The use of fenestrated and branched endovascular aneurysm repair for juxtarenal and thoracoabdominal aneurysms: a systematic review and cost-effectiveness analysis

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Declared competing interests of authors: SR Vallabhaneni is the chief investigator of the GLOBALSTAR project, which received an unrestricted research grant from COOK Medical. Rob Riemsma is a member of the National Institute for Health Research Health Technology Assessment and Efficacy and Mechanism Evaluation editorial boards.

Published December 2014
DOI: 10.3310/hta18700

Scientific summary

Endovascular aneurysm repair for JRAAAs and TAAAs

Health Technology Assessment 2014; Vol. 18: No. 70
DOI: 10.3310/hta18700

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Background

An aneurysm is dilatation of an artery. Abdominal aortic aneurysms (AAAs) account for 75% of all aortic aneurysms (AAs) and are located, by definition of the abdomen, below the diaphragm, most below the renal arteries. Those aneurysms that do not involve, but are close to the origin of, the renal arteries [juxtarenal AAAs (JRAAAs)] account for about 16% of AAAs. Thoracic AAs account for the other 25% of AAs. Of these, 15% extend into the abdomen and are therefore referred to as thoracoabdominal aortic aneurysms (TAAAs).

Because most aneurysms are asymptomatic, it is difficult to estimate their prevalence, but screening studies in the UK have estimated a prevalence of AAAs of 1.3–12.7%, depending on the age group studied and the definition of AAA. The incidence of symptomatic AAAs in men is approximately 25 per 100,000 patient-years at age 50 years, increasing to 78 per 100,000 in those older than 70 years of age. For TAAAs, the incidence estimate varies from under one to about three per 100,000 patient-years.

Patients with symptomatic TAAAs or AAAs need rapid medical attention given that the risk of rupture increases with the size of the aneurysm, and those aneurysms larger than 6 cm in diameter have an annual risk of rupture of 25%. Among patients with a ruptured AAA, the mortality rate is about 80%; even when they undergo emergency surgery, only about half survive beyond 30 days. Several studies indicate that without surgery the 5-year survival rate for patients with aneurysms larger than 5 cm is about 20%. For TAAAs, the 5-year survival without operation has been reported to be between 7% and 20%.

As well as concomitant medical treatment for any other cardiovascular disease, there are two main methods of repair, open surgical repair (OSR) and endovascular repair of an abdominal aortic aneurysm (EVAR). In the most recent appraisal by the National Institute for Health and Care Excellence (NICE), in 2009, EVAR was recommended as an option for an unruptured AAA that was infrarenal, i.e. below the renal arteries. It was recommended that EVAR for ruptured aneurysms be reserved for research only. For TAAAs there is no NICE guidance.

Recent solutions for more complicated aneurysms are ‘fenestrated’ EVAR (fEVAR) and ‘branched’ EVAR (bEVAR). fEVAR is where the stent graft fabric extends over the renal arteries, but perfusion to these arteries is preserved via accurately placed windows (fenestrations) within the stent graft fabric. The term ‘branched’ refers to the need to bridge the gap (created by increased diameter of aorta) between the main body of aortic stent graft and target vessels and not to any actual branch from the graft itself. The fEVAR and bEVAR procedures are more challenging than standard EVAR as graft positioning requires both longitudinal and rotational alignment of the fenestrations with the target vessels. Any misalignment can lead to partial or total covering of the ostia of the target vessel (shuttering), resulting in reduced blood flow or occlusion. Commissioners are receiving increasing requests for fEVAR and bEVAR, but it is not clear if the extra cost of fEVAR or bEVAR compared with the alternative of OSR is justified by advantages for patients. In the absence of recent UK evidence-based guidance on JRAAA and TAAAs, evidence synthesis with economic modelling is needed to answer these questions.

The current assessment will therefore attempt to evaluate the clinical effectiveness, safety and cost-effectiveness of fEVAR or bEVAR in comparison with conventional treatment for JRAAAs or TAAAs in the UK.

Methods

A systematic review was conducted using methods as recommended in the Centre for Reviews and Dissemination guidance for undertaking reviews in health care and the Cochrane Handbook for reviews of intervention studies. The target patient population for the review was adult patients who were eligible for fEVAR (age ≥ 18 years) with JRAAAs or eligible for bEVAR with TAAAs, i.e. with proximity to/involvement of target vessels such that EVAR was unsuitable.

The interventions under consideration were fEVAR and bEVAR, which use specially manufactured stent grafts with openings to allow blood to reach branches of the aorta. The comparators considered relevant for this assessment were OSR, which is the historic treatment method for JRAAAs or TAAAs, and no surgery (best medical therapy only).

n the first instance, randomised and non-randomised trials in which participants are assigned to the intervention group or comparator group were included. As no controlled trials were likely to be found, studies with a cohort design were included if they made a comparison with a control group. These studies are referred to as comparative. To qualify as comparative, studies had to demonstrate that there had been some attempt to make the populations receiving each of the treatments comparable and that any evidence of intent to select based on some prognostic factor would imply exclusion. Cost studies and cost-effectiveness analyses (CEAs) were also included.

Seven databases were searched from inception up to October 2013, including MEDLINE, EMBASE, Database of Abstracts of Reviews of Effects (DARE) and NHS Economic Evaluation Database (NHS EED). Two reviewers independently screened titles and abstracts of all reports identified by searches and discrepancies were discussed. Full copies of all studies deemed potentially relevant, after discussion, were obtained and two reviewers independently assessed these for inclusion; any disagreements were resolved by consensus or discussion with a third reviewer. Given that no studies met all of the inclusion criteria, a narrative account of the number of studies screened for inclusion and reasons for excluding studies was given.

Results

The literature searches for clinical effectiveness studies retrieved 3268 records that were screened at title and abstract stage. Based on titles and abstracts, 24 publications were ordered for full-paper screening. All 24 studies were excluded as none of the studies satisfied the inclusion criteria.

Sixteen studies were excluded on study design, six studies were excluded on intervention and two on comparator (chimney grafts). Among the six studies which were excluded on intervention, three studies were excluded because they compared EVAR with OSR, with no indication of fEVAR or bEVAR being used; one used EVAR with suprarenal fixation; and the other two were excluded because they reported results from surgeon-modified fenestrated–branched stent grafts, which are not considered as appropriate interventions for this evaluation. Five out of 16 studies that were excluded on study design reported a comparison. However, for all of the studies, the authors acknowledged that they had included groups which were not comparable at baseline as they had selectively assigned patients to the groups being compared, i.e. not the same population. Therefore, these studies were considered to be non-comparative studies.

The health economics search identified 70 titles and abstracts. Of these, seven were ordered for the full assessment based on initial screening. After full-text review no studies were included. Six of these seven studies estimated the cost-effectiveness of EVAR compared with OSR for patients with pararenal AAA who were defined as unsuitable for EVAR and, thus, these studies were excluded based on the population. Furthermore, five of them were presented at conferences and these abstracts were not presented in such a way that data could be extracted from them. The other study reported costs of fEVAR, but this was reported without sufficient details.

Our objective was to perform an economic evaluation of fEVAR and bEVAR for patients with JRAAAs and TAAAs. However, it was decided that a CEA evaluating fEVAR and bEVAR was not possible, partly because the systematic review assessing the clinical effectiveness showed that no comparative study has been done that could provide clinical effectiveness data. In addition, it was not feasible to obtain valid estimates for the other input parameters. Consequently, we decided to describe how an economic evaluation could be performed if more data were available. This includes those data that ideally would come from a randomised controlled trial (RCT) in each of two populations, i.e. those fit enough and those not fit enough for OSR, which would inform two distinct models.

Conclusion

The systematic review of clinical effectiveness studies showed that no comparative study has been done that could provide reliable clinical effectiveness data. All studies that compared either fEVAR or bEVAR with either OSR or no surgery explicitly selected patients based on prognosis, i.e. essentially the populations for each comparator were not the same. Therefore, it was decided that a CEA evaluating fEVAR and bEVAR was not possible. Consequently, we decided to describe how an economic evaluation could be performed if more data were available. This includes those data that ideally would come from a RCT in each of two populations, i.e. those fit enough and those not fit enough for OSR, which would inform two distinct models.

We recommend at least one clinical trial to provide an unbiased estimate of effect for fEVAR/bEVAR compared with OSR or no surgery. This trial should also collect data for a CEA.

Study registration

This study is registered as PROSPERO CRD42013006051.

Funding

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

Health Technology Assessment

HTA/HTA TAR

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 5.116

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, The Cochrane Library and the ISI Science Citation Index and is assessed for inclusion in the Database of Abstracts of Reviews of Effects.

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

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This report

The research reported in this issue of the journal was funded by the HTA programme as project number 13/09/01. The contractual start date was in October 2013. The draft report began editorial review in March 2014 and was accepted for publication in June 2014. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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