A systematic review update of the recent evidence for the safety and efficacy of elective endovascular repair in the management of infrarenal abdominal aortic aneurysms

Duncan Drury, Jonathan Michaels, Lisa Jones, Lynda Ayiku

ReBIP
REVIEW BODY FOR INTERVENTIONAL PROCEDURES

June 2005

INTERVENTIONAL PROCEDURES PROGRAMME
NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

REVIEW BODY REPORT

Title	A systematic review update of the recent evidence for the safety and efficacy of elective endovascular repair in the management of infrarenal abdominal aortic aneurysms
Produced by	School of Health and Related Research The University of Sheffield Regent Court 30 Regent Street Sheffield S10 4DA
Review Team	Duncan Drury, Jonathan Michaels, Lisa Jones, Lynda Ayiku
Correspondence to	Duncan Drury Research Fellow Sheffield Vascular Institute Sheffield Teaching Hospitals NHS Trust Northern General Hospital Herries Rd Sheffield S5 7AU Tel: +44 (0)114 2434343
Date completed	June 2005

TABLE OF CONTENTS

1 Objective of the review 1
2 Background 1
2.1 The interventional procedure under review 1
2.1.1 Description of the interventional procedure 1
2.1.2 Proposed clinical indications/contraindication and putative impact of the procedure 2
2.1.3 Personnel involved (e.g. surgeons, anaesthetists, nurses) and skill/experience required 2
2.1.4 Current use in the UK 2
2.1.5 Equipment or devices required 3
2.2 Description of the underlying health problem 3
2.2.1 Epidemiology 3
2.2.2 Aetiology and pathology 3
2.2.3 Natural history of abdominal aortic aneurysms 4
2.3 Potential complications of aneurysm repair 4
2.3.1 Endoleaks 4
2.4 Population 5
2.4.1 Suitable candidates and relevant subgroups 5
2.5 Current management and alternative procedures 5
3 Methods for reviewing evidence on efficacy and safety 5
3.1 Updated search strategy 5
3.2 Inclusion and exclusion criteria 6
3.2.1 Types of studies 6
3.2.2 Types of participants 6
3.2.3 Types of interventions 6
3.2.4 Types of outcome 6
3.3 Quality assessment strategy 7
3.4 Data extraction strategy 8
3.5 Data analysis 8
3.5.1 Data synthesis 8
4 Results of update searches 8
4.1 Type and quantity of evidence available 8
4.2 Number and type of included studies 9
4.2.1 Characteristics of the included studies 9
4.3 Number and type of excluded studies 12
4.4 Quality of the available evidence 13
4.4.1 Randomised controlled trials 13

4.4.2 Non-randomised controlled trials 14
4.4.3 Comparative observational studies 15
4.4.4 Case Series 16
4.5 Proportion of population for whom EVAR technically feasible 18
5 EVAR versus open repair 19
5.1 Major outcomes 19
5.1.1 30 day outcomes 19
5.1.2 Longer term outcomes 21
5.2 Complications 26
5.2.1 Common technical complications 27
5.2.2 Common non-technical complications 32
5.3 Other peri- and post-operative outcomes 36
5.3.1 Deployment success rate 36
5.3.2 Technical success rate 36
6 EVAR in high risk patients 41
6.1 Overview of the trial 41
6.2 Major outcomes 41
6.2.1 Mortality 41
6.2.2 Aneurysm rupture 42
6.2.3 Conversion to open repair 42
6.2.4 Secondary re-intervention rate 42
6.3 Technical complications 42
6.4 Other peri- and postoperative outcomes 43
6.4.1 Deployment success rate 43
6.4.2 Length of Hospital stay 43
7 EVAR data from case series 44
7.1 Overview of the efficacy findings from non-controlled studies (Case series and comparative studies) 44
7.1.1 Deployment success rate 44
7.1.2 Technical success rate 44
7.1.3 Aneurysm rupture following EVAR 46
7.1.4 Changes in aneurysm size 48
7.1.5 Primary conversion rate 48
7.1.6 Delayed conversion rate 50
7.1.7 Secondary intervention rate 51
7.1.8 Procedural blood loss 52
7.1.9 Length of ITU stay 53
7.2 Length of hospital stay 53

7.3 Overview of the Safety findings from non-controlled studies (Case series) 55
7.3.1 Common technical complications 55
7.3.2 Common non-technical complications 60
8 Discussion 66
8.1 EVAR versus open repair 66
8.1.1 Major outcomes 66
8.1.2 Complications 67
8.1.3 Other peri- and post-operative outcomes 67
8.2 EVAR in high risk patients 68
8.3 Assumptions, limitations and uncertainties 68
8.3.1 Size of aneurysm treated 69
8.3.2 Case mix 69
8.3.3 Operator experience and advances in technology 69
8.3.4 Primary outcomes 70
8.3.5 Long term safety and efficacy 70
8.3.6 High risk patients 71
9 CONCLUSIONS 73
9.1 Efficacy of EVAR 73
9.2 Safety of EVAR 73

APPENDICES

Appendix 1 Characteristics of the included studies 83
Appendix 2 Forest plots 115

LIST OF TABLES

Table 1 Summary of included studies 10
Table 2 Reasons for exclusion 13
Table 3 Summary of the quality assessment of the randomised controlled trials 14
Table 4 Summary of the quality assessment of the non-randomised controlled trials 15
Table 5 Summary of the quality assessment of the comparative observational studies 16
Table 6 Summary of the quality assessment of the case series 17
Table 7 Proportion of participants accepted for EVAR 18
Table 8 30 day mortality rate for EVAR versus open repair (RCTs) 19
Table 9 30 day mortality rate for EVAR versus open repair (NRCTs) 19
Table 10 Early (<30 days) aneurysm rupture rates following EVAR 20
Table 11 Primary conversion rates following EVAR (RCTs) 21
Table 12 Primary conversion rates following EVAR (NRCTs) 21
Table 13 Aneurysm-related mortality for EVAR versus open repair 21

Table 14 Non-aneurysm related mortality for EVAR versus open repair 22
Table 15 All-cause mortality at 1 year for EVAR versus open repair..... 22
Table 16 All-cause mortality at >1 year for EVAR versus open repair 23
Table 17 Delayed aneurysm rupture rates for EVAR versus open repair (RCT) 23
Table 18 Delayed aneurysm rupture rates for EVAR versus open repair (NRCT) 23
Table 19 Change in aneurysm size following EVAR..... 24
Table 20 Delayed conversion rates (RCT) 24
Table 21 Delayed conversion rates (NRCTs)..... 25
Table 22 Secondary intervention rates for EVAR versus open repair (RCT) 25
Table 23 Secondary intervention rates for EVAR versus open repair (NRCT) 26
Table 24 Incidence of common technical complications following EVAR (RCT and NRCT) 28
Table 25 Common non-technical complications for EVAR versus open repair 33
Table 26 Successful endograft deployment rate (RCT) 36
Table 27 Successful endograft deployment rate (NRCT)..... 36
Table 28 Primary technical success rate..... 37
Table 29 Thirty day technical success..... 37
Table 30 Procedural blood loss (RCT)..... 37
Table 31 Procedural blood loss (NRCT) 38
Table 32 Length of ITU stay (RCT)..... 38
Table 33 Length of ITU stay (NRCT) 39
Table 34 Length of hospital stay (RCT)..... 39
Table 35 Length of hospital stay (NRCT) 40
Table 36 Aneurysm rupture rates for EVAR verses no intervention 42
Table 37 Incidence of common technical complications in EVAR..... 43
Table 38 Successful endograft deployment rate..... 44
Table 39 Primary technical success rate..... 45
Table 40 Thirty day technical success..... 46
Table 41 Delayed aneurysm rupture rates following EVAR..... 46
Table 42 Early (<30 days) aneurysm rupture rates following EVAR 47
Table 43 Changes in aneurysm size following EVAR 48
Table 44 Primary conversion rates 49
Table 45 Delayed conversion rates..... 50
Table 46 Secondary intervention rates 51
Table 47 Procedural blood loss 52
Table 48 Length of ITU stay 53
Table 49 Length of hospital stay 54
Table 50 Incidence of common technical complications in EVAR..... 55

Table 51 Incidence of common non-technical complications (Case Series) 60

LIST OF FIGURES

Figure 1 30 day mortality rate for EVAR versus open repair: Forest plot 20
Figure 2 Secondary intervention rates for EVAR versus open repair: Forest plot 26
Figure 3 Incidence of Incidence of new or persisting endoleak following EVAR 30
Figure 4 Incidence of technical complications - other 31
Figure 5 Incidence of common non-technical complications: EVAR versus surgery 35
Figure 6 Cardiac event rate for EVAR versus open repair: Forest plot 115
Figure 7 Renal impairment rates for EVAR versus open repair: Forest plot 115
Figure 8 Blood loss for EVAR versus open repair: Forest plot 116
Figure 9 ITU stay for EVAR versus open repair: Forest plot 116

EXECUTIVE SUMMARY

Background

Endovascular aneurysm repair involves positioning of an endograft within the abdominal aorta by a transfemoral or transiliac route with the aim of exclusion of the aneurysm from within the circulation. The technique is being developed as an alternative therapeutic intervention to surgical repair in the treatment of abdominal aortic aneurysms, particularly in high risk surgical candidates in whom open repair is associated with significant levels of morbidity and mortality.

Objective

The purpose of this review was to provided an updated systematic review incorporating the latest evidence on EVAR.

Number and quality of included studies

From the initial reports identified from the updated searches, 52 were identified as being potentially relevant, and of these 31 were identified for inclusion in the review. Including the studies identified in the update, a total of 78 studies were identified for inclusion. There were 4 randomised controlled trials (6 reports), 17 non-randomised controlled trials, 22 comparative observational studies, 28 case series and 6 registry publications. The methodological quality of the included studies were variable. The quality of 3 of the 4 RCTs was very good. Across the other study designs little information was provided on drop outs, level of operator experience and generally analyses were not adjusted for confounding factors.

Summary of evidence

EVAR versus open repair

From a meta-analysis of RCT data, EVAR was associated with a lower 30-day mortality rate than open repair (OR 0.33, 95% CI 0.17 to 0.64). This finding was supported by the results from the NRCT data. Reports from two RCTS at 2 and 4 years follow-up, respectively, indicated that the early survival benefit in the EVAR group had been lost by the end of the first year post-procedure.

From one RCT during the median follow-up period of 35 months (IQR, 23 to 48 months), there was a non-significant difference in the average rupture rate following EVAR compared to open repair, (0.9% versus 0.2%). Following a failed attempt at EVAR, around 1.0% of the study population required conversion to open surgical repair during the perioperative period. One RCT reported that during follow-up an average of 1.9% of patients required a delayed surgical conversion for persistent endoleak, aneurysm expansion (with or without endoleak), or aneurysm rupture. One RCT reported a significantly higher secondary intervention rate following EVAR compared following open repair (OR 2.57, 95% CI 1.70 to 3.87; $p<0.00001$).

The rate of intervention following EVAR was almost three times the rate after open repair in another RCT, (HR 2.9, 95% CI 1.1 to 6.2; p=0.03).

From the safety data, the most common technical adverse event following EVAR was a type II endoleak (occurring in 18.9% participants at 1 year). Pulmonary complications and the incidence of blood loss and haemorrhagic events were significantly lower in the EVAR group. There was no significant difference in the rates of cardiac events, lower limb ischaemia, renal impairment, graft infection, colonic ischaemia or local wound complications. The results of the RCTs demonstrated that there was a significant reduction in ITU stay post EVAR compared to open repair. In addition, the RCTs showed a clear benefit for EVAR compared to open repair in terms of a significant reduction in total hospital stay.

EVAR in high risk patients

The EVAR 2 trial demonstrated a significantly higher 30-day mortality rate post EVAR in a population who were deemed to be unfit for open repair compared to no intervention. However this rate was reduced if only elective procedures were taken into account. In addition, aneurysm related death was found to be similar between both groups. There was no statistically significant difference in total mortality rates between the EVAR and no-intervention groups during the follow-up period. The rate of complications was significantly higher following EVAR compared to no intervention, and there was a high requirement for secondary intervention in the EVAR group (intervention rate of 11.5 per 100 person years). However, low primary and secondary conversion rates were maintained in this high-risk group.

Conclusions

Until the publication of the DREAM and EVAR trials, there had been a lack of level one evidence comparing the efficacy and safety of EVAR to open repair. From the RCT data it is clear that EVAR is a less invasive technique associated with a reduction in perioperative morbidity and mortality rates, compared to open repair. However these early benefits need to weighed against a need for more intensive follow-up, a significant rate of re-intervention and unknown long term success in preventing aneurysm related mortality. Medium term data from the RCTs has demonstrated no overall survival benefit following EVAR. The EVAR 2 trial is the only RCT to date that has compared EVAR to best medical therapy (BMT) in a group of patients unfit for open repair. Although clearly associated with higher rates of morbidity and mortality, there may still be a place for EVAR in the management of certain high-risk surgical candidates, as the risk of aneurysm related death is likely to be higher than that found in the EVAR 2 trial.

Finally, EVAR is a technique that is still developing and longer-term follow up and further research are required to determine its exact place in the management of abdominal aortic aneurysms.

LIST OF ABBREVIATIONS

AAA	Abdominal aortic aneurysm
CI	Confidence interval
CT	Computed tomography
EVAR	Endovascular aneurysm repair
HR	Hazard ratio
NR	Not reported
NRCT	Non-randomised comparative trial
NS	Not stated
OR	Odds ratio
RCT	Randomised controlled trial
WMD	Weighted mean difference

1 OBJECTIVE OF THE REVIEW

A systematic review of the evidence for the safety and efficacy of elective endovascular repair in the management of infrarenal abdominal aortic aneurysms was conducted in June 2004.[1] At this time there was a lack of level one (RCT) evidence available and this was being addressed by a number of ongoing RCTs including the EVAR 1 and 2 (UK), DREAM (Netherlands), ACE (France) and OVER (USA) trials. The purpose of this review was to update the previous review incorporating the latest evidence, including a number of publications from these RCTs.

2 BACKGROUND

2.1 The interventional procedure under review

2.1.1 Description of the interventional procedure

Endovascular aneurysm repair involves positioning of an endograft within the abdominal aorta by a transfemoral or transiliac route with the aim of exclusion of the aneurysm from within the circulation. The lower physiological stress of the minimally invasive endovascular approach is associated with lower morbidity and mortality rates, and consequently is a therapeutic option for high risk patients for whom conventional open repair would not be appropriate. Endovascular aneurysm repair has been performed not only as an elective procedure, but also on symptomatic and ruptured aneurysms. However, only the technique of elective aneurysm repair has been considered in this review.

Prior to undertaking endovascular aneurysm repair, the patient must undergo preoperative contrast-enhanced computed tomographic (CT) scanning to accurately determine aneurysm morphology. A full clinical assessment must also be carried out to identify any risk factors for open and endovascular repair. These two processes are required to ensure that the patient fulfils the clinical and anatomical inclusion criteria for endovascular aneurysm repair.

The procedure is carried out in an operating room or endovascular suite under general or regional anaesthesia. Access to the femoral arteries is achieved by surgical cut-down and the prosthesis is inserted via a preloaded delivery catheter system. One lumen of the catheter is used for guide wire access and flushing, whilst the other lumen contains the deployment line. The delivery system usually has a tapered balloon creating an atraumatic tip during insertion. Radio-opaque markers on the catheter and stent graft allow the endoprosthesis to be manoeuvred into position under fluoroscopic guidance. Before insertion of the introducer sheath, patients typically receive 5000 IU of heparin intravenously and a single dose of antibiotic medication is given prophylactically.

The stent-graft of appropriate size and configuration is selected on the basis of diagnostic imaging. The stent graft is usually oversized by 10-20% to decrease the incidence of type I endoleak. Following successful insertion of the stent-graft a completion angiogram is performed

to document exclusion of the aneurysm from the circulation. The femoral arteriotomies are closed according to standard surgical techniques and the patient is transferred to an appropriate after-care setting for observation.

2.1.2 Proposed clinical indications/contraindication and putative impact of the procedure

The use of EVAR in the treatment of infrarenal abdominal aortic aneurysms was established in 1991 by Parodi et al.[2] Since then, both the technique and devices have been developed so that this procedure may be used in elective, symptomatic and ruptured cases. The technique was initially developed in Europe and subsequently the AneuRx, Ancure and Guidant stent-graft devices were approved by the Food and Drug Administration (FDA) in September 1999.

Early trials have demonstrated lower mortality and early morbidity rates and consequently EVAR has been used with increasing frequency.[3-5] This is particularly true in the case of elderly and high-risk patients for whom traditional open repair carries significant risks.

In order to repair an aneurysm by endovascular methods, certain anatomical and morphological criteria must be met. However there are no fixed criteria and they differ between different centres and different stent-grafts. Typical criteria include: proximal neck length >10mm length, <26mm diameter and <60 degrees angulation; iliac artery diameter <16mm and >7mm. Significant iliac artery tortuosity or calcification, or circumferential thrombus at the proximal neck are usually contraindications.

2.1.3 Personnel involved (e.g. surgeons, anaesthetists, nurses) and skill/experience required

Endovascular aneurysm repair is a consultant led service, with either a vascular interventional radiologist or a vascular surgeon taking the lead role, depending upon the set-up of each centre. A consultant anaesthetist is present throughout the procedure and is responsible for the general or regional anaesthesia. Access to the femoral arteries is provided by a vascular surgeon via a surgical cut-down. Placement of the endovascular stent is carried out by either the radiologist or the surgeon, and a radiology assistant is required for this stage of the procedure. Nursing staff involved include a scrub nurse, and 2 support nurses to act as runners. An operating department assistant (ODA) is present to help the anaesthetist. Finally two radiographers are required to operate the radiology equipment. The surgeon or radiologist will typically have undergone a period of training in vascular interventional radiology.

2.1.4 Current use in the UK

There are currently around 40 centres in the UK undertaking EVAR for abdominal aortic aneurysms (AAA). The majority of these centres are involved in the EVAR trial (randomised

controlled trial comparing EVAR to open repair). Before being considered for participation in the trial, a new centre must submit outcome data on 20 cases.

2.1.5 Equipment or devices required

Commercially-available endovascular stent-grafts are of one of three designs: aortic tube graft, aortic uniiliac graft or aortic biiliac (bifurcated) graft. The stent-graft typically comprises a self-expanding nickel-titanium (nitinol) stent attached to a woven polyester fabric graft. The tube graft is composed of a single structure, whilst the bifurcated grafts are modular and comprise multiple segments. Tube grafts are no longer used in this country. The bifurcated graft consists of a proximal tube, a flow divider, a full-length ipsilateral iliac limb and a short contralateral stump for attachment of the second iliac limb. The stent-grafts are attached to the native aortic wall by a number of metallic wires, hooks and anchors. Additional modular components include aortic and iliac extender cuffs and are used for the treatment of type I endoleaks. The main stent-grafts used in this country are made by Cook (Zenith bifurcated graft, a custom made graft and an aortouniliac device), Medtronic (Talent endograft) and Gore (Excluder).

2.2 Description of the underlying health problem

2.2.1 Epidemiology

An abdominal aortic aneurysm (AAA) is defined as an abnormal dilatation of the artery that is 1.5 times the diameter of the normal segment. A diameter of greater than 3 cm is generally regarded as aneurysmal in the abdominal aorta. Most aneurysms are caused by degenerative disease affecting the vessel and this process is most common in the infrarenal segment of the abdominal aorta, accounting for 90-95% of AAAs. Approximately 75% of aneurysms are asymptomatic and are found incidentally during clinical examination or radiographic investigations. Therefore the exact prevalence is unknown but various screening studies have estimated it to be between 1.7%-6% in the older male population.[6-8] The incidence of AAAs is known to increase with age: the incidence rate for males over 50 years is approximately 25/100,000 increasing to 78/100,000 in those over 70 years.[9] AAAs are more common in men than women with a male: female ratio of 3.5-6: 1.[9] Furthermore a number of studies have suggested that the incidence of AAA is actually increasing.[10]

2.2.2 Aetiology and pathology

Aneurysmal disease is associated with degeneration of the vessel wall with loss of intima and a reduction in the elastin and collagen content of the media. The exact cause of these changes is largely unknown; however the risk factors for atherosclerotic disease (smoking, hypertension, hyperlipidaemia and diabetes mellitus) are thought to be largely responsible.

2.2.3 Natural history of abdominal aortic aneurysms

The natural history of AAA is one of progressive structural deterioration, gradual expansion and eventual rupture. An ectatic abdominal aorta is defined as one that is diffusely and irregularly dilated with a diameter less than 3 cm. One study demonstrated that the median growth rate was 0.65 mm/year with 19% becoming aneurysmal within a 2-year follow-up period.[11] Another study demonstrated expansion rates of 0.09 cm/year for aneurysms 2.6-2.9 cm, 0.16 cm/year for aneurysms 3.0-3.4 cm, and 0.32 cm/year for aneurysms 3.5-3.9cm.[12] Other studies have shown expansion rates of 0.2-0.4 cm/year for aneurysms <4 am diameter, 02-0.5 cm/year for aneurysms 4-5 cm and 0.3-0.7 cm/year for those larger than 5 cm.[13] The UK Small Aneurysm Trial demonstrated that ultrasound surveillance is a safe management option for patients with small abdominal aortic aneurysms (4.0 – 5.5 cm diameter) with an annual rupture rate of 1%.[14] After 3 years of surveillance, it has been shown that the annual rate of aneurysm rupture is 2.2%.[15;16]

2.3 Potential complications of aneurysm repair

Traditional open surgical repair of abdominal aortic aneurysms is associated with significant morbidity and mortality risks, particularly as there are significant levels of co-morbidity in the relevant population.

Common complications of open aneurysm repair include haemorrhage, local wound infections, chest infections, the need for post-operative ventilation and clinical cardiac events. Other less common complications include renal impairment (transient and permanent), lower limb ischaemia and trash foot, colonic ischaemia, graft infection and delayed rupture. In assessing the efficacy and safety of alternative therapeutic options, i.e. EVAR, it is important to consider all the above outcome measures. However, endovascular repair is also associated with certain other complications such as endoleak, stent migration and stent wire fracture from metal fatigue.

2.3.1 Endoleaks

Endoleaks are a well recognised complication following aneurysm repair that is specific to endovascular repair. The classification of endoleaks used in this review is that developed by White et al, 1998.

Type Ia - Perigraft leak from poor proximal attachment or seal

Type 1b - Perigraft leak from poor distal attachment or seal

Type II - Collateral backflow / retrograde endoleak

Type III - Mid-graft fabric tear / modular disconnection or poor seal

Type IV - Porosity – graft-wall fabric porosity or suture holes

2.4 Population

2.4.1 Suitable candidates and relevant subgroups

Patients with an infrarenal abdominal aortic aneurysm >5.5 cm diameter and larger, or >4.5 cm and has increased in size by >0.5 cm in the preceding 6 months.

2.5 Current management and alternative procedures

Intervention for AAA is designed to prevent the endpoint of rupture, which is associated with an overall mortality rate of approximately 80%, with only half of those undergoing emergency operation surviving. The UK Small Aneurysm Trial demonstrated that there was no long-term survival advantage from elective surgery on small aneurysms (<5.5 cm diameter). Therefore current guidelines recommend a size of 5.5 cm diameter and larger, or >4.5 cm and has increased in size by >0.5 cm in the preceding 6 months before elective treatment (open or endovascular) is undertaken. The only other alternative intervention for abdominal aortic aneurysms is traditional open repair. Elective open repair is associated with a mortality rate of 2-6%.

3 METHODS FOR REVIEWING EVIDENCE ON EFFICACY AND SAFETY

3.1 Updated search strategy

The update searches were undertaken at the end of March 2005 and aimed to identify all references relating to the safety and efficacy of using endovascular stents for the treatment of abdominal aortic aneurysms.

Sources searched

Twelve electronic bibliographic databases were searched, covering biomedical, health-related, science, and social science literature:

- BIOSIS
- Cinahl
- Central Database
- Cochrane Database of Systematic Reviews (CDSR)
- Centre for Reviews and Dissemination (CRD) Databases
- Database of Abstracts of Reviews of Effects (DARE)
- Embase
- Health Technology Assessment (HTA) Database
- Medline
- NHS Economic Evaluations Database (NHS EED)
- Science Citation Index
- Social Sciences Citation Index

Search terms

A combination of free-text and thesaurus terms were used. 'Population' terms (for example, abdominal aortic aneurysm, AAA) were combined with 'intervention' terms (for example, EVAR, endovascular aneurysm repair, endovascular stent). Copies of the search strategies used in the major databases are included in the previous review.[1]

Search restrictions

The update searches were restricted to English language articles.

3.2 Inclusion and exclusion criteria

3.2.1 Types of studies

Randomised controlled trials, controlled clinical trials, comparative observational studies, case series studies, and population-based registries assessing the efficacy and/or safety of EVAR were included. Systematic reviews and case reports were excluded from the review. Case series comprising less than fifty patients or containing less than 5 outcome measures of interest were excluded. For studies with multiple publications, those with the greatest number of participants, the longest follow-up, or the latest publications with the most amount of outcome data were included.

3.2.2 Types of participants

Studies including adults with asymptomatic infrarenal abdominal aortic aneurysms undergoing elective intervention were eligible for inclusion. Patients with symptomatic or ruptured aneurysms were excluded from this review.

3.2.3 Types of interventions

Endovascular aneurysm repair of abdominal aortic aneurysms. Thoracic and thoraco-abdominal aortic aneurysms were excluded.

3.2.4 Types of outcome

Efficacy

Main clinical outcomes:

- Successful endograft deployment
- Primary technical success – defined as complete exclusion of the aneurysm from the circulation immediately following completion of the procedure
- Thirty day technical success – defined as complete aneurysm exclusion at thirty days
- Secondary technical success – defined as complete aneurysm exclusion following a secondary intervention
- Aneurysm rupture following successful EVAR
- Changes in size of aneurysm during follow-up

- Primary conversion rate (conversion to open procedure)
- Delayed conversion rate (conversion to open procedure)
- Secondary intervention rate

Other clinical outcomes

- Proportion of population for whom EVAR technically feasible
- Procedural blood loss
- Length of ITU stay
- Total length inpatient stay

Safety

The frequency and type of adverse events were tabulated to assess the safety of EVAR. Safety endpoints were considered in the following categories:

- Technical problems
    - Stent migrations
    - Stent fracture
    - Stent wire fracture
    - Graft limb thrombosis
    - Graft stenosis
    - Graft kinking
    - Endoleak – type I, II and III
    - Access artery injury
    - Contrast reaction
- Major morbidity
    - Thirty day mortality rate
    - Subsequent death from aneurysm and non-aneurysm related causes
    - Cardiac event
    - Renal impairment
    - Graft infection
    - Colonic ischaemia
    - Lower limb ischaemia
    - Minor morbidity
    - Wound infection

3.3 Quality assessment strategy

The methodological quality of all full-text reports was assessed by one reviewer using three separate quality assessment forms. Full details of the quality assessment checklists used are reported in the previous review.[1]

3.4 Data extraction strategy

A data extraction form was specifically developed in an Access database to record details of the design of included studies, characteristics of participants, technical aspects of EVAR, and outcome measures of interest. Full details of the data extraction form are reported in the previous review.[1] Data extraction was carried out by one reviewer and checked for accuracy by a second. Reviewers were not blinded to the names of study authors, institutions, or publications.

3.5 Data analysis

The results of the data extraction and quality assessment for each included study are presented in structured tables and as a narrative summary. Data from multiple publications is included in the tables and highlighted, but were omitted from the calculations of overall rates and means where data from a later publication were available.

3.5.1 Data synthesis

For binary outcomes the pooled odds ratio and its 95% confidence interval were calculated using a fixed effects model in Review Manager Version 4.2.7. Where significant heterogeneity was indicated the results were recalculated using a random effects model. For continuous outcomes, a weighted mean difference and its 95% confidence interval were calculated, also in Review Manager Version 4.2.7. Where standard deviations were not reported by the authors they were estimated from the interquartile range (if available) using methods described in the Cochrane Reviewers Handbook (based on the width of the interquartile range being equivalent to approximately 1.35 times the standard deviation), in order to calculate a weighted mean difference (WMD). Such calculations make the assumption that the data follows a normal distribution. If this data was also not available, studies were not combined in the meta-analysis. For studies that did not include a comparison group, an overall mean and its 95% confidence interval was calculated.

4 RESULTS OF UPDATE SEARCHES

4.1 Type and quantity of evidence available

From the updated literature search, a further 52 reports were identified as being potentially relevant and full papers were obtained and assessed in detail for inclusion. In total, an additional 31 full-text papers[17-47] met the criteria for inclusion.

The mid-term results from the EVAR 1[45] and 2[46] trials, although not published at the time, were made available to the reviewers and are included in this report. In addition, two year data from

the DREAM trial[47] was published during the synthesis of this report and the study was included as it potentially contained significant level one evidence.

4.2 Number and type of included studies

In addition to the studies included in the previous review, a total of 78 studies were identified for inclusion. There were 4 randomised controlled trials (6 reports), 17 non-randomised controlled trials, 22 comparative observational studies, 28 case series and 6 registry publications. A summary of the included studies is shown in Table 1. Full characteristics of these studies are presented in Appendix 1.

The report was primarily concerned with the safety and efficacy of EVAR versus open repair and EVAR versus no intervention in patients unfit for open repair. Therefore, findings from non-controlled studies (i.e. case series and population registry data) are reported in a separate chapter.

4.2.1 Characteristics of the included studies

The number of participants in the included studies ranged from 40 to 7172 (total n=33,426) and the mean age (where reported) ranged from 65 to 85 years. The number of patients receiving EVAR ranged from 20 to 4613 (total n=23,416).

Mean follow-up ranged from 7 to 39 months. Forty-six studies had a mean follow-up of 12 months or more, and 15 had a mean follow-up of at least 24 months. The mean follow-up period was not recorded in 20 of the papers.

Forty-one of the primary studies were set in North-America, two were set in Australia, and the rest were set in Europe (6 UK papers and 3 EUROSTAR database publications). In addition, 22 of the studies were multi-centre studies. The device manufacturer funded eight of the studies and one was funded by the US government. The remaining studies did not declare a source of funding.

There appeared to be overlap in the patient populations in the included studies. Some studies, for example, were single-centre reports of patients, some of whom had been included in larger, multi-centre studies. However, the numbers of patients included in the trials was not always clearly reported in these articles. Where possible these studies have been grouped together. It is therefore not possible to give an accurate representation of the number of patients who have received EVAR in the included studies.

Table 1 Summary of included studies

Author, Year	RCT/NRCT/ Case series/ Comparative study	Mean age	Enrolled (all interventions)	N° receiving EVAR	Months of follow-up (range)
AbuRahma 2004[28]	Case Series	74	151	151	17 (1-46)
Albertini 2001[48]	Comp study	72	185	185	NR
Allaqaband 2004[21]	Comp Study	72	60	60	14
Alric 2002[49]	Case Series	73	88	88	21 (6-68)
Anderson 2004[50]	NRCT	NR	4769	1706	NR
Becquemin 2004[27]	Case Series	71	250	250	28
Becquemin 2000[51]	*NRCT*	*70*	*180[a]*	*73*	*7 (0-40)*
Bertrand 2000[52]	NRCT	71	386	193	NR
Biebl 2004[23]	Comp Study	72	182	182	(0-43)
Blankensteijn 2005[47]	RCT	70	351	173	21 (0-42)
Prinssen 2004[44]	*RCT*	*70*	*351*	*173*	*1*
Blum 2001[53]	Comp study	70	298	298	(2-50)
Bolke 2001[54]	NRCT	72	40	20	NR
Boult 2004[29]	Case Series (R)	75	950	950	NR
Burks 2002[55]	Case Series	NR	95	95	25 (6-44)
Carpenter 2004a[56]	Case Series	NR	227	227	11 (0-41)
Carpenter 2004b[17]	NRCT	73	258	192	NR
Cartes 2002[57]	Case Series	74	72	72	22 (1-46)
Cho 2004[30]	Case Series	73	50	50	34
Corriere 2004[24]	Case Series	72	220	220	NR
Cuypers 2001[58]	RCT	69	76	57	NR
Dalainas 2004[31]	Case Series	71	186	186	26 (9-60)
Espinosa 2005[32]	Case Series	71	193	193	36
Faries 2002[59]	Case Series	65	74	74	13 (6-48)
Flora 2003[60]	Comp study	73	108	108	20
Garcia-Madrid 2004[34]	NRCT	NR	83	53	26
Gilling-Smith 2000[61]	Case Series	71	55	55	18 (3-36)
Greenhalgh 2005a[d45]	RCT	74	1047	531	35 (23-48)[c]
Greenhalgh 2004[22]	*RCT*	*74*	*1047*	*531*	*1*
Greenhalgh 2005b[e 46]	RCT	76	238	166	29 (19-43)[c]
Hansman 2003[62]	NRCT	72	100	50	NR
Haulon 2003[63]	Case Series	68	96	96	27 (3-66)

Author, Year	RCT/NRCT/ Case series/ Comparative study	Mean age	Enrolled (all interventions)	N° receiving EVAR	Months of follow-up (range)
Hinchliffe 2004[20]	Case Series	74	269	269	12
Jordan 2004[36]	NRCT	73	404	259	28
Kocher 2004[37]	Case Series	71	120	120	21 (2-60)
Lee 2004[43]	NRCT	72	7172	2565	NR
Maldonado 2004[19]	Case Series	72	311	311	22 (2-72)
May 2000[64]	Case Series	72	266	266	>6
Minor 2004[39]	Case series	85	150	150	17 (1-61)
Moore 2003[65]	NRCT	73	684	573	(1-60)
Nolthenius 2001[66]	Case Series	70	77	77	>12
Ohki 2001[67]	Case Series	76[b]	239	239	15 (<75)
Ouriel 2003[68]	Comp study	75[b]	704	704	NR
Ouriel 2003[69]	Comp study	75	700[a]	700	12
Cao 2004[18]	NRCT	72	1119	534	33 (13-50)[c]
Parlani 2002[70]	*Comp study*	*70*	*336*	*336*	*14 (1-46)*
Zannetti 2001[71]	*Comp study*	*70*	*266[a]*	*266*	*11 (1-32)*
Resch 2002[72]	Case Series	71	164	164	39
Resch 2001[73]	*Comp study*	*71*	*158[a]*	*158*	*20 (10-36)*
Ricco 2003[74]	Case Series	72	1012	1012	11
Sampaio 2004[40]	Case Series	75	241	241	10 (1-71)
Elkouri 2003[75]	*Case Series*	*76*	*100*	*100*	*7 (1-60)*
Elkouri 2004[25]	*Case Series*	*74*	*355*	*94*	*NR*
Teufersbauer 2003[76]	NRCT	72	756	275	NR
Vasquez 2004[41]	Comp study	75	212	212	NR
Verhoeven 2004[42]	Case Series	70	308	308	36(±22)
Zeebregts 2004[77]	NRCT	72	286	93	19
Ziaja 2003[26]	Case Series	71	52	52	13 (1-39)
EUROSTAR database (n=4613)					
Fransen 2003[78]	Case Series (R)	71	4613	4613	21 (1-72)
Laheij 2002[79]	*Case Series (R)*	*NR*	*2863[a]*	*2863*	*NR*
Vallabhaneni 2001[80]	*Case Series (R)*	*71*	*2862[a]*	*2862*	*12 (0-72)*
Talent Clinical Trial (n=471)					
Criado 2001[81]	Comp study	NR	471	471	NR
Criado 2003[82]	*NRCT*	*76*	*366[a]*	*240*	*13*
Fairman 2004[33]	*Comp study*	*NR*	*237*	*237*	*21*

Author, Year	RCT/NRCT/ Case series/ Comparative study	Mean age	Enrolled (all interventions)	N° receiving EVAR	Months of follow-up (range)
AneuRx Clinical Trial (n=1193)					
Arko 2002[83]	NRCT	73	497	200	12 (1-60)
Arko 2003[84]	*Comp study*	*73*	*206[a]*	*206*	*32 (3-55)*
Ayerdi 2003[85]	Comp study	73	96	96	12
Howell 2000[86]	Case Series	72	215	215	14
Howell 2000[87]	*Comp study*	*72*	*89[a]*	*89*	*(1-18)*
Lee 2002[88]	Comp study	74	150	150	NR
Lee 2000[89]	*Case Series*	*74*	*67[a]*	*67*	*18*
Ramaiah 2002[90]	Comp study	74	260	260	NR
Shames 2003[91]	Comp study	73	245	245	11 (1-26)
Wolf 2002[92]	Comp study	75	189	189	13
Zarins 2000[93]	Case Series	NR	149	149	12 (1-39)
Zarins 2003b[94]	Case Series	NR	1193	1193	<48
Zarins 2003[95]	*Case Series*	*73*	*383[a]*	*383*	*36*
Zenith Clinical Trial (n=432)					
Greenberg 2004[35]	NRCT	NR	432	352	NR
Total		**72**	**33664**	**23582**	

[a]Excluded from count of enrolled population (all interventions and EVAR) as duplicate series

b Some participants may overlap with the Talent and AneuRx clinical trial populations

[c]IQR given for follow-up

[d] EVAR 1 Trial

[e] EVAR 2 Trial

NR – Not reported

(R) Registry publication

4.3 Number and type of excluded studies

Out of the 52 papers initially assessed as potentially relevant for the updated review, 21 papers were judged as being unsuitable for inclusion in the current review. A summary of the reasons for exclusion is shown in Table 2.

Table 2 Reasons for exclusion

Reason for exclusion	Number of articles
Not a primary study	2
Small case series (n<50)	0
Insufficient outcome data of interest	7
Ruptured AAA	0
More recent/relevant publication available	7
Other	5
Total	**21**

4.4 Quality of the available evidence

4.4.1 Randomised controlled trials

The results of the quality assessment of the four RCTs (six papers) is summarised in Table 3. How patients were assigned to treatment groups was reported and random in all of the included RCTs with the exception of the study by Cuypers et al.[58] Patients were randomised to EVAR with a 3:1 ratio, but no information is provided as to the method of randomisation. In the two EVAR trials,[45;46] patients were randomised using a 1:1 ratio in randomly sized permuted blocks. Abdominal aortic aneurysm repair cannot be blinded to the care provider or the patient as it is an invasive procedure, so these checklist items were not applicable. Primary outcome measures were presented as point estimates and measures of variability in all RCTs. In the study by Cuypers et al.[58] there was no record of losses to follow-up and it was unclear whether the procedure was undertaken by an experienced person. In the remaining studies, the losses to follow-up and level of operator experience were well documented.

Table 3 Summary of the quality assessment of the randomised controlled trials

Criteria	Yes	No	Unclear
Was the assignment to the treatment groups really random?	3	0	1
Was the treatment allocation concealed?	0	N/A	0
Were the groups similar at baseline in terms of prognostic factors?	4	0	0
Were the eligibility criteria specified?	4	0	0
Were the groups treated in the same way apart from the intervention received?	4	0	0
Was the outcome assessor blinded to the treatment allocation?	4	0	0
Was the care provider blinded?	0	N/A	0
Were the patients blinded?	0	N/A	0
Were the point estimates and measures of variability presented for the primary outcome measures?	4	0	0
Was the withdrawal/drop-out rate likely to cause bias?	0	3	1
Did the analyses include an intention-to-treat analysis?	4	0	0
Was the operation undertaken by somebody experienced in performing the procedure	3	0	1

4.4.2 Non-randomised controlled trials

These studies compared a group of patients undergoing EVAR against a group of patients undergoing open repair. A summary of the quality assessment of the 17 non-randomised controlled trials is presented in Table 4.

The participants were generally a representative sample, although the inclusion and exclusion criteria for the studies were only moderately-well documented overall and were only clear in nine studies[52;62;82] Enrolment of patients was reported to be consecutive in seven studies.[51;52;62;76] and data was collected prospectively in eleven studies.[50;76] The level of operator experience was not clearly documented in any of the studies.

Valid outcome measures were used in all studies, although only four considered all outcomes considered important.[65;82] Only two studies provided information on non-respondents or dropouts and in the remaining studies was unclear as whether participants lost to follow-up were likely to introduce bias. Analyses were adjusted for confounding factors in only two of the studies.

Table 4 Summary of the quality assessment of the non-randomised controlled trials

Criteria	Yes	No	Unclear
Were participants a representative sample selected from a relevant patient population?	14	0	3
Were the inclusion/exclusion criteria of participants clearly described?	9	3	5
Were participants entering the study at a similar point in their disease progression?	4	7	6
Was selection of patients consecutive?	7	2	8
Was data collection undertaken prospectively?	11	3	3
Were the groups comparable on demographic characteristics and clinical features?	5	11	1
Was the intervention (and comparison) clearly defined?	17	0	0
Was the intervention undertaken by someone experienced at performing the procedure?	0	0	17
Were the staff, place, and facilities where the patients were treated appropriate for performing the procedure? (E.g. access to back-up facilities?	10	0	7
Were all the important outcomes considered?	4	13	0
Were objective (valid and reliable) outcome measure/s used?	17	0	0
Was the assessment of main outcomes blind?	1	0	16
Was follow-up long enough to detect important effects on outcomes of interest?	9	0	8
Was information provided on non-respondents, dropouts?	2	14	1
Were participants lost to follow-up likely to introduce bias? (e.g. high drop-out rate; differential drop-out; no description of those lost)	0	2	15
Was length of follow-up similar between comparable groups	7	2	8
Were all the important prognostic factors identified?	12	4	1
Were the analyses adjusted for confounding factors?	2	15	0

4.4.3 Comparative observational studies

These studies compared two or more subgroups of patients undergoing endovascular repair. A summary of the quality assessment of the 22 comparative observational studies is presented in Table 5.

The participants were a representative sample from a relevant population in seventeen of the twenty-two studies. The inclusion and exclusion criteria were only clearly described in half of the studies. The groups were only comparable on demographic features in five of the studies; in three studies, this was not applicable as the groups were set by different demographic or clinical features. Objective outcome measures were used in all studies, although none reported on all important outcome measures of interest. The description of participants lost to follow-up was

poorly reported and consequently it was unclear whether this was likely to introduce bias. Important prognostic factors were reported in ten studies, and in only four studies were the analyses adjusted for confounding factors.

Table 5 Summary of the quality assessment of the comparative observational studies

Criteria	Yes	No	Unclear
Were participants a representative sample selected from a relevant patient population?	17	0	5
Were the inclusion/exclusion criteria of participants clearly described?	10	8	4
Were participants entering the study at a similar point in their disease progression?[a]	8	7	4
Was selection of patients consecutive?	8	2	9
Was data collection undertaken prospectively?	10	9	3
Were the groups comparable on demographic characteristics and clinical features?[b]	5	9	6
Was the intervention (and comparison) clearly defined?	22	0	0
Was the intervention undertaken by someone experienced at performing the procedure?	2	0	20
Were the staff, place, and facilities where the patients were treated appropriate for performing the procedure? (E.g. access to back-up facilities?	13	0	9
Were all the important outcomes considered?	0	6	22
Were objective (valid and reliable) outcome measure/s used?	22	0	0
Was the assessment of main outcomes blind?	0	22	0
Was follow-up long enough to detect important effects on outcomes of interest?	16	0	6
Was information provided on non-respondents, dropouts?	1	21	0
Were participants lost to follow-up likely to introduce bias? (e.g. high drop-out rate; differential drop-out; no description of those lost)	0	1	21
Was length of follow-up similar between comparable groups	13	3	6
Were all the important prognostic factors identified?	10	11	1
Were the analyses adjusted for confounding factors?	4	18	0

[a] Not relevant for 3 studies [b] Not relevant for 2 studies

4.4.4 Case Series

A summary of the quality assessment of the 33 case series studies is presented in Table 6.

The patients were a representative sample selected from a relevant population in two-thirds of the studies. The exclusion and inclusion criteria were only clearly described in a third of cases. Data collection was prospective in just over half of the studies, but selection of patients was

consecutive in a minority of studies. An attempt to blind the outcomes assessors was only made in one study.

The level of experience of the person performing the procedure was only documented in one of the studies reviewed. Although objective outcomes were used by all of the studies, only five studies reported on all outcomes considered important. Information on losses to follow-up was generally reported poorly and therefore it was unclear whether this was likely to introduce any bias.

Table 6 Summary of the quality assessment of the case series

Criteria	Yes	No	Unclear
Were participants a representative sample selected from a relevant patient population?	23	1	9
Are the inclusion/exclusion criteria of patients in the study clearly described?)	10	20	3
Were participants entering the study at a similar point in their disease progression?	5	17	11
Was selection of patients consecutive?	6	1	26
Were all important prognostic factors identified?	17	16	0
Was data collection undertaken prospectively?	18	5	10
Was the recruitment period clearly stated?	31	2	0
Was the intervention that which is being considered in the review? (or was it a significant modification?)	32	0	1
Was an attempt made to blind outcomes assessors?	1	32	0
Was the operation undertaken by someone experienced in performing the procedure?	1	0	32
Did the staff, place, and facilities where the patients were treated provide an appropriate environment for performing the procedure? (e.g. was the intervention undertaken in a centre with the necessary back-up facilities?)	21	0	12
Were objective (valid and reliable) outcome measures used?	33	0	0
Were all the important outcomes considered?	5	28	0
Was follow-up long enough to detect important effects on outcomes of interest?	29	0	4
Was information provided on non-respondents, dropouts?	11	22	0
Were participants lost to follow-up likely to introduce bias? (e.g. high drop-out rate; no description of those lost)	1	9	23
Were the main findings clearly described? (to allow replication)	32	0	1

4.5 Proportion of population for whom EVAR technically feasible

Eight of the included studies (listed in Table 7) reported on the proportion of participants that they considered to be suitable candidates for EVAR. This ranged from 20% to 72% with an overall rate of 51.5%.

Table 7 Proportion of participants accepted for EVAR

Author	Number referred for EVAR	Accepted for EVAR	
		No	%
RCT			
Greenhalgh 2004[22]	3927	2132	54
NRCT			
Cartes 2002[57]	159	72	45
Haulon 2003[63]	480	96	20
Becquemin 2000[51]	438	180	41
Zarins 2000[93]	353	190	54
Wolf 2002[92]	378	194	51
Espinosa 2004[32]	267	193	72
Kocher 2004[37]	170	120	70
Total	**6172**	**3177**	**51.5**

5 EVAR VERSUS OPEN REPAIR

5.1 Major outcomes

5.1.1 30 day outcomes

- **Mortality**

Thirty-day mortality rates are displayed in Tables 8 and 9, and Figure 1. Data from the RCTs[22;44;58] showed a significant reduction in 30-day mortality for EVAR compared to open repair, (OR 0.33; 95% CI 0.17 to 0.64). The results from the NRCTs are concordant with the above findings, showing a significant reduction following EVAR compared to open repair (OR 0.31; 95% CI 0.25 to 0.39).

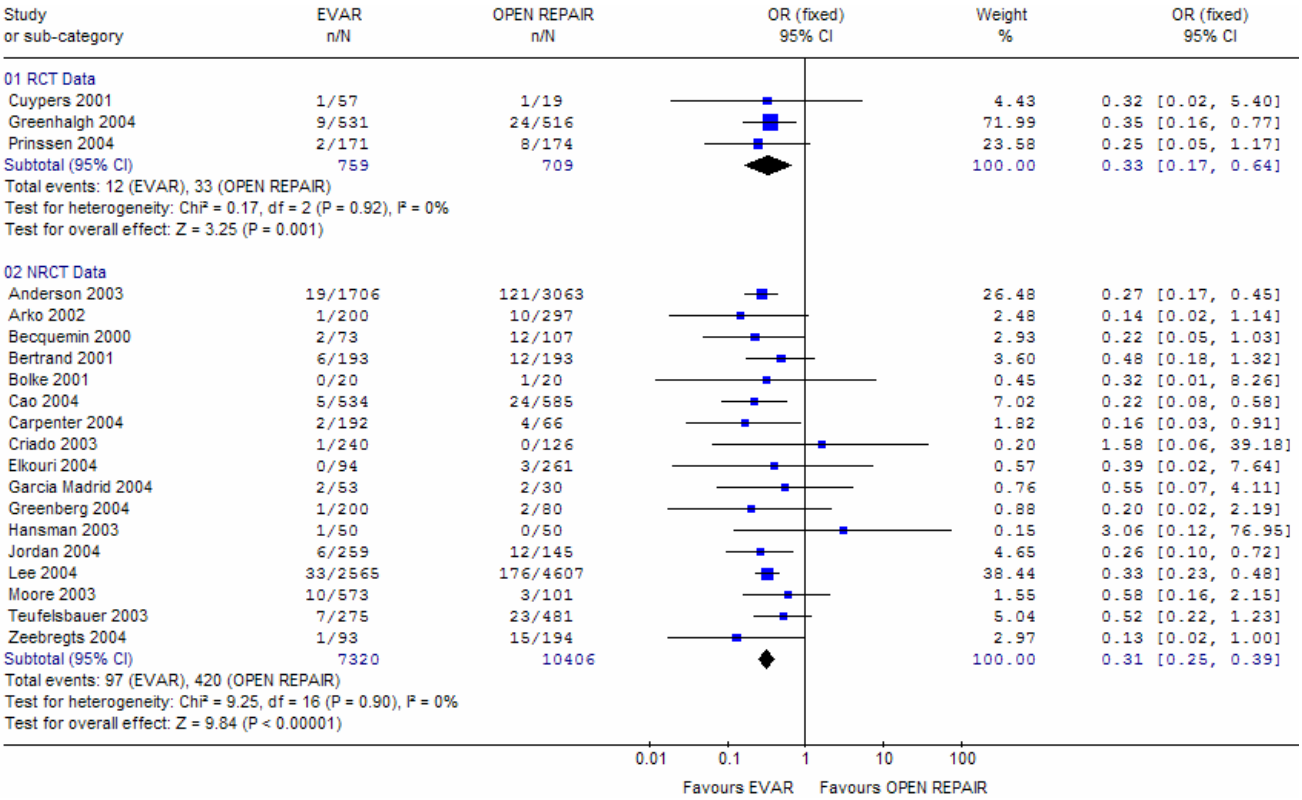
Table 8 30 day mortality rate for EVAR versus open repair (RCTs)

Study ID	EVAR		Open repair	
	n/N	%	n/N	%
Cuypers 2001[58]	1/57	1.8%	1/19	5.3%
Greenhalgh 2004[22]	9/531	1.7%	24/516	4.7%
Prinssen 2004[44]	2/171	1.1%	8/174	4.6%

Table 9 30 day mortality rate for EVAR versus open repair (NRCTs)

Study ID	EVAR		Open repair	
	n/N	%	n/N	%
Anderson 2003[50]	19/1706	1.1%	121/3063	4.0%
Arko 2002[83]	1/200	0.5%	10/297	3.4%
Becquemin 2000[51]	2/73	2.7%	2/107	1.9%
Bertrand 2001[52]	6/193	3.1%	12/193	6.2%
Bolke 2001[54]	0/20	0.0%	1/20	5.0%
Cao 2004[18]	5/534	0.9%	24/585	4.1%
Carpenter 2004b[17]	2/192	1.0%	4/66	6.1%
Criado 2003[82]	1/240	0.4%	0/126	0.0%
Elkouri 2004[25]	0/94	0%	3/261	1.1%
Garcia-Madrid 2004[34]	2/53	3.8%	2/30	6.7%
Greenberg 2004[35]	1/200	0.5%	2/80	2.5%
Hansman 2003[62]	1/50	2.0%	0/50	0.0%
Jordan 2004[36]	6/259	2.3%	12/145	8.3%
Lee 2004[43]	33/2565	1.3%	176/4607	3.8%
Moore 2003[65]	10/573	1.7%	3/101	3.0%
Teufelsbauer 2003[76]	7/275	2.5%	23/481	4.8%
Zeebregts 2004[77]	1/93	1.1%	15/194	7.7%

Figure 1 30 day mortality rate for EVAR versus open repair: Forest plot



- **Aneurysm rupture**

The primary objective of EVAR is to prevent subsequent rupture and its associated high morbidity and mortality rates. One NRCT[18] reported on early rupture rates occurring in the first 30 days post procedure (see Table 10). Data from the included case series indicated an overall early rupture rate of 0.3% (95% CI 0.2% to 0.5%).

Table 10 Early (<30 days) aneurysm rupture rates following EVAR

Author	Number of patients		Rupture
	EVAR	With rupture	Rate (%)
Cao 2004[18]	534	1	0.2

- **Primary conversion to open repair**

This is defined as the number of patients undergoing conversion to open surgery immediately following a failed attempt at endovascular repair.

From the two RCTs[44;45] that reported this outcome, the primary conversion rates were 0.8% and 1.8%, respectively (see Table 9). Twelve NRCTs (see Table 12) reported the primary conversion rate and the results are displayed in Table 10. The overall mean conversion rate was 2.4% (95% CI 1.8% to 3.0%). Data from the case series indicated a mean conversion rate of 1.2% (95% CI 1.0% to 1.4%).

Table 11 Primary conversion rates following EVAR (RCTs)

Author	Total number of EVAR	Primary conversion	
		Number of patients	Rate (%)
Greenhalgh 2005[45]	531	4	0.8
Prinssen 2004[44]	171	3	1.8

Table 12 Primary conversion rates following EVAR (NRCTs)

Author	Total number of EVAR	Primary conversion	
		Number of patients	Rate, % (95% CI)
Arko 2002[83]	200	2	1
Bertrand 2001[52]	193	6	3.1
Cao 2004[18]	534	7	1.3
Carpenter 2004b[17]	192	3	1.6
Criado 2003[82]	240	1	0.4
Elkouri 2004[25]	94	1	1.1
Garcia-Madrid 2004[34]	53	0	0
Greenberg 2004[35]	200	0	0
Hansman 2003[62]	50	0	0
Jordan 2004[36]	259	1	0.4
Moore 2003[65]	573	42	7.3
Zeebregts 2004[77]	93	1	1.1
	2681	**64**	**2.4 (1.8% - 3.0%)**

5.1.2 Longer term outcomes

- **Aneurysm-related mortality**

There were 4 studies[17;35;45;47] that had documented deaths that were directly attributable to the aneurysm. From the DREAM[47] and EVAR 1[45] trials, there was a significant reduction in AAA related deaths in the EVAR group from 30-days post-procedure which was maintained throughout the follow-up period. This difference in aneurysm-related mortality was based entirely on the difference in in-hospital (perioperative) mortality.

Table 13 Aneurysm-related mortality for EVAR versus open repair

Study ID	EVAR		Open repair	
	n/N	%	n/N	%
Blankensteijn 2005[47]	**2/173**	**1.2%**	**8/178**	**4.5%**
Greenhalgh 2005[45]	**19/543**	**3.5%**	**34/539**	**6.3%**
Carpenter 2004b[17]	1/192	0.5%	0/66	0%
Greenberg 2004[35]	1/200	0.5%	3/80	3.8%

- **Non-aneurysm related mortality**

There were three NRCT (see Table 14) that reported a mortality rate that was not AAA related. Overall, there was a significantly increased rate of death in the EVAR group compared to the open repair group (OR 1.42; 95% CI 1.07 to 1.89).

Table 14 Non-aneurysm related mortality for EVAR versus open repair

Study ID	EVAR		Open repair	
	n/N	%	n/N	%
Cao 2004[18]	101/534	18.9%	78/585	13.3%
Carpenter 2004b[17]	19/192	9.9%	9/66	13.6%
Criado 2003[82]	20/240	8.3%	6/126	4.8%

- **All-cause mortality**

Three NRCT (see Table 15) reported total mortality rates at one year, showing no significant difference in mortality in the EVAR group compared to the open repair group (OR 0.81, 95% CI 0.43 to 1.52; p=0.53).

Table 15 All-cause mortality at 1 year for EVAR versus open repair

Study ID	EVAR		Open repair	
	n/N	%	n/N	%
Becquemin 2000[51]	5/73	6.8%	3/107	2.8%
Greenberg 2004[35]	7/200	3.5%	3/80	3.8%
Zeebregts 2004[77]	7/93	7.5%	26194	13.4%

During more prolonged follow up the EVAR 1 trial[45] reported no significant difference in mortality rates between the EVAR and open repair groups. At four years, approximately 28% of the study population had died in the EVAR and open repair groups (hazard ratio 0.9, 95% CI 0.69 to 1.19; p=0.46).

At two years, the DREAM trial[47] reported cumulative survival rates of 89.6% following open repair and 89.7% following EVAR, a difference of -0.1 percentage points (95% CI -6.8 to 6.7 percentage points; p=0.86).

In both of the RCTs,[45;47] the initial significant reduction in 30-day mortality rate was lost by one year follow up. The EVAR 1 trial[45] reported a hazard ratio for EVAR compared to open repair during the first 6 months of 0.55 (95% CI 0.33 to 0.93) and 1.10 (95% CI 0.80 to 1.52) after 6 months.

Table 16 All-cause mortality at >1 year for EVAR versus open repair

Study ID	EVAR		Open repair	
	n/N	%	n/N	%
Greenhalgh 2005[45]	**100/543**	**18.4%**	**109/539**	**20.2%**
Carpenter 2004b[17]	20/192	10.4%	9/66	13.6%
Garcia-Madrid 2004[34]	5/53	9.4%	6/30	20%
Zeebregts 2004[77]	11/93	11.8%	27/194	13.9%

- **Aneurysm rupture rates**

The primary objective of EVAR is to prevent subsequent rupture and its associated high morbidity and mortality rates. Two RCTs and six NRCTs (see Tables 17 and 18, respectively) reported data on delayed rupture rates following EVAR.

Data from the RCTs gave a combined odds-ratio of 5.00 (95% CI 0.58 to 42.94; p=0.14). Of the six NRCTs, five studies reported delayed rupture rates of 0%. The study by Cao et al.[18] reported a rate of 1.1%.

Table 17 Delayed aneurysm rupture rates for EVAR versus open repair (RCT)

Study ID	EVAR		Open repair		Follow-up, months
	n/N	%	n/N	%	median (IQR)
Blankensteijn 2005[47]	0/178	0.0	0/173	0.0	21 (0-42)[a]
Greenhalgh 2005[45]	5/543	0.9	1/539	0.2	35 (23-48)

[a]Mean and range

Table 18 Delayed aneurysm rupture rates for EVAR versus open repair (NRCT)

Study ID	EVAR		Open repair		Follow-up, months
	n/N	%	n/N	%	median (IQR)
Becquemin 2000	0/73	0.0	0/107	0.0	7 (0-40)
Cao 2004[18]	6/529	1.1	0/585	0.0	Not Reported
Carpenter 2004b[17]	0/192	0.0	0/66	0.0	Not Reported
Criado 2003	0/190	0.0	0/240	0.0	Not Reported
Jordan 2004[36]	0/259	0.0	NS	-	Not Reported
Moore 2003	0/684	0.0	NS	-	NR (1-60)

- **Changes in aneurysm size**

Changes in aneurysm size following endovascular repair were reported in five NRCTs (see Table 19). Arko 2003[84] defined decrease in size as >10 mm decrease from pre-op size and an

increase as >5mm increase from pre-op size, whereas a change in size of 5mm either way was considered a significant increase or decrease in eight studies.[59;61;69;75;82;89;95;96] Overall, an increase in aneurysm size occurred in 4.1% of patients (95% CI 3.0% to 5.2%). Data from 17 case series indicated that overall 7.6% (95% CI 6.6% to 8.5%) of the EVAR population experienced an increase in size of their aneurysm.

Table 19 Change in aneurysm size following EVAR

Author	Number of cases	Changes in aneurysm size n (%)			Follow-up (mean)
		Increase	No change	Decrease	
Cao 2004[18]	506	39 (7.7)	NR	282 (55.7)	NR
Carpenter 2004b[17]	133[d]	2 (1.5)	NR	NR	22
Criado 2003[82]	240	2 (0.8)	NR	NR	13
Elkouri 2004[25]	94	2 (2.1)	28 (29.8)	63 (67)	NR
Greenberg 2004[35]	200	3 (1.5)	NR	NR	NR
Total	**1173**	**48 (4.1)**	**28 (28.9)**	**345 (57.5)**	

[d] n= number of patients who were available for evaluation at 24 months

- **Delayed conversion to open repair**

Any conversion to an open procedure following an initially successful endovascular repair is considered in this section and the results of the studies that reported this outcome are displayed in Tables 20 and 21. From one RCT[45] the delayed conversion rate was 1.9% and from six NRCTs the overall mean delayed conversion rate was 2.7% (95% CI 1.8% to 3.6%).

Table 20 Delayed conversion rates (RCT)

Author	N	Secondary conversions		Follow-up
		n	%	Median (IQR)
Greenhalgh 2005[45]	531	10	1.9	35(23-48)

Table 21 Delayed conversion rates (NRCTs)

Author	N	Secondary conversions		Follow-up
		n	%	Mean (range)
Becquemin 2000[51]	73	3	4.1	7 (0-40)
Cao 2004[18]	534	19	3.6	33 (13-50)
Carpenter 2004b[17]	192	3	1.6	NS
Criado 2003[82]	240	5	2.1	13 (NS)
Greenberg 2004[35]	200	4	2	NS
Hansman 2003[62]	50	1	2	NS
	1289	**35**	**2.7%**	
			(95% CI 1.8% - 3.6%)	

- **Secondary intervention rate**

Any procedure (surgical or radiological) that had been carried out to maintain exclusion of the aneurysm sac from the circulation or to maintain graft patency was counted as a secondary procedure and was included in this outcome analysis. The results of the included studies are shown in Tables 22 and 23, and Figure 2.

From the EVAR 1 trial[45] the secondary intervention rate following EVAR was 16.1% compared to 6.9% following open repair (OR 2.57, 95% CI 1.70 to 3.87; p<0.00001). From the DREAM trial[47] the rate of intervention was almost three times the rate after open repair, (hazard ratio 2.9, 95% CI 1.1 to 6.2; p=0.03). From 11 NRCTs the overall secondary intervention rate following EVAR was 20.2% compared to 6.4% following open repair (OR 3.23, 95% CI 1.94 to 5.37; p<0.00001).

Table 22 Secondary intervention rates for EVAR versus open repair (RCT)

Study ID	EVAR		Open repair		Follow-up, months
	n/N	%	n/N	%	median (IQR)
Greenhalgh 2005[45]	85/529	16.1%	36/519	6.9%	35 (23-48)

Table 23 Secondary intervention rates for EVAR versus open repair (NRCT)

Study ID	EVAR		Open repair		Follow-up, months
	n/N	%	n/N	%	median (IQR)
Arko 2002[83]	30/200	15.0	32/297	10.8	12 (1-60)
Becquemin 2000[51]	16/73	21.9	8/107	7.5	7 (0-40)
Cao 2004[18]	95/534	18.7	17/585	2.9	NS
Carpenter 2004b[17]	29/192	15.1	2/66	15.1	22 (NS)
Criado 2003[82]	9/240	3.8	NS	NS	13 (NS)
Elkouri 2004[25]	20/95	21.1	22/261	3.0	NS
Garcia-Madrid 2004[34]	9/53	17	1/30	3.3	26 (NS)
Greenberg 2004[35]	22/200	11	2/80	2.5	NS
Hansman 2003[62]	6/50	12.0	NS	NS	NS
Moore 2003[65]	212/573	37.0	NS	NS	NS (1-60)
Zeebregts 2004[77]	17/93	18.3	19/194	9.8	19 (NS)

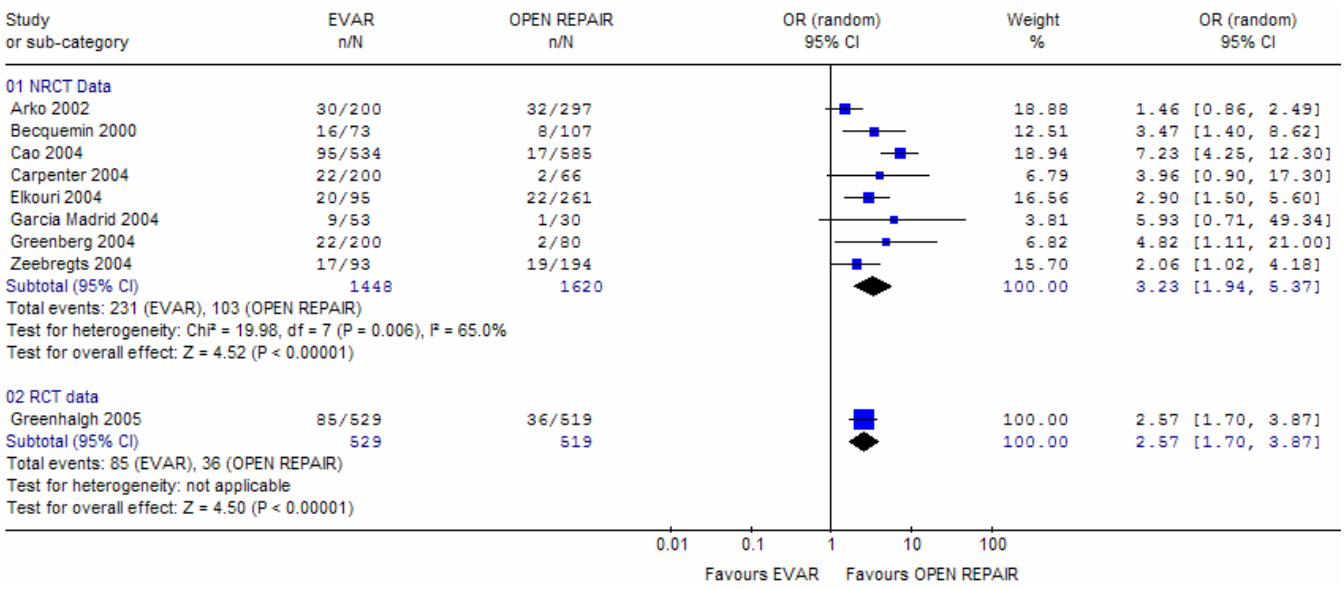


Figure 2 Secondary intervention rates for EVAR versus open repair: Forest plot

5.2 Complications

Safety findings are reported according to whether they were endovascular device-related (technical complications) or not (non-technical complications). As outcomes of interest were not

reported *a priori* in the majority of studies, in some cases it was not clear whether there were no cases of a complication, or whether the authors had chosen not to report this outcome.

5.2.1 Common technical complications

The incidence of the common technical complications is shown in Table 24 and the results are described below by complication.

- **Stent migration**

A total of 5 studies, reported cases of stent-graft migration following EVAR at <1 year and >1 year. Stent-graft migration was defined as >10 mm caudal displacement. At < 1 year the incidence was 1.4%, rising to 2.6% during follow up in the RCT.

- **Stent fracture**

There was no report of this adverse event in the included studies.

- **Stent wire fracture**

Only 2 studies reported on the outcome of stent wire fracture. This adverse event was reported from follow-up plain X-rays or CT scans and occurred with an overall incidence of 3.4% during follow-up periods up to 1 year.

- **Graft-limb thrombosis**

During the first 30-days, this was reported to occur in 6.4% of patients by the DREAM trial.[47] During follow up, incidence rates varied from 0.5% to 11.0% amongst the included studies, but the EVAR trial reported a rate of 2.6%.[45]

- **Graft stenosis**

Three studies reported this outcome. Within the first year, one NRCT[51] reported the rate as 5.5%, but one of the RCT[45] reported a rate of 0.8% during their follow-up period.

- **Type I endoleak**

< 30 days: This adverse event is defined as the occurrence of a type Ia or Ib endoleak in the first 30 days post-EVAR. In five NRCTs,[17;34;51;65;82] the incidence of this adverse event ranged from 0.8% to 11.0% with an overall rate of 4.6%.

1 year: Three NRCTs[17;62;82] reported 8 (2.3%) cases of type I endoleak during the first year with a range of 0% to 4.4%.

Beyond 1 year: Four NRCTs[17;34;65;82] reported 13 (2.4%) cases of type I endoleak during follow-up >1Y with a range of 0% to 4.4%. One RCT[45] reported a rate of 5.5% during follow-up.

- **Type II endoleak**

<30 days: This adverse event is defined as the occurrence of a type II endoleak in the first 30 days post-EVAR. In 5 NRCTs, [17;34;51;65;82] the incidences reported ranged from 8.4%[82] to 31.2%,[65] with an overall mean of 19.6%.

1 year: Three NRCTs[62;65;82] reported incidences with a range of 5.0%[82] to 21.8%[65] with an mean of 12.9% for this adverse event.

Beyond 1 year: There were 3 NRCT[17;34;65] that reported the incidence of type II endoleak beyond 1Y with a mean rate of 11.7%. One RCT[45] reported a rate of 18.9% during follow-up.

- **Type III endoleak**

Two NRCTs[17;34] reported this outcome, with reported incidences of 0% and 11.3%. The rate reported by one RCT[45] was 1.9% during follow-up.

- **Access artery injury:**

One NRCT[65] reported a rate of 12.9% for arterial injury but did not offer any further definitions for the type of injury sustained. In the case series studies, (Table XXX) types of arterial injury were listed as femoral artery damage[53], iliac artery dissection / injury[88], external iliac artery rupture[57], femoral or iliac artery dissection[86], false femoral aneurysm[74], femoral artery pseudoaneurysm / iliac dissection.[87] The overall rate of access artery injury was 1.3% from the case series.

- **Contrast reaction**

There was no report of this adverse event in the included studies.

- **'Overall complication' rate**

This was only reported by the EVAR 1 trial.[45] This trial was the only study to consider majority of the technical complications listed above. By 4 years, the proportion of patients with at least one complication following AAA repair was 41% in the EVAR group and 9% in the open repair group. Overall complication rates were 17.6 per 100 person years in the EVAR group and 3.3 per 100 person years in the open repair group, hazard ratio 4.9 (95% CI 3.5, 6.8), p<0.001.

Table 24 Incidence of common technical complications following EVAR (RCT and NRCT)

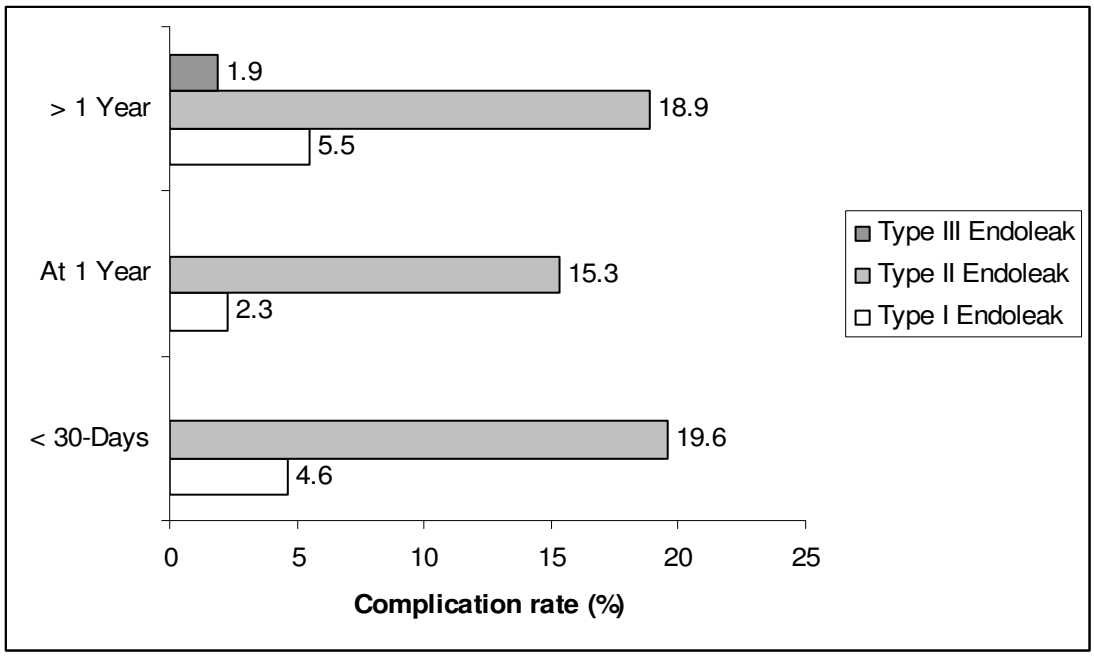
Complication	Author	EVAR n/N	% (95% CI)
Stent migration			
< 1 year	Criado 2003[82]	3/240	1.3%
	Hansman 2003[62]	1/50	2.0%
	Total	**4/290**	**1.4%**
> 1 year	**Greenhalgh 2005[45]**	**14/529**	**2.6%**
	Carpenter 2004b[17]	3/136	2.2%
	Greenberg 2004[35]	4/200	2%
Stent wire fracture	Criado 2003[82]	11/240	4.6%
up to 1 year	Greenberg 2004[35]	4/200	2%
Graft limb thrombosis			
<30 Days	**Prinssen 2004[44]**	**11/171**	**6.4%**

	Moore 2003[a65]	17/573	3.0%
<1 year	Arko 2002[83]	1/200	0.5%
	Becquemin 2000[51]	8/73	11.0%
	Hansman 2003[62]	2/50	4.0%
>1 year	**Greenhalgh 2005[45]**	**14/529**	**2.6%**
	Carpenter 2004b[17]	4/188	2.1%
	Moore 2003[65]	31/573	5.4%
Graft stenosis <1 year	Becquemin 2000[51]	4/73	5.5%
>1 year	**Greenhalgh 2005[45]**	**4/529**	**0.8%**
	Carpenter 2004b[17]	3/188	1.6%
Graft Kinking >1 year	**Greenhalgh 2005[45]**	**9/529**	**1.7%**
Type I endoleak	Becquemin 2000[51]	8/73	11.0%
< 30 days	Carpenter 2004b[17]	1/121	0.8%
	Criado 2003[82]	11/190	5.8%
	Garcia-Madrid 2004[34]	2/53	3.8%
	Moore 2003[65]	12/308	3.9%
up to 1 year	Carpenter 2004b[17]	0/140	0%
	Criado 2003[82]	7/159	4.4%
	Hansman 2003[62]	1/50	2.0%
>1 year	**Greenhalgh 2005[45]**	**29/529**	**5.5%**
	Carpenter 2004b[17]	0/90	0%
	Criado 2003[82]	8/179	4.5%
	Garcia-Madrid 2004[34]	1/53	1.9%
	Moore 2003[65]	4/225	1.8%
Type II endoleak	Becquemin 2000[51]	9/73	12.3%
<30 days	Carpenter 2004b[17]	22/121	18.2%
	Garcia-Madrid 2004[34]	3/53	5.7%
	Criado 2003[82]	16/190	8.4%
	Moore 2003[65]	96/308	31.2%

up to 1 year	Criado 2003[82]	8/159	5.0%
	Hansman 2003[62]	7/50	14.0%
	Moore 2003[65]	57/262	21.8%
>1 year	**Greenhalgh 2005[45]**	**100/529**	**18.9%**
	Carpenter 2004b[17]	3/90	3.3%
	Garcia-Madrid 2004[34]	2/53	3.8%
	Moore 2003[65]	38/225	16.9%
Type III endoleak	**Greenhalgh 2005[45]**	**10/529**	**1.9%**
>1 year	Carpenter 2004b[17]	0/144	0%
	Garcia-Madrid 2004[34]	6/53	11.3%
Access artery injury	Moore 2003[65]	74/573	12.9%

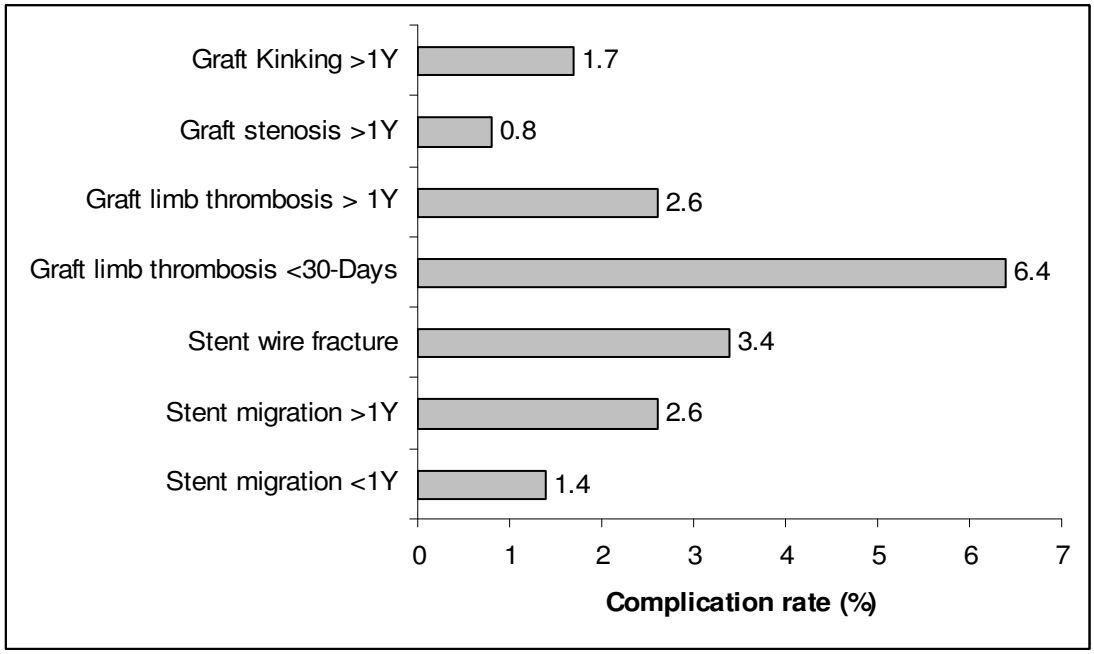
*Results from the RCT trial are stated in bold

Figure 3 Incidence of new or persisting endoleak following EVAR



Results are taken from RCT data where available or from the mean of NRCT if no RCT data available.

Figure 4 Incidence of technical complications - other



5.2.2 Common non-technical complications

The incidence of the non-technical adverse events are displayed in Table 25. Forest plots are available for selected outcomes in Appendix 2.

- **Cardiac event rate (<30 days)**

From the two RCTs[44;58] that reported this outcome, there was an slight reduction in cardiac events following EVAR, but this difference was not significant, (OR 0.81, 95% CI 0.35 to 1.86; p=0.52). From the 16 NRCTs, there was a significant reduction in cardiac event rate following EVAR, (OR 0.43, 95% CI 0.36 to 0.50; p<0.00001).

- **Renal impairment**

Data from the both the RCTs and NRCTs indicated that there was no significant difference in renal impairment between the two groups at 30-days. In addition, one NRCT[35] reported renal impairment rates during follow up of > 1 year and again found no significant difference between EVAR and open repair (OR 0.66, 95% CI 0.15 to 2.82; p=0.57).

- **Graft infection**

From the 2 RCT that reported this outcome, there was no significant difference in graft infection rates between the two groups at either 30-days, or during follow-up.

- **Colonic ischaemia**

From both the RCT and NRCT data, there was no significant difference in the rates of graft infection post either procedure.

- **Lower limb ischaemia:**

This outcome included cases of lower limb ischaemia in the perioperative (<30 day) period only. The incidence of this outcome was reported to vary between 0% and 4.2% following EVAR and 0.9% and 4.0% following open repair. There was no significant difference between EVAR and open repair (OR 0.88, 95% CI 0.47 to 1.64; p=0.69).

- **Pulmonary complications**

From the DREAM trial there was a significant reduction in pulmonary complications following EVAR compared to open repair, (OR 0.25, 95% CI 0.09 to 0.69; p=0.006).

A meta-analysis of the NRCT results also demonstrated a significant reduction in pulmonary complications following EVAR, (OR 0.19, 95% CI 0.14 to 0.24), p<0.00001).

- **Haemorrhage**

From the DREAM trial, there was a non significant reduction in the incidence of haemorrhage following EVAR, (OR 0.5, 95% CI 0.12 to 2.03; p=0.33).

However, a meta-analysis of the NRCT studies demonstrated a significant reduction in haemorrhage following EVAR, (OR 0.24, 95% CI 0.14 to 0.40; p<0.00001).

- **Local wound complications:**

All local wound complications were considered in this section and included haematoma formation, wound infection, lymph leak / lymphocoele, femoral nerve damage. A meta-analysis

of the nine NRCTs that reported this event demonstrated a slightly higher rate of complications after EVAR, but this did not reach a level of significance (OR 1.34, 95% CI 0.96 to 1.88; p=0.08).

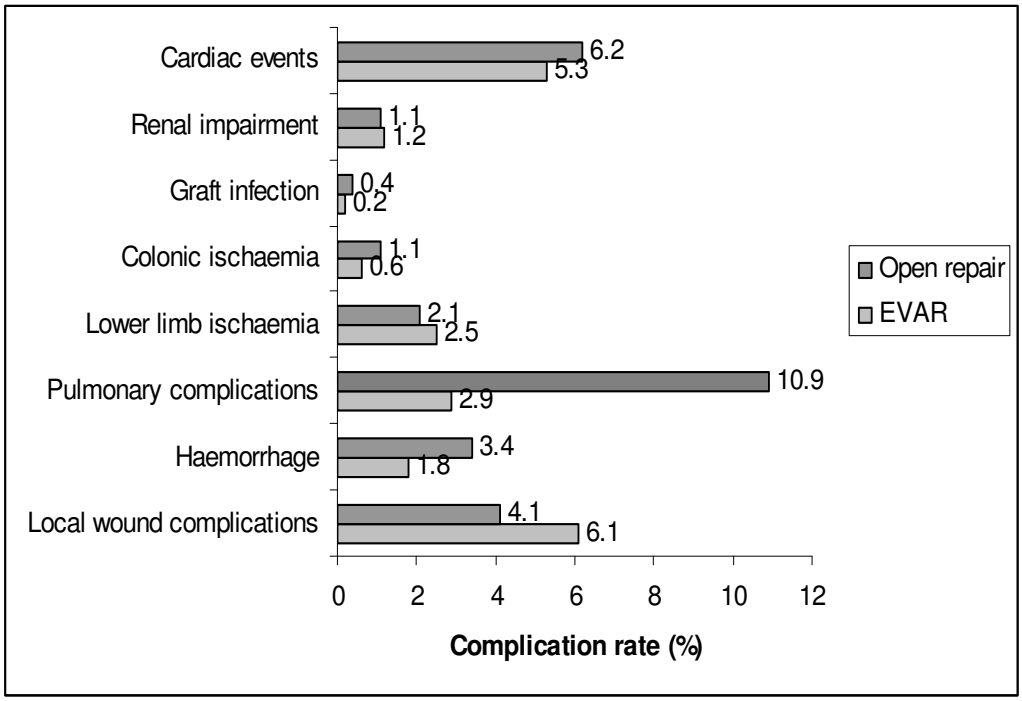
Table 25 Common non-technical complications for EVAR versus open repair

Study ID	EVAR		Open repair		P
	n/N	%	n/N	%	
Cardiac event rate (<30 days)					
Cuypers 2001[58]	**3/57**	**5.3%**	**2/19**	**10.5%**	
Prinssen 2004[44]	**9/171**	**5.3%**	**10/174**	**5.7%**	
Anderson 2003[50]	52/1706	3.0%	230/3063	7.5%	
Arko 2002[83]	10/200	5.0%	15/297	5.1%	
Becquemin 2000[51]	2/73	2.7%	7/107	6.5%	
Bertrand 2001[52]	26/193	13.5%	41/193	21.2%	
Bolke 2001[54]	1/20	5.0%	5/20	25.0%	
Cao 2004[18]	9/534	1.7%	25/585	4.3%	
Carpenter 2004b[17]	2/192	1.0%	5/66	7.6%	
Criado 2003[82]	3/240	1.3%	4/126	3.2%	
Elkouri 2004[25]	10/94	10.6%	57/261	21.8%	
Garcia-Madrid 2004[34]	2/53	3.8%	1/30	3.3%	
Greenberg 2004[35]	6/200	3.0%	9/80	11.3%	
Hansman 2003[62]	1/50	2.0%	1/50	2.0%	
Jordan 2004[36]	8/259	3.1%	9/145	6.2%	
Lee 2004[43]	77/2565	3.0%	320/4607	6.9%	
Moore 2003[65]	56/573	9.8%	23/111	20.7%	<0.01
Zeebregts 2004[77]	4/93	4.3%	12/194	6.2%	
Renal impairment (<30 days)					
Prinssen 2004[44]	**2/171**	**1.2%**	**2/174**	**1.1%**	
Arko 2002[83]	1/200	0.5%	1/297	0.3%	
Becquemin 2000[51]	3/73	4.1%	3/107	2.8%	
Bertrand 2001[52]	10/193	5.2%	21/193	10.9%	<0.02
Bolke 2001[54]	3/20	15.0%	4/20	20.0%	
Cao 2004[18]	6/534	1.1%	4/585	0.7%	
Criado 2003[82]	3/240	1.3%	4/126	3.2%	
Elkouri 2004[25]	4/94	4.3%	11/261	4.2%	
Greenberg 2004[35]	5/200	2.5%	9/80	11.3%	
Moore 2003[65]	31/573	5.4%	2/111	1.8%	
Renal impairment (>1 year)					
Greenberg 2004[35]	5/200	2.5%	3/80	3.8%	

Graft infection (< 30 days)					
Prinssen 2004[44]	**1/171**	**0.6%**	**2/174**	**1.1%**	
Graft infection (>1 year)					
Greenhalgh 2005[45]	**1/529**	**0.2%**	**2/519**	**0.4%**	
Colonic ischaemia (<30 days)					
Prinssen 2004[44]	**1/171**	**0.6%**	**2/174**	**1.1%**	
Cao 2004[18]	3/534	0.6%	2/585	0.3%	
Hansman 2003[62]	1/50	2.0%	0/50	0.0%	
Lower limb ischaemia (<30 days)					
Arko 2002[83]	2/200	1.0%	5/297	1.7%	
Cao 2004[18]	8/534	1.5%	14/585	2.4%	
Hansman 2003[62]	0/50	0.0%	2/50	4.0%	
Moore 2003[65]	24/573	4.2%	1/111	0.9%	
Pulmonary complications (<30 days)					
Prinssen 2004[44]	**5/171**	**2.9%**	**19/174**	**10.9%**	
Anderson 2003[50]	33/1706	1.9%	235/3063	7.7%	
Arko 2002[83]	0/200	0.0%	6/297	2.0%	
Becquemin 2000[51]	3/73	4.1%	14/107	13.1%	<0.05
Bertrand 2001[52]	10/193	5.2%	52/193	26.9%	<0.001
Bolke 2001[54]	2/20	10.0%	4/20	20.0%	
Cao 2004[18]	2/534	0.4%	27/585	4.6%	
Carpenter 2004b[17]	4/192	2.1%	5/66	6.1%	
Criado 2003[82]	2/240	0.8%	5/126	4.0%	
Elkouri 2004[25]	3/94	3.2%	42/261	16.1%	
Greenberg 2004[35]	2/200	1.0%	13/80	16.3%	
Hansman 2003[62]	1/50	2.0%	5/50	10.0%	
Jordan 2004[36]	2/259	0.8%	9/145	6.2%	
Moore 2003[65]	30/573	5.2%	25/111	22.5%	<0.01
Zeebregts 2004[77]	2/93	2.2%	42/194	21.6%	
Haemorrhage (<30 days)					
Prinssen 2004[44]	**3/171**	**1.8%**	**6/174**	**3.4%**	
Anderson 2003[50]	54/1706	3.2%	321/3063	10.5%	<0.001
Criado 2003[82]	67/240	27.9%	92/126	73.0%	<0.001
Moore 2003[65]	105/573	18.3%	40/111	36.0%	<0.01
Zeebregts 2004[77]	0/93	0%	23/194	11.9%	
Local wound complications (<30 days)					
Becquemin 2000[51]	1/73	1.4%	2/107	1.9%	

Bertrand 2001[52]	13/193	6.7%	14/193	7.3%	
Cao 2004[18]	13/534	2.4%	11/585	1.9%	
Criado 2003[22]	7/240	2.9%	6/126	4.8%	
Elkouri 2004[25]	6/94	6.4%	15/261	5.7%	
Hansman 2003[62]	3/50	6.0%	5/50	10.0%	
Jordan 2004[36]	6/259	2.3%	1/145	0.7%	
Moore 2003[65]	69/573	12.0%	4/111	3.6%	<0.05
Zeebregts 2004[77]	10/93	10.8%	14/194	7.2%	

Figure 5 Incidence of common non-technical complications: EVAR versus surgery



5.3 Other peri- and post-operative outcomes

5.3.1 Deployment success rate

The success of endograft deployment was documented in 7 studies (see Tables 26 and 27). Success is defined as accurate placement of the graft in the correct position without the need for surgical intervention / open conversion. The only RCT to report this outcome reported a rate of 97%.[45] In six NRCTs, the deployment success rate ranged from 93%[82] to 100%,[35] and overall averaged 96%, (95% CI 95.3% to 97.3%).

Table 26 Successful endograft deployment rate (RCT)

Author	Number of patients (n)		Deployment success rate (%)
	Undergoing EVAR	Successful deployment	
Greenhalgh 2005[45]	543	529	97%

Table 27 Successful endograft deployment rate (NRCT)

Author	Number of patients (n)		
	Undergoing EVAR	Successful deployment	% (95% CI)
Carpenter 2004b[17]	192	188	98
Criado 2003[82]	240	237	99
Elkouri 2004[25]	94	93	99
Greenberg 2004[35]	200	199	100
Moore 2003[65]	573	531	93
Zeebregts 2004[77]	93	92	99
	1392	**1340**	**96% (95.3% - 97.3%)**

5.3.2 Technical success rate

- **Primary technical success rate**

The primary technical success rate was reported in 3 of the NRCTs and not by any of the RCTs (see Table 28). Studies included in this section had reported success based either on completion angiograms or on pre-discharge angiograms. Primary technical success was defined as successful placement of the endoluminal-stent with complete exclusion of the aneurysm from the circulation. Where no definition was stated or where an alternative definition was used, there was sufficient data to determine the primary technical success rate as defined at the start of this section.

The success rate averaged 74% (95% CI 69.3%, 78%). This success rate was lower than that reported by the case series (83%) because of the variability in definition of this outcome.

Table 28 Primary technical success rate

Author	Number of patients (n)		Technical success rate
	Undergoing EVAR	Technical success	(%, 95% CI))
Criado 2003[82]	240	168	70
Garcia-Madrid 2004[34]	53	48	91
Elkouri 2004[25]	94	69	73
Total	**387**	**285**	**74% (69.3% – 78%)**

2.2.2 Thirty day technical success

The thirty day technical success rates are displayed in Table 29. This was defined as successful graft placement resulting in complete aneurysm exclusion, with or without prior secondary intervention. The success rate averaged 87% (95% CI 84.4% to 88.7%). This result was similar to that indicated by data from 10 case series, 90% (95% CI 88.4% to 90.7%).

Table 29 Thirty day technical success

Author	Number of patients (n)		Technical success rate
	Undergoing EVAR	Technical success	(%, 95% CI))
Becquemin 2000[51]	73	56	77
Cao 2004[18]	534	479	90
Criado 2003[82]	190	163	86
Greenberg 2004[35]	200	165	83
Total	**997**	**863**	**87% (84.4% – 88.7%)**

- **Blood loss**

The results of blood loss following EVAR or open repair are displayed in Tables 30 and 31. Forest plots are available in Appendix 2.

Blood loss was reported by one RCT.[44] The median blood loss was 250 ml following EVAR and 1500 ml following open repair (WMD -1260 ml, 95% CI -1420 to -1099; p<0.00001). Data from six NRCT (see Table 31) also indicated that there was a significant reduction in blood loss following EVAR (WMD -967 ml, 95% CI -1401.58 to -534.01; p<0.00001).

Table 30 Procedural blood loss (RCT)

Author	Number of participants	Blood loss in ml Median (IQR)	WMD (CI)
Prinssen 2004[44]			
EVAR	171	250 (100-500)	-1260 (-1420 to -1099)
Open	174	1500 (900-2100)	

Table 31 Procedural blood loss (NRCT)

Author	Number of participants		Blood loss (ml) EVAR Mean (SD)	Blood loss (ml) Open repair Mean (SD)
	EVAR	OPEN		
Bertrand 2001[52]	193	193	650 (1100)	1800 (1600)
Carpenter 2004b[17]	192	66	341	1583
Criado 2003[82]	240	126	345.5 (337.2)	1541.6 (1218.5)
Hansman 2003[62]	50	50	451 (363)	783 (514)
Moore 2003[65]	573	101	400	800
Cao 2004[18]	534	585	200 (100-300)	1400 (1000-2100)

[b]Values are median and IQR

- **Length of ITU stay**

The results of length of stay on ITU, where reported, are displayed in Tables 32 and 33.

From three RCTs (see Table 32), there was a significant reduction in ITU stay post EVAR compared to open repair (WMD -1.50 days, 95% CI -2.29 to -1.11; p<00001). From eight NRCTs (see Table 33) there was also a significant reduction in ITU stay post EVAR compared to open repair (WMD -0.89 days, 95% CI -1.45 to -0.33; p=0.002).

Table 32 Length of ITU stay (RCT)

Author	Number of participants		ITU stay, days Mean (SD)	
	EVAR	Open repair	EVAR	Open repair
Cuypers 2001[58]	57	19	0.8 (0.84)[a]	0.9 (3.58)[a]
Greenhalgh 2005[45]	543	539	0.7 (3.8)	2.4 (5.9)
Prinssen 2004[44]	171	174	1.5 (0.61)	3 (0.80)

[a]Value is median

Table 33 Length of ITU stay (NRCT)

Author	Number of participants		ITU stay days Mean (SD)	
	EVAR	Open repair	EVAR	Open repair
Bertrand 2001[52]	193	193	0.9 (1.46)	1.1 (1.47)
Bolke 2001[54]	20	20	1.2[b]	3.4
Carpenter 2004b[17]	192	66	0.78	4.1
Criado 2003[82]	240	126	0.6[b] (8.67)	2.3 (4.25)
Elkouri 2004[25]	94	261	1 (3.75)	2 (22.25)
Garcia-Madrid 2004[34]	53	30	0.1 (0.06)	1 (0.96)
Hansman 2003[62]	50	50	0.0 (0.3)	1.2 (0.5)
Moore 2003[65]	573	101	1.0[a]	1.1

[a]Median

[b] Statistically significant difference

[c] Calculation excludes medians

- **Length of hospital stay**

The results of length of hospital stay are displayed in Tables 34 and 35. All three of the RCTs reported a significant reduction in length of hospital stay following EVAR compared to open repair (WMD -6.76 days, 95% CI -7.53 to -5.99; p<0.00001). From a meta-analysis of 13 NRCTs, there was also a significant reduction in total hospital stay in the EVAR group compared to the open repair group (WMD -4.65 days, 95% CI -5.27 to -4.04; p<0.00001).

Table 34 Length of hospital stay (RCT)

Author	Number of participants		Hospital stay, days Mean (SD)		P
	EVAR	Open	EVAR	Open	
Cuypers 2001[58]	57	19	5 (2-21)[a]	11 (8-50)[a]	p<0.01
Greenhalgh 2005[45]	531	516	10.3 (17.8)	15.7 (16.9)	<0.00001
Prinssen 2004[44]	171	174	6 (3-6)[b]	13 (8-15)[b]	p<0.01

[a] Median and range

[b] IQR

Table 35 Length of hospital stay (NRCT)

Author	Number of participants		Mean length stay, days Mean (SD)		P
	EVAR	Open	EVAR	Open	
Anderson 2003[c50]	1706	3063	4	10	p<0.001
Arko 2002[83]	200	297	2.8 (2.8)	8.3 (4.5)	
Becquemin 2000[51]	73	107	7 (2)	13 (7)	p<0.01
Bertrand 2001[52]	193	193	10 (6)	14 (11)	p<0.01
Bolke 2001[54]	20	20	10	14	p<0.01
Cao 2004[18]	534	585	2 (2-3)[a]	6 (5-7)[a]	
Carpenter 2004b[17]	192	66	3	10	
Hansman 2003[62]	50	50	2.3 (1.9)	5.9 (2.2)	p<0.0001
Garcia-Madrid 2004[34]	53	30	2 (2-2)[a]	6 (5-7)[a]	
Jordan 2004[36]	259	145	4	12	
Lee 2004[43]	4607	2565	3.6 (5.9)	8.8 (7.8)	
Moore 2003[65]	564	108	2	6	p<0.0001
Zeebregts 2004[77]	93	81	9.2 (14)	19.2 (18.2)	

[a]Median and IQR

6 EVAR IN HIGH RISK PATIENTS

6.1 Overview of the trial

The EVAR 2 trial[46] was designed to assess whether EVAR would have an impact on survival in a group of patients deemed unfit for open repair. Therefore, 338 patients were entered into the trial, with 166 participants randomised to EVAR, and 172 to no intervention. However, in the EVAR arm of the trial, 14 patients died before surgery, 1 patient refused, 1 patient was unsuitable for EVAR and 4 patients underwent open repair, leaving 146 patients undergoing EVAR. In the no intervention arm of the trial, 47 of the 172 patients underwent AAA repair (35 by EVAR and 12 by open repair). The results provided below are, therefore displayed by intention to treat where available, but otherwise are stated as by intervention received (per protocol), depending upon what information was provided in the actual paper.

6.2 Major outcomes

6.2.1 Mortality

- **30-day mortality**

Using an intention to treat analysis, the 30-day mortality rate was 8.7% (13/150), but if only elective procedures are taken into account, the operative mortality reduced to 6.8% (10/147). Based upon analysis by intervention received, the 30 day mortality rate was 7.9% (14/178).

- **Mortality AAA related**

Aneurysm-related death based upon all-cause mortality by randomised group, was found to be 12% (20/166) in the EVAR group and 12.8% (22/172) in the no-intervention group, (adjusted hazard ratio 1.00, 95% CI 0.54 to 1.84). The authors undertook a *post hoc* analysis, dividing follow-up into the first 6 months after randomisation and the period after 6 months. The hazard ratios for AAA related mortality comparing EVAR and non intervention groups were 1.67 (95% CI 0.72 to 3.86) for the first 6 months and 0.53 (95% CI 0.20 to 1.39) for the period after 6 months.

- **All-cause mortality**

The total mortality rates were 44.6% (74/166) for the EVAR group and 39.5% (68/172) for the no-intervention group during the follow-up period. The difference was not statistically significant.

6.2.2 Aneurysm rupture

Based upon an intention to treat analysis, there was a 3.6% rupture rate pre-EVAR, the median time from randomisation to aneurysm exclusion was 163 days (IQR 78-477). In the perioperative period (<30 days), there was a 2.0% rupture rate and post-EVAR, there were no documented aneurysm ruptures. In the no-intervention group there were 21 ruptures in 172 participants giving a rupture rate of 12.2%. Results are shown in Table 36.

Table 36 Aneurysm rupture rates for EVAR verses no intervention

Time period	EVAR		No intervention	
	n/N	%	n/N	%
Pre-operation	6/166	3.6	21/172	12.2
<30-days post op[a]	3/150	2.0	-	-
<30-days post op[b]	1/178	0.6	0/47	0
>30-days post op	0/137	0	-	-

[a] intention to treat analysis

[b] analysis by treatment received

6.2.3 Conversion to open repair

Based upon analysis by treatment received, during the primary procedure there was just one primary conversion giving a primary conversion rate of 0.6% (1/178). During follow-up there were 2 further conversions equating to a delayed conversion rate of 1.2% (2/178).

6.2.4 Secondary re-intervention rate

According to the paper, the overall intention rate was 11.5 per 100 person years in the EVAR group and 1.8 per 100 person years in the no intervention group. At 4 years 26% of the EVAR group had required at least one intervention compared to only 4% in the no intervention group, (hazard ratio 5.8, 95% CI 2.4 to 14.0; p<0.001). However if the significant number of crossovers are considered as secondary interventions in the no-intervention group then the secondary intervention rate in this group becomes considerably greater, (approximately 30%).

6.3 Technical complications

The incidence of technical complications associated with EVAR are displayed in Table 37.

Table 37 Incidence of common technical complications in EVAR

Complication	Number of participants	Number of cases	%
Graft infection	178	1	0.6%
Stent migration	178	2	1.1%
Type I endoleak	178	11	6.2%
Type II endoleak	178	23	12.9%
Type III endoleak	178	6	3.4%
Graft thrombosis	178	8	4.5%
Graft stenosis	178	0	0%

Analysis by intention to treat revealed that 58/178 patients developed a complication following an initially successful EVAR equating to a total complication rate of 32.6% in this group during follow-up.

6.4 Other peri- and postoperative outcomes

6.4.1 Deployment success rate

From analysis by intention to treat, successful endograft deployment occurred in 89% (143/160) of participants. Analysis by treatment received (per protocol) gives a success rate of 97% (176/181).

6.4.2 Length of Hospital stay

The mean length of hospital stay was 12 days (versus 10 days in fit patients in EVAR group of EVAR 1 trial).

7 EVAR DATA FROM NON-CONTROLLED STUDIES

7.1 Overview of the efficacy findings from non-controlled studies (Case series and comparative studies)

7.1.1 Deployment success rate

The results from the case series are displayed in Table 38. The results were similar to the controlled studies with a success rate of 98%, (95% CI 97.6% to 98.3%)

Table 38 Successful endograft deployment rate

Author	Number of patients (n)		Deployment success
	Undergoing EVAR	Successful deployment	rate %, (95% CI)
AbuRahma 2004[28]	151	148	98
Allaqaband 2004[21]	60	59	98
Alric 2002[49]	88	86	98
Carpenter 2004a[56]	227	224	99
Cartes 2002[57]	72	71	99
Criado 2001[81]	471	456	93
Dalainas 2004[31]	186	182	98
Elkouri 2003[75]	100	97	97
Espinosa 2004[32]	193	191	99
Howell 2000[86]	215	214	100
Howell 2000[87]	*56*[a]	*56*	*100*
Lee 2002[88]	150	148	99
May 2000[64]	266	249	94
Minor 2004[39]	150	145	97
Nolthenius 2001[66]	77	74	96
Ramaiah 2002[90]	230	230	100
Vallabhaneni 2001[80]	2862	2812	98
Zarins 2000[93]	149	147	99
Total	**5647**	**5533**	**98% (97.6% - 98.3%)**

[a] n=56 patients who received an AneuRx stent

7.1.2 Technical success rate

- **Primary technical success rate**

Correct stent placement and complete aneurysm exclusion at completion or discharge angiogram was the definition in the majority of the studies.[53;57;81;82;93] No definition was provided by 4 studies.[56;61;80;86;87] Four studies stated an alternative definition of technical

success. Successful endograft deployment was used by Lee 2002.[88;89] Successful endograft deployment without the need for surgical conversion or death; lack of a persistent (>48 hours) type I or type III endoleak; and a patent graft was used by Okhi 2001.[67] The definition used by Ramaiah 2002[90] was that defined by the Society for Vascular Surgery / International Society for Cardiovascular reporting standards. The success rate averaged 83%, (95% CI 81.7% to 83.5%).

Table 39 Primary technical success rate

Author	Number of patients (n)		Technical success rate (%, 95% CI)
	Undergoing EVAR	Technical success	
AbuRahma 2004[28]	151	130	86
Blum 2001[53]	298	269	90
Boult 2004[29]	950	853	90
Carpenter 2004a[56;56]	227	183	81
Cartes 2002[57]	72	57	79
Criado 2001[81]	471	383	81
Fairman 2004[33]	*109*	*61*	*56*
Espinosa 2004[32]	193	178	92
Gilling-Smith 2000[61]	55	44	80
Hinchliffe 2004[20]	269	240	89
Howell 2000[86]	215	132	61
Howell 2000[87]	*89*	*57*	*64*
Lee 2002[88]	150	93	62
Lee 2000[89]	*67*	*36*	*54*
Kocher 2004[37]	120	109	91
Ohki 2001[67]	239	212	89
Ramaiah 2002[90]	260	220	85
Vallabhaneni 2001[80]	2862	2322	81
Zarins 2000[93]	149	94	63
Total	**6681**	**5519**	**83% (81.7% – 83.5%)**

- **Thirty day technical success**

The results of the 10 included case series are displayed in Table 40. The success rate was 90% (95% CI 88.4% to 90.7%).

Table 40 Thirty day technical success

Author	Number of patients (n)		Technical success rate,
	Undergoing EVAR	Technical success	% (95% CI)
Biebl 2004[23]	182	158	87
Boult 2004[29]	950	825	87
Carpenter 2004a[56]	205	179	87
Cartes 2002[57]	71	62	87
Criado 2001[81]	355[a]	342	96
Elkouri 2003[75]	100	86	86
Howell 2000[86]	215	200	93
Howell 2000[87]	*56[b]*	*53*	*95*
Lee 2000[89]	67	52	78
Ramaiah 2002[90]	260	260	100
Zarins 2000[93]	147	121	82
Total	**2552**	**2285**	**90% (88.4% - 90.7%)**

a n=355 patients who were available for evaluation

b n=56 patients who received an AneuRx stent

7.1.3 Aneurysm rupture following EVAR

There were 23 case series that had reported the delayed AAA rupture rate following over a mean of 18 months follow up, Table 28. Overall the mean rupture rate was 0.6% (95% CI 0.4%, 0.8%).

Table 41 Delayed aneurysm rupture rates following EVAR

Author	Number of patients		Rupture Rate, %	Follow-up (months)	
	Undergoing EVAR	With rupture	(95% CI)	Mean	Range
Alric 2002[49]	88	2	2.2	21	6-68
Biebl 2004[23]	182	0	0	16	0-43
Blum 2001[53]	298	4	1.3	35	2-50
Burks 2002[55]	95	0	0	25	6-44
Cartes 2002[57]	72	0	0	22	1-46
Corriere 2004[24]	220	0	0	NR	Not reported
Elkouri 2003[75]	100	1	1	7	1-60
Faries 2002[59]	74	0	0	13	6-48
Flora 2003[60]	108	0	0	20	Not reported
Gilling-Smith 2000[61]	55	1	1.8	18	3-36
Hinchliffe 2004[20]	255	2	0.8	12	Not reported

Howell 2000[86]	215	0	0	14	Not reported
Howell 2000[87]	*89*	*0*	*0*	*13*	*1-18*
Cho 2004[30]	45	0	0	34	Not reported
Laheij 2002[79]	2863	16	0.6	NR	Not reported
Lee 2000[89]	*67*	*0*	*0*	*18*	*Not reported*
Lee 2002[88]	150	0	0	1	Not reported
Nolthenius 2001[66]	77	0	0	12	>12 months
Ohki 2001[67]	239	2	0.8	16	<75 months
Ouriel 2003[68]	704	3	0.4	NR	Not reported
Parlani 2002[70]	336	2	0.6	14	1-46
Ramaiah 2002[90]	230	0	0	NR	Not reported
Verhoeven 2004[42]	306	1	0.3	36	Not reported
Zarins 2000[93]	149	1	0.7	12	1-39
Zarins 2003[95]	*383*	*3*	*0.8*	*36*	*Not reported*
Zarins 2003[94]	1193	15	1.3	NR	<48
Total	**8054**	**50**	**0.6 (0.4%-0.8%)**	**18**	**-**

NR – Not reported

Seven studies reported the early AAA rupture rate with a mean of 0.3%, (95% CI 0.2%, 0.5%).

Table 42 Early (<30 days) aneurysm rupture rates following EVAR

Author	Number of patients		Rupture Rate, %
	Undergoing EVAR	With rupture	(95%CI)
Albertini 2001[48]	185	3	1.6
Blum 2001[53]	298	1	0.3
Carpenter 2004a[56]	227	2	0.9
Ouriel 2003[68]	704	1	0.1
Ricco 2003[74]	1012	2	0.1
Zannetti 2001[71]	240	1	0.4
Zarins 2003[94]	1193	3	0.3
Total	**3859**	**13**	**0.3 (0.2%-0.5%)**

NR – Not reported

7.1.4 Changes in aneurysm size

From the 17 case series, 7.6% (95% CI 6.6, 8.5%) of the EVAR population increased in size (Table 43).

Table 43 Changes in aneurysm size following EVAR

Author	Number of cases	Changes in aneurysm size n (%)			Follow-up (mean)
		Increase	No change	Decrease	
Allaqaband 2004[21]	60	0 (0)	NR	NR	14
Arko 2003[84]	206	11 (5.3)	25 (12)	170 (82.5)	32
Biebl 2004[23]	182	5 (2.7)	NR	NR	16
Carpenter 2004a[56]	48[b]	4 (8)[a]	28 (58)	16 (33)	11
Cartes 2002[57]	72	0 (0)[a]	NR	NR	22
Elkouri 2003[75]	*97*	*2 (0.2)*	*32 (33)*	*63 (65)*	*7*
Fairman 2004[33]	*16*	*4 (25)*	*NR*	*NR*	*21*
Faries 2002[59]	65	8 (12.3)	NR	NR	13
Faries 2003[96]	70	3 (4.2)	27 (38.5)	40 (57.1)	25
Gilling-Smith 2000[61]	55	15 (27)	18 (33)	22 (40)	18
Haulon 2003[63]	96	1 (1)[a]	48 (50)	47 (49)	27
Howell 2000[86]	84	2 (0.9)[a]	59 (27)	23 (11)	14
Cho 2004[30]	45	7 (15)	4 (9)	8 (18)	34
Kocher 2004[37]	120	7 (5.8)	NR	NR	21
Lee 2000[89]	67	8 (12)	NR	NR	18
Minor 2004[39]	140	6 (4.3)	NR	NR	17
Ouriel 2003[69]	700	70 (10)	419 (60)	211 (30)	12
Parlani 2002[70]	326[c]	21 (6.4)[a]	182 (56)	127 (39)	14
Zarins 2003[95]	383	46 (12)	138 (36)	199 (52)	36
Total	**2832**	**214 (7.6)**	**948 (33.5)**	**863 (30.5)**	**20**

[a] No definition provided

[b] n=48 patients who were available for evaluation at 12 months

[c] n=326 patients with a successfully implanted stent-graft

NR – Not reported

7.1.5 Primary conversion rate

This was reported by 30 studies, (Table 44). The largest single publication is a multicentre study from the EUROSTAR database[80] that reported a primary conversion rate of 1.6%. Overall the mean conversion rate was 1.2% (95% CI 1.0%, 1.4%).

Table 44 Primary conversion rates

Author	Total number of EVAR	Primary conversion	
		Number of patients	Rate, % (95% CI)
Allaqaband 2004[21]	60	1	1.7
Albertini 2001[48]	185	2	1.1
Alric 2002[49]	88	1	1.1
Ayerdi 2003[85]	96	0	0
Blum 2001[53]	298	5	0.8
Boult 2004[29]	950	9	0.9
Carpenter 2004a[56]	227	3	1.3
Dalainas 2004[31]	186	4	2.2
Elkouri 2003[75]	*100*	*3*	*3*
Espinosa 2004[32]	193	1	0.5
Fairman 2004[33]	237	0	0
Flora 2003[a60]	108	11	10
Early group	26	7	27
Late group	82	4	4.5
Hinchliffe 2004[20]	269	0	0
Howell 2000[86]	215	0	0
Howell 2000[87]	*89*	*0*	*0*
Cho 2004[30]	50	1	2
Kocher 2004[37]	120	2	1.7
Lee 2002[88]	150	2	1.3
Maldonado 2004[19]	311	6	1.9
May 2002[64]	266	17	6.4
Minor 2004[39]	150	3	2.0
Nolthenius 2001[66]	77	2	2.6
Ouriel 2003[69]	700	3	0.4
Parlani 2002[70]	336	6	1.8
Ramaiah 2002[90]	260	0	0
Resch 2001[72]	164	8	4.9
Early group	90 [a]	8	8.9
Late group	68 [a]	0	0
Ricco 2003[74]	1012	11	1.1
Shames 2003[a91]	245	7	2.9
Males	203	1	0.5
Females	42	6	14
Vallabhaneni 2001[80]	2862	47	1.6
Zannetti 2001[71]	*266*	*6*	*2.3*

Verhoeven 2004[42]	308	1	0.3
Zarins 2000[93]	149	2	1.3
Zarins 2003[94]	1193	11	0.9
Total	**13806**	**166**	**1.2 (1.0% - 1.4%)**

[a] Data extracted from Resch 2001[73]

7.1.6 Delayed conversion rate

The results of the 28 case series are displayed in Table 45. The overall mean was 2.0% (95% CI 1.7%, 2.3%). The single largest study from the EUROSTAR database[80] reported a rate of 1.4%. The study with the longest follow-up,[72] which stated a period of 39 months, reported a delayed conversion rate of 9.1%.

Table 45 Delayed conversion rates

Author	Total number of EVAR	Secondary conversions		Follow-up	
		Number	%, (95% CI)	Mean	Range
Allaqaband 2004[21]	60	0	0	14	Not reported
Alric 2002[49]	88	3	3.4	21	6-68
Arko 2003[84]	206	3	1.5	32	3-55
Ayerdi 2003[85]	96	0	0	12	Not reported
Becquemin 2004[27]	250	11	4.4	28	Not reported
Biebl 2004[23]	182	3	1.6	Not reported	0-43
Blum 2001[53]	298	8	2.7	35	2-50
Parlani 2002[70]	*336*	*4*	*1.2*	*14*	*1-46*
Carpenter 2004a[56]	227	2	0.9	11	0-41
Dalainas 2004[31]	186	1	0.5	26	9-60
Elkouri 2003[75]	100	1	1	7	1-60
Fairman 2004[33]	237	6	2.5	21	Not reported
Faries 2002[59]	65	2	3.1	13	6-48
Flora 2003[60]	108	3	2.8	20	Not reported
Gilling-Smith 2000[61]	55	1	1.8	18	3-36
Howell 2000[87]	*89*	*2*	*2.2*	*13*	*1-18*
Howell 2000[86]	215	4	1.9	14	Not reported
Cho 2004[30]	50	1	2	34	Not reported
Jordan 2004[36]	259	4	1.5	28	Not reported
Lee 2000[89]	67	1	1.5	18	Not reported
Minor 2004[39]	150	1	0.7	17	1-61
Moore 2003[65]	573	2	0.3	Not reported	1-60

Ohki 2001[67]	239	5	2.1	16	<75 months
Ouriel 2003[69]	700	29	4.1	12	Not reported
Resch 2001[72]	164	15	9.1	39	Not reported
Resch 2001[73]	*158*	*15*	*9.4*	*20*	*10-36*
Ricco 2003[74]	1012	4	0.4	11	Not reported
Vallabhaneni 2001[80]	2862	41	1.4	12	0-72
Verhoeven 2004[42]	308	9	2.9	36	Not reported
Zarins 2000[93]	149	1	0.7	12	1-39
Zarins 2003[95]	*383*	*18*	*4.7*	*36*	*Not reported*
Zarins 2003[94]	1193	42	3.5	Not reported	Not reported
Total	**10099**	**203**	**2.0 (1.7% - 2.3%)**	**21**	

7.1.7 Secondary intervention rate

Overall the mean secondary intervention rate from the 32 included case series was 17.5 (95% CI 16.8%, 18.2%). Again, the largest single publication was from the EUROSTAR registry (Lahej 2002[79]), which reported a secondary intervention rate of 14%. The highest secondary intervention rate of 55% was documented from the study with the longest recorded follow-up with a mean of 39 months (Resch 2001[72]).

Table 46 Secondary intervention rates

Author	Total number of EVAR	Secondary interventions		Follow-up	
		Number	% (95% CI)	Mean	Range
Alric 2002[49]	88	6	6.8	21	6-68
Arko 2003[84]	*206*	*19*	*9.2*	*32*	*3-55*
Ayerdi 2003[85]	96	10	10.4	12	Not reported
Becquemin 2004	250	112	44.8	28	Not reported
Biebl 2004[23]	182	27	14.8	16	0-43
Blum 2001[53]	298	24	8.1	35	2-50
Bould 2004	950	23	2.4	Not reported	Not reported
Parlani 2002[70]	*336*	*19*	*5.7*	*14*	*1-46*
Carpenter 2004a[56]	227	17	7.5	11	0-41
Cartes 2002[57]	72	10	13.9	22	1-46
Dalainas 2004[31]	186	19	10.2	26	9-60
Faries 2002[59]	65	17	26	13	6-48
Flora 2003[60]	108	28	26.2	20	Not reported
Gilling-Smith 2000[61]	55	11	20.0	18	3-36
Haulon 2003[63]	96	38	39.6	27	3-66
Hincliffe 2004	269	21	7.8	12	Not reported

Howell 2001[86]	215	22	10.2	14	Not reported
Howell 2000[87]	*89*	*11*	*12.4*	*13*	*1-18*
Kocher 2004[37]	120	20	16.7	21	2-60
Laheij 2002[79]	2863	410	14.3	Not reported	Not reported
Lee 2000[89]	*67*	*17*	*24.5*	*18*	*Not reported*
Lee 2002[88]	150	7	4.7	Not reported	Not reported
May 2002[64]	266	43	16.2	6	> 6 months
Minor 2004[39]	150	24	16	17	1-61
Nolthenius 2001[66]	77	22	28.6	12	>12 months
Ohki 2001[67]	239	23	9.6	16	<75 months
Ouriel 2003[69]	700	173	24.7	12	Not reported
Ramaiah 2002[90]	230	41	17.8	Not reported	Not reported
Resch 2001[72]	164	91	55.5	39	Not reported
Resch 2001[73]	*158*	*71*	*44.9*	*20*	*10-36*
Ricco 2003[74]	1021	67	6.6	11	Not reported
Sampaio 2004[40]	241	66	27	10	1-71
Elkouri 2003[75]	*100*	*29*	*29.0*	*7*	*1-60*
Shames 2003[91]	245	36	14.7	11	1-26
Verhoeven 2004[42]	308	72	23.4	36	Not reported
Wolf 2002[92]	189	31	16.4	13	Not reported
Zarins 2000[93]	149	21	14.1	12	1-39
Zarins 2003[95]	383	67	17.5	36	Not reported
Total	**10652**	**1862**	**17.5 (16.8% - 18.2%)**	**19**	

7.1.8 Procedural blood loss

Studies that reported blood loss following EVAR are displayed in Table 47. The 13 studies were case series with a range of blood loss of 255 ml to 779 ml.

Table 47 Procedural blood loss

Author	Number of participants	Mean Blood loss (ml)
AbuRahma 2004[28]	151	263
Alric 2002[49]	88	779
Biebl 2004[23]	182	470
Carpenter 2004a[56]	227	350
Fairman 2004[33]		
Complicated neck	*153*	*320*
Uncomplicated neck	*66*	*351*
Dalainas 2004[31]	186	370

Elkouri 2003[75]	100	400
Howell 2001[86]	215	352
Howell 2000[87]	*56*[b]	*428*
Hinchliffe 2004[20]	269	400
Minor 2004[39]	150	369
Ohki 2001[67]	239	468
Parlani 2002[70]		
EVAR	*277*	*293*
AAA and IAA[a]	*59*	*445*
Ramaiah 2002[90]		
Early	30	400
Late	230	294
Vasquez 2004[41]		
EVAR	129	255
Renal impairment	83	278
Ziaja 2003[26] 2004	52	320
Total		

[a] Combined abdominal and iliac artery aneurysms

[b] results from late endovascular experience

7.1.9 Length of ITU stay

The results of the ITU length of stay are displayed in Table 48. EVAR was associated with a mean stay of 1.2 days.

Table 48 Length of ITU stay

Author	Number of participants	ITU stay (days)
AbuRahma 2004[28]	151	2
Cartes 2002[57]	72	0.3
Elkouri 2003[97]	100	1.0[a]
Kocher 2004[37]	120	2
Minor 2004[39]	150	0.1
Ziaja 2003[26]	52	2
Total	**645**	**1.2**

[a]Median

7.2 Length of hospital stay

Sixteen case series reported outcome data on length of hospital stay following EVAR, (Table 49). Overall from the 16 studies the average length of stay following EVAR was 5.5 days.

Table 49 Length of hospital stay

Author	Number of participants	Mean length stay, days
AbuRahma 2004[28]	151	5
Alric 2002[49]	88	9
Ayerdi 2003[85]	96 [a]	
Early EVAR	42	3[b]
Late EVAR	54	2[b]
Biebl 2004[23]		
EVAR	139	4
High-risk EVAR	49	4
Parlani 2002[70]	*336*	
EVAR	*277*	*2*
AAA + IAA	*59*	*2*
Zannetti 2001[71]	*266*	
EVAR	*240*	*3*
High risk EVAR	*26*	*8*
Carpenter 2004a[56]	227	4
Cartes 2002[57]	72	6
Dalainas 2004[31]	186	5
Kocher 2004[37]	120	6
Howell 2001[86]	215	2
Howell 2000[87]	*89*	
Early EVAR	*33*	*4*
Late EVAR	*56*	*2*
Minor 2004[39]	150	3
Nolthenius 2001[66]	77	3
Ohki 2001[67]	239	4
Ramaiah 2002[90]	260	
Early EVAR	30	4
Late EVAR	230	4
Ricco 2003[74]	1012	9
Samapaio 2004[40]		
Male	212	3
Female	29	4
Elkouri 2003[75]	*100*	*3*
Shames 2003[91]	245	
Male	203	3
Female	42	3

Total	**3518**	**5.5**

[a]Total number of EVAR participants

[b] Median

7.3 Overview of the Safety findings from non-controlled studies (Case series)

7.3.1 Common technical complications

The incidence of the common technical complications is shown in Table 50.

Table 50 Incidence of common technical complications in EVAR

Complication	Author	Number of participants	Number of cases	%
Stent migration				
<30 days	Vallabhaneni 2001[80]	2862	39	1.4%
> 1 year	Becquemin 2004[27]	250	4	1.6%
	Biebl 2004[23]	181	7	3.9%
	Blum 2001[53]	298	5	1.7%
	Flora 2003[60]	108	2	1.9%
	Fransen 2003[78]	4613	156	3.4%
	Hinchliffe 2004[20]	255	6	2.4%
	Cho 2004[30]	45	0	0%
	Nolthenius 2001[66]	77	6	8.2%
	Ouriel 2003[68]	704	51	7.2%
	Resch 2001[72]	164	31	18.9%
	Zarins 2003[95]	*383*	*24*	*6.3%*
	Zarins 2003[94]	137	13	9.5%
	Total	**6832**	**281**	**4.1%**
Stent wire fracture up to 1 year	Carpenter 2004a[56]	227	6	2.6%
Graft limb thrombosis <30 days	Burks 2002[55]	95	6	6.3%
	Howell 2000[86]	215	5	2.3%
	Kocher 2004[37]	118	4	3.4%
	Lee 2002[88]	150	1	0.7%
	Minor 2004[39]	145	3	2.1
	Parlani 2002[70]	336	4	1.2%
	Total	**1059**	**23**	**2.2%**

<1 year	Allaqaband 2004[21]	58	2	3.4%
	Albertini 2001[48]	135	2	1.5%
	Alric 2002[49]	88	3	3.4%
	Ayerdi 2003[85]	96	2	2.1%
	Blum 2001[53]	298	4	1.3%
	Carpenter 2004a[56]	227	0	0.0%
	Elkouri 2003[75]	100	4	4.0%
	Shames 2003[91]	241	10	4.1%
	Zarins 2000[93]	149	1	0.7%
	Total	**1392**	**28**	**2.0%**
>1 year	Becquemin 2004	250	15	6.0%
	Biebl 2004[23]	181	5	2.8%
	Espinosa 2004[32]	191	0	0%
	Flora 2003[60]	108	2	1.9%
	Fransen 2003[78]	4613	152	3.3%
	Haulon 2003[63]	96	8	8.3%
	Kocher 2004[37]	118	3	2.5%
	Maldonado 2004[19]	287	14	4.9%
	Nolthenius 2001[66]	77	3	2.3%
	Ohki 2001[67]	239	7	2.9%
	Ouriel 2003[68]	704	43	6.1%
	Verhoeven 2004[42]	306	15	4.9%
	Ziaja 2003[26]	52	5	9.6%
	Total	**7222**	**272**	**3.8%**
Graft stenosis 30 days	Vallabhaneni 2001[80]	2862	10	0.3%
<1 year	Elkouri 2003[75]	100	3	3.0%
>1 year	Becquemin 2004[27]	250	8	3.2%
	Carpenter 2004a[56]	188	3	1.6%
	Fransen 2003[78]	4613	66	1.4%
	Total	**5051**	**77**	**1.5%**
Type I endoleak < 30 days	AbuRahma 2004[28]	148	10	6.8%
	Boult 2004[29]	950	25	2.6%
	Gilling-Smith 2000[61]	55	6	10.9%
	Hinchliffe 2004[20]	255	2	0.8%

	Howell 2000[86]	215	2	0.9%
	Howell 2000[87]	*56*	*2*	*3.6%*
	Kocher 2004[37]	120	10	8.5%
	Lee 2002[88]	150	5	3.3%
	Minor 2004[39]	145	4	2.8%
	Parlani 2002[70]	336	3	1.2%
	Ziaja 2003[26]	52	5	9.6%
	Total	**2426**	**72**	**3.0%**
up to 1 year	Albertini 2001[48]	185	16	8.6%
	Blum 2001[53]	298	6	2.0%
	Carpenter 2004a[56]	227	7	3.1%
	Cartes 2002[57]	72	3	4.2%
	Haulon 2003[63]	91	13	14.3%
	Hinchliffe 2004[20]	255	2	0.8%
	Howell 2000[86]	84	2	2.4%
	Moore 2003[65]	262	9	3.4%
	Nolthenius 2001[66]	128	4	3.1%
	Ouriel 2003[68]	704	18	2.6%
	Total	**2306**	**80**	**3.5%**
>1 year	Allaqaband 2004[21]	58	1	1.7%
	Alric 2002[49]	88	3	3.4%
	Becquemin 2004	250	36	14.4%
	Burks 2002[55]	95	0	0.0%
	Dalainas 2004[31]	186	12	6.5%
	Faries 2002[59]	65	14	21.5%
	Flora 2003[60]	108	12	11.1%
	Fransen 2003[78]	4613	375	8.1%
	Haulon 2003[63]	77	2	2.6%
	Howell 2000[86]	132	6	4.5%
	Cho 2004[30]	45	0	0%
	May 2000[64]	266	21	7.9%
	Minor 2004[39]	140	6	4.3%
	Nolthenius 2001[66]	128	2	1.6%
	Ohki 2001[67]	239	7	2.9%
	Ouriel 2003[69]	700	25	3.6%
	Resch 2001[72]	164	20	12.2%
	Resch 2001[73]	*158*	*20*	*12.7%*
	Sampaio 2004[40]	212	9	4.2%

	Wolf 2002[92]	189	13	6.9%
	Zarins 2003[95]	383	10	2.6%
	Total	**8138**	**574**	**7.1%**
Type II endoleak	AbuRahma 2004[28]	148	6	4.1%
<30 days	Boult 2004[29]	950	44	4.6%
	Burks 2002[55]	95	19	20.0%
	Espinosa 2004[32]	193	7	3.8%
	Gilling-Smith 2000[61]	55	5	9.1%
	Hinchliffe 2004[20]	269	13	4.8%
	Howell 2000[86]	215	3	1.4%
	Lee 2002[88]	150	29	19.3%
	Minor 2004[39]	145	30	20.7%
	Parlani 2002[70]	336	22	6.5%
	Ziaza 2004	52	4	7.7%
	Total	**2608**	**182**	**7.0%**
up to 1 year	Albertini 2001[48]	185	10	5.4%
	Blum 2001[53]	298	9	3.0%
	Carpenter 2004a[56]	227	18	7.9%
	Cartes 2002[57]	30	1	3.3%
	Haulon 2003[63]	91	9	9.9%
	Hinchliffe 2004[20]	269	17	6.3%
	Howell 2000[86]	84	8	9.5%
	Ouriel 2003[68]	704	173	24.6%
	Zarins 2003[95]	383	55	14.4%
	Total	**2271**	**300**	**13.2%**
>1 year	Alric 2002[49]	88	5	5.7%
	Arko 2003[84]	206	40	19.4%
	Becquemin 2004	250	33	13.2%
	Dalainas 2004[31]	186	5	2.7%
	Espinosa 2004[32]	191	6	3.1%
	Faries 2002[59]	65	3	4.6%
	Flora 2003[60]	108	9	8.3%
	Fransen 2003[78]	4613	485	10.5%
	Haulon 2003[63]	77	16	20.8%
	Cho 2004[30]	45	8	17.8%
	May 2000[64]	383	4	1.0%
	Minor 2004[39]	140	11	7.9%

	Nolthenius 2001[66]	128	8	6.3%
	Ohki 2001[67]	239	13	5.4%
	Resch 2001[72]	164	23	14.0%
	Resch 2001[73]	*158*	*23*	*14.6%*
	Verhoeven 2004[42]	306	26	8.5%
	Zarins 2003[95]	573	61	10.6%
	Total	**7762**	**756**	**9.7%**
Type III endoleak <30 days	AbuRahma 2004[28]	148	0	0%
Type III endoleak >1 year	Alric 2002[49]	88	1	1.1%
	Becquemin 2004	250	12	4.8%
	Blum 2001[53]	298	5	1.7%
	Fransen 2003[78]	4613	225	4.9%
	Cho 2004[30]	45	0	0%
	Minor 2004[39]	54	1	1.9%
	Nolthenius 2001[66]	77	4	2.3%
	Ohki 2001[67]	239	1	0.4%
	Ouriel 2003[68]	704	23	3.3%
	Zarins 2003[95]	383	8	2.1%
	Total	**6751**	**280**	**4.1%**
Access artery injury	Allaqaband 2004[21]	60	2	3.3%
	Blum 2001[53]	298	5	1.7%
	Cartes 2002[57]	72	1	1.4%
	Espinosa 2004[32]	193	4	2.1%
	Howell 2000[86]	215	4	1.9%
	Howell 2000[87]	*89*	*8 [a]*	*9.0%*
	Lee 2002[88]	150	8	5.3%
	Minor 2004[39]	145	2	1.4%
	Ricco 2003[74]	1012	19	1.9%
	Shames 2003[91]	241	11	4.6%
	Total	**2386**	**32**	**1.3%**

[a] 6 out of 8 injuries occurred during initial experience

7.3.2 Common non-technical complications

The incidence of the common technical complications is shown in Table 51.

Table 51 Incidence of common non-technical complications (Case Series)

Study ID	Number of participants	Number of events	
		Number	%
Mortality rate (<30 days)			
AbuRahma 2004[28]	151	1	0.7%
Albertini 2001[48]	185	12	6.5%
Allaqaband 2004[21]	60	2	3.3%
Alric 2002[49]	88	3	3.4%
Ayerdi 2003[85]	96	0	0.0%
Becquemin 2004[27]	250	5	2.0%
Biebl 2004[23]	182	1	0.5%
Blum 2001[53]	270	1	0.4%
Boult 2004[29]	950	16	1.7%
Burks 2002[55]	95	2	2.1%
Parlani 2002[70]	*336*	*4*	*1.2%*
Zannetti 2001[71]	*266*	*3*	*1.1%*
Carpenter 2004a[56]	227	3	1.3%
Cartes 2002[57]	72	1	1.4%
Criado 2001[81]	*152*	*5*	*3.3%*
Dalainas 2004[31]	186	2	1.1%
Espinosa 2004[32]	193	7	3.6%
Faries 2002[59]	65	0	0.0%
Haulon 2003[63]	96	2	2.1%
Hinchliffe 2004[20]	269	11	4.1%
Howell 2000[86]	215	0	0.0%
Howell 2000[87]	*89*	*0*	*0.0%*
Cho 2004[30]	50	0	0%
Kocher 2004[37]	120	4	3.3%
Laheij 2002[79]	2863	85	3.0%
Vallabhaneni 2001[80]	*2862*	*85*	*3.0%*
Lee 2002[88]	150	2	1.3%
Lee 2000[89]	*67*	*2*	*3.0%*
Minor 2004[39]	150	5	3.3%
Nolthenius 2001[66]	77	4	5.2%
Ohki 2001[67]	239	20	8.4%
Ouriel 2003[68]	704	11	1.6%

Ramaiah 2002[90]	260	2	0.8%
Resch 2001[72]	164	7	4.3%
Resch 2001[73]	*158*	*7*	*4.4%*
Ricco 2003[74]	891	27	3.0%
Sampaio 2004[40]	241	4	1.7%
Elkouri 2003[75]	*100*	*0*	*0.0%*
Shames 2003[91]	245	4	1.6%
Vasquez 2004[41]	213	7	3.3%
Verhoeven 2004[42]	308	2	0.6%
Wolf 2002[92]	189	2	1.1%
Zarins 2000[93]	149	2	1.3%
Zarins 2003[94]	1193	22	1.8%
Ziaja 2003[26]	52	0	0%
Total	**11908**	**279**	**2.3%**
Mortality - AAA related (range 21-36 months)			
Alric 2002[49]	88	6	6.8%
Espinosa 2004[32]	57	1	1.8%
Ouriel 2003[69]	700	24	3.4%
Zarins 2003[95]	383	5	1.3%
Total	**1228**	**36**	**2.9%**
Mortality Non-AAA related (range 12-36 months)			
Allaqaband 2004[21]	58	1	1.7%
Ayerdi 2003[85]	96	1	1.0%
Espinosa 2004[32]	193	12	6.2%
Faries 2002[59]	65	8	12.3%
Haulon 2003[63]	96	11	11.5%
Howell 2001[86]	215	12	5.6%
Cho 2004[30]	45	7	15.6%
Kocher 2004[37]	118	13	11.0%
Minor 2004[39]	150	40	26.7%
Nolthenius 2001[66]	77	10	7.8%
Ohki 2001[67]	239	53	22.2%
Zarins 2000[93]	149	15	10.1%
Ziaja 2003[26]	52	2	3.8%
Total	**1553**	**185**	**11.9%**
Mortality – Total (up to 1 year)			
Becquemin 2004[27]	250	15	6.0%

Carpenter 2004a[56]	227	15	6.6%
Elkouri 2003[75]	100	3	3.0%
Ouriel 2003[69]	700	83	11.9%
Shames 2003[91]	241	14	5.8%
Wolf 2002[92]	189	27	14.3%
Zannetti 2001[71]	266	10	3.8%
Total	**1973**	**167**	**8.5%**

Mortality – Total (>1 year)

Alric 2002[49]	88	24	27.3%
Becquemin 2004	250	43	17.2%
Flora 2003[60]	108	9	8.3%
Gilling-Smith 2000[61]	55	8	14.5%
Lee 2000[89]	67	15	22.4%
Ouriel 2003[68]	704	143	20.3%
Ricco 2003[74]	891	47	4.6%
Vallabhaneni 2001[80]	2862	655	22.9%
Zarins 2003[94]	1193	250	21.0%
Zarins 2003[95]	*383*	*55*	*14.4%*
Total	**6218**	**1194**	**19.2%**

Cardiac event rate (<30 days)

AbuRahma 2004[28]	151	6	4.0%
Albertini 2001[48]	185	5	2.7%
Biebl 2004[23]	182	2	1.1%
Boult 2004[29]	950	69	7.3%
Burks 2002[55]	95	2	2.1%
Parlani 2002[70]	*336*	*4*	*1.2%*
Dalainas 2004[31]	182	3	1.6%
Elkouri 2003[75]	100	12	12.0%
Faries 2003[96]	70	2	2.9%
Haulon 2003[63]	96	3	3.1%
Kocher 2004[37]	118	6	5.1%
Lee 2002[88]	150	11	7.3%
Ramaiah 2002[90]	230	6	2.6%
Ricco 2003[74]	1012	8	0.8%
Vasquez 2004[41]	212	15	7.1%
Zarins 2000[93]	149	5	3.4%
Ziaja 2003[26]	52	2	3.8%
Total	**3934**	**157**	**4.0%**

Renal impairment (<30 days)			
AbuRahma 2004[28]	151	5	3.3%
Allaqaband 2004[21]	58	0	0%
Albertini 2001[48]	185	13	7.0%
Biebl 2004[23]	182	29	15.9%
Burks 2002[55]	95	3	3.2%
Carpenter 2004	192	2	1.0%
Dalainas 2004[31]	182	7	3.8%
Elkouri 2003[75]	*100*	*3*	*3.0%*
Haulon 2003[63]	96	5	5.2%
Kocher 2004[37]	120	0	0%
Lee 2002[88]	150	2	1.3%
Minor 2004[39]	145	2	1.4%
Ramaiah 2002[90]	230	3	1.3%
Ricco 2003[74]	1012	11	1.1%
Vasquez 2004[41]	212	6	2.8%
Zarins 2000[93]	149	1	0.7%
Ziaja 2003[26]	52	1	1.9%
Total	**3211**	**90**	**2.8%**
Renal impairment (>1 year)			
Alric 2002[49]	88	8	9.1%
Graft infection (< 30 days)			
Parlani 2002[70]	336	1	0.3%
Graft infection (up to 1 year)			
Blum 2001[53]	298	1	0.3%
Criado 2003[82]	240	1	0.4%
Gilling-Smith 2000[61]	55	1	1.8%
Total	**593**	**3**	**0.5%**
Graft infection (>1 year)			
Biebl 2004[23]	182	0	0%
Flora 2003[60]	108	1	0.9%
Howell 2001[86]	215	1	0.5%
Total	**505**	**2**	**0.4%**
Colonic ischaemia (<30 days)			

AbuRahma 2004[28]	151	3	2.0%
Alric 2002[49]	88	3	3.4%
Carpenter 2004a[56]	227	1	0.4%
Kocher 2004[37]	118	0	0%
Ricco 2003[74]	891	3	0.3%
Vasquez 2004[41]	212	3	1.4%
Zarins 2000[93]	149	1	0.7%
Total	**1836**	**14**	**0.8%**
Lower limb ischaemia (<30 days)			
Blum 2001[53]	298	6	2.0%
Ricco 2003[74]	891	16	1.6%
Vallabhaneni 2001[80]	2862	15	0.5%
Total	**4051**	**37**	**0.9%**
Pulmonary complications (<30 days)			
Albertini 2001[48]	185	2	1.1%
Carpenter 2004a[56]	227	6	2.6%
Elkouri 2003[75]	*100*	*5*	*5.0%*
Haulon 2003[63]	96	0	0.0%
Lee 2002[88]	150	4	2.7%
Ramaiah 2002[90]	230	3	1.3%
Ricco 2003[74]	891	6	0.7%
Vasquez 2004[41]	212	9	4.2%
Total	**1991**	**30**	**1.5%**
Haemorrhage (<30 days)			
AbuRahma 2004[28]	151	4	2.6%
Local wound complications (<30 days)			
AbuRahma 2004[28]	151	2	1.3%
Albertini 2001[48]	185	16	8.6%
Ayerdi 2003[85]	96	1	1.0%
Biebl 2004[23]	182	12	6.6%
Blum 2001[53]	298	9	3.0%
Burks 2002[55]	95	4	4.2%
Carpenter 2004a[56]	227	27	11.9%
Cartes 2002[57]	72	2	2.8%
Dalainas 2004[31]	182	27	14.8%
Elkouri 2003[75]	*100*	*10*	*10.0%*

Espinosa 2004[32]	193	6	3.1%
Howell 2000[86]	215	6	2.8%
Howell 2000[87]	*56*	*3*	5.4%
Kocher 2004[37]	118	5	4.2%
Minor 2004[39]	145	7	4.8%
Nolthenius 2001[66]	77	1	1.3%
Ramaiah 2002[90]	230	12	5.2%
Vasquez 2004[41]	212	8	3.8%
Ziaja 2003[26]	52	6	11.5%
Total	**2730**	**151**	**5.5%**
Local wound complications (>1 year)			
Faries 2002[59]	65	3	4.6%

8 DISCUSSION

8.1 EVAR versus open repair

Until the publication of the DREAM and EVAR trials, there had been a lack of level one evidence comparing the efficacy and safety of EVAR to open repair. Early publications from population registries (RETA and EUROSTAR) and case series had suggested a lower operative mortality, lower perioperative complications and reduced requirement for hospital beds and critical care for EVAR compared to open repair. In addition, questions had been raised with regards to the long term durability of EVAR. The current trials included in this updated review provide high quality evidence comparing the perioperative and medium-term safety and efficacy of EVAR to open repair.

8.1.1 Major outcomes

From a meta-analysis of the RCT data EVAR was associated with a 30-day mortality rate of 1.6% compared to 4.7% for open repair, (OR 0.33, 95% CI 0.17 to 0.64). This finding was supported by the results from the NRCT data, (OR 0.31, 95% CI 0.25 to 0.39). The EVAR 1 and DREAM trials both found a reduction in AAA-related mortality of approximately 3% in the EVAR group. This reduction in mortality was evident throughout the follow-up period and was found to be entirely attributable to the difference in perioperative mortality.

The EVAR 1 trial reported no significant difference in total mortality rates during follow up. At 4 years, approximately 28% of the study population had died in each group, (HR 0.9, 95% CI 0.69 to 1.19; p=0.46). During a shorter period of follow up (2 years), the DREAM trial reported cumulative survival rates of 89.6% following open repair and 89.7% following EVAR, a difference of -0.1 percentage point (95% CI -6.8 to 6.7 percentage points; p=0.86). In fact the early benefit in survival in the EVAR group was found to be lost by the end of the first year post procedure.

During the first thirty days, one NRCT studies reported a 0.3% rupture rate (this includes any intraoperative ruptures) following EVAR. From the EVAR 1 trial,[45] during the median follow-up period of 35 months (IQR, 23 to 48 months), there was an average rupture rate of 0.9% following EVAR and 0.2% following open repair, (p=ns). There was an increase in aneurysm size in 4.1% of the included study population, whilst 28.9% and 57.5% stayed the same size or decreased in size, respectively.

Following a failed attempt at EVAR, 1.0% (RCT data) and (2.4%, NRCT data) of the study population required conversion to open surgical repair during the perioperative period. From the EVAR 1 trial,[45] during the subsequent median follow-up period of 35 months (IQR, 23 to

48 months), an average of 1.9% required a delayed surgical conversion for persistent endoleak, aneurysm expansion (with or without endoleak), or aneurysm rupture.

From the EVAR 1 trial[45] the secondary intervention rate following EVAR was 16.1% compared to 6.9% following open repair (OR 2.57, 95% CI 1.70 to 3.87; p<0.00001). From the DREAM trial[47] the rate of intervention was almost three times the rate after open repair, (HR 2.9, 95% CI 1.1 to 6.2; p=0.03). From the NRCTs the secondary intervention rate following EVAR was 20.2% compared to 6.4% following open repair, (OR 3.23, 1.94 to 5.37; p<0.00001).

8.1.2 Complications

From the safety data, the most common technical adverse event following EVAR was a type II endoleak occurring in 20.7% participants by 1 month and occurring in 18.9% participants at 1 year. Other technical adverse events included stent migration (2.6% at >1 year), graft limb thrombosis (6.4% at <30-days and 2.6% at >1year), type I endoleak (5.5% at >1 year), type III endoleak (1.9% at >1 year), and access artery injury occurring in 4.8%.

The RCTs demonstrated no significant difference in cardiac event rate post EVAR or surgery, but the NRCT studies revealed a significant reduction in cardiac rate post EVAR, (OR 0.43, 95% CI 0.36 to 0.50; p<0.00001). In addition, there was also a significant reduction in pulmonary complications following EVAR compared to open repair, (OR 0.25, 95% CI 0.09 to 0.69; p=0.006), from the DREAM trial and (OR 0.19, 95% CI 0.14 to 0.24; p<0.00001) from the EVAR 1 trial. There was also a significant reduction in the incidence of blood loss and haemorrhagic events in the EVAR group. There was no significant difference in the rates of lower limb ischaemia, renal impairment, graft infection, colonic ischaemia or local wound complications between the two groups.

8.1.3 Other peri- and post-operative outcomes

Efficacy data extracted from RCTs and NRCTs revealed that the endograft was accurately deployed in 97% and 96% of the study population respectively. Using a definition of complete aneurysm exclusion following accurate graft placement, the technical success of EVAR was just 74% at the time of primary intervention, rising to 87% at 30 days after secondary interventions and spontaneous resolution of some endoleaks had occurred.

The results of the RCTs demonstrated that there was a significant reduction in ITU stay post EVAR compared to open repair, (WMD -1.50 days, 95% CI -2.29 to -1.11; p<00001). This finding was also supported by the results from the NRCTs, (WMD -0.89 days, 95% CI -1.45 to -0.33; p=0.002). In addition, the RCTs showed a clear benefit for EVAR compared to open

repair in terms of a significant reduction in total hospital stay, (WMD -6.76 days, 95% CI -7.53 to -5.99; p<0.00001).

8.2 EVAR in high risk patients

The EVAR 2 trial is the only RCT to date that has compared EVAR to 'no intervention' in a group of patients unfit for open repair. Furthermore, there are no other known trials planned comparing EVAR to 'no intervention' in this population. This trial, therefore, provides crucial information with regards to the efficacy and safety of EVAR in very high-risk patients, the group for which EVAR was originally conceived.

The EVAR 2 trial demonstrated a significantly higher 30-day mortality rate post EVAR in a population who were deemed to be unfit for open repair (8.7%, vs. 1.7% for fit patients in EVAR 1). However this rate was reduced to 6.8% if only elective procedures were taken into account. In addition, with a rate of approximately 12 %, aneurysm related death was found to be similar between both groups. The total mortality rates were 44.6% (74/166) for the EVAR group and 39.5% (68/172) for the no-intervention group during the follow-up period, a difference that was not statistically significant.

There was a significant rate of complications following EVAR in the EVAR 2 trial (58/178), equating to a complication rate of 32.6%. Accordingly there was a high requirement for secondary intervention in the EVAR group with an intervention rate of 11.5 per 100 person years. However, the low primary and secondary conversion rates were maintained in this high-risk group, both <1.5%.

The mean total hospital stay was slightly longer in unfit EVAR group, 12 days, compared to 10 days in patients who were deemed fit for open repair.

8.3 Assumptions, limitations and uncertainties

This review considers the use of EVAR for asymptomatic abdominal aortic aneurysm. In this situation treatment is carried out in asymptomatic patients to reduce the risk of complications, particularly rupture of the aneurysm, which is associated with high mortality. The efficacy and safety of the procedure needs to be considered in the context of the natural history of the condition and outcome of conventional treatment. A major limitation of the review relates to the heterogeneity of the study population and unknown criteria for patient selection for EVAR, amongst the NRCT and case series studies. There are two major issues in this respect, the size of aneurysm treated, which determines the risk of rupture in the untreated condition and the case mix of patients regarding age and comorbidity, which affects the risks associated with open surgical treatment.

8.3.1 Size of aneurysm treated

Current evidence from the UK Small Aneurysm Trial suggests that surgical intervention is worthwhile if the aneurysm is at least 5.5 cm diameter or greater than 4.5 cm and has increased by 0.5 cm in the 6 months prior to intervention. In many of the reported studies, the inclusion criteria included aneurysms of less than 5.5 cm in diameter. Furthermore, in studies where inclusion criteria are not defined, there is either no documentation of baseline aneurysm size, or the range of aneurysm size extends below 5.5 cm. The expected rupture rate of aneurysms of less than 5.5 cm is in the order of 0.5% per year so that the risks and success rate that would be acceptable are very different from those for patients with larger aneurysms. The data presented do not allow adequate subgroup analysis to determine whether safety and efficacy are related to aneurysm size.

8.3.2 Case mix

There are also other differences between study populations, with some studies including a significant proportion of patients in whom surgical treatment would be expected to carry high mortality. In those patients with a large aneurysm, co-morbidity or previous abdominal surgery that would add significantly to the risks of conventional treatment, the acceptable risks for EVAR may be considerably higher.

The EVAR 1 and DREAM studies are randomised controlled trials that have addressed a number of these issues. The problem of heterogeneity of the study population was minimised by randomly allocating patients to EVAR or open repair. This resulted in two groups that were well matched, therefore allowing more accurate comparisons between the two groups, as they only differ in terms of treatment received. All patients in these trials were deemed sufficiently medically fit and anatomically suitable to undergo either procedure. Furthermore, patients were only included in the study if the baseline aneurysm size was 5.0 cm or greater (DREAM) or 5.5 cm or greater (EVAR 1).

8.3.3 Operator experience and advances in technology

Another important consideration in interpreting these results is the issue of operator experience and advances in device technology. Studies included in this review were restricted to papers published from the year 2000 onwards, but the recruitment period in some papers precedes this date by five or more years. Consequently the participants included in this review are undergoing a procedure that may have been carried out by an operator with limited experience in a relatively new technique (EVAR was first introduced in 1991). Furthermore, the level of operator experienced was poorly documented in virtually all of the included studies and the effect of a learning curve for EVAR has been well reported. The level of operator experience was again addressed in the RCTs, as only experienced surgeons and

interventional radiologists were included. For the EVAR trials, before being considered for participation in the trial, a new centre must submit outcome data on 20 cases to an independent register (RETA).

There have been substantial improvements in endovascular device technology in recent years. The 'first-generation' stents were home-made tube devices constructed using ePTFE graft material and standard endovascular stents. These are no longer used due to the high level of complications associated with these devices. Further improvements of endovascular prostheses have led to the development of modular bifurcated and aorto-uniiliac devices. These developments coupled with advances in device-delivery systems, have led to a lower incidence of procedural and post-procedural complications. As a consequence, some of the long-term safety and efficacy data relates to devices that are no longer used, whilst there is little medium to long term data on devices in current usage.

8.3.4 Primary outcomes

There are differences in the primary outcome measure used for the reported studies and this raises questions about the most appropriate outcome measure for the assessment of efficacy. Primary technical success is a commonly used outcome, but as already described there is considerable variation in the definition and consequent variation in results. Furthermore it is clear that accurate stent-graft deployment and complete aneurysm exclusion at completion of the procedure does not equate to 'success' and prevention of long term aneurysm related mortality as subsequent delayed aneurysm rupture is a well documented event.

8.3.5 Long term safety and efficacy

From the RCTs there is a clear reduction in 30-day mortality rate with a mean mortality rate of 4.6% after open repair and 1.7% after EVAR, (OR 0.33, 95% CI 0.17 to 0.64). This result is supported from the findings of the NRCT studies and the low mortality rate from EVAR is in agreement with that reported from previous case series. In addition there are other significant early benefits from EVAR, namely a reduction in pulmonary complications, blood loss and haemorrhagic effects. However, both the EVAR 1 and DREAM studies have demonstrated that by one year, there is no difference in total mortality between EVAR and open repair, and the reduction in aneurysm-related mortality that persists following EVAR is accounted for by the initial lower perioperative mortality rate.

This would suggest that although initially superior at 30-days, long term there is no survival advantage of EVAR over open repair and in fact the longevity of the EVAR technique remains to be proven. There are several possible explanations to account for the overall higher mortality rate during the first year following EVAR. Open repair may have precipitated the

death of frail patients who would have died during the coming year. However it is possible that EVAR is associated with a higher rate of late mortality by failing to prevent late ruptures or by causing complications related to the significantly higher secondary intervention rate.

It is clear that there is a need for careful follow-up after this procedure. During the follow-up of participants in the studies reported in this review, there was a significantly higher complication rate following EVAR, compared to open repair; [overall complication rates were 17.6 per 100 person years in the EVAR group and 3.3 per 100 person years in the open repair group, (HR 4.9, 95% CI 3.5 to 6.8; p<0.001)]. In turn, this increased complication rate translated to significantly higher number of secondary interventions being required to maintain complete aneurysm exclusion, (OR 2.57, 95% CI 1.70 to 3.87; p<0.00001) in the EVAR group compared to the open repair group.

Not only are there additional costs involved in long-term follow-up of these patients (out-patient attendances, regular CT scans etc), but the patient themselves have to be willing to undergo such follow-up and regular radiological investigation and consequential intervention. The issue of unknown long-term results is particularly important as this is a prophylactic procedure in asymptomatic patients. Informed consent of a patient undergoing EVAR must therefore not only include the early survival advantage and decreased incidence of perioperative morbidity (particularly haemorrhagic and respiratory) but also the need for ongoing surveillance and secondary intervention, with no evidence of medium-term survival benefit, coupled with unknown and potentially inferior results in the long-term.

8.3.6 High risk patients

The technique of EVAR was initially established to treat high-risk surgical candidates for whom open repair would be associated with very significant mortality and morbidity. The EVAR 2 trial addressed this issue by comparing EVAR to best medical therapy in a group of unfit patients. The 30 day mortality result of EVAR in unfit patients was 7.9%, (compared to 1.7% in fit patients). However the rate of aneurysm-related mortality in the no intervention group was found to be significantly lower than the 25% suggested from unpublished data from the UK Small Aneurysm Study.

This significantly lower aneurysm-related mortality in the no-intervention group coupled with a higher 30-day mortality post EVAR and high rates of complications, (43% by 4 years) and secondary intervention, (11.5 per 100 person years) negated any potential benefit of EVAR over no intervention in unfit patients. Analysis by intention to treat demonstrated no significant difference in either aneurysm related mortality or total mortality during the follow-up period. However there are a number of considerations to be made when interpreting these results. It is possible that there may be an element of confounding due to the high rate of

crossover of patients on best medical therapy to exclusion by EVAR or surgery. Over twice as many patients underwent late aneurysm repair as died of aneurysm related causes and many of these patients had symptomatic or enlarging aneurysms that would have increased the aneurysm related mortality had such crossovers not occurred.

From the point of view of service provision, it should be noted that the results of this review demonstrated that EVAR is associated with a significant reduction in the requirement for hospital beds and critical care when compared to surgical repair. When undertaking surgical aneurysm repair in a high-risk patient, it can be difficult to organise the required critical care services, and consequently EVAR with its reduced requirements may have some advantages. However, there is also a clear need for a specialist team with appropriate equipment, training and facilities, which may not be easily provided in every unit currently undertaking aortic aneurysm repair. The widespread introduction of this technique may, therefore, require careful consideration of the organisation of specialist vascular services.

8.4 Ongoing research

In addition to the EVAR 1 and DREAM trials, there are other RCTs with similar protocols being conducted in France (ACE) and the United States (OVER). These trials are at a less advanced stage but their results are eagerly awaited. More importantly, there is still no long-term efficacy or safety data available for EVAR, and long-term follow-up data from the EVAR 1 and DREAM trials is of paramount importance.

9 CONCLUSIONS

EVAR is considered to be an alternative therapeutic intervention for the treatment of infra-renal abdominal aortic aneurysms and is being used with increased frequency worldwide. Three RCTs have published outcome data within the last year to allow more accurate assessment of EVAR. From such trials it is clear that EVAR is a less invasive technique associated with an attractive reduction in perioperative morbidity and mortality rates and shorter ITU and hospital lengths of stay. However these early benefits need to weighed against a need for more intensive follow-up, a significant rate of re-intervention and unknown long term success in preventing aneurysm related mortality. Medium term data from the RCTs has demonstrated no overall survival benefit following EVAR. However technology is developing rapidly and one can envisage many further developments over the next few years, which have the potential to reduce the rates of complications and secondary interventions.

Although clearly associated with higher rates of morbidity and mortality, there may still be a place for EVAR in the management of certain high-risk surgical candidates, as the risk of aneurysm related death is likely to be higher than that found in the EVAR 2 trial. Finally EVAR is a technique that is still developing and longer-term follow up and further research are required to determine its exact place in the management of abdominal aortic aneurysms.

9.1 Efficacy of EVAR

Results of the included studies have demonstrated that EVAR is a technique applicable to just over 50% of patients with infrarenal abdominal aortic aneurysms. There was a high 30-day technical success rate (87%), coupled with low primary (1.1%) and delayed (1.9%) conversion rates. In addition EVAR was associated with a significantly shorter length of stay in ITU and a reduced hospital length of stay when compared to surgical repair. Importantly EVAR was associated with very low early and delayed aneurysm rupture rates (0.2% and 0.9% respectively). However, EVAR was associated with a significantly greater secondary intervention rate during the follow-up period compared to open repair, (OR 2.57, 95% CI 1.70 to 3.87; $p<0.00001$).

9.2 Safety of EVAR

EVAR was associated with a significantly reduced 30-day mortality rate of 1.6% compared to 4.7% for open surgical repair. It was also associated with a reduction in post-operative complications, particularly respiratory and haemorrhagic events. However EVAR was still associated with all the adverse outcomes that accompany surgical repair (graft infection,

lower limb ischaemia, renal impairment, colonic ischaemia and local wound complications). There is no medium-term survival advantage of EVAR over open repair, but there is a significantly higher rate of complications associated with EVAR.

Reference List

(1) Drury D, Michaels J, Jones L, Ayiku L. A systematic review of the recent evidence for the safety and efficacy of elective endovascular repair in the mangement of infrarenal abdominal aortic aneurysms. National Institute of Health and Clinical Excellence 2004Available from: URL: http://www.nice.org.uk/page.aspx?o=234301

(2) Parodi JC, Palmaz JC, Barone HD. Transfemoral intraluminal graft implantations for abdominal aortic aneurysms. Ann Vasc Surg 1991;5:491-9.

(3) Parodi JC. Endovascular repair of abdominal aortic aneurysms and other arterial lesions. J Vasc Surg 1995;21:549-57.

(4) Mialhe C, Amicabile C, Becquemin JP, for the Stentor retrospective study group. Endovascular treatment of infra-renal abdominal aortic aneurysms by the Stentor system: preliminary results of 79 cases. J Vasc Surg 1997;26:199-209.

(5) May J, Woodburn K, White GH. Endovascular treatment of infrarenal abdominal aortic aneurysms. Ann Vasc Surg 1998;12:391-5.

(6) Bonamigo TP, Siqueira I. Screening for abdominal aortic aneurysms. Rev Hosp Clin Fac Med Sao Paulo 2003;58(2):63-8.

(7) Crawford CM, Hurtgen-Grace K, Talarico E, Marley J. Abdominal aortic aneurysm: an illustrated narrative review. J Manipulative Physiol Ther 2003;26(3):184-95.

(8) Kim LG, Thompson SG, Marteau TM, Scott RA. Multicentre aneurysm screening study group. Screening for abdominal aortic aneurysms: the effects of age and social deprivation on screening uptake, prevalence and attendance at follow-up in the MASS trial. J Med Screen 2004;11(1):50-3.

(9) Yii MK. Epidemiology of abdominal aortic aneurysm in an Asian population. Anz J Surg 2003;73(6):393-5.

(10) Best VA, Price JF, Fowkes FG. Persistent increase in the incidence of abdominal aortic aneurysm in Scotland, 1981-2000. Br J Surg 2003;90(12):1510-5.

(11) Baysnat PS, Aiono S, Warsi AA, Magee TR, Galland RB, Lewis MH. Natural history of the ectatic aorta. Cardiovasc Surg 2003;11(4):273-6.

(12) McCarthy RJ, Shaw E, Whyman MR, Earnshaw JJ, Poskitt KR, Heather BP. Recommendations for screening intervals for small aortic aneurysms. Br J Surg 2003;90(7):821-6.

(13) Hallin A, Bergqvist D, Holmberg L. Literature review of surgical management of abdominal aortic aneurysm. Eur J Vasc Endovasc Surg 2001;22(3):197-204.

(14) Mortality results for randomised controlled trial of early elective surgery or ultrasonographic surveillance for small abdominal aortic aneurysms. The UK Small Aneurysm Trial Participants. Lancet 1998;352(9141):1649-55.

(15) Brown LC, Powell JT. Risk factors for aneurysm rupture in patients kept under surveillance. UK Small Aneurysm Trial participants. Ann Surg 1999;230(3):289-96.

(16) Powell JT, Brown LC. The natural history of abdominal aortic aneurysms and their risk of rupture. Adv Surg 2001;35:173-85.

(17) Carpenter JP, Endologix I. Midterm results of the multicenter trial of the powerlink bifurcated system for endovascular aortic aneurysm repair. Journal of Vascular Surgery 2004 Nov;40(5):849-59.

(18) Cao P, Verzini F, Parlani G, Romano L, De Rango P, Pagliuca V, et al. Clinical effect of abdominal aortic aneurysm endografting: 7-year concurrent comparison with open repair. Journal of Vascular Surgery 2004 Nov;40(5):841-8.

(19) Maldonado TS, Rockman CB, Riles E, Douglas D, Adelman MA, Jacobowitz GR, et al. Ischemic complications after endovascular abdominal aortic aneurysm repair. Journal of Vascular Surgery 2004 Oct;40(4):703-9.

(20) Hinchliffe RJ, Goldberg J, MacSweeney ST, Zenith Users Group. A UK multi-centre experience with a second-generation endovascular stent-graft: results from the Zenith Users Group. European Journal of Vascular & Endovascular Surgery 2004 Jan;27(1):51-5.

(21) Allaqaband S, Mortada ME, Tumuluri R, Kumar A, Bajwa TK. Endovascular stent graft repair of abdominal aortic aneurysms in high-risk patients: a single center experience. J INTERVENT CARDIOL 2004;2004 Apr; 17(2):71-9.

(22) The EVAR Trial Participants. Comparison of endovascular aneurysm repair with open repair in patients with abdominal aortic aneurysm (EVAR trial 1), 30-day operative mortality results: randomised controlled trial.[see comment]. Lancet 2004;364(9437):843-8.

(23) Biebl M, Lau LL, Hakaim AG, Oldenburg WA, Klocker J, Neuhauser B, et al. Midterm outcome of endovascular abdominal aortic aneurysm repair in octogenarians: A single institution's experience. Journal of Vascular Surgery 2004;40(3):435-42.

(24) Corriere MA, Feurer ID, Becker SY, Dattilo JB, Passman MA, Guzman RJ, et al. Endoleak following endovascular abdominal aortic aneurysm repair: Implications for duration of screening. Annals of Surgery 2004;239(6):800-7.

(25) Elkouri S, Gloviczki P, McKusick MA, Panneton JM, Andrews J, Bower TC, et al. Perioperative complications and early outcome after endovascular and open surgical repair of abdominal aortic aneurysms. Journal of Vascular Surgery 2004;39(3):497-505.

(26) Ziaja K, Kuczmik W, Ziaja D, Kostyra J, Szaniewski K. Endovascular treatment of infrarenal aortic aneurysm - Three years of experience. Chirurgia Polska 2003;5(3):129-43.

(27) Becquemin JP, Kelley L, Zubilewicz T, Desgranges P, Lapeyre M, Kobeiter H, et al. Outcomes of secondary interventions after abdominal aortic aneurysm endovascular repair. Journal of Vascular Surgery 2004;39(2):298-305.

(28) AbuRahma AF, Stone PA, Bates MC, Khan TN, Prigozen JM, Welch CA. Endovascular repair of abdominal aortic aneurysms using 3 commercially available devices: Midterm results. Journal of Endovascular Therapy 2004;11(6):641-8.

(29) Boult M, Babidge W, Maddern G, Fitridge R. Endoluminal repair of abdominal aortic aneurysm - Contemporary Australian experience. European Journal of Vascular and Endovascular Surgery 2004;28(1):36-40.

(30) Cho JS, Dillavou ED, Rhee RY, Makaroun MS. Late abdominal aortic aneurysm enlargement after endovascular repair with the excluder device. Journal of Vascular Surgery 2004;39(6):1236-41.

(31) Dalainas I, Nano G, Casana R, Tealdi DG. Mid-term results after endovascular repair of abdominal aortic aneurysms: A four-year experience. European Journal of Vascular and Endovascular Surgery 2004;27(3):319-23.

(32) Espinosa G, Ribeiro M, Riguetti C, Caramalho MF, Mendes WD, Santos SR. Six-year experience with talent stent-graft repair of abdominal aortic aneurysms. J ENDOVASC THER 2005 Feb;12(1):35-45.

(33) Fairman RM, Velazquez OC, Carpenter JP, Woo E, Baum RA, Golden MA, et al. Midterm pivotal trial results of the Talent Low Profile System for repair of abdominal aortic aneurysm: analysis of complicated versus uncomplicated aortic necks. Journal of Vascular Surgery 2004 Dec;40(6):1074-82.

(34) Garcia-Madrid C, Josa M, Riambau V, Mestres CA, Muntana J, Mulet J. Endovascular versus open surgical repair of abdominal aortic aneurysm: a comparison of early and intermediate results in patients suitable for both techniques. European Journal of Vascular & Endovascular Surgery 2004 Oct;28(4):365-72.

(35) Greenberg RK, Chuter TAM, Sternbergh C, Fearnot NE. Zenith AAA endovascular graft: Intermediateterm results of the US multicenter trial. Journal of Vascular Surgery 2004;39(6):1209-18.

(36) Jordan WD, Alcocer F, Wirthlin DJ, Westfall AO, Whitley D, Smith-III RB, et al. Abdominal Aortic Aneurysms in "High-Risk" Surgical Patients: Comparison of Open and Endovascular Repair. Annals of Surgery 2003;237(5):623-30.

(37) Kocher M, Utikal P, Koutna J, Bachleda P, Buriankova E, Herman M, et al. Endovascular treatment of abdominal aortic aneurysms - 6 Years of experience with Ella stent-graft system. European Journal of Radiology 2004;51(2):181-8.

(38) Leurs LJ, Hobo R, Buth J, EUROSTAR C. The multicenter experience with a third-generation endovascular device for abdominal aortic aneurysm repair. A report from the EUROSTAR database. Journal of Cardiovascular Surgery 2004 Aug;45(4):293-300.

(39) Minor ME, Ellozy S, Carroccio A, Oak J, Chae K, Agarwal G, et al. Endovascular aortic aneurysm repair in the octogenarian: is it worthwhile? Archives of Surgery 2004 Mar;139(3):308-14.

(40) Sampaio SM, Panneton JM, Mozes GI, Andrews JC, Noel AA, Karla M, et al. Endovascular abdominal aortic aneurysm repair: does gender matter? Annals of Vascular Surgery 2004 Nov;18(6):653-60.

(41) Vasquez J, Rahmani O, Lorenzo AC, Wolpert L, Podolski J, Gruenbaum S, et al. Morbidity and mortality associated with renal insufficiency and endovascular repair of abdominal aortic aneurysms: a 5-year experience. Vascular & Endovascular Surgery 2004 Mar;38(2):143-8.

(42) Verhoeven EL, Tielliu IF, Prins TR, Zeebregts CJ, van Andringa de Kempenaer MG, Cina CS, et al. Frequency and outcome of re-interventions after endovascular repair for abdominal aortic aneurysm: a prospective cohort study. European Journal of Vascular & Endovascular Surgery 2004 Oct;28(4):357-64.

(43) Lee WA, Carter JW, Upchurch G, Seeger JM, Huber TS. Perioperative outcomes after open and endovascular repair of intact abdominal aortic aneurysms in the United States during 2001. Journal of Vascular Surgery 2004;39:491-6.

(44) Prinssen M, Verhoeven ELG, Buth J, Cuypers PWM, van Sambeek MRHM, Balm R, et al. A randomized trial comparing conventional and endovascular repair of abdominal aortic aneurysms. New England Journal of Medicine 2004;351(16):1607-18.

(45) The EVAR Trial Participants. Comparison of endovascular aneurysm repair with open repair in patients with abdominal aortic aneurysm (EVAR trial 1), mid-term survival, graft durability, quality of life and costs: randomised controlled trial. Lancet 2005.

(46) The 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.

(47) Blankensteijn JD, de Jong SECA, 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. New England Journal of Medicine 2005;352(23):2398-405.

(48) Albertini JN, Branchereau A, Hopkinson B, Magnan PE, Bartoli JM, Whitaker - SC, et al. Mortality and morbidity following endovascular repair of abdominal aortic aneurysm: Analysis of two single centre experiences. European Journal of Vascular and Endovascular Surgery 2001;22(5):429-35.

(49) Alric P, Hinchliffe RJ, MacSweeney ST, Wenham PW, Whitaker SC, Hopkinson BR. The Zenith aortic stent-graft: a 5-year single-center experience. J ENDOVASC THER 2002 Dec;9(6):719-28.

(50) Anderson PL, Arons RR., Moskowitz AJ., Gelijns A, Magnell C, Faries PL, et al. A statewide experience with endovascular abdominal aortic aneurysm repair: rapid diffusion with excellent early results. Journal of Vascular Surgery 2004 Jan;39(1):10-9.

(51) Becquemin JP, Bourriez A, d'Audiffret A, Zubilewicz T, Kobeiter H, Allaire E, et al. Mid-term results of endovascular versus open repair for abdominal aortic aneurysm in patients anatomically suitable for endovascular repair. European Journal of Vascular and Endovascular Surgery 2000;19(6):656-61.

(52) Bertrand M, Godet G, Koskas F, Cluzel P, Fleron MH, Kieffer E, et al. Endovascular treatment of abdominal aortic aneurysms: Is there a benefit regarding postoperative outcome? European Journal of Anaesthesiology 2001;18(4):245-50.

(53) Blum U, Hauer M, Pfammatter T, Voshage G. Percutaneous endoprosthesis for treatment of aortic aneurysms. World Journal of Surgery 2001 Mar;25(3):347-52.

(54) Bolke E, Jehle PM, Storck M, Braun C, Schams S, Steinbach G, et al. Endovascular stent-graft placement versus conventional open surgery in infrarenal aortic aneurysm: a prospective study on acute phase response and clinical outcome. Clinica Chimica Acta 2001 Dec;314(1-2):203-7.

(55) Burks JA, Jr., Faries PL, Gravereaux EC, Hollier LH, Marin ML. Endovascular repair of abdominal aortic aneurysms: stent-graft fixation across the visceral arteries. Journal of Vascular Surgery 2002 Jan;35(1):109-13.

(56) Carpenter J.P., Anderson W.N., Brewster DC, Kwolek C, Makaroun M, Martin J, et al. Multicenter pivotal trial results of the Lifepath System for endovascular aortic aneurysm repair. Journal of Vascular Surgery 2004 Jan;39(1):34-43.

(57) Cartes-Zumelzu F, Lammer J, Hoelzenbein T, Cejna M, Schoder M, Thurnher S, et al. Endovascular placement of a nitinol-ePTFE stent-graft for abdominal aortic aneurysms: initial and midterm results. Journal of Vascular & Interventional Radiology 2002 May;13(5):465-73.

(58) 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. British Journal of Surgery 2001;88(8):1059-65.

(59) Faries PL, Briggs VL, Rhee JY, Burks JA, Jr., Gravereaux EC, Carroccio A, et al. Failure of endovascular aortoaortic tube grafts: a plea for preferential use of bifurcated grafts. Journal of Vascular Surgery 2002 May;35(5):868-73.

(60) Flora HS, Chaloner EJ, Sweeney A, Brookes J, Raphael MJ, Adiseshiah M. Secondary intervention following endovascular repair of abdominal aortic aneurysm: a single centre experience. European Journal of Vascular & Endovascular Surgery 2003 Sep;26(3):287-92.

(61) Gilling-Smith GL, Martin J, Sudhindran S, Gould DA, McWilliams RG, Bakran - A, et al. Freedom from endoleak after endovascular aneurysm repair does not equal treatment success. European Journal of Vascular and Endovascular Surgery 2000;19(4):421-5.

(62) Hansman MF, Neuzil D, Quigley TM, Hauptmann E, Fotoohi M, Robinson D, et al. A comparison of 50 initial endoluminal endograft repairs for abdominal aortic aneurysm with 50 concurrent open repairs. American Journal of Surgery 2003 May;185(5):441-4.

(63) Haulon S, Devos P, Willoteaux S, Mounier-Vehier C, Sokoloff A, Halna P, et al. Risk factors of early and late complications in patients undergoing endovascular aneurysm repair. European Journal of Vascular & Endovascular Surgery 2003 Feb;25(2):118-24.

(64) May J, White GH, Waugh R, Petrasek P, Chaufour X, Arulchelvam M, et al. Life-table analysis of primary and assisted success following endoluminal repair of abdominal aortic aneurysms: The role of supplementary endovascular intervention in improving outcome. European Journal of Vascular and Endovascular Surgery 2000;19(6):648-55.

(65) Moore WS, Matsumura JS, Makaroun MS, Katzen BT, Deaton DH, Decker M, et al. Five-year interim comparison of the Guidant bifurcated endograft with open repair of abdominal aortic aneurysm. Journal of Vascular Surgery 2003;38(1):46-55.

(66) Tutein-Nolthenius RP, van Herwaarden JA, van den Berg JC, van Marrewijk C, Teijink JAW, Moll FL. Three year single centre experience with the AneuRx aortic stent graft. European Journal of Vascular and Endovascular Surgery 2001;22(3):257-64.

(67) Ohki T, Veith FJ, Shaw P, Lipsitz E, Suggs WD, Wain RA, et al. Increasing incidence of midterm and long-term complications after endovascular graft repair of abdominal aortic aneurysms: a note of caution based on a 9-year experience. Annals of Surgery 2001 Sep;234(3):323-34.

(68) Ouriel K, Greenberg RK, Clair DG, O'hara PJ, Srivastava SD, Lyden SP, et al. Endovascular aneurysm repair: gender-specific results. Journal of Vascular Surgery 2003 Jul;38(1):93-8.

(69) Ouriel K, Srivastava SD, Sarac TP, O'hara PJ, Lyden SP, Greenberg RK, et al. Disparate outcome after endovascular treatment of small versus large abdominal aortic aneurysm. Journal of Vascular Surgery 2003 Jun;37(6):1206-12.

(70) Parlani G, Zannetti S, Verzini F, De Rango P, Carlini G, Lenti M, et al. Does the presence of an iliac aneurysm affect outcome of endoluminal AAA repair? An analysis of 336 cases. European Journal of Vascular and Endovascular Surgery 2002;24(2):134-8.

(71) Zannetti S, De Rango P, Parlani G, Verzini F, Maselli A, Cao P. Endovascular abdominal aortic aneurysm repair in high-risk patients: A single centre experience. European Journal of Vascular and Endovascular Surgery 2001;21(4):334-8.

(72) Resch T, Malina M, Lindblad B, Ivancev K. The evolution of z stent-based stent-grafts for endovascular aneurysm repair: A life-table analysis of 7.5-Year followup. Journal of the American College of Surgeons 2002;194(1 SUPPL.):S74-S78.

(73) Resch T, Malina M, Lindblad B, Ivancev K. The impact of stent-graft development on outcome of AAA repair - A 7-year experience. European Journal of Vascular and Endovascular Surgery 2001;22(1):57-61.

(74) Ricco JB, Goeau-Brissonniere O, Rodde-Dunet MH, Marty M, Fender P, Allemand H, et al. Use of abdominal aortic endovascular prostheses in France from 1999 to 2001. Journal of Vascular Surgery 2003;38(6):1273-81.

(75) Elkouri S, Gloviczki P, McKusick MA, Panneton JM, Andrews JC, Bower TC, et al. Endovascular repair of abdominal aortic aneurysms: initial experience with 100 consecutive patients. Mayo Clinic Proceedings 2003 Oct;78(10):1234-42.

(76) Teufelsbauer H, Prusa AM, Wolff K, Sahal M, Polterauer P, Lammer J, et al. The impact of endovascular stent grafting on reducing mortality rates after surgical treatment of abdominal aortic aneurysms. European Journal of Vascular and Endovascular Surgery 2003;26(5):494-500.

(77) Zeebregts CJ, Geelkerken RH, van der PJ, Huisman AB, de Smit P, van Det RJ. Outcome of abdominal aortic aneurysm repair in the era of endovascular treatment. British Journal of Surgery 2004 May;91(5):563-8.

(78) Fransen GAD. Frequency, Predictive Factors, and Consequences of Stent-Graft Kink Following Endovascular AAA Repair. J ENDOVASC THER 2003 Sep;10(5):913-8.

(79) Laheij RJ, Van Marrewijk CJ, Buth J, Harris PL, EUROSTAR C. The influence of team experience on outcomes of endovascular stenting of abdominal aortic aneurysms. European Journal of Vascular & Endovascular Surgery 2002 Aug;24(2):128-33.

(80) Vallabhaneni SR, Harris PL. Lessons learnt from the EUROSTAR registry on endovascular repair of abdominal aortic aneurysm repair. European Journal of Radiology 2001;39(1):34-41.

(81) Criado FJ, Wilson EP, Fairman RM, Abul-Khoudoud O, Wellons E. Update on the Talent aortic stent-graft: a preliminary report from United States phase I and II trials. Journal of Vascular Surgery 2001 Feb;33(2 Suppl):S146-S149.

(82) Criado FJ, Fairman RM, Becker GJ, Talent LPS Pivotal Clinical Trial investigators. Talent LPS AAA stent graft: results of a pivotal clinical trial. Journal of Vascular Surgery 2003 Apr;37(4):709-15.

(83) Arko FR, Hill BB, Olcott C, IV, Harris EJ, Jr., Fogarty TJ, Zarins CK. Endovascular repair reduces early and late morbidity compared to open surgery for abdominal aortic aneurysm. J ENDOVASC THER 2002 Dec;9(6):711-8.

(84) Arko FR, Filis KA, Hill BB, Fogarty TJ, Zarins CK. Morphologic changes and outcome following endovascular abdominal aortic aneurysm repair as a function of aneurysm size. Archives of Surgery 2003 Jun;138(6):651-5.

(85) Ayerdi J, McLafferty RB, Markwell SJ, Solis MM, Parra JR, Gruneiro LA, et al. Indications and outcomes of AneuRx phase III trial versus use of commercial AneuRx stent graft. Journal of Vascular Surgery 2003 Apr 1;37(4):739-43.

(86) Howell MH, Strickman N, Mortazavi A, Hallman CH, Krajcer Z. Preliminary results of endovascular abdominal aortic aneurysm exclusion with the AneuRx stent-graft.[comment]. Journal of the American College of Cardiology 2001 Oct;38(4):1040-6.

(87) Howell MH, Zaqqa M, Villareal RP, Strickman NE, Krajcer. Endovascular exclusion of abdominal aortic aneurysms: Initial experience. Texas-Heart-Institute-Journal [print] 2000;2000;@27:136-45.

(88) Lee WA, Wolf YG, Hill BB, Cipriano P, Fogarty TJ, Zarins CK. The first 150 endovascular AAA repairs at a single institution: how steep is the learning curve? J ENDOVASC THER 2002 Jun;9(3):269-76.

(89) Lee WA, Wolf YG, Fogarty TJ, Zarins CK. Does complete aneurysm exclusion ensure long-term success after endovascular repair? J ENDOVASC THER 2000 Dec;7(6):494-500.

(90) Ramaiah VG, Westerband A, Thompson C, Ravi R, Rodriguez JA, DiMugno L, et al. The AneuRx stent-graft since FDA approval: single-center experience of 230 cases.[comment]. J ENDOVASC THER 2002 Aug;9(4):464-9.

(91) Shames ML, Sanchez LA, Rubin BG, Choi ET, Geraghty PJ, Flye MW, et al. Delayed complications after endovascular AAA repair in women. J ENDOVASC THER 2003 Feb;10(1):10-5.

(92) Wolf YG, Arko FR, Hill BB, Olcott C, Harris EJ, Jr., Fogarty TJ, et al. Gender differences in endovascular abdominal aortic aneurysm repair with the AneuRx stent graft. Journal of Vascular Surgery 2002 May;35(5):882-6.

(93) Zarins CK, Wolf YG, Lee WA, Hill BB, Olcott C, IV, Harris EJ, et al. Will endovascular repair replace open surgery for abdominal aortic aneurysm repair? Annals of Surgery 2000 Oct;232(4):501-7.

(94) Zarins CK. The US AneuRx Clinical Trial: 6-year clinical update 2002. Journal of Vascular Surgery 2003 Apr 1;37(4):904-8.

(95) Zarins CK, Bloch DA, Crabtree T, Matsumoto AH, White RA, Fogarty TJ. Aneurysm enlargement following endovascular aneurysm repair: AneuRx clinical trial. Journal of Vascular Surgery 2004 Jan;39(1):109-17.

(96) Faries PL, Cadot H, Agarwal G, Kent KC, Hollier LH, Marin ML. Management of endoleak after endovascular aneurysm repair: cuffs, coils, and conversion. Journal of Vascular Surgery 2003 Jun;37(6):1155-61.

(97) Walsh PW, Chin-Quee S, Moore JE, Jr. Flow changes in the aorta associated with the deployment of a AAA stent graft. Medical Engineering & Physics 2003 May;25(4):299-307.

Appendix 1 Characteristics of the included studies

<table>
<tr><th>Author(s)</th><th>Participant characteristics</th><th>Intervention details</th><th>Results</th></tr>
<tr>
<td>AbuRahma 2004[28]

Design: Case series

Type: EVAR

Country: North America

Setting: Single centre

Recruitment period: Autumn 1999 onwards

Funding: Not stated</td>
<td>Inclusion criteria: Not stated

Exclusion criteria: Not stated

Patient population
<table>
<tr><th></th><th>EVAR</th></tr>
<tr><td>No of participants:</td><td>151</td></tr>
<tr><td>No of males:</td><td>137 (91%)</td></tr>
<tr><td>Average age (range):</td><td>74 (54-88)</td></tr>
<tr><td>Max AAA diameter (cm):</td><td>NS</td></tr>
<tr><td>No referred for EVAR:</td><td>NS</td></tr>
<tr><td>No for whom EVAR is appropriate:</td><td>NS</td></tr>
</table>
Co-morbidities:
<table>
<tr><th></th><th>EVAR</th></tr>
<tr><td>Hypertension</td><td>73%</td></tr>
<tr><td>Diabetes mellitus</td><td>23%</td></tr>
<tr><td>Smoking</td><td>77%</td></tr>
<tr><td>COPD</td><td>48%</td></tr>
<tr><td>CAD</td><td>72%</td></tr>
</table>
Length of follow-up (range): 17 months (1-46 months)

Losses to follow-up: Not stated</td>
<td>Total number of EVAR: 151

Stent make
Ancure: 88
AneuRx: 46
Excluder: 17

Graft type
Not stated

Comparator(s): None</td>
<td>
<table>
<tr><th>Clinical outcomes</th><th>EVAR</th></tr>
<tr><td>Total number:</td><td>151</td></tr>
<tr><td>Deploy success:</td><td>148</td></tr>
<tr><td>Technical success:</td><td>130</td></tr>
<tr><td>Duration:</td><td>NS</td></tr>
<tr><td>30-day mortality rate:</td><td>1</td></tr>
<tr><td>Blood loss (ml):</td><td>263</td></tr>
<tr><td>Days in ITU:</td><td>2</td></tr>
<tr><td>Days in hospital:</td><td>5</td></tr>
</table>
Change in aneurysm size
<table>
<tr><td>Average post-AAA size:</td><td>NS</td></tr>
<tr><td>Increase size:</td><td>NS</td></tr>
<tr><td>Decrease size:</td><td>NS</td></tr>
<tr><td>No change in size:</td><td>NS</td></tr>
</table>
Other outcomes
<table>
<tr><td>Primary conversion:</td><td>NS</td></tr>
<tr><td>Delayed conversion:</td><td>NS</td></tr>
<tr><td>Secondary intervention EVAR:</td><td>NS</td></tr>
</table>
<table>
<tr><th rowspan="2">Adverse events</th><th rowspan="2">Follow-up</th><th colspan="3">EVAR</th></tr>
<tr><th>n</th><th>N</th><th>%</th></tr>
<tr><td>Local wound complication</td><td><30 days</td><td>2</td><td>151</td><td>1.3</td></tr>
<tr><td>Cardiac event</td><td><30 days</td><td>6</td><td>151</td><td>4.0</td></tr>
<tr><td>Haemorrhage</td><td><30 days</td><td>4</td><td>151</td><td>2.6</td></tr>
<tr><td>Colonic ischaemia</td><td><30 days</td><td>3</td><td>151</td><td>2.0</td></tr>
<tr><td>Renal impairment</td><td><30 days</td><td>5</td><td>151</td><td>3.3</td></tr>
<tr><td>Type I endoleak</td><td><30 days</td><td>10</td><td>151</td><td>6.6</td></tr>
<tr><td>Type II endoleak</td><td><30 days</td><td>6</td><td>151</td><td>4.0</td></tr>
<tr><td>Type III endoleak</td><td><30 days</td><td>0</td><td>151</td><td>0</td></tr>
<tr><td>Type IV endoleak</td><td><30 days</td><td>2</td><td>151</td><td>1.3</td></tr>
</table>
</td>
</tr>
</table>

Author(s)

Allaqaband 2004[21]

Design: Comparative observational study

Type: EVAR vs. EVAR (Normal vs. High risk)

Country: North America

Setting: Single centre

Recruitment period: February 2000 to July 2002

Funding: Not stated

Participant characteristics

Inclusion criteria: AAA >5.0 cm or >4.0cm and increased by 0.5 cm in 6 months. AAA neck > 15 mm length and 18-26 mm diameter.

Exclusion criteria: Ruptured AAA

Patient population

	EVAR
No of participants:	60
No of males:	58 (97%)
Average age (range):	72 (54-88)
Max AAA diameter (cm):	6
No referred for EVAR:	NS
No for whom EVAR is appropriate:	NS

Co-morbidities:

	EVAR
Hypertension	62%
Smoking	50%
COPD	25%
Cardiac event	43%

All patients were high risk and unsuitable for open repair. Classified according to the Society for Vascular Surgery/International Society for Cardiovascular Society (level I to level III).

Length of follow-up (range): 14 (NS)

Losses to follow-up: Not stated

Intervention details

Total number of EVAR: 60

Stent make
AneuRx: 57
Ancure: 3

Graft type
Not stated

Comparator(s): None

Results

Clinical outcomes	EVAR	High risk EVAR
Total number:	15	45
Deploy success:	15	44
Technical success:	NS	NS
Duration:	NS	NS
30-day mortality rate:	0	2
Blood loss (ml):	NS	NS
Days in ITU:	NS	NS
Days in hospital:	NS	NS

Change in aneurysm size

Average post-AAA size:	NS
Increase size:	0
Decrease size:	NS
No change in size:	NS

Other outcomes

Primary conversion:	1
Delayed conversion:	0
Secondary intervention EVAR:	NS
Secondary intervention High risk EVAR	NS

Adverse events	Follow-up	EVAR		
		n	N	%
Access artery injury	<30 days	2	60	3.3
Type I endoleak	NS	1	58	1.7
Graft limb thrombosis	<3 months	2	58	3.4
Mortality non AAA	6 months	1	58	1.7
Renal impairment	<30 days	0	58	0

Author(s)

Becquemin 2004[27]

Design: Comparative observational study

Type: EVAR vs. EVAR

Country: France

Setting: Single centre

Recruitment period: January 1995 to December 2002

Funding: Not stated

Participant characteristics

Inclusion criteria: Nonruptured atherosclerotic abdominal aneurysms

Exclusion criteria: Ruptured and iliac aneurysms

Patient population

	EVAR
No of participants:	250
No of males:	234 (94%)
Average age (range):	71 (NS)
Max AAA diameter (cm):	5
No referred for EVAR:	NS
No for whom EVAR is appropriate:	NS

Co-morbidities:

	EVAR
Hypertension	NS
Smoking	NS
COPD	NS
Cardiac event	NS
ASA III/IV	149

Length of follow-up (range): 28 months

Losses to follow-up: Not stated

Intervention details

Total number of EVAR: 250

Stent make
Stentor: 8
Vanguard: 58
EVT: 13
Talent: 6
Stenway: 10
Cook: 111
AneuRx: 21
Excluder: 22

Graft type
Not stated

Comparator(s): None

Results

Clinical outcomes	EVAR I (without secondary intervention)	EVAR II (with secondary intervention)
Total number:	182	68
Deploy success:	NS	NS
Technical success:	NS	NS
Duration:	NS	NS
30-day mortality rate:	4	1
Blood loss (ml):	NS	NS
Days in ITU:	NS	NS
Days in hospital:	NS	NS

Change in aneurysm size

Average post-AAA size:	NS
Increase size:	NS
Decrease size:	NS
No change in size:	NS

Other outcomes

Primary conversion:	NS
Delayed conversion:	11
Secondary intervention EVAR I	0
Secondary intervention EVAR II:	112

Adverse events	Follow-up	EVAR		
		n	N	%
Type I endoleak	NS	36	250	14.4
Type II endoleak	NS	33	250	13.2
Stent migration	NS	4	250	1.6
Graft limb thrombosis	NS	15	250	6.0
Mortality Total	1 year	15	250	6.0
Mortality Total	3 years	43	250	17.2
Type III endoleak	NS	12	250	4.8
Graft stenosis	NS	8	250	3.2

Author(s)

Biebl 2004[23]

Design: Comparative observational study (retrospective)

Type: EVAR vs. EVAR

Country: North America

Setting: Single centre

Recruitment period: June 1999 to September 2003

Funding: Not stated

Participant characteristics

Inclusion criteria: Not stated

Exclusion criteria: Iliac diameter <7 mm, Proximal neck with mural thrombus, angulation >60 degrees

Patient population

	EVAR
No of participants:	182
No of males:	169 (93%)
Average age (range):	72
Max AAA diameter (cm):	6
No referred for EVAR:	NS
No for whom EVAR is appropriate:	NS

Co-morbidities:

	<80 yrs	>80 yrs
Hypertension	68%	63%
Diabetes mellitus	14%	10%
Smoking	47%	29%
COPD	47%	55%
CAD	60%	65%
ASA IV	16%	14%

Length of follow-up (range): 16 months (0 to 43 month)

Losses to follow-up:

Intervention details

Total number of EVAR: 182

Stent make
AneuRx: 87
Zenith: 40
Talent: 18

Graft type
Not stated

Comparator(s):

Results

Clinical outcomes	<80 yrs	>80 yrs
Total number:	133	49
Deploy success:	NS	NS
Technical success:	130	47
Duration (min):	182	179
30-day mortality rate:	1	0
Blood loss (ml):	470	470
Days in ITU:	NS	NS
Days in hospital:	4	4

Change in aneurysm size

Average post-AAA size:	NS
Increase size:	5
Decrease size:	NS
No change in size:	NS

Other outcomes

Primary conversion:	NS
Delayed conversion:	3
Secondary intervention:	27

Adverse events	Follow-up	EVAR		
		n	N	%
Local wound complication*	<30 days	12	182	6.6
Stent migration	NS	7	182	3.9
Graft infection	NS	0	182	0
Cardiac event	<30 days	2	182	1.1
Graft limb thrombosis	NS	5	182	2.8
AAA rupture	NS	0	182	0
Renal impairment	<30 days	29	182	15.9
Mortality Total	1 year	12	182	6.6
Graft migration	NS	7	182	3.8
Endoleak (type unspecified)	<30 days	22	182	12.1
Type I endoleak	NS	6	182	3.3
Type II endoleak	NS	31	182	17.0
Type III endoleak	NS	1	182	0.5
*included wound infection and groin lymphoceles				

<table>
<tr><th>Author(s)</th><th>Participant characteristics</th><th>Intervention details</th><th>Results</th></tr>
<tr>
<td>Blankensteijn 2005

Design: RCT

Type: EVAR versus open repair

Country: Netherlands & Belgium

Setting: Multicentre

Recruitment period: November 2000 to December 2003

Funding: Netherlands National Health Insurance Council</td>
<td>See Prinssen 2004[44]

Length of follow-up (range)
Open repair: mean 21 months (0-39)
EVAR: mean 22 months (1-42)

Losses to follow-up: 19</td>
<td>Total number of EVAR: 173

Stent make
See Prinssen 2004[44]

Graft type
See Prinssen 2004[44]

Comparator(s)
Open repair: 178</td>
<td>
<table>
<tr><th>Clinical outcomes</th><th>EVAR</th><th>Open repair</th></tr>
<tr><td>Total number:</td><td colspan="2" rowspan="8">See Prinssen 2004[44]</td></tr>
<tr><td>Deploy success:</td></tr>
<tr><td>Technical success:</td></tr>
<tr><td>Duration (min):</td></tr>
<tr><td>30-day mortality rate:</td></tr>
<tr><td>Blood loss (ml):</td></tr>
<tr><td>Days in ITU:</td></tr>
<tr><td>Days in hospital:</td></tr>
</table>

Cumulative survival rate at 2 years: 89.6% open repair vs. 89.7% EVAR (difference of -0.1 percentage points, 95% CI -6.8 to 6.7 percentage points; p=0.86)

Cumulative rate of aneurysm-related death at 2 years: 5.7% open repair vs. 2.1% EVAR (difference of 3.7 percentage points, 95% CI -0.5 to 7.9 percentage points; p=0.05)

Rates of survival free of severe events at 2 years: 80.6% open repair vs. 83.1% EVAR (difference of -2.5 percentage points, 95% CI -10.9 to 5.9 percentage points; p=0.39)

Rate of re-intervention at 9 months: EVAR vs. open repair HR 2.9, 95% CI 1.1 to 6.2; p=0.03

<table>
<tr><th rowspan="2">Event</th><th rowspan="2">Follow-up</th><th colspan="3">EVAR</th><th colspan="3">Open repair</th></tr>
<tr><th>n</th><th>N</th><th>%</th><th>n</th><th>N</th><th>%</th></tr>
<tr><td>All cause mortality</td><td>NS</td><td>20</td><td>173</td><td>11.6</td><td>18</td><td>178</td><td>10.1</td></tr>
<tr><td>Cardiovascular deaths</td><td>NS</td><td>7</td><td>173</td><td>4.0</td><td>5</td><td>178</td><td>2.8</td></tr>
<tr><td>Aneurysm-related</td><td>NS</td><td>2</td><td>173</td><td>1.2</td><td>8</td><td>178</td><td>4.5</td></tr>
</table>
</td>
</tr>
</table>

<table>
<tr><th>Author(s)</th><th>Participant characteristics</th><th>Intervention details</th><th>Results</th></tr>
<tr>
<td>Boult 2004[29]

Design: Population-based registry

Type: EVAR

Country: Australia

Setting: Multicentre

Recruitment period: November 1999 to May 2001

Funding: Not stated</td>
<td>Inclusion criteria: Not stated

Exclusion criteria: Not stated

Patient population
<table>
<tr><th></th><th>EVAR</th></tr>
<tr><td>No of participants:</td><td>950</td></tr>
<tr><td>No of males:</td><td>816 (86%)</td></tr>
<tr><td>Average age (range):</td><td>75 (NS)</td></tr>
<tr><td>Max AAA diameter (cm):</td><td>6</td></tr>
<tr><td>No referred for EVAR:</td><td>NS</td></tr>
<tr><td>No for whom EVAR is appropriate:</td><td>NS</td></tr>
</table>
Co-morbidities:
<table>
<tr><th></th><th>EVAR</th></tr>
<tr><td>Hypertension</td><td>NS</td></tr>
<tr><td>Smoking</td><td>NS</td></tr>
<tr><td>COPD</td><td>NS</td></tr>
<tr><td>Cardiac event</td><td>NS</td></tr>
<tr><td>ASA III</td><td>59%</td></tr>
</table>
Length of follow-up (range): Not stated

Losses to follow-up: Not stated</td>
<td>Total number of EVAR: 950

Stent make
Zenith: 785
Ancure: 14
AneuRx: 62
Excluder: 41
Talent: 35
Vanguard: 7

Graft type
Bifurcated: 865

Comparator(s): None</td>
<td>
<table>
<tr><th>Clinical outcomes</th><th>EVAR</th></tr>
<tr><td>Total number:</td><td>950</td></tr>
<tr><td>Deploy success:</td><td>NS</td></tr>
<tr><td>Technical success:</td><td>853</td></tr>
<tr><td>Duration:</td><td>NS</td></tr>
<tr><td>30-day mortality rate:</td><td>16</td></tr>
<tr><td>Blood loss (ml):</td><td>NS</td></tr>
<tr><td>Days in ITU:</td><td>NS</td></tr>
<tr><td>Days in hospital:</td><td>7.4</td></tr>
</table>
Change in aneurysm size
<table>
<tr><td>Average post-AAA size:</td><td>NS</td></tr>
<tr><td>Increase size:</td><td>NS</td></tr>
<tr><td>Decrease size:</td><td>NS</td></tr>
<tr><td>No change in size:</td><td>NS</td></tr>
</table>
Other outcomes
<table>
<tr><td>Primary conversion:</td><td>9</td></tr>
<tr><td>Delayed conversion:</td><td>NS</td></tr>
<tr><td>Secondary intervention EVAR:</td><td>223</td></tr>
</table>
<table>
<tr><th rowspan="2">Adverse events</th><th rowspan="2">Follow-up</th><th colspan="3">EVAR</th></tr>
<tr><th>n</th><th>N</th><th>%</th></tr>
<tr><td>Type I endoleak</td><td><30 days</td><td>25</td><td>950</td><td>2.6</td></tr>
<tr><td>Type II endoleak</td><td><30 days</td><td>44</td><td>950</td><td>4.6</td></tr>
<tr><td>Cardiac event</td><td><30 days</td><td>69</td><td>950</td><td>7.3</td></tr>
<tr><td>Graft related complications*</td><td>NS</td><td>131</td><td>950</td><td>13.7</td></tr>
<tr><td colspan="5">*included failed access, access vessel complications, failed and misplaced deployment of endografts, imperfect seal, twist/kink/obstruction and embolisation.</td></tr>
</table>
Patients unsuitable for open repair
410 patients were unsuitable for open repair. 30 day mortality rate was 2.4% (10/410), 17% had graft related complications (70/410) and 26.6% (109/410) had systemic complications.
</td>
</tr>
</table>

Author(s)

Cao 2004[18]

Design: Non-randomised controlled trial

Type: EVAR vs. Open repair

Country: Italy

Setting: Single centre

Recruitment period: January 1997 to December 2003

Funding: Not stated

Participant characteristics

Inclusion criteria: Not stated

Exclusion criteria: Repeat aortic surgery, thoracoabdominal or suprarenal aneurysms, Ruptured AAA.

Patient population

	EVAR	Open repair
No of participants:	534	585
No of males:	502 (94%)	527 (90%)
Average age (range):	73 (NS)	72 (NS)
Median AAA diameter (cm):	5.2	5.6
No referred for EVAR:	NS	NS
No for whom EVAR is appropriate:	NS	NS

Co-morbidities:

	EVAR	Open repair
Hypertension	66%	66%
Diabetes mellitus	9%	7%
Smoking	NS	NS
COPD	56%	38%
CAD	46%	37%
ASA IV	16%	6%

Length of follow-up (range): Not stated

Losses to follow-up: 1

Intervention details

Total number of EVAR: 534

Stent make
AneuRx: 239
Zenith: 109
Excluder: 71
Talent: 69
Quantum/Fortron: 31
Anaconda: 11
Endologix: 3
Endofit: 1

Graft type
Tube: 4
Bifurcated: 520
Uniiliac: 10

Comparator(s)
Open repair: 585

Results

Clinical outcomes	EVAR	Open repair
Total number:	534	585
Deploy success:	NS	-
Technical success:	NS	-
Duration (min):	120	180
30-day mortality rate:	5	24
Blood loss (ml):	200	1400
Days in ITU:	NS	NS
Days in hospital:	2	6

Change in aneurysm size

Average post-AAA size:	NS
Increase size:	39
Decrease size:	282
No change in size:	NS

Other outcomes

Primary conversion:	7
Delayed conversion:	19
Secondary intervention EVAR:	84
Secondary intervention Open repair:	17

Adverse events	Follow-up	EVAR			Open repair		
		n	N	%	n	N	%
Local wound complications	<30 days	13	534	2.4	13	585	2.2
Type I endoleak	NS	1	529	0.2	-	-	-
Type II endoleak	NS	31	529	5.9	-	-	-
Cardiac event	<30 days	9	534	1.7	25	585	4.3
Colonic ischaemia	<30 days	3	534	0.6	2	585	0.3
Lower limb ischaemia	<30 days	8	534	1.5	14	585	2.4
AAA rupture	<30 days	1	534	0.2	-	-	-
AAA rupture	NS	6	529	1.1	-	-	-
Renal impairment	<30 days	6	534	1.1	4	585	0.7
Pulmonary complications	<30 days	2	534	0.4	-	-	-
Respiratory complications*	NS	2	534	0.4	27	585	4.6
Mortality non AAA-related	NS	101	534	18.9	78	585	13.3

*included pneumonia, respiratory faliure and pneunothorax

Author(s)

Carpenter 2004[17]

Design: Non-randomised controlled trial

Type: EVAR vs. Open repair

Country: North America

Setting: Multicentre

Recruitment period: July 2000 to March 2003

Funding: Not stated

Participant characteristics

Inclusion criteria: AAA neck ≥ 15 mm length, < 60 degree angle, 18-26 mm diameter. AAA ≥ 4 cm diameter or rapidly growing. Dispensable inferior mesenteric artery. Infrarenal AAA. Fit for open repair

Exclusion criteria: Pregnancy, Connective tissue disorder. Life expectancy less than two years. Ruptures.

Patient population

	EVAR	Open repair
No of participants:	192	66
No of males:	170 (88%)	57 (86%)
Average age (range):	73 (52-88)	69 (56-83)
Max AAA diameter (cm):	5.1	5.8
No referred for EVAR:	NS	-
No for whom EVAR is appropriate:	NS	-

Co-morbidities:

	EVAR	Open repair
Hypertension	64%	70%
Diabetes mellitus	13%	18%
Smoking	83%	86%
COPD	32%	24%
Cardiac event	46%	59%

Length of follow-up (range): 22 months (NS)

Losses to follow-up:

Intervention details

Total number of EVAR: 192

Stent make
Powerlink: 192

Graft type
Tube: 0
Bifurcated: 192
Uniiliac: 0

Comparator(s)
Open repair: 66

Results

Clinical outcomes	EVAR	Open repair
Total number:	192	66
Deploy success:	188	-
Technical success:	167	-
Duration:	136	222
30-day mortality rate:	2	4
Blood loss (ml):	341	1583
Days in ITU:	1	4
Days in hospital:	3	10

Change in aneurysm size

Average post-AAA size:	4
Increase size:	2
Decrease size:	NS
No change in size:	NS

Other outcomes

Primary conversion:	3
Delayed conversion:	3
Secondary intervention EVAR:	29
Secondary intervention Open repair:	NS

Adverse events	Follow-up	EVAR			Open repair		
		n	N	%	n	N	%
Type I endoleak	<30 days	1	121	0.8	-	-	-
Type I endoleak	1 year	0	144	0	-	-	-
Type I endoleak	2 years	0	90	0	-	-	-
Type II endoleak	<30 days	22	121	18.2	-	-	-
Type II endoleak	1 year	16	144	11.1	-	-	-
Type II endoleak	2 years	3	90	3.3	-	-	-
Stent migration	NS	3	136	2.2	-	-	-
Cardiac event	<30 days	2	192	1.0	5	66	7.6
Mortality AAA related	NS	1	192	0.5			
Graft limb thrombosis	NS	4	188	2.1	-	-	-
Mortality total	NS	19	192	9.9	9	66	13.6
AAA rupture	NS	0	192	0	0	66	0
Type III endoleak	NS	0	144	0	-	-	-
Graft stenosis	NS	3	188	1.6	-	-	-
Renal impairment	<30 days	2	192	1.0	6	66	9.1
Pulmonary complications	<30 days	4	192	2.1	5	66	7.6

Author(s)

Cho 2004[30]

Design: Case series

Type: EVAR

Country: North America

Setting: Single centre

Recruitment period: May 1999 to July 2002

Funding: Not stated

Participant characteristics

Inclusion criteria: Not stated

Exclusion criteria: Not stated

Patient population

	EVAR
No of participants:	50
No of males:	NS
Average age (range):	73 (NS)
Max AAA diameter (cm):	5
No referred for EVAR:	0
No for whom EVAR is appropriate:	0

Co-morbidities:

	EVAR
Hypertension	NS
Smoking	NS
COPD	NS
Cardiac event	NS

Length of follow-up (range): 34 (NS)

Losses to follow-up: 5

Intervention details

Total number of EVAR: 50

Stent make
Excluder: 50

Graft type
Not stated

Comparator(s): None

Results

Clinical outcomes	EVAR
Total number:	50
Deploy success:	NS
Technical success:	NS
Duration:	NS
30-day mortality rate:	0
Blood loss (ml):	NS
Days in ITU:	NS
Days in hospital:	NS

Change in aneurysm size

Average post-AAA size:	5
Increase size:	7
Decrease size:	4
No change in size:	8

Other outcomes

Primary conversion:	1
Delayed conversion:	1
Secondary intervention EVAR:	0

Adverse events	Follow-up	EVAR		
		n	N	%
Mortality non AAA	6 months	3	49	6.1
AAA rupture	NS	0	45	0
Stent migration	NS	0	45	0
Mortality non AAA	NS	7	45	15.6
Type II endoleak	NS	8	45	17.8
Type I endoleak	NS	0	45	0
Type III endoleak	NS	0	45	0

Comments
Post AAA size 4.7 at 2 years, but 4.9 cm at 3 years.
Changes in size documented at last follow-up

Author(s)

Corriere 2004[24]

Design: Case series (retrospective)

Type: EVAR

Country: North America

Setting: Single centre

Recruitment period: 1993 to 2002

Funding: Not stated

Participant characteristics

Inclusion criteria: Not stated

Exclusion criteria: Not stated

Patient population

	EVAR
No of participants:	220
No of males:	194 (88%)
Average age (range):	72 (43-92)
Mean AAA diameter (cm):	6
No referred for EVAR:	NS
No for whom EVAR is appropriate:	NS

Co-morbidities:

	EVAR
Hypertension	NS
Smoking	NS
COPD	NS
Cardiac event	NS

Length of follow-up (range): Not stated

Losses to follow-up: Not stated

Intervention details

Total number of EVAR: 220

Stent make
Ancure: 158
Excluder: 51
AneuRx: 11

Graft type
Tube: 11
Bifurcated: 205
Uniiliac: 4

Comparator(s): None

Results

Clinical outcomes	EVAR
Total number:	NS
Deploy success:	NS
Technical success:	NS
Duration:	NS
30-day mortality rate:	NS
Blood loss (ml):	NS
Days in ITU:	NS
Days in hospital:	NS

Change in aneurysm size

Average post-AAA size:	NS
Increase size:	NS
Decrease size:	NS
No change in size:	NS

Other outcomes

Primary conversion:	NS
Delayed conversion:	NS
Secondary intervention EVAR:	NS
Secondary intervention High risk EVAR	NS

Adverse events	Follow-up	EVAR		
		n	N	%
Type I endoleak	NS	13	220	5.9
Type II endoleak	NS	35	220	15.9
Type III endoleak	NS	1	220	0.5
Endoleak (undefined)	NS	6	220	2.7
AAA rupture	NS	0	220	0

<table>
<tr><th>Author(s)</th><th>Participant characteristics</th><th>Intervention details</th><th>Results</th></tr>
<tr>
<td>Dalainas 2004[31]

Design: Case series (retrospective)

Type: EVAR

Country: Italy

Setting: Single centre

Recruitment period: October 1998 to January 2003

Funding: Not stated</td>
<td>Inclusion criteria: AAA ≥5 cm males, ≥4cm females, >4 cm and increased in size by 0.5cm in 6 months. Short life expectancy, anatomical criteria (proximal aneurysm neck length and diameter, the angulation between the longitudinal axis of the proximal neck and the longitudinal axis of the aneurysm, the diameter and status of the iliac arteries).

Exclusion criteria: Not stated

Patient population
<table>
<tr><th></th><th>EVAR</th></tr>
<tr><td>No of participants:</td><td>186</td></tr>
<tr><td>No of males:</td><td>140 (75%)</td></tr>
<tr><td>Average age (range):</td><td>71 (61-88)</td></tr>
<tr><td>Max AAA diameter (cm):</td><td>6</td></tr>
<tr><td>No referred for EVAR:</td><td>NS</td></tr>
<tr><td>No for whom EVAR is appropriate:</td><td>NS</td></tr>
</table>
Co-morbidities:
<table>
<tr><th></th><th>EVAR</th></tr>
<tr><td>Hypertension</td><td>62%</td></tr>
<tr><td>Diabetes mellitus</td><td>6%</td></tr>
<tr><td>Smoking</td><td>85%</td></tr>
<tr><td>COPD</td><td>9%</td></tr>
<tr><td>CAD</td><td>37%</td></tr>
</table>
Length of follow-up (range): mean 26 months (9 to 60)

Losses to follow-up: Not stated</td>
<td>Total number of EVAR: 186

Stent make
Excluder: 89
Lifepath:33
Endologix: 31
Vanguard: 23
Anaconda: 9
Talent: 1

Graft type
Tube: 7
Bifurcated: 166
Uniiliac: 13

Comparator(s): None</td>
<td>
<table>
<tr><th>Clinical outcomes</th><th>EVAR</th></tr>
<tr><td>Total number:</td><td>186</td></tr>
<tr><td>Deploy success:</td><td>182</td></tr>
<tr><td>Technical success:</td><td>NS</td></tr>
<tr><td>Duration (min):</td><td>182</td></tr>
<tr><td>30-day mortality rate:</td><td>2</td></tr>
<tr><td>Blood loss (ml):</td><td>370</td></tr>
<tr><td>Days in ITU:</td><td>NS</td></tr>
<tr><td>Days in hospital:</td><td>5</td></tr>
</table>
Change in aneurysm size
<table>
<tr><td>Average post-AAA size:</td><td>NS</td></tr>
<tr><td>Increase size:</td><td>NS</td></tr>
<tr><td>Decrease size:</td><td>NS</td></tr>
<tr><td>No change in size:</td><td>NS</td></tr>
</table>
Other outcomes
<table>
<tr><td>Primary conversion:</td><td>4</td></tr>
<tr><td>Delayed conversion:</td><td>4</td></tr>
<tr><td>Secondary intervention EVAR:</td><td>19</td></tr>
</table>
<table>
<tr><th rowspan="2">Adverse events</th><th rowspan="2">Follow-up</th><th colspan="3">EVAR</th></tr>
<tr><th>n</th><th>N</th><th>%</th></tr>
<tr><td>Local wound complications</td><td><30 days</td><td>27</td><td>182</td><td>14.8</td></tr>
<tr><td>Type I endoleak</td><td>NS</td><td>12</td><td>182</td><td>6.6</td></tr>
<tr><td>Type II endoleak</td><td>NS</td><td>5</td><td>182</td><td>2.7</td></tr>
<tr><td>Cardiac event</td><td><30 days</td><td>3</td><td>182</td><td>1.6</td></tr>
<tr><td>Renal impairment</td><td><30 days</td><td>7</td><td>182</td><td>3.8</td></tr>
</table>
</td>
</tr>
</table>

Author(s)

Elkouri 2004[25]

Design: Non-randomised controlled trial (retrospective)

Type: EVAR vs. Open repair

Country: North America

Setting: Single centre

Recruitment period: December 1999 to December 2001

Funding:

Participant characteristics

Inclusion criteria: Asymptomatic, elective AAA

Exclusion criteria: Juxta-renal, false or mycotic aneurysms, dissected or ruptured aneurysms

Patient population

	EVAR	Open repair
No of participants:	94	261
No of males:	85 (90%)	229 (88%)
Average age (range):	73 (52-90)	77 (61-98)
Max AAA diameter (cm):	6	6
No referred for EVAR:	NS	-
No for whom EVAR is appropriate:	NS	-

Co-morbidities:

	EVAR	Open repair
Hypertension	81%	69%
Smoking (current)	12%	18%
COPD	30%	25%
CAD	61%	59%

Length of follow-up (range): Not stated

Losses to follow-up: 44

Intervention details

Total number of EVAR: 94

Stent make
Ancure: 38
AneuRx: 53
Endologix: 3

Graft type
Not stated

Comparator(s)
Open repair: 261

Results

Clinical outcomes	EVAR	Open repair
Total number:	94	261
Deploy success:	93	-
Technical success:	69	-
Duration:	NS	NS
30-day mortality rate:	0	3
Blood loss (ml):	NS	NS
Days in ITU:	1	2
Days in hospital:	3	8

Change in aneurysm size

Average post-AAA size:	NS
Increase size:	2
Decrease size:	28
No change in size:	63

Other outcomes

Primary conversion:	1
Delayed conversion:	NS
Secondary intervention EVAR:	20
Secondary intervention Open repair:	21

Adverse events	Follow-up	EVAR			Open repair		
		n	N	%	n	N	%
Local wound complications	<30 days	6	94	6.4	15	261	5.7
Cardiac event	<30 days	10	94	10.6	57	261	21.8
Renal impairment	<30 days	4	94	4.3	11	261	4.2
Pulmonary complications	<30 days	3	94	3.2	42	261	16.1
Graft related complications	<30 days	12	94	12.8	10	261	3.8
Endoleak (not specified)	NS	26	94	27.7	-	-	-

Author(s)

Espinosa 2005[32]

Design: Case series

Type: EVAR

Country: Brazil

Setting: Single centre

Recruitment period: June 1997 to June 2003

Funding:

Participant characteristics

Inclusion criteria: AAA >4.5 cm or >0.5cm increase in 6 months.

Exclusion criteria: AAA <4.0 cm, Prox neck <0.5 cm, rupture, suprarenal AAA, Bilateral iliac occlusion

Patient population

	EVAR
No of participants:	193
No of males:	171 (89%)
Average age (range):	71 (52-89)
Max AAA diameter (cm):	6
No referred for EVAR:	267
No for whom EVAR is appropriate:	193

Co-morbidities:

	EVAR
ASA I	13.5%
ASA II	43.5%
ASA III	38.9%
ASA IV	3.6%

Length of follow-up (range): 36 months

Losses to follow-up: 26

Intervention details

Total number of EVAR: 193

Stent make
Talent: 193

Graft type
Tube: 2
Bifurcated: 177
Uniiliac: 12

Comparator(s): None

Results

Clinical outcomes	EVAR
Total number:	193
Deploy success:	191
Technical success:	178
Duration:	NS
30-day mortality rate:	7
Blood loss (ml):	NS
Days in ITU:	NS
Days in hospital:	NS

Change in aneurysm size

Average post-AAA size:	NS
Increase size:	NS
Decrease size:	NS
No change in size:	NS

Other outcomes

Primary conversion:	1
Delayed conversion:	NS
Secondary intervention EVAR:	NS

Adverse events	Follow-up	EVAR		
		n	N	%
Access artery injury	NS	4	193	2.1
Local wound complications	NS	6	193	3.1
Type II endoleak	<30 days	7	193	3.8
Type II endoleak	NS	6	191	3.1
Mortality AAA related	3 years	1	57	
Graft limb thrombosis	NS	0	191	0
Mortality non AAA	1 year	6	159	3.8
Mortality non AAA	5 years	25	193	13.0
AAA rupture	NS	1	193	0.5
Spinal cord ischaemia	NS	1	193	0.5

Author(s)

Fairman 2004[33]

Design: Comparative observational study (retrospective)

Type: EVAR vs. EVAR (Complicated vs. uncomplicated aortic necks)

Country: North America

Setting: Multicentre

Recruitment period: Not stated

Funding: Not stated

Participant characteristics

Inclusion criteria: Not stated. Complicated neck criteria included short <15 mm, angulated >45 degrees, calcified, thrombus lined, dilated >28 mm.

Exclusion criteria: Neck angulation >65 degrees

Patient population

	EVAR
No of participants:	237
No of males:	NS
Average age (range):	NS
Max AAA diameter (cm):	NS
No referred for EVAR:	NS
No for whom EVAR is appropriate:	NS

Co-morbidities:

	EVAR
Hypertension	NS
Smoking	NS
COPD	NS
Cardiac event	NS

Length of follow-up (range): 21 months

Losses to follow-up: Not stated

Intervention details

Total number of EVAR: 237

Stent make
Talent (low profile system):237

Graft type
Tube: 0
Bifurcated: 237
Uniiliac: 0

Comparator(s):

Results

Clinical outcomes	Complicated	Uncomplicated
Total number:	153	66
Deploy success:		
Technical success:		
Duration:	177	160
30-day mortality rate:		
Blood loss (ml):	321	351
Days in ITU:		
Days in hospital:		

Change in aneurysm size

	1 year (n=119)	2 years (n=16)	3 years (n=14)
Average post-AAA size:	NS	NS	NS
Increase size:	0	4	1
Decrease size:	29	8	7
No change in size:	90	4	6

Other outcomes

Primary conversion:	0
Delayed conversion:	6
Secondary intervention Complicated:	NS
Secondary intervention Uncomplicated:	NS

Adverse events	Follow-up	Complicated			Uncomplicated		
		n	N	%	n	N	%
Type I endoleak	NS	16	153	10.5	10	66	15.2
Type II endoleak	NS	18	153	11.8	8	66	12.1
Endoleak (type unknown)	NS	12	153	7.8	12	66	18.2
Renal complications	<30 days	23	153	15.0	6	66	9.1
Renal complications	NS	42	153	27.5	9	66	13.6

Author(s)

Garcia-Madrid 2004[34]

Design: Non-randomised controlled trial

Type: EVAR vs. Open repair

Country: Spain

Setting: Single centre

Recruitment period: March 1997 to August 2000

Funding: Fellowship grant from the Foundation Clinic

Participant characteristics

Inclusion criteria: AAA >5.0cm, patient suitable for EVAR or open repair.

Exclusion criteria: Ruptured, juxtarenal, iliac aneurysms.

Patient population

	EVAR	Open repair
No of participants:	53	30
No of males:	51 (96%)	28 (93%)
Median age (range):	73 (52-85)	70 (50-90)
Mean AAA diameter (cm):	6.2	6.4
No referred for EVAR:	NS	-
No for whom EVAR is appropriate:	NS	-

Co-morbidities:

	EVAR	Open repair
Hypertension	85%	60%
Diabetes mellitus	24%	7%
Smoking	87%	65%
COPD	70%	50%
Cardiac event	54%	54%

Length of follow-up (range): 26 months

Losses to follow-up: Not stated

Intervention details

Total number of EVAR: 53

Stent make
Not stated

Graft type
Tube: 1
Bifurcated: 47
Uniiliac: 5

Comparator(s)
Open repair: 30

Results

Clinical outcomes	EVAR	Open repair
Total number:	53	30
Deploy success:	NS	NS
Technical success:	48	30
Duration (min):	125	180
30-day mortality rate:	2	2
Blood loss (ml):	NS	NS
Days in ITU:	2 hours	17 hours
Days in hospital:	2	6

Change in aneurysm size

Average post-AAA size:	NS
Increase size:	NS
Decrease size:	NS
No change in size:	NS

Other outcomes

Primary conversion:	0
Delayed conversion:	NS
Secondary intervention EVAR:	1
Secondary intervention Open repair:	9

Adverse events	Follow-up	EVAR			Open repair		
		n	N	%	n	N	%
Type I endoleak	<30 days	2	53	3.8	-	-	-
Type I endoleak	NS	1	53	1.9	-	-	-
Type II endoleak	<30 days	3	53	5.7	-	-	-
Type II endoleak	NS	2	53	3.8	-	-	-
Cardiac event	<30 days	2	53	3.8	1	30	3.3
Mortality total	3 years	6	53	11.0	8	30	27.0
Type III endoleak	NS	6	53	11.3	-	-	-

Author(s)

Greenberg 2004[35]

Design: Non-randomised controlled trial

Type: EVAR vs. Open surgery

Country: North America

Setting: Multicentre

Recruitment period: January 2000 to June 2001

Funding: Cook Inc.**z**

Participant characteristics

Inclusion criteria: Not stated

Exclusion criteria: Not stated

Patient population

	EVAR	Open repair
No of participants:	352	80
No of males:	NS	NS
Average age (range):	NS	NS
Max AAA diameter (cm):	NS	NS
No referred for EVAR:	NS	NS
No for whom EVAR is appropriate:	NS	NS

Co-morbidities:

	EVAR	Open repair
Hypertension	NS	NS
Smoking	NS	NS
COPD	NS	NS
Cardiac event	NS	NS

Length of follow-up (range): Not stated

Losses to follow-up: Not stated

Intervention details

Total number of EVAR: 352
Standard risk: 200
High risk: 100
Roll-in group*: 52

Stent make
Zenith: 352

Graft type
Not stated

Comparator(s)
Open repair: 80

*received treatment at centres that were achieving familiarity with the device.

Results

Clinical outcomes	EVAR	Open repair
Total number:	200	80
Deploy success:	199	79
Technical success*:	165	-
Duration:	NS	NS
30-day mortality rate:	1	2
Blood loss (ml):	NS	NS
Days in ITU:	NS	NS
Days in hospital:	NS	NS

*Defined as no Type I or III endoleak at 30 days

Change in aneurysm size

Average post-AAA size:	NS
Increase size:	3*
Decrease size:	NS
No change in size:	NS
*at 1 year	

Other outcomes

Primary conversion:	0
Delayed conversion:	4
Secondary intervention EVAR:	22
Secondary intervention Open repair	2

Adverse events	Follow-up	EVAR			Open repair		
		n	N	%	n	N	%
Stent migration	1 year	4	200	2.0	-	-	-
Graft infection	NS	2	200	1.0	-	-	-
Cardiac event	<30 days	6	200	3.0	9	80	11.3
Mortality AAA related	1 year	1	200	0.5	3	80	3.8
Mortality Total	1 year	7	200	3.5	3	80	3.8
Wire fracture	1 year	4	200	2.0	-	-	-
Renal impairment	<30 days	5	200	2.5	9	80	11.3
Renal impairment	1 year	5	200	2.5	3	80	3.8
Pulmonary complications	<30days	2	200	1.0	13	80	16.3

<table>
<tr><th>Author(s)</th><th>Participant characteristics</th><th>Intervention details</th><th>Results</th></tr>
<tr>
<td>Greenhalgh 2004[22]

Design: Randomised controlled trial

Type: EVAR vs. Open repair (EVAR I)

Country: United Kingdom

Setting: Multicentre

Recruitment period: September 1999 to December 2003

Funding: National Health Service Research and Development Health Technology Assessment Programme.</td>
<td>Inclusion criteria: Aged >60 Years. AAA >5.5cm. Anatomically suitable for EVAR. Medically suitable for OR.

Exclusion criteria: Not stated

Patient population
<table>
<tr><th></th><th>EVAR</th><th>Open repair</th></tr>
<tr><td>No of participants:</td><td>543</td><td>539</td></tr>
<tr><td>No of males:</td><td>494 (91%)</td><td>489 (91%)</td></tr>
<tr><td>Average age (range):</td><td>74.2 (NS)</td><td>74.0 (NS)</td></tr>
<tr><td>AAA diameter (cm):</td><td>6.5</td><td>6.5</td></tr>
<tr><td>No referred for EVAR:</td><td>NS</td><td>-</td></tr>
<tr><td>No for whom EVAR is appropriate:</td><td>NS</td><td>-</td></tr>
</table>
Co-morbidities:
<table>
<tr><th></th><th>EVAR</th><th>Open repair</th></tr>
<tr><td>Diabetes</td><td>9%</td><td>12%</td></tr>
<tr><td>Smoking</td><td>89%</td><td>92%</td></tr>
<tr><td>Cardiac disease</td><td>44%</td><td>43%</td></tr>
</table>
Length of follow-up (range): 30 days

Losses to follow-up: 24</td>
<td>Total number of EVAR: 531

Stent make
Zenith: 271
Talent: 175
Excluder: 37
AneuRx: 21
Quantum/Teramed: 11

Graft type
Tube: 0
Bifurcated: 478
Uniiliac: 53

Comparator(s)
Open repair: 516</td>
<td>
<table>
<tr><th>Clinical outcomes</th><th>EVAR</th><th>Open repair</th></tr>
<tr><td>Total number:</td><td>531</td><td>516</td></tr>
<tr><td>Deploy success:</td><td>NS</td><td>NS</td></tr>
<tr><td>Technical success:</td><td>NS</td><td>NS</td></tr>
<tr><td>Duration:</td><td>180</td><td>200</td></tr>
<tr><td>30-day mortality rate:</td><td>9</td><td>24</td></tr>
<tr><td>Blood loss (ml):</td><td>NS</td><td>NS</td></tr>
<tr><td>Days in ITU:</td><td>NS</td><td>NS</td></tr>
<tr><td>Days in hospital:</td><td>7</td><td>12</td></tr>
</table>
Change in aneurysm size
<table>
<tr><td>Average post-AAA size:</td><td>NS</td></tr>
<tr><td>Increase size:</td><td>NS</td></tr>
<tr><td>Decrease size:</td><td>NS</td></tr>
<tr><td>No change in size:</td><td>NS</td></tr>
</table>
Other outcomes
<table>
<tr><td>Primary conversion:</td><td>10</td></tr>
<tr><td>Delayed conversion:</td><td>NS</td></tr>
<tr><td>Secondary intervention EVAR:</td><td>52</td></tr>
<tr><td>Secondary intervention High risk EVAR</td><td>30</td></tr>
</table>
<table>
<tr><th rowspan="2">Adverse events</th><th rowspan="2">Follow-up</th><th colspan="3">EVAR</th></tr>
<tr><th>n</th><th>N</th><th>%</th></tr>
<tr><td colspan="5">None reported</td></tr>
</table>
</td>
</tr>
</table>

Author(s)	Results
Greenhalgh 2005a[45] Design: RCT Type: EVAR versus open repair Country: UK Setting: Multicentre Recruitment period: September 1999 to December 2003 Funding: National Health Service Research and Development Health Technology Assessment Programme. Length of follow-up (range): median 2.9 years (IQR 1.9-4.0) Losses to follow-up: 6 *For Participant Characteristics and Intervention Details see Greenhalgh 2004*[22]	

Outcome by intention to treat	EVAR	Open repair	Hazard ratio (HR) from Cox regression model								
			Crude			Primary Adjusted[b]			Secondary Adjusted[c]		
			HR	95% CI	p	HR	95% CI	p	HR	95% CI	p
Aneurysm-related deaths [a]	19/543	34/539	0.55	[0.31-0.96]	(0.04)	0.55	[0.31-0.96]	(0.04)	0.51	[0.29-0.92]	(0.02)
Deaths from all causes	100/543	109/539	0.90	[0.69-1.18]	(0.46)	0.90	[0.69-1.19]	(0.46)	0.88	[0.67-1.16]	(0.36)

[a] Defined as deaths occurring within 30 days of any surgery for abdominal aortic aneurysm plus deaths with underlying cause given as ICD10 codes I713-I719.
[b] Adjusted for age, sex, forced expiratory volume in 1 second (FEV_1), AAA diameter, log[creatinine] and statin use.
[c] Adjusted for already included variables in the primary adjustment plus body mass index, smoking, systolic blood pressure and serum cholesterol.

Complications - <30 days after primary AAA repair	EVAR n=543	Open repair n=539
Procedure related AAA (elective)		
AAA rupture => emergency repair	7	23
Died of rupture after elective AAA repair	1	1
Other cardiovascular	1	0
Total no. of deaths (total no. of patients)	0	1
	9(532)	*25(518)*

Complications - >30 days after primary AAA repair	EVAR n=543	Open repair n=539
Procedure related AAA (elective)		
Late in-hospital death after AAA rupture	1	1
Died of rupture after elective AAA repair	1	0
Coronary heart disease	5	1
Stroke	22	16
Other cardiovascular	9	6
Cancer, lung	6	3
Cancer, other	10	10
Respiratory	11	17
Renal	4	13
Other	4	1
Total no. of deaths (total no. of patients)	8	3
	81(523)	*71(493)*

Greenhalgh 2005a[45] continued

Post operative complication (Total number of complications)*	**EVARs n=529 †**		**Open repair n=519 †**	
	Complication N	**Re-intervention N**	**Complication N**	**Re-intervention N**
Graft rupture (9)	9	3	0	0
Graft infection (3)	1	1	2	0
Graft migration (14)	12	7		
‡ Endoleak type I (29)	27	17		
‡ Endoleak type III (10)	8	4		
Graft kinking (9)	6	2		
# Endotension (6)	6	0	1	0
‡ Endoleak type II (100)	79	17	1	0
Technical deployment problems (2)	2	2		
Unspecified endoleak (4)	4	4		
Graft thrombosis (14)	12	10	1	1
Graft stenosis (4)	2	0	1	0
Distal embolisation from graft (2)	1	0	0	0
Renal infarction (3)	3	0	0	0
Anastomotic aneurysm (2)	0	0	1	1
Iliac dilatation (6)	1	1	5	2
Re-exploration of open repair (16)	-	-	16	16
Other surgery required (29)	13 (13)	13	16	16
Totals (262 complications in 230 patients)	**186/529 = 35% [95% CI 31-39]**	**81/529=15% [95% CI 12-19]**	**44/519 = 8% [95% CI 6-11]**	**36/519=7% [95% CI 5-9]**

Author(s)

Greenhalgh 2005b[46]

Design: RCT

Type: EVAR versus no intervention

Country: UK

Setting: Multicentre

Recruitment period: September 1999 to December 2003

Funding: National Health Service Research and Development Health Technology Assessment Programme.

Participant characteristics

Inclusion criteria: Anatomic suitability for EVAR, aneurysm diameter 5.5 cm or greater, judged unfit for open repaor.

Exclusion criteria: Reported elsewhere

Patient population

	EVAR	No intervention
No of participants:	166	172
No of males:	141 (85%)	147 (85%)
Average age (range):	76.8 (NS)	76.0 (NS)
Max AAA diameter (cm):	6.7	6.6
No referred for EVAR:	NS	NS
No for whom EVAR is appropriate:	NS	NS

Co-morbidities:

	EVAR	No intervention
Diabetes	15%	13%
Smoking	94%	93%
Cardiac disease	65%	73%

Length of follow-up (range): median 2.4 years (IQR 1.6 to 3.6)

Losses to follow-up:

Intervention details

Total number of EVAR: 150

Stent make
Zenith: 60%
Talent: 22%
Excluder: 7%

Graft type
Bifurcated: 87%

Comparator(s)
No intervention: 172

Results

Clinical outcomes	EVAR
Total number:	166
Deploy success:	-
Technical success:	-
Duration:	-
30-day mortality rate:	13/150 (9%)
Elective cases:	*10/147 (7%)*
Blood loss (ml):	-
Days in ITU:	-
Days in hospital:	12

Other outcomes

Primary conversion:	2
Delayed conversion:	1
Secondary intervention EVAR:	11.5 per 100 person years
Secondary intervention no intervention:	1.8 per 100 person years

Death	EVAR	No intervention	Hazard Ratio [95% CI] (p) Crude
Aneurysm related	20/166	22/172	1.01 [0.55-1.84] (0.98)
1st 6 months	-	-	1.67 [0.72-3.86]
2nd 6 months	-	-	0.53 [0.20-1.39]
All-cause	74/166	68/172	1.21 (0.87-1.69) (0.25)
1st 6 months	-	-	1.31 [0.70-2.45]
2nd 6 months	-	-	1.18 [0.80-1.73]
All-cause*			1.07 [0.75-1.52] (0.70)
Aneurysm related*			0.77 [0.41-1.45] (0.43)

*per protocol

Author(s)	Participant characteristics	Intervention details	Results

Hinchliffe 2004[20]

Design: Case series

Type: EVAR

Country: UK

Setting: Multicentre

Recruitment period: April 1998 to November 2002

Funding: Not stated

Inclusion criteria: Not stated

Exclusion criteria: Not stated

Patient population

	EVAR
No of participants:	269
No of males:	241 (90%)
Average age (range):	74 (NS)
Max AAA diameter (cm):	6
No referred for EVAR:	0
No for whom EVAR is appropriate:	0

Co-morbidities:

	EVAR
Hypertension	42.8%
Diabetes	13.8%
Smoking (current)	24.5%
COPD	19.7%
CAD	10.9%

*21 symptomatic aneurysms.

Length of follow-up (range): 12 (NS)

Losses to follow-up: 0

Total number of EVAR: 269

Stent make
Zenith: 269

Graft type
Tube: 0
Bifurcated: 249
Uniiliac: 20

Comparator(s): None

Clinical outcomes	EVAR
Total number:	269
Deploy success:	0
Technical success:	240
Duration:	150
30-day mortality rate:	11
Blood loss (ml):	Median 400
Days in ITU:	0
Days in hospital:	0

Change in aneurysm size

Average post-AAA size:	NS
Increase size:	NS
Decrease size:	NS
No change in size:	NS

Other outcomes

Primary conversion:	0
Delayed conversion:	0
Secondary intervention EVAR:	21

Adverse events	Follow-up	EVAR		
		n	N	%
Type I endoleak	<30 days	2	255	0.8
Type II endoleak	<30 days	13	255	5.1
Type I endoleak	NS	2	255	0.8
Type II endoleak	NS	17	255	6.7
AAA rupture	NS	2	255	0.8
Stent migration	2 years	1	255	0.4
Cardiac event	NS	5	255	2.0
Mortality Total	NS	28	255	11.0

Comments
6/11 deaths occurred in the symptomatic group

Author(s)

Jordan 2004[36]

Design: Non-randomised controlled trial

Type: EVAR vs. Open repair

Country: North America

Setting: Single centre

Recruitment period: January 2000 to June 2002

Funding: Not stated

Participant characteristics

Inclusion criteria: Not stated

Exclusion criteria: Not stated

Patient population

	All patients
No of participants:	404
No of males:	347 (86%)
Average age (range):	73 (24-93)
Max AAA diameter (cm):	6
No referred for EVAR:	0
No for whom EVAR is appropriate:	0

Co-morbidities: Not stated

Patients were classified as low or high risk. High risk criteria included: Age >80Y, severe cardiac, pulmonary, renal or hepatic dysfunction, hostile abdomen, re-do aortic surgery.

Length of follow-up (range): 28 months (NS)

Losses to follow-up: 0

Intervention details

Total number of EVAR: 259 (n=130 high risk)

Stent make
AneuRx: 129
Ancure: 124
Unspecified: 6

Graft type
Not stated

Comparator(s): None
Open repair: 145 (n=87 high risk)

Results

Clinical outcomes	**EVAR**	**Open repair**
Total number:	259	145
Deploy success:	NS	NS
Technical success:	NS	NS
Duration:	NS	NS
30-day mortality rate:	6	12
Blood loss (ml):	NS	NS
Days in ITU:	NS	NS
Days in hospital:	4	12

Change in aneurysm size

Average post-AAA size:	NS
Increase size:	NS
Decrease size:	NS
No change in size:	NS

Other outcomes

Primary conversion:	1
Delayed conversion:	4
Secondary intervention EVAR:	0
Secondary intervention Open repair	0

Adverse events	**Follow-up**	**EVAR**			**Open repair**		
		n	**N**	**%**	**n**	**N**	**%**
Respiratory complications	NS	2	259	0.8	9	145	6.2
Cardiac event	NS	8	259	3.1	9	145	6.2
Renal impairment	NS	4	259	1.5	3	145	2.1
Local wound complications	NS	6	259	2.3	1	145	0.7
AAA rupture	NS	0	259	0	-	-	-

Comments
Includes 19 emergency procedures
All deaths occurred in high risk patients, none in low risk group.

Author(s)

Kocher 2004[37]

Design: Case series

Type: EVAR

Country: Czech

Setting: Single centre

Recruitment period: April 1996 onwards

Funding: Not stated

Participant characteristics

Inclusion criteria: Not stated

Exclusion criteria: Not stated

Patient population

	EVAR
No of participants:	120
No of males:	102 (85%)
Average age (range):	71 (49-89)
Max AAA diameter (cm):	0
No referred for EVAR:	170
No for whom EVAR is appropriate:	120

Co-morbidities:

	EVAR
Hypertension	82%
Diabetes	41%
COPD	30%
CAD	94%
ASA III/IV	102

Length of follow-up (range): 21 months (2-60 months)

Losses to follow-up: 2 patients

Intervention details

Total number of EVAR: 120

Stent make
Ella: 120

Graft type
Tube: 4
Bifurcated: 97
Uniiliac: 19

Comparator(s): None

Results

Clinical outcomes	EVAR
Total number:	120
Deploy success:	0
Technical success:	109
Duration (min):	98
30-day mortality rate:	4
Blood loss (ml):	0
Days in ITU:	2
Days in hospital:	6

Change in aneurysm size

Average post-AAA size:	NS
Increase size:	7
Decrease size:	44
No change in size:	24

Other outcomes

Primary conversion:	2
Delayed conversion:	0
Secondary intervention EVAR:	20
Secondary intervention High risk EVAR	0

Adverse events	Follow-up	EVAR		
		n	N	%
Type I endoleak	<30 days	10	120	8.3
Cardiac event	<30 days	6	120	5.0
Local wound complications*	<30 days	5	120	4.2
Colonic ischaemia	<30 days	0	120	0.0
Renal complications	<30 days	0	120	0.0
Spinal cord ischaemia	<30 days	0	120	0.0
Graft limb thrombosis	<30 days	4	120	3.3
Type II endoleak	NS	9	120	7.5
Graft limb thrombosis	NS	3	120	2.5
Mortality non AAA	NS	13	120	10.8

*including wound haematoma and lymphatic fistula

Comments
20 additional procedures were undertaken - 11 were at time of original procedure

Author(s)

Lee 2004[43]

Design: Non-randomised controlled trial

Type: EVAR vs. Open repair

Country: North America

Setting: Multicentre

Recruitment period: 2001

Funding: Not stated

Participant characteristics

Inclusion criteria: Age greater than 49 years

Exclusion criteria: Ruptured AAA, dissected AAA, coarctation, Marfans, Turners, PAN.

Patient population

	EVAR	Open repair
No of participants:	2565	4607
No of males:	2164 (84%)	1007 (22%)
Average age (range):	73 (NS)	72 (NS)
Max AAA diameter (cm):	NS	NS
No referred for EVAR:	NS	-
No for whom EVAR is appropriate:	NS	-

Co-morbidities:

	EVAR	Open repair
Hypertension	57%	53%
Diabetes	11%	11%
COPD	25%	29%
IHD	20%	14%

Length of follow-up (range): Not stated

Losses to follow-up: Not stated

Intervention details

Total number of EVAR: 2565

Stent make
Not stated

Graft type
Not stated

Comparator(s)
Open repair: 4607

Results

Clinical outcomes	EVAR	Open repair
Total number:	2565	4607
Deploy success:	NS	NS
Technical success:	NS	NS
Duration:	NS	NS
30-day mortality rate:	33	176
Blood loss (ml):	NS	NS
Days in ITU:	NS	NS
Days in hospital:	4	9

Change in aneurysm size

Average post-AAA size:	NS
Increase size:	NS
Decrease size:	NS
No change in size:	NS

Other outcomes

Primary conversion:	NS
Delayed conversion:	NS
Secondary intervention EVAR:	NS
Secondary intervention High risk EVAR	NS

Adverse events	Follow-up	EVAR			Open repair		
		n	N	%	n	N	%
Cardiac event	<30 days	77	2565	3.0	320	4607	6.9

Comments
None

Author(s)

Maldonado 2004[19]

Design: Case series (retrospective)

Type: EVAR

Country: North America

Setting: Single centre

Recruitment period: 1994 to 2003

Funding: Not stated

Participant characteristics

Inclusion criteria: Asymptomatic AAA

Exclusion criteria: Not stated

Patient population

	EVAR
No of participants:	311
No of males:	267 (86%)
Average age (range):	72 (58-93)
Max AAA diameter (cm):	6
No referred for EVAR:	NS
No for whom EVAR is appropriate:	NS

Co-morbidities:

	EVAR
Hypertension	NS
Smoking	NS
COPD	NS
Cardiac event	NS

Length of follow-up (range): 22 months (2-72)

Losses to follow-up: 24

Intervention details

Total number of EVAR: 311

Stent make
Ancure: 238
Excluder: 30
AneuRx: 28
Zenith: 15

Graft type
Tube: 14
Bifurcated: 297
Uniiliac: 0

Comparator(s): None

Results

Clinical outcomes	EVAR
Total number:	311
Deploy success:	NS
Technical success:	NS
Duration:	NS
30-day mortality rate:	2
Blood loss (ml):	NS
Days in ITU:	NS
Days in hospital:	NS

Change in aneurysm size

Average post-AAA size:	NS
Increase size:	NS
Decrease size:	NS
No change in size:	NS

Other outcomes

Primary conversion:	6
Delayed conversion:	0
Secondary intervention EVAR:	0
Secondary intervention High risk EVAR	0

Adverse events	Follow-up	EVAR		
		n	N	%
Ischaemic complications	NS	28	311	9.0
Lower limb ischaemia	NS	21	28	75.0
Pelvic ischaemia	NS	7*	28	25.0
Colonic ischaemia	NS	4	28	14.3
Buttock ischaemia	NS	2	28	7.1
Spinal cord ischaemia	NS	2	28	7.1
Graft limb thrombosis	NS	14	28	4.9
*2 patients died perioperatively				

Comments
None

Author(s)

Minor 2004[39]

Design: Case series

Type: EVAR

Country: North America

Setting: Single centre

Recruitment period: January 1997 to August 2002

Funding: Not stated

Participant characteristics

Inclusion criteria: Age ≥80 years

Exclusion criteria: Not stated

Patient population

	EVAR
No of participants:	150
No of males:	119 (79%)
Average age (range):	85 (80-95)
Mean AAA diameter (cm):	7
No referred for EVAR:	NS
No for whom EVAR is appropriate:	NS

Co-morbidities:

	EVAR
Hypertension	74%
Diabetes	16%
Smoking	30%
COPD	19%
CAD	75%

Length of follow-up (range): 17 months (1-61)

Losses to follow-up: Not stated

Intervention details

Total number of EVAR: 150

Stent make
Talent: 95
AneuRx: 6
Ancure: 5
Custom-made: 28
Excluder: 4
Vanguard: 5
Teramed: 2

Graft type
Tube: 16
Bifurcated: 87
Uniiliac: 42

Comparator(s): None

Results

Clinical outcomes	EVAR
Total number:	150
Deploy success:	145
Technical success:	143
Duration (min):	217
30-day mortality rate:	5
Blood loss (ml):	369
Days in ITU:	0
Days in hospital:	3

Change in aneurysm size

Average post-AAA size:	6.1
Increase size:	6 (4.3%)
Decrease size:	NS
No change in size:	NS

Other outcomes

Primary conversion:	3
Delayed conversion:	1
Secondary intervention:	21

Adverse events	Follow-up	EVAR		
		n	N	%
Access artery injury	<30 days	2	145	1.4
Type I endoleak	<30 days	4	145	2.8
Graft limb thrombosis	<30 days	3	145	2.1
Local wound complications	<30 days	7	145	4.8
Cardiac event	<30 days	7	145	4.8
Renal impairment	<30 days	2	145	1.4
Type II endoleak	<30 days	30	145	20.7
Type II enoleak	NS	11	140	7.9
Type I endoleak	NS	6	140	4.3
Type III endoleak	2 years	1	54	1.9
Mortality non AAA	NS	40	150	26.7

Comments
6/140 aneurysms increased in size during follow-up.

Author(s)

Prinssen 2004[44]

Design: Randomised controlled trial

Type: EVAR vs. Open repair (DREAM)

Country: Netherlands

Setting: Multicentre

Recruitment period: November 2000 to December 2003

Funding:

Participant characteristics

Inclusion criteria: Not stated

Exclusion criteria: Emergency repairs, inflammatory AAAs, CTDs, life expectancy <2Y

Patient population

	EVAR	Open repair
No of participants:	171	174
No of males:	159 (93%)	157 (90%)
Average age (range):	71 (NS)	70 (NS)
Max AAA diameter (cm):	6	6
No referred for EVAR:	NS	-
No for whom EVAR is appropriate:	NS	-

Co-morbidities:

	EVAR	Open repair
Hypertension	58%	54%
Diabetes	10%	10%
Smoking	65%	54%
COPD	28%	18%
Cardiac disease	41%	47%

Length of follow-up (range): 1 month (NS)

Losses to follow-up: 6

Intervention details

Total number of EVAR: 171

Stent make
Talent: 46
Zenith: 57
Excluder: 37

Graft type
Tube: 3
Bifurcated: 162
Uniiliac: 6

Comparator(s)
Open repair: 174

Results

Clinical outcomes	EVAR	Open repair
Total number:	171	174
Deploy success:	NS	NS
Technical success:	NS	NS
Duration:	135	151
30-day mortality rate:	2	8
Blood loss (ml):	394	1654
Days in ITU:	2	3
Days in hospital:	6	13

Change in aneurysm size

Average post-AAA size:	NS
Increase size:	NS
Decrease size:	NS
No change in size:	NS

Other outcomes

Primary conversion:	NS
Delayed conversion:	NS
Secondary intervention EVAR:	NS
Secondary intervention High risk EVAR	NS

Adverse events	Follow-up	EVAR			Open repair		
		n	N	%	n	N	%
Renal impairment	<30 days	2	171	1.2	2	174	1.1
Pulmonary complications	<30 days	5	171	2.9	19	174	10.9
Cardiac event	<30 days	9	171	5.3	10	174	5.7
CV/Spinal cord complications	<30 days	1	171	0.6	2	174	1.1
Colonic ischaemia	<30 days	1	171	0.6	2	174	1.1
Haemorrhage	<30 days	3	171	1.8	6	174	3.4
Graft infection	<30 days	1	171	0.6	2	174	1.1
Local wound complications	<30 days	6	171	3.5	6	174	3.4
Graft complications	<30 days	6	171	3.5	0	174	0.0
Graft limb thrombosis	<30 days	11	171	6.4	5	174	2.9

Comments
None

Author(s)

Sampaio 2004[40]

Design: Comparative observational study (retrospective)

Type: EVAR vs. EVAR

Country: North America

Setting: Single centre

Recruitment period: December 1996 to May 2003

Funding: Not stated

Participant characteristics

Inclusion criteria: Not stated

Exclusion criteria: Patient refusal, anastomotic aneurysms

Patient population

	EVAR
No of participants:	241
No of males:	212 (88%)
Average age (range):	75 (47-98)
Max AAA diameter (cm):	6
No referred for EVAR:	0
No for whom EVAR is appropriate:	0

Co-morbidities:

	Male	Female
Hypertension	73%	90%
Diabetes	19%	4%
Smoking	84%	48%
COPD	29%	38%
Cardiac event	34%	21%
Renal disease	13%	17%

Length of follow-up (range): 10 months (1-71)

Losses to follow-up: Not stated

Intervention details

Total number of EVAR: 241

Stent make
AneuRx: 175
Ancure: 42
Excluder: 6
Talent: 1
Vanguard: 5
Endologix: 6
EVT: 6

Graft type
Not stated

Comparator(s): None

Results

Clinical outcomes	EVAR male	EVAR female
Total number:	212	29
Deploy success:	NS	NS
Technical success:	NS	NS
Duration:	NS	NS
30-day mortality rate:	2	2
Blood loss (ml):	NS	NS
Days in ITU:	NS	NS
Days in hospital:	3	4

Change in aneurysm size

Average post-AAA size:	NS
Increase size:	NS
Decrease size:	7
No change in size:	NS

Other outcomes

Primary conversion:	0
Delayed conversion:	0
Secondary intervention EVAR male:	59
Secondary intervention EVAR female:	7

Adverse events	Follow-up	EVAR male			EVAR female		
		n	N	%	n	N	%
Type I endoleak	2 years	11	212	5.2	1	29	3.4
Type II endoleak	2 years	45	212	21.2	11	29	37.9
Prox neck inc	1 year	34	212	16.0	14	29	48.3

Comments
Female
F/u 11.7 months (range 1-61)
Mean Age 79.9 Y (66-89)
AAA Neck shorter and wider in female than male ($p<0.0001$)
EIA diameter narrower in female ($p<0.0001$)
More intra-operative manoeuvres required in female group

Author(s)

Vasquez 2004[41]

Design: Comparative observational study

Type: EVAR vs. EVAR

Country: North America

Setting: Single centre

Recruitment period: August 1998 to December 2003

Funding: Not stated

Participant characteristics

Inclusion criteria: Not stated

Exclusion criteria: AAA rupture, haemodialysis

Patient population

	EVAR
No of participants:	212
No of males:	187 (88%)
Average age (range):	75 (NS)
Max AAA diameter (cm):	6
No referred for EVAR:	0
No for whom EVAR is appropriate:	0

Co-morbidities:

	EVAR	Renal EVAR
Smoking	89%	89%
Diabetes	13%	16%
Cardiac event	23%	47%

Length of follow-up (range): Not stated

Losses to follow-up: Not stated

Intervention details

Total number of EVAR: 212

Stent make
AneuRx: 138
Talent: 59
Excluder: 14
Ancure: 2

Graft type
Not stated

Comparator(s): None

Results

Clinical outcomes	EVAR	Renal EVAR
Total number:	129	83
Deploy success:	NS	NS
Technical success:	NS	NS
Duration:	NS	NS
30-day mortality rate:	2	5
Blood loss (cc):	255	278
Days in ITU:	NS	NS
Days in hospital:	NS	NS

Change in aneurysm size

Average post-AAA size:	NS
Increase size:	NS
Decrease size:	NS
No change in size:	NS

Other outcomes

Primary conversion:	NS
Delayed conversion:	NS
Secondary intervention EVAR:	NS
Secondary intervention High risk EVAR	NS

Adverse events	Follow-up	EVAR		
		n	N	%
Renal impairment	<30 days	6*	212	2.8
Cardiac event	<30 days	15	212	7.1
Pulmonary complications	<30 days	9	212	4.2
Local wound complications	<30 days	8	212	3.8
Neurologic event	<30 days	5	212	2.4
Colonic ischaemia	<30 days	3	212	1.4

*5/6 renal impairments occurred in renal group.

Comments
None

Author(s)

Verhoeven 2004[42]

Design: Case series

Type: EVAR

Country: Netherlands

Setting: Single centre

Recruitment period: September 1996 to May 2003

Funding: Not stated

Participant characteristics

Inclusion criteria: AAA > 5.0 cm or sacular AAA > 4.0 cm, or assoc with IAA > 3.5cm.

Exclusion criteria: Not stated

Patient population

	EVAR
No of participants:	308
No of males:	290 (94%)
Average age (range):	70 (NS)
Mean AAA diameter (cm):	6
No referred for EVAR:	NS
No for whom EVAR is appropriate:	NS

Co-morbidities:

	EVAR
Hypertension	54%
Diabetes	8%
Smoking	56%
COPD	32%
Cardiac event	53%
Renal disease	13%

Length of follow-up (range): 36 months (NS)

Losses to follow-up: Not stated

Intervention details

Total number of EVAR: 308

Stent make
Zenith: 120
Vanguard: 68
Excluder: 56
Talent: 52
Quantum: 12

Graft type
Tube: 5
Bifurcated: 298
Uniiliac: 5

Comparator(s): None

Results

Clinical outcomes	EVAR
Total number:	308
Deploy success:	NS
Technical success:	NS
Duration:	NS
30-day mortality rate:	1
Blood loss (ml):	NS
Days in ITU:	NS
Days in hospital:	NS

Change in aneurysm size

Average post-AAA size:	NS
Increase size:	NS
Decrease size:	NS
No change in size:	NS

Other outcomes

Primary conversion:	1
Delayed conversion:	9
Secondary intervention :	72*

*in 47 patients

Adverse events	Follow-up	EVAR		
		n	N	%
Stent migration	NS	25	306	8.2
Graft limb thrombosis	NS	15	306	4.9
Type II endoleak	NS	26	306	8.5
AAA rupture	NS	1	306	0.3

Comments
Secondary technical success rate of 297/306 (97%).
Secondary intervention success rate of 80 % after endovascular techniques and 96% after open techniques.

Author(s)

Zeebregts 2004[77]

Design: Non-randomised controlled trial

Type: EVAR vs. Open repair

Country: Netherlands

Setting: Single centre

Recruitment period: April 1998 to January 2003

Funding: Not stated

Participant characteristics

Inclusion criteria: Infrarenal AAA. AAA >5.0 cm for pre-EVAR then >5.5 cm.

Exclusion criteria: Emergency ruptured AAAs, false aneurysms. For EVAR - neck length <10 mm or neck diam > 35 mm. Severe neck calcification or thrombus or iliac tortuosity.

Patient population

	EVAR
No of participants:	286
No of males:	260 (91%)
Average age (range):	70 (47-92)
Max AAA diameter (cm):	6
No referred for EVAR:	NS
No for whom EVAR is appropriate:	NS

Co-morbidities:

	EVAR
Hypertension	NS
Smoking	NS
COPD	NS
Cardiac event	NS

Length of follow-up (range): 19 months (NS)

Losses to follow-up: Not stated

Intervention details

Total number of EVAR: 93

Stent make
AneuRx: 71
Talent: 15
Zenith: 6

Graft type
Tube: 1
Bifurcated: 82
Uniiliac: 9

Comparator(s)
Open repair: 194

Results

Clinical outcomes	EVAR	Open repair
Total number:	93	194
Deploy success:	92	-
Technical success:	NS	NS
Duration:	148	NS
30-day mortality rate:	1	15
Blood loss (ml):	NS	NS
Days in ITU:	NS	NS
Days in hospital:	9	18

Change in aneurysm size

Average post-AAA size:	NS
Increase size:	NS
Decrease size:	NS
No change in size:	NS

Other outcomes

Primary conversion:	1
Delayed conversion:	0
Secondary intervention EVAR:	17
Secondary intervention Open repair:	0

Adverse events	Follow-up	EVAR			Open repair		
		n	N	%	n	N	%
Local wound complications	<30 days	10	0		14		
Cardiac event	<30 days	4	0		12		
Pulmonary complications	<30 days	2	0		42		
Haemorrhage	<30 days	0	0		23		
Mortality total	1 year	7	0		26		
Mortality total	2 years	11	0		27		

Comments
3 groups (open pre-EVAR (n=113), open post EVAR (n=82) and EVAR (n=93))

Author(s)

Ziaja 2003[26]

Design: Case series

Type: EVAR

Country: Poland

Setting: Single centre

Recruitment period: July 2000 to June 2003

Funding: Not stated

Participant characteristics

Inclusion criteria: Not stated

Exclusion criteria: Not stated

Patient population

	EVAR
No of participants:	52
No of males:	NS
Average age (range):	71 (53-80)
Max AAA diameter (cm):	NS
No referred for EVAR:	NS
No for whom EVAR is appropriate:	NS

Co-morbidities:

	EVAR
Hypertension	85%
Diabetes	10%
Smoking	50%
COPD	8%
Cardiac event	94%

Length of follow-up (range): 13 months (1-39)

Losses to follow-up: Not stated

Intervention details

Total number of EVAR: 52

Stent make
Zenith: 28
Powerlink: 23
Excluder: 1

Graft type
Not stated

Comparator(s): None

Results

Clinical outcomes	EVAR
Total number:	52
Deploy success:	NS
Technical success:	NS
Duration (min):	122
30-day mortality rate:	0
Blood loss (ml):	320
Days in ITU:	2
Days in hospital:	NS

Change in aneurysm size

Average post-AAA size:	NS
Increase size:	NS
Decrease size:	NS
No change in size:	NS

Other outcomes

Primary conversion:	0
Delayed conversion:	NS
Secondary intervention EVAR:	NS

Adverse events	Follow-up	EVAR		
		n	N	%
Mortality non AAA	<1 year	2	52	3.8
Graft limb thrombosis	NS	5	52	9.6
Type I endoleak	<30 days	5	52	9.6
Type II endoleak	<30 days	4	52	7.7
Stent migration	NS	2	52	3.8
Local wound complications	<30 days	6	52	11.5
Renal impairment	<30 days	1	52	1.9
Cardiac event	<30 days	2	52	3.8

Comments
2 Cases were symptomatic AAA.

Appendix 2 Forest plots

2.1 Complications

Figure 6 Cardiac event rate for EVAR versus open repair: Forest plot

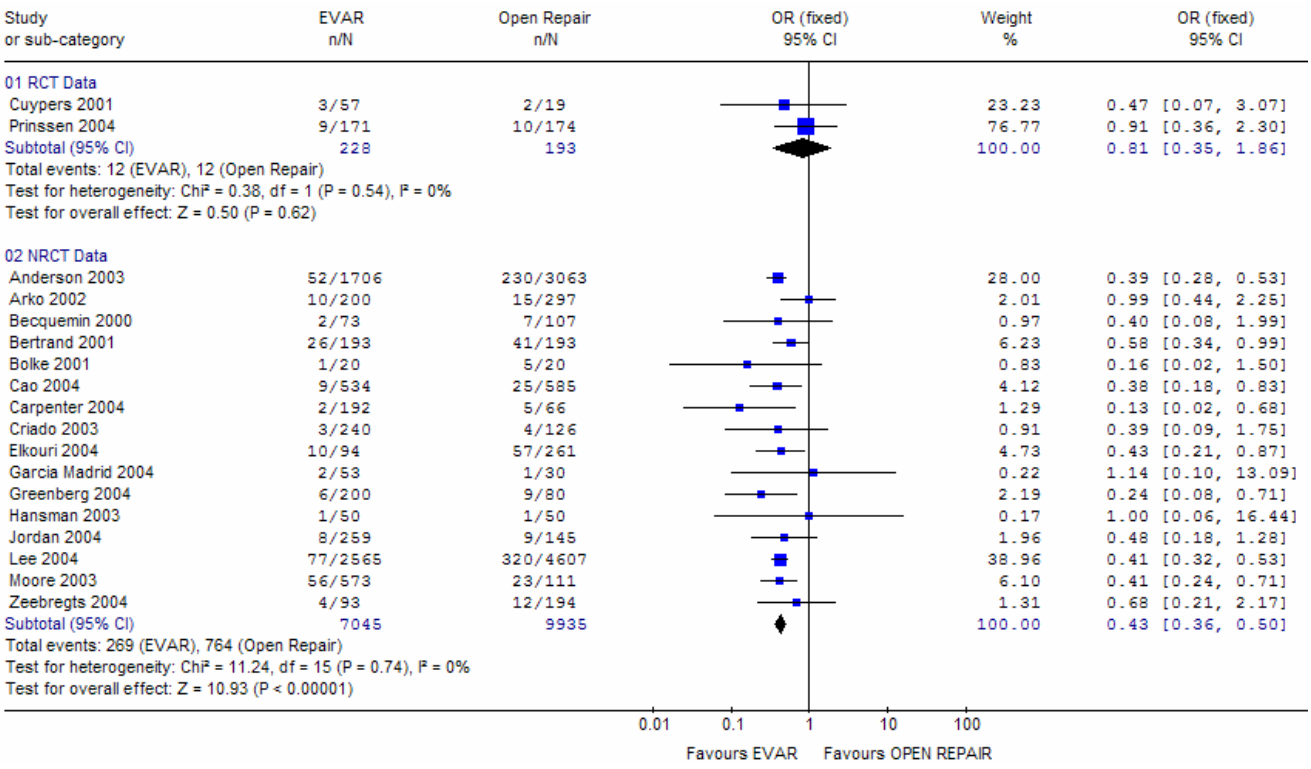
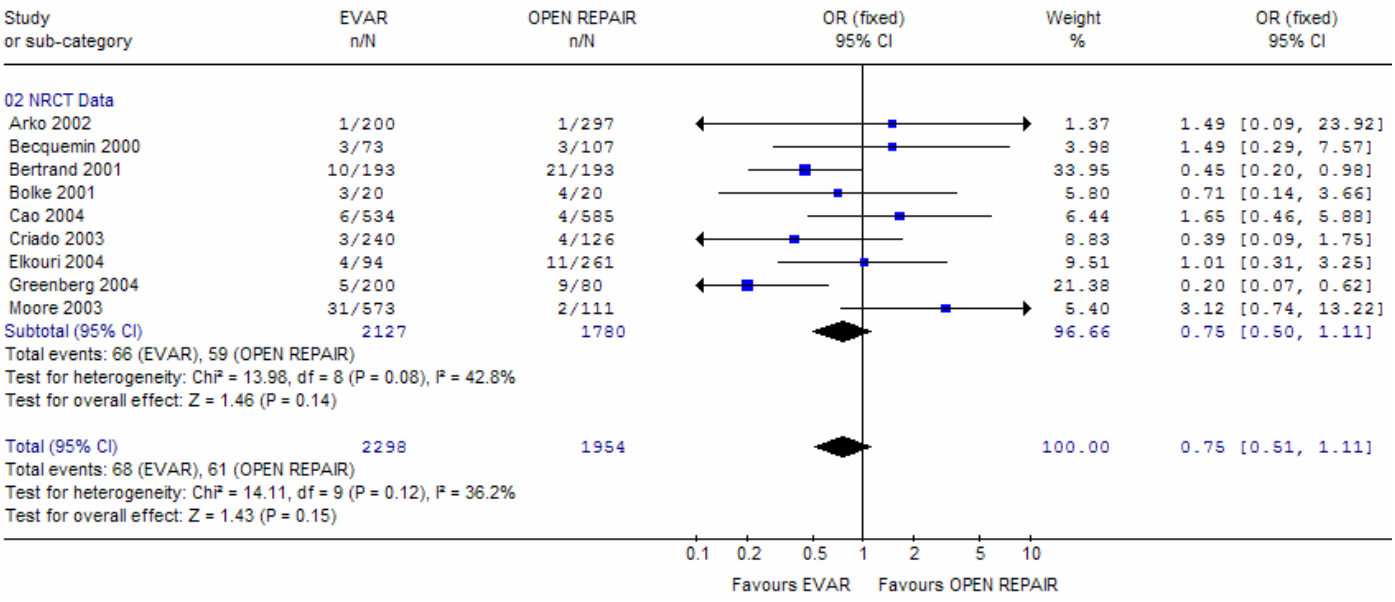


Figure 7 Renal impairment rates for EVAR versus open repair: Forest plot



2.2 Other peri- and postoperative outcomes

Figure 8 Blood loss for EVAR versus open repair: Forest plot

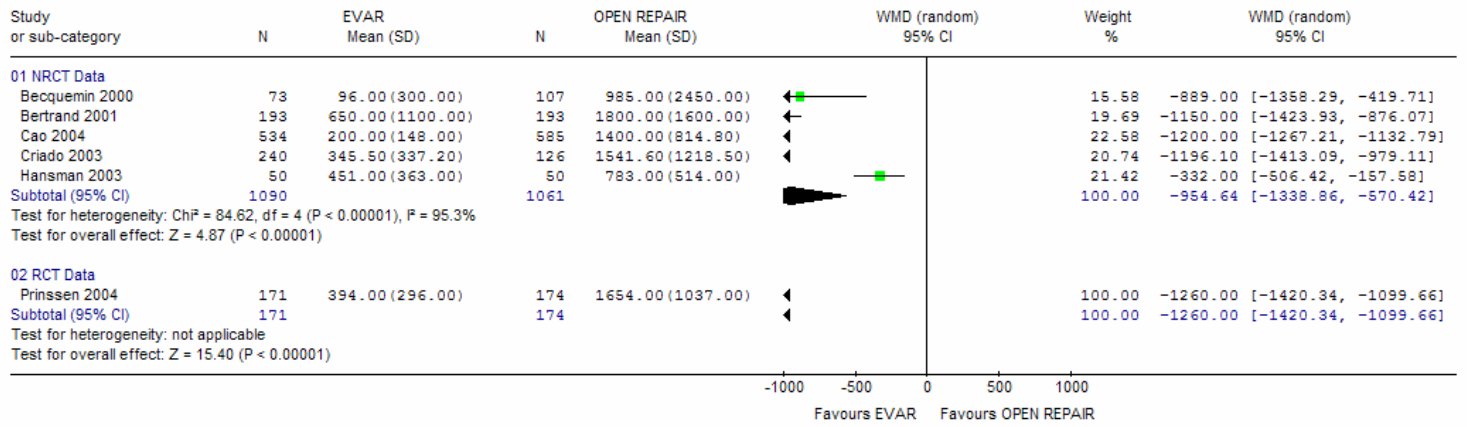


Figure 9 ITU stay for EVAR versus open repair: Forest plot