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Title **Percutaneous Heart Valve Implantation in Congenital and Degenerative Valve Disease. A Rapid Health Technology Assessment**

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Aim

To summarize evidence supporting the use of percutaneous heart valves in (1) degenerative aortic valve and (2) congenital pulmonary outflow tract disease, as compared to conservative medical therapy or traditional surgical valve replacement.

Conclusions and results

(1) The position of percutaneous aortic valve (PAV) insertion within the management spectrum of aortic valve stenosis is unknown. Results from randomized controlled trials (RCT) are not available, and clinical data can only be deduced from observational studies. Issues on safety and clinical effectiveness involving the use of PAV remain unanswered. The ongoing US-based PARTNER-IDE RCT is expected to clarify if inoperable patients are better off with PAV than with medical treatment, and if patients at high risk for surgery have a lower risk with PAV than with conventional aortic valve replacement.

(2) Conservative (ie, medical) treatment is not an option in patients with a degenerated pulmonary homograft conduit, although optimal timing for correction is unknown. The feasibility and safety of percutaneous pulmonary valve (PPV) insertion is excellent, at least in the hands of one operator. Short-term hemodynamic and clinical performance is good. Long-term durability of the valve is not known. Long-term effectiveness in postponing future surgery is unknown. Unfortunately, no RCTs are planned to resolve these questions.

Recommendations

(1) Reimbursement of PAV cannot be defended because of patient safety concerns and a poorly defined target population. The decision whether to reimburse PAV technology is to be reconsidered when the results of the ongoing PARTNER IDE RCT become available. If this RCT provides evidence on safety and effectiveness of the PAV, its acceptability (cost effectiveness) and affordability (budget impact) need to be assessed.

(2) For PPV, conditional reimbursement is proposed because of uncertainties about clinical effectiveness. Because of the skills needed to perform this procedure, and the limited number of eligible patients, a maximum concentration of this service (ie, restricted to 1 center) is desirable. With conditional reimbursement, every case should be well documented in a registry. An annual re-evaluation should be done to assess procedure-related mortality and long-term effectiveness of the device.

Methods

Standard HTA report, eventually resulting in the finding that current evidence is based on published and unpublished case series only.

Further research/reviews required

(1) For PAV: await the results of the ongoing PARTNER-IDE RCT.

(2) For PPV: an RCT devoted to long-term effectiveness would require a follow-up of many decades and is therefore unrealistic. Existing and new case series should be closely followed.

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