Sutureless replacement versus transcatheter valve implantation in aortic valve stenosis: A propensity-matched analysis of 2 strategies in high-risk patients

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Objective: This propensity-matched study compared clinical and echocardiographic outcomes between patients undergoing transcatheter aortic valve implantation (TAVI) and sutureless aortic valve replacement.

Methods: From January 2010 to March 2012, 122 patients (age 79.4 ± 5.3 years, logistic euroSCORE 12% ± 8.4%) underwent minimally invasive sutureless aortic valve replacement, and 122 (age 84.6 ± 6.2 years, logistic euroSCORE 20.9% ± 2.5%) underwent TAVI. After propensity matching, 37 matched pairs were available for analysis.

Results: Preoperative characteristics and risk scores of matched groups were comparable. In-hospital mortalities were 0% in the sutureless group and 8.1% (n = 3) in the TAVI group ($P = .24$). Permanent pacemaker implantation was required in 4 patients in the sutureless group and 1 patient in the TAVI group (10.8% vs 2.7%; $P = .18$). A neurologic event was recorded in 2 patients of each group. Predischarge echocardiographic data showed higher paravalvular leak rate in the TAVI group (13.5% vs 0%; $P = .027$). At mean follow-up of 18.9 ± 10.1 months, overall cumulative survival was 91.9% and significantly differed between groups (sutureless 97.3% vs TAVI 86.5%; $P = .015$). In the TAVI group, a significant difference in mortality was observed between patients with (n = 20) and without (n = 17) paravalvular leak (25% vs 0%; $P = .036$).

Conclusions: Combining the advantage of standard diseased valve removal with shorter procedural times, minimally invasive sutureless aortic valve replacement may be the first-line treatment for high-risk patients considered in the ''gray zone'' between TAVI and conventional surgery. (J Thorac Cardiovasc Surg 2014;147:561-7)

According to the recent guidelines of the European Society of Cardiology on the management of valvular heart disease,[1] aortic valve replacement (AVR) is recommended as first-line therapy in patients with severe symptomatic aortic valve stenosis to improve both symptoms and survival. In the last few years, in particular after the publication of the Cohort A results of the PARTNER (Placement of AoRTic TraNscathetER Valve) trial,[2] there has been great debate regarding alternative therapeutic strategies such as transcatheter aortic valve implantation (TAVI) for high-risk patients with symptomatic severe aortic valve stenosis. From the dualism between the surgical and transcatheter approaches, a new option has emerged: recent studies have demonstrated better clinical and cosmetic results with minimally invasive techniques for AVR versus conventional surgery.[3] The drawback of minimally invasive surgery is that it generally requires longer crossclamp and operative times. This may expose patients to potential additive risks, especially if the procedure is performed by surgeons who are not experts or are still on the learning curve. Although there are no data supporting this observation, a high level of surgical skills is required for these procedures because of the increasing use of technology, and a learning curve is unavoidable. More recently, sutureless AVR devices have been developed that enable short procedural times and also easy implantation of the aortic valve prosthesis when using a minimally invasive surgical approach.[4-7] In case of the Perceval S (Sorin Group Srl, Saluggia, Italy), this hybrid solution is somewhere between conventional surgical AVR, as it allows removal of the native diseased valve, and the transcatheter approach, as the bioprosthetic valve is mounted on an expandable stent fixed to the

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Abbreviations and Acronyms

AVR = aortic valve replacement
CABG = coronary artery bypass grafting
CORONARY = Coronary Artery Bypass Surgery Off- or On-Pump Revascularization Study
PARTNER = Placement of AoRTic TraNscathetER Valve [trial]
TAVI = transcatheter aortic valve implantation
TRITON = Surgical Treatment of Aortic Stenosis With a Next Generation Surgical Aortic Valve [trial]

aortic annulus without sutures. Although follow-up data are relatively short term, this implantation technique is reported to be associated with very short procedural times.[8]

The aim of this single-center study was to assess retrospectively and compare all consecutive patients who have undergone TAVI or minimally invasive sutureless AVR in the last 2 years at our Center, after careful evaluation by our multidisciplinary heart team including cardiologists, cardiac surgeons, and cardiac anesthesiologists. A propensity score analysis was used to create matched pairs comparable for perioperative risk.

MATERIALS AND METHODS

We collected data of all patients with the diagnosis of severe aortic valve stenosis with an indication for surgery in our center since 2010. Two specific programs were initiated in our institution at the same time: the first program was developed in collaboration between cardiologists and cardiac surgeons for the use of TAVI (Sapien and Sapien XT; Edwards Lifesciences Inc, Irvine Calif), whereas the second program involved use of the Perceval S sutureless prosthesis. Every week, during an interdepartmental conference, we evaluated all patients affected by severe aortic valve stenosis referred to our center from peripheral hospitals, private practices, or our emergency department, considering comorbidities and surgical risk to determine the best therapy. In all patients aged older than 65 years with an indication for isolated AVR considered candidates for surgery (irrespective of euroSCORE), a low frailty score (evaluated by clinical inspection and other factors not included in the euroSCORE or Society of Thoracic Surgeons scoring system, such as poor mobility, nonvascular degenerative neurologic diseases including Parkinson and Alzheimer diseases, home oxygen therapy, liver cirrhosis), and compatible echocardiographic findings (symmetric aortic annulus with a diameter 19-27 mm and a sinotubular junction/annulus ratio <1.3), a Perceval S sutureless valve was implanted earlier as part of a premarket study (Cavalier Study) and later (after European Community approval in 2011) as routine use. During the premarket study, patients also signed an additional informed consent for the experimental use of the new type of prosthesis (not yet CE mark approved). An informed consent for the use of personal data and follow-up contact was also signed by all patients. The study was approved by the local ethics committee.

All patients with frailty factors judged at very high surgical risk or with a logistic euroSCORE greater than 20% underwent a TAVI procedure as part of a multicenter registry (Source XT) for the use of the Sapien XT prosthesis. The transfemoral approach was considered as the first-line strategy, leaving the transapical approach in case of inadequate vascular access. Patients assigned to the TAVI strategy with concomitant coronary artery disease underwent coronary angioplasty with stent implantation before TAVI if the coronary anatomy seemed favorable. Conversely, patients with unsuitable coronary anatomy underwent combined sutureless AVR and coronary artery bypass grafting (CABG), except for 1 patient with isolated ostial right coronary artery lesion who underwent transaortic TAVI and off-pump CABG (Table 1).[9] Patients with a bicuspid aortic valve were excluded from both sutureless and TAVI implantation.

After 2 years of extensive experience with both procedures, a total of 244 patients were operated on, equally distributed between the TAVI and sutureless groups (n = 122 each). Patients of both groups were comparable for clinical and surgical characteristics, and a retrospective propensity score analysis was performed. For the matched pair samples, postoperative and follow-up clinical and echocardiographic data were obtained. All patients were followed up at our outpatient clinic and were evaluated clinically and by questionnaire to assess events between visits. In particular, the need for rehospitalization for cardiovascular of other causes was recorded. Prosthetic valve function was evaluated with transthoracic echocardiography. The presence of paravalvular regurgitation was defined according to current guidelines as none or trace, mild, moderate, or severe.[10] All echocardiographic examinations were performed by either of 2 echocardiographists with a Philips iE33 ultrasound machine (Philips, Eindhoven, The Netherlands).

The Perceval implantation technique has been described previously.[11] If associated CABG surgery had to be performed, distal coronary anastomoses preceded prosthesis implantation, and proximal surgical sutures either were performed during primary crossclamping, after tangential clamping of the ascending aorta, or were avoided completely if suitable. General anesthesia with endotracheal intubation was used in both groups. Our heart team prefers this technique because it allows performance of intraoperative transesophageal echocardiography. In patients undergoing TAVI by the transfemoral route, the endotracheal tube was removed immediately after the procedure if appropriate. In all other cases, patients were extubated in the intensive care unit. Transfemoral procedures were performed through a minimally invasive direct vascular access: the access site was chosen according to computed tomographic findings, size of the common femoral artery, amount of calcification of the vessel and iliac arteries, and tortuosity, or in selected cases with the Prostar percutaneous closure device (Abbott Vascular, Santa Clara, Calif). Before all TAVI procedures, the cardiac apex and intended optimal coaxial alignment were localized by transthoracic echocardiography. The surgical technique for positioning and deploying the Sapien XT valve prosthesis has been well described and standardized for both the transapical and transfemoral approaches.[12,13]

Statistical Analysis

Categoric variables were summarized as frequencies (%), and continuous variables were summarized as mean ± SD. A propensity score matching (1:1) was performed to control selection bias as a result of nonrandom assignment to the groups. The propensity score was defined as the probability of receiving TAVI. This was estimated by means of a multivariate regression analysis. The following patient characteristics and major preoperative risk factors were entered into the model: age, sex, body surface area, logistic euroSCORE, previous cardiac surgery, hypertension, hyperlipidemia, left ventricular ejection fraction, renal disease, previous myocardial infarction, chronic obstructive pulmonary disease, peripheral vascular disease, and New York Heart Association functional class. Once the propensity score had been estimated for each subject, a receiver operating characteristic curve area proved the performance of the model (Figure 1). The P value of the Hosmer-Lemeshow test was .016, and C statistic for the fitted logistic regression model was 0.8 ($P < .001$), indicating that the model fitting was excellent. Pairs were generated with the 5:1 digit matching approach.