

NICE interventional procedures consultation document, February 2022

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Aortic remodelling hybrid stent insertion during surgical repair of an acute type A aortic dissection

An acute type A aortic dissection is a tear in the upper part of the main blood vessel that carries blood from the heart to the body (aorta). The aorta may rupture or reduce blood flow to the organs. In this procedure, which is done during surgical repair of the dissection, a small metal tube with felt sewed on one end (hybrid stent) is inserted into part of the aorta (the aortic arch). The aim is to improve blood flow and encourage healing (remodelling) of the aorta.

NICE is looking at aortic remodelling hybrid stent insertion during surgical repair of an acute type A aortic dissection.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts with knowledge of the procedure.

This document contains the [draft guidance for consultation](#). Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance

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- prepare a second draft, which will go through a [resolution process](#) before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 17 March 2022

Target date for publication of guidance: July 2022

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1 Draft recommendations

- 1.1 Evidence on the safety and efficacy of aortic remodelling hybrid stent insertion during surgical repair of an acute type A aortic dissection is limited in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research. Find out [what special arrangements mean on the NICE interventional procedures guidance page](#).
- 1.2 Clinicians wanting to do aortic remodelling hybrid stent insertion during surgical repair of an acute type A aortic dissection should:
- Inform the clinical governance leads in their healthcare organisation.
 - Give patients (and their families and carers as appropriate) clear written information to support [shared decision making](#), including [NICE's information for the public](#).
 - Ensure that patients (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
 - Audit and review clinical outcomes of all patients having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into [NICE's interventional procedure outcomes audit tool](#) (for use at local discretion).
 - Enter details about all patients having aortic remodelling hybrid stent insertion during surgical repair of an acute type A aortic dissection into the [NICOR Adult Cardiac Surgery Audit](#). Contact bartshealth.nicor-generalenquiries@nhs.net for details.
 - Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.
- 1.3 Healthcare organisations should:

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- Ensure systems are in place that support clinicians to collect and report data on outcomes and safety for every patient having this procedure.
- Regularly review data on outcomes and safety for this procedure.

1.4 This procedure should only be done in specialised centres by surgeons experienced in aortic surgery and with special training in this procedure.

1.5 Further research could include randomised controlled trials and analysis of registry data. It should include details of patient selection and report 30-day mortality, quality of life, and long-term outcomes including aortic remodelling and complications.

2 The condition, current treatments and procedure

The condition

2.1 An aortic dissection is a serious condition in which a tear occurs in the inner layer of the aorta. Blood flows through the tear and into the wall of the aorta. This forces the inner and middle layers of the aorta to split apart (dissect), creating 2 passages (a true lumen and a false lumen). As more blood flows into the new false lumen the dissection extends along the aorta. This can lead to aortic rupture or decreased blood flow (ischaemia or malperfusion) to organs.

2.2 Aortic dissections are classified into 2 types, depending on which part of the aorta is affected. Type A dissection involves a tear in the ascending part of the aorta. The tear may also occur in the aortic arch, which may extend into the abdomen or back into the ascending aorta. Type B dissection involves a tear in the aorta

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beyond the arch, usually in the descending thoracic aorta.
Dissections can be acute or chronic.

Current treatments

2.3 Treatments for aortic dissection include medicines (to control hypertension) and surgery (to repair the aorta and possible replacement of the aortic valve). Type of treatment depends on the chronicity, site location, and whether there are complicating features. Acute type A aortic dissection is life threatening and needs immediate surgery. The goals of surgical repair are to seal the false lumen and resolve malperfusion.

The procedure

2.4 Insertion of aortic remodelling hybrid stent is incorporated into open hemiarch repair for an acute type A aortic dissection, under general anaesthesia. The device is a self-expanding bare-metal stent with a short felt sewing cuff end. It aims to resolve malperfusion and promote positive remodelling of the aorta.

2.5 During the hemiarch aortic reconstruction, once circulatory arrest is established, the ascending aorta is transected and resected in the standard manner. A hybrid stent is then inserted until the entire device is inside the true lumen. This is usually done under direct vision, although it can be implanted using a guidewire. The cuff end of the stent is placed level with the edge of the transected aorta and attached with interrupted sutures. The uncovered portion of the stent expands along the aortic arch into the descending aorta. The remainder of the surgical hemiarch aortic reconstruction is completed in the usual way.

3 Committee considerations

The evidence

- 3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 3 sources, which was discussed by the committee. The evidence included 1 single-arm trial, 1 retrospective case series and 1 additional paper, which reported the outcomes of the malperfusion subgroups from the clinical trial. It is presented in [the summary of key evidence section in the interventional procedures overview](#).
- 3.2 The professional experts and the committee considered the key efficacy outcomes to be: reduction in false lumen diameter, improvement in aortic remodelling, resolution of organ malperfusion, survival and quality of life.
- 3.3 The professional experts and the committee considered the key safety outcomes to be: bleeding, extension of further dissection, infection and death.
- 3.4 One patient organisation submission was received and discussed by the committee. Patient commentary was sought but none was received.

Committee comments

- 3.5 The committee was informed that acute type A aortic dissection is a rare condition with a high mortality, and this procedure has a role in managing dissections involving supra-aortic vessels.
- 3.6 The committee noted that many approaches are available to manage acute type A aortic dissection and there is no single defined standard of care.

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Chair, interventional procedures advisory committee

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