What evidence is there of an association between TAVI procedure volume and patient outcome(s)

What is a scoping report

A technologies scoping report ascertains the quantity and quality of the published, secondary clinical and cost-effectiveness evidence on health technologies under consideration by decision makers within NHSScotland. It is based on a rapid, high-level scope of the evidence on a topic being considered by the Scottish Health Technologies Group (SHTG). In addition, a scoping report:

- highlights gaps and uncertainties in the evidence base
- clarifies definitions relating to the research question(s) on that topic
- allows further development and specification of the research question(s)
- identifies who will be involved in the evidence review product
- gives a recommendation on whether a further evidence review should proceed
- takes approximately 1 month to complete and
- allows realistic timescales to be set for any subsequent evidence product.

Scoping reports do not make recommendations for NHSScotland. If SHTG prepares an evidence note on this topic, an Advice Statement will be produced. Further information on scoping reports is available at www.healthcareimprovementscotland.org.

Key definitions

Aortic stenosis (AS): an obstruction of normal blood flow across the aortic valve caused by calcification, which may have a degenerative, rheumatic or congenital aetiology.

Surgical aortic valve replacement (AVR): open-heart surgery to replace the diseased aortic valve with a mechanical prosthetic valve. This is the current standard treatment for patients with severe symptomatic AS who are well enough to undergo surgery.

Transcatheter aortic valve implantation (TAVI): a minimally invasive procedure in which a bioprosthetic replacement aortic valve is delivered inside a catheter, either percutaneously through the vascular system or directly through an incision in the chest.

Background

A scoping report was undertaken in June 2014 to inform a review of TAVI service planning in Scotland. A literature search up to June 2014 did not identify any published volume-outcome studies of TAVI and the report concluded that there was insufficient evidence on which to base an advice statement. The information most relevant to the NHSScotland context was the National Planning Forum (NPF) TAVI Subgroup report of 2010 which noted that while the optimum number of cases for a TAVI centre to perform is uncertain, larger volume centres are recommended and, based on the British Cardiovascular Interventional Society/Society for Cardiothoracic Surgery suggestion, a minimum number of cases per year is thought to be between 25–50. This view was echoed in the expert evidence where it was also suggested that, in the long term, an optimal service would require around 35–50 cases per year (http://www.gov.scot/Resource/0039/00392167.pdf).

This scoping report updates that work.

The following questions were scoped:

1. What evidence is there of an association between TAVI procedure volume per hospital/centre per annum and patient outcomes?
2. What evidence is there of an association between TAVI procedure volume per surgeon/ cardiologist per annum and patient outcomes?
3. What evidence is there for a minimum volume threshold per hospital/centre or surgeon/ cardiologist per annum to ensure safe provision of TAVI?

For study inclusion and exclusion criteria see Table 1.
Table 1 Study inclusion and exclusion criteria

<table>
<thead>
<tr>
<th>Population</th>
<th>Patients undergoing TAVI for severe, symptomatic aortic stenosis; operable or inoperable (that is eligible or ineligible for surgical AVR)</th>
</tr>
</thead>
</table>
| Intervention | ■ TAVI  
■ Any device  
■ Transfemoral (TF), transapical (TA), or transaortic TAo) implantation  
■ Studies that do and studies that do not differentiate results by device type and/or implantation route will be eligible for inclusion |
| Outcomes | Mortality (in-hospital, 30-day, longer term if reported), procedural success, complications (intraoperative, in-hospital, 30-day), adverse events (in-hospital, 30-day) |
| Study design | ■ Systematic reviews  
■ Additional primary studies, prospective or retrospective, of any design, that evaluated the potential association between TAVI procedure volume (hospital/centre or surgeon cardiologist) and at least one patient outcome (see above)  
■ Studies that used volume as a continuous or categorical variable for analysis of volume-outcome association, and used any method of analysis will be eligible for inclusion  
■ Studies that used any approach to define high and low volume categories will be eligible for inclusion  
■ Studies that adjusted for patient risk (case mix)  
■ Preference will be given to studies that used clinical data rather than administrative data to adjust for patient risk  
■ Preference will be given to studies that explored factors other than volume (such as processes of care, learning curve) that might explain observed volume-outcome associations  
■ For studies of hospital volume, preference will be given to studies that examined the interaction between hospital volume and practitioner (surgeon cardiologist) volume |
| Other | Studies available in full and in English |
| Excluded studies | ■ Primary studies lacking adequate adjustment for case mix  
■ Unpublished reports and other data not available in full (such as conference abstracts, letters, editorials) |

Literature search

Healthcare Improvement Scotland conducted systematic searches of the secondary and primary literature to identify relevant reports published in English between 2013 and August 2016. Key websites were also searched for guidelines and policy documents. A full list of resources searched and terms used is available on request.

Evidence base

Table 2 Included evidence sources

<table>
<thead>
<tr>
<th>Publication type</th>
<th>Number of publications</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cross-sectional study</td>
<td>3</td>
<td>1-3</td>
</tr>
<tr>
<td>Consensus guidelines</td>
<td>1</td>
<td>4</td>
</tr>
</tbody>
</table>

Findings

Three cross-sectional studies were identified which explored the impact of hospital procedure volume on short term outcomes following TAVI\(^1\text{,}^3\). A summary of study characteristics and findings is in table 3. The source data for all three was the 2012 United States (US) National Inpatient Sample (NIS). This database is a subset of the Healthcare Cost and Utilization Project sponsored by the Agency for Healthcare Research and Quality (AHRQ) and is a stratified 20% sample of discharges from US community hospitals. Based on around 1,500 observations in the database, all three studies estimated that around 7,500 patients received TAVI in 2012. For two of the studies, weighting was conducted using the AHRQ sampling weights and national estimates closely reflected the source data\(^1\text{,}^3\). This meant that the volume cut-off thresholds examined were applicable only to the NIS and the study authors emphasise that these are not representative of actual numbers in clinical practice. Both these studies reported that, at the volume cut-off thresholds used, higher hospital volume predicts improved outcomes. The third study examined volume and outcome as a secondary study objective and used weighting software applied to hospital groupings which were defined according to reimbursement recommendations\(^2\). This led to national estimates where around 90% of the patients were categorised as having received the
procedure in a centre performing >20 TAVI per year. At the cut-offs used in their analysis there was no relationship identified between hospital volume and mortality when adjusted for patient characteristics.

The use of NIS data has many limitations. While it does provide information on co-morbidities, the database contains routinely collected data and does not include detailed information on important patient characteristics which may influence outcomes such as echocardiographic findings. Only in-hospital outcomes are included so longer term outcomes are not investigated. Additionally, since this is data from 2012, it may not reflect outcomes with the current generation of devices and it may be that, as some centres were newly adopting the technology during 2012, their categorisation as low volume could have been problematic to the analyses.

A 2015 position statement from the Cardiac Society of Australia and New Zealand and the Australia and New Zealand Society of Cardiac and Thoracic Surgeons references previous European and American consensus documents and recommends a minimum program volume of 20 TAVI per year or 40 per two years\(^4\). It states that TAVI programs should be established in high volume cardiac surgery centres where on-site valve surgery is performed.

### Table 3 Summary of study characteristics and findings

<table>
<thead>
<tr>
<th>Country/Source data</th>
<th>Badheka 2015(^1)</th>
<th>Kim 2015(^3)</th>
<th>de Blasi 2016(^2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients included</td>
<td>≥60 years with complete data for age, gender, death n=1,481 procedures n=7,405 (national weighted estimate extrapolated from dataset)</td>
<td>n=7,660 (national weighted estimate extrapolated from dataset)</td>
<td>≥18 years n=7,635 (national estimate weighted using reimbursement recommendations)</td>
</tr>
<tr>
<td>Outcomes</td>
<td>In-hospital mortality In-hospital mortality composite with procedural complications</td>
<td>In-hospital mortality Stroke/vascular complications Bleeding/acute renal failure/myocardial infarction (MI)/pacemaker</td>
<td>In-hospital mortality In-hospital morbidity</td>
</tr>
<tr>
<td>Definitions of hospital volume</td>
<td>Patient numbers divided into quartiles by annual procedure volume ≤5 / 6-10 / 11-20 / &gt;20</td>
<td>Low volume definitions ≤20 transfemoral (TF) TAVI ≤10 transapical (TA) TAVI</td>
<td>Hospitals grouped into categories: procedures per year &lt;20 /20-39 /40-59 /≥60 volume also examined as a continuous variable</td>
</tr>
<tr>
<td>Adjustment for co-morbidity</td>
<td>Severity of co-morbid conditions defined using Deyo modification of Charlson Co-morbidity index</td>
<td>Variables included previous cardiac intervention, pulmonary disease, obesity</td>
<td>Variables included hypertension, endocarditis, coagulopathy</td>
</tr>
<tr>
<td>Findings</td>
<td>Patients treated in hospitals in the lowest volume quartile had higher in-hospital mortality when compared with those treated in the highest volume quartile: adjusted odds ratio (OR) 0.38, 95% CI (0.27 to 0.54) (p&lt;0.001) A similar finding was reported for in-hospital mortality composite with procedural complications. Adjusted OR for 0.71 95% CI (0.62 to 0.82) (p&lt;0.001)</td>
<td>After adjustment, low volume hospital was independent predictor of in-hospital death and bleeding but not myocardial infarction (MI) for TF TAVI OR death 1.55 95% CI (1.09 to 2.21) (p=0.02) For TA- TAVI low volume was a strong predictor of in-hospital death, MI and need for pacemaker OR death 3.08 95% CI (1.69 to 5.65) (p&lt;0.001)</td>
<td>On rigorous multivariate analysis, annual TAVI volume did not predict in-hospital mortality There were no significant differences among the stratified hospitals with respect to overall in-hospital morbidity</td>
</tr>
</tbody>
</table>
Further work for Healthcare Improvement Scotland

With only three studies identified, all of which used the same US routinely collected source data, scoping indicates that the quantity of published evidence currently available on this topic is insufficient to support the production of an evidence note, systematic review or health technology assessment. It is, therefore, proposed that the technologies scoping report is published for information and that SHTG does not undertake any further review of the evidence until requested by the clinical community, dependent on new published reports.

Equality and diversity

Healthcare Improvement Scotland is committed to equality and diversity in respect of the nine equality groups defined by age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion, sex, and sexual orientation. As a scoping report summarises information and does not provide recommendations a full equality impact assessment is not deemed necessary.

The scoping report process has been assessed and no adverse impact across any of these groups is expected. The completed equality and diversity checklist is available on www.healthcareimprovementscotland.org.

Acknowledgements

Lorna Thompson, Lead Author/Health Services Researcher
Ewan Gray, Health Economist
Carolyn Sleith, Information Scientist
Marina Logan, Team Support Administrator
Members of the SHTG evidence review committee and National Planning Forum TAVI Review Group

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NICE has accredited the process used by Healthcare Improvement Scotland to produce its evidence review products. Accreditation is valid for 5 years from January 2013. More information on accreditation can be viewed at www.nice.org.uk/accreditation

References


