TITLE: Percutaneous Heart Valve Replacement for Valvular Heart Disease: A Review of the Clinical Effectiveness, Cost-Effectiveness, and Guidelines

DATE: 14 January 2010

CONTEXT AND POLICY ISSUES:

Aortic stenosis is primarily an age-related degenerative disease that results in narrowing of the aortic valve and resistance to the flow of blood from the left ventricle to the aorta.\(^1,2\) As the narrowing worsens patients may develop symptoms such as shortness of breath on exertion, angina, dizziness or syncope, and may experience heart failure and possibly sudden death.\(^1\) In patients with aortic regurgitation, the aortic valve leaks allowing blood from the aorta to flow back into the ventricle. This backflow results in dilation of the left ventricle and may cause heart failure.\(^2\) Surgical replacement of the faulty valve is the recommended treatment of severe aortic stenosis or regurgitation, which has a high success rate.\(^1,3\) Operative 30-day mortality rates of 3% to 5% have been reported in patients less than 70 years, and 5% to 15% in older adults.\(^1\) It is estimated that one third to two thirds of patients with severe aortic stenosis are not referred for surgery.\(^4\) Many of these patients may be considered poor surgical candidates due to advanced age and the presence of significant co-morbidities. In these patients there are few treatment options available. Medical management with various pharmacotherapies is used to control symptoms only.\(^2\) Balloon valvuloplasty is considered a short term treatment until cardiac surgery can be done, or as a palliative treatment.\(^1\) Percutaneous aortic valve replacement techniques have emerged to provide an option for patients who are unable to undergo surgical valve replacement.\(^2\)

There are numerous percutaneous aortic heart valve devices under development.\(^2,3\) Two devices have been reported most frequently in the literature: Edwards-Sapien (Lifesciences, Irvine CA, USA) and CoreValve (Medtronic, Minneapolis, MN, USA). These devices consist of a stent frame with animal pericardial valve leaflets and are available in different sizes.\(^2\) There are two different insertion techniques currently in use. The transarterial retrograde approach involves insertion of a sheath through the femoral, iliac, or subclavian artery to the aorta and aortic valve.\(^2\) It may not be suitable for patients with vascular disease. The second technique (transapical) requires a small incision in the ribcage and through the apex of the ventricle to access the aortic valve.\(^2\) A third procedure, the antegrade trans-septal technique, has fallen out of use.\(^2\)

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Congenital right ventricular outflow tract disorders disrupt the flow of blood from the right ventricle to the lungs. Children with these disorders often require surgical repair early in life and repeat surgeries to maintain valve patency and prevent long term heart damage. Peripheral pulmonary valve replacement has emerged to delay or minimize the number of surgeries over the patient’s lifespan. The Melody (Medtronic) peripheral pulmonary valve is the most studied device. It is inserted via a catheter threaded from the femoral vein using standard right heart catheterization techniques. Patients must be at least 20 kg to undergo the percutaneous procedure.

This report will provide a summary of the clinical and cost-effectiveness data, and guidelines for use of percutaneous valve replacement technologies.

RESEARCH QUESTIONS:

1. What is the clinical effectiveness of percutaneous heart valve replacement for the treatment of patients with valvular heart disease?
2. What is the cost-effectiveness of percutaneous heart valve replacement for the treatment of patients with valvular heart disease?
3. What are the guidelines for the use of percutaneous heart valves for patients with valvular heart disease?

METHODS:

A limited literature search was conducted on key health technology assessment resources, including OVID Medline, The Cochrane Library (Issue 4, 2009), University of York Centre for Reviews and Dissemination (CRD) databases, ECRI, EuroScan, international health technology agencies, and a focused Internet search. The search was limited to English language articles published between 2004 and December 2009. Filters were applied to limit the retrieval to health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, controlled clinical trials, observational studies, economic studies, and guidelines.

HTIS reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment (HTA) reports are presented first followed by observational studies and evidence-based guidelines.

SUMMARY OF FINDINGS:

Our search identified one HTA and four cohort or case-control studies. Two horizon scanning reports produced by HTA organizations were also found. The studies summarized in these reports were included in the full HTA and therefore these documents have not been summarized. Four guidelines were identified in the search.

Health technology assessments

The HTA conducted by the Belgian Health Care Knowledge Centre assessed the clinical and cost issues related to percutaneous heart valve implantation in congenital pulmonary outflow
tract disease and degenerative aortic valve disease. The authors conducted a systematic search for published clinical and economic studies. The report describes the findings of three HTAs (UK: NICE, France: Haute Autorité de Santé, Austria: Ludwig Bolzmann Institut) and 25 case series or case reports on percutaneous aortic valve replacement, and two HTAs (UK: NICE, Austria: Ludwig Bolzmann Institut) and 12 case series or case reports in patients undergoing percutaneous pulmonary valve replacement. No randomized controlled trials were found in either patient group and all results reported were based on case series.

Aortic valve replacement

Published case series (excluding data available in conference abstracts) described the outcomes in a total of 333 patients with an average age between 80 and 85 years who underwent percutaneous aortic valve replacement. These reports showed that percutaneous aortic valves were successfully implanted in 75% to 93% of eligible patients. Severe complications occurred including stroke (3% to 10%), myocardial infarction, severe bleeding, paravalvular leakage, arrhythmia, vascular complications (10% to 15%), and cardiac tamponade. One month mortality rates varied from 12% to 25% using the transarterial retrograde technique and from 8% to 18% with the transapical technique. Patients with successful valve replacement showed improvement in New York Heart Association (NYHA) functional class in the short term. One case series of 40 patients reported an improvement in quality of life six months after the procedure. Quality of life was not reported in any other case series. Four case series reported six-month mortality rates (transarterial: 18% to 25%, transapical: 26% to 41%). If data from conference abstracts were included, the range of the outcomes reported were generally larger.

The French HTA recommended conditional reimbursement of percutaneous aortic valve replacement in patients at high risk of conventional surgery or in those who were inoperable. The procedure should be limited to specialized cardiac centers and all patients’ data included in a registry. Reimbursement should be time-limited, to be re-assessed when further clinical data on effectiveness became available. The Austrian HTA concluded that reliable estimates of safety and effectiveness cannot be made with the available data. Recommendations from the NICE review are summarized in the guidelines section of this document.

Pulmonary valve replacement

The case series in patients with right outflow tract dysfunction all originated from a single physician. In the latest report, 163 patients were screened for percutaneous pulmonary valve replacement and 155 were found to be eligible. The median age was 21 years (range 7 to 71 years) and 42% were female. Valve replacement was successful in 150 patients (97%) with twelve patients (7.7%) experiencing complications, two of which died (1.3%). Two additional patients died after 8 and 35 months. The total mortality was 2.6% with a median length of follow up of 28 months (range 0 to 84 months). Minimal or no valve regurgitation was present in 80% of patients at 36 months. Freedom from reoperation (percutaneous or surgical) was 93% and 86% after 10 and 30 months respectively. Some of the valve failures were related to the design of the device and changes were made by the manufacturer. With the second generation device, freedom from reoperation was 92% after 24 months. The number of procedural complications fell from 6% in the first cohort of 50 patients to 2.9% in the second cohort (105 patients) as experience was gained with the procedure. In the case series summarized in the two HTAs, median NYHA functional class improved from class II preoperatively to class 1 after 10 months.
Pressure gradients and valve regurgitation also improved in this series of 59 patients. The Austrian HTA recommended restricted reimbursement for the procedure in specialized centers and mandatory registration of cases for ongoing re-evaluation.\textsuperscript{2} The recommendations from the NICE review are summarized in the guidelines section of this document.

No economic analyses were identified by the HTA authors in the literature search.\textsuperscript{2} The HTA’s author stated that reliable estimates of the cost-effectiveness would be difficult to determine unless clinical studies with comparable populations in the intervention and control groups are conducted. Data on the patient population who are eligible (particularly in aortic stenosis), costs, and quality of life are also required.\textsuperscript{2}

The HTA by van Brabandt\textsuperscript{2} concluded the following about percutaneous aortic valve replacement:

> A reimbursement of percutaneous aortic valve can currently not be defended because of patient safety concerns, and a poorly defined target population. Published data is not convincing that the procedural mortality risk related to percutaneous aortic valve insertion is lower than the risk incurred by conventional surgery in comparable patients. Moreover, it is unclear which patients might benefit from the technology, because clinical effectiveness not only depends on the natural history of the aortic stenosis but also on the patient’s life expectancy related to co-morbidities. The very high 6-month mortality rates render the appropriateness of the procedure questionable. The conclusions of this report can be considered up-to-date as long as no data from an ongoing randomized controlled trial have become available. For ethical reasons, patients should only be subject to percutaneous aortic valve insertion within the boundaries of a randomized controlled trial.(page v)\textsuperscript{2}

Regarding percutaneous pulmonary valve insertion, the HTA’s authors stated that the technology appears as safe as surgery based on the case series data. Randomized controlled trials to determine the optimal timing and appropriateness of percutaneous valve replacement relative the current practice of “watchful waiting” would require decades of follow-up. If reimbursement is considered it should be conditional, given the uncertainty in clinical effectiveness. Considering the limited number of patients and the technical expertise required, the authors suggested that the number of centers performing the procedure should be restricted. Patients should be entered into a registry with yearly re-evaluation of mortality and effectiveness.\textsuperscript{2}

**Observational studies**

Two cohort studies\textsuperscript{4,6} described the treatments and outcomes of patients with aortic stenosis who were thought to be poor surgical candidates and were therefore referred for percutaneous aortic valve replacement (Table 1). These patients were assessed for eligibility for percutaneous valve replacement or other therapies. The first series (Otten\textsuperscript{4}) included 100 patients, of which 39 received percutaneous valves, 14 received surgical valve replacement, and the remainder received symptomatic treatments [balloon valvuloplasty (3) or medical management (44)]. Of these, 28 were unsuitable for percutaneous valve replacement (labeled “not a candidate” group) due to aortic size, severe co-morbidities, or due to low severity of aortic stenosis. Patients were similar in age but differed between treatment groups on the predicted operative mortality risk based on the Euroscore. Patients who refused valve therapy had the highest risk and patients who underwent surgical valve replacement were the lowest risk. Patients were followed for a
mean of 13 months (range 0 to 30 months). One year survival was 87%, 62%, 40%, and 77% for the percutaneous valve, surgical valve replacement, refused valve treatment, and “not a candidate” treatment groups.\(^4\)

The second cohort (Dewey\(^6\)) described 105 patients with severe aortic stenosis who, after assessment for treatment eligibility, received either percutaneous aortic valve replacement (20%), surgical valve replacement (15%), medical management (50%), or balloon valvuloplasty with medical management therapy (15%).\(^6\) The mean age was similar between groups but the severity was statistically significantly different (p=0.019). Patients who received surgical valve replacement had the lowest predicted surgical mortality (6%) based on the Society of Thoracic Surgeons Predicted Risk of Mortality score (STS-PROM). In the other treatment groups the predicted risk was approximately 11%. Thirty day mortality rates were lowest in the surgical valve replacement group (6.3%) compared to 9.5% in the percutaneous valve group, 12.5% in the valvuloplasty group, and 13.5% in the medical management group.\(^6\) Six-month survival rate was 75%, 84%, 52%, and 58% in the percutaneous, surgical, valvuloplasty, and medical management groups respectively.

The authors of these two studies concluded that the patients screened for percutaneous valve replacement were a heterogeneous group\(^6\) and not all patients were suitable for percutaneous therapy.\(^4,6\) Survival was lowest among those who refused valve therapy (and received medical management) in one cohort\(^4\) and among those who received balloon valvuloplasty or medical management in the second cohort.\(^6\)

The report by Zierer et al.\(^5\) described 21 high risk patients who underwent percutaneous aortic valve replacement for severe aortic stenosis. These patients were matched to 30 similar patients who underwent surgical valve replacement using a minimally invasive technique (partial upper sternotomy). Patients were followed on average for 12 months. Of the patients who underwent percutaneous therapy, two patients had complications during the procedure that required conversion to open surgery. In three patients (14%), paravalvular leakage could not be resolved and mild valvular insufficiency remained. Two other patients required stent angioplasty for coronary obstruction related to the procedure. There was one intraoperative death. Valve replacement was successful with no major complications in all patients who underwent the surgical technique. Operative time was 154 minutes (standard deviation [SD] 33 minutes) in the percutaneous group and 208 minutes (SD 28) in the surgical group (p=0.004). The mean hospital stay was 5.0 days (SD 0.9) in the percutaneous group compared to 12.0 days (SD 3.4) in the surgical group (p<0.001). Ventilation time and intensive care unit stay were also statistically significantly lower in the percutaneous group compared to the surgical group. One-year survival was 76% and 83% in the percutaneous and surgical groups respectively (p=not significant). The authors concluded that postoperative recovery was faster after percutaneous valve replacement than minimally invasive surgical valve replacement with comparable mortality.\(^5\)

The article by Descoutures et al.\(^7\) described 66 elderly patients referred to a tertiary centre for management of severe aortic stenosis. Twenty seven patients were assessed as low surgical risk and underwent surgical aortic valve replacement. The remaining 39 patients were considered high risk. Of these high risk patients, 27 patients had contraindications to percutaneous valve replacement and received either medical management (16), valvuloplasty (7) or were referred for surgical valve replacement (4). Twelve patients underwent percutaneous
valve replacement. The differences between groups were evident when viewing the baseline characteristics. Low-risk patients who underwent surgical valve replacement were statistically significantly younger with lower operative risk scores. In the 12 patients who underwent percutaneous valve replacement, the surgery was unsuccessful in two and three patients died perioperatively. There were no further deaths after six months follow up. In the 27 high-risk patients with contraindications to percutaneous valve therapy, eight patients (30%) died within six months. There was one death (4%) in the low-risk surgical valve replacement group within six months of surgery. The authors concluded that percutaneous valve replacement offers a treatment option to elderly high-risk patients with severe aortic stenosis.

Table 1. Cohort and Case-Control Studies in Patients With Severe Aortic Stenosis

<table>
<thead>
<tr>
<th>Author, year, type</th>
<th>Population, time window, country</th>
<th>Treatment (device)</th>
<th>N</th>
<th>Mean age (years)</th>
<th>Operative risk score **</th>
<th>30 day mortality (%)</th>
<th>6 month survival (%)</th>
<th>1 year survival (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Otten 2008 cohort</td>
<td>Patients with severe aortic stenosis considered poor candidates for SAVR referred for PAVR Sep 2005 to Sept 2007 Netherlands</td>
<td>PAVR*</td>
<td>39</td>
<td>81</td>
<td>Euro-score (%): 15</td>
<td>NR</td>
<td>97</td>
<td>87</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SAVR</td>
<td>14</td>
<td>81</td>
<td>9</td>
<td>NR</td>
<td>85</td>
<td>62</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PABV</td>
<td>3</td>
<td>82</td>
<td>22</td>
<td>NR</td>
<td>NR</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Refused valve therapy§</td>
<td>16</td>
<td>82</td>
<td>25</td>
<td>NR</td>
<td>70</td>
<td>40</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Not candidate for PAVR§</td>
<td>28</td>
<td>82</td>
<td>17</td>
<td>NR</td>
<td>NR</td>
<td>77</td>
</tr>
<tr>
<td>Dewey 2008 cohort</td>
<td>Patients with severe aortic stenosis considered poor candidates for SAVR referred for PAVR Dec 2005 to Dec 2007 US</td>
<td>PAVR†</td>
<td>21</td>
<td>81</td>
<td>STS-PROM (%) : 11</td>
<td>9.5</td>
<td>74.6</td>
<td>NR</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SAVR</td>
<td>16</td>
<td>78</td>
<td>6</td>
<td>6.3</td>
<td>84.4</td>
<td>NR</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PABV</td>
<td>16</td>
<td>78</td>
<td>12</td>
<td>12.5</td>
<td>52.0</td>
<td>NR</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Medical management</td>
<td>52</td>
<td>81</td>
<td>11, p=0.019</td>
<td>13.5</td>
<td>58.0</td>
<td>NR</td>
</tr>
<tr>
<td>Zierer 2009 matched cohort</td>
<td>High risk patients with severe symptomatic aortic stenosis Jan 2006 to Apr 2007 Germany</td>
<td>PAVR (Cribier-Edwards: transapical)</td>
<td>21</td>
<td>85</td>
<td>Euro-score (%): 38</td>
<td>14</td>
<td>NR</td>
<td>76</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Minimally invasive SAVR</td>
<td>30</td>
<td>82</td>
<td>35</td>
<td>10, p=NS</td>
<td>NR</td>
<td>83, p=NS</td>
</tr>
<tr>
<td>Descoutures 2008 cohort</td>
<td>Patients &gt;70 years of age referred for management of severe symptomatic aortic stenosis</td>
<td>PAVR (Edwards-Sapien: transarterial)</td>
<td>12</td>
<td>85</td>
<td>Euro-score (%): 31</td>
<td>25 ‡</td>
<td>75</td>
<td>NR</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SAVR (low risk group)</td>
<td>27</td>
<td>81</td>
<td>10</td>
<td>4</td>
<td>96</td>
<td>NR</td>
</tr>
</tbody>
</table>
Guidelines and recommendations

The National Institute for Health and Clinical Excellence (NICE) produced two guidance documents on the use of percutaneous valve implantation in patients with aortic stenosis (2008)\textsuperscript{11} and right ventricular outflow tract dysfunction (2007).\textsuperscript{10}

The guidance stated that the evidence for percutaneous pulmonary valve replacement is limited to a small number of patients but the procedure shows good efficacy in the short term.\textsuperscript{10} Evidence on percutaneous aortic valve replacement is limited to small numbers of high-risk patients with severe aortic stenosis.\textsuperscript{11} Percutaneous aortic valve replacement has the potential for serious complications however the patient population selected for this procedure have a poor prognosis without treatment and are considered high-risk for standard surgical aortic valve replacement.\textsuperscript{11} No long term data is available for either population.\textsuperscript{10,11}

Physicians who wish to perform these procedures should do so with special arrangements for clinical governance, consent, and for audit or research.\textsuperscript{10,11} Patients must be made aware of the procedure’s long term uncertainty. Patients undergoing pulmonary valve replacement will require repeat operations. Those patients undergoing aortic valve replacement should be aware of the risks including serious complications, the need for emergency cardiac surgery, and death. Patients should be selected after input from a multidisciplinary team. The procedure should be performed only by specialists with training and experience in interventional cardiology in units with the training and equipment to deal with potential complications. Data from all patients should be entered into the UK Central Cardiac Audit Database.\textsuperscript{10,11}

The guidance statements were based a rapid review of the literature and specialist opinion. From their systematic search, two case series in 67 patients with right ventricular outflow tract dysfunction, and seven case series in a total of 251 patients with aortic stenosis met their inclusion criteria.\textsuperscript{10,11}

The European Association of Cardio-Thoracic Surgery (EACTS) and the European Society of Cardiology (ESC) published in 2008 a consensus statement on percutaneous aortic valve replacement in patients with aortic stenosis.\textsuperscript{12} The guidance was based on limited data reported in oral communication with few peer-reviewed journals. Members of the EACTS and ESC met in November 2007 to develop the consensus statement. Edwards Lifesciences provided funding for the meeting. The report authors concluded that percutaneous aortic valve replacement is feasible and can provide hemodynamic and clinical improvement for up to 2 years in patients with severe aortic stenosis who are high-risk or unable to undergo surgical valve replacement. Long term safety and valve durability are unknown. A multidisciplinary team, including surgeons

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### Table: Percutaneous Heart Valves

<table>
<thead>
<tr>
<th>Author, year, type</th>
<th>Population, time window, country</th>
<th>Treatment (device)</th>
<th>N</th>
<th>Mean age (years)</th>
<th>Operative risk score **</th>
<th>30 day mortality (%)</th>
<th>6 month survival (%)</th>
<th>1 year survival (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct 2006 to Apr 2007 France</td>
<td>Contraindication to PAVR ψ</td>
<td>27</td>
<td>84</td>
<td>0.03</td>
<td>24 p&lt;0.0001</td>
<td>7</td>
<td>70</td>
<td>NR</td>
</tr>
</tbody>
</table>

NR=not reported; NS=not statistically significant; PABV=percutaneous balloon valvuloplasty; PAVR=percutaneous aortic valve replacement; SAVR=surgical aortic valve replacement; STS-PROM=Society of Thoracic Surgeons Predicted Risk of Mortality

* device and insertion technique not specified; † transarterial retrograde or transapical insertion technique, device not specified; ‡ in hospital mortality; ** predicted 30 day operative mortality; ψ patients received medical management, balloon valvuloplasty or “high-risk” aortic valve replacement surgery; § patients received medical management.
and cardiologists, should select patients, perform the surgery, and monitor outcomes. The procedure should be limited to high-risk patients but, after further evaluation, may be suitable for lower risk patients. Careful evaluation is required to avoid uncontrolled diffusion.\textsuperscript{12}

A summary of statements from the American Heart Association (AHA) in 2008 was provided in the HTA by van Brabandt.\textsuperscript{2} They stated that percutaneous aortic valve replacement requires specific skills and that even after FDA approval, the technique should only be used in a small number of experienced centers until it has been thoroughly tested. Extrapolating results from high-risk patients to those with lower risk is not advisable considering the excellent results achieved by surgical valve replacement.\textsuperscript{2}

Limitations

From the data available it is not possible to determine the effectiveness of percutaneous valve replacement therapies relative to surgical valve replacement, medical management or balloon valvuloplasty. The case series and cohort studies reported have selection bias issues that must be considered when interpreting results. Patients who were selected for each treatment type had different prognoses therefore it is not possible to compare outcomes between these populations. Little is know about the natural history of aortic stenosis in patients who do not undergo surgical valve replacement.\textsuperscript{12}

High surgical risk and operability status are difficult to quantify. It has been shown that risk scoring tools, such as the Euroscore, overestimate the surgical mortality in high-risk patients undergoing surgical aortic valve replacement.\textsuperscript{13-16} Thus, comparing predicted mortality to observed data following percutaneous valve replacement may be misleading. Data from randomized controlled trials are needed to determine the optimal therapy for high risk patients. Two randomized controlled trials in patients with severe aortic stenosis are in progress (Appendix).\textsuperscript{17,18}

The impact on health related quality of life is unknown. Quality of life may not be altered by successful valve replacement, particularly in a debilitated elderly population.\textsuperscript{2}

Long term (> 1 year) information on the performance of the valves (residual regurgitation or lifespan of valve) is unknown.

The pulmonary valve case series data comes from a single physician.

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING:

Percutaneous valve replacement is an evolving technology with ongoing changes to the devices and the insertion techniques. The safety and efficacy of percutaneous valve replacement relative to surgical valve replacement, medical management, or valvuloplasty is unknown. Evidence available is limited to observational data which has methodological limitations. Percutaneous pulmonary and aortic valve replacement is technically feasible based on data from a small number of published cases. The literature suggests that successful implantation improves functional status. Impact on health related quality of life and longevity of the devices is not known. Studies report that the aortic valve replacement procedure is technically challenging and has the potential for major complications including death.
No information was identified on the cost-effectiveness of percutaneous valve replacement.

Two European guidelines suggest percutaneous aortic valve replacement may be a treatment option for patients with severe aortic stenosis who are at high risk for surgery or have contraindications to surgical valve replacement. One UK guideline suggested that percutaneous pulmonary valve replacement may be an option in patients with right ventricular outflow tract dysfunction. All guidelines cautioned against uncontrolled diffusion of this evolving technology.

The absence of data from randomized controlled trials, long term outcome data, and economic information may wish to be considered when deciding about the use of percutaneous valve replacement.

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REFERENCES:


APPENDIX: Randomized Controlled Trials on Percutaneous Valve Replacement Listed With Clinicaltrials.Gov

<table>
<thead>
<tr>
<th>Title</th>
<th>PARTNER: Placement of Aortic Transcatheter Valve Trial(^\text{17})</th>
<th>Transapical Transcatheter Treatment versus Conventional Surgery in Patients with Native Aortic Valve Stenosis(^\text{18})</th>
</tr>
</thead>
<tbody>
<tr>
<td>ID number</td>
<td>NCT00530894</td>
<td>NCT00986193</td>
</tr>
<tr>
<td>Sponsor</td>
<td>Edwards Lifesciences</td>
<td>Skejby Hospital, Denmark</td>
</tr>
<tr>
<td>Condition</td>
<td>Aortic stenosis</td>
<td>Aortic stenosis</td>
</tr>
<tr>
<td>Study design</td>
<td>RCT, open label, multiple centres</td>
<td>RCT, open label, multiple centres, phase II</td>
</tr>
<tr>
<td>Interventions</td>
<td>Cohort 1: high surgical risk patients (n=690(^3)) Edwards Sapien transcatheter heart valve (transapical or transarterial techniques), or Surgical valve replacement Cohort 2: patients who are not a surgical candidate (n=350(^3)) Edwards Sapien transcatheter heart valve, or Medical management and/or balloon aortic valvuloplasty</td>
<td>Transapical aortic valve implantation using Edwards SAPIEN valve, or Conventional aortic valve surgery</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Cohort 1: 1 year survival; functional improvement (NYHA class); freedom from major cardiac or cerebral adverse events; prosthetic valve dysfunction; hospital stay, total hospital days over 1 year follow-up; quality of life; composite of survival, hospitalization and NYHA class. Cohort 2: death during study period; functional improvement (NYHA class); total hospital days over 1 year follow-up; quality of life</td>
<td>Death, cerebral vascular incident or renal failure requiring dialysis (1 month) Echocardiographic results, valve performance (1 month)</td>
</tr>
<tr>
<td>Estimated enrollment</td>
<td>1040 patients</td>
<td>200 patients</td>
</tr>
<tr>
<td>Start date</td>
<td>April 2007</td>
<td>Dec 2008</td>
</tr>
<tr>
<td>Expected completion date</td>
<td>Sept 2014</td>
<td>Dec 2015</td>
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