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Transapical versus Conventional Aortic Valve Replacement—A Propensity-Matched Comparison

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ABSTRACT

Introduction: The goal of this study was to compare the short- and long-term outcomes after aortic valve (AV) surgery carried out via standard sternotomy/partial sternotomy versus transapical transcatheter AV implantation (taTAVI).

Patients and Methods: All 336 patients who underwent taTAVI between 2006 and 2010 were compared with 4533 patients who underwent conventional AV replacement (AVR) operations between 2001 and 2010. Using propensity score matching, we identified and consecutively compared 2 very similar groups of 167 patients each. The focus was on periprocedural complications and long-term survival.

Results: The 30-day mortality rate was 10.8% and 8.4% (*P* = .56) for the conventional AVR patients and the TAVI patients, respectively. The percentages of postoperative pacemaker implantations (15.0% versus 6.0%, *P* = .017) and cases of renal failure requiring dialysis (25.7% versus 12.6%, *P* = .004) were higher in the TAVI group. Kaplan-Meier curves diverged after half a year in favor of conventional surgery. The estimated 3-year survival rates were 53.5% ± 5.7% (TAVI) and 66.7% ± 0.2% (conventional AVR).

Conclusion: Our study shows that even with all the latest successes in catheter-based AV implantation, the conventional surgical approach is still a very good treatment option with excellent long-term results, even for older, high-risk patients.

INTRODUCTION

The last few years have led to a surge in transcatheter aortic valve implantations (TAVI). The advances in this field have shifted the therapy for patients at an assumed high perioperative risk with conventional AV replacement (AVR) to either transfemoral or transapical valve implantation. It has been shown, however, that the commonly used risk predictors have often failed to deliver a good picture of the very old "high-risk" population and that new risk scores need to be developed [George 2011]. The TAVI benefits of a minimally invasive access, short procedure times, and no necessity for cardiopulmonary bypass are obvious. However, the results regarding (at least minimal) paravalvular leaks, partial coronary occlusion, and pacemaker implantation are not always predictable, and an imperfect valve function may affect a patient's outcome, particularly over the long term. On the other hand, conventional AVR—with its requirement for general anesthesia, at least a partial sternotomy, and use of a heart-lung machine—always leaves perfect results, with no residual calcium and no paravalvular leaks. Additionally, the long-term durability has been proved for most conventional valve prostheses.

It is generally accepted that TAVI should be considered for older, high-risk patients, and guidelines as to when a patient is at high risk have been published [Vahanian 2008]. It is still unclear, however, whether the minimally invasive TAVI procedure actually renders better results in these patients, particularly over the long run. At our institution, TAVI has been performed during the last 5 years in parallel with conventional AVR.

The aim of this study was to use propensity score analysis to compare the 2 surgical approaches with respect to short- and long-term clinical outcomes.

PATIENTS AND METHODS

Patients

We compared 336 patients who underwent TAVI operations between 2006 and 2010 with a reference group of 4533 patients who underwent conventional AVR operations between 2001 and 2010. The data were drawn from our prospective institutional database. The institutional review board approved the study for anonymous analysis and waived additional patient consent.

Surgical Technique

Standard AVR was performed via complete sternotomy (3666 patients) or upper partial sternotomy (867 patients). The use of cold blood or crystalloid cardioplegia was the choice of the surgeon.

The technique for TAVI has been described elsewhere and has essentially remained unchanged over the years [Walther 2009].

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Table 1. Patient Characteristics and Preoperative Details by Surgical Approach for the Propensity-Matched Patients*

Preoperative Data	Conventional AVR (n = 167)	Transapical AVR (n = 167)	Standardized Difference
Age, years	80.5 ± 4.6	79.8 ± 5.4	14.5
Female sex, n	108 (64.7%)	108 (64.7%)	0.0
BMI, kg/m²	26.3 ± 3.9	26.3 ± 4.6	1.0
Diabetes mellitus, n	74 (44.3%)	66 (39.5%)	9.7
Arterial hypertension, n	146 (87.4%)	141 (84.4%)	8.6
Pulmonary hypertension (>60 mm Hg), n	14 (8.4%)	15 (9.0%)	2.1
Smoker, n	38 (22.8%)	39 (23.4%)	1.4
Hyperlipoproteinemia, n	80 (47.9%)	83 (49.7%)	3.6
COLD, n	23 (13.8%)	23 (13.8%)	0.0
Liver cirrhosis, n	5 (3.0%)	9 (5.4%)	12.0
POAD, n	43 (25.7%)	46 (27.5%)	4.1
Preoperative creatinine, mg/dL	1.0 ± 0.6	1.1 ± 0.8	2.9
Preoperative dialysis, n	1 (0.6%)	3 (1.8%)	11.0
Previous cardiac surgery, n	28 (16.8%)	36 (21.6%)	12.2
LVEF, %	56.3 ± 14.1	56.0 ± 14.7	2.5
Logistic EuroSCORE, %	18.3 ± 14.0	18.7 ± 11.1	2.7

*Data are presented as the mean ± SD where indicated. AVR indicates aortic valve replacement; BMI, body mass Index; COLD, chronic obstructive lung disease; POAD, peripheral occlusive arterial disease; LVEF, left ventricular ejection fraction.

Table 2. Early Outcome for Propensity-Matched Patients*

	Conventional AVR	Transapical AVR	*P*†
Intraoperative data			
Operation time, min	144.9 ± 39.2	93.0 ± 50.8	<.0001
Partial sternotomy, n	23 (13.8%)	—	
Conversion to sternotomy, n	—	3 (1.8%)	
Postoperative data			
In-hospital mortality, n	18 (10.8%)	14 (8.4%)	.557
LCO (ECMO/IABP), n	7 (4.2%)	14 (8.4%)	.189
CPR, n	14 (8.4%)	14 (8.4%)	1.150
Reoperation for pericardial effusion, n	2 (1.2%)	5 (3.0%)	.453
Reoperation for bleeding, n	11 (6.6%)	9 (5.4%)	.815
Transfused PRBC, units	1.0 ± 0.0	1.1 ± 0.7	.736
Cerebral ischemia, n	7 (4.2%)	4 (2.4%)	.508
Permanent stroke, n	3 (1.8%)	1 (0.6%)	.714
Transitory psychological disorder, n	7 (4.2%)	9 (5.4%)	.791
Sepsis, n	10 (6.0%)	6 (3.6%)	.454
New dialysis, n	21 (12.6%)	43 (25.7%)	.004
Tracheotomy, n	8 (4.8%)	16 (9.6%)	.152
New pacemaker, n	10 (6.0%)	25 (15.0%)	.017
Aortic regurgitation at discharge, n			
None or trivial	149 (100%)	94 (61%)	
Grade 1		51 (33%)	
Grade 2		7 (5%)	
Grade >2		1 (1%)	

*Data are expressed as the mean ± SD where indicated. AVR indicates aortic valve replacement; LCO, low cardiac output syndrome; ECMO, extracorporeal membrane oxygenation; IABP, intra-aortic balloon pump; CPR, cardiopulmonary resuscitation; PRBC, packed red blood cells.

†Boldface entries indicate statistical significance ($P < .05$).

Patient Selection

From 2006, when TAVI became possible, all patients older than 75 years and with a EuroSCORE >9 were screened for TAVI operations. Additionally, patients with rare but typical risk factors for conventional surgery were considered for a TAVI procedure. These factors included a porcelain aorta, previous chest radiation, previous mediastinitis, status post coronary bypass grafting with patent grafts, and others. The final decision for or against TAVI was made on an individual basis by a team of at least 1 cardiac surgeon and 1 cardiologist. Of note is that the so-called "transfemoral first" strategy is not followed at our institution. The distributions of transfemoral and transapical cases were almost equivalent during the inclusion period for this study. Therefore, the transapical cohort is somewhat atypical compared with others described in the literature, because the number of patients with severe peripheral artery disease is relatively low.

Follow-up

Follow-up information on all patients was collected through outpatient visit with the patient and telephone contact with the referring physician, or via questionnaire. The follow-up was 100% complete with a mean (±SD) length of 1.8 ± 1.5 years.

Statistical Analysis

Throughout this report, categorical variables are expressed as proportions, and continuous variables are expressed as the mean ± SD. The differences between the TAVI and conventional surgery groups limited direct comparisons of the patients. To compensate for these differences, we used logistic regression analysis with multiple preoperative variables to calculate a propensity score for receiving TAVI (Table 1). The validity of the propensity score model was confirmed by the value of the c statistic ($c = 0.93$).

A true matched-pair analysis was performed. On the basis of the propensity score, matched pairs were created by the "greedy match" method [Austin 2007], with a caliper width of 0.02 yielding groups of 167 patients each. The balance between the groups was reconfirmed by calculating the standardized differences for each variable after matching.

The outcomes of the matched groups were then compared with the Student *t* test for dependent variables and with the McNemar test as appropriate.

For analysis of long-term survival, Kaplan-Meier curves were calculated and compared by applying Cox regression analysis for matched data pairs.

RESULTS

Early Outcomes

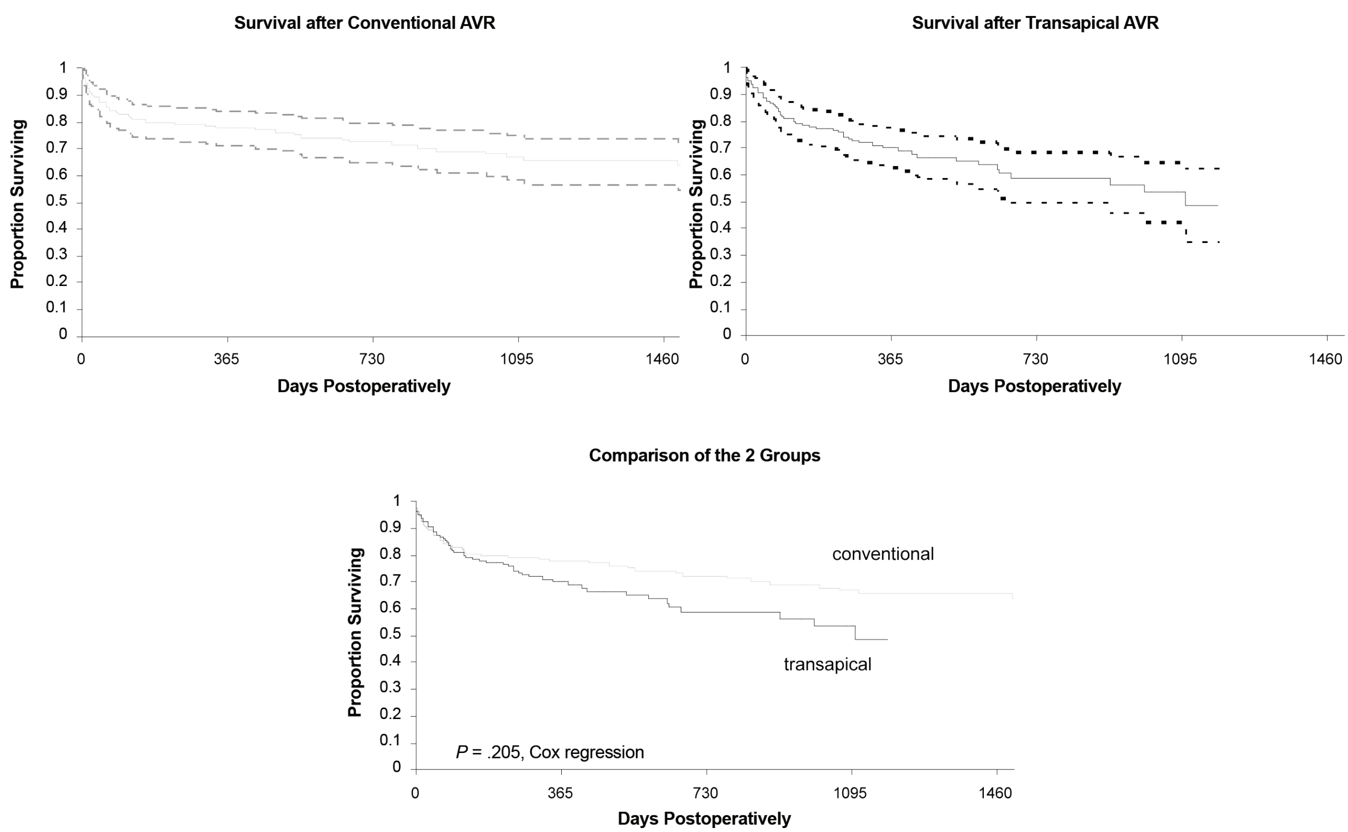
Among the matched patients, the conventional approach led to a longer total time of surgery (145 ± 39 minutes versus 93 ± 51 minutes, $P < .0001$). The 30-day mortality rate was 10.8% and 8.4% for the conventional AVR patients and the TAVI patients, respectively ($P = .56$). The percentages of postoperative pacemaker implants (15.0% versus 6.0%, $P = .017$) and cases of renal failure requiring dialysis (25.7% versus 12.6%, $P = .004$) were higher in the TAVI group. Apart from these results, there were no significant differences with respect to most of the other postoperative outcome variables (Table 2).

Late Outcomes

One patient who had undergone a TAVI procedure was readmitted with severe aortic regurgitation and underwent a complication-free conventional AVR 2 months after the initial operation. Apart from this case, there were no cases of reoperation or endocarditis reported during follow-up. The estimated mean long-term survival rates for the matched patients in the TAVI and conventional AVR groups were 70.1% ± 3.8% and 77.9% ± 3.3%, respectively, at 1 year; the corresponding survival rates at 3 years were 53.5% ± 5.7% and 66.7% ± 4.2%. The survival curves run parallel for approximately half a year and diverge thereafter in favor of the conventional operation (Figure). The difference between the survival curves failed to reach statistical significance ($P = .205$)

DISCUSSION

There is an ongoing discussion regarding the advantages and disadvantages of TAVI procedures. The surge in the numbers of operations in this field has been nourished by recent publications. In particular, the superior 1-year survival rate after a TAVI procedure for previously inoperable patients compared with patients who underwent



Long-term survival for matched patients. Top, Kaplan-Meier estimates, including 95% confidence intervals (dashed lines). Bottom, comparison of the 2 survival curves. AVR indicates aortic valve replacement.

conservative medical treatment has proved the usefulness of these new procedures [Drews 2011]. With this new therapeutic means for formerly inoperable or very high–risk patients, the limits for treating AV disease have been pushed far toward an older age and toward the acceptance of more comorbidity. The results are far from perfect, however, and the advantage of the short-term low invasiveness of the procedure is offset by a high rate of paravalvular leaks (minimal to severe) [Buellesfeld 2011], a higher rate of pacemaker implantations [Aktug 2011; Koos 2011], and a high rate of at least minor impacts to the brain [Ghanem 2010; Drews 2011]. Whether these drawbacks will influence the long-term results and quality of life remains unclear. The group of operable but old and high-risk patients needs particular attention. The long-term results of prospective randomized studies will be available in the near future. Until then, propensity score matching is the closest approximation we can get.

Compared with the matched control group, TAVI patients had a similar perioperative complication rate, with more pacemaker implants and a higher incidence of renal failure in our study. Furthermore, the long-term survival rate after TAVI was similar to the rates for other published series of transapical and transfemoral valve programs [Buellesfeld 2011; Ewe 2011; Gotzmann 2011]. Of interest is that the survival curves of our groups run parallel for approximately 200 days. Afterwards they diverge in favor of the conventional surgery. One can only speculate as to the reason for this phenomenon. The higher incidence of at least temporary dependence on dialysis might play a major role. In addition, the influence of paravalvular leaks over the long term is unknown and could be a reason for a worse outcome.

The perioperative 30-day mortality rates for TAVI that have been reported in the literature have a wide range, between 4% and 15% [Buellesfeld 2011; Ewe 2011; Nuis 2011]. This variation is most certainly the result of selecting different patients and differences in institutional experience and/or practice.

The first randomized comparison of TAVI and conventional surgery in high-risk patients, the Partner Trial Cohort A, showed a lower perioperative mortality for TAVI patients on an intention-to-treat basis. The mortality rates after 1 year were similar. The tradeoff was a higher rate of cerebrovascular events and severe vessel complications in the TAVI group [Smith 2011].

In a comparison similar to that of our study, Walther and colleagues compared the first 100 patients who underwent a TAVI procedure to a control group of patients who underwent conventional AVR and obtained similar results after 1 year [Walther 2010]. Another propensity-matched comparison of the transfemoral and transapical approaches yielded no major differences between these 2 operations with respect to outcome [Johansson 2011].

All of the other published studies were not randomized or propensity matched. Most authors conclude that the current risk models are not suitable for evaluation and decision-making with respect to whether a patient should be treated conventionally or by TAVI [Buellesfeld 2011; George 2011].

Long-term results for TAVI are still rare. Buellesfeld and colleagues recently presented 2-year follow-up data for the 18F Medtronic CoreValve (Medtronic, Minneapolis, MN, USA) prosthesis. With a 30-day mortality rate of 15.2% and a 2-year mortality rate of 38.1%, the results are within the range reported for other series [Buellesfeld 2011].

Summary

A review of the latest studies and the results of this study reveal that the question regarding which patient is best treated with which treatment option cannot be answered yet. Our study is intended to contribute to the growing pool of long-term results in the interesting field of TAVI. Until more studies with longer postoperative follow-up periods become available, the idea of heart teams consisting of cardiologists and cardiac surgeons is probably the best concept for decisions oriented to individual patients.

Conclusion

The presented study shows that even with all the euphoria about catheter-based AV implantation, the conventional surgical approach is still a very good treatment option with excellent long-term results, even for older patients.

Limitations

The current study is retrospective in nature and is therefore subject to the inherent weaknesses of a retrospective analysis. It has to be noted that this limitation is only partly overcome by use of a propensity-matched analysis.

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