Differences in Risk Assessment of Percutaneous Aortic Valve Replacement Between Cardiologists and Cardiac Surgeons

Thomas Grebel; Julia Schumm, MD

Background—Percutaneous aortic valve replacement (PAVR) for aortic stenosis is an attractive alternative to operative valve replacement. Several devices are evaluated, but their efficacy and safety are critically discussed. An interdisciplinary approach with collaboration of cardiac surgeons and cardiologists is widely requested. We analyzed how cardiologists and cardiac surgeons assess the possibilities and risks of PAVR and whether there are substantial differences between the judgments of these 2 groups.

Methods and Results—Fifty-one cardiologists and 54 cardiac surgeons from German hospitals completed an online questionnaire consisting of 11 questions dealing with typical risks and benefits of PAVR. Answers to all questions differed significantly between surgeons and cardiologists. Risks as impaired hemodynamic outcome, paravalvular leakage, or embolic events were deemed higher for PAVR than for an operation from both groups, but cardiologists rated those risks significantly lower than cardiac surgeons (P<0.01 for all questions). A regression analysis with a latent variable approach for possible advantages of PAVR (like minor operative trauma, faster recovery, less pain) showed that the fact of being a cardiologist has a significant impact on the rating of PAVR advantages (r=0.719, P<0.01), whereas personal experience showed no significant effect.

Conclusions—Cardiologists and cardiac surgeons agree on possible risks and advantages of PAVR, but the extent differs significantly between the 2 groups. Cardiologists have a far more optimistic view of PAVR and are likely to favor an interventional approach. More and better evidence based information may help to overcome group related prejudices. (Circ Cardiovasc Qual Outcomes. 2009;2:00-00.)

Key Words: heart valves ■ balloon valvuloplasty ■ risk assessment

Valvular aortic stenosis is present in 2% to 4% of elderly patients in Western countries,1-2 and its incidence will increase further because of the ageing population. National registries show that aortic valve disease is the second most common indication for cardiac surgery after coronary artery bypass grafting, and that by now almost half of the patients submitted to cardiac surgery are older than 70 years of age.3 The decision between medical management and surgical intervention for aortic stenosis may be difficult, especially for high-risk patients. Many symptomatic patients do not undergo surgical aortic valve replacement for different reasons,4 although up to now no pharmacological therapies have demonstrated outcomes superior or equal to surgery. The opportunity of a percutaneous aortic valve replacement (PAVR) is highly attractive in this context, and different devices are currently under clinical evaluation.5-7 However, unlike open surgical procedures, percutaneous valve replacement is far from being an established technique, and efficacy and safety aspects are critically discussed. An interdisciplinary approach with collaboration of cardiac surgeons and interventional cardiologists is requested in recent publications8,9 and already practiced in many centers adopting this new technique. Willingness to subject appropriate patients in clinical trials to PAVR will largely be determined by the treating physician’s attitude toward this innovative interventional approach. We sought to determine how cardiologists and cardiac surgeons assess the possibilities and potential risks of this new technique and whether there are substantial differences between the judgments of these 2 groups.

Methods

A cross-sectional survey of cardiologists and cardiac surgeons was undertaken. 1211 physicians from German university hospitals and heart centers (staff of cardiological and cardiac surgery departments) were contacted by e-mail and asked to answer an online questionnaire. The questionnaire consisted of 11 questions dealing with typical risks of PAVR and operative valve replacement (the whole survey form is shown as an appendix in the supplements). The participating physicians were asked to compare risks of PAVR with those of the gold-standard (ie, operative valve replacement) using a 7-step Likert scale. In a final part of the questionnaire, participants were able to name further risks they thought important to consider in PAVR.
WHAT IS KNOWN

- Percutaneous aortic valve replacement is an emerging alternative therapy for high-risk and inoperable patients with severe symptomatic aortic valve stenosis.
- As cardiologists and cardiac surgeons collaborate for this procedure, they will have to reach a consensus about indications and risk assessment, but it was not yet analyzed whether cardiologist and surgeons share the same view on this new technique.

WHAT THE STUDY ADDS

- We found significant differences in judgment of PAVR between cardiologists and surgeons, and on the whole, the surgeons’ assessment was much more negative than the cardiologists.
- The specialty of the physician has more impact on the perception of PAVR than the fact of personal experience.
- In the future, when analyzing new techniques with a lack of evidence based information, special care should be taken that opinions of physicians from all involved branches are taken into account.

Statistical Analysis

The Kolmogorov-Smirnov test was used to analyze whether the answers of cardiologists and cardiac surgeons were normally distributed. As this was not the case, the Mann-Whitney test was used to compare both groups at a probability value of 0.05. To investigate the link between the subjective evaluation of device-associated complications and the possible advantages of PAVR, we ran several regression models considering each possible advantage of PAVR as a dependent variable explicitly and, in and aggregated form, as latent variable. Data were analyzed in Stata (version 10.0).

Both authors had full access to all the data in the study and take responsibility for its integrity. Both authors have read and agree to the manuscript as written.

Results

Fifty-one cardiologists, 54 cardiac surgeons, and 5 physicians of other specialities (total n=110) returned a complete questionnaire, which comes up to a response rate of 9%. Twenty-one participants (24%) stated to have personal experience in PAVR; between groups, it is 28% of the cardiologists and 20% of all answering cardiac surgeons who already have experience in this procedure. The results of the survey are illustrated in the box-and-whisker plots in Figures 1 and 2. The answers to all questions differed significantly between surgeons and cardiologists. Taking a closer look at such differences, the risk of impaired postoperative hemodynamics, risk of paravalvular leakage, or embolic events was deemed higher for PAVR than for an operation from both groups, but cardiologists rated those risks significantly lower than cardiac surgeons (3.5±2 versus 2.0±1.5, P<0.01; 2.4±1.3 versus 1.3±0.5, P<0.01; 3.1±1.5 versus 1.8±1.2, P<0.01). Both cardiologists and surgeons estimate that there are advantages of PAVR like minor operative trauma, faster recovery, and less pain, but in cardiologists this was significantly more pronounced (Figures 1 and 2, respectively). Cardiologists tend to value possible risks lower and possible advantages of PAVR higher than cardiac surgeons.

In Table 1, some general regression results are shown. The dependent variable given in the upper most row of each regression depicts a possible advantage of PAVR. In models 1 to 5, those variables were investigated explicitly using ordered probit regressions, whereas in model 6 an ordinary least square regression was run on the (latent) variable PAVR adv. This variable contracts all variables on possible advantages. The explanatory variable device-associated complications also is a latent variable, which is constructed out of the retrieved possible complications (impaired postoperative hemodynamics, risk of
Cardiac surgeons criticized cardiologists as being too euphoric and surgeons named 67 further risks, cardiologists 32. Nine cardiac thought to be important with regard to PAVR (Table 2). Cardiac overall significant effect on such advantages of PAVR.

<table>
<thead>
<tr>
<th>Coefficient</th>
<th>Device-associated complications</th>
<th>Cardiologist</th>
<th>Experience</th>
<th>Observations</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.134 (0.0948)</td>
<td>0.660 (0.291)</td>
<td>0.536 (0.290)</td>
<td>87</td>
</tr>
<tr>
<td></td>
<td>0.154* (0.0915)</td>
<td>1.040 (0.296)</td>
<td>0.503* (0.281)</td>
<td>88</td>
</tr>
<tr>
<td></td>
<td>0.380 (0.0896)</td>
<td>0.405 (0.279)</td>
<td>0.252 (0.277)</td>
<td>89</td>
</tr>
<tr>
<td></td>
<td>0.421† (0.0883)</td>
<td>0.407 (0.269)</td>
<td>0.186 (0.262)</td>
<td>88</td>
</tr>
<tr>
<td></td>
<td>0.131 (0.0876)</td>
<td>1.175‡ (0.293)</td>
<td>0.450* (0.271)</td>
<td>85</td>
</tr>
<tr>
<td></td>
<td>0.300‡ (0.10)</td>
<td>0.719† (0.19)</td>
<td>0.296 (0.18)</td>
<td>85</td>
</tr>
</tbody>
</table>

SEs are shown in parentheses. The pseudo-$R^2$ the McFadden pseudo-$R^2$. PAVR adv. indicates latent variable for all possible advantages of PAVR; device-associated complications, latent variable for all possible complications associated with PAVR.

$\times P<0.01$, †$P<0.05$, ‡$P<0.01$.

paravalvular leakage, risk of repeated operation, and risk of embolic events). When regressing the variable “device-associated complications” on the possible (single) advantages of PAVR, there seems to be a positive correlation, even though not significant for all variables: the less negative the evaluation of possible complications associated with PAVR, the more beneficial PAVR is for the patient (compare row “device-associated complications” in Table 1). There is a significant and positive correlation for being a cardiologist and rating PAVR as advantageous ($r=0.719$, $P<0.01$), whereas experience shows no overall significant effect on such advantages of PAVR.

Participants were allowed to name further risks, which they thought to be important with regard to PAVR (Table 2). Cardiac surgeons named 67 further risks, cardiologists 32. Nine cardiac surgeons criticized cardiologists as being too euphoric and careless about the interventional approach. Cardiac surgeons claimed that PAVR should not be used in general.

**Discussion**

Percutaneous aortic valve replacement represents an emerging alternative therapy for high-risk and inoperable patients with severe symptomatic aortic valve stenosis. Currently, there are 2 commercially available devices, the Edwards-Sapien valve (Edwards Lifesciences Inc) and the CoreValve Revalving System (CoreValve Inc). Although more than 1000 patients have been treated with PAVR since the first-in-man study in 2002, it is very difficult to make a definitive statement about outcome, results, and risks for several reasons. There seems to be a learning curve, as well for the implantation itself as for patient selection. Also, implantation technique as well as device design underwent substantial changes over time, so early results (as well as early results from new centers) may not be representative. Finally, there are hardly any long-term results (only 1 year in most studies) and up to now, there is no randomized controlled trial. As there are only estimates for the percentage of procedural success, mortality, and typical complications, in our survey we did not ask for risk assessment in percent, but agreement in a Likert scale.

However, lack of evidence-based information is a problem encountered by every new technique. Thinking back about the beginnings of coronary angioplasty, many physicians and especially cardiac surgeons were deeply concerned about the introduction of percutaneous transluminal coronary angioplasty into clinical practice. With the development of catheterization techniques, percutaneous transluminal coronary angioplasty has replaced coronary artery bypass graft as first-line approach in coronary artery disease, even though coronary artery bypass graft is still recognized as the gold standard. Valve surgery on the other hand is still a stronghold for the cardiac surgeon, but minimally invasive procedures become increasingly important.

Sixteen percent of cardiac surgeons in our survey voiced their concern that cardiologists are too euphoric and too careless about this new technique, and some think that PAVR should not be used at all. In fact, in spite of the promising results of recent clinical studies, it should be remembered that there are decades of experience and many large clinical studies supporting the efficacy of aortic valve surgery, for patients with low operative risk as well as for octogenarians with comorbidities.

On the other hand, there is no evidence that interventional cardiologists are foolhardy daredevils. A study comparing cardiologists’ perception of risk of coronary procedures found that interventionalists perceive higher risks than noninterventionalists in a substantial number of patients, without an overall difference. Differences in judgments between cardiologists and other internists were also analyzed in a number of studies and mostly showed that neither group was more accurate in risk assessment. To our knowledge, there are no studies comparing risk judgment from cardiologists and cardiac surgeons, but we think it improbable that surgeons should be generally more risk-averse than cardiologists.

Still, the answers to all questions in our survey differed significantly between the 2 groups. On the whole, the surgeons’ assessment was much more negative than the cardiologists. Apprehension to lose one of the last surgical strongholds may play a part in the surgeons’ perception—and of course, anticipation to broaden the options of the interventionalist may play...
a part in the cardiologists’. Interestingly, the specialty of the physician has more impact on the perception of PAVR than the fact of personal experience. Being a cardiologist has a large positive impact on the rating of PAVR advantages on a 1%-significance level ($r=0.719$, $P<0.01$). On the contrary, experience shows no significant effect on the perception of possible advantages of PAVR. As it seems likely that physicians with personal experience are aware of the results of current clinical trials, the differences between cardiologists and surgeons can hardly be attributed to different knowledge, but rather to a different “cultural imprint.” Or, put in other words: job matters.

**Limitations**

There are some limitations of our study that may affect interpretation of its results. The response rate was 9%. Had all physicians responded, the results might have been different. Online questionnaires do often suffer from low response rates. However, the answering physicians came from different hospitals and different geographic areas within Germany, so we still think the results are generalizable. Considering that PAVR is a very new technique, a large percentage of participants (24%) stated to have personal experience with percutaneous valve replacement. We suspect that physicians personally involved with PAVR were more interested in our survey, but there were no significant differences between the answers of physicians with or without experience, although there were not enough participants to have the power to find small differences.

**Conclusions**

New methods and devices pose a challenge for risk assessment, especially as long as few data are available. Physicians of different specialties may focus on different aspects of innovative treatments. Opinions of physicians from all involved branches should therefore be taken into account to maximize transparency and candor of risk assessment. As surgeons and cardiologists collaborate for PAVR, they will have to reach a consensus about indications and judgments in general as well as for the individual patient. At the moment there are significant disagreements concerning the extent of risks and possible advantages of PAVR between the 2 groups. More and better evidence-based information, preferably from randomized controlled trials, as well as an intensified interdisciplinary communication may help to overcome group related prejudices.

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**Disclosures**

Dr Schumm was a consultant for JenaValve Technology GmbH, Munich, Germany.

**References**


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SUPPLEMENTAL MATERIAL
APPENDIX

Survey form (German/English):

Ich bin  Kardiologe□ Kardiochirurg□ Sonstiges□
I am cardiologist □ cardiac surgeon □ others □

1. Ich habe Erfahrung im Umgang mit PAVR. JA □ NEIN □
1. I have experience in the application of PAVR Yes □ No □

Im Vergleich zum operativen, kardiochirurgischen Aortenklappenersatz führt PAVR zu…
Compared to conventional operative valve replacement, PAVR is associated with…

2. … einer besseren postoperativen Hämodynamik.
   Stimme gar nicht zu  1  2  3  4  5  6  7  Stimme voll und ganz zu  weiß nicht □
2. … better postoperative hemodynamics
   completely disagree  1  2  3  4  5  6  7  completely agree  don’t know □

3. …geringerem Risiko von Leckflüssen zwischen Prothese und nativer Klappe.
   Stimme gar nicht zu  1  2  3  4  5  6  7  Stimme voll und ganz zu  weiß nicht □
3. … lower risk of paravalvular leakage.
   completely disagree  1  2  3  4  5  6  7  completely agree  don’t know □

4. …einem geringeren Risiko von Wiederholungseingriffen.
   Stimme gar nicht zu  1  2  3  4  5  6  7  Stimme voll und ganz zu  weiß nicht □
4. … lower risk of repeated operation.
   completely disagree  1  2  3  4  5  6  7  completely agree  don’t know □

5. …einem geringeren Risiko von thrombotischen und thrombembolischen Ereignissen.
   Stimme gar nicht zu  1  2  3  4  5  6  7  Stimme voll und ganz zu  weiß nicht □
5. …lower risk of embolic events.
   completely disagree  1  2  3  4  5  6  7  completely agree  don’t know □

6. .. einem geringeren operativen Trauma beim Patienten.
   Stimme gar nicht zu  1  2  3  4  5  6  7  Stimme voll und ganz zu  weiß nicht □
6. less operative trauma.
completely disagree 1 2 3 4 5 6 7 completely agree don’t know □

7. ... einer schnelleren Genesungszeit beim Patienten.
Stimme gar nicht zu 1 2 3 4 5 6 7 Stimme voll und ganz zu weiß nicht □
7.... faster recovery
completely disagree 1 2 3 4 5 6 7 completely agree don’t know □

8. ... ist PAVR für Patienten (>70 Jahre) generell besser geeignet.
Stimme gar nicht zu 1 2 3 4 5 6 7 Stimme voll und ganz zu weiß nicht □
8. ... more adequacy for older patients.
completely disagree 1 2 3 4 5 6 7 completely agree don’t know □

9. ... einer besseren körperlichen Funktionsfähigkeit des Patienten.
Stimme gar nicht zu 1 2 3 4 5 6 7 Stimme voll und ganz zu weiß nicht □
9.... better functionality.
completely disagree 1 2 3 4 5 6 7 completely agree don’t know □

10. ... geringeren körperlichen Schmerzen beim Patienten.
Stimme gar nicht zu 1 2 3 4 5 6 7 Stimme voll und ganz zu weiß nicht □
10. ... less physical pain.
completely disagree 1 2 3 4 5 6 7 completely agree don’t know □

11. ... einem geringeren Risiko von postinterventionellen Durchgangssyndromen.
Stimme gar nicht zu 1 2 3 4 5 6 7 Stimme voll und ganz zu weiß nicht □
11. ... less psychotic episodes.
completely disagree 1 2 3 4 5 6 7 completely agree don’t know □

Zusätzliche Kommentare
Welche zusätzlichen Risiken sehen Sie, die den Einsatz von PAVR betreffen?

Additional comments
Which additional risks do You perceive concerning the use of PAVR?