6.5599	0.0040	197,736
	CDU and CTA, then CDU	4752	24	6.5551	–0.0048	Dominated
	CEU and CTA, then CEU	5661	933	6.5601	0.0003	3,702,825
0.9	CDU	3832		6.5547		
	CTA	4049	217	6.5591	0.0044	49,742
	CEU	4746	697	6.5603	0.0012	566,664
	CDU and CTA, then CDU	4772	26	6.5559	–0.0045	Dominated
	CEU and CTA, then CEU	5678	932	6.5605	0.0002	4,974,254
1.0	CDU	3852		6.5554		
	CTA	4151	299	6.5614	0.0060	50,171
	CEU	4764	613	6.5607	–0.0007	Dominated
	CDU and CTA, then CDU	4792	641	6.5566	–0.0048	Dominated
	CEU and CTA, then CEU	5695	1545	6.5608	–0.0005	Dominated

TABLE 55 One-way sensitivity analysis: specificity of the CTA test

Value (%)	Strategy	Cost (£)	Incremental costs (£)	QALYs	Incremental QALYs	ICER (£)
0.5	CDU	4023		6.5536		
	CTA	4753	730	6.5531	–0.0005	Dominated
	CEU	4931	908	6.5596	0.0060	151,652
	CDU and CTA, then CDU	5089	157	6.5550	–0.0046	Dominated
	CEU and CTA, then CEU	5923	991	6.5600	0.0004	2,582,245
0.6	CDU	3962		6.5534		
	CTA	4548	586	6.5526	–0.0009	Dominated
	CEU	4878	916	6.5595	0.0061	150,596
	CDU and CTA, then CDU	5007	129	6.5547	–0.0048	Dominated
	CEU and CTA, then CEU	5867	989	6.5599	0.0004	2,761,378
0.7	CDU	3907		6.5533		
	CTA	4340	433	6.5522	–0.0012	Dominated
	CEU	4827	919	6.5595	0.0061	149,598
	CDU and CTA, then CDU	4927	100	6.5545	–0.0049	Dominated
	CEU and CTA, then CEU	5807	980	6.5598	0.0003	2,886,831
0.8	CDU	3860		6.5533		
	CTA	4141	281	6.5519	–0.0014	Dominated
	CEU	4780	920	6.5595	0.0062	148,725
	CDU and CTA, then CDU	4852	72	6.5544	–0.0050	Dominated
	CEU and CTA, then CEU	5747	966	6.5598	0.0003	2,948,485
0.9	CDU	3819		6.5532		
	CTA	3959	140	6.5518	–0.0015	Dominated
	CEU	4739	920	6.5594	0.0062	148,029
	CDU and CTA, then CDU	4783	44	6.5544	–0.0051	Dominated
	CEU and CTA, then CEU	5688	950	6.5598	0.0003	2,948,570
0.95	CDU	3801		6.5532		
	CTA	3875	74	6.5517	–0.0015	Dominated
	CEU	4720	919	6.5594	0.0062	147,760
	CDU and CTA, then CDU	4750	30	6.5543	–0.0051	Dominated
	CEU and CTA, then CEU	5660	940	6.5598	0.0003	2,929,045
1.0	CDU	3784		6.5532		
	CTA	3797	13	6.5517	–0.0015	Dominated
	CEU	4702	918	6.5594	0.0062	147,549
	CDU and CTA, then CDU	4719	17	6.5543	–0.0051	Dominated
	CEU and CTA, then CEU	5633	931	6.5598	0.0003	2,899,056

TABLE 56 One-way sensitivity analysis: proportion of CTA indeterminate results

Value (%)	Strategy	Cost (£)	Incremental costs (£)	QALYs	Incremental QALYs	ICER (£)
0	CDU	3791		6.5532		
	CTA	3828	37	6.5517	–0.0015	Dominated
	CEU	4709	919	6.5594	0.0062	147,626
	CDU and CTA, then CDU	4732	22	6.5543	–0.0051	Dominated
	CEU and CTA, then CEU	5644	935	6.5598	0.0003	2,912,177
10	CDU	3791		6.5532		
	CTA	4045	254	6.5517	–0.0015	Dominated
	CEU	4709	919	6.5594	0.0062	147,626
	CDU and CTA, then CDU	4739	30	6.5543	–0.0051	Dominated
	CEU and CTA, then CEU	5651	941	6.5597	0.0003	3,152,095
20	CDU	3791		6.5532		
	CTA	4262	472	6.5517	–0.0015	Dominated
	CEU	4709	919	6.5594	0.0062	147,626
	CDU and CTA, then CDU	4747	38	6.5543	–0.0052	Dominated
	CEU and CTA, then CEU	5658	948	6.5597	0.0003	3,430,618
30	CDU	3791		6.5532		
	CTA	4480	689	6.5517	–0.0015	Dominated
	CEU	4709	919	6.5594	0.0062	147,626
	CDU and CTA, then CDU	4754	45	6.5543	–0.0052	Dominated
	CEU and CTA, then CEU	5665	955	6.5597	0.0003	3,757,877

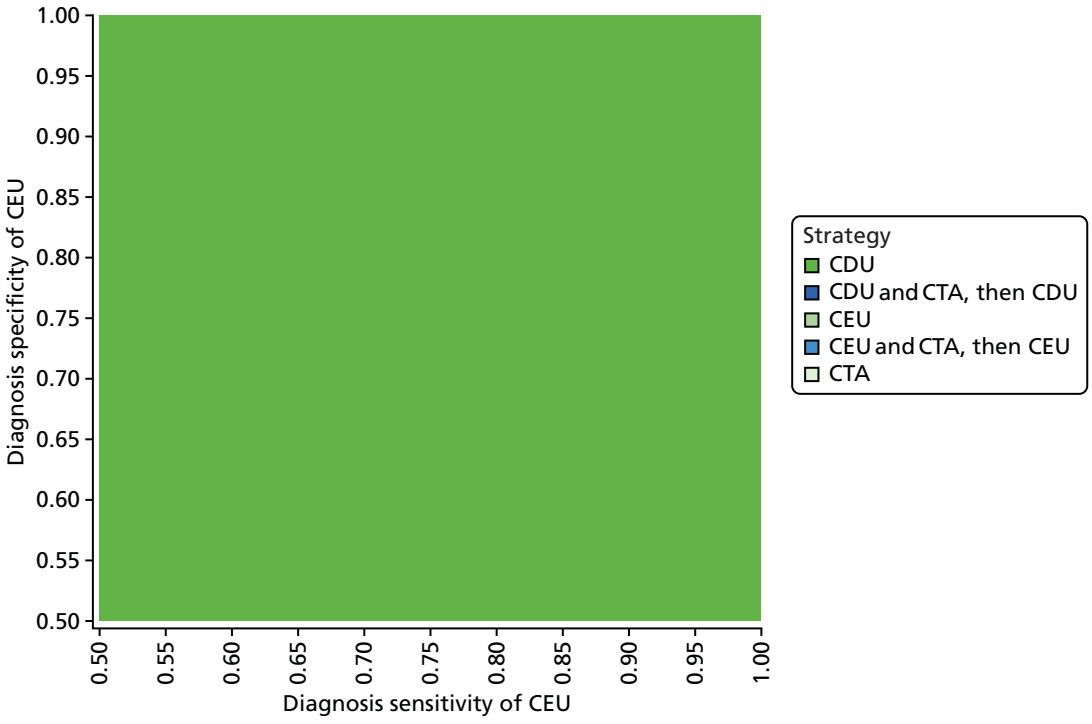

FIGURE 14 Two-way sensitivity analysis: CEU sensitivity and specificity (based on net benefit, willingness-to-pay threshold of £30,000).

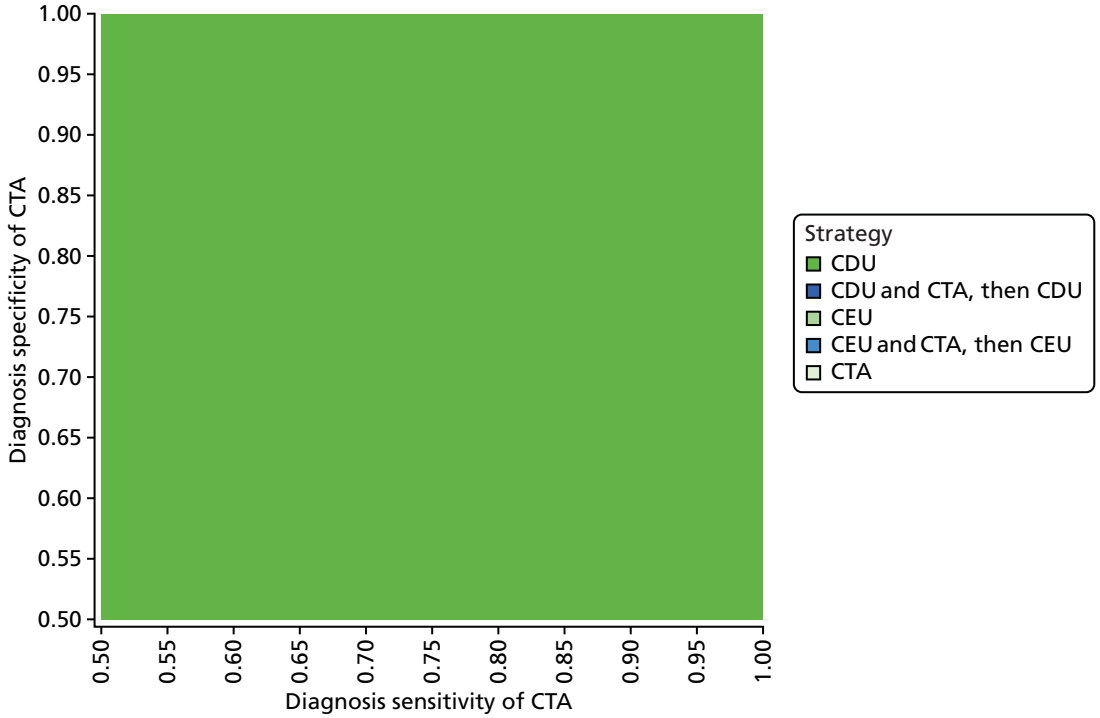

FIGURE 15 Two-way sensitivity analysis: CTA sensitivity and specificity (based on net benefit, willingness-to-pay threshold of £30,000).

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