Advice Statement 001/17	March 2017

Is Transcatheter aortic valve implantation (TAVI) clinically and cost effective for severe symptomatic aortic stenosis in adults at high surgical risk?

This advice has been produced following completion of evidence note 64 by Healthcare Improvement Scotland (update of evidence note 52), in response to an enquiry from the National Planning Forum TAVI Review Group.

Background

TAVI is an alternative to conventional surgical aortic valve replacement (AVR) for operable patients with severe symptomatic aortic stenosis (AS) at high risk for surgical complications. A Scottish national TAVI service was established in September 2012 in a single centre at the Royal Infirmary of Edinburgh, offering TAVI only to patients deemed not suitable for conventional AVR surgery.

The population prevalence of patients likely to benefit sufficiently from TAVI has yet to be established. 120-140 TAVI procedures are carried out each year in Edinburgh, 75% via transfemoral route, 15% direct aortic route and 10% transapical route. In total, combining individuals with aortic stenosis who are unsuitable for surgery and those at high surgical risk, it is estimated that between 90 to 390 patients per year in Scotland could be eligible for TAVI.

Clinical effectiveness

- The CoreValve US randomised controlled trial (RCT) demonstrated that TAVI is superior to surgical AVR with regard to death from any cause at 1 year (13.9% vs 18.7%, p=0.04) and 2 years (22.2% vs 28.6%, p<0.05). The trial inclusion criterion to be considered high surgical risk was ≥15% predicted risk of mortality at 30 days post AVR. Patients recruited to the trial had a mean society of thoracic surgeons (STS) score of 7.8% and the 30 day observed mortality in the group receiving AVR was 4.5%.
- Cohort A of the PARTNER I RCT reported that TAVI is not inferior to surgical AVR with regard to death from any cause at 1 year. No evidence for a difference was found for quality of life at 1 year or in mortality at 2 years and 5 years. The trial inclusion criterion to be considered high surgical risk was >15% predicted risk of mortality at 30 days post AVR. Patients recruited to the trial had a mean STS score of 11.8% and the 30 day observed mortality in the group receiving AVR was 6.5%.
- The CoreValve US trial used only the CoreValve TAVI device and transfemoral (n=323), transapical or direct aortic (n=67) access routes. The PARTNER trial used only the SAPIEN™ TAVI device and transfemoral (n=244) or transapical (n=104) implantation.
- Secondary studies have reported overall effects on mortality superior, equivalent or inferior to surgical AVR depending on the specific inclusion criteria of the studies.

The heterogeneity of results highlights the potential for outcomes to vary in different situations, for example, depending on patient selection criteria, device type or access route. However, current evidence is insufficient to identify the specific factors contributing most to this heterogeneity.

Safety

- The evidence reviewed identified an increased risk of major vascular complications, permanent pacemaker implantation, and moderate to severe paravalvular regurgitation related to the use of TAVI compared with surgical AVR. There was mixed evidence relating to neurological adverse events including stroke; risk was increased in the PARTNER trial but lower risk in the CoreValve US trial. TAVI was associated with a lower incidence of major bleeding, acute kidney injury and new or worsening atrial fibrillation compared to surgical AVR.
- NICE interventional procedure guidance on TAVI in this population notes that clinicians should ensure that patients understand the balance of benefits and harms including the risk of stroke and death and the uncertainty about the procedure's long term efficacy.

Cost effectiveness

- A recent economic evaluation utilising the CoreValve US trial estimates were adapted to the NHS Scotland setting. The results indicate that TAVI may be a cost-effective treatment option for severe AS patients at high surgical risk.
- The results of sensitivity analyses indicate that the key drivers of the cost-effectiveness results are mortality at 2 years and index admission costs. Index admission costs for TAVI are greater than those for surgical AVR due to greater device costs outweighing lower hospital stay costs. Cost-effectiveness is contingent upon the TAVI device costs being less than £19,500 (to meet a £20,000 ICER threshold) to £24,000 (to meet a £30,000 ICER threshold) and survival benefits from TAVI being comparable to those observed in the CoreValve US trial. Threshold analysis suggests TAVI mortality at 2 years less than 23.2% (£20,000 ICER threshold) to 25.3% (£30,000 ICER threshold) (base case 22.2%) is required for TAVI to be considered cost effective compared to AVR. The mean device cost (including discounts) currently paid by NHS Scotland is within the limits noted above.
- The adapted economic model includes key assumptions from the original economic evaluation as well as some additional simplifying assumptions. Decision makers should consider the validity of these assumptions when determining the applicability of the analysis to NHS Scotland.
- In six published economic evaluations predating the CoreValve US trial the balance of evidence indicated that TAVI compared with surgical AVR was not cost effective in high surgical risk patients with AS at currently accepted UK thresholds.

Conclusion

- The evidence reviewed offers support for the provision of TAVI for adults with AS who are deemed to be at high surgical risk, although it is worth noting the uncertainty surrounding the generalisability of the trial participants' risk scores to clinical practice in Scotland. Compared with surgical AVR, TAVI was found to be clinically effective and cost effective, subject to the modelling conditions outlined above.
- The evidence review identified a number of ongoing RCTs comparing TAVI with

surgical AVR using other devices in a range of patient risk categories that could provide important evidence in the future.

Advice context:

The status of SHTG Advice Statements is advisory.

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 finalisation of the Evidence Note (Systematic literature search conducted in September 2013). 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 considered for review on a 2-yearly basis. The evidence will be updated if requested by the clinical community, dependent on new published reports. 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.

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Chair
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