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[Intervention Review]

Stent graft types for endovascular repair of thoracic aortic aneurysms

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ABSTRACT

Background

The UK prevalence of thoracic aneurysm is estimated at 10.4 per 100,000 person-years. Progressive and unpredictable enlargement can lead to rupture. Endovascular repair of thoracic aortic aneurysms involves a stent graft system being introduced via the femoral artery and manipulated within the aorta under radiological guidance. Following endograft deployment, a seal is formed at the proximal and distal landing zones to exclude the aneurysm sac from the circulation. With the increasing popularity of endovascular repair there has been an increase in the number of commercially available stent graft designs on the market. This is an update of the review first published in 2013.

Objectives

This review aimed to assess the different stent graft types for endovascular repair of thoracic aortic aneurysms.

Search methods

The Cochrane Vascular Group Trials Search Co-ordinator (TSC) searched the Specialised Register (last searched February 2015) and the Cochrane Register of Studies CENTRAL (2015, Issue 1). Trial databases were searched by the TSC for details of ongoing and unpublished studies.

Selection criteria

All published and unpublished randomised controlled trials (RCTs) of stent graft types in the repair of thoracic aortic aneurysms were sought without language restriction.

Data collection and analysis

Data collection and analysis was conducted in accordance with the *Cochrane Handbook for Systematic Reviews of Interventions*.

Main results

No studies were identified that met the inclusion criteria. It was not possible to assess the quality of the evidence in the absence of studies eligible for inclusion in the review.

Authors' conclusions

Unfortunately, no data exist regarding direct comparisons of the performance of different stent graft types. High quality RCTs evaluating stent graft types in thoracic endovascular aneurysm repair are required.

PLAIN LANGUAGE SUMMARY

Different stent graft types to repair thoracic aortic aneurysms

Background

An aneurysm is a localised widening of an artery. The thoracic aorta is the largest artery in the body, delivering blood from the heart to the arms and head. If an aneurysm occurs in the thoracic aorta it can expand and may rupture, resulting in death. Open surgery can treat these aneurysms, which involves opening the chest and placing an artificial graft over the widening. A new alternative treatment involves an artificial stent graft, delivered through an arterial blood vessel in the groin, fixed over the widening. This technique is called endovascular repair. There are many different types of stent grafts available. They differ in how they are inserted into/access the blood vessel, how they attach to the walls of the artery and the design and materials they are made from.

Study characteristics and key results

We searched for evidence directly comparing the different types of stent grafts in aneurysm repair (current until February 2015). This review found no evidence from randomised controlled trials to determine if any specific stent graft performs better than another type of stent graft. More research is required to help surgeons decide which specific type of stent graft to use.

Quality of the evidence

It was not possible to assess the quality of the evidence in the absence of studies eligible for inclusion in the review.

BACKGROUND

Description of the condition

An aneurysm is a localised pathological dilatation of an arterial wall. The incidence is 10.4 per 100,000 person-years (Clouse 1998; Olsson 2006). Thoracic aortic aneurysms (TAA) are relatively rare and comprise 2% to 5% of all degenerative aneurysms, with the majority of aortic aneurysms affecting the abdominal aorta (Steckmeier 2001). Patients are frequently being diagnosed with a TAA on routine imaging for unrelated presentations (Clouse 1998).

Thoracic aortic aneurysms have a multifactorial pathology involving environmental and genetic risk factors. The disease process shares a number of common risk factors with occlusive atherosclerotic disease, namely smoking, male gender and elevated diastolic blood pressure, but there is an inverse association with diabetes mellitus and no risk attributed to hypercholesterolaemia (Blanchard 2000). A genetic predisposition is supported by a relative risk of 1.9 in people with a family history (Larsson 2009).

The growth rate for TAAs has been estimated at 0.1 cm per year (Elefteriades 2008). When the aneurysm diameter exceeds 5.5 cm for the ascending and 6.5 cm for the descending thoracic aorta, the risk of rupture rises substantially (Elefteriades 2008). For aneurysms exceeding 6 cm in diameter, death, rupture or dissection is estimated at 15.6% per year (Davies 2002), with 97% to 100% overall mortality rate for rupture (Johansson 1995).

The recommendation for elective surgical repair is based upon estimates of rupture risk versus operative mortality and complication rates. Open surgical repair is performed under general anaesthesia and involves thoracotomy with extensive surgical resection and aortic prosthetic graft insertion, thus excluding the aneurysmal section. Open repair is associated with a 30-day mortality of between 4.8% and 17%, with peri-operative complications including spinal cord, cerebral and visceral ischaemia with resultant paraplegia, stroke and renal failure, respectively (LeMaire 2003). Evolving refinements in thoracic operative technique and peri-operative innovations have reduced the complication rate, however many patients have substantial comorbidities which preclude their suitability for open repair and increase the likelihood of post-operative complications (Coselli 2000; Głowiczki 2002).

Description of the intervention

Endovascular aneurysm repair (EVAR) has developed since the early 1990s in response to the need for a minimally invasive technique (Dake 1994; Parodi 1991). The stent graft consists of a modular system of fabric tubes (often polyester or polytetrafluoroethylene (PTFE)) with an expanding metal stent framework (stainless steel or nitinol). The procedure can be performed under epidural anaesthesia, allowing inclusion of patients who are high-risk candidates for general anaesthesia. Access to the aorta is achieved via incisions in the groin, whereby guidewires, catheters and subsequently the stent graft system are introduced via the femoral artery and manipulated within the aorta under radiological guidance. Following endograft deployment, a seal is formed at the proximal and distal landing zones to exclude the aneurysm sac from the circulation. A number of anatomical criteria are used to assess the patient's suitability for EVAR including

the morphology of the proximal and distal landing zones and the dimensions of the access vessels.

Stent graft design has progressed quickly since the first prototype devices. With the increasing popularity of endovascular repair there has been an increase in the number of commercially available stent graft designs on the market. Many factors influence the way surgeons select stent grafts and there is now a need for a robust comparative evaluation of their performance.

How the intervention might work

The benefit of endovascular repair for TAAs remains unclear as there are no randomised controlled trials comparing endovascular with open repair. Analysis of published data implies that endovascular repair has a reduced early mortality and peri-operative complication rate (Abraham 2013). Endovascular aneurysm repair also offers benefits in terms of shorter hospital stay, reduced anaesthetic time and decreased blood loss. Long-term data are not currently available.

A number of stent graft-related late complications have been reported including graft migration (movement of the graft out of the deployed position), endoleak (the continued flow of blood into an aneurysmal sac after endovascular repair) and stent graft fracture (holes that develop in the fabric of the stent graft). This necessitates periodic computed tomography (CT) surveillance imaging to assess device integrity and positioning, and thus exposes patients to repeated irradiation. Re-intervention is necessary for the correction of device-related complications.

Stent graft design has evolved significantly since the first devices were handmade in theatre. Several different grafts are currently available on the market from various manufacturers. The stents differ in design, materials used and deployment techniques. Different device designs are likely to have different complication rates (Kelso 2009). For example, fabric porosity led to the withdrawal of the original Gore device in 2004 (Tanski 2007). Secondary intervention rates may differ depending on the graft type (Sampram 2003), including late conversion to open repair (Harris 2000).

The evolution of stent graft design is driven to address both short- and long-term aims. In the short term, designs aim to allow introduction of the device, particularly through challenging iliac anatomy, accurate graft positioning and deployment, and successful immediate sealing at the landing zones. In the long term, the aim is to reduce late migration and disconnection or other device-related failures that would lead to secondary interventions.

Device performance has been carefully regulated both in the US and Europe, which has led to the detection of device failure and resulted in either withdrawal or modification of the device. For example, the early designs for the Ancure device had fixational hook fractures reported (Najibi 2001); and the AneuRx (Medtronic) stent graft, a modular heavily stented and sutured device, suffered from reports of endoleak in the follow-up period and was withdrawn from the market (Katzen 2005).

Devices rely on a combination of radial force provided by metal stents (usually self expanding) and hooks or barbs to engage the vessel wall. The graft is also oversized relative to the vessel diameter in order to enhance friction attachment.

Thoracic aneurysm repair poses additional challenges upon stent graft design beyond those of abdominal aneurysm repair (Greenberg 2008). Increased haemodynamic forces at the distal arch of the aorta mean that there is a greater emphasis upon secure graft fixation, which, if compromised, may result in graft migration. Conformity of the stent graft to the distal arch is another consideration and is an area of current product design. Poor approximation of the endograft to the sealing zone may result in collapse of the graft from haemostatic pressures on the underside of the graft with resultant pseudocoarctation, migration or type I endoleak. Product design is ongoing in tackling this problem, for example the Cook Medical Zenith TX2 device with Proform has a modified deployment with a constraining suture on the proximal stent to ensure optimised positioning within the aorta (Thompson 2009). Thoracic devices must navigate often tortuous, heavily calcified aortas before deployment. This creates a potential increased risk of post-operative stroke and paraplegia from embolisation during the procedure and coverage of lumbar arteries along the aorta (Bicknell 2009).

Why it is important to do this review

Several established stent graft types are available for use in TAA repair and new devices are constantly emerging. Many patients have an anatomy that is suitable for repair with a number of the available grafts. Comparison of early and late complications is needed to allow clinicians to make an informed choice. In addition, patient factors that affect the outcome with certain graft types may be identified.

OBJECTIVES

This review aimed to assess the different stent graft types for endovascular repair of thoracic aortic aneurysms (TAAs).

METHODS

Criteria for considering studies for this review

Types of studies

Only randomised controlled trials (RCTs) were eligible for inclusion. We planned to include cross-over trials in the review for completeness but data from the first phase only would have been included in meta-analyses as the cross-over is not a valid design in this context.

Types of participants

Individuals with TAA visualised by computed tomographic (CT) or ultrasonographic techniques, or both.

Types of interventions

Any stent graft type versus another stent graft type.

Types of outcome measures

We planned to consider the following outcome measures.

Primary outcomes

1. Short-term mortality (30-day or in-hospital mortality, i.e. procedure-related).

Secondary outcomes

1. Major complications, e.g. open conversion, haemorrhage, myocardial infarction, stroke, paraplegia, renal failure (20% rise in creatinine level above normal reference limits), respiratory failure (need for post-operative mechanical ventilation), pneumonia, bowel ischaemia, lower limb ischaemia, etc.
2. Aneurysm exclusion (no flow in the aneurysm sac, or further extravasation (escape of blood from the vessel into the tissues) beyond the sac on follow-up imaging 30 days after the procedure).
3. Minor complications, e.g. access site haematoma, wound infection, etc.
4. Long-term complications and mortality; device-related, re-intervention rates and cause of death.

Search methods for identification of studies

All published and unpublished RCTs of stent graft types in the repair of TAAs were sought without language restriction.

Electronic searches

The Cochrane Vascular Group Trials Search Co-ordinator (TSC) searched the Specialised Register (last searched February 2015) and the Cochrane Register of Studies (CRS) <http://www.metaxis.com/CRSWeb/Index.asp> (CENTRAL) (2015, Issue 1). See Appendix 1 for details of the search strategy used to search the CRS. The Specialised Register is maintained by the TSC and is constructed from weekly electronic searches of MEDLINE, EMBASE, CINAHL, AMED; and through handsearching relevant journals. The full list of the databases, journals and conference proceedings which have been searched, as well as the search strategies used, are described in the [Specialised Register](#) section of the Cochrane Vascular Group module in the *Cochrane Library* (www.cochranelibrary.com).

The following trial databases were searched by the TSC for details of ongoing and unpublished studies using the terms (stent and thoraco) and (stent and aneurysm):

- World Health Organization International Clinical Trials Registry Platform (<http://apps.who.int/trialsearch/>);
- ClinicalTrials.gov (<http://clinicaltrials.gov/>);
- Current Controlled Trials (<http://www.controlled-trials.com/>).

Searching other resources

The reference lists of articles retrieved by the searches were checked.

Data collection and analysis

We planned to conduct data collection and analysis in accordance with the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2008).

Selection of studies

Two of three review authors (JMD, RR, RC) scanned the titles and abstracts of articles retrieved by the search and removed those that were clearly irrelevant. The full text of all potentially eligible studies was retrieved. Two of three review authors (JMD, RR, RC) independently examined the full text articles for compliance with the inclusion criteria and aimed to select studies eligible

for inclusion in the review. The review authors corresponded with study investigators when required to clarify study eligibility (for example with respect to participant eligibility criteria and allocation method). Disagreements as to study eligibility were resolved by consensus.

Data extraction and management

The review authors planned to extract data from eligible studies using a data extraction form designed and pilot-tested by the review authors. If studies had multiple publications, the main trial report would have been used as the reference and additional details supplemented from secondary papers. The review authors planned to correspond with study investigators in order to resolve any data queries as required. The authors intended for two review authors (one a topic area specialist) to independently extract the data, and any disagreement between these review authors would have been resolved by a third review author.

Assessment of risk of bias in included studies

The review authors planned to assess risk of bias of the included studies including: sequence generation; allocation concealment; blinding of participants, providers and outcome assessors; completeness of outcome data; selective outcome reporting; and other potential sources of bias. We planned for two review authors to assess these six domains, with any disagreements resolved by consensus or by discussion with a third author.

The review authors planned to describe all judgements fully, present the conclusions in a 'Risk of bias' table and incorporate the interpretation of review findings by means of sensitivity analyses (see below).

Measures of treatment effect

For dichotomous data, the review authors planned to calculate Peto odds ratios for the number of events in the control and intervention groups of each study. For continuous data the authors planned to calculate mean differences between treatment groups if all studies reported exactly the same outcomes. If similar outcomes were reported on different scales, the authors planned to calculate standardised mean differences. The review authors planned to present 95% confidence intervals for all outcomes.

Unit of analysis issues

The primary analysis was planned to be per individual randomised. Only first-phase data from cross-over trials was intended to be included.

Dealing with missing data

The review authors planned to analyse the data on an intention-to-treat basis where possible and planned to attempt to obtain missing data from the original investigators. Where these were unobtainable, the authors planned to impute individual values for the primary outcomes only. If studies reported sufficient detail to calculate mean differences but no information was given on associated standard deviations (SD), we would have assumed the outcome to have an SD equal to the highest SD from other studies within the same analysis. For other outcomes, only the available data would have been analysed. Any imputation undertaken would have been subjected to a sensitivity analysis (see below).

Assessment of heterogeneity

We planned to consider whether the clinical and methodological characteristics of the included studies were sufficiently similar for meta-analysis to provide a meaningful summary. The authors planned to assess statistical heterogeneity by the measure of the I^2 statistic. An I^2 measurement greater than 50% would be taken to indicate substantial heterogeneity (Higgins 2008). If substantial heterogeneity had been detected, possible explanations would have been explored in sensitivity analyses (see below).

Assessment of reporting biases

In view of the difficulty in detecting and correcting for publication bias and other reporting biases, the authors aimed to minimise their potential impact by ensuring a comprehensive search for eligible studies and by being alert for duplication of data. If there had been 10 or more studies in an analysis, the authors planned to use a funnel plot to explore the possibility of small study effects (a tendency for estimates of the intervention effect to be more beneficial in smaller studies).

Data synthesis

We planned to combine the data from primary studies using fixed-effect models in the following comparison:

1. any stent graft type versus another stent graft type.

An increase in the odds of a particular outcome, which may be beneficial or detrimental, would have been displayed graphically in the meta-analyses to the right of the centre-line and a decrease in the odds of an outcome to the left of the centre-line.

Subgroup analysis and investigation of heterogeneity

No subgroup analysis was expected. If substantial heterogeneity had been detected, possible explanations would have been explored in a sensitivity analysis.

Sensitivity analysis

The review authors planned to conduct sensitivity analyses for the primary outcomes to determine whether the conclusions were robust to arbitrary decisions made regarding the eligibility and analysis. These analyses include consideration of whether conclusions would be different if:

1. eligibility were restricted to studies without high risk of bias;
2. studies with outlying results had been excluded;
3. alternative imputation strategies had been adopted;
4. a random-effects model had been adopted.

RESULTS

Description of studies

No studies were identified that met any of the inclusion criteria.

Results of the search

See Figure 1.

Figure 1. Study flow diagram.

The search results were independently reviewed by two of three authors (JMD, RR, RC). Unfortunately, no RCTs were identified for inclusion in this review.

Excluded studies

Three studies were excluded. [NCT01354119](#) was excluded as it compared surgical intervention with a conservative control group. [NCT00922454](#) was excluded as it compared interventions for the management of abdominal aortic aneurysms. [ChiCTR-TRC-12002844](#) was excluded as it is a study (ongoing) evaluating the same intervention in both treatment groups.

Risk of bias in included studies

It was not possible to review methodological quality in the absence of studies eligible for inclusion in the review.

Effects of interventions

Unfortunately, no published or unpublished RCTs were found comparing stent graft types in the treatment of thoracic aortic aneurysms.

DISCUSSION

Summary of main results

This review documents that there are no published RCTs that compare different stent graft types for thoracic aortic aneurysm (TAA) repair, assessing early and late mortality and major complications. The paucity of evidence is reflected in other topics considering endovascular repair for TAAs. The most recent Cochrane review comparing open surgery versus endovascular repair for thoracic aortic aneurysms ([Abraha 2013](#)) was unable to identify any published RCTs. When [Abraha 2013](#) considered non-randomised data a benefit was demonstrated in terms of early mortality and complications favouring endovascular repair.

Specialist vascular centres are adopting endovascular repair as a viable treatment option for thoracic aneurysms. As these centres test the various stent grafts available there becomes a greater impetus for robust evidence to be provided to support their choice of stent graft. A number of stent graft types are available on the market, each with their own device-related advantages and disadvantages ([Ali 2008](#)). The challenge to all of the stent grafts available are twofold: (i) the need for a low-profile device with accurate deployment; (ii) the ability of the stent to conform to the thoracic aorta ([Svensson 2008](#)). Large delivery systems

are unacceptable if there is significant tortuosity and narrowing of the iliofemoral access vessels, as they can cause trauma to these vessels. The device must be able to form a complete seal at the proximal and distal attachment sites to prevent type I endoleaks post-endovascular repair, which would necessitate further intervention. The thoracic aorta can also pose extra demands on stent graft design for anatomically challenging cases, for example when there is severe angulation of the descending thoracic aorta or inadequate proximal or distal landing sites for the device. A number of devices give the surgeon the option of a proximal or distal 'free flow' uncovered bare stent section to avoid coverage of major branching vessels. In addition, there are emerging stent grafts with tailor-made fenestrations to allow for major branch vessel flow, which must be ordered on an individual basis (Greenberg 2008; Greenburg 2010).

Endovascular repair is associated with late complications that are not associated with open surgery, including endoleaks, graft migration and stent fractures. The specific contribution of stent graft type selection to these outcome measures is poorly characterised, with no direct comparisons between stent graft types. It is imperative that high quality data is produced to characterise the influence of stent graft type selection with regards to these specific outcome measures.

Overall completeness and applicability of evidence

High quality RCTs evaluating stent graft types in thoracic endovascular aneurysm repair for TAAs are required. When designing these trials, careful consideration of outcome measures is required. Trials would need to assess all relevant outcomes and should be divided into two categories:

- (i) durability of stent graft type, e.g. endoleak rate, re-intervention rate, open-conversion rate, and rupture-free survival;
- (ii) clinical outcome measures, e.g. early and late mortality, major complications, hospital stay.

Quality of the evidence

It was not possible to assess the quality of the evidence in the absence of studies eligible for inclusion in the review.

Potential biases in the review process

None.

Agreements and disagreements with other studies or reviews

This review agrees with the Cochrane review on stent graft types for abdominal aortic aneurysm repair (Duffy 2015) that there is a lack of robust evidence to support the use of one stent graft type over another in endovascular repairs of (thoracic) aortic aneurysms.

AUTHORS' CONCLUSIONS

Implications for practice

Non-randomised data suggest that endovascular repair of thoracic aneurysms could be a good alternative to open surgical repair. However, endovascular repair is associated with endoleaks, graft migration and stent fractures requiring secondary intervention.

Unfortunately, no data exist regarding comparisons of the performance of different stent graft types in reducing these complications.

Therefore, this review cannot provide guidance to clinicians in their selection of stent graft type.

Implications for research

High quality randomised controlled trials evaluating stent graft types in thoracic endovascular aneurysm repair for thoracic aortic aneurysms are needed.

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Rolph R, Duffy JMN, Modarai B, Clough RE, Taylor P, Waltham M. Stent graft types for endovascular repair of thoracic aortic aneurysms. *Cochrane Database of Systematic Reviews* 2013, Issue 3. [DOI: [10.1002/14651858.CD008448.pub2](https://doi.org/10.1002/14651858.CD008448.pub2)]

CHARACTERISTICS OF STUDIES

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
ChiCTR-TRC-12002844	ChiCTR-TRC-12002844a was excluded as it is evaluating the same intervention in both treatment groups
NCT00922454	NCT00922454 was excluded as it compared interventions for the management of abdominal aortic aneurysms
NCT01354119	NCT01354119 compared surgical intervention with a conservative control group

APPENDICES

Appendix 1. Search strategy for CRS

#1	MESH DESCRIPTOR Aortic Aneurysm	98
#2	MESH DESCRIPTOR Aortic Aneurysm, Abdominal	382
#3	MESH DESCRIPTOR Aortic Aneurysm, Thoracic	44
#4	aort*:TI,AB,KY	5838
#5	(juxta renal):TI,AB,KY	0
#6	juxtarenal:TI,AB,KY	2
#7	(juxta renal or juxtarenal):TI,AB,KY	2
#8	(pararenal or para renal):TI,AB,KY	2
#9	(suprarenal or supra renal):TI,AB,KY	23
#10	(short neck* or shortneck*):TI,AB,KY	9
#11	(visceral aortic segment):TI,AB,KY	0
#12	thorac*:TI,AB,KY	7993
#13	abdominal:TI,AB,KY	16097
#14	#4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13	27859
#15	aneur?sm*:TI,AB,KY	2243
#16	#14 AND #15	924
#17	(JRAAA or JRAAAAs or PAAA or PAAAAs or TAAA or TAAAAs or JPAA or JPAAAs or SRA or SRAs or SRAA or SRAAs):TI,AB,KY	59
#18	((aort* near3 (ballon* or dilat* or bulg* or expan*))) :TI,AB,KY	64
#19	#1 OR #2 OR #3	516
#20	#16 OR #17 OR #18 OR #19	1009
#21	MESH DESCRIPTOR Stents EXPLODE ALL TREES	2697
#22	(stent* or graft* or tevar or endograft* or evar or fevar or f-evar):TI,AB,KY	19771
#23	(powerlink or talent or excluder or aorfix or zenith or endologix or anaconda or Triascular or Cordis or Endurant or Quantum or Aneurx or Ancure):TI,AB,KY	253
#24	MESH DESCRIPTOR Blood Vessel Prosthesis EXPLODE ALL TREES	381
#25	MESH DESCRIPTOR Blood Vessel Prosthesis Implantation EXPLODE ALL TREES	364

(Continued)

#26	MESH DESCRIPTOR Vascular Surgical Procedures	479
#27	endovascular:TI,AB,KY	967
#28	fenestrat*:TI,AB,KY	84
#29	chimney:TI,AB,KY	12
#30	#21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29	21023
#31	#20 AND #30	418

WHAT'S NEW

Date	Event	Description
4 June 2015	New search has been performed	Search re-run. No new included studies. Three excluded studies were identified.
4 June 2015	New citation required but conclusions have not changed	Search re-run. No new included studies. Minor text changes made. No change to conclusions.

CONTRIBUTIONS OF AUTHORS

RR: main reviewer, involved in all aspects of the review.

JMD: main reviewer, involved in all aspects of the review.

MW: involved in drafting the manuscript, revising it critically for important intellectual content and final approval of the version for publication.

DECLARATIONS OF INTEREST

RR: none known

JMD: none known

MW: none known

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INDEX TERMS

Medical Subject Headings (MeSH)

Aortic Aneurysm, Thoracic [*surgery]; Endovascular Procedures [*methods]; Stents [*classification]

MeSH check words

Humans