Statement from the Regional HTA Centre of Region Västra Götaland, Sweden

Transcatheter aortic valve prosthesis implantation (TAVI)

Question at issue:

How does transcatheter aortic valve prosthesis implantation (TAVI) affect quality of life, and morbidity, compared with medical treatment or open surgery, among adult patients with aortic valvular disease?

PICO (Patient, Intervention, Comparison, Outcome)

P = Adult patients with aortic valvular disease (stenosis, insufficiency (regurgitation), or a combination of stenosis and insufficiency), considered inoperable or with a high surgical risk.
I = Transcatheter implantation of aortic valve prosthesis.
C = Medical treatment, or open surgery
O = Primary: Mortality (30-days and long-term follow-up)
Secondary: Quality of life.
Morbidity (e.g. need of pacemaker, stroke), complications.
Number of hospitalizations after the intervention, primary success of the intervention.
Physical activity according to the NYHA classification, valve area, valve gradient.

Summary of the health technology assessment:

Method and patient category:
Aortic stenosis is the most common cardiac valvular disease and may lead to sudden death. Median survival after the onset of symptoms is two to three years. Surgical valve replacement is an efficient treatment carrying a 3-5% risk of one-month mortality, but some patients are not accepted for surgery, mainly because of high surgical risk. Today, 60-70% of all the patients with severe aortic stenosis are treated surgically, whereas the remaining patients are managed non-surgically. TAVI is a novel minimally invasive technique for treatment of symptomatic aortic stenosis, among patients that are deemed inoperable, or judged to have a high surgical risk. The valve is held in place by a stent and is inserted through the femoral artery, or through the left cardiac ventricle by means of a small thoracotomy.

Level of evidence:
The current HTA-report is based on a recent Belgian HTA-report (Van Brabandt, 2008) where literature search was conducted in July 2008, while the current HTA includes the reports published between 2008-01-01 and 2009-11-20. The literature search resulted in 11 additional publications (five non-randomized controlled studies, and six case reports), which together with Van Brabandt (2008) form the scientific basis for this report. Van Brabandt (2008) concludes that TAVI in a six to 12 months perspective improves hemodynamics and reduces the symptoms of severe aortic stenosis. 30-days and 6-months mortality rates are high (6-22%, and 10-45%, respectively), and there are no studies showing that TAVI improves survival and quality of life, compared to open surgery.

VÄSTRA GÖTALANDSREGIONEN
SAHLGRENSKA UNIVERSITETSSJUKHUSET

Sahlgrenska Universitetssjukhuset
HTA-centrum
Röda Stråket 8, 413 45 Göteborg
TELEFON växel 031-342 00 00, direkt 031-342 15 56

The current HTA-report concludes that:

- TAVI improves hemodynamic function, relieves symptoms, and improves the physical function, for patients with severe aortic stenosis (insufficient strength of evidence ⊕OOO).
- Comparative studies showing that TAVI prolongs life, and improves quality of life compared to open surgery are absent.
- Comparative studies, showing that TAVI is superior to medical treatment, considering mortality, morbidity, and quality of life, for patients deemed inoperable, or with high surgical risk, are absent.

Risks

TAVI is associated with a significant frequency of procedure related complications. Vascular complications are predominant and are reported in up to 32 % of the cases. Death/myocardial infarction/stroke within 30-days are reported in 2.5-14.9% of the cases, and 5-6% of the patients will need a pacemaker.

Ethical aspects:

Is it justifiable, considering the current level of evidence, to offer a highly specialized and expensive treatment, with a relatively high risk of severe complications to selected patients with aortic stenosis, considered inoperable, or with a high surgical risk. Invasive treatment of such patients, today managed non-operatively, may lead to crowding-out of other patient groups.

Economical aspects

The cost of TAVI within the Sahlgrenska University Hospital is 325,000 SEK/patient. There are no data available on the treatment costs for possible TAVI patients that today are treated non-surgically. The total cost of open surgical treatment of aortic stenosis for patients older than 80 years is 225,000 SEK/patient.

Concluding remarks

TAVI is a minimally invasive technique for patients with severe aortic stenosis, that have been considered inoperable, or with a high surgical risk. Hemodynamic results following TAVI have been promising, but the level of evidence for all studied outcomes is insufficient for treatment of inoperable, or high surgical risk patients with severe aortic stenosis. The method is expensive and comparisons to currently available non-invasive treatment are absent. Serious complications occur with TAVI in patients considered inoperable, or with a high surgical risk.

On behalf of the Regional HTA Centre of Region Västra Götaland, Sweden.

Göteborg, Sweden, 2010-02-24

Christina Bergh, Professor, MD.
Head of Regional HTA Centre of Region Västra Götaland, Sweden.

VÄSTRA GÖTALANDSREGIONEN
SAHLGRENSKA UNIVERSITETSSJUKHUSET

Sahlgrenska Universitetssjukhuset
HTA-centrum
Röda Stråket 8, 413 45 Göteborg
TELEFON växel 031-342 00 00, direkt 031-342 15 56