

**Key words:** Type B dissection; equipoise; endoluminal repair; randomised controlled trial (RCT); grey area

# Controversies and consensus in the endoluminal management of thoracic aortic dissections

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## Abstract

Endoluminal repair of thoracic aortic dissections is an evolving technique used to exclude acute dissections where the entry point lies distal to the left subclavian. The technique is limited by paucity of data and uncertainty about long-term outcomes. It has certainly proved to be an attractive option in patients who would otherwise be considered for surgery due to the high morbidity and mortality associated with operative repair. The expansion of this new technology has led to a number of controversies about its use, which include the lack of level one data, compounded by a lack of equipoise precluding a randomised controlled trial. Some investigators have suggested its use in uncomplicated dissection, but its role in improving survival is unclear. However, this application may have equipoise.

## Introduction

The refining of endoluminal devices and the growing experience with abdominal aortic endoluminal exclusion has led investigators to offer treatment to patients who have technically amenable thoracic aortic dissections. This extension of endoluminal repair has generated significant controversy. There are six main points of debate which are currently unresolved and raise further issues themselves. In this article, I will briefly review the current status of endoluminal thoracic repair for dissection and then discuss in detail the areas of controversy.

## Current status of endoluminal thoracic repair of aortic dissection

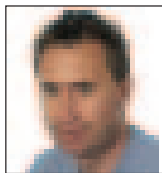
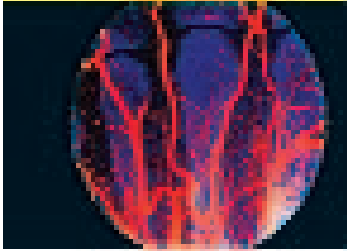
The technique of endoluminal repair has become standardised, despite the range of devices available. Most grafts are deployed through an access sheath, which is withdrawn, exposing the self-expanding endoprosthesis. Grafts consist of a stainless steel or Nitinol endo- or exoskeleton with a PTFE or Dacron sleeve. Fenestrated grafts are being developed but

currently most prostheses are non-modular tubes. Placement is image-guided with fluoroscopy and/or transoesophageal ultrasound. Exclusion of entry sites distal to the subclavian is achievable and often the left subclavian artery needs to be excluded to ensure good coverage of an isthmic tear. Surgical access via a common femoral arteriotomy is usual and implantation is commonly in the radiology or endovascular suite. Most patients will require general anaesthesia, although spinal anaesthesia is an accepted alternative. The mortality of endoluminal repair of complicated dissection is around 5%, with paraplegia <1%.<sup>1</sup> Access site complications are the most common adverse events.

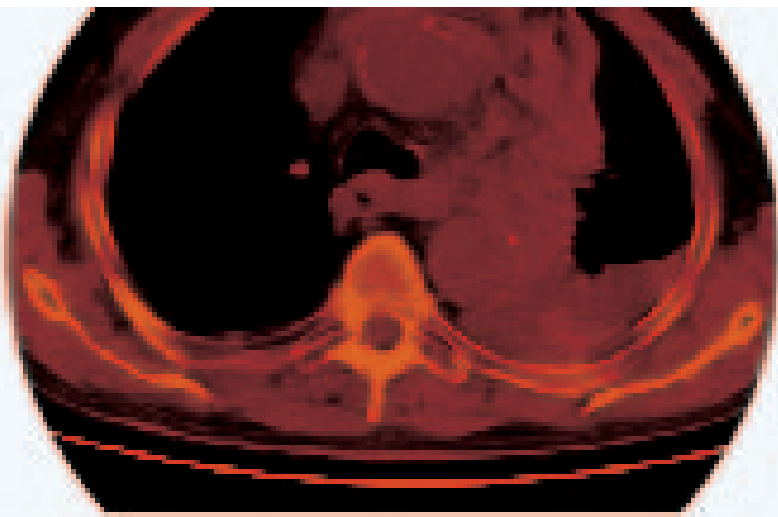
## Should endoluminal thoracic repair be subject to a randomised controlled trial?

Most new technology and treatments need robust safety and efficacy level one data before they can be offered as part of standard clinical practice.<sup>2</sup> This ideally should come from a randomised controlled trial (RCT). In order for a procedure to undergo a randomised trial, clinicians must have a grey area. This means that a clinician must be uncertain as to which is the best form of treatment and therefore ethically able to randomise the patient between two therapeutic options – this is known as equipoise.

In the absence of equipoise, it is not feasible to proceed with a randomised trial because if a clinician believes one therapy offers an advantage over the other, he is unable to randomise the patient. The high mortality and morbidity associated with the surgical treatment of complicated type B dissections has meant that few clinicians have equipoise and most would favour endoluminal exclusion, even though there is an absence of level one data and doubt exists as to the durability of the endoprostheses. The mortality rate for surgical repair of complicated type B dissection is in the range 31–79%.<sup>3</sup> The mortality of endoluminal repair is approximately 5%,<sup>4</sup> and this vast disparity in mortality



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rates has pushed clinicians towards embracing endoluminal repair without the requirement of burden of proof offered by randomised controlled trials.

The procedure has been embraced primarily due to the poor alternative option offered by surgery. Popular current practice is to offer endoluminal repair to patients who would normally be offered surgery, e.g. dissections with secondary dilatation, rupture, branch vessel ischaemia or ongoing pain. Critics would say this rapid move to endoluminal repair represents an unquestioning embrace of new technology without sufficient data. The supporters of an endoluminal strategy would counter with "as early aviators prudently observed, there is no need to randomise the parachute".<sup>5,6</sup>

Whatever the rights or wrongs of the above debate, an RCT for complicated type B dissections comparing endoluminal repair with surgery is unlikely to occur, as equipoise does not exist.

#### **Data collection – how should we proceed in the absence of a randomised controlled trial?**

This is a difficult question to answer and the most popular alternative is a registry with 100% data capture – this approach has practical limitations but is the chosen option in New Zealand. This model is clearly inferior to a RCT but may be the only pragmatic alternative and may satisfy critics of the procedure and investigators who feel nervous about the unquestioning embrace of a new technology. In my opinion, complete data collection with rigorous follow-up including imaging, is a satisfactory alternative to a RCT – the Safety and Efficacy Register of New Interventional Procedures (SERNIP; now transferred to the National Institute for Clinical Excellence (NICE)) has also condoned this approach.<sup>7</sup> The acceptance of new technology without appropriate data has caused problems in the past and we need to learn from those experiences. Reliance on single centre series with

historical controls is problematic and a registry may be a solution. However, future surprises may await and perceived improvements in care are not always borne out with time.

#### **Should we exclude uncomplicated dissections?**

In the previous section, discussion was limited to exclusion of complicated dissections. However, there are many patients with type B dissections that are haemodynamically stable, without a peri-aortic haematoma or branch vessel involvement – should endoluminal repair be offered to these patients? Greater understanding of the long-term natural history of type B dissections has suggested the prognosis of these patients is poor, particularly for those with persisting bi-luminality.<sup>8</sup> Only 50% of patients of type B dissection on medical management will be alive in 5 years. This raises the question of whether acute endoluminal exclusion improves survival?

Of relevance is the ability to safely deploy an endoprosthesis and exclude the pseudolumen, rendering the thoracic aorta uniluminal in acute uncomplicated dissections, with a view to decrease aortic-related deaths. More cautious investigators point out that only 20% of the deaths in this group are due to aortic events and the majority appear to be secondary to co-morbidities. Therefore, endoluminal exclusion with its 5% risk of paraplegia, stroke or death may be inappropriate.

Many investigators feel endoluminal exclusion of uncomplicated type B dissections is over-treatment and the cost-burden of such an endoluminal strategy is not insignificant. Once again, the durability of the devices must be considered prior to adopting this strategy. Uncomplicated dissection is an area where more clinicians are likely to have equipoise and might be fertile ground for a randomised controlled trial. However, despite having equipoise, a RCT in this area may still be

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problematic due to the rapidly changing technology. Devices placed at the beginning of the trial may bear no resemblance to those being placed closer to the trial's conclusion and this would lay the RCT open to potential criticism on outdated technology. There are solutions to these questions of technological equipoise, i.e. offering a pragmatic trial where patients are merely randomised to the best medical therapy for endoluminal repair – whatever is current at the time – and running tracker trials within the main trial. It may be difficult to get suitable numbers for this trial and a multinational trial may be essential.

A recent publication by Umana *et al*<sup>9</sup> addressed this problem and they compared (non-randomised) uncomplicated dissections that had been treated surgically with those that had been treated medically. It was found that survival and freedom from complications were identical in each group, further fuelling the debate.

### Should chronic dissections be treated with endoluminal exclusion?

Most investigators have traditionally felt that the window for endoluminal exclusion is within two weeks of the event. This is due to the motility of the membrane separating the true lumen from the pseudolumen. The placement of the single endoluminal prosthesis across the entry point (which is usually at the aortic isthmus) diverts blood into the true lumen. This causes decompression of the false lumen and collapse with apposition of the membrane against the wall, thus closing off the pseudolumen. Beyond two weeks, the membrane starts to become thicker and more organised and is less likely to collapse. The older the dissection, the less achievable is false lumen exclusion. If the endoluminal prosthesis is placed in a chronic type B dissection, this result is less likely and

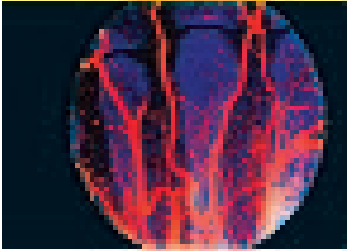
continued patency of the pseudolumen may occur through natural fenestrations. For a strategy of treatment of chronic dissections to be embraced, it is important that outcome data support an improvement in survival, and as of yet, these data are not available.

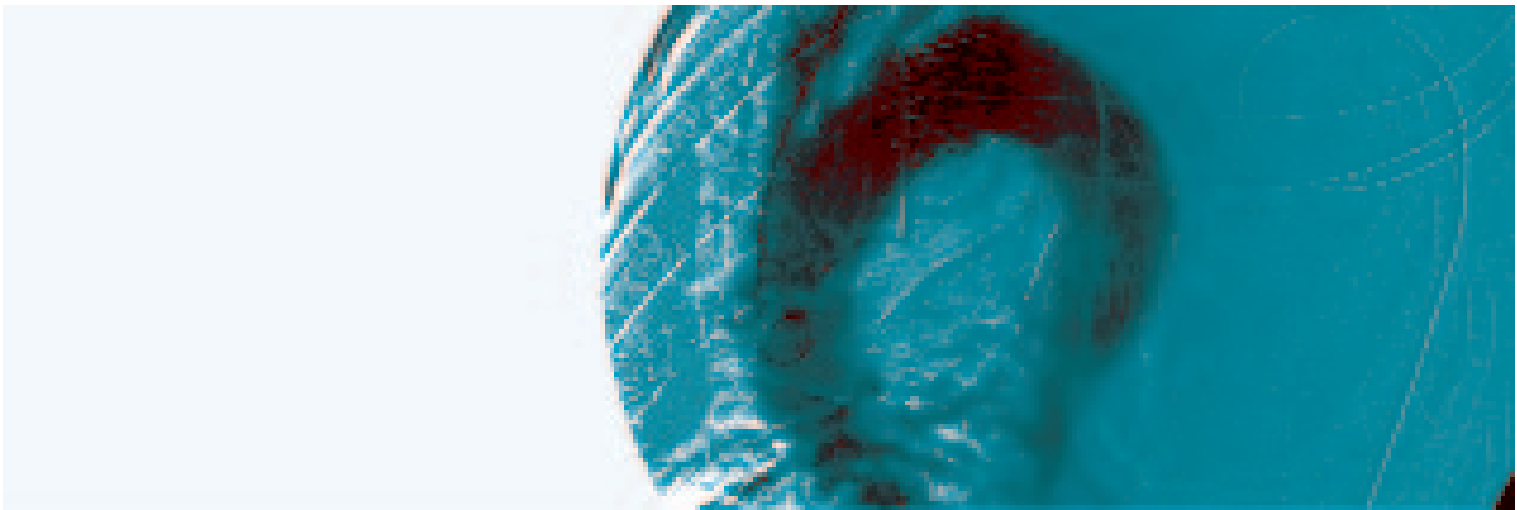
### Should we exclude intramural haematoma?

Intramural haematoma (IH) is a variant of thoracic aortic dissection. The natural history is less well understood and the aetiology may be different from dissection, with some investigators suggesting it is a bleed in the wall arising from the vasa vasorum rather than representing entry of flowing blood via a defect in the intima.<sup>10</sup> Similar to uncomplicated dissection, it is unclear as to the appropriate management. However, IH can become complicated and most investigators would treat these cases in a similar manner to complicated distal thoracic aortic dissections, i.e. with endoluminal exclusion. This is our view and Figures 1 to 4 demonstrate a recent complicated intramural haematoma successfully treated with endoluminal exclusion.

### Conclusions

When new technology rolls in, it is better to get on the roller than to become part of the road. This is a commonly held belief by many medical practitioners. However, new technology needs a cautious embrace and an evidence-based evolution. Unquestioning acceptance of new technology has a history of problems and unexpected outcomes. Endoluminal thoracic repair for acute dissection is an exciting area and offers a new therapeutic option for aortic dissection with a reduced morbidity and mortality. However, there are many unanswered questions that need further debate and only with the acquisition of good quality prospective data will these controversies be safely converted





to consensus

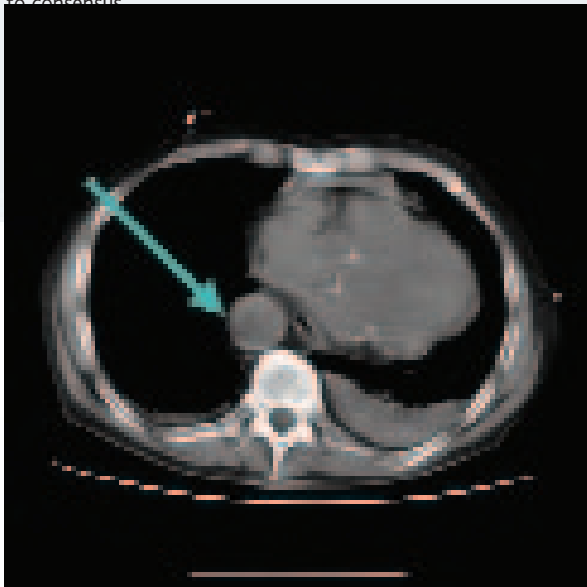


Figure 1. CT scan of thoracic aorta without contrast showing a hyper-dense crescent (arrowed), consistent with an acute intramural haematoma.

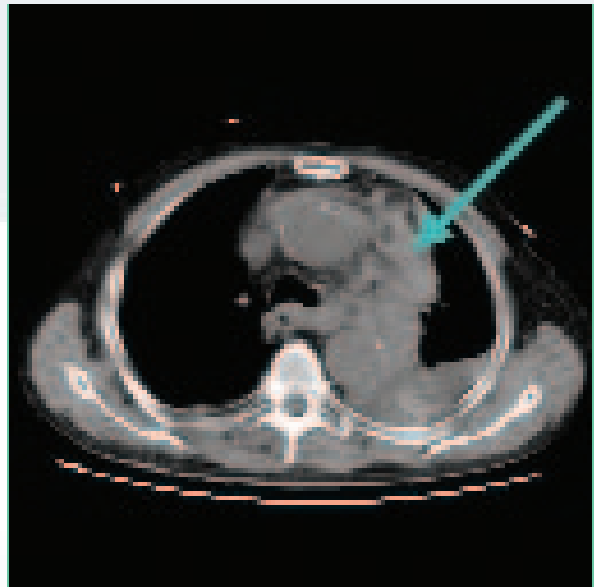


Figure 2. Same patient as for Figure 1 showing mediastinal haematoma (arrow) consistent with contained rupture.

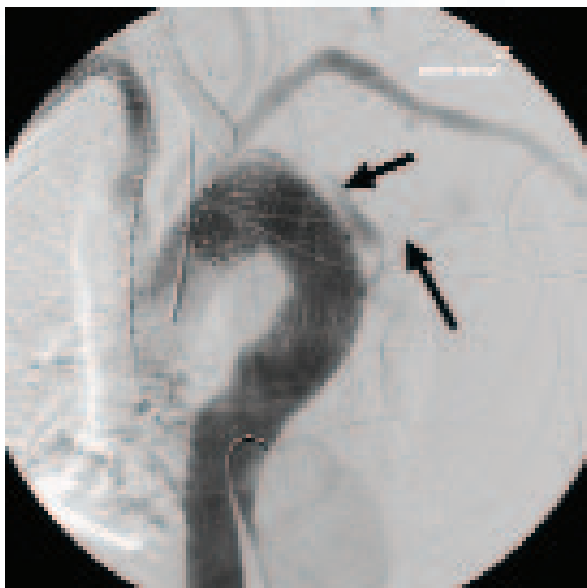


Figure 3. Aortogram showing acute rupture into the left hemithorax (arrows). Note the left hemithorax no longer contains aerated lung due to large haemothorax.

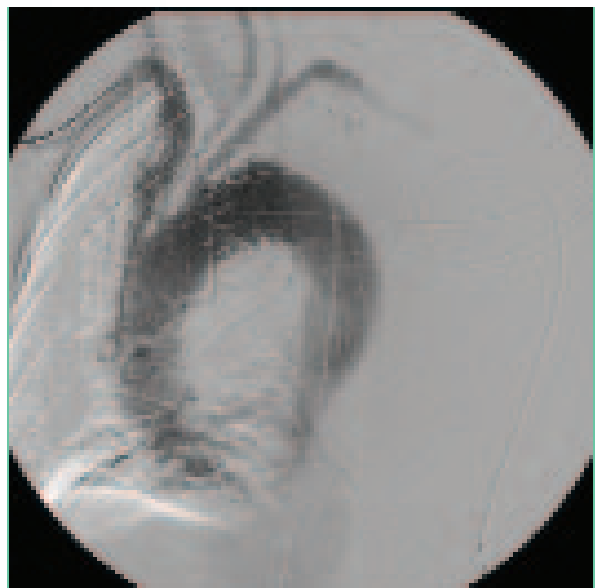
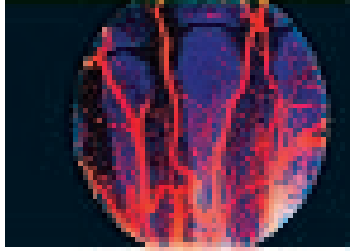


Figure 4. Completion aortography after endoluminal exclusion confirming successful exclusion of leak.

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## Key Learning

- Endoluminal exclusion of acute dissection with entry points distal to the left subclavian is technically achievable
- Mortality and morbidity for this procedure are lower than for surgical options in complicated dissections
- Complicated dissections are defined as those with ongoing pain, rupture, acute aneurysmal dilatation, or branch vessel ischaemia
- A RCT for endoluminal exclusion of acute complicated B dissection is unlikely due to the lack of equipoise
- Endoluminal exclusion of uncomplicated type B dissections is controversial
- Endoluminal exclusion of chronic dissections (greater than 2 weeks) is controversial
- Randomised controlled trials of new technology are difficult due to lack of technological equipoise
- Alternative methods of data collection in the absence of RCTs are important, e.g. registry

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