

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

Percutaneous pulmonary valve insertion for patients needing right ventricular outflow reinterventionQuestion at issue:

Is percutaneous pulmonary valve insertion equivalent, or superior, to open surgery for dysfunctional subpulmonary homograft, regarding procedure related complications, hemodynamic variables, and health-related quality of life?

PICO (Patient, Intervention, Comparison, Outcome)

- P = Adult patients, previously operated for cardiac dysfunction, having a dysfunctional subpulmonary homograft
- I = Percutaneous pulmonary valve insertion
- C = Homograft replacement with open surgery
- O = Primary outcome: Survival
 Secondary outcomes: Number of open reoperations (during the life course)
 Procedure-related complications
 Health-related quality of life (HRQL), measured with a validated instrument
 RVEDD (right ventricular end diastolic diameter) RVI (right ventricular index in ml/m²)
 Regurgitation fraction (% , measured with heart MRI)

Summary of the health technology assessment:Method and patient category:

The present treatment concerns patients with congenital heart disease (“blue babies”) that previously have been treated with open surgery, where a graft with a valve and a pulmonary artery from a deceased individual, has been placed between the right ventricle and the pulmonary artery. During their childhood these patients have normally been subjected to two or three open thoracic surgeries, since the homografts used usually have a functional survival limited to seven to 10 years. The current novel technology is intended to be used instead of open reoperation. The method involves percutaneous (minimally invasive) placement of a percutaneously inserted pulmonary valvular graft (Melody, Medtronic) in the pulmonary artery position. The stent graft is inserted percutaneously and delivered to the desired position. The number of patients in the Region Västra Götaland is estimated to be 50, with an annual need for homograft replacement of three to five.

Level of evidence:

The literature search identified 13 full text articles which were sent for assessment to the HTA project group. Six out of these were excluded (duplicate publications). Six articles (all from the same research group) were included, and form the basis for the current HTA report, whereas the seventh, a NICE report, was commented upon, but not assessed. Two of the articles included a comparison with results of open surgery and were assessed using a checklist, and contributed to the evidence grading. The remaining four articles were assessed for complications. The HTA report published by NICE included only two case series, and two case presentations, and did not contribute with any additional information. Studies with direct comparisons regarding hemodynamics, and HRQL, measured with validated instruments, were absent.

Studied outcomes:Direct patient benefit:

Mortality/survival was studied in two articles: one perioperative death among 104 treated with open surgery, no deaths among 70 stent graft treated patients. The scientific support is insufficient

regarding the question, if valved stent is equivalent, or superior, to open surgery.

Health-related quality of life (HRQL), measured with a validated scale: No studies found. There is no scientific evidence regarding the issue if valved stent is equivalent, or superior, to open surgery concerning HRQL effects.

Other outcomes:

RVI (right ventricular index, ml/m², = right ventricular end-diastolic volume, indexed to body surface area) is after open surgery reduced from 151±49 to 97±32% (n=25, p<0.0001) and after percutaneous pulmonary valve insertion from 106±27 to 89±25% (n=11, p<0.002). The patient groups are not comparable. The scientific support is insufficient regarding the question if valved stent is equivalent, or superior, to open surgery

Regurgitation fraction (retrograde leakage to the heart from the pulmonary artery), %, measured with cardiac MRI. Regurgitation is reduced by open surgery : 43±8% to 9±11% (n=25, p<0.0001), and by percutaneous pulmonary valve insertion: 34±13% to 5±9% (n=11, p<0.0001). The patient groups are not comparable. The scientific support is insufficient for the question if percutaneous pulmonary valve insertion is equivalent, or superior, to open surgery.

Side effects

Open reoperation after percutaneous pulmonary valve insertion is reported in one study (without comparison to open surgery). It included 155 consecutive patients, and reported 7, 14, 16, and 30% after 10, 30, 50, and 70 months, respectively.

Serious perioperative complications were reported in one study (without comparison to open surgery) where six (3.9%) emergency operations were reported in 152 consecutive percutaneous pulmonary valve insertions.

Stent fractures (ruptures in the metal mesh) were reported in one study (comparison to open surgery irrelevant) with 31% stent fractures after three years of follow-up in 123 consecutive patients. 49% of the patients with stent fractures needed some percutaneous intervention during the follow up.

Ethical aspects:

It is ethically questionable to introduce a novel technology into routine care when patient benefits and adverse effects after medium, and long-term are incompletely known.

Economic aspects

Open surgery: 11 consecutive patients 2007-8 at the Sahlgrenska University Hospital showed an average cost per patient of 336,000 SEK, half of which is operation cost and ICU care. Graft material approximated 50,000 SEK.

Percutaneous pulmonary valve insertion: calculations are based on five consecutive patients in 2008: average cost per patient 331,000 SEK. the major part is graft material (275,000 SEK). No ICU costs.

Concluding remarks

Percutaneous pulmonary valve insertion is less invasive, and a much more tolerable procedure for the patient, compared with open surgery with homograft. Despite 800 performed percutaneous pulmonary valve insertions worldwide, the evidence base is poor, and only two studies including some comparison with open surgery have been published so far. Considering the question if valved stent is equivalent, or superior, compared to open surgery the scientific support is insufficient regarding all the studied outcomes.

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

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