Advice Statement 001/14 **May 2014**

Is Transcatheter aortic valve implantation (TAVI) clinically and cost effective for severe symptomatic aortic stenosis in adults who are not eligible for surgery?

This advice has been produced following completion of evidence note 51 by Healthcare Improvement Scotland (update of evidence note 38), in response to an enquiry from the National Planning Forum TAVI Review Group

Background

- An evidence note update was prepared in response to an enquiry from the National Planning Forum TAVI Review Group.
- TAVI is a treatment option for selected patients with severe symptomatic aortic stenosis (AS) who are not suitable candidates for conventional surgical aortic valve replacement. The current alternative for these patients is conservative palliative medical management. The population prevalence of patients likely to benefit sufficiently from TAVI has yet to be established.
- A Scottish national TAVI service was established in September 2012 in a single centre at the Royal Infirmary of Edinburgh. The centre currently offers TAVI to selected patients deemed inoperable following multidisciplinary team assessment. The centre provided TAVI to 75 patients between October 2012 and January 2014.

Clinical effectiveness

- There is evidence from cohort B of the PARTNER randomised controlled trial (RCT) of an absolute reduction of 20% in the risk of death from any cause at 1 year following TAVI compared with medical management. The mortality benefit was sustained up to 2 years of follow up. Quality of life assessed up to 1 year was better among patients who had undergone TAVI. The evidence note identifies limitations of the PARTNER trial.
- The PARTNER trial used only the SAPIEN™ TAVI device and excluded patients who were not eligible for transfemoral (TF) implantation therefore the results may not be generalisable to important patient subgroups, other TAVI devices and alternative implantation routes. Prospective registry data indicate better mortality outcomes among TAVI patients eligible for TF implantation.

Safety

- The evidence reviewed identified an increased risk of major vascular complications and neurological adverse events, including stroke, related to the use of TAVI.
- Longer term follow up data are needed to reliably assess the durability of implanted TAVI devices.

Cost effectiveness

- Two out of three UK economic evaluations concluded that in inoperable patients TAVI may be cost effective compared with medical management at currently accepted UK thresholds. In contrast, three out of five non-UK analyses suggested that TAVI may not be cost effective.

- A key driver of the cost effectiveness within the economic evaluations is the assumption relating to the mortality rate of TAVI and medical management. When the economic evaluation assumed an absolute annual mortality reduction of ≥20% with TAVI compared with medical management, the results indicated that TAVI was cost effective.

Context/conclusion

- Despite remaining uncertainty over cost effectiveness and the safety issues associated with the use of TAVI in patients ineligible for surgery, the evidence of clinical benefit supports the use of TAVI for inoperable patients and the ongoing collection of patient selection and outcome data.

- TAVI technology continues to evolve. Rapid progress is being made in device modification and patient selection such that the published evidence base may not fully capture the emergent evidence for the latest generation of TAVI devices.

- The National Planning Forum TAVI expert review and clinical oversight groups will continue to monitor the operation and outcomes of the national TAVI service.

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.

Chair
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