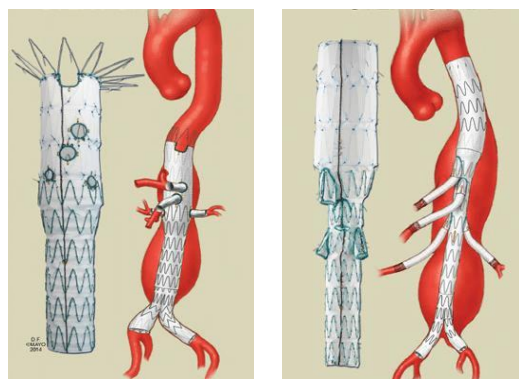


Advice Statement 006/18

May 2018

What is the clinical and cost-effectiveness of complex endovascular aneurysm repair in patients with juxta-renal or thoraco-abdominal aortic aneurysm compared with open surgical repair and how should these technologies be delivered in NHSScotland?

Figure 1: fenestrated (left) and branched (right) endovascular stent grafts



Advice for NHSScotland

Complex endovascular repair (EVAR) of juxta-renal aneurysms or thoraco-abdominal aneurysms offers an alternative to open surgical repair (OSR) and is used particularly for patients with perceived moderate/high operative risk. This is a novel treatment associated with limited and low quality evidence. Based on the published literature alone, it is difficult to establish its advantage over OSR in terms of post-operative mortality and complication rates, or to assess its cost-effectiveness.

Within the literature, patient selection between complex EVAR and OSR appears to be variable owing to a lack of consensus regarding grading of operative risk. NHS Scotland should develop a service configuration model that supports a consistent approach and optimises outcomes for patients being assessed and undergoing this intervention. A National Services Scotland (NSS) review of the national thoraco-abdominal aortic aneurysm (TAAA) service is currently underway, and will address issues regarding service provision.

NHSScotland is required to consider Scottish Health Technology Group (SHTG) advice.

Why is SHTG looking at this topic?

Complex endovascular aneurysm repair techniques are high cost procedures and there was perceived to be uncertainty in their clinical and cost-effectiveness. There is variation in the use of these procedures between NHS boards and it is not clear which model of delivery would be most appropriate. Hence SHTG was asked to assess the clinical and cost-effectiveness evidence for these procedures and identify the groups of patients that would benefit most, to help inform future service planning. This work was requested by Andrew Tambyraja, Clinical Director, Edinburgh Vascular Service, Royal Infirmary of Edinburgh, and was accepted onto the SHTG programme to support evidence-informed use of these procedures in NHSScotland.

Evidence Note 78 was produced by Healthcare Improvement Scotland in response to this request.

Background

- An aortic aneurysm is a permanent and localized enlargement (dilation) of the aorta by $\geq 50\%$ of its normal vessel diameter and, based on the location, can be classified into abdominal aortic aneurysm (AAA) or thoracic aortic aneurysm (TAA). A juxta-renal aortic aneurysm (JRAA) is a type of AAA extending up to but not involving the renal arteries and leaving a proximal neck between the renal artery and the aneurysm, while in the case of a para-renal aortic aneurysm (PRAA) there is no aortic neck beneath the renal arteries. A thoraco-abdominal aortic aneurysm (TAAA) is an aneurysm of the descending thoracic aorta extending into the abdominal aorta.
- Of the 25,500 men tested in 2016 in the Scottish Abdominal Aortic Aneurysm National Screening Programme, 376 (1.5%) had a positive result indicating an AAA of 3.0 cm or greater. Estimates of true incidence of JRAA or TAAA are not available, but it is considered that they account for approximately 15% of all AAAs or TAAs.
- Open surgery repair (OSR) has been traditionally seen as the gold standard treatment for aortic aneurysms; however, endovascular techniques have become increasingly common, particularly in patients deemed high risk for morbidity and mortality with OSR.
- In the past few years, complex EVAR techniques (fenestrated, branched, or chimney EVAR) have increasingly been used to manage anatomically challenging aneurysms such as JRAAs and TAAAs ineligible for standard EVAR.

Clinical effectiveness

- One case-control study compared 30-day outcomes in a small prospective registry-based case series (n=268) of high risk patients treated with fenestrated/branched EVAR (F/B-EVAR) with a larger retrospective cohort of controls (n=1678) treated with OSR. Both cohorts had a mixture of para/juxta-renal AAA (PRAA/JRAA) and TAAA (infra-diaphragmatic and supra-diaphragmatic) and the cohorts were not comparable in terms of risk and other characteristics. There was no statistically significant difference in 30-day mortality between the F/B-EVAR cohort and OSR cohort. After stratification by aneurysm anatomy, mortality was significantly higher with F/B-EVAR only for infra-diaphragmatic TAAA. In the extension study, 2-year mortality did not significantly differ between the cohorts and F/B-EVAR was associated with a higher rate of readmissions (2.2 vs.1.7, $p < 0.01$). Table 1 presents the clinical effectiveness information from this study.

Table 1: 30-day and 2-year mortality between complex EVAR and OSR for various aneurysm anatomies

	F/B-EVAR n=268	OSR n=1678	p-value
30-day mortality			
Pooled PRAA/JRAA and TAAA	6.7%	5.4%	0.40
PRAA/JRAA	4.3%	5.8%	0.26
Supra-diaphragmatic TAAA	11.9%	19.7%	0.70
Infra-diaphragmatic TAAA	11.9%	4.0%	0.01

2-year mortality			
Pooled PRAA/JRAA and TAAA	14.9%	11.8%	0.15
PRAA/JRAA	11.2%	11.4%	0.96
Infra-diaphragmatic TAAA	17.1%	8.4%	0.09
Supra-diaphragmatic TAAA	28.6%	31.0%	0.79

- Three systematic reviews and one HTA were identified that reported pooled outcome estimates for various complex EVAR techniques in populations with different aneurysm anatomies. However, these were based on low quality evidence, generally retrospective case series reporting short-term outcomes, in which patient cohorts are unlikely to be comparable in terms of urgency of treatment (elective/non-elective), anatomy, risk profile, and other demographics. The systematic reviews reported a 30-day mortality for the treatment of JRAA ranging from 1.4% to 4.1% with F-EVAR, 3.1% to 4.1% with OSR, and 5.3% with chimney-EVAR. Hospital length of stay reported was higher for OSR.
- The literature on volume-outcome and learning curve relationship in complex EVAR surgery is limited. One literature review indicated that the provision of complex EVAR procedures in high-volume centres appears to be associated with lower levels of perioperative mortality.

Safety

- The systematic reviews of case series reported higher postoperative major complication rates, such as cardiac and pulmonary complications, ischemic stroke, blood loss, or renal impairment for OSR compared with the endovascular techniques. However, a higher rate of re-intervention was reported with endovascular techniques and their durability is uncertain due to the general lack of long-term follow-up data.
- The complications reported in the prospective cohort study included higher rates of spinal cord ischemia, myocardial infarction, paraplegia and stroke in the F/B-EVAR cohort compared to the OSR cohort. This may be due to pooling outcomes together with B-EVAR.

Cost effectiveness

- These surgical interventions are costly and involve several consumables; the cost for the stent graft alone ranges from £12,000 to £30,000.
- Alongside the case-control study presented in the clinical effectiveness section, a short-term cost-effectiveness analysis was carried out where the results were expressed as cost per death averted. The findings were inconclusive and are not generalisable to NHSScotland.

Patient and social aspects

- None of the identified studies for the clinical and cost effectiveness review explored patient experiences or preferences relating specifically to complex EVAR techniques for the treatment of JRAA or TAAA.

Context

- The evidence on how these technologies should be delivered in clinical setting is limited. A national multicentre, cross-disciplinary consensus model in which more than 90% of the UK F-EVAR centres participated, was developed to suggest

indications for F-EVAR. Consensus was reached for the use of F-EVAR in patients at moderate risk from open repair and need for suprarenal clamping, and that it was less likely to be indicated in patients aged 85 years or more with 5.5-6 cm aneurysms, or short-necked infra-renal aortic aneurysms.

- A policy document from NHS England recommends the provision of complex EVAR techniques in centres with a catchment of two million people performing at least 100 aortic procedures annually and which have a projected annual case load for these specific interventions in excess of 24-30 cases in order to maintain high levels of expertise in all professionals involved in the care pathway.
- Within NHSScotland, these surgical procedures are currently performed in Grampian, Greater Glasgow & Clyde, Lanarkshire, Lothian and Tayside. Data from Grampian show a total of eight F-EVAR procedures performed during 2017 with an average cost of £21,910 for the high end consumables only. In Lothian there were eight F-EVAR and one B-EVAR procedures performed over the last seven years with a 0% 30-day mortality rate. Greater Glasgow & Clyde data indicate that 13 F-EVAR procedures have been performed between August 2016 and February 2018 at an average consumables cost of £20,653 per procedure.
- A review is currently being undertaken of the national Thoraco-Abdominal Aortic Aneurysm (TAAA) Service to make recommendations as to the preferred service configuration for NHSScotland. The review will take into account the factors behind the published evidence.

Further research

- Randomised controlled trials are required to progress from the exploration phase to the assessment phase of the IDEAL Framework for surgical innovation (<http://www.ideal-collaboration.net/>)
- ISRCTN85731188 is a UK prospective comparison study of open surgery, minimal invasive surgery and medical management for complex aortic aneurysms that is expected to run until June 2022 at the Royal Liverpool University Hospital. This study is likely to add promising results to the limited evidence base currently available.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full. This advice represents the view of the SHTG at the date noted.

It is provided to inform NHS boards in Scotland when determining the place of health technologies for local use. The content of this Advice Statement was based upon the evidence and factors available at the time of publication. An international evidence base is reviewed and thus its generalisability to NHSScotland should be considered by those using this advice to plan services. It is acknowledged that the evidence constitutes only one of the sources needed for decision making and planning in NHSScotland. Readers are asked to consider that new trials and technologies may have emerged since first publication and the evidence presented may no longer be current. SHTG Advice Statements are intended to inform a decision at a particular point in time. They will however be considered for review if requested by stakeholders, based upon the availability of new published evidence which is likely to materially change the advice given. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgment in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

SHTG Advice Statements will be considered for review if new evidence becomes available which is likely to materially change the advice. Stakeholders may submit a request, highlighting new evidence to shtg.hcis@nhs.net

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**Chair
Scottish Health Technologies Group**



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