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# Appendices

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## Endovascular stents for abdominal aortic aneurysms: a systematic review and economic model

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# Appendix 4

# Data extraction tables

## Data extraction tables – RCTs

**Blankensteijn JD, de Jong SEC, Prinssen M, van der Ham AC, Buth J, van Sterkenburg SMM, *et al*. Two-year outcomes after conventional or endovascular repair of abdominal aortic aneurysms. *N Engl J Med* 2005;352:2398–405**[41,40,93,169,170]

| | |
|---|---|
| Author (main publication) | Blankensteijn 2005[41] |
| Study publications | Main publication Blankensteijn 2005;[41] 30-day outcomes from Prinssen 2004;[40] quality of life outcomes from Prinssen 2004;[93] design and methods Prinssen 2002[169] |
| Study name | DREAM |
| Country where study was performed | Netherlands and Belgium |
| Multicentre | 26 centres in the Netherlands and four in Belgium |
| Centre entry criteria for trial | Surgical teams that had performed at least five endovascular procedures were eligible. Teams that had performed fewer than 20 procedures were required to have an experienced proctor assist them during the procedure. Scrub nurses and radiology technicians had to be trained specifically for EVAR. Participating centres required to have a yearly volume of at least 30 conventional AAA repairs and 50 endovascular procedures |
| Patient entry criteria for trial | Age limitations: not reported; aneurysm size: at least 5 cm in diameter; suitable for open repair: yes; suitable for EVAR: yes; elective repair: non-symptomatic for which an intervention is indicated; emergency repair: patients needing emergency repair were excluded<br>Patients with inflammatory aneurysms, anatomic variations, connective tissue disease, a history of organ transplantations or a life expectancy of less than 2 years were excluded from the study. Patients needed to have an adequate infrarenal neck |
| Number of patients randomised | 351 patients of whom 339 had an operation according to the randomised assignment |
| Number of patients randomised to EVAR | 173; one patient assigned to EVAR underwent open repair |
| Number of patients randomised to comparator | 178; five patients assigned to open repair underwent EVAR |
| Criteria assessing fitness for surgery/EVAR/open repair | Fitness for EVAR: determined by endograft-dependent anatomic criteria<br>Fitness for open repair: determined by an internist or cardiologist |
| Age of population | Mean (SD): 70.1 years [EVAR 70.7 (6.6), open repair 69.6 (6.8)] |
| Gender | 91.7% male (EVAR 93.1%, open repair 90.4%) |
| Aneurysm diameter | Mean (SD): 6 cm [EVAR 6 (0.9), open repair 6 (0.85)] |
| Aneurysm anatomy | Not reported |
| Smoking history | Current smokers: 209 (59.6%) [EVAR 111 (64.2%), open repair 98 (55.1%)] |
| Diabetes | 35 (10%) [EVAR 18 (10.4%), open repair 17 (9.6%)] |
| Heart disease | 154 (43.8%) [EVAR 71 (41%), open repair 83 (46.6%)] |
| Hypertension | 198 (56.4%) [EVAR 101 (58.4%), open repair 97 (54.5%)] |

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| Renal disease | 28 (8%) [EVAR 13 (7.5%), open repair 15 (8.4%)] |
| Respiratory disease | 81 (23%) [EVAR 48 (27.7%), open repair 33 (18.5%)] |
| Fitness scores | ASA I: 81 (23%) [EVAR 37 (21.4%), open repair 44 (24.7%)]; ASA II: 32 (66%) [EVAR 122 (70.5%), open repair 110 (61.8%)]; ASA III: 38 (10.8%) [EVAR 14 (8.1%), open repair 24 (13.5%)]; ASA IV: 0 |
| Body mass index (BMI) | Mean (SD): 26.5 kg/m$^2$ [EVAR 26.3 (3.4), open repair 26.6 (4.1)] |
| Dates of procedure | November 2000–December 2003 |
| Time lapse between randomisation and procedure | Median: 39 days; range: 1–183 days |
| Elective or emergency procedure | Elective: 173 (100%); emergency: 0 |
| Type of device (EVAR) | Zenith: 7 (33.3%); Talent: 6 (26.9%); Excluder: 37 (21.6%); Other: 30 (17.5%) |
| Graft type (EVAR) | Uni-iliac: 6 (3.5%); bi-iliac: 160 (94%); endovascular tube graft: 1 (0.6%) |
| Anaesthesia | Local: 9 (5.3%); regional: 68 (39.8%); general: 94 (54.9%) |
| Open repair or non-surgical procedure | Open repair: particular open technique used was at the discretion of the surgeon |
| Dates of procedure | November 2000–December 2003 |
| Time lapse between randomisation and procedure | Median: 39 days; range: 4–260 days |
| Elective or emergency procedure | Elective: 178 (100%); emergency: 0 |
| Anaesthesia | Local: 1 (0.6%) (crossover to EVAR); regional: 2 (1.1%) (crossover to EVAR); general: 171 (98.3%) (all patients except 3 crossovers) |
| Intention to treat or per protocol | Intention to treat |
| Method for generating measures of effect | Cox proportional hazards regression; used to estimate HRs for reintervention rates |
| Covariates adjusted for | Not reported |
| Follow-up | Minimum follow-up: 1 month; maximum follow-up: 42 months; mean duration of follow-up was 21 months in the open repair group and 22 months in the EVAR group |
| 30-day mortality | Number (%) of EVAR patients died: 2/171 (1.2%); number (%) of comparator patients died: 8/174 (4.6%) |
| Aneurysm-related mortality at follow-up | Defined as death resulting from aneurysm rupture, graft infection or thrombosis; any death occurring within 30 days after the original procedure or a reintervention; or any death occurring more than 30 days after the original procedure or a reintervention but during the same admission.<br>Number of EVAR patients died: 3/173; number of comparator patients died: 9/178; cumulative rate from Kaplan–Meier curve: EVAR 2.1%, open repair 5.7% |
| All-cause mortality at follow-up | Number of EVAR patients died: 20/173; number of comparator patients died: 18/178; cumulative rate from Kaplan–Meier curve: EVAR 10.3%, open repair: 10.4% |
| Rupture | No documented postoperative ruptures but rupture was considered a possible cause of death in two patients<br>No documented postoperative ruptures |
| Endoleak | Not reported |

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| Device migration | Not reported |
| Reinterventions | Correction of endoleak (EVAR group only): 2 (1.2%) of which 1 was classed as severe (0.6%)<br>HR: 9 months: 2.9 (95% CI 1.1 to 6.2, $p = 0.03$) favouring open repair; > 9 months: 1.1 (95% CI 0.1 to 9.3, $p = 0.95$) |
| Major adverse events (30-day period) | Not reported |
| Quality of life (QoL) measure used | Medical Outcomes Study Short Form-36 (SF-36). Baseline scores were compared with the scores of the general Dutch population of the same age. Changes in QoL scores over time were calculated relative to the preoperative level. Standardised effect sizes were calculated<br>EQ-5D<br>Questionnaire about sexual function reported elsewhere[170] but no data extracted |
| Baseline scores | EVAR population mean (SD): preoperative score (based on 97% response rate, statistically greater than rate for open repair): physical function (PF) 70.1 (22.8), social functioning (SF) 70.0 (25.3), role physical (RP) 52.9 (45.5), role limitations emotional (RE) 60.7 (44.0), mental health (MH) 68.0 (20.1), vitality (VT) 60.0 (23.3), bodily pain (BP) 71.8 (28.2), general health (GH) 62.9 (18.5)<br>Comparator population mean (SD): preoperative score (based on 83% response rate): PF 70.8 (22.9), SF 73.6 (22.8), RP 57.4 (44.3), RE 64.8 (44.2), MH 68.8 (19.8), VT 60.4 (20.5), BP 73.1 (27.1), 60.8 (18.6) |
| Follow-up scores | EVAR population mean (SD): time points with response rates: 3 weeks (97%), 6 weeks (86%), 3 months (93%), 6 months (95%) and 12 months (94%)<br>Comparisons with baseline: at 3 weeks EVAR showed a statistically significant decrease compared with baseline on five of the eight SF domains (PF, SF, RP, VT, BP). At 6 weeks after surgery three (SF, RE, VT) of the five decreased domains had returned to baseline; PF and RP showed a partial but statistically significant recovery. At 3 months the group had recovered to baseline on all domains; there was a significant increase on MH. At 12 months there was a statistically significant increase on RE and MH and a decease on PF<br>EQ-5D showed a significant decrease 3 weeks after surgery and at 6 weeks recovered to baseline and remained so at 3 months. At 6 months and 12 months there were statistically significant increases compared with baseline<br>Comparator population mean (SD): time points with response rates: 3 weeks (73%), 6 weeks (75%), 3 months (87%), 6 months (87%) and 12 months (91%)<br>Comparisons with baseline: at 3 weeks open repair showed a statistically significant decrease on six of the eight SF domains (PF, SF, RP, RE, VT and BP). At 6 weeks open repair showed a partial recovery on all of the impaired domains, significantly for PE, SF and VT. At 3 months open repair recovered to baseline level on all domains; there was a statistically significant increase on MH and GH. At 12 months open repair showed a significantly higher QoL than at baseline on three of the eight domains (SF, RE and MH); all other domains were at baseline level<br>Mean difference between populations: EQ-5D 3 weeks: EVAR –0.6, open repair –0.5 ($p = 0.857$); 6 weeks: EVAR –0.3, open repair –0.1 ($p = 0.426$); 3 months: EVAR 0, open repair 0.2 ($p = 0.646$); 6 months: EVAR –0.2, open repair 0.3 ($p = 0.005$); 12 months: EVAR –0.1, open repair 0.5 ($p = 0.004$) |
| Length of hospital and ICU stay | EVAR: mean 6 days, median 4 days (IQR 3–6), $p < 0.001$ for comparison with open repair<br>EVAR: mean 0.66 days (16 hours), median 3 hours (IQR 0–20), $p < 0.001$ for comparison with open repair<br>Number of days in hospital for open repair population: mean 13 days, median 10 days (IQR 8–15)<br>Number of days in ICU for open repair population: mean 3 days (72 hours), median 23 hours (IQR 21–47) |
| Duration of surgery | EVAR: mean 135 minutes, median 120 minutes (IQR 105–150), $p < 0.001$ for comparison with open repair<br>Duration of surgery for open repair population: mean 151 minutes, median 150 minutes (IQR 120–170) |
| Length of stay for reintervention | Not reported |

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| Costs | Not reported |
| Analysis by type of device | No |
| Analysis by neck angulation | No |
| True randomisation | Yes |
| Adequate concealment of treatment allocation | Yes |
| Outcome assessor blinded | Yes; an outcome adjudication committee made up of five vascular surgeons assessed the class and severity of complications independently and blinded to treatment. Disagreements were resolved in a plenary consensus meeting |
| Baseline characteristics comparable between groups | Yes |
| Eligibility criteria reported | Yes |
| Withdrawals or exclusions accounted for | Yes |
| Power calculation reported | Yes; 80% power to show a reduction of 50% in composite end point of operative mortality and moderate or severe complications at the two-sided 5% level with EVAR as opposed to open repair; 400 patients were required |
| Intention to treat analysis | Yes |

**Cuypers PWM, Gardien M, Buth J, Peels CH, Charbon JA, Hop WCJ. Randomized study comparing cardiac response in endovascular and open abdominal aortic aneurysm repair. *Br J Surg* 2001;88:1059–65[44,94]**

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|---|---|
| Author (main publication) | Cuypers 2001[44] |
| Study publications | Main publication Cuypers 2001;[44] quality of life data from Lottman 2004[94] |
| Country where study was performed | Netherlands |
| Multicentre | Yes |
| Centre entry criteria for trial | Not reported |
| Patient entry criteria for trial | Age limitations: not reported; aneurysm size: > 50 mm; suitable for open repair: yes |
| Number of patients randomised | 76 patients |
| Number of patients randomised to EVAR | 57 |
| Number of patients randomised to comparator | 19 |
| Criteria assessing fitness for surgery/EVAR/open repair | Fitness for EVAR: 12-lead electrocardiogram (ECG) and dobutamine stress echocardiogram (DSE). Exclusion criteria: adverse aneurysm morphology for endografting, contrast allergy, medical conditions precluding open surgery<br>Fitness for open repair (specify measurement tool if reported): 12-lead ECG and DSE. Exclusion criteria: adverse aneurysm morphology for endografting, contrast allergy, medical conditions precluding open surgery |
| Age of population | Mean: 68.5 years (EVAR 69, open repair 68); range: EVAR 52–82, open repair 52–81 |
| Gender | 92% male [EVAR 54/57 (95%), open repair 16/19 (84%)] |
| Aneurysm diameter | Mean: 5.4 cm (EVAR 5.6, open repair 5.2); range: EVAR 5.2–8.4, open repair 4.0–6.1 |
| Aneurysm anatomy | Not reported |
| Smoking history | Current smokers: 41% [EVAR 26 (46%), open repair 5 (26%)] |
| Diabetes | 16% [EVAR 8 (14%), open repair 4 (21%)] |
| Heart disease | 46% [history of coronary artery disease: EVAR 25 (44%), open repair 10 (53%)] |
| Hypertension | 56% [EVAR 31 (54%), open repair 12 (63%)] |
| Renal disease | Not reported |
| Respiratory disease | 28% [COPD: EVAR 17 (30%), open repair 4 (21%)] |
| Fitness scores | ASA II: 64% [EVAR 34 (60%), open repair 15 (79%)]; ASA III: 36% [EVAR 23 (40%), open repair 4 (21%)] |
| Body mass index (BMI) | Not reported |
| Dates of procedure | September 1996–October 1999 |
| Time lapse between randomisation and procedure | Not reported |

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| Elective or emergency procedure | Not reported; probably elective, no mention of emergency |
| Type of device (EVAR) | Stentor: 3 (5%); Vanguard: 22 (39%); AneuRx: 30 (52%); Lifepath: 1 (2%); 1 (2%) had open repair |
| Graft type (EVAR) | Bi-iliac: 57 (100%) |
| Anaesthesia | General: 57 (100%) patients |
| Open repair or non-surgical procedure | Open repair |
| Dates of procedure | September 1996–October 1999 |
| Time lapse between randomisation and procedure | Not reported |
| Elective or emergency procedure | Not reported; one emergency open repair, but analysed as EVAR |
| Anaesthesia | General: 19 (100%) patients |
| Intention to treat or per protocol | Intention to treat: as randomised, not as treated |
| Method for generating measures of effect | Not reported |
| Covariates adjusted for | Not reported |
| Follow-up | Actual follow-up = 30 days |
| 30-day mortality | Number (%) of EVAR patients died: 1 (2%); number (%) of comparator patients died: 1 (2%) |
| Aneurysm-related mortality at follow-up | Number (%) of EVAR patients died: 1 (2%) (pre 30 days); number (%) of comparator patients died: 1 (2%) (pre 30 days) |
| All-cause mortality at follow-up | Number (%) of EVAR patients died: 2 (2%) (pre 30 days); number (%) of comparator patients died: 1 (2%) pre 30 days |
| Rupture | Number of EVAR patients: one patient randomised to EVAR had an AAA rupture prior to surgery and received urgent open repair; number of comparator patients: none reported |
| Endoleak | Not reported |
| Device migration | Not reported |
| Reinterventions | Conversion to open repair (EVAR group only): one patient randomised to EVAR received an urgent open AAA repair because of aneurysm rupture prior to receiving EVAR. There were no other conversions to open repair |
| Major adverse events (30-day period) | Number (%) of cardiac events for EVAR patients: 3 (5%); number (%) of cardiac events for open repair patients: 2 (11%) |
| Quality of life (QoL) measure used | Medical Outcomes Study Short Form-36 (SF-36)<br>EQ-5D |
| Baseline scores | EVAR population mean (SD):<br>SF-36 ($n = 54$): physical functioning: 68 (24); social functioning: 83 (24); role limitations: physical 62 (45), emotional 64 (48); mental health: 69 (27); vitality: 63 (26); pain: 84 (25); general health perceptions: 52 (30)<br>EQ-5D ($n = 53$): mobility: no problems 53%, problems 47%, confined to bed 0%; self-care: no problems 83%, some problems 17%, unable to 0%; usual activities: no problems 57%, some problems 36%, unable to 7%; pain/discomfort: none 62%, some 32%, extreme 6%; anxiety/depression: none 62%, some 30%, extreme 8%; health self-evaluation (maximum 100): 67 (18) |

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| Follow-up scores | Comparator population mean (SD):<br>SF-36 ($n = 18$): physical functioning: 68 (26); social functioning: 78 (20); role limitations: physical 52 (43), emotional 65 (45); mental health: 71 (26); vitality: 68 (28); pain: 83 (30); general health perceptions: 53 (19)<br>EQ-5D ($n = 18$): mobility: no problems 50%, problems 50%, confined to bed 0%; self-care: no problems 100%, some problems 0%, unable to 0%; usual activities: no problems 44%, some problems 56%, unable to 0%; pain/discomfort: none 55%, some 39%, extreme 6%; anxiety/depression: none 50%, some 22%, extreme 18%; health self-evaluation (maximum 100): 61 (17)<br>Total population mean (SD):<br>SF-36 ($n = 72$): physical functioning: 68; social functioning: 81.8; role limitations: physical 59.5, emotional 64.3; mental health: 69.5; vitality: 64.3; pain: 83.8; general health perceptions: 52.3<br>EQ-5D ($n = 71$): mobility: no problems 52.2%, problems 47.8%, confined to bed 0%; self-care: no problems 87.3%, some problems 17% (EVAR), unable to 0%; usual activities: no problems 42.5%, some problems 41%, unable to 7% (EVAR); pain/discomfort: none 60.2%, some 33.8%, extreme 6%; anxiety/depression: none 59%, some 28%, extreme 10.5%; health self-evaluation (maximum 100): 65.5<br>Mean difference between populations:<br>SF-36 ($n = 72$): physical functioning: 0; social functioning: 5; role limitations: physical 10, emotional 1; mental health: 2; vitality: 5; pain: 1; general health perceptions: 1<br>EQ-5D ($n = 71$): mobility: no problems 3%, problems 3%, confined to bed 0; self-care: no problems 17%, some problems 17%, unable to 0; usual activities: no problems 13%, some problems 20%, unable to 7%; pain/discomfort: none 7%, some 7%, extreme 0; anxiety/depression: none 12%, some 8%, extreme 10%; health self-evaluation: 6<br>EVAR population mean (SD):<br>1-month follow-up:<br>SF-36 ($n = 52$): physical functioning: 61 (24), $p < 0.05$ (between-group comparisons); social functioning: 71 (27); role limitations: physical 44 (42), $p < 0.05$ (between-group comparisons), emotional 56 (46); mental health: 74 (23); vitality: 55 (24), $p < 0.05$ (between-group comparisons); pain: 70 (28), $p < 0.05$ (between-group comparisons); general health perceptions: 47 (26)<br>EQ-5D ($n = 52$): mobility: no problems 42%, problems 54%, confined to bed 4%; self-care: no problems 85%, some problems 13%, unable to 2%; usual activities: no problems 46%, $p < 0.05$ (between-group comparisons), some problems 42%, unable to 12%; pain/discomfort: none 58%, some 36%, extreme 6%; anxiety/depression: none 73%, some 23%, extreme 4%; health self-evaluation (maximum 100): 68 (14)<br>3-month follow-up:<br>SF-36 ($n = 52$): physical functioning: 70 (26); social functioning: 86 (16); role limitations: physical 64 (46), emotional 79 (37); mental health: 73 (23); vitality: 63 (26); pain: 88 (17); general health perceptions: 63 (30)<br>EQ-5D ($n = 50$): mobility: no problems 52%, problems 46%, confined to bed 2%; self-care: no problems 86%, some problems 12%, unable to 2%; usual activities: no problems 62%, some problems 34%, unable to 4%; pain/discomfort: none 60%, some 40%, extreme 0%; anxiety/depression: none 80%, some 18%, extreme 2%; health self-evaluation (maximum 100): 67 (18)<br>Comparator population mean (SD):<br>1-month follow-up:<br>SF-36 ($n = 17$): physical functioning: 44 (27); social functioning: 56 (33); role limitations: physical 13 (25), $p < 0.01$ (within-group comparisons relative to preoperatively), emotional 40 (46); mental health: 63 (25); vitality: 39 (25), $p < 0.01$ (within-group comparisons relative to preoperatively; pain: 45 (32), $p < 0.01$ (within-group comparisons relative to preoperatively); general health perceptions: 54 (24)<br>EQ-5D ($n = 17$): mobility: no problems 29%, problems 65%, confined to bed 6%; self-care: no problems 82%, some problems 12%, unable to 6%; usual activities: no problems 12%, $p < 0.01$ (within-group comparisons relative to preoperatively), some problems 53%, unable to 35%; pain/discomfort: none 29%, some 65%, extreme 6%; anxiety/depression: none 65%, some 29%, extreme 6%; health self-evaluation (maximum 100): 61 (16) |

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| | 3-month follow-up:<br>SF-36 ($n = 17$): physical functioning: 77 (23); social functioning: 83 (16); role limitations: physical 57 (45), emotional 69 (43); mental health: 77 (24); vitality: 64 (26); pain: 83 (17); general health perceptions: 43 (23)<br>EQ-5D ($n = 17$): mobility: no problems 53%, problems 47%, confined to bed 0%; self-care: no problems 88%, some problems 6%, unable to 6%; usual activities: no problems 65%, some problems 29%, unable to 6%; pain/discomfort: none 59%, some 41%, extreme 0%; anxiety/depression: none 82%, some 12%, extreme 6%; health self-evaluation (maximum 100): 61 (17)<br>Total population mean (SD):<br>1-month follow-up:<br>SF-36 ($n = 69$): physical functioning: 56.8; social functioning: 67.3; role limitations: physical 36.4, emotional 52.1; mental health: 71.3; vitality: 51.1; pain: 63.8; general health perceptions: 48.7<br>EQ-5D ($n = 69$): mobility: no problems 38.8%, problems 56.7%, confined to bed 4.5%; self-care: no problems 84.3%, some problems 12.8%, unable to 3%; usual activities: no problems 37.6%, some problems 44.7%, unable to 17.7%; pain/discomfort: none 50.9%, some 43.1%, extreme 6%; anxiety/depression: none 71%, some 24.5%, extreme 4.5%; health self-evaluation: 66.3<br>3-month follow-up:<br>SF-36 ($n = 69$): physical functioning: 71.7; social functioning: 85.3; role limitations: physical 62.3, emotional 76.5; mental health: 74; vitality: 63.2; pain: 86.8; general health perceptions: 58.1<br>EQ-5D ($n = 67$): mobility: no problems 52.3%, problems 46.3%, confined to bed 2% (EVAR); self-care: no problems 86.5%, some problems 10.5%, unable to 3%; usual activities: no problems 62.8%, some problems 32.7%, unable to 4.5%; pain/discomfort: none 59.8%, some 40.3%, extreme 0; anxiety/depression: none 80.5%, some 16.5%, extreme 3%; health self-evaluation: 65.5<br>Mean difference between populations:<br>1-month follow-up:<br>SF-36 ($n = 69$): physical functioning: 17; social functioning: 15; role limitations: physical 31, emotional 16; mental health: 11; vitality: 16; pain: 25; general health perceptions: 7<br>EQ-5D ($n = 69$): mobility: no problems 13%, problems 11%, confined to bed 2%; self-care: no problems 3%, some problems 1%, unable to 4%; usual activities: no problems 34%, some problems 11%, unable to 23%; pain/discomfort: none 29%, some 29%, extreme 0; anxiety/depression: none 8%, some 6%, extreme 2%; health self-evaluation: 7<br>3-month follow-up:<br>SF-36 ($n = 69$): physical functioning: 7; social functioning: 3; role limitations: physical 7, emotional 10; mental health: 4; vitality: 1; pain: 5; general health perceptions: 20<br>EQ-5D ($n = 67$): mobility: no problems 1%, problems 1%, confined to bed 2%; self-care: no problems 2%, some problems 6%, unable to 4%; usual activities: no problems 3%, some problems 5, unable to 2%; pain/discomfort: none 1%, some 1%, extreme 0%; anxiety/depression: none 2%, some 6%, extreme 4%; health self-evaluation: 6% |
| Length of hospital and ICU stay | Number of days in hospital for EVAR population: 5 days (2–21 days); number of hours in ICU for EVAR population: 19 hours (8–90 hours)<br>Number of days in hospital for open repair population: 11 days (8–50 days); number of hours in ICU for open repair population: 21 hours (16–360 hours) |
| Duration of surgery | Duration of surgery for EVAR population: 180 minutes (65–320 minutes)<br>Duration of surgery for open repair population: 180 minutes (120–270 minutes) |
| Length of stay for reintervention | Length of stay for EVAR population: not applicable; length of stay for open repair population: not applicable |
| Costs | Not reported |
| Analysis by type of device | No |
| Analysis by neck angulation | No |
| True randomisation | Unclear |

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| Adequate concealment of treatment allocation | Unclear |
| Outcome assessor blinded | Unclear |
| Baseline characteristics comparable between groups | Yes; aneurysm size and ASA slightly better in open repair group |
| Eligibility criteria reported | Yes |
| Withdrawals or exclusions accounted for | Yes |
| Power calculation reported | Yes |
| Intention to treat analysis | Yes |

**EVAR trial participants. Endovascular aneurysm repair versus open repair in patients with abdominal aortic aneurysm (EVAR trial 1): randomised controlled trial. *Lancet* 2005;365:2179–86[43,42,171,9,23,95]**

| | |
|---|---|
| Author (main publication) | EVAR trial participants 2005[43] |
| Study publications | Main publication EVAR trial participants 2005;[43] 30-day operative mortality results from EVAR trial participants 2004;[42] design and methodology Brown 2004;[9] device-specific results EVAR trial participants 2007;[95] survival by fitness EVAR trial participants 2007[23] |
| Study name | EVAR I |
| Country where study was performed | UK |
| Multicentre | Yes |
| Centre entry criteria for trial | Centre performed at least 20 EVAR procedures |
| Patient entry criteria for trial | Minimum age 60 years, no maximum age limit; aneurysm size: mean diameter at least 5.5 cm; suitable for open repair: yes; suitable for EVAR: yes; elective repair; emergency repair: tender aneurysms and contained ruptures eligible if at least 5.5 cm and suitable EVAR equipment available at short notice |
| Number of patients randomised | 1082 |
| Number of patients randomised to EVAR | 543 |
| Number of patients randomised to comparator | 539 |
| Criteria assessing fitness for surgery/EVAR/open repair | Fitness for EVAR: determined locally by the surgeon, radiologist, anaesthetist and cardiologist. Guidelines on cardiac, respiratory and renal status were provided<br>Fitness for open repair: determined locally by the surgeon, radiologist, anaesthetist and cardiologist. Guidelines on cardiac, respiratory and renal status were provided |
| Age of population | Mean (SD): 74 (6.0) years [EVAR 74.2 (6.0), open repair 74.0 (6.1)] |
| Gender | 91% male [EVAR 494 (91%), open repair 489 (91%)] |
| Aneurysm diameter | Mean (SD): 6.5 cm [EVAR 6.5 (0.9), open repair 6.5 (1.0)]<br>Measurement tool used: spiral CT scan or conventional CT combined with conventional angiography |
| Aneurysm anatomy | Not reported |
| Smoking history | Current smokers: 232 (21%) [EVAR 115 (21%), open repair 117 (22%)]; past smokers: 747 (69%) [EVAR 367 (68%), open repair 380 (70%)]; never smoked: 102 (9%) [EVAR 61 (11%), open repair 41 (8%)] |
| Diabetes | 111 (10%) [EVAR 49 (9%), open repair 62 (12%)] |
| Heart disease | 463 (43%) [EVAR 234 (44%), open repair 229 (43%)] |
| Hypertension | Not reported |
| Renal disease | Not reported |
| Respiratory disease | Not reported |

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| Fitness scores | Reported in reference 23. Analysis by fitness groups was based on 626 patients randomised to EVAR and 626 randomised to open repair up to 31 August 2004. Patients were classified as good, moderate or poor fitness based on modified Customized Probability Index scores. Good fitness 579 (301 EVAR, 278 open repair); moderate fitness 331 (160 EVAR, 171 open repair); poor fitness 338 (164 EVAR, 174 open repair); missing fitness 4 (1 EVAR, 3 open repair) |
| Body mass index (BMI) | Mean (SD): 26.4 kg/m$^2$ [EVAR 26.4 (4.6), open repair 26.4 (4.4)] |
| Dates of procedure | September 1999–1 July 2004 for main analysis. Additional patients recruited up to 31 August 2004 included in some analyses |
| Time lapse between randomisation and procedure | Median: 43 days (IQR 28–69); range: 28–70 days |
| Elective or emergency procedure | Elective: 512 (94% of randomised patients); emergency: 0 (0%) |
| Type of device (EVAR) | Zenith: 261 (51%) (based on $n = 512$; $n = 318$ in later analysis based on patients randomised up to August 2004); Talent: 167 (33%) (based on $n = 512$; $n = 187$ in later analysis based on patients randomised up to August 2004); Excluder: 36 (7%) (based on $n = 512$; $n = 37$ in later analysis based on patients randomised up to August 2004); Quantum or Teramed 10 (2%) (based on $n = 512$) |
| Graft type (EVAR) | Uni-iliac: 51 (10%) (based on $n = 512$); bi-iliac: 461 (90%) (based on $n = 512$) |
| Anaesthesia | Not reported |
| Open repair or non-surgical procedure | Open repair |
| Dates of procedure | September 1999–1 July 2004 for main analysis. Additional patients recruited up to 31 August 2004 included in some analyses |
| Time lapse between randomisation and procedure | Median: 35 days (IQR 19–55); range: 20–59 days |
| Elective or emergency procedure | Elective: 496 (92.0% of randomised patients); emergency: unclear [possibly 3 (<1%)] |
| Anaesthesia | Not reported |
| Intention to treat or per protocol | ITT: main analysis, including all randomised patients (EVAR 543, open repair 539). ITT analysis for 30-day mortality based on all randomised patients who underwent aneurysm repair (EVAR 531, open repair 516)<br>Per protocol: analysis for 30-day and in-hospital mortality included patients who received the allocated elective treatment, excluding emergency repairs and patients converted from EVAR to open repair during the primary procedure (512 EVAR, 496 open) |
| Method for generating measures of effect | Cox proportional hazards regression: used for all-cause and aneurysm-related mortality<br>Logistic regression: used for 30-day operative and in-hospital mortality |
| Covariates adjusted for | For all-cause mortality and aneurysm-related mortality: primary covariates: age, sex, forced expiratory volume in 1 second ($FEV_1$), AAA diameter, log (creatinine), statin use at baseline; secondary covariates: BMI, smoking status, systolic blood pressure, serum cholesterol concentrations<br>For 30-day operative mortality: age, sex, $FEV_1$, AAA diameter, log (creatinine), statin use at baseline, time between randomisation and surgery |
| Follow-up | Minimum follow-up: 1 year (at 31 December 2004)<br>Maximum follow-up: not reported (24% of patients followed up for 4 years as at 31 December 2004)<br>Median follow-up: 2.9 years (IQR 1.9–4.0) at December 2004 |

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| 30-day mortality | Number of EVAR patients (%) died: 9/531 (1.7%) ITT; 8/512 (1.6%) per protocol. Analysis by fitness groups (based on 626 patients randomised to EVAR up to 31 August 2004): all patients 10/610 (1.6%); good fitness 3/294 (1.0%); moderate fitness 4/155 (2.6%); poor fitness 3/160 (1.9%)<br>Number of comparator patients (%) died: 24/516 (4.7%) ITT; 23/496 (4.6%) per protocol. Analysis by fitness groups (based on 626 patients randomised to open repair up to 31 August 2004): good fitness 11/268 (4.1%); moderate fitness 6/162 (3.7%); poor fitness 8/163 (4.9%) |
| Aneurysm-related mortality at follow-up | All deaths within 30 days of any surgery for AAA unless over-ruled by postmortem findings or a separate procedure (unrelated to the aneurysm) took place between aneurysm repair and death and was identified as the cause of death. Deaths for which the underlying cause was attributed to ICD codes 1713–19 were also classified as aneurysm-related. Deaths within 30 days of any aneurysm surgery were categorised as procedure-related. Late complications of aneurysm repair (> 30 days after operation) were also classified as aneurysm-related procedure deaths<br>Number of EVAR patients died: 19/543 (3 before surgery, 9 within 30 days of surgery, 7 > 30 days after surgery). Analysis by fitness groups (based on 626 patients randomised to EVAR up to 31 August 2004): all patients 22/626; good fitness 8/301; moderate fitness 6/160; poor fitness 8/164<br>Number of comparator patients died: 34/539 (7 before surgery, 25 within 30 days of surgery, 2 > 30 days after surgery). Analysis by fitness groups (based on 626 patients randomised to EVAR up to 31 August 2004): all patients 36/626; good fitness 15/278; moderate fitness 7/171; poor fitness 14/174<br>Cumulative rate from Kaplan–Meier curve: EVAR 4%; open repair 7% (4-year point estimates).<br>HR: 0.55 (95% CI 0.31 to 0.96). Analysis by fitness groups (based on 626 patients randomised to EVAR and 626 randomised to open repair up to 31 August 2004): all patients 0.60 (95% CI 0.35 to 1.02); good fitness 0.49 (95% CI 0.21 to 1.15); moderate fitness 0.91 (95% CI 0.31 to 2.70); poor fitness 0.60 (95% CI 0.25 to 1.44)<br>Adjusted HR: adjusted for primary covariates: 0.55 (95% CI 0.31 to 0.96); adjusted for primary and secondary covariates: 0.51 (95% CI 0.29 to 0.92). Analysis by fitness groups (based on 626 patients randomised to EVAR up to 31 August 2004): all patients 0.61 (95% CI 0.36 to 1.04); good fitness 0.49 (95% CI 0.21 to 1.16); moderate fitness 1.00 (95% CI 0.33 to 3.00); poor fitness 0.50 (95% CI 0.21 to 1.23) |
| All-cause mortality at follow-up | Number of EVAR patients died: 100/543 (10 before surgery, 9 within 30 days of surgery, 81 > 30 days after surgery). Analysis by fitness groups (based on 626 patients randomised to EVAR up to 31 August 2004): all patients 138/626; good fitness 50/301; moderate fitness 38/160; poor fitness 50/164<br>Number of comparator patients died: 109/539 (13 before surgery, 25 within 30 days of surgery, 71 > 30 days after surgery). Analysis by fitness groups (based on 626 patients randomised to open repair up to 31 August 2004): all patients 145/626; good fitness 59/278; moderate fitness 37/171; poor fitness 49/174<br>Cumulative rate from Kaplan–Meier curve: EVAR 26%; open repair 29% (4-year point estimates). Analysis by fitness groups (based on 626 patients randomised to EVAR and 626 to open repair up to 31 August 2004): good fitness 22% (95% CI 18% to 26%); moderate fitness 26% (95% CI 21% to 32%); poor fitness 30% (95% CI 25% to 36%)<br>HR: 0.90 (95% CI 0.69 to 1.18). Analysis by fitness groups (based on 626 patients randomised to EVAR and 626 randomised to open repair up to 31 August 2004): all patients 0.93 (95% CI 0.74 to 1.18); good fitness 0.76 (95% CI 0.52 to 1.11); moderate fitness 1.11 (95% CI 0.71 to 1.75); poor fitness 1.02 (95% CI 0.68 to 1.51)<br>Adjusted HR: adjusted for primary covariates: 0.90 (95% CI 0.69 to 1.19); adjusted for primary and secondary covariates: 0.88 (95% CI 0.67 to 1.16). Analysis by fitness groups (based on 626 patients randomised to EVAR and 626 randomised to open repair up to 31 August 2004): all patients 0.94 (95% CI 0.74 to 1.18); good fitness 0.76 (95% CI 0.52 to 1.11); moderate fitness 1.13 (95% CI 0.72 to 1.79); poor fitness 0.97 (95% CI 0.65 to 1.45) |
| Rupture | Number of EVAR patients: three fatal ruptures within 30 days; one further in-hospital death from rupture; nine with graft rupture at follow-up (of 529 patients with repair completed)<br>Number of comparator patients: two fatal ruptures within 30 days; one further in-hospital death from rupture; none with graft rupture at follow-up (of 519 patients with repair completed)<br>Cumulative rate from Kaplan–Meier curve: not reported<br>HR: not reported |

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| Endoleak | Type I endoleak: 27 (17 with reintervention) at follow-up (of 529 EVAR patients with repair completed). Unspecified endoleak reported in 4 patients (4 with reintervention)<br>Type II endoleak: 79 (17 with reintervention) at follow-up (of 529 EVAR patients with repair completed)<br>Type III endoleak: 8 (4 with reintervention) at follow-up (of 529 EVAR patients with repair completed)<br>Cumulative rate from Kaplan–Meier curve: not reported<br>HR: not applicable |
| Device migration | 12 patients (7 with reintervention) at follow-up (of 529 EVAR patients with repair completed) |
| Reinterventions | Conversion to open repair (EVAR group only): 10/531 at 30 days (ITT)<br>Correction of endoleak (EVAR group only): 18/531 at 30 days (ITT)<br>Re-exploration of open repair (open group only): 15/516 at 30 days (ITT) (16 of 519 patients with open repair completed at follow-up)<br>Cumulative rate from Kaplan–Meier curve: EVAR 20%; open repair 6% (4-year point estimates)<br>HR: 2.7 (95% CI 1.8 to 4.1) |
| Major adverse events (30-day period) | Not reported |
| Quality of life (QoL) measure used | Medical Outcomes Study Short Form-36 (SF-36): physical component and mental component summary scores reported<br>EQ-5D |
| Baseline scores | EVAR population mean (SD): EQ-5D: 0.75 (0.22) (541 patients); SF-36 physical component summary: 39.92 (5.92) (533 patients), SF-36 mental component summary: 43.59 (6.79) (533 patients)<br>Comparator population mean (SD): EQ-5D: 0.74 (0.23) (531 patients); SF-36 physical component summary: 39.83 (5.90) (534 patients), SF-36 mental component summary: 43.95 (6.73) (534 patients)<br>Mean difference between populations: EQ-5D: 0.01 (SE 0.01); SF-36 physical component summary: 0.08 (SE 0.36), SF-36 mental component summary: –0.35 (SE 0.41) |
| Follow-up scores | EVAR population mean (SD): EQ-5D: 0–3 months 0.73 (0.21) (238 patients), 3–12 months 0.71 (0.25) (476 patients), 12–24 months 0.74 (0.24) (398 patients); SF-36 physical component summary: 0–3 months 37.82 (5.92) (225 patients), 3–12 months 37.77 (5.73) (466 patients), 12–24 months 38.17 (5.83) (359 patients); SF-36 mental component summary: 0–3 months 43.86 (7.02) (225 patients), 3–12 months 44.64 (6.67) (466 patients), 12–24 months 44.54 (6.43) (359 patients)<br>Comparator population mean (SD): EQ-5D: 0–3 months 0.67 (0.25) (245 patients), 3–12 months 0.73 (0.23) (414 patients), 12–24 months 0.75 (0.25) (371 patients); SF-36 physical component summary: 0–3 months 36.14 (5.45) (242 patients), 3–12 months 37.81 (5.84) (394 patients), 12–24 months 38.33 (5.78) (339 patients); SF-36 mental component summary: 0–3 months 44.04 (7.31) (242 patients), 3–12 months 44.18 (6.81) (394 patients), 12–24 months 44.76 (6.81) (339 patients)<br>Mean difference between populations:<br>EQ-5D: 0–3 months: crude 0.06 (SE 0.02), adjusted for baseline score 0.05 (SE 0.02); 3–12 months: crude –0.01 (SE 0.02), adjusted for baseline score –0.01 (SE 0.01); 12–24 months: crude –0.01 (SE 0.02), adjusted for baseline score –0.02 (SE 0.02)<br>SF-36 physical component summary: 0–3 months: crude 1.68 (SE 0.53), adjusted for baseline score 1.66 (SE 0.50); 3–12 months: crude –0.05 (SE 0.40), adjusted for baseline score 0.04 (SE 0.37); 12–24 months: crude –0.16 (SE 0.44), adjusted for baseline score –0.15 (SE 0.40)<br>SF-36 mental component summary: 0–3 months: crude –0.18 (SE 0.66), adjusted for baseline score –0.05 (SE 0.66); 3–12 months: crude 0.46 (SE 0.46), adjusted for baseline score 0.41 (SE 0.45); 12–24 months: crude –0.22 (SE 0.50), adjusted for baseline score –0.29 (SE 0.49) |

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| Length of hospital and ICU stay | Number of days in hospital for EVAR population: mean 10.3 (SD 17.8), median 7 (IQR 5–10); number of days in ICU for EVAR population: mean 0.7 (SD 3.8) (intensive therapy, intensive care or cardiac intensive care units)<br>Number of days in hospital for open repair population: mean 15.7 (SD 16.9), median 12 (IQR 9–16); number of days in ICU for open repair population: mean 2.4 (SD 5.9) (intensive therapy, intensive care or cardiac intensive care units) |
| Duration of surgery | Duration of surgery for EVAR population: median 180 minutes (IQR 140–215)<br>Duration of surgery for open repair population: median 200 minutes (IQR 155–240) |
| Length of stay for reintervention | Not reported |
| Costs | Costs for EVAR: primary hospital admission: main procedure £7569, hospital stay £3015, other £235, total £10,819; secondary procedures, adverse events, scans £2439; total including 4-year follow-up £13,258<br>Costs for comparator: primary hospital admission: main procedure £2811, hospital stay £6304, other £89, total £9204; secondary procedures, adverse events, scans £741; total including 4-year follow-up £9945 |
| Analysis by type of device | Reintervention rate, aneurysm-related mortality and all-cause mortality were compared for patients receiving Zenith ($n = 318$) and Talent ($n = 187$) endografts. There were no significant differences between devices for any outcome: adjusted HR 0.79 (95% CI 0.51 to 1.21) for reintervention, 0.88 (95% CI 0.29 to 2.65) for aneurysm-related mortality and 0.79 (95% CI 0.53 to 1.19) for all-cause mortality |
| Analysis by neck angulation | No |
| True randomisation | Yes |
| Adequate concealment of treatment allocation | Yes |
| Outcome assessor blinded | Yes; specifically stated for mortality[43] |
| Baseline characteristics comparable between groups | Yes |
| Eligibility criteria reported | Yes |
| Withdrawals or exclusions accounted for | Yes |
| Power calculation reported | Yes |
| Intention to treat analysis | Yes |

**EVAR trial participants. Endovascular aneurysm repair and outcome in patients unfit for open repair of abdominal aortic aneurysm (EVAR trial 2): randomised controlled trial. *Lancet* 2005;365:2187–92[46,9,43,95,23]**

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| Author (main publication) | EVAR trial participants 2005[46] |
| Study publications | Main publication EVAR trial participants 2005;[46] design and methodology Brown 2004;[9] device-specific results EVAR trial participants 2007;[95] survival by fitness EVAR trial participants 2007[23] |
| Study name | EVAR II |
| Country where study was performed | UK |
| Multicentre | Yes |
| Centre entry criteria for trial | Centre performed at least 20 EVAR procedures |
| Patient entry criteria for trial | Minimum age: 60 years, no maximum age limit; mean diameter: 5.5 cm or greater; suitable for open repair: no; suitable for EVAR: yes; emergency repair: tender aneurysms and contained ruptures eligible if at least 5.5 cm and suitable EVAR equipment available at short notice |
| Number of patients randomised | 338 |
| Number of patients randomised to EVAR | 166 |
| Number of patients randomised to comparator | 172 |
| Criteria assessing fitness for surgery/EVAR/open repair | Fitness for EVAR: tender aneurysms and contained ruptures eligible if at least 5.5 cm and suitable EVAR equipment available at short notice |
| Age of population | Mean (SD): 76.4 years (6.45) (based on *n* = 338) [76.8 (6.2) EVAR, 76.0 (6.7) non-surgical treatment]; based on *n* = 143: 77.3 (6.8) Zenith device, 75.4 (6.1) Talent |
| Gender | 288 (85%) male (based on *n* = 339) [141 (85%) EVAR, 147 (85%) non-surgical treatment]; based on *n* = 143: 98/109 (89.9%) Zenith device, 28/34 (82.4%) Talent] |
| Aneurysm diameter | Median: 6.4 cm EVAR, 6.3 cm non-surgical treatment; range: 6.0–7.4 cm EVAR, 6.0–7.0 cm non-surgical treatment<br>Measurement tool used: CT scan |
| Aneurysm anatomy | AAA tender at randomisation (based on *n* = 339): 12 patients (4%) [4 (2%) EVAR, 8 (5%) non-surgical treatment]<br>based on *n* = 143: AAA top neck diameter: 2.4 cm (SD 0.3) Zenith device, 2.4 cm (SD 0.4) Talent; AAA lower neck diameter: 2.6 cm (SD 0.3) Zenith, 2.5 cm (SD 0.5) Talent; AAA neck length: 2.8 cm (SD 1.5) Zenith, 2.8 cm (SD 1.0) Talent |
| Smoking history | Current smokers: 57 (17%) (based on *n* = 339) [29/166 (17%) EVAR, 28/172 (16%) non-surgical treatment]; 27 (19%) (based on *n* = 143) [25/109 (22.9%) Zenith, 2/34 (5.9%) Talent]<br>Past smokers: 259 (77%) (based on *n* = 339) [127/166 (77%) EVAR, 132/172 (77%) non-surgical treatment]; 107 (75%) (based on *n* = 143) [76/109 (69.7%) Zenith, 31/34 (91.2%) Talent]<br>Never smoked: 22 (6%) (based on *n* = 339) [10/166 (6%) EVAR, 12/172 (7%) non-surgical treatment]; 9 (6%) (based on *n* = 143) [8/109 (7.3%) Zenith, 1/34 (2.9%) Talent] |
| Diabetes | 47 (14%) |
| Heart disease | 233 (69%) |
| Hypertension | Not reported |

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| Renal disease | Not reported |
| Respiratory disease | Not reported |
| Fitness scores | Reported in reference 23. Fitness scores were assigned to patients randomised up to August 2004 (c.f. EVAR I). Mean CPI fitness score 10.0 (SD 11.3) for 404 patients (197 EVAR and 207 no intervention). Little difference between randomised groups (details not reported). Comparison of fitness – 179 patients underwent elective AAA repair in EVAR group and 60 patients in no intervention group: Student's *t*-test: EVAR 10.5 (SD 11.8), no intervention 6.3 (SD 9.6), $p = 0.014$ |
| Body mass index (BMI) | Mean (SD): 26.35 kg/m$^2$ (based on $n = 339$) [26.4 (4.9) EVAR, 26.3 (4.4) non-surgical treatment]; 26.85 (based on $n = 143$) [26.9 (5.0) Zenith, 26.8 (4.6) Talent] |
| Dates of procedure | September 1999–31 December 2003 (to August 2004 for extra patients included in some of the analyses) |
| Time lapse between randomisation and procedure | Median: 57 days (IQR 39–82) 150 patients randomised to EVAR; 163 days (IQR 78–477) 47 patients crossed over from non-surgical treatment group (35 had EVAR, 12 had open repair) |
| Elective or emergency procedure | Not reported |
| Type of device (EVAR) | Zenith: 86 (59) (based on $n = 150$; $n = 109$ in later analysis based on patients randomised up to August 2004); Talent: 31/150 (21%) ($n = 34$ in later analysis based on patients randomised up to August 2004); Excluder: 10/150 (7%); 9/150 (6%) AneuRx (Medtronic); 5/150 (3%) Quantum (Cordis, Johnson & Johnson, Waterloo, Belgium); 2/150 (1%) Bard device (Bard, New Jersey); 1/150 (< 1%) Anson Aorfix (Lambard Medical, Oxford, UK); 1/150 (< 1%) EVT (Guidant, Indianapolis); 1/150 (< 1%) Edwards Lifepath (Edwards Lifesciences, Switzerland) |
| Graft type (EVAR) | Uni-iliac: 14 (10%) (based on $n = 143$ in later analysis based on patients randomised up to August 2004) (7 using Zenith device and 7 using Talent device); bi-iliac: 131 (87%) based on $n = 150$, 127 (89%) based on $n = 143$ in later analysis based on patients randomised up to August 2004 (102 using Zenith device and 25 using Talent device) |
| Anaesthesia | Local: not explicitly reported in main publication, 66 (46%) based on $n = 143$ in later analysis based on patients randomised up to August 2004 (49 using Zenith device and 17 using Talent device)<br>General: 83/150 (55%), 73 (51%) based on $n = 143$ in later analysis based on patients randomised up to August 2004 (59 using Zenith device and 14 using Talent device); 27 (16%) (47 crossovers) |
| Open repair or non-surgical procedure | Non-surgical procedure (any relevant details) |
| Dates of procedure | September 1999–31 December 2003 (to August 2004 for extra patients included in some analyses) |
| Time lapse between randomisation and procedure | Not applicable |
| Elective or emergency procedure | Not applicable |
| Anaesthesia | Not applicable |
| Intention to treat or per protocol | Main analyses by ITT, as per predefined statistical analysis plan<br>Post hoc per protocol mortality analysis – patients excluded if they contravened their allocated treatment with censorship at the time of protocol violation |
| Method for generating measures of effect | Cox proportional hazards regression |
| Covariates adjusted for | Primary adjustments for age, sex, forced expiratory volume in 1 second (FEV1), AAA diameter, log (creatinine) and statin use. Secondary adjustments for variables in primary adjustment, plus BMI, smoking, systolic blood pressure and serum cholesterol (based on $n = 339$) |

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| Follow-up | Median follow-up: 2.4 years (IQR 1.6–3.6) at December 2004 |
| 30-day mortality | Number (%) of EVAR patients died: 13/150 (9%) (95% CI 5 to 15); number (%) of comparator patients died: 1/47 crossovers (2%) |
| Aneurysm-related mortality at follow-up | Definition of aneurysm-related mortality at follow-up: all deaths within 30 days of any surgery for AAA unless over-ruled by postmortem findings or a separate procedure (unrelated to the aneurysm) took place between aneurysm repair and death and was identified as the cause of death. Deaths for which the underlying cause was attributed to ICD codes I713–I9 were also classified as aneurysm-related. Deaths within 30 days of any aneurysm surgery were categorised as procedure-related. Late complications of aneurysm repair (> 30 days after operation) were also classified as aneurysm-related procedure deaths<br>Number of EVAR patients died: 20 (based on $n = 166$); based on $n = 143$: 7/109 (2.8 events per 100 person-years) Zenith, 3/34 (4.0 events per 100 person-years) Talent<br>Number of comparator patients died: 22<br>HR: 1.01 (95% CI 0.55 to 1.84, $p = 0.98$); post hoc comparing EVAR and non-surgical treatment: 1.67 (95% CI 0.72 to 3.86) up to 6 months after randomisation, 0.53 (95% CI 0.20 to 1.39) > 6 months after randomisation<br>Adjusted HR: primary adjusted (based on $n = 339$): 1.00 (95% CI 0.54 to 1.84, $p = 1.0$); secondary adjusted: 0.99 (95% CI 0.53 to 1.84, $p = 0.97$) |
| All-cause mortality at follow-up | Number of EVAR patients died: 74 patients (14 before EVAR) (based on $n = 166$); 46/109 (18.5 events per 100 person-years) Zenith, 18/34 (23.9 events per 100 person-years) Talent (based on $n = 143$)<br>Number of comparator patients died: 68 patients<br>Cumulative rate from Kaplan–Meier curve: EVAR 66%, non-surgical treatment 62% (4-year point estimates)<br>HR: 1.21 (95% CI 0.87 to 1.69, $p = 0.25$) ITT (based on $n = 339$); post hoc per protocol analysis:1.07 (95% CI 0.75 to 1.52, $p = 0.70$); post-hoc comparing EVAR and no intervention: 1.31 (95% CI 0.70 to 2.45) up to 6 months after randomisation, 1.18 (95% CI 0.80 to 1.73) > 6 months after randomisation<br>Adjusted HR: primary adjusted (based on $n = 339$):1.21 (95% CI 0.86 to 1.69, $p = 0.27$); secondary adjusted:1.24 (95% CI 0.88 to 1.75, $p = 0.22$) |
| Rupture | Number of EVAR patients: 9 prior to elective treatment; 1/178 patients (includes crossovers) graft rupture after successful treatment<br>Number of comparator patients: 23 [crude rupture rate 9 per 100 person-years (95% CI 6.0 to 13.5)] |
| Endoleak | Type I endoleak: 11/178 patients who received EVAR – not ITT (10 complications after EVAR)<br>Type II endoleak: 23/178 patients who received EVAR – not ITT (17 complications after EVAR)<br>Type III endoleak: 6/178 patients who received EVAR – not ITT (5 complications after EVAR) |
| Device migration | Number of patients: 2/178 patients who received EVAR – not ITT (1%) |
| Reinterventions | Correction of endoleak (EVAR group only): 14 patients (based on $n = 178$ who received EVAR – not ITT); 16 patients (based on $n = 143$): 5/109 (4.6%) type I – Zenith; 1/34 (2.9%) type I – Talent; 4/109 (3.7%) type II – Zenith; 0/34 type II – Talent; 3/109 (2.8%) type III – Zenith; 1/34 (2.9%) type III – Talent; 0/109 unspecified endoleak – Zenith; 2/34 (5.9%) unspecified – Talent<br>Graft rupture – 1 patient (based on $n = 178$ who received EVAR – not ITT); graft kinking – 1 patient; endotension – 1 patient; graft thrombosis – 5 patients; anastomotic aneurysm – 1 patient; technical problem on graft insertion – 1 patient; other surgery required – 8 patients<br>Based on $n = 143$: graft kinking 1/109 (0.9%) Zenith device; endotension 1/34 (2.9%) Talent; graft thrombosis: 1/109 (0.9%) Zenith, 1/34 (2.9%) Talent; other surgery (cardiac/abdominal or vascular): 5/109 (4.6%) Zenith, 2/34 (5.9%) Talent; other/unknown reintervention: 2/109 (1.8%) Zenith, 2/34 (5.9%) Talent<br>HR: reintervention rate – 11.5 per 100 person-years EVAR, 1.8 per 100 person-years non-surgical treatment; by 4 years: 26% EVAR, 4% non-surgical treatment, HR 5.8 (95% CI 2.4 to 14, $p < 0.0001$) |
| Major adverse events (30-day period) | Not reported |

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| Quality of life (QoL) measure used | Medical Outcomes Study Short Form-36 (SF-36)<br>EQ-5D |
| Baseline scores | EVAR population mean (SD): EQ-5D weighted index score: 0.58 (0.31) (164 patients); SF-36 physical component summary: 35.47 (6.63) (160 patients); SF-36 mental component summary: 45.13 (7.92) (160 patients)<br>Comparator population mean (SD): EQ-5D weighted index score: 0.63 (0.28) (171 patients); SF-36 physical component summary: 35.12 (6.23) (171 patients); SF-36 mental component summary: 46.31 (6.97) (171 patients)<br>Mean difference between populations: EQ-5D weighted index score: –0.05; SF-36 physical component summary: 0.35; SF-36 mental component summary: –1.18 |
| Follow-up scores | EVAR population mean (SD): EQ-5D weighted index score: 0–3 months: 0.57 (0.28), 3–12 months: 0.64 (0.28), 12–24 months: 0.65 (0.24); SF-36 physical component summary: 0–3 months: 33.96 (5.13), 3–12 months: 34.33 (6.10), 12–24 months: 34.54 (5.89); SF-36 mental component summary: 0–3 months: 45.76 (8.65), 3–12 months: 44.76 (7.21), 12–24 months: 45.36 (7.20)<br>Comparator population mean (SD): EQ-5D weighted index score: 0–3 months: 0.56 (0.29), 3–12 months: 0.60 (0.26), 12–24 months: 0.60 (0.30); SF-36 physical component summary: 0–3 months: 35.60 (5.70), 3–12 months: 35.12 (6.42), 12–24 months: 36.01 (6.92); SF-36 mental component summary: 0–3 months: 44.03 (SD 7.78), 3–12 months: 44.84 (7.85), 12–24 months: 44.67 (7.93)<br>Mean difference between populations:<br>EQ-5D weighted index score: 0–3 months: crude 0.01 (SE 0.05), adjusted for baseline score 0.03 (SE 0.05) (139 patients); 3–12 months: crude 0.04 (0.03), adjusted for baseline score 0.06 (0.03) (241 patients); 12–24 months: crude 0.05 (0.04), adjusted for baseline score 0.04 (0.04) (156 patients)<br>SF-36 physical component summary: 0–3 months: crude –1.64 (1.00), adjusted for baseline score –1.86 (0.88) (134 patients); 3–12 months: crude –0.78 (0.83), adjusted for baseline score –1.11 (0.77) (224 patients); 12–24 months: crude –1.47 (1.12), adjusted for baseline score –0.64 (1.04) (130 patients)<br>SF-36 mental component summary: 0–3 months: crude 1.73 (1.47), adjusted for baseline score 2.30 (1.38) (134 patients); 3–12 months: crude –0.08 (1.00), adjusted for baseline score 0.94 (0.95) (224 patients); 12–24 months: crude –0.70 (1.32), adjusted for baseline score 0.50 (1.29) (130 patients) |
| Length of hospital and ICU stay | Not reported |
| Duration of surgery | Not reported |
| Length of stay for reintervention | Not reported |
| Costs | Costs for EVAR: costs per patient of primary procedure and admission to hospital £11,016; over 4 years £13,632<br>Non-surgical treatment: costs per patient of primary procedure and admission to hospital £3518; over 4 years £4983 |
| Analysis by type of device | Reported in later publication.[95] Reintervention rate, aneurysm-related mortality and all-cause mortality were compared for patients receiving Zenith ($n = 109$) and Talent ($n = 34$) endografts. There were no significant differences between devices for any outcome: adjusted HR 0.69 (95% CI 0.29 to 1.62, $p = 0.391$) for reintervention, 0.94 (95% CI 0.21 to 4.27, $p = 0.939$) for AAA-related mortality and 0.85 (95% CI 0.45 to 1.60, $p = 0.616$) for all-cause mortality |
| Analysis by neck angulation | No |
| True randomisation | Yes |
| Adequate concealment of treatment allocation | Yes |
| Outcome assessor blinded | Yes for mortality and aneurysm-related mortality[43] |

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| Baseline characteristics comparable between groups | Yes, although slightly higher percentage in the no intervention group with history of cardiac disease (65% EVAR, 73% no intervention) |
| Eligibility criteria reported | Yes |
| Withdrawals or exclusions accounted for | Yes |
| Power calculation reported | Yes |
| Intention to treat analysis | Yes; in addition, post hoc per protocol analysis calculated |

**Hinchliffe RJ, Bruijstens L, MacSweeney ST, Braithwaite BD. A randomised trial of endovascular and open surgery for ruptured abdominal aortic aneurysm – results of a pilot study and lessons learned for future studies. *Eur J Vasc Endovasc Surg* 2006;32:506–13[47]**

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|---|---|
| Author (main publication) | Hinchliffe 2006[47] |
| Country where study was performed | UK, University Hospital Nottingham |
| Multicentre | No |
| Centre entry criteria for trial | Not reported; investigator-initiated single-centre trial |
| Patient entry criteria for trial | Minimum age 50 years; exclusion criteria included neck diameter > 3.2 cm and neck length < 0.5 cm; suitable for open repair: yes; suitable for EVAR: no (suitability for EVAR was not an entry criterion; patients randomised to EVAR but found to be unsuitable were given open repair); emergency repair: clinically suspected or radiologically confirmed rupture of infrarenal AAA.<br>Other patient exclusion criteria: no endovascular team available; full selection of emergency stent grafts not available; inability to give verbal or written consent; unconscious patient; allergy to radiological contrast, stainless steel or polyester; severe comorbidity that would preclude intensive care treatment following open repair; previous EVAR; women of childbearing potential not taking contraception; pregnant and lactating women |
| Number of patients randomised | 32 |
| Number of patients randomised to EVAR | 15 |
| Number of patients randomised to comparator | 17 |
| Criteria assessing fitness for surgery/EVAR/open repair | Fitness for EVAR: opinion of the operating surgeon. Absolute contraindications to EVAR: no evidence of aneurysm rupture; juxtarenal aneurysm; neck diameter > 3.2 cm; external iliac artery diameter < 0.6 cm. Relative contraindications to EVAR: proximal neck length < 1 cm; excessive thrombus in the proximal neck; common iliac artery length < 2.5 cm; heavily calcified iliac arteries<br>Fitness for open repair: opinion of the duty consultant vascular surgeon |
| Age of population | Median: EVAR 74 (IQR 68.8–79.5); open 80 (IQR 73.8–83.8) |
| Gender | 75% (24/32) male |
| Aneurysm diameter | Median 8.5 cm (IQR 8.0–10.0) in patients who had EVAR<br>Measurement tool used: CT scan |
| Aneurysm anatomy | In patients who had EVAR, median suprarenal diameter was 2.8 cm (IQR 2.5–3.1), neck length 1.5 cm (IQR 0.9–2.2) and neck diameter 2.6 cm (IQR 2.3–2.9) |
| Smoking history | Current smokers: 10/32 (31%); past smokers: 11/32 (34%); never smoked: 11/32 (34%) |
| Diabetes | Not reported |
| Heart disease | 8/32 (25%) |
| Hypertension | 13/32 (41%); measurement tool not reported |
| Renal disease | 3/32 (9%) |
| Respiratory disease | 3/32 (9%) with chronic obstructive airways disease |
| Fitness scores | Not reported; not applicable to this patient population |
| Body mass index (BMI) | Not reported |

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| Dates of procedure | 1 September 2002–31 December 2004 |
| Time lapse between randomisation and procedure | Median time from clinical diagnosis to operation: 75 minutes (IQR 64–126) |
| Elective or emergency procedure | Emergency: 13 (100%) (13/15 randomised patients underwent EVAR) |
| Type of device (EVAR) | All patients received a two-piece aorto-uni-iliac stent graft made with Gianturco stents with an uncovered suprarenal component |
| Graft type (EVAR) | Uni-iliac: 11 (100%) (of 13 patients who underwent EVAR, 1 was converted to open repair and 1 to axillobifemoral graft) |
| Anaesthesia | General: 13 (100%) |
| Open repair or non-surgical procedure | Open repair |
| Dates of procedure | 1 September 2002–31 December 2004 |
| Time lapse between randomisation and procedure | Median time from clinical diagnosis to operation: 100 minutes (IQR 46–138) |
| Elective or emergency procedure | Emergency: 15 (100%) (14/17 randomised patients underwent open repair and one patient crossed over from the EVAR group) |
| Anaesthesia | General: 15 (100%) |
| Intention to treat or per protocol | ITT: planned interim analysis reported |
| Method for generating measures of effect | Not applicable |
| Covariates adjusted for | Not reported |
| Follow-up | Not reported |
| 30-day mortality | 8/15 (53%) EVAR (ITT); perioperative mortality of those undergoing EVAR was 6/13 (46%)<br>9/17 (53%) open repair (ITT); perioperative mortality of those undergoing open repair was 6/14 (43%) |
| Aneurysm-related mortality at follow-up | Not reported |
| All-cause mortality at follow-up | Not reported |
| Rupture | Not reported; not applicable as all patients had ruptured AAA |
| Endoleak | Type I endoleak: 2 |
| Device migration | Not applicable |
| Reinterventions | Conversion to open repair: 2; correction of endoleak (EVAR group only): 2; reexploration of open repair (open group only): 3 within the first 24 hours |
| Major adverse events (30-day period) | Number (%) of cardiac events for EVAR patients: 5 (45%) (based on 11 patients who survived procedure); all events were moderate<br>Number (%) of cardiac events for open repair patients: 7 (58%) (based on 12 patients who survived procedure); 6 events were moderate and 1 severe<br>Number (%) of EVAR patients suffering stroke: 1 (9%) (based on 11 patients who survived procedure) with severe cerebrovascular complications<br>Number (%) of open repair patients suffering stroke: 0 (0%) |

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| Quality of life (QoL) measure used | Not applicable |
| Baseline scores | Not applicable |
| Follow-up scores | Not applicable |
| Length of hospital and ICU stay | Number of days in hospital for EVAR population: median 10 days (IQR 6–28)<br>Number of days in hospital for open repair population: median 12 days (IQR 4–52) |
| Duration of surgery | Duration of surgery for EVAR population: median 160 minutes (IQR 150–234)<br>Duration of surgery for open repair population: median 150 minutes (IQR 141–204) |
| Length of stay for reintervention | Not reported |
| Costs | Not reported |
| Analysis by type of device | Not applicable |
| Analysis by neck angulation | No |
| True randomisation | Unclear |
| Adequate concealment of treatment allocation | No |
| Outcome assessor blinded | Unclear |
| Baseline characteristics comparable between groups | Yes |
| Eligibility criteria reported | Yes |
| Withdrawals or exclusions accounted for | Yes |
| Power calculation reported | Yes. Power calculation required 100 patients for trial to have 90% power to detect a reduction in mortality from 50% with open repair to 25% with EVAR |
| Intention to treat analysis | Yes |

**Soulez G, Thérasse E, Monfared AA, Blair JF, Choiniére M, Elkouri S, *et al*. Pain and quality of life assessment after endovascular versus open repair of abdominal aortic aneurysms in patients at low risk. *J Vasc Interv Radiol* 2005;16:1093–100[45]**

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|---|---|
| Author (main publication) | Soulez 2005[45] |
| Country where study was performed | Canada |
| Multicentre | Not reported |
| Centre entry criteria for trial | Not reported |
| Patient entry criteria for trial | Maximum age 80 years; aneurysm size: non-ruptured AAA measuring at least 5 cm in diameter, located below the renal arteries |
| Number of patients randomised | 40 |
| Number of patients randomised to EVAR | 20 |
| Number of patients randomised to comparator | 20 |
| Criteria assessing fitness for surgery/EVAR/open repair | Fitness for EVAR: cardiac evaluation according to American College of Cardiology/American Heart Association Guidelines. Fit if New York Heart Association (NYHA) cardiac score 1/2; left ventricular ejection fraction > 30%; chronic obstructive pulmonary disease with max. expiratory volume > 1.5 l/s; serum creatinine level < 150 μmol/l; no contraindication to anticoagulants or to contrast material; and myocotic aneurysm. Morphological exclusion criteria: proximal aortic aneurysm neck > 30 mm in diameter or < 15 mm in length; angulation of proximal aneurysm neck > 60°; iliac arteries with marked tortuosity or < 7 mm in diameter; AAA extending into both external iliac arteries, dominant inferior mesenteric artery, and a large accessory renal artery ≥ 3 mm with its origin within the aneurysm<br>Fitness for open repair (specify measurement tool if reported): cardiac evaluation according to American College of Cardiology/American Heart Association Guidelines. Fit if NYHA cardiac score 1/2; left ventricular ejection fraction > 30%; chronic obstructive pulmonary disease with max. expiratory volume > 1.5 l/s; serum creatinine level < 150 μmol/l; no contraindication to anticoagulants or to contrast material; and myocotic aneurysm. Morphological exclusion criteria: proximal aortic aneurysm neck > 30 mm in diameter or < 15 mm in length; angulation of proximal aneurysm neck > 60°; iliac arteries with marked tortuosity or < 7 mm in diameter; AAA extending into both external iliac arteries, dominant inferior mesenteric artery, and a large accessory renal artery ≥ 3 mm with its origin within the aneurysm |
| Age of population | Mean (SD): 70.5 years [70.3 (6.4) EVAR, 71.2 (7.6) open repair] |
| Gender | 39 patients (98%) male [19/20 (95%) EVAR, 20/20 (100%) open repair] |
| Aneurysm diameter | Mean (SD): 5.2 cm [5.31 cm (0.48) EVAR, 5.09 cm (1.61) open repair]<br>Measurement tool used: spiral CT |
| Aneurysm anatomy | Neck angulation: aneurysm neck not > 60° |
| Smoking history | Current smokers: 8 (20%) [5 (25%) EVAR, 3 (15%) open repair]; past smokers: 27 (68%) [14 (70%) EVAR, 13 (65%) open repair]; never smoked: 5 (12%) [1 (5%) EVAR, 4 (20%) open repair] |
| Diabetes | Yes: 6 (15%) [1 (5%) EVAR, 5 (25%) open repair] |
| Heart disease | Yes: 27 (68%) [13 (65%) EVAR, 14 (70%) open repair] |
| Hypertension | Yes: 18 (45%) [8 (40%) EVAR, 10 (50%) open repair] |
| Renal disease | Yes: creatinine clearance < 50 ml/min: 6 (15%) [1 (5%) EVAR, 5 (25%) open repair] |

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| Respiratory disease | Yes: 9 (22%) [6 (30%) EVAR, 3 (15%) open repair] |
| Fitness scores | Cardiac status: NYHA class 1: 18 (45%) [10 (50%) EVAR, 8 (40%) open repair]; NYHA class 2: 22 (55%) [10 (50%) EVAR, 12 (60%) open repair] |
| Body mass index (BMI) | Mean (SD): 17 (42%) BMI > 30 kg/m$^2$ [8 (40%) > 30 EVAR, 9 (45%) > 30 open repair] |
| Dates of procedure | September 1998–July 2002 |
| Time lapse between randomisation and procedure | Not reported |
| Elective or emergency procedure | Not reported; probably elective |
| Type of device (EVAR) | Talent: 20 patients (100%) |
| Graft type (EVAR) | Bi-iliac: 20 (100%) EVAR patients |
| Anaesthesia | Local: 1 (5%) EVAR; regional: 1 (5%) EVAR; general: 18 (90%) EVAR |
| Open repair or non-surgical procedure | Open repair |
| Dates of procedure | September 1998–July 2002 |
| Time lapse between randomisation and procedure | Not reported |
| Elective or emergency procedure | Elective |
| Anaesthesia | General: 20 (100%) |
| Intention to treat or per protocol | Not reported |
| Method for generating measures of effect | Not applicable |
| Covariates adjusted for | Not reported |
| Follow-up | Minimum follow-up: 9 months EVAR, 12 months open repair; maximum follow-up 48 months EVAR, 48 months open repair; median follow-up: range 9–48 months EVAR, 12–48 months open repair |
| 30-day mortality | Number (%) of EVAR patients died: 0%; number (%) of comparator patients died: 0% |
| Aneurysm-related mortality at follow-up | Number (%) of EVAR patients died: 1 (5%); number (%) of comparator patients died: 0%<br>Cumulative rate from Kaplan–Meier curve: $p = 0.80$; log-rank test (includes survival and reinterventions) |
| All-cause mortality at follow-up | Not reported |
| Rupture | Number of EVAR patients (%): 1 (5%); number of comparator patients (%): 0% |
| Endoleak | Type I endoleak: 2 (10%) EVAR; type II endoleak: 3 (15%) EVAR |
| Device migration | Not reported |
| Reinterventions | Correction of endoleak (EVAR group only): 4 patients<br>Re-exploration of open repair (open group only): 1 patient – operative treatment on an emergency basis with graft limb thrombosis, 7 months after surgery |
| Major adverse events (30-day period) | Not reported |

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| Quality of life (QoL) measure used | Medical Outcomes Study Short Form-36 (SF-36) |
| Baseline scores | Not reported |
| Follow-up scores | EVAR population mean (SD): follow-up at 24 months: physical functioning: 50; role physical: 48; bodily pain: 56; general health perceptions: 58; energy/vitality: 48; social functioning: 60; role emotional: 58; mental health: 58<br>Comparator population mean (SD): follow-up at 24 months: physical functioning: 62; role physical: 66; bodily pain: 62; general health perceptions: 66; energy/vitality: 62; social functioning: 78; role emotional: 76; mental health: 70 |
| Length of hospital and ICU stay | Number of days in hospital for EVAR population: 4.5 (SD 2.4) days; number of hours in ICU for EVAR population: 3.4 (SD 11.3) hours<br>Number of days in hospital for open repair population: 11.5 (SD 8.1) days; number of hours in ICU for open repair population: 38.5 (SD 33) hours |
| Duration of surgery | Duration of surgery for EVAR population: 110 (SD 32) minutes<br>Duration of surgery for open repair population: 127 (SD 50) minutes |
| Length of stay for reintervention | Length of stay for EVAR population: 1.7 (SD 5.7) days (aneurysmal disease)<br>Length of stay for open repair population: 3 (SD 8) days (aneurysmal disease) |
| Costs | Not reported |
| Analysis by type of device | Not applicable |
| Analysis by neck angulation | No |
| True randomisation | Unclear |
| Adequate concealment of treatment allocation | Unclear |
| Outcome assessor blinded | Unclear |
| Baseline characteristics comparable between groups | Yes |
| Eligibility criteria reported | Yes |
| Withdrawals or exclusions accounted for | Yes |
| Power calculation reported | No |
| Intention to treat analysis | Unclear |

## Data extraction tables – registries

**Ashley S, Ridler B, Baker S, Kinsman R, Prytherch D, Vascular Society of Great Britain and Ireland. *Fourth National Vascular Database report 2004*. Henley-on-Thames: Dendrite Clinical Systems; 2005[16]**

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| Author | Ashley 2005[16] |
| Registry name | National Vascular Database |
| Country/countries included in registry | UK |
| Multicentre | 59 centres (listed on page 12) |
| Centre entry criteria | Not reported |
| Patient entry criteria | Suitable for open repair: yes |
| Number of patients treated with comparator | Open infrarenal aortic aneurysm surgery: 4545 |
| Criteria assessing fitness for surgery/EVAR/open repair | Not reported |
| Age of population | Mean 72.5 years (SE 0.12) |
| Gender | 3756/4449 patients (84.4%) male |
| Aneurysm diameter | Range: majority of unruptured AAAs: 5.0–7.9 cm; majority of ruptured AAAs: 6.0–8.9 cm;<br>< 5 cm: 88 patients; 5–5.9 cm: 775; 6–6.9 cm: 1113; 7–7.9 cm: 588; 8–8.9 cm: 404; 9–9.9 cm: 136; > 9.9 cm: 109; unspecified: 1251 |
| Measurement tool | Not reported |
| Aneurysm anatomy | Not reported |
| Smoking history | Not reported |
| Diabetes | Not reported |
| Heart disease | Cardiac history: myocardial infarction (MI) ≤ 6 months ago; MI > 6 months ago; heart failure ≤ 1 month ago; heart failure > 1 month ago; orthopnoea; angina – controlled/on exertion; angina – uncontrolled/at rest: 2011 patients (44.2%) |
| Hypertension | Not reported |
| Renal disease | Not reported |
| Respiratory disease | Not reported |
| Fitness scores | Not reported |
| Body mass index (BMI) | Not reported |
| Open repair or non-surgical procedure | Open repair |
| Dates of procedure | Registered 1999–31 March 2004 |
| Time lapse between registration and procedure | Not reported |
| Elective or emergency procedure | Elective: unruptured AAA: 1734 patients; crude mortality rate: 6.3% (95% CI 5.2 to 7.6%)<br>Emergency: non-elective unruptured AAA: 423; crude mortality rate: 9.2% (95% CI 6.7 to 12.5%)<br>Unspecified: unruptured AAA: 743; crude mortality rate: 6.7% (95% CI 5.1 to 8.8%) |

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| Anaesthesia | Local: (0.02%); regional: epidural: 34 (0.7%); general: general: 2461 (54.1%), general + epidural: 1503 (33.1%); total: 3964 (87.2%); unspecified: 546 (12%) |
| Intention to treat or per protocol | Not reported |
| Follow-up | Not reported |
| 30-day mortality | Crude mortality rate: unruptured: 6.8% (95% CI 5.9 to 7.8%); ruptured: 41% (95% CI 37.7 to 44.3%); total: 14.8% (95% CI 13.7 to 16.0%) |
| Aneurysm-related mortality at follow-up | Not reported |
| All-cause mortality at follow-up | Not reported |
| Rupture | Not reported |
| Endoleak | Not applicable |
| Device migration | Not applicable |
| Reinterventions | Not reported |
| Major adverse events (30-day period) | Not reported |
| Quality of life measure used | Not reported |
| Baseline scores | Not reported |
| Follow-up scores | Not reported |
| Length of hospital and ICU stay | Average: unruptured: 13 days (SE 0.21); ruptured: 15.2 days (SE 0.55) |
| Duration of surgery | < 30 minutes: 9/2326 patients (0.4%); 30–59 minutes: 28 patients (1.2%); 60–89 minutes: 145 patients (6.2%); 90–119 minutes: 356 patients (15.3%); 120–149 minutes: 506 patients (21.8%); 150–179 minutes: 456 patients (19.6%); 180–209 minutes: 363 patients (15.6%); 210–239 minutes: 154 patients (6.6%); 240–269 minutes: 136 patients (5.8%); 270–299 minutes: 65 patients (2.8%); 300–329 minutes: 41 patients (1.8%); 330–359 minutes: 22 patients (1%); > 359 minutes: 45 patients (1.9%); unspecified: 2219 patients |
| Length of stay for reintervention | Not reported |
| Costs | Not reported |

**EUROSTAR collaborators.** ***Progress report: endografts in current use only (Anaconda, Ancure, AneuRx, Endologix, Excluder, Fotron, Lifepath, Talent & Zenith)*****. Eindhoven, the Netherlands: EUROSTAR Data Registry Centre; 2006**[54,55]

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|---|---|
| Author | EUROSTAR collaborators 2006[54] |
| Registry name | EUROSTAR |
| Country/countries included in registry | Europe |
| Multicentre | 177 centres |
| Centre entry criteria | Sufficient expertise in centre, which is involvement in a series of at least 10 stent graft procedures for AAA; throughput of at least 10 patients/year; and patients managed by collaborating vascular surgeons and international radiologists |
| Patient entry criteria | Minimum age 21 years<br>Aneurysm size (specify, e.g. diameter, length or not reported): patients with aortic aneurysms < 3 cm with iliac aneurysms, pseudoaneurysms or previous (conventional/endovascular) grafts were excluded; aortic aneurysms measuring 3–4 cm included if they were associated with iliac aneurysms<br>Anatomic configuration suitable for stented tube or bifurcated prosthesis: infrarenal neck length ≥ 1.5 cm and width < 2.5 cm; iliac artery angulation < 90° (or correctable angulation); common iliac artery < 1.2 cm in diameter and non-stenotic (> 0.6 cm diameter after balloon dilatation, if necessary)<br>Elective repair (specify relevant details): elective AAA operation, without symptoms of rupture or expansion |
| Number of patients treated with EVAR | 8345 |
| Criteria assessing fitness for surgery/EVAR/open repair | Not reported |
| Age of population | Mean age at operation: 72.5 (SD 7.8) years; range: 34–100 years |
| Gender | 93.2% male |
| Aneurysm diameter | Mean transverse diameter: 5.84 cm (SD 1.16 cm); range: 3.0–17.2 cm |
| Measurement tool | CT scan, intra-arterial digital subtraction arteriogram (IA-DSA), MRI or intravascular ultrasound (IVUS) |
| Aneurysm anatomy | Mean aortic neck angulation: 55.8° (SD 35.8°); range: 4–240° |
| Smoking history | Current smokers: 1885/8107 patients (23.3%) (SVS/ISCVS risk score 2/3); past smokers: 2252/8107 patients (27.8%) (SVS/ISCVS risk score 1; none current, but smoked in last 10 years); never smoked: 3970/8107 patients (49%) (SVS/ISCVS risk score 0; no tobacco use or none for last 10 years) |
| Diabetes | Yes: 1045/8126 patients (12.9%) |
| Heart disease | Cardiac: 4957/8141 patients (60.9%) (SVS/ISCVS risk score 1–3); carotid: 1436/8038 patients (17.9%) (SVS/ISCVS risk score 1–3) |
| Hypertension | Yes: 5337/8142 patients (65.5%) (SVS/ISCVS risk score 1–3) |
| Renal disease | Yes: 1155/8066 patients (14.3%) creatinine 1.5–3.0 mg/dl, creatinine clearance 30–50 ml/min (SVS/ISCVS risk score 1); 252/8066 patients (3.1%) creatinine 3.0–6.0 mg/dl, creatinine clearance 15–30 ml/min (SVS/ISCVS risk score 2); 131/8066 (1.6%) patients creatinine > 6.0 ml/dl, creatinine clearance < 15 ml/min or on dialysis or with transplant |
| Respiratory disease | Pulmonary: 3419/8079 patients (42.3%) (SVS/ISCVS risk score 1–3) |

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| Fitness scores | ASA I: 635/8288 (7.7%); ASA II: 3467/8288 patients (41.8%); ASA III: 3643/8288 patients (44%); ASA IV: 543/8288 (7%) (indicating that a patient is too frail to justify open repair); 2037/8345 patients (24.4%) unfit for open repair when factors other than ASA (e.g. obesity, previous laparotomies were considered) |
| Body mass index (BMI) | 2186/8248 patients (26.5%) considered obese |
| Dates of procedure | Not reported; data related to 'older' devices excluded from the report |
| Time lapse between registration and procedure | Not reported |
| Type of device (EVAR) | Zenith: 3290/8304 patients (39.6%); Talent: 2349/8304 patients (28.3%); Excluder: 1155/8304 patients (13.9%); AneuRx: 984/8304 patients (11.8%); Endologix: 161/8304 patients (1.9%); Lifepath: 134/8304 patients (1.6%); Fortron: 92/8304 patients (1.1%); EVT: 73/8304 patients (0.9%); Anaconda: 66/8304 patients (0.8%) |
| Graft type (EVAR) | Bi-iliac: 7497/8345 patients (89.8%)<br>Straight: 156/8345 patients (1.9%); tapered: 561/8345 patients (6.7%); unknown: 131/8345 patients (1.6%) |
| Anaesthesia | Local: 515/8345 patients (6.2%); regional: 2091/8345 patients (25.1%); general: 5739/8345 patients (68.8%) |
| Intention to treat or per protocol | ITT according to reference 55 |
| Follow-up | Minimum follow-up: 30-days; maximum follow-up: 96 months (8 years) |
| 30-day mortality | 190/8345 patients (2.3%) |
| Aneurysm-related mortality at follow-up | Not reported |
| All-cause mortality at follow-up | 789/8345 patients (9.5%) late mortality (i.e. after 30 days, up to 96 months)<br>Cumulative rate from Kaplan–Meier curve: 979; proportion deaths: 0.390; proportion surviving: 0.610; survival SE: 0.036 |
| Rupture | 30-days: 4; follow-up: 37; total: 41 (0.5%)<br>Cumulative rate from Kaplan–Meier curve: freedom from rupture at 84 months: total number: 41; proportion of ruptures: 0.031; proportion rupture free: 0.969 (SE 0.011) |
| Endoleak | Cumulative rate from Kaplan–Meier curve: 30-days: 496; follow-up: 827; total: 1323; proportion endoleaks: 0.325; proportion endoleak free: 0.675 (SE 0.021) |
| Device migration | 30-days: 6; follow-up: 148; total: 154 |
| Reinterventions | Conversion to open repair: 30-day conversion: 75 patients (0.9%); follow-up conversion: 102 patients (1.2%); total: 177 patients (2.1%)<br>Cumulative rate from Kaplan–Meier curve:<br>Freedom from secondary interventions at 84-month follow-up: total number: 749; proportion of secondary interventions: 0.18; proportion of secondary intervention free survival: 0.82 (SE 0.013)<br>Freedom from secondary interventions and death at 96-month follow-up: total number: 1606; proportion of death and secondary interventions: 0.48; proportion of secondary intervention free survival: 0.52 (SE 0.022) |
| Major adverse events (30-day period) | Number of cardiac events: 272<br>Number of patients suffering stroke: cerebral: 57<br>Systemic complications from operation to discharge: pulmonary: 174; renal: 181; total systemic complications: 928 |

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|---|---|
| Quality of life measure used | Not reported |
| Baseline scores | Not reported |
| Follow-up scores | Not reported |
| Length of hospital and ICU stay | 8169 patients (98 patients with hospital stay < 1 day): mean: 5.9 (SD 8.1) days; range: 0–183 days |
| Duration of surgery | 8065 patients: mean duration: 130 (SD 58) minutes; range: 25–720 minutes |
| Length of stay for reintervention | Not reported |
| Costs | Not reported |

**Thomas SM, Beard JD, Ireland M, Ayers S. Results from the prospective Registry of Endovascular Treatment of Abdominal Aortic Aneurysms (RETA): mid term results to five years. *Eur J Vasc Endovasc Surg* 2005;29:563–70[56,58,57]**

| | |
|---|---|
| Author | Thomas 2005;[56] additional data from undated Vascular Surgical Society report[57] and Thomas 2001[58] |
| Registry name | RETA |
| Country/countries included in registry | UK |
| Multicentre | 41 centres submitted cases |
| Centre entry criteria | Not reported (UK members of the Vascular Surgical Society and British Society of Interventional Radiology registered cases on a voluntary basis) |
| Patient entry criteria | Age limitations: not reported; aneurysm size: not reported; suitable for open repair: yes (patients classified as fit or unfit for open repair were included); suitable for EVAR: yes; elective repair: no criteria specified but majority of cases were elective repair of asymptomatic (83.2%) or symptomatic (13.5%) AAA; emergency repair: no criteria specified but small numbers of cases were repair of acute non-ruptured (1.6%) or stable ruptured (1.4%) AAA |
| Number of patients treated with EVAR | 1000 cases from 41 centres |
| Criteria assessing fitness for surgery/EVAR/open repair | Fitness for EVAR: based on aneurysm morphology but no specific details reported<br>Fitness for open repair: fit: patients in ASA grades I–III; unfit: patients in ASA grades IV or V specified as unfit for open repair because of comorbidity, also those classified as 'fit' by ASA grade but with other features making them high risk (unsuitable) for open repair |
| Age of population | Median: 73 years; range: 44–93 years |
| Gender | Percentage male (total population): 90% (based on 514 cases)[57] |
| Aneurysm diameter | Median 6 cm; 42% classified as large aneurysms (> 6 cm); range: 2.5–15 cm |
| Measurement tool | Not reported |
| Aneurysm anatomy | Median infrarenal neck length: 2.4 cm |
| Smoking history | Not reported |
| Diabetes | Not reported |
| Heart disease | Not reported |
| Hypertension | Not reported |
| Renal disease | Not reported |
| Respiratory disease | Not reported |
| Fitness scores | Not reported; 22.7% (226/997) were classified as unfit for open repair; 699/997 were classified as fit for open repair (ASA I–III) |
| Body mass index (BMI) | Not reported |
| Dates of procedure | January 1996–March 2000 |
| Time lapse between registration and procedure | Not reported |
| Type of device (EVAR) | Zenith: 144 (14.4%); Talent: 117 (11.7%); Excluder: 19 (1.9%); Ancure: 60 (6%); AneuRx: 254 (25.4%); Bard device: 11 (1.1%); Baxter device: 1 (0.1%); Gianturco-Dacron ('homemade'): 123 (12.3%); Gianturco-PTFE ('homemade'): 17 (1.7%); Hol B Endostent: 1 (0.1%); Ivanchev-Malmo ('homemade'): 2 (0.2%); Palmaz/PTFE ('homemade'): 64 (6.4%); Stenford: 2 (0.2%); Vanguard: 174 (17.4%); missing: 11 (1.1%) |

| | |
|---|---|
| Graft type (EVAR) | Uni-iliac: 263 (26.4%); bi-iliac: 702 (70.4%); aortic tube: 32 (3.2%); missing data: 3 |
| Anaesthesia | Regional: 52/993 (5.2%); general: general alone 908/993 (91.4%), general and regional 32/993 (3.2%) |
| Follow-up | Minimum follow-up: 30 days; maximum follow-up: 5 years<br>Return rates for requested follow-up data: 87% at 1 year; 77% at 2 years; 65% at 3 years; 52% at 4 years; 51% at 5 years<br>Mean 3.1 years |
| 30-day mortality | 58/992 (5.8%) |
| Aneurysm-related mortality at follow-up | Fatal rupture at 1 year: 6 (0.8%); fatal rupture at 2 years: 3 (0.8%) |
| All-cause mortality at follow-up | At 1 year: 86/721 (11.9%), missing 7, at risk 728*; 1–2 years: 37/369 (10%), missing 1, at risk 372; 2–3 years: 13/162 (8%), at risk 161; 3–4 years: 5/63 (7.9%), at risk 65<br>*at end of follow-up period[57]<br>Published paper reports 11% mortality in year 1 and rates of 10%, 7%, 10% and 8% at 2, 3, 4 and 5 years post procedure[56] |
| Rupture | Rupture during deployment: 3 (0.3%)[57]<br>Cumulative rate from Kaplan–Meier curve: 2% at 5-year follow-up[56] |
| Endoleak | Type I endoleak: proximal 54 within 30 days;[56] distal 19 within 30 days[56]<br>Type II endoleak: 44 within 30 days[56]<br>Type III endoleak: 15 within 30 days[56]<br>Cumulative rate from Kaplan–Meier curve: freedom from endoleak: 88% at 1 year, 80% at 2 years, 76% at 3 years, 71% at 4 years, 68% at 5 years[56] |
| Device migration | 9 (0.9%) with device migration requiring conversion to open repair (immediate outcome); new cases at 1-year follow-up: 3/631; new cases at 2-year follow-up: 9/331; new cases at 3-year follow-up: 0/148; new cases at 4-year follow-up: 2/56[57] |
| Reinterventions | Conversion to open repair: immediate outcome: 33/996 (3.3%)<br>Correction of endoleak: some included under 'conversion to open repair'; totals not clearly reported<br>Cumulative rate from Kaplan–Meier curve: freedom from reintervention: 87% at 1 year, 77% at 2 years, 70% at 3 years, 65% at 4 years, 62% at 5 years[56] |
| Major adverse events (30-day period) | Number of cardiac events: 42 (4.2%) myocardial infarction/arrhythmia/left ventricular failure[57]<br>Number of patients suffering stroke: 15 (1.5%) cerebrovascular accident/confusion/paraplegia[57]<br>Cumulative rate from Kaplan–Meier curve: 30-day rates:[56] any complication: 272/976 (27.8%); technical complication: 55/976 (5.6%); wound complications: 78/976 (8%); renal failure: 40/976 (4.1%); colonic ischaemia: 6/976 (0.6%); other medical complication: 147/976 (15.1%) |
| Quality of life measure used | Not applicable |
| Baseline scores | Not applicable |
| Follow-up scores | Not applicable |
| Length of hospital and ICU stay | Median: 6 days (range 3 to > 30)[57] |
| Duration of surgery | Median: 150 minutes (range 30–540 minutes)[57] |
| Length of stay for reintervention | Not reported |
| Costs | Not reported |

## Data extraction tables – risk models

**Biancari F, Hobo R, Juvonen T. Glasgow Aneurysm Score predicts survival after endovascular stenting of abdominal aortic aneurysm in patients from the EUROSTAR registry. *Br J Surg* 2006;93:191–4[59,55]**

| | |
|---|---|
| Author | Biancari 2006[59] |
| Country where study was performed | 160 centres in Europe |
| Type of study | Evaluation/validation of existing risk assessment algorithm Glasgow Aneurysm Score (GAS) |
| Registry | Dates enrolled and/or treated: October 1996–March 2005<br>EUROSTAR |
| Number of patients | 5498 patients: 59.5% co-existing myocardial disease; 5.7% cerebrovascular disease; 18.2% renal disease<br>1833 GAS < 74.4; 1832 GAS < 74.4–83.6; 1833 GAS > 83.6 |
| Age of population | Median age: 72.7 years (IQR 67.3–77.7 years) |
| Gender | 94.1% male |
| Aneurysm diameter | Median aortic diameter 5.6 cm (IQR 5.1–6.3 cm)<br>Measurement tool used: CT scan and intra-arterial digital subtraction angiography (DSA) |
| Type of device (EVAR) | Zenith: 1916 patients (34.8%); Talent: 1557 (28.3%); Excluder: 737 (13.4%); AneuRX: 907 patients (16.5%); Lifepath: 119 (2.2%); Powerlink (Endologix): 92 (1.7%); Fortron: 77 (1.4%); EVT: 69 (1.3%); Anaconda: 24 (0.4%) |
| Graft type (EVAR) | Not reported |
| Anaesthesia | Not reported |
| Risk factor(s) used in model and definitions | Composite risk score: GAS: risk score = (age in years) + (7 points for myocardial disease) + (10 points for cerebrovascular disease) + (14 points for renal disease). Myocardial disease refers to previously documented myocardial infarction and/or ongoing angina pectoris. Cerebrovascular disease refers to all grades of stroke and includes transient ischaemic attack. Renal disease refers to a history of acute or chronic renal failure and/or a creatinine level above 133 μmol/l and/or creatinine clearance below 50 ml/min. An SVS/ISCVS risk score of 1 or more |
| Definition of outcomes | No definition provided |
| Follow-up period | 1, 3, 6, 12, 18 and 24 months, and annually thereafter (median follow-up: 18 months, IQR 6–24 months) |
| Methods of analysis | Univariate analysis was carried out using the chi-squared test for categorical data. The Mann–Whitney test was used for univariate analysis of the distribution of the GAS in subgroups. Receiver operator characteristic (ROC) curves were used to evaluate the performance of the GAS and to identify its best cut-off value in predicting immediate postoperative death. Multivariate logistic regression with backward selection was used to determine independent associations of risk factors with 30-day mortality rate. Kaplan–Meier analysis with log-rank test and multivariate Cox proportional hazards regression analysis with backward selection was used to estimate the influence of different variables on long-term outcome ($p < 0.05$ considered statistically significant) |
| 30-day mortality | Aneurysm size: area under ROC curve: 0.65 (95% CI 0.60 to 0.70)<br>Composite risk score: multivariate analysis showed GAS independently predicted postoperative death ($p < 0.001$). ROC curve showed GAS with area under curve of 0.70 (95% CI 0.66 to 0.74, $p < 0.001$) for predicting postoperative death. Best cut-off value 86.6 (sensitivity 56.1%, specificity 76.2%, accuracy 75.6%, positive predictive value 6.4%, negative predictive value 98.4%) |
| Aneurysm-related mortality at follow-up | No risk factors investigated |

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|---|---|
| All-cause mortality at follow-up | Composite risk score: multivariate analysis showed overall survival differed significantly among GAS tertiles (i.e. < 74.4, 74.4–83.6, > 83.6) ($p < 0.001$); 5-year overall survival rate for patients with GAS > 83.6 = 65.2% |
| Reintervention | No risk factors investigated |
| Endoleak | No risk factors investigated |
| Study sample adequately described | Yes |
| Included risk variables clearly defined | Yes |
| Covariates considered to build the multivariate model | Yes |
| Interactions between variables explored | Yes |
| Continuous variables handled appropriately | Unclear |
| More than 10 events per included variable | Yes |
| Confidence intervals or other measures of uncertainty presented | Yes |

**Boult M, Maddern G, Barnes M, Fitridge R. Factors affecting survival after endovascular aneurysm repair: results from a population based audit. *Eur J Vasc Endovasc Surg* 2007;34:156–62[60,92]**

| | |
|---|---|
| Author | Boult 2007;[60] additional data from Boult 2006[92] |
| Country where study was performed | Australia |
| Type of study | Development of risk assessment algorithm<br>Specific risk factors following EVAR |
| Registry | Dates enrolled and/or treated: 1 November 1999–16 May 2001<br>Australian national audit of EVAR |
| Number of patients | 961 |
| Age of population | Mean (SD): 75.0 (6.9) years |
| Gender | 86% male |
| Aneurysm diameter | Mean (SD): men 5.8 (1.05) cm; women 5.5 (0.9) cm |
| Type of device (EVAR) | Zenith: 788 (82%); Talent: 37 (3.8%); Excluder: 43 (4.5%); Ancure: 14 (1.5%); AneurRx: 67 (7%); Vanguard: 7 (0.7%)<br>Numbers calculated from reported % |
| Graft type (EVAR) | Not reported |
| Anaesthesia | Not reported |
| Risk factor(s) used in model and definitions | Age; gender; smoking status (no definition provided); graft configuration and device type (no definition provided); ASA fitness rating I, II, III or IV; pre-existing conditions: number of comorbidities (used for reinterventions/complications); fitness for open procedure: ASA score was used to assess patient fitness for surgery;[92] renal function (creatinine): normal: pre-operative creatinine $< 120$ μmol/l, mid-range: pre-operative creatinine 120–159 μmol/l, high: pre-operative creatinine $\geq 160$ μmol/l; aneurysm size: maximum aneurysm diameter; aortic neck and aneurysm angle: aortic neck angle $\geq 45°$ was considered significant angulation; aortic neck length: $< 1.5$ cm, $\geq 1.5$ cm; sac size change (preoperative and postoperative); modified White's grading scale (based on aortic neck length, aortic neck angulation, thrombus present or absent, aortic sac angulation, iliac artery tortuosity and iliac artery calcification); patient type (public or private) |
| Definition of outcomes | Aneurysm-related mortality: death occurring within 30 days of the primary procedure or any secondary procedure, or death from an aneurysm-related cause (e.g. rupture) occurring at any time following the primary procedure<br>All-cause mortality: includes perioperative mortality (within 30 days) and deaths during follow-up<br>Endoleak: type I or II endoleaks<br>Reintervention: any reintervention or complication detected prior to discharge or at follow-up |
| Follow-up period | Annual follow-up due to continue until 2008. Mortality data were obtained in November 2004, September 2005 and August 2006. Follow-up for complications/reinterventions and endoleaks was 6 months to 5 years[92] |
| Methods of analysis | Logistic regression was used to determine which factors affected the likelihood of complications or reinterventions following EVAR and which aneurysm-related factors affected the occurrence of type I and II endoleaks. Stratified right-censored Kaplan–Meier survival analysis was used to determine which factors significantly influenced all-cause and aneurysm-related mortality using the log-rank (Mantel–Haenszel) test. Parametric survival analysis with log-exponential distribution was used to calculate expected 3- and 5-year survival |
| 30-day mortality | No risk factors investigated |

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|---|---|
| Aneurysm-related mortality at follow-up | Age: no significant effect<br>Gender: no significant effect<br>Smoking status: no significant effect<br>Graft configuration and device type: no significant effect<br>ASA: significant effect ($p = 0.002$)<br>Renal function (creatinine): no significant effect<br>Aneurysm size: significant effect ($p = 0.001$)<br>Aortic neck and aneurysm angle: no significant effect<br>Aortic neck length: significant effect of infrarenal neck length ($p = 0.001$)<br>Infrarenal neck diameter: no significant effect |
| All-cause mortality at follow-up | Age: significant effect on 3-year and 5-year survival ($p < 0.001$)<br>Gender: no significant effect on 3-year and 5-year survival<br>Smoking status: no significant effect on 3-year and 5-year survival<br>Graft configuration and device type: no significant effect of graft configuration or device brand on 3-year and 5-year survival<br>ASA: significant effect on 3-year and 5-year survival ($p < 0.001$)<br>Renal function (creatinine): significant effect on 3-year and 5-year survival ($p < 0.001$)<br>Aneurysm size: significant effect on 3-year and 5-year survival ($p < 0.001$)<br>Aortic neck and aneurysm angle: infrarenal neck diameter: significant effect on 3-year survival ($p = 0.006$) but not for 5-year survival ($p = 0.093$), no significant effect of infrarenal neck length or aneurysm angle<br>Aortic neck length: no significant effect on 3-year and 5-year survival<br>Other (give details): combination of ASA score, maximum aneurysm diameter, age and serum creatinine. Predicted 3-year and 5-year survival probabilities are presented for combinations of ASA II, III or IV; maximum diameter 5, 5.8 or 7.4 cm; age 70, 77 or 83 years; and creatinine 85 or 125 μmol/l |

| | | **Age (years)** | | | | | |
|---|---|---|---|---|---|---|---|
| | | **70 years** | | **77 years** | | **83 years** | |
| | | **Creatinine (μmol/l)** | | | | | |
| **ASA** | **Max. diameter** | **85** | **125** | **85** | **125** | **85** | **125** |
| ***Predicted survival at 3 years*** | | | | | | | |
| ASA II | 5 cm | 91% | 88% | 87% | 84% | 83% | 79% |
| | 5.8 cm | 89% | 87% | 86% | 82% | 81% | 77% |
| | 7.4 cm | 87% | 83% | 82% | 77% | 77% | 71% |
| ASA III | 5 cm | 86% | 82% | 81% | 76% | 75% | 69% |
| | 5.8 cm | 84% | 80% | 78% | 73% | 72% | 66% |
| | 7.4 cm | 80% | 75% | 73% | 67% | 66% | 59% |
| ASA IV | 5 cm | 79% | 74% | 72% | 65% | 64% | 56% |
| | 5.8 cm | 76% | 71% | 69% | 62% | 60% | 52% |
| | 7.4 cm | 71% | 64% | 62% | 54% | 53% | 44% |

| | | | Age (years) | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | 70 years | | 77 years | | 83 years | |
| | | | Creatinine (μmol/l) | | | | | |
| | ASA | Max. diameter | 85 | 125 | 85 | 125 | 85 | 125 |
| | ***Predicted survival at 5 years*** | | | | | | | |
| | ASA II | 5 cm | 85% | 81% | 79% | 74% | 74% | 68% |
| | | 5.8 cm | 83% | 79% | 77% | 72% | 71% | 64% |
| | | 7.4 cm | 79% | 74% | 72% | 65% | 64% | 57% |
| | ASA III | 5 cm | 77% | 72% | 70% | 63% | 62% | 54% |
| | | 5.8 cm | 75% | 69% | 67% | 60% | 58% | 50% |
| | | 7.4 cm | 69% | 62% | 60% | 52% | 50% | 41% |
| | ASA IV | 5 cm | 67% | 60% | 57% | 49% | 48% | 39% |
| | | 5.8 cm | 64% | 56% | 53% | 45% | 43% | 34% |
| | | 7.4 cm | 56% | 48% | 45% | 36% | 34% | 25% |
| Reintervention | Age: significant association between increased age and complications or reinterventions: prior to discharge $p < 0.001$; at follow-up $p < 0.001$<br>Gender: no significant effect<br>Smoking status: no significant effect<br>Graft configuration and device type: no significant effect of device type<br>ASA: significant association between higher ASA score and complications or reinterventions: prior to discharge $p < 0.001$; at follow-up $p < 0.001$<br>Pre-existing conditions: significant association between higher number of pre-existing conditions and complications or reintervention: prior to discharge ($p < 0.001$); at follow-up ($p = 0.001$)<br>Fitness for open procedure: significant association between unsuitability for open repair and complications or reinterventions: prior to discharge ($p < 0.001$); at follow-up ($p < 0.001$)<br>Aneurysm size: significant association between larger aneurysm size and complications or reinterventions: prior to discharge $p = 0.031$; at follow-up $p = 0.006$<br>Aortic neck and aneurysm angle: significant association between greater aneurysm angulation and complications or reinterventions: prior to discharge no significant effect; at follow-up $p = 0.037$<br>Aortic neck length: no significant effect of infrarenal neck length and diameter<br>No significant effect of modified White's grading scale | | | | | | | | |
| Endoleak | Age: no significant effect<br>Gender: male gender: type I endoleaks: no significant effect; type II endoleaks: significant association ($p = 0.007$)<br>Smoking status: no significant effect<br>Device type: no significant effect<br>ASA: higher ASA score: type I endoleaks: no significant effect; type II endoleaks: significant association ($p = 0.039$).<br>Pre-existing conditions: no significant effect<br>Fitness for open procedure: no significant effect<br>Aneurysm size: larger aneurysm diameter: type I endoleaks: significant association ($p = 0.025$); type II endoleaks: no significant effect<br>Aortic neck and aneurysm angle: aortic neck angulation > 45°: type I endoleaks: significant association ($p = 0.026$); type II endoleaks: no significant effect<br>Aortic neck length: shorter infrarenal neck length: type I endoleaks: significant association ($p = 0.012$); type II endoleaks: no significant effect<br>No significant effect of modified White's grading scale | | | | | | | | |

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|---|---|
| Study sample adequately described | Yes; relevant details included in both papers |
| Included risk variables clearly defined | Yes; most were self-explanatory or definitions were given |
| Covariates considered to build the multivariate model | Yes; variables considered subjective, ambiguous or with highly incomplete data were not entered into statistical analyses |
| Interactions between variables explored | Unclear; nothing reported about this |
| Continuous variables handled appropriately | Unclear; few details of statistical methodology reported |
| More than 10 events per included variable | No; large numbers of variables included in logistic regression models[92] |
| Confidence intervals or other measures of uncertainty presented | No; most modelling results reported as *p*-values only |

**Brewster DC, Jones JE, Chung TK, Lamuraglia GM, Kwolek CJ, Watkins MT, *et al*. Long-term outcomes after endovascular abdominal aortic aneurysm repair – the first decade. *Ann Surg* 2006;244:426–38[61]**

| | |
|---|---|
| Author | Brewster 2006[61] |
| Country where study was performed | USA |
| Type of study | Specific risk factors following EVAR |
| Case series | Case series: 7 January 1994–31 December 2005<br>Name of centre: Massachusetts General Hospital (MGH) |
| Number of patients | 873 |
| Age of population | Mean (SD): 75.7 (7.6) years; range: 49–99 years<br>73 (8.4%) patients were aged ≤ 65 whereas 233 (26.8%) were aged ≥ 80 |
| Gender | 81.4% male |
| Aneurysm diameter | Mean (SD): 5.68 (1.06) cm |
| Type of device (EVAR) | Zenith: 183 (21%); Talent: 0; Excluder: 110 (12.6%); AneuRx: 294 (33.7%); EVT/Ancure: 90 (10.3%); Vanguard: 39 (4.5%); Lifepath: 15 (1.7%); MGH custom made: 123 (14.1%); Hybrid custom made: 5 (0.6%); Quantum: 9 (1%); Powerlink: 5 (0.6%) |
| Graft type (EVAR) | Uni-iliac: 65 (7.4%); bi-iliac: 785 (90%); tube 23 (2.6%) |
| Anaesthesia | Local: a small number (unstated); regional: > 90% (exact percentage not stated); general: a small number < 10% (not stated) |
| Risk factor(s) used in model and definitions | Increased age (not defined)<br>Device type: use of first generation (no longer generally available) or current device<br>Renal insufficiency (not defined)<br>Large AAA is defined as ≥ 5.5 cm<br>Family history of aneurysmal disease: postoperative factors: endoleak related to reintervention; reintervention related to aneurysm-related mortality |
| Definition of outcomes | Aneurysm-related mortality: defined as death from any cause within 30 days of the primary EVAR procedure, death within ≤ 30 days of any secondary reintervention or surgical conversion, or any death due to aneurysm rupture or device complication. Secondary reintervention: late conversion to open repair |
| Follow-up period | At discharge or within 1 month of EVAR, 6 and 12 months and yearly thereafter. Mean follow up was 2.25 years with follow-up for 5 or more years available for 20% of the patients |
| Methods of analysis | Subgroup comparisons of demographic data were assessed using two-tailed *t*-tests for continuous variables and chi-squared tests for categorical data. Late outcomes were assessed using Kaplan–Meier life table analysis, and the log-rank test was used when comparing subgroups. Stepwise logistic regression was performed to identify variables associated with study end points (multivariate analysis). No details of covariates reported |
| 30-day mortality | Renal dysfunction was a predictor of mortality risk (OR 18.4, $p = 0.003$) (not clear that this was from multivariate analysis) |
| Aneurysm-related mortality at follow-up | OR 7.1 (no CI presented) for renal insufficiency<br>OR 1.1 (no CI presented) for large perioperative AAA size; small aneurysm 2 (0.5%), large aneurysm 25 (5.7%), $p < 0.001$<br>OR 9.5 (no CI presented) for family history of aneurysmal disease |
| All-cause mortality at follow-up | OR 1.1 for increased age (unspecified)<br>OR 14.1 (no CI presented) for renal dysfunction<br>OR 1.1 (no CI presented) for large aneurysm size |

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| Reintervention | Says female gender a predictor of late conversion to open repair but no OR reported<br>Secondary endovascular reinterventions: OR 1.5 (no CI presented) for use of early generation devices<br>Late conversion to open repair: OR 5.3 (no CI presented) for use of early generation devices |
| Endoleak | No risk factors investigated |
| Study sample adequately described | Yes |
| Included risk variables clearly defined | No |
| Covariates considered to build the multivariate model | Not reported; none of the covariates reported |
| Interactions between variables explored | Unclear |
| Continuous variables handled appropriately | Unclear |
| More than 10 events per included variable | No |
| Confidence intervals or other measures of uncertainty presented | No |

**Brown LC, Greenhalgh RM, Howell S, Powell JT, Thompson SG. Patient fitness and survival after abdominal aortic aneurysm repair in patients from the UK EVAR trials. *Br J Surg* 2007;94:709–16[23]**

| | |
|---|---|
| Author | Brown (EVAR trial participants) 2007[23] |
| Country where study was performed | UK |
| Type of study | Evaluation/validation of existing risk assessment algorithm |
| Trial | Patients randomised September 1999–August 2004<br>EVAR I and EVAR II RCT |
| Number of patients | EVAR I: 1252 (626 randomised to EVAR and 626 to open repair); EVAR II: 404 |
| Age of population | Not reported |
| Gender | Not reported |
| Aneurysm diameter | Not reported |
| Type of device (EVAR) | Not reported; reported in other publications[95] |
| Graft type (EVAR) | Not reported |
| Anaesthesia | Not reported |
| Risk factor(s) used in model and definitions | Age: investigated as a risk factor for 30-day mortality in EVAR I (post hoc analysis): < 71 years, 71–77 years, > 77 years<br>Composite risk score: patients were classified as good, moderate or poor fitness based on a modified Customized Probability Index score (based on cardiovascular disease, respiratory dysfunction, renal dysfunction and medication status). The modification was the exclusion of cerebrovascular disease and by weighting severe aortic stenosis and arrhythmia as risk factors similarly to ischaemic heart disease |
| Definition of outcomes | 30-day mortality: not specifically defined in paper<br>Aneurysm-related mortality: not specifically defined in paper<br>All-cause mortality: not specifically defined in paper |
| Follow-up period | 4 years; mean follow-up 3.8 years (minimum 1.3 years) |
| Methods of analysis | Logistic regression was used to analyse 30-day operative mortality for all patients in EVAR I who had elective aneurysm repair within their randomised group. An interaction term between randomised group and fitness score was included to assess whether the benefit of EVAR varied according to fitness level. Crude and adjusted (for age, sex and aneurysm diameter at randomisation) ORs were calculated. A post hoc analysis was performed to investigate any interaction between age (kept as a continuous variable) and randomised group. Cox regression was used to analyse aneurysm-related and all-cause mortality for all patients in EVAR I within their randomised groups. Crude and adjusted (for age, sex and aneurysm diameter at randomisation) HRs were calculated. An interaction term between randomised group and fitness score was included to assess whether the benefit of EVAR varied according to fitness level. Kaplan–Meier estimates were used to present all-cause mortality curves truncated at 4 years of follow-up by fitness group within EVAR I |
| 30-day mortality | Age: EVAR I trial data only; no significant effect of age on benefit of EVAR over open repair in EVAR I<br>Age < 71 years: OR 0.33 (95% CI 0.03 to 3.26); age 71–77 years: OR 0.32 (95% CI 0.08 to 1.19); > 77 years: OR 0.41 (95% CI 0.15 to 1.11); $p = 0.657$ (test for interaction)<br>Composite risk score: modified Customized Probability Index score: no significant effect of Customized Probability Index fitness group on benefit of EVAR over open repair in EVAR I<br>Good fitness: adjusted OR 0.23 (95% CI 0.06 to 0.84), $p = 0.027$; moderate fitness: adjusted OR 0.70 (95% CI 0.19 to 2.56), $p = 0.586$; poor fitness: adjusted OR 0.29 (95% CI 0.07 to 1.17), $p = 0.082$; $p$-value for test of interaction for adjusted model = 0.363 |

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| Aneurysm-related mortality at follow-up | Composite score: modified Customized Probability Index score: mortality rates were 0.9/100 person-years for good fitness, 1.2/100 person-years for moderate fitness and 1.6/100 person-years for poor fitness<br>There was no significant effect of fitness group on benefit of EVAR over open repair in EVAR 1 (no interaction between fitness score and randomised group)<br>Crude HRs: good fitness: 0.49 (95% CI 0.21 to 1.15), $p = 0.100$; moderate fitness: 0.91 (95% CI 0.31 to 2.70), $p = 0.862$; poor fitness: 0.60 (95% CI 0.25 to 1.44), $p = 0.254$<br>Adjusted HRs: good fitness: 0.49 (95% CI 0.21 to 1.16), $p = 0.106$; moderate fitness: 1.00 (95% CI 0.33 to 3.00), $p = 0.999$; poor fitness: 0.50 (95% CI 0.21 to 1.23), $p = 0.131$; $p$-value for test of interaction for adjusted model = 0.371 |
| All-cause mortality at follow-up | Composite risk score: modified Customized Probability Index score: mortality rates were 5.3/100 person-years for good fitness, 7.7/100 person-years for moderate fitness and 9.9/100 person-years for poor fitness<br>There was no significant effect of fitness group on benefit of EVAR over open repair in EVAR 1 (no interaction between fitness score and randomised group)<br>Crude HRs: good fitness: 0.76 (95% CI 0.52 to 1.11), $p = 0.151$; moderate fitness: 1.11 (95% CI 0.71 to 1.75), $p = 0.643$; poor fitness: 1.02 (95% CI 0.68 to 1.51), $p = 0.941$<br>Adjusted HRs: good fitness: 0.76 (95% CI 0.52 to 1.11), $p = 0.151$; moderate fitness: 1.13 (95% CI 0.72 to 1.79), $p = 0.595$; poor fitness: 0.97 (95% CI 0.65 to 1.45), $p = 0.873$; $p$-value for test of interaction for adjusted model = 0.281 |
| Reintervention | No risk factors investigated |
| Endoleak | No risk factors investigated |
| Study sample adequately described | Yes |
| Included risk variables clearly defined | Yes |
| Covariates considered to build the multivariate model | Yes |
| Interactions between variables explored | Yes; use of specific interaction terms reported |
| Continuous variables handled appropriately | Yes; e.g. age kept as a continuous variable |
| More than 10 events per included variable | Yes |
| Confidence intervals or other measures of uncertainty presented | Yes |

**Bush RL, Johnson ML, Hedayati N, Henderson WG, Lin PH, Lumsden AB. Performance of endovascular aortic aneurysm repair in high-risk patients: results from the Veterans Affairs National Surgical Quality Improvement Program. *J Vasc Surg* 2007;45:227–33[62]**

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| Author | Bush 2007[62] |
| Country where study was performed | USA |
| Type of study | Specific risk factors following EVAR |
| Registry | Enrolled between 1 May 2001 and 31 December 2004<br>Enrolled onto the National Surgical Quality Improvement Program (NSQIP) organised through the Department of Veterans Affairs (VA) |
| Number of patients | 2368 (1580 open repair, 788 EVAR) |
| Age of population | Overall mean: 72.2 years [EVAR: 72.9 (SD 6.7), open repair: 71.8 (SD 6.4); ($p < 0.001$)] |
| Gender | Total male: 2352 (99.3%) [EVAR: 1568 (99.2%), open repair: 784 (99.4%)] |
| Aneurysm diameter | Not reported |
| Type of device (EVAR) | Not reported |
| Graft type (EVAR) | Not reported |
| Anaesthesia | Not reported |
| Risk factor(s) used in model and definitions | Minimum criteria for entry into study included age ≥ 60 years; ASA classification III or IV<br>Pre-existing conditions: comorbid conditions, including history of cardiac, respiratory or hepatic disease, cardiac revascularisation and low serum albumin (< 3.4 g/l)<br>Renal function: elevated creatinine ≥ 2.0 mg/dl) based on Revised Cardiac Risk Index |
| Definition of outcomes | 30-day mortality obtained from NSQIP database; 1-year mortality calculated using death dates obtained from VA Beneficiary Identification Record Locator System (BIRLS) and VA Patient Treatment File (PTF). Perioperative complications: adverse cardiac events, renal dysfunction, pulmonary complications, wound complications, neurological complications, postoperative bleeding requiring transfusion, and graft failure (a return to the operating room – NSQIP guideline) |
| Follow-up period | 2-year follow-up |
| Methods of analysis | All clinical outcomes were tested for association with type of AAA repair and with the presence of the six additional high-risk comorbidities. The effect of type of operation performed was then tested for its unique association with the morbidity and mortality outcomes (30-day, 1-year, any complication) after adjusting for the number of high-risk comorbidities and 20 additional demographic and clinical covariates, using multivariable logistic regression models. Models assessed for goodness of fit by Hosmer–Lemeshow statistic and for discrimination by the c-index. Kaplan–Meier analysis and log-rank tests assessed time to death (all-cause mortality only) |
| 30-day mortality | Association of type of surgery with outcomes (adjusted for number of high-risk conditions and additional covariates): EVAR (30-day mortality): OR 0.65 (95% CI 0.42 to 1.03, $p = 0.067$)<br>No significant association between highest-risk cohort (ASA IV) and 30-day mortality rate ($p = 0.48$), or highest-risk cohort (ASA IV) and 1-year mortality rate ($p = 0.17$) |
| Aneurysm-related mortality at follow-up | No risk factors investigated |
| All-cause mortality at follow-up | 1-year mortality for type of procedure: EVAR: OR 0.68 (95% CI 0.51 to 0.91, $p = 0.0094$)<br>Kaplan–Meier analysis: survival advantage in EVAR patients compared with open repair for 2-year follow-up (log-rank test $\chi^2 = 5.23$, $p = 0.0222$) |
| Reintervention | No risk factors investigated |

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| Endoleak | No risk factors investigated |
| Study sample adequately described | Yes |
| Included risk variables clearly defined | Yes |
| Covariates considered to build the multivariate model | Not reported; unclear |
| Interactions between variables explored | Unclear |
| Continuous variables handled appropriately | Yes |
| More than 10 events per included variable | Yes |
| Confidence intervals or other measures of uncertainty presented | Yes |

**Buth J. Endovascular repair of abdominal aortic aneurysms. Results from the EUROSTAR registry. EUROpean collaborators on Stent-graft Techniques for abdominal aortic Aneurysm Repair. *Semin Interv Cardiol* 2000;5:29–33[63]**

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| Author | Buth 2000[63] |
| Country where study was performed | 90 centres in 15 European countries |
| Type of study | Specific risk factors following EVAR |
| Registry | Dates enrolled and/or treated: January 1994–July 1999<br>EUROSTAR registry |
| Number of patients | 1892 (362 patients treated before September 1996 were recorded retrospectively and the remainder prospectively) |
| Age of population | Mean: 70 years; range: 37–90 years |
| Gender | 91% male |
| Aneurysm diameter | Median 5.6 cm; range: 2.8–15 cm |
| Type of device (EVAR) | Zenith: 0%; Talent: 13% (246/1892 calculated); Excluder: 3% (57/1892 calculated); Vanguard: 42% (795/1892 calculated); Stentor: 17% (322/1892 calculated); AneuRx: 17% (322/1892 calculated); Cook: 4% (76/1892 calculated); EVT: 3% (57/1892 calculated); other: 1% (19/1892 calculated) |
| Graft type (EVAR) | Aorto-uni-iliac device 2% (38/1892 calculated); modular bifurcation device 89% (1684/1892 calculated); one-piece bifurcation device 3% (57/1892 calculated); aorto-aortic straight tube endograft 6% (114/1892 calculated) |
| Anaesthesia | Not reported |
| Risk factor(s) used in model and definitions | Age: categorised as ≤ 75 or > 75 years<br>Gender: female<br>ASA medical risk class (I–IV) |
| Definition of outcomes | Early mortality: mortality within 30 days. Early endoleak: endoleak detected by angiogram at the end of the procedure or within the first month |
| Follow-up period | Outcomes within 30 days of procedure |
| Methods of analysis | Paper states that multivariate analysis was performed but methods not reported |
| 30-day mortality | Significant association between ASA class III and increased 30-day mortality (OR 2.3)<br>Significant association between ASA class IV and increased 30-day mortality (OR 6.5) |
| Aneurysm-related mortality at follow-up | No risk factors investigated |
| All-cause mortality at follow-up | No risk factors investigated |
| Reintervention | No risk factors investigated |
| Endoleak | Significant association between age > 75 years and occurrence of early endoleak (OR 1.9)<br>Significant association between female gender and occurrence of early endoleak (OR 1.7) |
| Study sample adequately described | Yes |
| Included risk variables clearly defined | No; not all variables investigated were reported |

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| Covariates considered to build the multivariate model | Not reported |
| Interactions between variables explored | Unclear |
| Continuous variables handled appropriately | Unclear |
| More than 10 events per included variable | Unclear; very limited details reported |
| Confidence intervals or other measures of uncertainty presented | No |

**Buth J, Harris PL, van Marrewijk C, Fransen G. The significance and management of different types of endoleaks. *Semin Vasc Surg* 2003;16:95–102[66]**

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| Author | Buth 2003[66] |
| Country where study was performed | 110 European centres |
| Type of study | Specific risk factors following EVAR. Relates some aneurysm features to risk of developing endoleak following EVAR |
| Registry | Dates enrolled and/or treated: not reported<br>EUROSTAR registry |
| Number of patients | 3595 patients (320 with and 3275 without type II endoleak 1 month after EVAR or at any time thereafter) |
| Age of population | Not reported |
| Gender | Not reported |
| Aneurysm diameter | Not reported |
| Type of device (EVAR) | Not reported; device type not reported for analysis of type II endoleaks |
| Graft type (EVAR) | Not reported |
| Anaesthesia | Not reported |
| Risk factor(s) used in model and definitions | Age, smoking status, aortic neck diameter and length, preoperative patency of inferior mesenteric artery; ankle–arm blood pressure index ($< 0.87$ or $\geq 0.87$) |
| Definition of outcomes | Endoleaks (type I, II, III or multiple) were detected by regular imaging during follow-up using contrast-enhanced CT (84% of cases), angiography (4%), magnetic resonance angiography (3%) or duplex ultrasound (8%) |
| Follow-up period | Patients were followed up at 1, 6, 12, 18 and 24 months and annually thereafter. Mean/maximum follow-up not reported but 2-year cumulative survival rates are reported |
| Methods of analysis | Patients were evaluated with respect to age, gender, smoking, obesity, fitness for open repair, ASA physical status classification. The experience of the operating physicians and type of device used were also evaluated. Data on aneurysm morphology (neck diameter and length, aneurysm diameter and angulation) were also analysed. Discrete data were analysed using chi-squared tests with the Fisher correction in the case of small subgroups. Continuous variables were compared using the Mann–Whitney *U*-test. The incidence of time-dependent variables was compared using a log-rank test. Multivariate analysis was performed of selected variables found to be significantly associated with events at the univariate analysis. Multivariate regression analysis was used for binary outcomes and Cox proportional hazards regression was used for multivariate analysis of time-dependent variables. Factors other than those listed above were included in the multivariate analysis for type II endoleak and results are not reported for all factors listed |
| 30-day mortality | No risk factors investigated |
| Aneurysm-related mortality at follow-up | No risk factors investigated |
| All-cause mortality at follow-up | No risk factors investigated |
| Reintervention | No risk factors investigated |

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| Endoleak | Significant association between age and risk of type II endoleak (95% CI 1.01 to 1.06, $p = 0.001$)<br>Significant association between current smoking and decreased risk of type II endoleak (95% CI 0.38 to 0.87, $p = 0.008$)<br>Significant association between length of infrarenal neck and risk of type II endoleak (95% CI 1.01 to 1.03, $p = 0.006$)<br>Significant association between preoperative patent inferior mesenteric artery and risk of type II endoleak (95% CI 1.03 to 1.99, $p = 0.031$)<br>Significant association between ankle–arm blood pressure index < 0.87 and reduced risk of type II endoleak (95% CI 0.23 to 0.68, $p = 0.0007$) |
| Study sample adequately described | No |
| Included risk variables clearly defined | No; however, included variables were fairly self-explanatory |
| Covariates considered to build the multivariate model | Not reported |
| Interactions between variables explored | Unclear |
| Continuous variables handled appropriately | Unclear |
| More than 10 events per included variable | Yes; 320 endoleaks and so the answer appears to be yes, although only variables with a significant association with type II endoleak were reported |
| Confidence intervals or other measures of uncertainty presented | Yes |

**Buth J, Laheij RJF. Early complications and endoleaks after endovascular abdominal aortic aneurysm repair: report of a multicenter study. *J Vasc Surg* 2000;31:134–45[64]**

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| Author | Buth 2000[64] |
| Country where study was performed | Europe (56 centres in 15 countries) |
| Type of study | Specific risk factors following EVAR |
| Registry | Dates enrolled and/or treated: January 1994–March 1999<br>EUROSTAR registry<br>Patients treated before September 1996 were registered retrospectively, with prospective registration after September 1996 |
| Number of patients | 1554 (362 registered retrospectively, 1192 registered prospectively) |
| Age of population | Mean: 70 years; range: 37–90 years |
| Gender | 91.4% (1421/1554) male |
| Aneurysm diameter | Median 5.6 cm; range: 2.8–15 cm<br>Measurement tool used: contrast-enhanced CT scanning and usually also angiography |
| Type of device (EVAR) | Talent: 160/1554 (10.3%); Stentor: 330/1554 (21.2%); Vanguard: 741/1554 (47.7%); EVT: 52/1554 (3.3%); AneuRx: 215/1554 (13.8%); other: 56/1554 (3.6%) |
| Graft type (EVAR) | Aorto-uni-iliac device combined with femorofemoral bypass graft 27/1554 (1.7%); modular bifurcation device 1387/1554 (89.3%); one-piece bifurcation device 42/1554 (2.7%); aorto-aortic straight tube endograft 98/1554 (6.3%) |
| Anaesthesia | Not reported |
| Risk factor(s) used in model and definitions | Age: categorised as ≤ 65, 65–75 and ≥ 75 years<br>Gender: female<br>Smoking status: scored according to the SVS/ISCVS scoring system (score 0–3)<br>Device type (brand name)<br>ASA physical status classification (score I–IV)<br>Pre-existing conditions: cardiac status, scored according to the SVS/ISCVS scoring system (score 0–3)<br>Fitness for open procedure (definition not stated)<br>Maximum aneurysm diameter<br>Infrarenal neck diameter; severe angulation of the iliac arteries (definition not stated)<br>Ankle–arm blood pressure index (definition not stated)<br>Procedural aspects (need for adjuvant procedures, duration of procedure; the latter only considered for correlation if it was not thought likely to be a result of the outcome event), experience of the surgical team and date of the procedure were also analysed |
| Definition of outcomes | 30-day mortality: mortality within the first postoperative month. Endoleaks: categorised into types I–IV following the classification of White *et al*. Endoleaks were divided into those detected at the end of the procedure (documented by completion angiography) and those detected during the first postoperative month. Multivariate results were only reported for the first time period |
| Follow-up period | Study was limited to events occurring during the first postoperative month |
| Methods of analysis | Risk factor variables were first correlated with outcome events using the chi-squared test and Mann–Whitney test for continuous parameters (univariate analysis). Significantly associated variables were then selected stepwise (using backward selection) for a multivariate logistic regression model. The model was tested for stability of the coefficients and their standard errors |

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| 30-day mortality | Age: no significant association reported<br>Gender: no significant association reported<br>Smoking status: no significant association reported<br>No significant association with device type reported<br>Significant association between ASA class and 30-day mortality: OR 2.3, 95% CI 1.0 to 5.2, $p = 0.04$ for ASA class III; OR 6.8, 95% CI 2.7 to 17.4, $p = 0.0001$ for ASA class IV<br>No significant association with cardiac status reported<br>Fitness for open procedure: no significant association reported<br>No significant association with maximum aneurysm diameter reported<br>No significant association with infrarenal neck diameter or severe angulation of the iliac arteries reported<br>Other (give details): no significant association with ankle and arm blood pressure index reported |
| Aneurysm-related mortality at follow-up | No risk factors investigated |
| All-cause mortality at follow-up | No risk factors investigated |
| Reintervention | No risk factors investigated. Reinterventions during admission and in the first postoperative month were included in the category of procedure-related and device-related complications but were not analysed separately. No patient factors were significantly associated with this category of complications |
| Endoleak | Significant association between age ≥ 75 years and endoleak at completion of the procedure: OR 1.9, 95% CI 1.3 to 2.9, $p = 0.0009$<br>Significant association between female gender and endoleak at completion of the procedure: OR 1.7, 95% CI 1.1 to 2.7, $p = 0.02$<br>Significant negative association between current smoking and endoleak at completion of the procedure: OR 0.45, 95% CI 0.2 to 0.9, $p = 0.02$<br>No significant association with device type reported for endoleak at completion of the procedure<br>ASA: no significant association reported for endoleak at completion of the procedure<br>Pre-existing conditions: no significant association with cardiac status reported for endoleak at completion of the procedure<br>Fitness for open procedure: no significant association reported for endoleak at completion of the procedure<br>No significant association with maximum aneurysm diameter reported for endoleak at completion of the procedure<br>No significant association with infrarenal neck diameter or severe angulation of the iliac arteries reported for endoleak at completion of the procedure<br>No significant association with ankle and arm blood pressure index reported for endoleak at completion of the procedure |
| Study sample adequately described | Yes |
| Included risk variables clearly defined | Yes; all included variables listed and most were clearly defined or self-explanatory |
| Covariates considered to build the multivariate model | Yes |
| Interactions between variables explored | Unclear; no interaction term reported |
| Continuous variables handled appropriately | Unclear; justification was not provided for the way that continuous variables were categorised |
| More than 10 events per included variable | Yes for endoleak detected at the end of the procedure; no for mortality within 1 month (16 variables, 40 events) |
| Confidence intervals or other measures of uncertainty presented | Yes |

**Buth J, van Marrewijk CJ, Harris PL, Hop WCJ, Riambau V, Laheij RJF. Outcome of endovascular abdominal aortic aneurysm repair in patients with conditions considered unfit for an open procedure: a report on the EUROSTAR experience. *J Vasc Surg* 2002;35:211–19[65,55]**

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| Author | Buth 2002[65] |
| Country where study was performed | 101 European institutions |
| Type of study | Specific risk factors following EVAR |
| Registry | Dates enrolled and/or treated: June 1996–March 2001<br>454 patients from previous studies[55] excluded as data had been enrolled retrospectively in the registry. Only patients with prospective enrolment, which was at least 1 day before the EVAR was performed, were included<br>EUROSTAR |
| Number of patients | 3075 patients; 2525 normal operative risk (group A), 399 with conditions indicating unfit for open surgical repair (group B), 151 with conditions unfit for general anaesthesia necessary for surgical repair (group C) |
| Age of population | Mean: group A: 70.9 years; group B: 71.6 years; group C: 72.6 years; total: 71.7 years (patients in group C older than those in group A) |
| Gender | Percentage male (total population): group A: 2341/2525 (92.7%); group B: 368/399 (92.2%); group C: 142/151 (94%); total: 2851 (92.7%) |
| Aneurysm diameter | Mean (SD): group A: 5.62 cm (1.06 cm); group B: 5.83 cm (1.19 cm) ($p \leq 0.001$); group C: 5.95 cm (1.38 cm) ($p \leq 0.001$); total: 5.66 cm<br>Measurement tool used: CT scan |
| Type of device (EVAR) | Zenith: 464 (15.1%); Talent: 525 (17.1%); Excluder: 216 (7.0%); Vanguard: 910 (29.6%); AneuRx: 794 (25.8%); EVT/Ancure: 65 (2.1%); other: 101 (3.1%)<br>No statistical differences in the frequency of any device used in patients at high risk |
| Graft type (EVAR) | Straight or aorto-uni-iliac: group A: 149 (5.9%); group B: 37 (9.3%) ($p \leq 0.001$); group C: 17 (11.3%) ($p \leq 0.001$); total: 203 (6.6%) |
| Anaesthesia | Regional/local anaesthesia: group A: 596 (23.6%); group B: 112 (28.1%); group C: 98 (64.8%) ($p \leq 0.001$); total: 806 (26.2%) |
| Risk factor(s) used in model and definitions | ASA physical status classification used as general risk indicator (status III/IV). SVS/ISCVS-NA (International Society for Cardiovascular Surgery – North American Chapter) indicated more specific risk factors or conditions of different systems: diabetes, smoking, hypertension, hyperlipidaemia, cardiac, carotid, renal, pulmonary (risk score $\geq 1$)<br>Physician's prospective assessment of risk according to one of following categories also taken into account: normal medical condition (group A), condition that was unfit for an open surgical repair of the AAA (group B) or condition unfit for general anaesthesia as needed for open repair (group C). Patients with unfit conditions for both open surgery and general anaesthesia categorised in group C. Seven groups of factors define (retrospectively) unfit category: cardiovascular conditions (including cerebrovascular, status post heart transplant); pulmonary diseases; malignant diseases; abdominal approach and local anatomic factors (e.g. previous laparotomies, hostile abdomen, obesity, retroperitoneal fibrosis, abdominal irradiation, inflammatory aneurysm, aortitis, dissections, enterostoma, bladder substitute, uretherostoma, skin infections, osteomyelitis of sternum, peritoneal dialysis, kidney transplant, status post liver transplant, pancreatitis); specified general disorders (e.g. haemotological rheumatoid arthritis, connective tissue disease, haemodialysis, chronic renal failure, peritoneal dialysis, liver disorders, neurological disorders, muscle dystrophy, myasthenia, Parkinson's disease, paraplegia, schizophrenia); poor condition – non-specified general disorders (ASA IV, advanced age, multiple non-specified comorbidity); ankle–brachial pressure index $< 0.87$ |

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| Definition of outcomes | Primary outcome success: freedom from death, rupture, conversion and secondary intervention. Secondary outcome success: freedom from death, rupture and conversion. Death rate calculated from the observed data, discarding first month deaths and adding deaths as the result of aneurysm rupture |
| Follow-up period | 2-year follow-up |
| Methods of analysis | Association between most relevant clinical variables and different outcome events assessed with multivariate analysis. If subgroup differences statistically significant, ORs were calculated. If outcome event occurred during follow-up period, Cox proportional hazards regression model used and relative risk (RR) calculated. Cumulative rate of patient survival estimated with life table analysis |
| 30-day mortality | Age of 70 years or more: OR 3.0 ($p = 0.0004$)<br>ASA III/IV: OR 1.9 ($p = 0.03$)<br>History of cardiac symptoms: $p$ = NS; pulmonary disorders: $p$ = NS; diabetes: $p$ = NS; obesity: $p$ = NS<br>Renal insufficiency: OR 2.5 ($p = 0.0003$)<br>Mortality rate: 77 patients (2.5%) (A vs B/C, $p = 0.001$); multivariate analysis (including preoperative and operative variables and risk groups A, B, and C): combined risk groups B/C compared with group A: OR 1.8 ($p = 0.039$)<br>Ankle–brachial index < 0.87: $p$ = NS<br>Experience of team: $p$ = NS |
| Aneurysm-related mortality at follow-up | No risk factors investigated |
| All-cause mortality at follow-up | Preoperative risk classifications (ASA/SVS) for groups B/C: RR 1.8 ($p = 0.001$) (exclusion of early deaths at multivariate analysis)<br>Total for groups B/C: first month and late deaths combined: cardiac disorders: 28/151 (18.5%); malignant diseases: 10/151 (6.6%); stroke: 7/151 (4.6%); pulmonary disorders: 8/151 (5.3%)<br>Exclusion of early deaths at multivariate analysis: pulmonary disorders: RR 1.6 ($p = 0.005$)<br>Aneurysm size 2-year survival rates: entire cohort, $p = 0.0001$; group A, $p = 0.0001$; groups B/C, $p = 0.023$<br>Exclusion of early deaths at multivariate analysis: aneurysm diameter: RR 1.8 ($p = 0.0002$)<br>Exclusion of early deaths at multivariate analysis: team experience > 60 procedures independently associated with late death: RR 0.6 ($p = 0.02$) |
| Reintervention | No risk factors investigated |
| Endoleak | No risk factors investigated |
| Study sample adequately described | Yes |
| Included risk variables clearly defined | Yes |
| Covariates considered to build the multivariate model | Not reported; unclear |
| Interactions between variables explored | Unclear |
| Continuous variables handled appropriately | Yes |
| More than 10 events per included variable | Yes |
| Confidence intervals or other measures of uncertainty presented | Yes |

**Cuypers PW, Laheij RJ, Buth J. Which factors increase the risk of conversion to open surgery following endovascular abdominal aortic aneurysm repair? The EUROSTAR collaborators. *Eur J Vasc Endovasc Surg* 2000;20:183–9[67]**

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| Author | Cuypers 2000[67] |
| Country where study was performed | Europe (65 centres) |
| Type of study | Specific risk factors following EVAR |
| Registry | Dates enrolled and/or treated: January 1994–July 1999<br>EUROSTAR registry |
| Number of patients | 1871 (49 with conversion to open repair and 1822 without conversion) |
| Age of population | Mean (SD): 69.7 years for total population [72.6 (7.0) for patients with conversion; 69.6 (8.3) for patients without conversion] |
| Gender | 91.8% male (84% for patients with conversion; 92% for patients without conversion) |
| Aneurysm diameter | Mean (SD): 5.6 cm for total population [6.1 (1.2) for patients with conversion; 5.6 (1.1) for patients without conversion] |
| Graft type (EVAR) | Uni-iliac: 48/1871 (2.6%); bi-iliac: 1721/1871 (92.0%); tube: 102/1871 (5.5%) |
| Anaesthesia | Not reported |
| Risk factor(s) used in model and definitions | Age kept as a continuous variable<br>Device type (brand name)<br>Pre-existing conditions: hypertension, smoking, diabetes (not included in multivariate model) and COPD status were defined according to the SVS/ISCVS scoring system (present if score $> 0$). Other risk factors not explicitly defined<br>Aneurysm diameter (continuous variable)<br>Proximal neck length and neck diameter (continuous variables)<br>Other risk factors analysed included patient factors (gender, ASA classification, weight, smoking status, of which only weight was included in the multivariate analysis), aneurysm morphology, experience of the operating team and year of procedure |
| Definition of outcomes | Conversion: all primary (during the initial procedure and within the first postoperative month) and secondary (during follow-up) conversions to open repair |
| Follow-up period | Mean follow-up 6 (IQR 1–12) months. Follow-up clinical examinations and imaging studies were performed at 1, 3, 6, 12, 18 and 24 months, and annually thereafter |
| Methods of analysis | The variables analysed were patient characteristics (age, gender, ASA classification, weight, hypertension, smoking, diabetes and pulmonary status), aneurysm morphology (angulation of the aortic neck, the aneurysm and iliac arteries, aortic neck diameter and length, maximum aneurysm diameter, common iliac artery diameter and aortic diameter at the level of the bifurcation), operating team experience, year of procedure and type of device. The association of variables with conversion to open repair was assessed by chi-squared analysis for categorical variables. *t*-tests were used for continuous variables with approximately normal distribution and the Mann–Whitney test was used for other continuous variables. Variables were categorised as patient-, anatomic- or procedure-related and correlations were calculated for each group. Variables that were significantly associated with conversion in the univariate analysis were entered in a multivariate regression model |
| 30-day mortality | No risk factors investigated |
| Aneurysm-related mortality at follow-up | No risk factors investigated |
| All-cause mortality at follow-up | No risk factors investigated |

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| Reintervention | No significant association between age (continuous variable) and conversion to open repair in multivariate analysis ($p = 0.08$)<br>Significant association between EVT and Talent devices and conversion to open repair in multivariate analysis: OR 7.7, 95% CI 3.19 to 18.59, $p < 0.01$ for EVT; OR 3.4, 95% CI 1.42 to 8.38, $p < 0.01$ for Talent. No significant association for other device types<br>Significant association between presence of chronic obstructive pulmonary disease and conversion to open repair in multivariate analysis: OR 2.22, 95% CI 1.12 to 4.37, $p = 0.02$<br>No significant association between aneurysm diameter (continuous variable) and conversion to open repair in multivariate analysis ($p = 0.14$)<br>Significant association between proximal neck length (continuous variable) and conversion to open repair in multivariate analysis ($p < 0.01$)<br>Significant association between weight (continuous variable) and conversion to open repair in multivariate analysis ($p = 0.02$). Significant association between neck diameter (continuous variable) and conversion to open repair in multivariate analysis ($p = 0.04$) |
| Endoleak | No risk factors investigated |
| Study sample adequately described | Yes |
| Included risk variables clearly defined | Yes |
| Covariates considered to build the multivariate model | Yes |
| Interactions between variables explored | Unclear |
| Continuous variables handled appropriately | Yes; continuous variables appear to have been treated as continuous |
| More than 10 events per included variable | No; only 49 conversions in total |
| Confidence intervals or other measures of uncertainty presented | Yes |

**Diehm N, Hobo R, Baumgartner I, Do DD, Keo HH, Kalka C, *et al*. Influence of pulmonary status and diabetes mellitus on aortic neck dilatation following endovascular repair of abdominal aortic aneurysms: a EUROSTAR report. *J Endovasc Ther* 2007;14:122–9[68]**

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| Author | Diehm 2007[68] |
| Country where study was performed | 164 European centres |
| Type of study | Specific risk factors following EVAR |
| Registry | Dates enrolled and/or treated: December 1996–November 2005<br>EUROSTAR registry |
| Number of patients | 6383; pulmonary status: normal 3650 (57%), impaired 2733 (43%); diabetes mellitus: no 5573 (87.3%), yes 810 (12.7%) |
| Age of population | Mean (SD): 72.4 (7.6) years for total population; pulmonary status: normal 71.7 (7.9), impaired 73.3 (7.2); diabetes mellitus: no 72.4 (7.7), yes 72.1 (7.3) |
| Gender | 93.8% (5985/6383) male |
| Aneurysm diameter | Mean: 5.87 cm (calculated) for total population; pulmonary status: normal 5.82 (1.08), impaired 5.94 (1.15); diabetes mellitus: no 5.86 (1.11), yes 5.91 (1.13) |
| Type of device (EVAR) | Zenith: 2409 (37.7%); Talent: 1757 (27.5%); Excluder: 883 (13.8%); AneuRx: 895 (14%); Fortron: 84 (1.3%); Powerlink: 123 (1.9%); Lifepath: 121 (1.9%); EVT: 67 (1.1%); Anaconda: 44 (0.8%) |
| Graft type (EVAR) | Not reported |
| Anaesthesia | Not reported |
| Risk factor(s) used in model and definitions | Pre-existing conditions: pulmonary status and diabetes mellitus were classified according to the SVS risk classification. For pulmonary function a score of 0 means no pulmonary impairment; scores of 1–3 indicate increasing levels of impairment measured by pulmonary function tests and chest radiography. For diabetes mellitus (DM) a score of 0 indicates normoglycaemia, 1 indicates adult-onset DM controlled by diet, 2 indicates adult-onset DM controlled by insulin and 3 indicates the presence of juvenile-onset DM |
| Definition of outcomes | 30-day mortality, aneurysm-related mortality, all-cause mortality at follow-up: not specifically defined. Reintervention: conversion to open repair and all endovascular reinterventions. Endoleak: type I endoleak (proximal and distal) |
| Follow-up period | Patients were followed up at 1, 3, 6, 12, 18 and 24 months, and annually thereafter. Mean follow-up was 21.1 (SD 18.4) months (range 0–96) |
| Methods of analysis | Patients were classified as good pulmonary status (SVS score 0) or impaired pulmonary status (SVS score 1–3). Within the same statistical model patients were classified as non-diabetic (SVS score 0) or diabetic (SVS score 1–3) for a second statistical analysis. Differences between groups were assessed using the Mann–Whitney *U*-test for continuous data and chi-squared test for discrete variables. Kaplan–Meier life table analyses were performed to analyse study end points as well as cumulative rates of neck dilatation and type I endoleak. Multivariate logistic regression analysis (adjusted for smoking, age, gender, comorbidities, fitness for open repair, co-existing common iliac artery aneurysm, neck and aneurysm size, arterial angulation, aneurysm classification, oversizing ≥ 15% and type of stent graft) was used to determine independent associations of pulmonary status and DM with 30-day outcomes. Cox proportional hazards models (adjusted for smoking, age, gender, comorbidities, fitness for open repair, co-existing common iliac artery aneurysm and type of stent graft) were used to determine independent associations of impaired pulmonary status and DM with 4-year outcomes |
| 30-day mortality | No significant association between pulmonary status and 30-day mortality ($p = 0.08$). No significant association between DM and 30-day mortality ($p = 0.27$) |

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| Aneurysm-related mortality at follow-up | Significant association between impaired pulmonary status and 4-year aneurysm-related mortality (3.3% normal status vs 6.8% impaired status, $p = 0.006$). No significant association between DM and 4-year aneurysm-related mortality (4.6% no diabetes vs 6.1% with diabetes, $p$ = NS) |
| All-cause mortality at follow-up | Significant association between impaired pulmonary status and 4-year all-cause mortality (19.0% normal status vs 31.0% impaired status, $p < 0.0001$). No significant association between DM and 4-year all-cause mortality (23.4% no diabetes vs 27.7% with diabetes, $p$ = NS) |
| Reintervention | No significant association between pulmonary status and 30-day conversion to open repair (1.0% normal status vs 1.1% impaired status, $p = 0.93$). No significant association between DM and 30-day conversion to open repair (1.0% no diabetes vs 1.4% with diabetes, $p = 0.21$). No significant association between pulmonary status and 4-year conversion to open repair (5.3% normal status vs 4.9% impaired status, $p$ = NS). No significant association between DM and 4-year conversion to open repair (5.4% no diabetes vs 3.3% with diabetes, $p$ = NS). No significant association between pulmonary status and 4-year endovascular reinterventions (8.6% normal status vs 10.5% impaired status, $p$ = NS). No significant association between DM and 4-year endovascular reinterventions (9.5% no diabetes vs 7.0% with diabetes, $p$ = NS) |
| Endoleak | No significant association between pulmonary status and 4-year type I endoleak (8.1% normal status vs 9.1% impaired status, $p$ = NS). No significant association between DM and 4-year type I endoleak (8.5% no diabetes vs 7.8% with diabetes, $p$ = NS) |
| Study sample adequately described | Yes |
| Included risk variables clearly defined | Yes |
| Covariates considered to build the multivariate model | Yes |
| Interactions between variables explored | Unclear |
| Continuous variables handled appropriately | Yes; justification provided for classification of pulmonary/diabetic status |
| More than 10 events per included variable | Yes |
| Confidence intervals or other measures of uncertainty presented | No; only *p*-values presented for models of outcomes of interest |

**Hobo R, Buth J. Secondary interventions following endovascular abdominal aortic aneurysm repair using current endografts. A EUROSTAR report. *J Vasc Surg* 2006;43:896–902[69]**

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| Author | Hobo 2006[69] |
| Country where study was performed | Europe (131 centres) |
| Type of study | Specific risk factors following EVAR |
| Registry | Dates enrolled and/or treated: December 1999–December 2004<br>EUROSTAR registry |
| Number of patients | 2846 patients with follow-up of at least 12 months or reintervention within the first 12 months |
| Age of population | Mean: 72.0 (SD 7.5) years; range: 43–100 years |
| Gender | 94% (2688/2846) male |
| Aneurysm diameter | Mean: 5.8 cm; range: 4–11 cm<br>Measurement tool used: not explicitly reported; aneurysm diameter was determined over the minor axis at the site of the largest cross-section |
| Type of device (EVAR) | Zenith: 1147/2846 (40.3%); Talent: 791/2846 (27.8%); Excluder: 421/2846 (14.8%); AneuRx: 264/2846 (9.3%); Lifepath: 67/2846 (2.4%); Fortron: 52/2846 (1.8%); Powerlink: 51/2846 (1.8%); EVT: 36/2846 (1.3%); Anaconda: 17/2846 (0.6%) |
| Graft type (EVAR) | Not reported |
| Anaesthesia | Not reported |
| Risk factor(s) used in model and definitions | Age<br>Gender<br>Type of device (brand name)<br>ASA physical status score (I–IV)<br>Systemic comorbidities (no further details reported)<br>Preoperative aneurysm diameter (categorised as < 5.5 cm, 5.5–6.0 cm, 6.0–6.5 cm and > 6.5 cm)<br>Other risk factors included requirement for an adjuvant procedure and proximal or midgraft endoleak evident at the time of the primary procedure |
| Definition of outcomes | Secondary interventions (reinterventions) were categorised as transabdominal (with or without conversion to open repair), extra-anatomic and transfemoral interventions. Results from the multivariate model refer to all interventions |
| Follow-up period | Minimum follow-up 12 months after procedure unless a reintervention occurred before the 12-month visit. Patients were followed up for a mean of 11 (SD 12) months after reintervention (range 0–47 months) |
| Methods of analysis | Kaplan–Meier life tables were used to derive cumulative incidence and survival curves for all types of secondary interventions. Relative risk (RR) ratios were calculated to correlate secondary interventions with their indications at the follow-up visit preceding reintervention. A multivariate Cox proportional hazards model was used to calculate independent associations of baseline (patient and operative) factors with survival free of reintervention during the postoperative and entire follow-up periods |
| 30-day mortality | No risk factors investigated; 30-day mortality was investigated using multivariate logistic regression but results were related to reinterventions and not to patient risk factors |
| Aneurysm-related mortality at follow-up | No risk factors investigated |
| All-cause mortality at follow-up | No risk factors investigated; all-cause mortality was investigated using multivariate logistic regression but results were related to reinterventions and not to patient risk factors |

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| Reintervention | Age: no significant association with secondary interventions<br>Gender: no significant association with secondary interventions<br>No significant association of device type with secondary interventions<br>ASA: no significant association with secondary interventions<br>No significant association of systemic comorbidities with secondary interventions<br>No significant association of preoperative diameter (with thresholds at 5.5, 6 and 6.5 cm) with secondary interventions<br>Independent baseline risk factors for reintervention were requirement for adjuvant procedure ($p = 0.0001$), proximal endoleak ($p = 0.004$) and midgraft endoleak ($p = 0.017$) evident at the primary procedure |
| Endoleak | No risk factors investigated |
| Study sample adequately described | Yes |
| Included risk variables clearly defined | No; limited details reported |
| Covariates considered to build the multivariate model | Yes; independent associations with outcomes sought |
| Interactions between variables explored | Unclear |
| Continuous variables handled appropriately | Unclear |
| More than 10 events per included variable | Yes; 247 reinterventions |
| Confidence intervals or other measures of uncertainty presented | No; only *p*-values reported |

**Hobo R, Kievit J, Leurs LJ, Buth J. Influence of severe infrarenal aortic neck angulation on complications at the proximal neck following endovascular AAA repair: a EUROSTAR study. *J Endovasc Ther* 2007;14:1–11[70,55]**

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| Author | Hobo 2007[70] |
| Country where study was performed | 159 centres in 18 European countries |
| Type of study | Specific risk factors following EVAR |
| Registry | Dates enrolled and/or treated: October 1996–January 2006<br>EUROSTAR |
| Number of patients | 5183 patients: 1152 with severe neck angulation (SNA), 4031 without SNA |
| Age of population | Overall mean age: 72.6 years, $p < 0.0001$; SNA present: 74.3 (SD 7.5) years; SNA absent: 72.1 (SD 7.7) years |
| Gender | SNA present: 1040 (90.3%) male; SNA absent: 3820 (94.8%) male; total: 4860 (93.8%) male |
| Aneurysm diameter | Mean AAA sac diameter: SNA present: 6.38 (SD 1.26) cm; SNA absent: 5.79 (SD 1.04) cm; total: 5.9 cm, $p < 0.0001$<br>Measurement tool used: CT scan |
| Type of device (EVAR) | Zenith: 2486 patients (48%); Talent: 1796 patients (34.6%); Excluder: 901 patients (17.4%) |
| Graft type (EVAR) | Not reported |
| Anaesthesia | Not reported |
| Risk factor(s) used in model and definitions | Device (brand name)<br>SNA defined as $> 60°$ angle between the infrarenal aortic neck and the longitudinal axis of the aneurysm |
| Definition of outcomes | Complications defined as proximal type I endoleak (short and long term), infrarenal aortic neck dilatation, proximal stent graft migration, and rupture of the aneurysm. Proximal neck dilatation defined as an increase of at least 0.4 cm compared with the proximal neck diameter at the preoperative measurement. Long-term incidences of proximal type I endoleak, stent graft migration, aneurysm rupture, secondary interventions and all-cause and aneurysm-related mortality: no specific definitions |
| Follow-up period | 1, 3, 6, 12, 18 and 74 months, then annually thereafter. Mean follow-up 19.9 (SD 17.9) months |
| Methods of analysis | Short-term outcome variables were assessed using chi-squared, Mann–Whitney and logistic regression analyses. Kaplan–Meier life tables and Cox proportional hazards models used to assess long-term outcome variables. Results presented as adjusted OR or HR with 95% CI (adjusted for age, gender, risk factors, morphological factors and experience) |
| 30-day mortality | Aortic neck and aneurysm angle: OR (adjusted) 0.89 (95% CI 0.62 to 1.30, $p$ = NS) |
| Aneurysm-related mortality at follow-up | Aortic neck and aneurysm angle: HR (adjusted) 1.02 (95% CI 0.75 to 1.38, $p$ = NS) |
| All-cause mortality at follow-up | Aortic neck and aneurysm angle: HR (adjusted) 0.87 (95% CI 0.72 to 1.03, $p$ = NS) |
| Reintervention | Secondary intervention (long term) associated with SNA in patients who received Talent device: HR 1.54 (95% CI 1.05 to 2.24, $p = 0.0259$)<br>Aortic neck and aneurysm angle: short-term outcomes (30 days): OR (adjusted) 0.96 (95% CI 0.64 to 1.43, $p$ = NS); long-term outcomes (follow-up): OR (adjusted) 1.29 (95% CI 1.00 to 1.67, $p = 0.0488$) |

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| Endoleak | Graft configuration and device type:<br>Short-term outcomes (30 days) (proximal type I endoleak): Excluder device: OR (adjusted) 4.49 (95% CI 1.31 to 15.32, $p = 0.0166$); short-term outcomes (30 days) (proximal type I endoleak): Talent device: OR (adjusted) 2.29 (95% CI 1.38 to 3.80, $p = 0.0014$); long-term outcomes (follow-up) (proximal type I endoleak): Talent device: HR (adjusted) 2.09 (95% CI 1.27 to 3.44, $p = 0.0036$); short-term outcomes (30 days) (proximal type I endoleak): Zenith device: OR (adjusted) 2.62 (95% CI 1.49 to 4.63, $p = 0.0009$)<br>Aortic neck and aneurysm angle:<br>Short-term outcomes (30 days) (proximal type I endoleak): OR (adjusted) 2.32 (95% CI 1.60 to 3.37, $p < 0.0001$); long-term outcomes (follow-up) (proximal type I endoleak): OR (adjusted) 1.80 (95% CI 1.25 to 2.58, $p = 0.0016$) |
| Study sample adequately described | Yes |
| Included risk variables clearly defined | Yes |
| Covariates considered to build the multivariate model | Not reported; unclear |
| Interactions between variables explored | Unclear |
| Continuous variables handled appropriately | Yes |
| More than 10 events per included variable | Yes |
| Confidence intervals or other measures of uncertainty presented | Yes |

**Lange C, Leurs LJ, Buth J, Myhre HO, EUROSTAR collaborators. Endovascular repair of abdominal aortic aneurysm in octogenarians: an analysis based on EUROSTAR data. *J Vasc Surg* 2005;42:624–30[71]**

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| Author | Lange 2005[71] |
| Country where study was performed | 153 European institutions within the EUROSTAR registry |
| Type of study | Specific risk factors following EVAR |
| Registry | Dates enrolled and/or treated: 1996–2004<br>EUROSTAR |
| Number of patients | 4433 patients: 697 patients aged over 80 years; 4198 patients < 80 years of age |
| Age of population | Mean (SD): patients < 80 years 70.3 (6.5) years; octogenarians 83.4 (2.9) years<br>Range: patients < 80 years 43–79 years; octogenarians 80–100 years |
| Gender | Patients < 80 years 94.8% male; octogenarians 90.2% male ($p < 0.0001$) |
| Aneurysm diameter | Mean (SD): patients < 80 years 5.76 (1.04) cm; octogenarians 6.2 (1.22) cm ($p < 0.0001$)<br>Measurement tool used: between the outer walls on the axial CT slices |
| Type of device (EVAR) | Not reported; only commercially available CE-approved stent grafts were permitted |
| Graft type (EVAR) | Uni-iliac: patients < 80 years 212 (5.1%); octogenarians 54 (7.8%) ($p = 0.0038$) |
| Anaesthesia | Local: patients < 80 years 232 (5.5%); octogenarians 32 (4.6%) ($p$ = NS)<br>Regional: patients < 80 years 1012 (24.2%); octogenarians 180 (25.8%) ($p$ = NS)<br>General: patients < 80 years 2947 (70.3%); octogenarians 485 (69.6%) ($p$ = NS) |
| Risk factor(s) used in model and definitions | Age (patients > 80 years) |
| Definition of outcomes | Deaths occurring within ≤ 30 days of the procedure were categorised as operative deaths and deaths occurring > 30 days were categorised as late deaths. Aneurysm-related deaths included 30-day deaths and deaths that occurred as a result of aneurysm rupture or endograft infection or deaths ≤1 month after a secondary surgical procedure for late complications of the aneurysm |
| Follow-up period | 1, 6, 12, 18, 24 months and annually thereafter. Mean follow-up period was 14 months in octogenarians, 19 months in younger patients |
| Methods of analysis | Differences in findings between the two age groups (< 80 years and > 80 years) were assessed by chi-squared tests for discrete variables and by *t*-tests or Wilcoxon rank sum tests for continuous variables. Multivariate regression was used to correct for other risk factors. Life table analyses were conducted for outcomes at follow-up and multivariate analysis of time-dependent variables was assessed by Cox proportional hazards |
| 30-day mortality | Patients < 80 years: 89 (2.1%); octogenarians: 38 (5.5%); adjusted *p*-value 0.0007; OR 0.48 (95% CI 0.31 to 0.73) |
| Aneurysm-related mortality at follow-up | Patients < 80 years: 117 (2.8%); octogenarians: 49 (7.0%); adjusted *p*-value < 0.0001; HR 2.15 (95% CI 1.52 to 3.05) |
| All-cause mortality at follow-up | Patients < 80 years: 392 (9.4%); octogenarians: 109 (15.9%); adjusted *p*-value < 0.0001; HR 1.65 (95% CI 1.32 to 2.06) |
| Reintervention | Overall conversion to open repair: patients < 80 years: 95 (2.3%); octogenarians 18 (2.6%); adjusted *p*-value NS; HR 1.35 (95% CI 0.81 to 2.27)<br>Late conversion to open repair: patients < 80 years: 55 (1.3%); octogenarians 9 (1%); adjusted *p*-value NS; HR 1.03 (95% CI 0.46 to 2.29) |

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| Endoleak | Endoleaks: patients < 80 years 677 (16.2%); octogenarians 148 (21.2%); adjusted *p*-value < 0.0001; HR 1.46 (95% CI 1.21 to 1.76)<br>Type I – proximal: patients < 80 years 97 (2.4%); octogenarians 21 (3.2%); adjusted *p*-value NS; HR 1.29 (95% CI 0.79 to 2.12)<br>Type I – distal patients: < 80 years 72 (1.8%); octogenarians 17 (2.6%); adjusted *p*-value NS; HR 1.65 (95% CI 0.94 to 2.89)<br>Type II patients: < 80 years 140 (3.4%); octogenarians 33 (5.0%); adjusted *p*-value 0.0059; HR 1.87 (95% CI 1.20 to 2.91)<br>Type III patients: < 80 years 483 (11.8%); octogenarians 97 (14.8%); adjusted *p*-value 0.0056; HR 1.40 (95% CI 1.10 to 1.76) |
| Study sample adequately described | Yes |
| Included risk variables clearly defined | Yes |
| Covariates considered to build the multivariate model | Yes |
| Interactions between variables explored | Unclear |
| Continuous variables handled appropriately | Yes |
| More than 10 events per included variable | Yes |
| Confidence intervals or other measures of uncertainty presented | Yes |

**Leurs LJ, Buth J, Harris PL, Blankensteijn JD. Impact of study design on outcome after endovascular abdominal aortic aneurysm repair. A comparison between the randomized controlled DREAM-trial and the observational EUROSTAR-registry. *Eur J Vasc Endovasc Surg* 2007;33:172–6[72,169,55]**

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| Author | Leurs 2007[72] |
| Country where study was performed | Europe wide |
| Type of study | Specific risk factors following EVAR |
| Registry | EUROSTAR: enrolled 1 December 1996 (only patients registered post 1999 included) |
| Trial | Enrolment commenced in 2000<br>Dutch Randomised Endovascular Aneurysm Management (DREAM) trial<br>RCT |
| Number of patients | EUROSTAR: 856; DREAM: 177; total: 1033 patients |
| Age of population | Mean (SD): DREAM: 70.6 (6.51) years; EUROSTAR: 71.6 (7.67) years; $p$ = NS |
| Gender | Male (total population): DREAM: 165 (93.2%); EUROSTAR: 793 (92.6%); total: 958 (92.7%); $p$ = NS |
| Aneurysm diameter | Mean (SD): DREAM: 6.06 (0.89) cm; EUROSTAR: 6.04 (1.02) cm<br>Measurement tool used: EUROSTAR: CT and intra-arterial digital subtraction angiography (DSA); DREAM: not reported |
| Type of device (EVAR) | Zenith: 369 (35.7%); Talent: 382 (37%); Excluder: 114 (11%); AneuRx: 89 (8.6%); Lifepath: 7 (0.7%); Endologix: 8 (0.8%); Fortron: 31 (3.0%); EVT: 10 (1.0%); Anaconda: 21 (2.0%); unknown: 2 (0.2%) |
| Graft type (EVAR) | Uni-iliac: 53 patients (5.1%); bi-iliac: 999 patients (96.7%); straight tube: 11 (1.1%); unknown: 8 (0.8%)<br>894 patients included for EUROSTAR graft type, therefore total percentage > 100 |
| Anaesthesia | Local: 94 (9.1%); regional: 320 (31%); general: 619 (59.9%) |
| Risk factor(s) used in model and definitions | Advanced age (not defined)<br>ASA physical status classification I, II or III (ASA IV patients not included)<br>Pre-existing conditions: comorbidity: pulmonary impairment (not defined), diabetes (not defined)<br>Larger aneurysm diameter at baseline (size not defined)<br>(Baseline variables included diabetes, smoking, hypertension, hyperlipidaemia, carotid disease, cardiac disease, renal disease, pulmonary disease, but not all variables were analysed) |
| Definition of outcomes | All-cause mortality defined as survival. Reintervention defined as secondary intervention or procedure (not defined) |
| Follow-up period | 1-, 3- and 5-year follow-up |
| Methods of analysis | Differences between groups were assessed using chi-squared tests for discrete variables and Wilcoxon rank sum tests for continuous variables. Multivariate Cox models were used to determine whether baseline and follow-up variables were independently associated with adverse outcomes. Kaplan–Meier analysis was used for survival analysis |
| 30-day mortality | No risk factors investigated |
| Aneurysm-related mortality at follow-up | No risk factors investigated |

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| All-cause mortality at follow-up | Age: total: HR 1.06 (95% CI 1.03 to 1.09, $p < 0.0001$); DREAM: HR 1.14 (95% CI 1.07 to 1.23, $p = 0.0002$)<br>Pulmonary impairment: total: HR 1.74 (95% CI 1.19 to 2.54, $p = 0.0046$)<br>Diabetes mellitus: DREAM: HR 4.46 (95% CI 1.41 to 14.05, $p = 0.0107$)<br>Larger aneurysm diameter at baseline: HR 1.02 (95% CI 1.01 to 1.04, $p = 0.0091$) |
| Reintervention | Age: total: HR 1.03 (95% CI 1.00 to 1.07, $p = 0.0363$) |
| Endoleak | No risk factors investigated |
| Study sample adequately described | Yes |
| Included risk variables clearly defined | No |
| Covariates considered to build the multivariate model | Not reported; unclear |
| Interactions between variables explored | Unclear |
| Continuous variables handled appropriately | Unclear |
| More than 10 events per included variable | Unclear |
| Confidence intervals or other measures of uncertainty presented | Yes |

**Leurs LJ, Hobo R, Buth J. The multicenter experience with a third-generation endovascular device for abdominal aortic aneurysm repair – a report from the EUROSTAR database. *J Cardiovasc Surg* 2004;45:293–300[73]**

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|---|---|
| Author | Leurs 2004[73] |
| Country where study was performed | 65 centres in Europe |
| Type of study | Specific risk factors following EVAR |
| Registry | Dates enrolled and/or treated: 6-year period to April 2004<br>EUROSTAR |
| Number of patients | 676 (group A with aneurysm < 5.5 cm: 300; group B with aneurysm ≥ 5.5 cm: 376) |
| Age of population | Mean: group A: 71.2 years; group B: 72.8 years ($p = 0.0006$); overall: 72.1 years (calculated)<br>Range: group A: 43–92 years; group B: 49–96 years |
| Gender | 626 (93%) male |
| Aneurysm diameter | Mean: 5.67 cm (group A: 4.87; group B: 6.32) ($p < 0.0001$)<br>Range: 4–10 cm (group A: 4–5.4; group B: 5.5–10) |
| Type of device (EVAR) | Excluder: 676 (100%) |
| Graft type (EVAR) | Bi-iliac: 676 (100%) |
| Anaesthesia | Local: 78 (12%); regional: 207 (31%); general: 391 (58%) |
| Risk factor(s) used in model and definitions | Age<br>Pulmonary insufficiency, hypertension (not defined)<br>Fitness for open procedure<br>Renal function (creatinine)<br>Aneurysm size<br>Study cohort was divided into two groups: group A with aneurysms < 5.5 cm and group B with aneurysms ≥ 5.5 cm |
| Definition of outcomes | Overall deaths included death related to comorbidity and conditions unrelated to the aneurysm. Aneurysm-related deaths included 30-day deaths and deaths that occurred as a result of aneurysm rupture or endograft infection or deaths within 1 month of a secondary surgical procedure for late complications of the aneurysm. Only endoleaks that were identified at 1 month and thereafter were included in the analysis; endoleaks at the completion angiography were not included |
| Follow-up period | 1, 6, 12, 18 and 24 months and annually thereafter. Mean duration of follow-up was 13.5 months (1–60 months) |
| Methods of analysis | All variables with a significant correlation with an adverse event and variables appearing clinically related, including size classification, were entered into a multivariate Cox analysis to assess independent associations |
| 30-day mortality | No risk factors investigated |
| Aneurysm-related mortality at follow-up | Age of the patient was not found to be an independent risk factor for aneurysm-related mortality in multivariate analysis<br>Pulmonary insufficiency was not found to be an independent risk factor for aneurysm-related mortality in multivariate analysis<br>Unfitness for open repair was not found to be an independent risk factor for aneurysm-related mortality in multivariate analysis<br>Renal insufficiency was not found to be an independent risk factor for aneurysm-related mortality in multivariate analysis<br>Large aneurysm size was not found to be an independent risk factor for aneurysm-related mortality in multivariate analysis |

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| All-cause mortality at follow-up | Advanced age influenced all-cause mortality (HR 1.05, 95% CI 1.0 to 1.1)<br>Unfitness for open repair influenced all-cause mortality (HR 2.6, 95% CI 1.2 to 5.6)<br>Large aneurysm size (group B patients) had a higher risk of all-cause death in multivariate analysis (HR 2.9, 95% CI 1.2 to 6.7) |
| Reintervention | No risk factors investigated |
| Endoleak | No risk factors investigated |
| Study sample adequately described | Yes |
| Included risk variables clearly defined | No |
| Covariates considered to build the multivariate model | Yes |
| Interactions between variables explored | Unclear |
| Continuous variables handled appropriately | Unclear |
| More than 10 events per included variable | No |
| Confidence intervals or other measures of uncertainty presented | Yes |

**Leurs LJ, Kievit J, Dagnelie PC, Nelemans PJ, Buth J. Influence of infrarenal neck length on outcome of endovascular abdominal aortic aneurysm repair. *J Endovasc Ther* 2006;13:640–8[74,55]**

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|---|---|
| Author | Leurs 2006[74] |
| Country where study was performed | 165 European institutions |
| Type of study | Specific risk factors following EVAR |
| Registry | Dates enrolled and/or treated: recruitment began October 1996<br>EUROSTAR |
| Number of patients | 3499 patients: 2822 patients with infrarenal neck length > 1.5 cm (group A); 485 patients 1.1–1.5 cm (group B); 192 patients ≤ 1.0 cm (group C) |
| Age of population | Mean (SD): group A: 73.2 (7.7) years; group B: 73.5 (7.3) years; group C: 72.4 (7.5) years ($p$ = NS); overall mean: 73.2 years |
| Gender | Percentage male (total population): group A: 2645/2822 (93.7%); group B: 459/485 (94.6%); group C: 186/192 (96.9%) ($p$ = NS); total: 3290 (94.0%) |
| Aneurysm diameter | Mean (SD): group A: 6.13 (1.07) cm; group B: 6.22 (1.13) cm; group C: 6.29 (1.10) cm ($p$ = 0.0314); overall mean: 6.1 cm<br>Measurement tool used: CT scan and intra-arterial digital subtraction angiography (DSA) |
| Type of device (EVAR) | Zenith: % not reported; Talent: % not reported |
| Graft type (EVAR) | Not reported |
| Anaesthesia | Not reported |
| Risk factor(s) used in model and definitions | Infrarenal neck length: > 1.5 cm (group A), 1.1–1.5 cm (group B), < 1.1 cm (group C) |
| Definition of outcomes | Outcome reporting adhered to guidelines of the Society for Vascular Surgery/American Association for Vascular Surgery (SVS/AAVS). Team experience defined as at least 30 EVAR cases per year |
| Follow-up period | 1, 3, 6, 12, 18 and 24 months and annually thereafter |
| Methods of analysis | Comparison of patient, morphological and centre-related characteristics among the three infrarenal neck length groups was performed using chi-squared tests and Wilcoxon rank sum tests for categorical and continuous variables respectively. All variables that differed significantly among the three groups according to these univariate analyses were included as covariates in multivariate outcome analyses. Logistic multivariate regression analysis performed for early complications (30 days); ORs with 95% CIs calculated. For late outcomes (1–48 months) multivariate Cox proportional hazards models fitted (HRs with 95% CIs). Kaplan–Meier method, with log-rank analysis hazard ratios and survival curves |
| 30-day mortality | Aortic neck length: OR group B vs A (adjusted): 1.77 (95% CI 1.08 to 2.87); OR group C vs A (adjusted): 1.40 (95% CI 0.65 to 3.02) |
| Aneurysm-related mortality at follow-up | Aortic neck length: HR group B vs A (adjusted): 1.52 (95% CI 0.50 to 4.61) |
| All-cause mortality at follow-up | Aortic neck length: HR group B vs A (adjusted): 1.20 (95% CI 0.83 to 1.72); HR group C vs A (adjusted): 1.45 (95% CI 0.92 to 2.27) |

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| Reintervention | Aortic neck length<br>Conversion to open repair (30 days): OR group B vs A (adjusted): 0.70 (95% CI 0.21 to 2.36); OR group C vs A (adjusted): 1.33 (95% CI 0.30 to 5.84)<br>Conversion to open repair (48-month follow-up): HR group B vs A (adjusted): 1.74 (95% CI 0.58 to 5.28); HR group C vs A (adjusted): 0.84 (95% CI 0.11 to 6.43)<br>Secondary intervention – transfemoral (48-month follow-up): HR group B vs A (adjusted): 0.73 (95% CI 0.39 to 1.36); HR group C vs A (adjusted): 1.13 (95% CI 0.55 to 2.36)<br>Secondary intervention – transabdominal (48-month follow-up): HR group B vs A (adjusted): 1.78 (95% CI 0.66 to 4.84); HR group C vs A (adjusted) 0.75 (95% CI 0.10 to 5.68)<br>Secondary intervention – extra-anatomic (48-month follow-up): HR group B vs A (adjusted): 1.53 (95% CI 0.66 to 3.53); HR group C vs A (adjusted): 0.50 (95% CI 0.07 to 3.68) |
| Endoleak | Aortic neck length<br>Proximal type I endoleak (30 days): OR (adjusted) group B vs A: 1.38 (95% CI 0.80 to 2.37); OR (adjusted) group C vs A: 4.46 (95% CI 2.61 to 7.61)<br>Proximal type I endoleak (48-month follow-up): HR (adjusted) group B vs A: 1.98 (95% CI 1.16 to 3.38); HR (adjusted) group C vs A: 2.32 (95% CI 1.17 to 4.60)<br>Distal type I endoleak (30 days): OR (adjusted) group B vs A: 0.45 (95% CI 0.16 to 1.24); OR (adjusted) group C vs A: 0.49 (95% CI 0.12 to 2.05)<br>Distal type I endoleak (48-month follow-up): HR (adjusted) group B vs A: 0.48 (95% CI 0.19 to 1.19); HR (adjusted) group C vs A: 1.22 (95% CI 0.52 to 2.85)<br>Type II endoleak (30 days): OR (adjusted) group B vs A: 0.88 (95% CI 0.63 to 1.23); OR (adjusted) group C vs A: 0.45 (95% CI 0.23 to 0.89)<br>Type II endoleak (48-month follow-up): HR (adjusted) group B vs A: 0.79 (95% CI 0.56 to 1.13); HR (adjusted) group C vs A: 0.71 (95% CI 0.40 to 1.24)<br>Type III endoleak (30 days): OR (adjusted) group B vs A: 0.60 (95% CI 0.26 to 1.40); OR (adjusted) group C vs A: 0.77 (95% CI 0.24 to 2.51)<br>Type III endoleak (48-month follow-up): HR (adjusted) group B vs A: 0.86 (95% CI 0.47 to1.57); HR (adjusted) group C vs A: 0.17 (95% CI 0.02 to 1.19) |
| Study sample adequately described | Yes |
| Included risk variables clearly defined | Yes |
| Covariates considered to build the multivariate model | Yes |
| Interactions between variables explored | Unclear |
| Continuous variables handled appropriately | Yes |
| More than 10 events per included variable | Yes |
| Confidence intervals or other measures of uncertainty presented | Yes |

**Leurs LJ, Laheij RJF, Buth J. Influence of diabetes mellitus on the endovascular treatment of abdominal aortic aneurysms. *J Endovasc Ther* 2005;12:288–96[75,55]**

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| Author | Leurs 2005[75] |
| Country where study was performed | 163 European centres |
| Type of study | Specific risk factors following EVAR |
| Registry | Dates enrolled and/or treated: between May 1994 and December 2003<br>EUROSTAR |
| Number of patients | 6017 patients: 731 with diabetes mellitus: 21 with type I diabetes, 505 with diet-controlled type II diabetes and 205 with insulin-controlled type II diabetes |
| Age of population | With diabetes, mean age 71.9 years; without diabetes, mean age 71.7 years; total, mean age 71.8 years<br>Range: with diabetes: 37–100 years; without diabetes: 28–100 years; total range: 28–100 years<br>Age > 70 years: with diabetes: 451 (61.70%); without diabetes: 3213 (60.82%); total: 3664 (60.9%) |
| Gender | Percentage male (total population): with diabetes: 690 (94.39%); without diabetes: 4933 (93.32%); total: 5623 (93.5%) |
| Aneurysm diameter | Max. AAA diameter > 6 cm: with diabetes: 224 (31.33%); without diabetes: 1488 (28.81%); total: 1712 (28.5%)<br>Measurement tool used: not reported |
| Type of device (EVAR) | Not reported |
| Graft type (EVAR) | Not reported |
| Anaesthesia | Not reported |
| Risk factor(s) used in model and definitions | Composite risk score diabetes vs non-diabetes: the ASA risk classification and the SVS risk score were used to represent the patient risk profile. An SVS risk score of 1 and 2 indicated diet-controlled (oral hypoglycaemic agent) or insulin-controlled type II diabetes respectively; type I diabetes was indicated by a risk score of 3 |
| Definition of outcomes | Intraoperative complications: device-related sequelae, procedural failure and arterial complications. Postoperative (in-hospital) complications: systemic, procedure- and device-related, and accessing site/lower limb. Late complications: endoleaks, kinking, thrombosis and migration occurring after 30 days |
| Follow-up period | 4-year follow-up; mean follow-up of 19.36 (SD 18.88) months (range 0–96 months) |
| Methods of analysis | ORs (95% CI) calculated for time-independent variables with multivariate logistic regression analysis. HRs calculated using Cox proportional hazards model for time-dependent characteristics. Models adjusted for patient age, sex, ASA classification, SVS risk factors, obesity and unfitness for traditional open surgery or general anaesthesia. Life table analyses and Kaplan–Meier survival estimates used to analyse survival. Statistical significance set at $p < 0.05$ |
| 30-day mortality | Pre-existing conditions: with diabetes: 29/731 patients (4.37%); without diabetes: 102/5286 patients (2.11%); OR (adjusted): 1.67 (95% CI 1.71 to 2.61, $p < 0.024$) |
| Aneurysm-related mortality at follow-up | No risk factors investigated |
| All-cause mortality at follow-up | Pre-existing conditions: with diabetes: 67/731 patients (9.16%); without diabetes: 452/5286 patients (8.55%); total: 519 (8.6%); HR (adjusted): 1.15 (95% CI 0.88 to 1.50) |

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| Reintervention | Secondary intervention (follow-up): with diabetes: 71/731 (9.71%); without diabetes: 586/5286 (11.09%); HR (adjusted): 1.07 (95% CI 0.83 to 1.38)<br>Early conversion (30 days): with diabetes: 13/731 (1.81%); without diabetes: 62/5286 (1.20%); OR (adjusted): 1.57 (95% CI 0.84 to 2.95)<br>Late conversion (follow-up): with diabetes: 11/731 (1.50%); without diabetes: 118/5286 (2.23%); HR (adjusted): 1.02 (95% CI 0.54 to 1.91) |
| Endoleak | Endoleak (30 days): with diabetes: 105/731 (14.36%); without diabetes: 864/5286 (16.35%) (significant between two groups, $p < 0.035$); OR (adjusted): 0.87 (95% CI 0.70 to 1.10)<br>Endoleak type I proximal (30 days): with diabetes: 22/731 (3.01%); without diabetes: 160/5286 (3.03%); OR (adjusted): 0.91 (95% CI 0.57 to 1.46)<br>Endoleak type I distal (30 days): with diabetes: 15/731 (2.05%); without diabetes: 125/5286 (2.36%); OR (adjusted): 0.88 (95% CI 0.51 to 1.53)<br>Endoleak type II (30 days): with diabetes: 51/731 (6.97%); without diabetes: 466/5286 (8.82%); OR (adjusted): 0.86 (95% CI 0.63 to 1.17)<br>Endoleak type III (30 days): with diabetes: 12/731 (1.64%); without diabetes: 125/5286 (2.36%); OR (adjusted): 0.66 (95% CI 0.36 to 1.22)<br>Endoleak (follow-up): with diabetes: 119/731 (16.28%); without diabetes: 953/5286 (18.03%); HR (adjusted): 1.05 (95% CI 0.87 to 1.28)<br>Endoleak type I proximal (follow-up): with diabetes: 20/731 (2.74%); without diabetes: 157/5286 (2.97%); HR (adjusted): 1.03 (95% CI 0.64 to 1.67)<br>Endoleak type I distal (follow-up): with diabetes: 27/731 (3.69%); without diabetes: 218/5286 (4.12%); HR (adjusted): 1.09 (95% CI 0.72 to 1.63)<br>Endoleak type II (follow-up): with diabetes: 67/731 (9.17%); without diabetes: 563/5286 (10.65%); HR (adjusted): 0.96 (95% CI 0.74 to 1.25)<br>Endoleak type III (follow-up): with diabetes: 28/731 (3.83%); without diabetes: 227/5286 (4.29%); HR (adjusted): 1.19 (95% CI 0.80 to 1.78) |
| Study sample adequately described | Yes |
| Included risk variables clearly defined | Yes |
| Covariates considered to build the multivariate model | Yes |
| Interactions between variables explored | Unclear |
| Continuous variables handled appropriately | Unclear |
| Confidence intervals or other measures of uncertainty presented | Yes |

**Leurs LJ, Stultiens G, Kievit J, Buth J. Adverse events at the aneurysmal neck identified at follow-up after endovascular abdominal aortic aneurysm repair: how do they correlate? *Vascular* 2005;13:261–7[76,55]**

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|---|---|
| Author | Leurs 2005[76] |
| Country where study was performed | 147 centres in Europe |
| Type of study | Specific risk factors following EVAR |
| Registry | Dates enrolled and/or treated: between 1994 and 2004<br>EUROSTAR |
| Number of patients | 4233 patients |
| Age of population | Range: 37–101 years |
| Gender | 3967 (93.7%) male |
| Aneurysm diameter | Mean: 5.8 cm; range: 4.0–11.0 cm<br>Measurement tool used: CT scan |
| Type of device (EVAR) | Zenith: 1185 patients (28%); Talent: 892 (21.1%); Excluder: 469 (11.1%); Lifepath: 63 (1.5%); EVT/Ancure: 142 (3.4%); others (including Fortron, Anaconda, Endologix and homemade devices): 164 (3.9%); Vanguard/Stentor: 646 (1.5%); AneuRx: 672 (15.9%) |
| Graft type (EVAR) | Not reported |
| Anaesthesia | Not reported |
| Risk factor(s) used in model and definitions | Device to neck diameter ratio ≥ 1.20<br>Device main diameter (not defined)<br>Device-related factors: use of aortic extension cuff, absence of proximal bare stent fixation<br>Hypertension and smoking (not defined)<br>Aneurysm diameter (not defined)<br>Neck diameter and angulation (not defined)<br>Neck length (not defined) |
| Definition of outcomes | Dilatation of the infrarenal aneurysm neck was defined as an increase in diameter measured 0.3 cm distally from the lower renal artery – outer wall to outer wall across the minor diameter on the axial CT slice. Growth of aneurysm neck defined as diameter increase of at least 0.4 cm relative to the preoperative measurements on CT. Device migration diagnosed using judgement of management teams (extent of migration not included in analyses as rarely quantified in millimetres device displacement). Proximal endoleak: endoleaks in the first month not counted |
| Follow-up period | Follow-up with plain abdominal radiography performed at 1 month, 1 year and annually thereafter. Mean or maximum follow-up not reported |
| Methods of analysis | Chi-squared tests were used for comparison of discrete variables, and *t*-tests or Wilcoxon rank sum tests for continuous variables. Multivariate Cox proportional hazards model was used to determine anatomic and operative variables, with an independent correlation with neck growth and device migration, respectively, as the outcome event |
| 30-day mortality | No risk factors investigated |
| Aneurysm-related mortality at follow-up | No risk factors investigated |
| All-cause mortality at follow-up | No risk factors investigated |
| Reintervention | No risk factors investigated |

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| Endoleak | Smoking status: HR 0.96 (95% CI 0.61 to 1.52, $p = 0.87$)<br>Graft configuration and device type: without suprarenal fixation system or hooks: HR 0.75 (95% CI 0.4 to 1.15, $p = 0.18$)<br>Device to neck diameter ratio ≥ 1.20: HR 0.97 (95% CI 0.48 to 1.56, $p = 0.63$)<br>Device main diameter: HR 1.01 (95% CI 0.89 to 1.14, $p = 0.93$)<br>Use of aortic extension cuff: HR 0.91 (95% CI 0.28 to 2.88, $p = 0.87$)<br>Hypertension: HR 1.25 (95% CI 0.83 to 1.87, $p = 0.28$)<br>Aneurysm diameter: HR 1.00 (95% CI 0.99 to 1.01, $p = 0.66$)<br>Neck diameter: HR 1.04 (95% CI 0.90 to 1.19, $p = 0.63$)<br>Significant neck angulation (positive correlation): HR 2.02 (95% CI 1.37 to 2.99, $p = 0.0004$)<br>Aortic neck length: HR 0.97 (95% CI 0.95 to 0.99, $p = 0.0043$) (negative correlation)<br>Postoperative factors: infrarenal neck dilatation: HR 0.85 (95% CI 0.55 to 1.31, $p = 0.45$); migration: HR 3.11 (95% CI 1.83 to 5.30, $p < 0.0001$) |
| Study sample adequately described | Yes |
| Included risk variables clearly defined | Yes |
| Covariates considered to build the multivariate model | Yes |
| Interactions between variables explored | Unclear |
| Continuous variables handled appropriately | Unclear |
| More than 10 events per included variable | Unclear |
| Confidence intervals or other measures of uncertainty presented | Yes |

**Leurs LJ, Visser P, Laheij RJF, Buth J, Harris PLH, Blankensteijn JD. Statin use is associated with reduced all-cause mortality after endovascular abdominal aortic aneurysm repair. *Vascular* 2006;14:1–8[77,72]**

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|---|---|
| Author | Leurs 2006[77] |
| Country where study was performed | 165 institutions in Europe |
| Type of study | Specific risk factors following EVAR |
| Registry | Enrolled 1 December 1996<br>EUROSTAR |
| Number of patients | 5892 patients, 731 (12.4%) statin users |
| Age of population | Mean (SD): statin users: 70.1 (7.3) years; non-users 72.6 (7.7) years ($p < 0.0001$); total: 72.3 years |
| Gender | Percentage male: total: 5545 (94.1%); statin users: 694 (94.9%); non-users: 4851 (94.0%) ($p$ = NS) |
| Aneurysm diameter | Overall mean: 5.86 cm; statin users: 5.82 (0.96) cm; non-users: 5.87 (1.11) cm ($p$ = NS)<br>Measurement tool used: CT and intra-arterial digital subtraction angiography (DSA) |
| Type of device (EVAR) | Not reported; only commercially available CE-approved stent grafts used |
| Graft type (EVAR) | Not reported |
| Anaesthesia | Not reported |
| Risk factor(s) used in model and definitions | Age ≥ 70 years<br>ASA class ≥ III<br>Pre-existing conditions: moderate/severe SVS/ISCVS risk score: diabetes, smoking, hypertension, cardiac disease, carotid disease, renal disease, pulmonary disease<br>Pre-operative statin therapy |
| Definition of outcomes | Death within 30 days of initial procedure defined as operative death. Death after 30 days defined as late death. Aneurysm-related death included 30-day death and death that occurred as a result of aneurysm rupture or endograft infection or within 1 month after a secondary surgical procedure for late complications of the aneurysm |
| Follow-up period | 1, 3, 6, 12, 18 and 24 months and annually thereafter (mean duration 17 months) |
| Methods of analysis | Univariate analysis was carried out to correlate the two patient groups with preoperative patient characteristics, comorbidity, risk factors and aneurysmal morphology at the time of the initial procedure. Differences in baseline characteristics between the two groups were assessed using chi-squared tests for discrete variables and Wilcoxon rank sum tests for continuous variables. Multivariate Cox proportional hazards model used to identify effect of statin use on late outcomes with adjustment for potential confounders (ASA class ≥ III, diabetes, hypertension, cardiac and carotid impairment, obesity and age > 70 years). 30-day outcomes after EVAR analysed by multivariate logistic regression, follow-up outcomes assessed by Kaplan–Meier survival analysis |
| 30-day mortality | No risk factors investigated |
| Aneurysm-related mortality at follow-up | Patient age > 70 years: HR 2.38 (95% CI 1.63 to 3.48, $p < 0.0001$)<br>ASA class ≥ III: HR 3.21 (95% CI 2.27 to 4.53, $p < 0.0001$)<br>Statin use: HR 0.57 (95% CI 0.32 to 1.03, $p$ = NS) |
| All-cause mortality at follow-up | Patient age > 70 years: HR 1.96 (95% CI 1.62 to 2.38, $p < 0.0001$)<br>ASA class ≥ III: HR 1.90 (95% CI 1.59 to 2.28, $p < 0.0001$)<br>Cardiac status: HR 1.24 (95% CI 1.03 to 1.49, $p = 0.022$)<br>Statin use: adjusted HR 0.72 (95% CI 0.54 to 0.98, $p = 0.034$) |

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| Reintervention | There was no significant association between statin use and increased risk for conversion: HR (adjusted): 0.58 (95% CI 0.29 to 1.13, $p$ = NS) |
| Endoleak | No risk factors investigated |
| Study sample adequately described | Yes |
| Included risk variables clearly defined | No |
| Covariates considered to build the multivariate model | Not reported; unclear |
| Interactions between variables explored | Unclear |
| Continuous variables handled appropriately | Unclear |
| More than 10 events per included variable | Unclear |
| Confidence intervals or other measures of uncertainty presented | Yes |

**Lifeline Registry of Endovascular Aneurysm Repair Steering Committee. Lifeline Registry of Endovascular Aneurysm Repair: Registry data report. *J Vasc Surg* 2002;35:616–20[78]**

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|---|---|
| Author | Lifeline Registry 2002[78] |
| Country where study was performed | USA |
| Type of study | Specific risk factors following EVAR |
| Registry | Dates enrolled and/or treated: not reported<br>Lifeline Registry includes data on EVAR from 40 centres |
| Number of patients | 1646 |
| Age of population | Mean: 73.1 (SD 7.9) years |
| Gender | 88.6% male |
| Aneurysm diameter | Mean: 5.57 cm (SD not reported) |
| Type of device (EVAR) | Not reported |
| Graft type (EVAR) | Not reported |
| Anaesthesia | Not reported |
| Risk factor(s) used in model and definitions | Age<br>Pre-existing conditions: chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF), renal failure (not defined)<br>Aneurysm size categorised as < 4.0, 4.0–4.9, 5.0–5.9, 6.0–6.9, 7.0–7.9 and > 8.0 cm |
| Definition of outcomes | All-cause mortality at follow-up (1 year): survival |
| Follow-up period | 1 year (80% followed up for 1 year) |
| Methods of analysis | Logistic regression analysis of 1-year survival |
| 30-day mortality | No risk factors investigated |
| Aneurysm-related mortality at follow-up | No risk factors investigated |
| All-cause mortality at follow-up | Increasing age associated with reduced 1-year survival<br>COPD and CHF associated with reduced 1-year survival compared with patients with no comorbidities<br>Renal failure associated with reduced 1-year survival compared with patients with no comorbidities<br>Increasing aneurysm size associated with reduced 1-year survival |
| Reintervention | No risk factors investigated |
| Endoleak | No risk factors investigated |
| Study sample adequately described | Yes |
| Included risk variables clearly defined | No |
| Covariates considered to build the multivariate model | Not reported; unclear – limited reporting in paper |
| Interactions between variables explored | Unclear; limited details given |
| Continuous variables handled appropriately | No; aneurysm size categorised |
| More than 10 events per included variable | Unclear |
| Confidence intervals or other measures of uncertainty presented | No; only general statements |

**Lifeline Registry of EVAR Publications Committee. Lifeline registry of endovascular aneurysm repair: long-term primary outcome measures. *J Vasc Surg* 2005;42:1–10[79,78]**

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|---|---|
| Author | Lifeline Registry 2005[79] |
| Country where study was performed | USA |
| Type of study | Specific risk factors following EVAR |
| Registry | Registry established 1998<br>This report from the Lifeline Registry includes 5-year data from clinical trials of four EVAR devices: AnCure, AneuRx, Excluder and Powerlink |
| Number of patients | 2664 |
| Age of population | Mean: 73.1 (SD 7.8) years; range: 45–96 years |
| Gender | 88.6% male |
| Aneurysm diameter | Mean: 5.58 (SD 1.02) cm; range: 2.1–12.0 cm |
| Type of device (EVAR) | Zenith: 0%; Talent: 0%; Excluder: 235/2664 (8.8%); AnCure: 1040/2664 (39.0%); AneuRx: 1204/2664 (45.2%); Powerlink: 185/2664 (6.9%) |
| Graft type (EVAR) | Not reported |
| Anaesthesia | Not reported |
| Risk factor(s) used in model and definitions | Age: not specified<br>Female gender<br>Pre-existing conditions: coronary artery disease (CAD) or myocardial infarction (MI), congestive heart failure (CHF), hypertension, chronic obstructive pulmonary disease (COPD), diabetes mellitus<br>Renal failure (serum creatinine > 3 mg)<br>Aneurysm size: not defined |
| Definition of outcomes | Operative mortality: death during initial hospitalisation or up to 30 days postoperatively. Aneurysm-related death: death from any cause up to 30 days postoperatively or up to 30 days after a reintervention for aneurysm or any death due to graft complication or aneurysm rupture. All-cause mortality: survival. Aneurysm rupture: not defined. Conversion to open repair: not defined |
| Follow-up period | At least 5 years; mean follow-up 2.8 (SD 1.6) years; maximum 6.7 years |
| Methods of analysis | Predictive risk factors for specified outcomes were identified by Cox proportional hazards multivariate logistic regression |
| 30-day mortality | No risk factors investigated |
| Aneurysm-related mortality at follow-up | Age: HR 1.041 (95% CI 1.00 to 1.09, $p = 0.061$)<br>Female gender: HR 1.65 (95% CI 0.71 to 3.82, $p = 0.24$)<br>CAD/MI: HR 2.43 (95% CI 0.58 to 10.25, $p = 0.23$); CHF: HR 2.15 (95% CI 1.00 to 4.67, $p = 0.053$); hypertension: HR 0.92 (95% CI 0.48 to 1.80, $p = 0.82$); COPD: HR 1.26 (95% CI 0.65 to 2.45, $p = 0.50$); diabetes mellitus: HR 0.98 (95% CI 0.38 to 2.533, $p = 0.97$)<br>Renal failure: HR 1.78 (95% CI 0.52 to 6.01, $p = 0.36$)<br>Aneurysm size: HR 1.03 (95% CI 1.01 to 1.06, $p = 0.01$) |

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| All-cause mortality at follow-up | Age: HR 1.04 (95% CI 1.03 to 1.1, $p < 0.0001$)<br>Female gender: HR 1.04 (95% CI 0.77 to 1.40, $p = 0.82$)<br>CAD/MI: HR 1.61 (95% CI 1.14 to 2.27, $p = 0.01$); CHF: HR 2.32 (95% CI 1.82 to 2.96); hypertension: HR 1.01 (95% CI 0.83 to 1.2, $p = 0.95$); COPD: HR 1.84 (95% CI 1.51 to 2.23, $p < 0.0001$); diabetes mellitus: HR 1.15 (95% CI 0.88 to 1.51, $p = 0.30$)<br>Renal failure: HR 1.57 (95% CI 1.06 to 2.31, $p = 0.02$)<br>Aneurysm size: HR 1.02 (95% CI 1.01 to 1.03, $p < 0.0001$) |
| Reintervention | No risk factors investigated |
| Endoleak | No risk factors investigated |
| Study sample adequately described | Yes |
| Included risk variables clearly defined | No; diagnostic criteria for specific comorbidities not stated |
| Covariates considered to build the multivariate model | Yes; baseline characteristics |
| Interactions between variables explored | No; no specific interaction terms reported |
| Continuous variables handled appropriately | Yes; kept as continuous not categorised |
| More than 10 events per included variable | Unclear; not all results detailed; may be 'no' for AAA-related death |
| Confidence intervals or other measures of uncertainty presented | Yes |

**Lottman PEM, van Marrewijk CJ, Fransen GAF, Laheij RJF, Buth J. Impact of smoking on endovascular abdominal aortic aneurysm surgery outcome. *Eur J Vasc Endovasc Surg* 2004;27:512–18[80]**

| | |
|---|---|
| Author | Lottman 2004[80] |
| Country where study was performed | 107 centres in Europe |
| Type of study | Specific risk factors following EVAR |
| Registry | Dates enrolled and/or treated: January 1994–July 2001<br>EUROSTAR registry |
| Number of patients | 3270 [of whom 853 (26%) were smokers] |
| Age of population | Range: 9% were aged ≤ 60 years, 34% were aged 61–70 years, 46% were aged 71–80 years, 11% were aged ≥ 80 years |
| Gender | 93% male |
| Aneurysm diameter | Range: 1442 (44%) aneurysm diameter < 5.5 cm, 1748 (56%) aneurysm diameter of 5.5 cm |
| Type of device (EVAR) | Not reported |
| Graft type (EVAR) | Not reported |
| Anaesthesia | Not reported |
| Risk factor(s) used in model and definitions | The study population was divided into two groups: smokers and non-smokers. Smokers were those who did smoke at the time of enrolment (both those who smoked less than one packet a day and those who smoked more than one packet a day; corresponds to SVS/ICCVS risk score 2 or 3). Non-smokers were those who did not smoke at enrolment (including those who had smoked in the last 10 years; corresponds to SVS/ICCVS risk score 0 or 1) |
| Definition of outcomes | Late mortality: death after first 30 days. Reinterventions: late reinterventions defined as those after 30 days postoperatively; late conversions defined as those after 30 days postoperatively. Endoleak: type I proximal, type I distal, type II and type III |
| Follow-up period | Median follow-up 12 months (range 0–84 months) |
| Methods of analysis | For outcomes up to 30 days postoperatively differences between the groups were analysed using chi-squared tests or the Fisher exact test, or the rank test for non-parametric data. Outcomes after the first 30 days were analysed using the Kaplan–Meier method. Differences in survival were assessed for significance by means of log-rank tests. Multivariate Cox proportional hazards models were used to examine the relationship of smoking with late events, adjusted for baseline characteristics: age, gender, morphological data, pre-existing comorbidity, device, year of operation and operating team experience. A $p$-value of $< 0.01$ was considered statistically significant |
| 30-day mortality | No risk factors investigated |
| Aneurysm-related mortality at follow-up | No risk factors investigated |
| All-cause mortality at follow-up | Smoking status: no significant effect of smoking status |
| Reintervention | Smoking status:<br>Late reinterventions: no significant effect of smoking status; late conversion: no significant effect of smoking status |
| Endoleak | Smoking status:<br>Late endoleak (all): no significant effect of smoking status; late endoleak (type I proximal): no significant effect of smoking status; late endoleak (type I distal): no significant effect of smoking status; late endoleak (type II): HR 0.64 (95% CI 0.5 to 0.9) (association with smoking); late endoleak (type III): no significant effect of smoking status |

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| Study sample adequately described | Yes; EUROSTAR |
| Included risk variables clearly defined | Yes |
| Covariates considered to build the multivariate model | Yes; baseline characteristics considered (listed in methods) |
| Interactions between variables explored | No; no mention of a term for any specific interaction |
| Continuous variables handled appropriately | No; age was grouped as ≤ 60, 61–70, 71–80 and ≥80 years. Also, other measurements such as aneurysm diameter dichotomised |
| More than 10 events per included variable | Yes |
| Confidence intervals or other measures of uncertainty presented | No |

**Mohan IV, Laheij RJ, Harris PL; EUROSTAR collaborators. Risk factors for endoleak and the evidence for stent-graft oversizing in patients undergoing endovascular aneurysm repair. *Eur J Vasc Endovasc Surg* 2001;21:344–9[81]**

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| Author | Mohan 2001[81] |
| Country where study was performed | European |
| Type of study | Specific risk factors following EVAR |
| Registry | Dates enrolled and/or treated: January 1994–January 2000<br>EUROSTAR |
| Number of patients | 2146 (although baseline risk factors assessed in 2194) |
| Age of population | Range: 37–92 years; median: 70 years |
| Gender | 92% male |
| Aneurysm diameter | Range: 2.1–15.0 cm; median: 5.6 cm |
| Type of device (EVAR) | Zenith: 6%; Talent: 13%; Excluder: 4%; Vanguard: 40%; Stentor: 15%; AneuRx: 18%; EVT: 3%; other: 1% |
| Graft type (EVAR) | Bi-iliac: 92% patients |
| Anaesthesia | Not reported |
| Risk factor(s) used in model and definitions | Age < 65 years, 65–75 years, > 75 years<br>Gender male or female<br>Smoking (current > 20/day, current < 20/day, stopped < 10 years, stopped > 10 years)<br>Device type (trade name)<br>Type of aortic device, device diameter and use of aortic cuff<br>ASA classification class I, II, III or IV<br>Pre-existing conditions: obesity (not defined)<br>Fitness for open procedure (not defined)<br>Aneurysm diameter < 5.0 cm, 5.0–6.0 cm, > 6.0 cm<br>Aortic neck and aneurysm angle<br>Aortic neck length<br>Experience of surgeon |
| Definition of outcomes | Endoleak (all) as identified immediately after stent graft deployment. Endoleak (proximal) as identified immediately after stent graft deployment |
| Follow-up period | Assessment immediately after stent graft deployment only |
| Methods of analysis | The clinical features of patients with endoleak were compared with those of patients without endoleak. Data analysed by chi-squared test. A multivariate analysis was performed using variables identified from the univariate analysis as being significantly associated with endoleak. A logistic regression model was constructed excluding backward elimination factors not associated with proximal endoleak. ORs with 95% CIs calculated. Patients with missing data were eliminated from the analysis |
| 30-day mortality | No risk factors investigated |
| Aneurysm-related mortality at follow-up | No risk factors investigated |
| All-cause mortality at follow-up | No risk factors investigated |
| Reintervention | No risk factors investigated |

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| Endoleak | Age: all endoleak: < 65 years (24%): multivariate analysis OR 1; 65–75 years (46%): multivariate analysis OR 0.77 (95% CI 0.56 to 1.07, $p = 0.87$); > 75 years (30%): multivariate analysis OR 1.35 (95% CI 0.96 to 1.90, $p = 0.08$); proximal endoleak: no significant association with age<br>Gender: all endoleak: female (8%): multivariate analysis OR 1; male (92%): multivariate analysis OR 0.71 (95% CI 1.47 to 1.07, $p = 0.097$); proximal endoleak: no significant association with gender<br>Smoking status: all endoleak: current (> 20/day) (10%): multivariate analysis OR 1; current < 20/day (19%): no significant association; stopped < 10 years (29%): no significant association; stopped > 10 years (43%): multivariate analysis OR 1.72 (95% CI 1.10 to 2.80, $p = 0.03$); proximal endoleak: no significant association with smoking status<br>Graft configuration and device type: no significant association with endoleak or proximal endoleak<br>ASA: no significant association with endoleak or proximal endoleak<br>Pre-existing conditions: obesity: no association with endoleak or proximal endoleak<br>Fitness for open procedure: no significant association with endoleak or proximal endoleak<br>Aneurysm size: all endoleak: aneurysm diameter < 5.0 cm (26%): multivariate analysis OR 1; aneurysm diameter 5.0–6.0 cm (49%): multivariate analysis OR 1.45 (95% CI 1.06 to 1.99, $p = 0.02$); aneurysm diameter > 6.0 cm (25%): multivariate analysis OR 1.60 (95% CI 1.13 to 2.27, $p = 0.008$); proximal endoleak: no significant association with aneurysm size<br>Aortic neck and aneurysm angle: no significant association with endoleak or proximal endoleak<br>Aortic neck length: the length of the proximal aortic neck was significantly associated with proximal endoleak: OR 0.93 (95% CI 0.89 to 0.96, $p = 0.0001$)<br>Other (give details): experience of surgeon: no significant association with endoleak or proximal endoleak |
| Study sample adequately described | Yes |
| Included risk variables clearly defined | Yes |
| Covariates considered to build the multivariate model | Yes |
| Interactions between variables explored | Unclear |
| Continuous variables handled appropriately | No; age and aneurysm diameter categorised |
| More than 10 events per included variable | Unclear; unclear for proximal endoleak |
| Confidence intervals or other measures of uncertainty presented | Yes |

**Peppelenbosch N, Buth J, Harris PL, van Marrewijk C, Fransen G. Diameter of abdominal aortic aneurysm and outcome of endovascular aneurysm repair: does size matter? A report from EUROSTAR. *J Vasc Surg* 2004;39:288–97[82]**

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| Author | Peppelenbosch 2004[82] |
| Country where study was performed | 110 European centres |
| Type of study | Specific risk factors following EVAR |
| Registry | EUROSTAR<br>Patients enrolled over 6 years up to June 2002<br>This cohort includes patients from 110 institutions |
| Number of patients | 4392 |
| Age of population | Mean: small aneurysms (4.0–5.4 cm): *n* = 1962, mean age 69.7 years; medium aneurysms (5.5–6.4 cm): *n* = 1528, mean age 72.1 years; large aneurysms (≥ 6.5 cm): *n* = 902, mean age 73.3 years<br>Range: small aneurysms (4.0–5.4 cm): *n* = 1962, age range 43–94 years; medium aneurysms (5.5–6.4 cm): *n* = 1528, age range 49–109 years; large aneurysms (≥ 6.5 cm): *n* = 902, age range 50–93 years |
| Gender | Percentage male: small aneurysms (4.0–5.4 cm): 93%; medium aneurysms (5.5–6.4 cm): 93%; large aneurysms (≥ 6.5 cm): 95%; total population: 93.2% |
| Aneurysm diameter | Mean: 57.2 cm (SD not reported); range: 4.0–14.5 cm |
| Type of device (EVAR) | Zenith: 891 (20.3%); Talent: 821 (18.7%); Excluder: 341 (7.8%); AneuRx: 877 (20.0%); EVT/Ancure: 150 (3.4%); Stentor: 282 (6.4%); Vanguard: 905 (21%); other/unknown: 125 (2.9%) |
| Graft type (EVAR) | Aorto-uni-iliac: 193 (4.4%); straight tube: 149 (3.4%); bi-iliac: 405 (92.2%) |
| Anaesthesia | Not reported |
| Risk factor(s) used in model and definitions | Age<br>Gender<br>Graft configuration and device type: a dichotomous categorisation of devices was used, with Stentor and Vanguard as one category and all other devices in the other<br>ASA<br>Pre-existing conditions<br>Fitness for open procedure<br>Renal function (creatinine)<br>Aneurysm size: small aneurysms (4.0–5.4 cm), medium aneurysms (5.5–6.4 cm), large aneurysms (≥ 6.5 cm)<br>Aortic neck and aneurysm angle<br>Aortic neck length |
| Definition of outcomes | 30-day mortality: death within 30 days of initial procedure. Aneurysm-related mortality at follow-up: all operative deaths and those related to aneurysm rupture or endograft infection or within 1 month of a secondary surgical procedure to treat a late complication of the aneurysm. All-cause mortality at follow-up: late deaths that occurred more than 30 days after initial procedure. Endoleak: type I proximal and type I distal, type II and type III; only endoleaks identified at 1 month or after included. Reintervention: late conversion to open repair |
| Follow-up period | Mean follow-up: 18.4 months; range 1–72 months |
| Methods of analysis | Preoperative patient characteristics, comorbid conditions and aneurysm anatomy at initial procedure and details of procedure and devices were correlated with univariate analysis. Differences in findings between groups were assessed with chi-squared tests for discrete variables and Mann–Whitney test for continuous variables. All variables with significant correlation with an adverse outcome were entered into a multivariate Cox analysis. |

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| | A dichotomous categorisation of devices was used, with Stentor and Vanguard as one category and all other devices in the other. This variable device category was entered into multivariate analysis irrespective of the result of the univariate analysis. Cumulative rates of freedom from aneurysm-related death were assessed with life table analysis. Only rates with SE < 10% are indicated. Significant differences between study groups were assessed with log-rank testing |
| 30-day mortality | No risk factors investigated; no multivariate analysis |
| Aneurysm-related mortality at follow-up | Age: multivariate HR: 1.1 (95% CI 1.04 to 1.09) (misprint or rounding up of HR?)<br>Gender: no significant association (multivariate analysis)<br>Graft configuration and device type: association with Stentor or Vanguard device: multivariate HR: 1.5 (95% CI 1.1 to 2.3)<br>ASA: no significant association (multivariate analysis)<br>Pulmonary condition: multivariate HR: 1.7 (95% CI 1.1 to 2.4)<br>Association with lack of fitness for open repair: multivariate HR: 1.7 (95% CI 1.1 to 2.4)<br>Association with renal insufficiency: multivariate HR: 1.8 (95% CI 1.2 to 2.7)<br>Aneurysm-related mortality: association with large aneurysm size: multivariate HR: 2.5 (95% CI 1.6 to 4.0)<br>Late aneurysm death: association with large aneurysm size: multivariate HR: 6.0 (95% CI 2.6 to 14.1)<br>Aortic neck and aneurysm angle: no significant association (multivariate analysis)<br>Aortic neck length: no significant association (multivariate analysis) |
| All-cause mortality at follow-up | No risk factors investigated; only death not related to aneurysm repair reported |
| Reintervention | Age: no significant association (multivariate analysis)<br>Gender: no significant association (multivariate analysis)<br>Graft configuration and device type: no significant association (multivariate analysis)<br>ASA: no significant association (multivariate analysis)<br>Pre-existing conditions: no significant association (multivariate analysis)<br>Fitness for open procedure: no significant association (multivariate analysis)<br>Renal function (creatinine): no significant association (multivariate analysis)<br>Association with large aneurysm size: multivariate HR: 1.6 (95% CI 1.1 to 2.3)<br>Aortic neck and aneurysm angle: no significant association (multivariate analysis)<br>Aortic neck length: no significant association (multivariate analysis) |
| Endoleak | No risk factors investigated; no multivariate analysis |
| Study sample adequately described | Yes |
| Included risk variables clearly defined | No; aneurysm size specified but other risk factors unclear |
| Covariates considered to build the multivariate model | Yes |
| Interactions between variables explored | Unclear; no interaction terms specified |
| Continuous variables handled appropriately | Unclear; aneurysm size categorised, age kept as continuous |
| More than 10 events per included variable | Unclear; number of events not reported for most variables |
| Confidence intervals or other measures of uncertainty presented | Yes |

**Riambau V, Laheij RJ, Garcia-Madrid C, Sanchez-Espin G, EUROSTAR group. The association between co-morbidity and mortality after abdominal aortic aneurysm endografting in patients ineligible for elective open surgery.** ***Eur J Vasc Endovasc Surg*** **2001;22:265–70**[83,55,172]

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| Author | Riambau 2001[83] |
| Country where study was performed | 88 centres from European countries |
| Type of study | Specific risk factors following EVAR |
| Registry | Dates enrolled and/or treated: between January 1994 and August 1998<br>Patients operated on before July 1996 were included in the retrospective part of the study; after this date patients were included prospectively<br>EUROSTAR |
| Number of patients | 2862 patients: 2481 normal condition, 272 unfit for open procedure, 109 unfit for anaesthesia |
| Age of population | < 65 years: normal condition: 600 (24.2%); unfit for open procedure: 58 (21.3%); unfit for anaesthesia: 15 (13.8%); total: 673 (23.5%)<br>65–75 years: normal condition: 1157 (46.6%); unfit for open procedure: 113 (41.5%); unfit for anaesthesia: 44 (40.3%); total: 1314 (45.9%)<br>> 75 years: normal condition: 724 (29.2%); unfit for open procedure: 101 (37.2%); unfit for anaesthesia: 50 (45.9%); total: 875 (30.6%); $p = 0.001$ |
| Gender | Total: 2640 (92.2%) male |
| Aneurysm diameter | Overall mean: 5.62 cm<br>Normal condition: 5.56 (SD 1.07) cm; unfit for open procedure: 5.96 (SD 1.19) cm; unfit for anaesthesia: 6.05 (SD 1.43) cm; $p = 0.001$<br>Measurement tool used: CT scan |
| Type of device (EVAR) | Zenith: 239 (8.4%); Talent: 383 (13.4%); Excluder: 137 (4.8%); AneuRX: 707 (24.7%); EVT: 127 (4.4%); Stentor: 310 (10.8%); Vanguard: 892 (31.2%) |
| Graft type (EVAR) | Not reported |
| Anaesthesia | Not reported |
| Risk factor(s) used in model and definitions | Patients unfit for open surgery and/or unfit for anaesthesia were considered as patients ineligible for elective open repair because of their poor medical condition. Co-existing diseases (diabetes mellitus, hypertension, hyperlipidaemia, cardiac status, carotid disease, renal status and pulmonary status) reported according to the SVS/ICCVS risk score. Patients fit for open surgery or general anaesthesia considered in good medical condition. Patients unfit for open surgery or general anaesthesia considered in poor medical condition |
| Definition of outcomes | Early/late mortality (not defined) |
| Follow-up period | 1, 3, 6, 12, 18 and 24 months and annually thereafter |
| Methods of analysis | Associations between health status and clinical outcome were calculated by age-adjusted mortality rates. Univariate and multivariate regression analysis based on Cox proportional hazards models were used to assess correlations between mortality, comorbidity and health status. Exact Fisher's test was applied to determine the correlation between the previous medical condition at entry and the cause of death. Survival analysis was calculated using Kaplan–Meier testing |
| 30-day mortality | No risk factors investigated |
| Aneurysm-related mortality at follow-up | No risk factors investigated |

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| All-cause mortality at follow-up | Death among patients, by comorbidity at baseline<br>Hyperlipidaemia: patients with normal condition: RR (age adjusted) 0.78 (95% CI 0.6 to 1.1); patients unfit for open surgery: RR (age adjusted) 1.25 (95% CI 0.7 to 2.1)<br>Cardiac disease: normal condition: RR (age adjusted) 1.07 (95% CI 0.8 to 1.4); patients unfit for open surgery: RR (age adjusted) 1.14 (95% CI 0.6 to 2.2)<br>Renal insufficiency: normal condition: RR (age adjusted) 1.41 (95% CI 1.0 to 2.1); patients unfit for open surgery: RR (age adjusted) 1.59 (95% CI 0.9 to 2.8)<br>Pulmonary disease: patients fit for open surgery: RR (age adjusted) 1.40 (95% CI 1.0 to 1.9); patients unfit for open surgery: RR (age adjusted) 1.29 (95% CI 0.7 to 2.3)<br>Diabetes mellitus: patients fit for open surgery: RR (age adjusted) 1.66 (95% CI 1.1 to 2.5, $p < 0.05$); patients unfit for open surgery: RR (age adjusted) 1.42 (95% CI 0.7 to 2.8)<br>There were no significant associations between all-cause mortality at follow-up and smoking ($p = 0.9$), hypertension ($p = 0.8$) or carotid disease ($p = 0.13$) |
| Reintervention | No risk factors investigated |
| Endoleak | No risk factors investigated |
| Study sample adequately described | Yes |
| Included risk variables clearly defined | Yes |
| Covariates considered to build the multivariate model | Not reported; unclear |
| Interactions between variables explored | Unclear |
| Continuous variables handled appropriately | Yes |
| More than 10 events per included variable | Yes |
| Confidence intervals or other measures of uncertainty presented | Yes |

**Ruppert V, Leurs LJ, Steckmeier B, Buth J, Umscheid T. Influence of anesthesia type on outcome after endovascular aortic aneurysm repair: an analysis based on EUROSTAR data. *J Vasc Surg* 2006;44:16–21[84]**

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| Author | Ruppert 2006[84] |
| Country where study was performed | 164 collaborating European vascular centres |
| Type of study | Specific risk factors following EVAR. Main focus of paper is the influence of anaesthesia type on AAA outcomes. Only patient risk factors relate to endoleak rate and these appear to be documented in the text only |
| Registry | Dates enrolled and/or treated: July 1997–August 2004<br>EUROSTAR |
| Number of patients | 5557 |
| Age of population | Mean: 72 years; range: 41–100 years |
| Gender | Not reported |
| Aneurysm diameter | Mean (SD): total: 5.85 cm; general anaesthesia: 5.81 cm (1.07); regional anaesthesia: 5.94 cm (1.12); local anaesthesia: 5.9 cm (1.1)<br>Range: total: 4–14.5 cm; general anaesthesia: 4–13 cm; regional anaesthesia: 4–14.5 cm; local anaesthesia: 4–10 cm |
| Type of device (EVAR) | Zenith: 1923 (34.6%); Talent: 1492 (26.8%); Excluder: 767 (13.8%); Anaconda: 26 (0.5%); AneuRx: 938 (16.9%); Endologix: 116 (2.1%); EVT: 71 (1.3%); Fortron: 82 (1.5%); Lifepath: 115 (2.1%) |
| Graft type (EVAR) | Bifurcated: 4904 (91.6%); tube: 108 (2%); tapered: 340 (6.4%) |
| Anaesthesia | Local: 310 (6%); regional: 1399 (25%); general: 3848 (69%) |
| Risk factor(s) used in model and definitions | Age: not defined<br>Aneurysm size: not defined |
| Definition of outcomes | Not defined |
| Follow-up period | 1, 6, 12, 18 and 24 months and annually thereafter. Mean or median follow-up unclear |
| Methods of analysis | Multivariate regression analysis for early complications |
| 30-day mortality | No risk factors investigated |
| Aneurysm-related mortality at follow-up | No risk factors investigated |
| All-cause mortality at follow-up | No risk factors investigated |
| Reintervention | No risk factors investigated |
| Endoleak | Advanced age (not specified) was independently associated with endoleak rate (no data provided)<br>Device type (tube, tapered or bifurcated) was not independently associated with increased risk for endoleak. However, AneuRx, Talent and Fortron devices were independently associated with increased risk (no data provided)<br>Aneurysm size independently associated with endoleak rate (no data provided) |
| Study sample adequately described | No |
| Included risk variables clearly defined | No |

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| Covariates considered to build the multivariate model | Yes |
| Interactions between variables explored | Unclear |
| Continuous variables handled appropriately | Unclear |
| More than 10 events per included variable | Yes |
| Confidence intervals or other measures of uncertainty presented | No |

**Sampram ESK, Karafa MT, Mascha EJ, Clair DG, Greenberg RK, Lyden SP, *et al*. Nature, frequency, and predictors of secondary procedures after endovascular repair of abdominal aortic aneurysm. *J Vasc Surg* 2003;37:930–7[85]**

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| Author | Sampram 2003[85] |
| Country where study was performed | USA |
| Type of study | Specific risk factors following EVAR |
| Case series | 1996–2002<br>Name of centre: Cleveland Clinic, Ohio, USA |
| Number of patients | 703 |
| Age of population | Mean: 75 (SD 8.1) years; range: 48–100 years |
| Gender | 86% male |
| Aneurysm diameter | Mean: 5.4 (SD 1.0) cm in minor dimension and 5.8 (SD 1.1) cm in major dimension<br>Measurement tool used: preoperative helical CT with 3-mm axial reconstruction. Angiography and intravascular ultrasound were used when measurements were deemed inaccurate on the basis of CT scans, in the presence of suspected renal or iliac occlusive disease or when required as part of a clinical trial |
| Type of device (EVAR) | Zenith: 325/703 (46%); Talent: 39/703 (6%); AneuRx: 203/703 (29%); Ancure: 63/703 (9%); other devices: 73/703 (10%) |
| Graft type (EVAR) | Not reported |
| Anaesthesia | Not reported |
| Risk factor(s) used in model and definitions | Age: per year as continuous variable<br>Gender<br>Device type (brand name)<br>Aneurysm size: measured on the CT scan with the greatest minor sac dimension on any axial image<br>Non-patient risk factors including procedure date and various procedural variables |
| Definition of outcomes | Reinterventions (secondary procedures): any subsequent procedure, whether percutaneous or open surgical, related to AAA repair or associated complications. Procedures performed because of wound complications were recorded but not analysed |
| Follow-up period | Mean: 12.2 (SD 11.7) months; range: 0–65 months |
| Methods of analysis | Kaplan–Meier survival analysis was used to express survival, freedom from aneurysm-related death and freedom from reintervention. Cox analysis was used to evaluate time to reintervention for baseline variables (including procedure date, patient demographic parameters and aneurysm size) and procedural details (including device type, placement of renal or aortic stents, hypogastric embolisation and use of iliac conduits for access). HRs and associated 95% CIs were calculated. Multivariate Cox proportional hazards modelling was used to define independent predictors of reintervention |
| 30-day mortality | No risk factors investigated |
| Aneurysm-related mortality at follow-up | No risk factors investigated |
| All-cause mortality at follow-up | No risk factors investigated |

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| Reintervention | No significant association between age and risk of reintervention in univariate analysis: HR 1.00 (95% CI 0.98 to 1.03, $p = 0.95$)<br>No significant association between male gender and risk of reintervention in univariate analysis: HR 1.10 (95% CI 0.60 to 2.02, $p = 0.76$)<br>No significant association between device type and risk of reintervention in univariate analysis: $p = 0.32$; HRs relative to AneuRx device reported in the paper<br>Significant association between minor sac axis and major sac axis and risk of reintervention in univariate analysis: HR 1.36 (95% CI 1.15 to 1.62, $p < 0.001$) for minor axis, HR 1.37 (95% CI 1.16 to 1.62, $p < 0.001$) for major axis. Significant association between minor aneurysm axis and risk of reintervention in multivariate analysis: HR 1.35 (95% CI 1.13 to 1.60, $p < 0.001$)<br>Significant association between procedure date and aortic stent and risk of reintervention in univariate analysis: HR 1.55 (95% CI 1.24 to 1.94, $p < 0.001$) for date, HR 2.93 (95% CI 1.35 to 6.36, $p = 0.007$) for aortic stent. Significant association between procedure date and risk of reintervention in multivariate analysis: HR 1.53 (95% CI 1.22 to 1.92, $p < 0.001$)<br>No significant association between renal stent, hypogastric embolisation or iliac conduit and risk of reintervention in univariate analysis: HR 0.95 (95% CI 0.38 to 2.33, $p = 0.90$) for renal stent, HR 1.24 (95% CI 0.66 to 2.34, $p = 0.50$) for hypogastric embolisation, HR 1.03 (95% CI 0.32 to 3.25, $p = 0.96$) for iliac conduit |
| Endoleak | No risk factors investigated. Correction of endoleaks included under reinterventions |
| Study sample adequately described | Yes |
| Included risk variables clearly defined | No; however, risk variables were fairly self-explanatory |
| Covariates considered to build the multivariate model | Not reported |
| Interactions between variables explored | Unclear |
| Continuous variables handled appropriately | Yes; age kept as years |
| More than 10 events per included variable | Yes; 128 procedures. Unclear how many variables were included in the final model but answer is probably yes |
| Confidence intervals or other measures of uncertainty presented | Yes |

**Timaran CH, Veith FJ, Rosero EB, Modrall JG, Arko FR, Clagett GP, *et al*. Endovascular aortic aneurysm repair in patients with the highest risk and in-hospital mortality in the United States. *Arch Surg* 2007;142:520–5[86]**

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| Author | Timaran 2007[86] |
| Country where study was performed | USA |
| Type of study | Specific risk factors following EVAR<br>Evaluation/validation of existing risk assessment algorithm |
| Registry | The data were from the Nationwide Inpatient Sample from the Healthcare Cost and Utilization Project. This is the largest all-payer inpatient database in the USA. It represents a 20% stratified sample of inpatient admissions to US academic, community and acute care hospitals nationwide (approximately 1000 hospitals in 35 states) |
| Number of patients | 65,502 |
| Age of population | Not reported: 4.6% aged 50–59 years; 24.7% aged ≥ 80 years |
| Gender | 82.9% male |
| Aneurysm diameter | Not reported |
| Type of device (EVAR) | Not reported |
| Graft type (EVAR) | Not reported |
| Anaesthesia | Not reported |
| Risk factor(s) used in model and definitions | Age categorised as: 50–59, 60–69, 70–79, ≥ 80 years<br>Gender: female sex<br>Composite risk score: the Charlson Comorbidity Index (CCI) score is a validated measure for use with administrative data that correlates with in-hospital morbidity and mortality after surgical procedures (including elective AAA repairs). Each of the indicated diagnoses is assigned a weight and summed to provide a patient's total score [0 (low risk) to > 3 (high risk)]<br>Emergent or urgent EVAR admission during weekend |
| Definition of outcomes | 30-day mortality: defined as in-hospital mortality (i.e. in hospital for EVAR) |
| Follow-up period | Unclear – in-hospital period only |
| Methods of analysis | In-hospital mortality was adjusted for age, sex, CCI or risk stratification using multivariate logistic regression analysis. Results expressed as OR with 95% CIs |
| 30-day mortality | Age: from multivariate regression model: OR 1.04 (95% CI 1.03 to 1.04, $p < 0.001$)<br>Gender: female sex: from multivariate regression model: OR 1.46 (95% CI 1.26 to 1.68, $p < 0.001$)<br>Composite risk score: CCI score (0 to > 3): from multivariate regression model: OR 1.12 (95% CI 1.06 to 1.20, $p < 0.001$). A higher CCI score was associated with early death: CCI 0: 1.8%, CCI 1: 2.0%, CCI 2: 2.2%, CCI ≥ 3: 3.7% ($p < 0.001$). Stratified analysis that included only elective EVAR found the per point CCI score to be an independent predictor of in-hospital mortality (OR 1.38, 95% CI 1.29 to 1.47)<br>Emergent or urgent EVAR: from multivariate regression model: OR 8.25 (95% CI 7.21 to 9.44, $p < 0.001$)<br>Admission during weekend: from multivariate regression model: OR 2.05 (95% CI 1.70 to 2.47, $p < 0.001$) |
| Aneurysm-related mortality at follow-up | No risk factors investigated |
| All-cause mortality at follow-up | No risk factors investigated |

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| Reintervention | No risk factors investigated |
| Endoleak | No risk factors investigated |
| Study sample adequately described | Yes |
| Included risk variables clearly defined | Yes |
| Covariates considered to build the multivariate model | Yes; not clear what they all are |
| Interactions between variables explored | Unclear; interaction term not reported |
| Continuous variables handled appropriately | No; age and number of procedures by surgeons categorised |
| More than 10 events per included variable | Unclear; probably 'yes' because of large sample |
| Confidence intervals or other measures of uncertainty presented | Yes |

**Torella F. Effect of improved endograft design on outcome of endovascular aneurysm repair. *J Vasc Surg* 2004;40:216–21[87]**

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| Author | Torella 2004[87] |
| Country where study was performed | EUROSTAR (unspecified) |
| Type of study | Specific risk factors following EVAR |
| Registry | Dates enrolled and/or treated: May 1994–June 2002<br>EUROSTAR |
| Number of patients | 3992 (1224 withdrawn devices vs 2768 current devices) |
| Age of population | Mean (SD): 72 (7.9) years for current devices; 70 (7.7) years for withdrawn devices ($p < 0.0001$) |
| Gender | Percentage male (total population): 93% (94% current devices, 91% withdrawn devices, $p = 0.0002$) |
| Aneurysm diameter | Mean (SD): current devices 5.7 (10.8) cm and withdrawn devices 5.6 (10.5) cm<br>206 (7.4%) patients with current devices had aneurysm neck diameters in excess of 2.6 cm and would not have been suitable to receive a withdrawn device |
| Type of device (EVAR) | Zenith: 780 current, 0 withdrawn (10/96 to date); Talent: 739 current, 0 withdrawn (10/96 to date); Excluder: 337 current, 0 withdrawn (1/98 to date); AneuRx: 857 current, 0 withdrawn (12/96 to date); EVT: 55 current, 51 withdrawn (6/98 to date, 1/95 to 5/98); Stentor: 0 current, 277 withdrawn (5/94 to 9/98); Vanguard: 0 current, 896 withdrawn (3/96 to date) |
| Graft type (EVAR) | Bi-iliac: 3992 (100%) |
| Anaesthesia | Not reported |
| Risk factor(s) used in model and definitions | Age (not defined)<br>Male sex<br>Graft configuration and device type: current versus withdrawn devices<br>Fitness for open procedure: unfitness for open procedure<br>Diameter and sac diameter<br>Neck diameter<br>Aortic neck length<br>Team experience (> 60 cases) |
| Definition of outcomes | Aneurysm-related mortality defined as late aneurysm-related mortality, i.e. death due to aneurysm rupture or within 30 days of a secondary intervention. Reintervention: conversion to open repair |
| Follow-up period | Follow-up time points were 1, 3, 6, 12 and 18 months after surgery and yearly thereafter. Follow-up results to 3 years presented |
| Methods of analysis | Independent variables for multivariate analysis were chosen on the basis of significant differences between the two groups at univariate testing ($p < 0.001$). Variables included in this analysis were type of device (current or withdrawn), age, male sex, unfitness for open repair, team experience, aneurysm diameter, neck length and neck diameter. Further multivariate analysis included isolated late type II endoleak and related secondary transfemoral interventions as covariates to confirm the role of device type in aneurysm-related death. Cox regression with stepwise backward elimination of unrelated factors was used for multivariate analyses |
| 30-day mortality | No risk factors investigated |
| Aneurysm-related mortality at follow-up | Older age was associated with aneurysm-related death (HR 1.09, 95% CI 1.06 to 1.12, $p < 0.0001$). Further multivariate analysis with endoleak type II and associated interventions as covariates confirmed that older age was associated with aneurysm-related death (HR 1.09, 95% CI 1.06 to 1.2, $p < 0.0001$ for 1-year increase above mean)<br>Male sex was not significantly associated with aneurysm-related death |

| | |
|---|---|
| | Current endografts resulted in a significant reduction in aneurysm-related death (HR 0.51, 95% CI 0.34 to 0.75, $p = 0.0008$). Further multivariate analysis with endoleak type II and associated interventions as covariates confirmed that current devices had a protective effect on aneurysm-related death (HR 0.52, 95% CI 0.35 to 0.79, $p = 0.001$) |
| | Unfitness for open surgery was predictive of aneurysm-related death (HR 2.08, 95% CI 1.4 to 3.1, $p = 0.0004$). Further multivariate analysis with endoleak type II and associated interventions as covariates confirmed that unfitness for open surgery was associated with aneurysm-related death (HR 2.25, 95% CI 1.5 to 3.3, $p < 0.0001$) |
| | Larger aneurysm diameter was associated with aneurysm-related death (HR 1.03, 95% CI 1.01 to 1.04, $p = 0.0004$). Further multivariate analysis with endoleak type II and associated interventions as covariates confirmed that aneurysm diameter was associated with aneurysm-related death (HR 1.03, 95% CI 1.01 to 1.04, $p = 0.0005$ for 1-mm increase above mean) |
| | Mid-neck diameter was not significantly associated with aneurysm-related death |
| | Neck length was not significantly associated with aneurysm-related death |
| | Team experience (> 60 cases) was not significantly associated with aneurysm-related death |
| All-cause mortality at follow-up | No risk factors investigated |
| Reintervention | Older age was not significantly associated with late conversion to open repair |
| | Male sex was not significantly associated with late conversion to open repair |
| | Use of current device was significantly associated with late conversion to open repair (HR 0.49, 95% CI 0.28 to 0.86, $p = 0.014$). Further multivariate analysis with endoleak type II and associated interventions as covariates confirmed that current devices had a protective effect on late conversion to open repair (HR 0.47, 95% CI 0.27 to 0.82, $p = 0.008$) |
| | Unfitness for open repair was not significantly associated with late conversion to open repair |
| | Sac diameter (mm) was significantly associated with late conversion to open repair (HR 1.03, 95% CI 1.01 to 1.05, $p = 0.015$). Further multivariate analysis with endoleak type II and associated interventions as covariates confirmed that larger aneurysm size (1-mm increase above mean) was associated with late conversion to open repair (HR 1.03, 95% CI 1.01 to 1.05, $p = 0.0015$) |
| | Mid-neck diameter was significantly associated with late conversion to open repair (HR 1.10, 95% CI 1.01 to 1.20, $p = 0.027$). Further multivariate analysis with endoleak type II and associated interventions as covariates confirmed that neck diameter (1-mm increase above mean) was associated with late conversion to open repair (HR 1.20, 95% CI 1.03 to 1.22, $p = 0.0085$) |
| | Neck length was significantly associated with late conversion to open repair (HR 0.95, 95% CI 0.92 to 0.98, $p = 0.0003$) |
| | Team experience was not significantly associated with late conversion to open repair |
| Endoleak | No risk factors investigated |
| Study sample adequately described | Yes |
| Included risk variables clearly defined | Yes |
| Covariates considered to build the multivariate model | Yes |
| Interactions between variables explored | Unclear |
| Continuous variables handled appropriately | Yes |
| More than 10 events per included variable | Yes |
| Confidence intervals or other measures of uncertainty presented | Yes |

**van Marrewijk CJ, Fransen G, Laheij RJF, Harris PL, Buth J. Is a type II endoleak after EVAR a harbinger of risk? Causes and outcome of open conversion and aneurysm rupture during follow-up. *Eur J Vasc Endovasc Surg* 2004;27:128–37[89]**

| | |
|---|---|
| Author | van Marrewijk 2004[89] |
| Country where study was performed | 114 European institutions |
| Type of study | Specific risk factors following EVAR |
| Registry | Dates enrolled and/or treated: 1996–June 2002<br>EUROSTAR<br>Of the overall cohort of 4613 patients, 1018 were excluded from this study because of retrospective enrolment, stent graft models other than AneuRx, Excluder, Talent, Vanguard or Zenith, or the presence of type I, III or any combination of endoleaks during follow-up |
| Number of patients | 3595 |
| Age of population | Mean: 71.2 years (calculated) (SD not reported); range: 37–100 years |
| Gender | 94% male |
| Aneurysm diameter | Mean: 5.7 cm (SD not reported) |
| Type of device (EVAR) | Zenith: 879 (24.5%); Talent: 775 (21.6%); Excluder: 349 (9.7%); AneuRx: 833 (23.2%); Vanguard: 759 (21.1%) |
| Graft type (EVAR) | Not reported |
| Anaesthesia | Not reported |
| Risk factor(s) used in model and definitions | Age (definition not stated)<br>Only risk factors that were found to be significantly associated with type II endoleak were reported<br>Gender (definition not stated)<br>Current smoking<br>Device type<br>ASA<br>Pre-existing conditions: obesity (not defined)<br>Fitness for open procedure<br>Renal function (creatinine) (definition not stated)<br>Aneurysm size (definition not stated)<br>Aortic neck and aneurysm angle (definition not stated)<br>Aortic neck length (definition not stated)<br>Preoperative patency of inferior mesenteric artery<br>Ankle–arm blood pressure index ≥ 0.87<br>Experience of surgeons |
| Definition of outcomes | Endoleak type II only |
| Follow-up period | 15 months; range 0–72 months |
| Methods of analysis | Clinical features of patients with type II endoleak were compared with features of patients without endoleak (age, gender, smoking status, obesity, fitness for open repair, ASA grade, experience of surgeon, type of device, aneurysm morphology). Discrete data were analysed using chi-squared tests and Fisher's correction in case of small subgroups. A multivariate analysis was performed by selecting variables found to be significantly associated with events in the univariate analysis. Continuous variables were compared using the Mann–Whitney *U*-test. A Cox proportional hazards model was used for multivariate analysis of time-dependent variables |
| 30-day mortality | No risk factors investigated |

| | |
|---|---|
| Aneurysm-related mortality at follow-up | No risk factors investigated |
| All-cause mortality at follow-up | No risk factors investigated |
| Reintervention | No risk factors investigated |
| Endoleak | Association with patient's age: $p = 0.001$ (95% CI 1.01–1.06)<br>Gender: no significant association<br>Smoking status: current smoking: association $p = 0.008$ (95% CI 0.38–0.87)<br>Graft configuration and device type: device type: no significant association<br>ASA: no significant association<br>Obesity: no significant association<br>Renal insufficiency: no significant association<br>Aneurysm size: no significant association<br>Infrarenal neck diameter: no significant association<br>Length of infrarenal neck: association $p = 0.006$ (95% CI 1.01–1.03)<br>Preoperative patency of IMA: association $p = 0.031$ (95% CI 1.03–1.99)<br>Ankle–arm blood pressure index ≤ 0.87: association $p = 0.0007$ (95% CI 0.23–0.68)<br>Experience of surgeon: no significant association |
| Study sample adequately described | Yes |
| Included risk variables clearly defined | Yes; some were not, e.g. experience of surgeons |
| Covariates considered to build the multivariate model | Yes |
| Interactions between variables explored | Unclear; interaction term not reported |
| Continuous variables handled appropriately | Unclear; risk factors not reported as being categorised |
| More than 10 events per included variable | Yes |
| Confidence intervals or other measures of uncertainty presented | Yes, although actual HRs were not |

**van Eps RGS, Leurs L, Hobo R, Harris PL, Buth J. Impact of renal dysfunction on operative mortality following endovascular abdominal aortic aneurysm surgery. *Br J Surg* 2007;94:174–8[88]**

| | |
|---|---|
| Author | van Eps 2007[88] |
| Country where study was performed | 165 European centres |
| Type of study | Specific risk factors following EVAR |
| Registry | Dates enrolled and/or treated: December 1996–January 2005<br>EUROSTAR |
| Number of patients | 5167 patients [4198 (81.2%) had normal renal function, 969 (18.8%) had renal dysfunction] |
| Age of population | Overall mean: 72 years; patients with normal renal function: 71.7 (SD 7.6) years; patients with renal dysfunction: 73.6 (SD 7.5) years ($p < 0.001$)<br>Range: patients with normal renal function: 43–95 years; patients with renal dysfunction: 45–100 years |
| Gender | Overall: 4870 (94.3%) male; patients with normal renal function: 3936 (93.8%); patients with renal dysfunction: 934 (96.4%) ($p < 0.001$) |
| Aneurysm diameter | Mean (SD): patients with normal renal function: 5.81(1.08) cm; patients with renal dysfunction: 5.96 (1.17) cm ($p < 0.001$)<br>Range: patients with normal renal function: 4–17.2 cm; patients with renal dysfunction: 4–14.5 cm |
| Type of device (EVAR) | Not reported |
| Graft type (EVAR) | Not reported |
| Anaesthesia | Not reported |
| Risk factor(s) used in model and definitions | Age (not defined)<br>ASA risk classification score ≥ 3<br>According to the SVS stratification model: preoperative renal function: 0, no known renal disease [serum creatinine < 133 μmol/ml (< 1.5 mg/dl) and creatinine clearance > 50 ml/min]; 1, serum creatinine 133–265 μmol/ml (1.5–3 mg/dl) and creatinine clearance 30–50 ml/min; 2, serum creatinine 265–532 μmol/ml (3.0–6.0 mg/dl) and creatinine clearance 15–30 ml/min; 3, serum creatinine > 532 μmol/ml and creatinine clearance < 15 ml/min or on dialysis or with transplant<br>Aneurysm size<br>Pulmonary impairment |
| Definition of outcomes | Not defined |
| Follow-up period | Not stated |
| Methods of analysis | Tests to analyse associations between complications and renal dysfunction were conducted. The model was adjusted for differences found in univariate analysis. Analyses were performed for renal dysfunction (SVS categories 1–3) versus no renal dysfunction and then further analyses were conducted for less severe renal dysfunction (SVS category 1) versus no renal dysfunction. ORs were calculated for time-independent outcome variables with multivariable logistic regression analysis |

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|---|---|
| 30-day mortality | Age at operation (not specified) was an independent risk factor for early death (OR 1.1, 95% CI 1.0 to 1.1, $p < 0.001$)<br>ASA grade III or above was an independent risk factor for early death (OR 2.7, 95% CI 1.7 to 4.2, $p < 0.001$)<br>The 30-day mortality rate in patients with renal dysfunction was significantly higher than that in patients with normal renal function (6.2% vs 2.0%, $p < 0.001$). An increase of 5.5% was also seen in those with milder forms of renal dysfunction (SVS category 1). In multivariate analysis preoperative renal dysfunction was an independent risk factor for operative mortality (OR 2.3, 95% CI 1.6 to 3.3, $p < 0.001$)<br>Aneurysm size was an independent risk factor for early death (unsure of data)<br>Pulmonary impairment was an independent risk factor for early death (OR 1.6, 95% CI 1.1 to 2.3, $p = 0.012$) |
| Aneurysm-related mortality at follow-up | No risk factors investigated |
| All-cause mortality at follow-up | No risk factors investigated |
| Reintervention | No risk factors investigated |
| Endoleak | There was no significant association between endoleak and renal dysfunction (16.2% normal renal function vs 15.6% impaired renal function) |
| Study sample adequately described | Yes |
| Included risk variables clearly defined | No |
| Covariates considered to build the multivariate model | Yes |
| Interactions between variables explored | Unclear |
| Continuous variables handled appropriately | Unclear |
| More than 10 events per included variable | No |
| Confidence intervals or other measures of uncertainty presented | Yes |

**Zarins CK, Crabtree T, Bloch DA, Arko FR, Ouriel K, White RA. Endovascular aneurysm repair at 5 years: does aneurysm diameter predict outcome? *J Vasc Surg* 2006;44:920–9[90]**

| | |
|---|---|
| Author | Zarins 2006[90] |
| Country where study was performed | USA |
| Type of study | Specific risk factors following EVAR<br>Aneurysm diameter |
| Trial | Trial dates: 1998–9<br>Non-RCT<br>Prospective multicentre trial of the AneuRx stent graft |
| Number of patients | 923 |
| Age of population | Small AAA (< 5.0 cm): mean 71.3 (SD 7.1) years; medium AAA (5.0–5.9 cm): mean 73.4 (SD 7.6) years; large AAA (≥ 6.0 cm): mean 74.6 (SD 8.6) years |
| Gender | Percentage male (total population): small AAA (< 5.0 cm): 90%; medium AAA (5.0–5.9 cm): 88%; large AAA (≥ 6.0 cm): 88% |
| Aneurysm diameter | Mean: 5.7 (SD 1.5) cm<br>Measurement tool used: maximum transverse aneurysm diameter as measured on the preprocedure CT scan |
| Type of device (EVAR) | AneuRx: 923 patients (100%) |
| Graft type (EVAR) | Bi-iliac: 923 patients (100%) |
| Anaesthesia | Not reported |
| Risk factor(s) used in model and definitions | Age<br>ASA<br>Pre-existing conditions: peripheral vascular disease (PVD), chronic obstructive pulmonary disease (COPD)<br>Aneurysm size categorised as small AAA (< 5.0 cm), medium AAA (5.0–5.9 cm), large AAA (> 6.0 cm) |
| Definition of outcomes | All-cause mortality: survival at 5 years. Aneurysm-related death: perioperative and late. Surgical conversion: elective and emergent |
| Follow-up period | 5 years |
| Methods of analysis | The outcomes of interest were expressed as Kaplan–Meier estimates with standard errors. Differences between the three categories of aneurysm size (small, medium, large) were determined using the ordered log-rank test. The null hypothesis that the results for all three groups are equal was tested against the ordered alternative hypothesis. To consider the effect of influential baseline covariates that were out of balance between the three groups, multivariate Cox proportional hazards models were created for outcomes found to be statistically significantly different across the three groups (age, ASA grade, family AAA history, obesity, previous procedures, COPD and PVD) |
| 30-day mortality | No risk factors investigated |
| Aneurysm-related mortality at follow-up | PVD: effect on AAA-related death at 5 years: HR 2.18, $p = 0.05$<br>Effect of aneurysm size on AAA-related death at 5 years: HR 2.01, $p = 0.03$ |
| All-cause mortality at follow-up | Effect of age on 5-year survival: HR 1.05, $p < 0.0001$<br>Effect of ASA on 5-year survival: HR 1.48, $p = 0.0003$<br>COPD effect on 5-year survival: HR 1.84, $p < 0.0001$<br>PVD effect on 5-year survival: HR 1.50, $p = 0.002$<br>Effect of aneurysm size on survival at 5 years: HR 1.35, $p = 0.001$ |

| | |
|---|---|
| Reintervention | Effect of aneurysm size on surgical conversion at 5 years' follow-up: HR 1.83, $p = 0.007$<br>Family history of AAA, effect on surgical conversion at 5 years: HR 2.32, $p = 0.02$ |
| Endoleak | No risk factors investigated |
| Study sample adequately described | Yes |
| Included risk variables clearly defined | Yes; aneurysm size defined but others less clear |
| Covariates considered to build the multivariate model | Yes |
| Interactions between variables explored | Unclear; no specific interaction term reported |
| Continuous variables handled appropriately | No; aneurysm size categorised |
| More than 10 events per included variable | Yes; see Table II |
| Confidence intervals or other measures of uncertainty presented | No; HRs and/or *p*-values only |

# Appendix 5

## Table of excluded studies with rationale

***Patient group not AAA (19)***

Akert 2004[173]

Almagor 1997[174]

Bell 2004[175]

Dawkins 2006[176]

Dawkins 2006[177]

DeRubertis 2007[178]

Eyraud 2000[179]

Faggioli 1998[180]

Gotohda 1998[181]

Hamdan 2002[182]

Huber 1995[183]

Hutter 2007[184]

LeMaire 2001[185]

Leurs 2004[186]

Leurs 2007[187]

Prytherch 2001[188]

Salenius 1992[189]

Schouten 2005[190]

West 2006[191]

***RCT but not EVAR vs. open repair or non-surgical management (8)***

UK Small Aneurysm Trial participants 2000[192]

Ashton 2007[193]

Laohapensang 2005[194]

Lindholt 2006[195]

Lindholt 2007[196]

Multicentre Aneurysm Screening Study Group 2002[4]

Powell 2007[197]

UK Small Aneurysm Trial participants 2007[198]

***Registry but not EUROSTAR, RETA or NVD (3)***

Akkersdijk 2004[199]

Kantonen 1997[200]

Sicard 2006[201]

***Risk model but not modelling risk following EVAR (26)***

Berry 2001[202]

Biancari 2003[203]

*continued*

Brown 1999[2]
Chahwan 2007[204]
Collins 2001[205]
Conrad 2007[206]
Dillavou 2006[207]
Dueck 2004[24]
Eckstein 2007[208]
Hadjianastassiou 2006[209]
Hadjianastassiou 2007[20]
Heller 2000[210]
Hertzer 2005[211]
Hua 2005[212]
Huber 2001[213]
Katz 1997[214]
Koning 2006[215]
Korhonen 2004[216]
Le Manach 2005[217]
Leon, Jr 2005[218]
McPhee 2007[219]
Menard 2003[220]
Noel 2001[221]
Ouriel 2005[222]
United Kingdom Small Aneurysm Trial 2002[7]
Wald 2006[223]

***Risk model but not modelling relevant outcome (2)***

Ouriel 2003[224]
Zarins 2003[225]

***Risk model but fewer than 500 patients (94)***

Acosta 2007[226]
Alonso-Perez 2001[227]
Alric 2003[228]
Antonello 2007[229]
Aune 2001[230]
Aziz 2003[231]
Azizzadeh 2006[232]
Becker 2001[233]
Biancari 2003[234]
Biebl 2005[235]
Bown 2004[236]
Bui 2003[237]
Bush 1995[238]
Calderwood 2004[239]
Cao 2002[240]
Carpenter 2002[241]

Chaikof 2002[242]
Chang 2003[243]
Chiesa 2006[244]
Cochennec 2007[245]
Conners 2002[18]
Conners 2002[246]
Cuypers 1999[247]
Dawson 2007[248]
de Virgilio 1999[249]
de Virgilio 2002[250]
de Virgilio 2006[251]
de Virgilio 2006[252]
Dias 2001[253]
Elkouri 2004[254]
Fairman 2006[255]
Faizer 2007[25]
Forbes 2006[256]
Golledge 2007[257]
Greenberg 2003[258]
Harris 2005[259]
Haug 2005[260]
Haulon 2003[261]
Higashiura 2007[262]
Hirzalla 2006[27]
Ho 2006[263]
Hovsepian 2001[264]
Hugl 2007[265]
Jordan 2003[266]
Kohsaka 2006[267]
Kovacs 2003[268]
Larzon 2005[269]
Larzon 2005[270]
Laukontaus 2005[271]
Laukontaus 2006[272]
Lazarides 1997[273]
Leo 2005[274]
Leo 2005[275]
Leo 2006[276]
Lo 2004[277]
Manis 2006[278]
Masuda 2004[279]
Matsumura 1998[280]
Mehta 2005[281]
Moore 2007[282]

*continued*

Neary 2003[283]
Nesi 2004[30]
Pamler 2002[284]
Parlani 2003[285]
Parmer 2006[286]
Peppelenbosch 2006[287]
Polterauer 2005[288]
Prytherch 2001[289]
Robbins 2005[290]
Rockman 2002[291]
Sampaio 2004[292]
Sbarigia 2005[293]
Schouten 2005[294]
Schouten 2007[295]
Shames 2003[296]
Sharif 2007[297]
Sharif 2007[29]
Shuhaiber 2002[298]
Silverberg 2006[299]
Slovut 2003[300]
Tambyraja 2004[301]
Tambyraja 2005[302]
Teufelsbauer 2002[303]
Timaran 2004[304]
Timaran 2005[305]
Torsello 2006[306]
Treska 2003[307]
Verzini 2000[308]
Verzini 2002[309]
Vogel 2005[310]
Walker 1999[311]
Wolf 2002[312]
Yii 2003[313]
Zeebregts 2004[314]

## Feedback

The HTA programme and the authors would like to know your views about this report.

The Correspondence Page on the HTA website (www.hta.ac.uk) is a convenient way to publish your comments. If you prefer, you can send your comments to the address below, telling us whether you would like us to transfer them to the website.

***We look forward to hearing from you.***

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