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Percutaneous Heart Valve Replacement for Aortic Stenosis: State of the Evidence

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"Percutaneous Heart Valve Replacement of Aortic Stenosis: State of the Evidence"
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Clinical Bottom Line: The evaluation of percutaneous heart valve replacement compared to the gold standard of surgical aortic valve replacement in high risk patients shows some evidence that supports the notion that percutaneous heart valve replacement could be effective but there isn't enough evidence to support it yet.

Introduction: Aortic valve replacement is one of the most common surgical procedures for the elderly accounting for 60%-70%. There has been an introduction of a new technology with percutaneous heart valve replacements which has been used in europe since 2007. Currently in the US this technology hasn't been approved by the FDA and the current article is evaluating the current data comparing PCHVR with the standard open heart surgery that is used for valve replacement.

Objectives- To investigate current research on percutaneous heart valve replacement to evaluate it potential place in future care for heart valve replacement.

Level of evidence: 2b there is not enough evidence but there isn't major disagreement in the medical community either

Source of funding: Agency for Healthcare Research and Quality,
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Study Design: The review was based on a technical brief commissioned by the Agency for Healthcare Research and Quality (7). They also searched PubMed and EMBASE from 1 January 1990 to 15 October 2009 to identify articles published in English that described studies of PHVR for aortic stenosis in adults. For the current review, they updated the PubMed search through 1 June 2010. Included articles were required to report at least 1 clinical outcome (for example, mortality, hemodynamic measurements of success, and successful implantation rates). We abstracted data from eligible articles into evidence tables. Abstracted data included date of publication; country; study design; study objectives; duration of follow-up; number, age, and sex of participants; valve name; size of catheter; implementation approach; implantation rates; and clinical outcomes, including hemodynamic measurements, 30-day survival rates, complications, and device dysfunction rates. We focused on device implantation success rates and 30-day survival rates as outcome measures. In addition, we evaluated the published literature for variables associated with surgery or setting that may affect short-term clinical outcomes for PHVR.

Interventions: This was a meta-analysis review of all current data. All studies included only adults with symptomatic, severe aortic stenosis who were considered to be at high surgical risk with conventional SAVR. The mean age of patients was older than 80 years. The scores from the European System for Cardiac Operative Risk Evaluation (EuroSCORE), which predicts risk for death associated with open heart surgery, were reported in 21 of the 34 case series. Mean or median logistic EuroSCOREs among the patients represented ranged from 11% to 41%, with 15 studies (71%) reporting a mean or median EuroSCORE greater than 23%. Six PHV manufacturers were represented in the included studies, but most patients received valves produced either by Edwards Lifesciences, Irvine, California (*n* _ 1040), or Medtronic, Minneapolis, Minnesota (*n* _ 1316) (**Table 2**). Delivery through the femoral artery was used in 1804 patients (76%), and the transapical approach (Ascendra valve system by Edwards Lifesciences only) was used in 514 patients (22%). Fifty-seven patients (2%) had prostheses delivered through the femoral vein, subclavian artery, axillary artery, or ascending aorta. The largest uncontrolled case series included 646 patients. Twenty-two case series (65%) included follow-up data 30 days after the procedure or until death of the patient. Seven case series (698 patients) provided clinical outcomes data 1 or more years after the procedure.

Participants: 84 published reports representing 76 distinct studies and 2375 unique patients.

Inclusion Criteria: Literature was searched for on both PubMed and EMBASE from 1 January 1990 to 1 June 2010. Articles had to be about studies of PHVR for aortic stenosis in adults and had to be published in English.

Exclusion Criteria: Required to report at least 1 clinical outcome (mortality, hemodynamic measurements of success, and successful implantation rates).

Primary Outcome Measure: Device implantation success rates and 30-day survival rates.

Secondary Outcome Measure: Effect of patient characteristics, prosthesis characteristics, and implantation approach on short-term clinical outcomes in patients undergoing PHVR.

Analysis: Review of literature.

Results: Acute procedural success – successful PHV implantation without major adverse cardiac or cerebral events- in this report was 94%. 30-day survival was 89%. The amount and quality of the published datat, and the way in which the data are reported, make it difficult to identify any specific patient characteristics related to outcomes associated with PHVR. By manufacturer: Edwards SAPIEN 30-day survival was 88% & implantation succcess was 93%, Medtronic CoreValve 30-day survival was 91% & implantation success was 95%. Implantation and 30-day survival rates were 93% and 90%, respectively, for the femoral artery approach and 94% and 88%, respectively, for the transapical approach.

Adverse Events: Procedural complication rates reported in the 2 largest published series identified, representing 339 and 646 patients who had PHVR with Edwards Lifesciences or Medtronic CoreValve devices, respectively were major access site complications (13%), life-threatening arrhythmias (8.1%). Need for hemodynamic support (4.1%) with Edwards SAPIEN valve. Valve-in valve implantation or implantation of a second valve (2.6%), vascular access site complications (1.9%), and ventricular perforation with CoreValve.

Limitations: No comparison of PHVR to current SAVR method. No results from prospective, randomized, controlled trials of PHVR have yet been reported. Lack of uniformly assessed outcomes; subjective nature of patient selection, and inadequate data to determine which factors, such as patient, prosthetic, or implantation characteristics may be associated with better outcomes. Implantation techniques, and operator experience introduce dynamic, time-dependent factors that confound assessment of acute and longer-term outcomes.