NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Centre for Health Technology Evaluation

Review Decision

Review of MTG16: The E-vita open plus for the treatment of complex aneurysms and dissections of the thoracic aorta

This guidance was issued in December 2013.

NICE proposes an amendment of published guidance if there are no changes to the technology, clinical environment or evidence base which are likely to result in a change to the recommendations. However the recommendations may need revision to correct any inaccuracies, usually in relation to providing a more accurate estimate of the results of the cost modelling. The decision to consult on an amendment of published guidance depends on the impact of the proposed amendments and on NICE's perception of their likely acceptance with stakeholders. NICE proposes an update of published guidance if the evidence base or clinical environment has changed to an extent that is likely to have a material effect on the recommendations in the existing guidance.

1. Review decision

Amend the guidance without an external consultation.

2. Original objective of guidance

To assess the case for adoption of E-vita open plus for the treatment of complex aneurysms and dissections of the thoracic aorta.

3. Current guidance

1.1 The case for adopting the E-vita open plus for treating complex aneurysms and dissections of the thoracic aorta, in a carefully selected group of people, is supported by the evidence.

1.2 Using the E-vita open plus could remove the need for a second procedure and the associated risk of serious complications, and it should therefore be considered for people:

- *who would otherwise need a 2-stage repair procedure because their aortic disease extends into or beyond the distal part of their aortic arch (into the proximal descending aorta), but*

- *who would not need additional intervention (such as stent grafting) in the descending aorta.*

1.3 The E‑vita open plus is estimated to generate cost savings compared with current 2-stage repair from about 2 years after the procedure. The estimated cost saving per patient at 5 years after the procedure is around £13,800 when compared with 2-stage repair involving open insertion of a vascular graft, £9850 when compared with 2-stage repair involving endovascular stent grafting and £12,000 when compared with open surgical debranching followed by endoluminal stent grafting. At 10 years after the procedure, the estimated cost savings range from around £21,850 to £28,160 across the 3 comparators.

4. Rationale

No new evidence has been identified which is likely to change the existing recommendations. The proposed amendments to the guidance are minor factual changes that have no material effect on the recommendations.

5. New evidence

The search strategy from the original assessment report was re-run. References from December 2013 onwards were reviewed. Additional searches of clinical trials registries were also carried out and relevant guidance from NICE and other professional bodies was reviewed to determine whether there have been any changes to the care pathways. The company was asked to submit all new literature references relevant to their technology along with updated costs and details of any changes to the technology itself or the CE marked indication for use for their technology. The results of the literature search are discussed in the 'Summary of evidence and implications for review' section below. See Appendix 2 for further details of ongoing and unpublished studies.

5.1 Technology availability and changes

There have been no significant changes to the technology.

5.2 Clinical practice

The E‑vita open plus device is predominantly used for aortic arch aneurysms and there have been no significant changes to the clinical pathway since this guidance was published.

Four expert advisers provided feedback on the E‑vita open plus device, 3 of whom have used the device. The experts confirmed there have been no significant changes to the clinical pathway since this guidance was published. They stated that the technology was in use in a small number of selected

patients in specialist centres, and that newer techniques were being evaluated for use in the proximal descending aorta.

5.3 NICE facilitated research

Not applicable.

5.4 New studies

The EAC re-ran the literature searches since the guidance publication and identified 7 relevant studies. All studies included E-vita Open Plus as an intervention and were non-comparative.

- Erkanli et al. (2017) reported a single-centre retrospective study with 9 patients in Turkey.
- Hoffman et al. (2013) reported a single centre, retrospective study with 32 patients in Turkey.
- .Kozlov et al. (2018) reported a Russian single centre, retrospective study in 37 patients.
- Verhoye et al. (2014) reported on a single centre, retrospective study in 16 patients in France.
- Verhoye et al. (2017) reported on a French multicentre, retrospective registry study in 94 patients.
- Iafrancesco et al. (2017) reported on 137 patients with aortic dissection who had survived 1–year follow-up period in a multicentre, retrospective, registry study that took place in 5 countries in Europe.
- Jakob et al. (2017) reported on a German single centre, prospective study in 178 consecutive patients

The EAC reviewed these studies and concluded that the clinical evidence has not changed significantly since the original guidance was published in 2013. All of the included papers concluded the E-vita Open Plus was safe and effective for use in treating complex aneurysms and dissections of the thoracic aorta. Results from the reviewed studies were compared to the EAC's meta-analysis results in the original assessment report and were broadly in agreement. Jakob et al. (2017) had the longest follow-up period (7

years) and they concluded that E-vita Open Plus has good long-term clinical effectiveness and safety, with low incidences of stent failure and reintervention. One in-progress prospective cohort study based in the UK was identified which is designed to collect data about the effectiveness of treatments for patients with thoracic aortic aneurysms (ETTAA study)

5.5 Cost model update

The EAC reviewed the cost model analysis from the original guidance and concluded that the model is still relevant because the pathway has not changed. The costs in the updated model were revised to reflect current values. The major cost changes in the updated model relate to acute care costs of adverse events and staff costs. In the original model, the acute care cost of all adverse events was £2,155 and in the revised model the acute care costs depend on the type of adverse event and range from £498 for bleeding to £11,663 for paraplegia. Staff costs in the revised model were taken from the Personal Social Services Research Unit (PPSRU) 2017 and were often cheaper.

Figure 1; Base case cost-savings of E-vita open plus after 5 years

Estimated saving per patient	Two stage with vascular graft	Two stage with endovascular stent graft	Open debranching with endoluminal stent graft
2018 cost model	£13,334	£10,225	£12,536
Original 2013 cost model	£13,800	£9,850	£12,000

Base case results from the revised 2018 model for the estimated cost saving per patient at 5 years are shown in figure 1 compared with the values in the current guidance. The estimated cost savings at 10 years range from £21,850 to £28,160 across the comparators in the current guidance and are estimated as £ 22,704 to £29, 210 in the 2018 cost model.

6. Summary of new information and implications for review

The additional clinical evidence identified since the original guidance was published in 2013 broadly supports the recommendations from the original guidance. All of the included papers concluded the E-vita Open Plus was safe and effective for use in

treating complex aneurysms and dissections of the thoracic aorta. The experts confirmed that is still has a place in current patient pathways which have not changed significantly. The revisions to the cost model indicate that the technology is still cost-saving in the longer term compared with all the comparators. The review proposal is to amend the guidance without a consultation to include the new estimates for the cost saving.

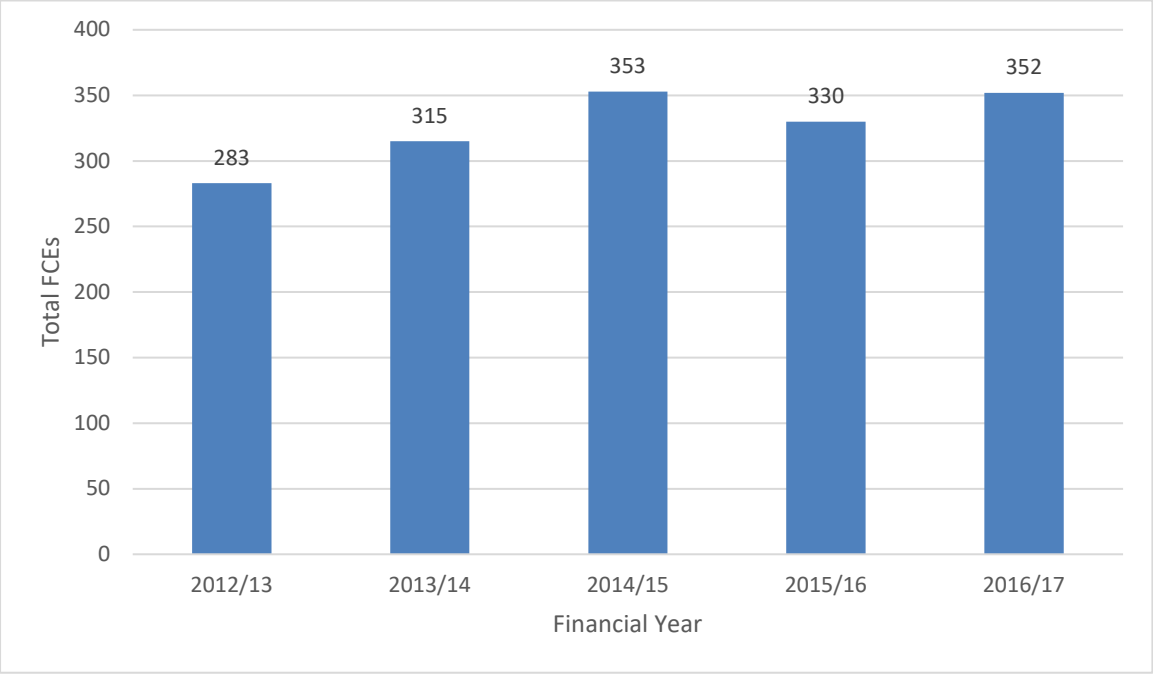
7. Implications for other guidance producing programmes

None highlighted at internal consultation.

8. Implementation

The Adoption and Impact Team provided finished consultant episodes (FCEs) data relating to procedures carrying out an endovascular insertion of stent graft for thoracic aortic aneurysm. A FCE is the period of time a patient spends under the care and responsibility of one consultant team.

Figure 1: Endovascular insertion of stent graft procedures for thoracic aortic aneurysms (2012-2016)



Based on Figure 1, following the publication of MTG 16 in December 2013, there is an increase in activity of this procedure.

9. Equality issues

No equality issues were identified in the original guidance. Considerations relating to people with connective tissue disorders are included in sections 3.11, 5.24 and 6.2 of the medical technology guidance.

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Appendix 1 – explanation of options

If the published Medical Technologies Guidance needs updating NICE must select one of the options in the table below:

Options	**Consequences**	**Selected – 'Yes/No'**
Amend the guidance and consult on the review proposal	The guidance is amended but the factual changes proposed have no material effect on the recommendations.	No
Amend the guidance and do not consult on the review proposal	The guidance is amended but the factual changes proposed have no material effect on the recommendations.	Yes
Standard update of the guidance	A standard update of the Medical Technologies Guidance will be planned into NICE's work programme.	No
Update of the guidance within another piece of NICE guidance	The guidance is updated according to the processes and timetable of that programme.	No

If the published Medical Technologies Guidance does not need updating NICE must select one of the options in the table below.

Options	**Consequences**	**Selected – 'Yes/No'**
Transfer the guidance to the 'static guidance list'	The guidance remains valid and is designated as static guidance. Literature searches are carried out every 5 years to check whether any of the Medical Technologies Guidance on the static list should be flagged for review.	Yes
Defer the decision to review the guidance	NICE will reconsider whether a review is necessary at the specified date.	No
Withdraw the guidance	The Medical Technologies Guidance is no longer valid and is withdrawn.	No

Appendix 2 – supporting information

Registered and unpublished trials

Trial name and registration number	Details
Effective Treatments for Thoracic Aortic Aneurysms (ETTAA Study): A Prospective Cohort Study NCT02010892	https://clinicaltrials.gov/ct2/show/NCT02010892

Appendix 3 – changes to guidance

Proposed amendments to original guidance

Section of MTG	Original MTG	Proposed amendment
1.3	The E-vita open plus is estimated to generate cost savings compared with current 2-stage repair from about 2 years after the procedure. The estimated cost saving per patient at 5 years after the procedure is around £13,800 when compared with 2-stage repair involving open insertion of a vascular graft, £9850 when compared with 2-stage repair involving endovascular stent grafting and £12,000 when compared with open surgical debranching followed by endoluminal stent grafting. At 10 years after the procedure, the estimated cost savings range from around £21,850 to £28,160 across the 3 comparators.	The E-vita open plus is estimated to generate cost savings compared with current 2-stage repair from about 2 years after the procedure. The estimated cost saving per patient at 5 years after the procedure is around £13,334 when compared with 2-stage repair involving open insertion of a vascular graft, £10,225 when compared with 2-stage repair involving endovascular stent grafting and £12,536 when compared with open surgical debranching followed by endoluminal stent grafting. At 10 years after the procedure, the estimated cost savings range from around £22,704 to £29,210 across the 3 comparators. [2018 – see section 5.23]
5.23		For the guidance review, the external assessment centre revised the model to reflect 2018 costs. The major changes in the update relate to acute care costs of adverse events and staff costs. In the original model, the acute care cost of adverse events was calculated as £2,155 and in the revised model the costs depend on the type of adverse event and range from £498 for bleeding to £11,663 for paraplegia. Staff costs in the revised model were taken from the Personal Social Services Research Unit

		(PPSRU) 2017 and were often cheaper. Base-case results for the 2018 revised model shows the estimated cost saving per patient at 5 years after the procedure is around £13,334 compared with 2-stage repair involving open insertion of a vascular graft, £10,225 compared with 2-stage repair involving endovascular stent grafting and £12,536 compared with open surgical debranching followed by endoluminal stent grafting. These saving increase across the 3 comparators in the longer term. Further details of the 2018 revised model are in the revised model summary. [2018]

References

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Hoffman, A. L. Damberg, G. Schalte, et al. (2013) "Thoracic stent graft sizing for frozen elephant trunk repair in acute type A dissection." Journal of Thoracic & Cardiovascular Surgery 145(4): 964-9

M. Iafrancesco, N. Goebel, J. Mascaro, et al. (2017) "Aortic diameter remodelling after the frozen elephant trunk technique in aortic dissection: results from an international multicentre registry." European Journal of Cardio-Thoracic Surgery 52(2): 310-318

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J.-P. Verhoye, A. Anselmi, A. Kaladji, et al. (2014) "Mid-term results of elective repair of extensive thoracic aortic pathology by the Evita Open Plus hybrid endoprosthesis only." European journal of cardio-thoracic surgery : official journal of the European Association for Cardio-thoracic Surgery 45(5): 812-7

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