Early and intermediate outcome after aortic valve replacement with a sutureless bioprosthesis: Results of a multicenter study

Antonino S. Rubino, MD,^a Giuseppe Santarpino, MD,^b Herbert De Praetere, MD,^c Keiichiro Kasama, MD,^c Magnus Dalén, MD,^d Ulrik Sartipy, MD,^d Jarmo Lahtinen, MD,^e Jouni Heikkinen, MD,^e Wanda Deste, MD,^a Francesco Pollari, MD,^b Peter Svenarud, MD, PhD,^d Bart Meuris, MD, PhD,^c Theodor Fischlein, MD,^b Carmelo Mignosa, MD, FECS, ^a and Fausto Biancari, MD, PhD^e

Objective: The aim of this study was to evaluate the outcome of aortic valve replacement with the sutureless Perceval S aortic valve bioprosthesis (Sorin Biomedica Cardio Srl, Saluggia, Italy).

Methods: This is a retrospective analysis of 314 patients (mean age, 77.9 ± 5.0 years, mean European System for Cardiac Operative Risk Evaluation II, $9.0\% \pm 7.6\%$) who underwent aortic valve replacement with the Perceval S valve with (94 patients) or without (220 patients) concomitant coronary artery bypass surgery at 5 European centers.

Results: The Perceval S valve was successfully implanted in all but 1 patient (99.7%). The mean aortic crossclamping time was 43 ± 20 minutes (isolated procedure, 39 ± 15 minutes; concomitant coronary surgery, 52 ± 26 minutes). Severe paravalvular leak occurred in 2 patients (0.6%). In-hospital mortality was 3.2% (1.4% after isolated procedure and 7.4% after concomitant coronary surgery). In-hospital mortality was 2.8% and 4.0% among patients with a European System for Cardiac Operative Risk Evaluation II less than 10% and 10% or greater, respectively ($P = .558$). Octogenarians had slightly higher in-hospital mortality (5.2% vs 2.0%, $P = .125$; after isolated procedure: 2.7% vs 0.7%, $P = .223$; after concomitant coronary surgery: 9.5% vs 5.8%, $P = .491$) compared with younger patients. Full sternotomy did not increase the in-hospital mortality risk compared with ministernotomy or minithoracotomy access (1.3% vs 1.4%, when adjusted for baseline covariates: $P = .921$; odds ratio, 0.886; 95% confidence interval, 0.064-12.346). One-year survival was 90.5%. Freedom from valve-related mortality, stroke, endocarditis, and reoperation was 99.0%, 98.1%, 99.2%, and 98.3%, respectively.

Conclusions: The sutureless Perceval S valve is associated with excellent early survival in high-risk patients, particularly among those undergoing an isolated procedure. Further studies are needed to prove the durability of this bioprosthesis. (J Thorac Cardiovasc Surg 2014;148:865-71)

Severe aortic valve stenosis is a common cardiac disease among the elderly,^{1,2} and aortic valve replacement (AVR) is still the treatment of choice.³ Among octogenarians, AVR has been shown to provide late survival similar to that in an age- and gender-matched general population.⁴ The expected significant aging of the population and the evidence of a survival benefit in patients with a low gradient

severe aortic valve stenosis⁵ will soon lead to a significant increase in the need for AVR, particularly in very elderly patients with multiple comorbidities. Transcatheter aortic valve replacement (TAVR) has been embraced with enthusiasm and has expanded the therapeutic possibilities to patients ineligible for conventional AVR. Conversely, the significantly increased costs, the inability to remove the calcified aortic valve, and the resultant high incidence of paravalvular leakage have been recognized as important limitations of TAVR. Accordingly, a number of sutureless aortic valve bioprostheses⁶ have been developed during the last few years to facilitate surgical AVR and circumvent prolonged aortic crossclamping and cardiopulmonary bypass time and their related increased risk of mortality and morbidity.⁷ Therefore, the aim of this study was to assess the early and intermediate outcome after AVR with the sutureless Perceval S aortic valve bioprosthesis (Sorin Biomedica Cardio Srl, Saluggia, Italy) in a multicenter European study.

METHODS

We performed a retrospective analysis of a consecutive series of patients who underwent operation between September 2007 and September 2013 at 5 European institutions (Belgium, Finland, Germany, Italy, and Sweden).

From the Cardiac Surgery Unit,^a A.O.U. Policlinico-Vittorio Emanuele, University of Catania, Catania, Italy; Department of Cardiac Surgery,^b Klinikum Nürnberg, Nürnberg, Germany; Department of Cardiac Surgery,^c University Hospital Gasthuisberg, Leuven, Belgium; Division of Cardiothoracic Surgery,^d Department of Molecular Medicine and Surgery, Karolinska Institutet, Karolinska University Hospital, Stockholm, Sweden; and Department of Surgery,^e Oulu University Hospital, Oulu, Finland.

Disclosures: Antonino S. Rubino reports grant support from Sorin. Bart Meuris, Theodor Fischlein, and Carmelo Mignosa report consulting fees from Sorin. All other authors have nothing to disclose with regard to commercial support.

Read at the 94th Annual Meeting of the American Association for Thoracic Surgery, Toronto, Ontario, April 26-30, 2014.

Received for publication Dec 21, 2013; revisions received March 20, 2014; accepted for publication March 28, 2014; available ahead of print June 20, 2014.

Address for reprints: Antonino S. Rubino, MD, Cardiac Surgery Unit, A.O.U. "Policlinico-Vittorio Emanuele," Ferrarotto Hospital, University of Catania, Via Citelli, 95124 Catania, Italy (E-mail: antonio.rubino@hotmail.com).

0022-5223/\$36.00

Copyright © 2014 by The American Association for Thoracic Surgery

<http://dx.doi.org/10.1016/j.jtcvs.2014.03.052>

Abbreviations and Acronyms

AVR	= aortic valve replacement
CABG	= coronary artery bypass grafting
CI	= confidence interval
euroSCORE	= European System for Cardiac Operative Risk Evaluation
OR	= odds ratio
TAVR	= transcatheter aortic valve replacement

The baseline and operative characteristics of these patients are summarized in [Tables 1 and 2](#). The operative risk of these patients was estimated according to the European System for Cardiac Operative Risk Evaluation (euroSCORE) II.⁸

Permission to perform this study was granted by the ethical committees of each participating center. The inclusion criterion for this study was any isolated AVR with or without concomitant coronary artery bypass grafting (CABG) using the Perceval S sutureless aortic valve prosthesis. Patients undergoing any other concomitant cardiac procedure were excluded. Data on patients' characteristics and operative details were retrieved retrospectively from patients' records. Follow-up data were retrieved by reviewing hospital records or contacting the patient or her/his cardiologist or general practitioner.

Indication for and Implantation Technique of Perceval S Prosthesis

The Perceval S sutureless aortic valve prosthesis was mostly indicated in patients with a perceived high operative risk. The implantation of this valve was considered feasible when the aortic annulus size was between 19 and 27 mm, and the ratio between the sinotubular diameter and the aortic annulus was no more than 1.3. The ascending aorta was incised transversally 1.5 cm above the sinotubular junction. The aortic valve was removed, and the annulus was decalcified in the usual fashion in patients at each center. Three 4/0 polypropylene guiding sutures were passed at the nadir of the aortic annulus. An appropriately sized prosthesis was collapsed in a side table and placed into the manufacturer's holder. The 3 guiding sutures were passed through the 3 green holes arising from the annular ring of the prosthesis, which was consequently seated on the debrided annulus. The aortic valve was opened, and the holder was removed. The field was rinsed with warm saline, and the prosthesis was dilated at 4 atm for 30 seconds. After closure of the aortotomy, transesophageal echocardiography was performed to assess the correct implantation of the prosthesis and the presence of any valve leak.

Outcome End Points

The main end points of this study were all-cause in-hospital and 1-year mortality. Secondary outcome end points were implantation success, aortic prosthesis valve-related mortality, stroke, reoperation on the aortic valve, and prosthesis endocarditis. Implantation success was defined as an implanted Perceval S that did not require replacement during the same operation with another Perceval S or conventional valve prosthesis.

Statistical Analysis

Statistical analysis was performed using SPSS version 20 (IBM SPSS Inc, Chicago, Ill). Fisher exact test, chi-square test, and Mann-Whitney test were used for univariate analysis. No attempt to replace missing values was made. Survival analysis was performed using the Kaplan-Meier and Cox proportional hazards methods. The area under the receiver operating

characteristic curve was used to represent the discriminatory ability of the euroSCORE II. The accuracy of the euroSCORE II was assessed by the Brier score,⁹ which is the average squared difference between the predicted probability and the true occurrence of operative mortality. A Brier score should be as close to 0 as possible, with 0.25 as an acceptable upper cutoff.

RESULTS

This analysis included 314 patients who underwent AVR with the sutureless Perceval S aortic valve ([Table 1](#)). In addition to the high prevalence of octogenarians (36.9%), there was a rather high prevalence of female patients (60.2%), patients with renal failure (creatinine clearance <50 mL/min or dialysis, 23.5%), patients with peripheral artery disease (23.9%), and patients with increased systolic pulmonary pressure (>30 mm Hg, 44.4%). However, most of these patients had a left ventricular ejection fraction greater than 50% (86.3%), and surgery was performed on elective basis in all but 2 patients (99.4%).

Concomitant CABG was performed in 94 patients (29.9%). Minimally invasive access was used in 140 patients (44.6%) ([Table 2](#)). In the overall series, the mean aortic crossclamping time was 43 ± 20 minutes, and cardiopulmonary bypass time was 73 ± 28 minutes. These were markedly shorter in patients undergoing isolated AVR ([Table 2](#)). In particular, the aortic crossclamping time was less than 30 minutes in 79 patients (25.2%), more specifically in 64 patients (29.1%) who underwent isolated AVR and in 15 patients (16.0%) who underwent concomitant CABG.

Early Outcome

The Perceval S valve was successfully implanted in all but 1 patient (99.7%). Severe paravalvular leak was detected intraoperatively in 2 patients (0.6%), mild paravalvular leak was detected in 38 patients (12.1%), and no paravalvular leak was detected in 274 patients (87.3%).

Redo conventional AVR was required during the same in-hospital stay in 3 patients: the 2 patients with the mentioned severe paravalvular leakage and 1 patient with prosthesis dislodgment.

In-hospital mortality in the overall series was 3.2% (1.4% after isolated aortic valve procedure and 7.4% after concomitant CABG, $P = .009$). Six patients died of multi-organ failure, 3 patients died of sepsis, and 1 patient died of respiratory failure. Among these early deaths, only 2 patients had mild paravalvular leak and the remaining 8 patients did not have any paravalvular leak. None of them required reoperation on the valve prosthesis, and no valve-related early mortality occurred in this series. Other early adverse events and length of stay in the intensive care unit and in hospital are summarized in [Table 3](#).

The mean euroSCORE II in the overall series was $9.0\% \pm 7.6\%$ (median, 7.0%; range, 1.08-60.0). The area under the

TABLE 1. Baseline characteristics of patients who underwent aortic valve replacement with the Perceval S sutureless aortic valve bioprosthesis

Clinical variables	No. (%)
Age (y)	77.9 ± 5.0
Octogenarians	116 (36.9)
Female	189 (60.2)
Diabetes	94 (29.9)
Insulin-dependent diabetes	32 (10.2)
Creatinine clearance	
>85 mL/min	114 (36.3)
50-85 mL/min	126 (40.1)
<50 mL/min	73 (23.2)
On dialysis	1 (0.3)
New York Heart Association class	
I	1 (0.3)
II	60 (19.1)
III	243 (77.4)
IV	10 (3.2)
Poor mobility	41 (13.1)
Chronic lung disease	56 (17.8)
Extracardiac arteriopathy	75 (23.9)
Left ventricular ejection fraction	
>50%	271 (86.3)
31%-50%	42 (13.4)
21%-30%	1 (0.3)
Systolic pulmonary artery pressure	
≤30 mm Hg	143 (45.5)
31-55 mm Hg	136 (43.3)
>55 mm Hg	35 (11.1)
Indication for surgery	
Stenosis	176 (56.1)
Regurgitation	1 (0.3)
Mixed pathology	137 (43.6)
Peak gradient (mm Hg)	84.6 ± 23.6
Mean gradient (mm Hg)	51.9 ± 18.3
AVA (cm ²)	0.68 ± 0.2
Active endocarditis	0 (0)
Critical preoperative state	1 (0.3)
Elective procedure	312 (99.4)
Previous cardiac surgery	24 (7.6)
Aortic valve surgery	9 (2.9)
Permanent pace-maker	9 (2.9)
euroSCORE II (%)	9.0 ± 7.6

Continuous variables are reported as mean ± standard deviation; dichotomous variables are reported as counts and percentages in parentheses. Definition criteria for preoperative variables are according to euroSCORE II. AVA, Aortic valve area; *euroSCORE*, European System for Cardiac Operative Risk Evaluation.

receiver operating characteristic curve for this risk scoring method was 0.65 (95% confidence interval [CI], 0.48-0.81). The Brier score for the euroSCORE II in this series was 0.038, indicating a good precision in prediction probability. However, the Brier score increased markedly with increasing quartiles (<4, 4-7, 7-11, and >11) of the euroSCORE II (0.014, 0.023, 0.043, and 0.073, respectively).

In this series, we observed a marked increase in the operative mortality in the upper quartile of the euroSCORE

TABLE 2. Operative data on patients who underwent aortic valve replacement with the Perceval S sutureless aortic valve bioprosthesis

Operative data	No. (%)
Access	
Full sternotomy	174 (55.4)
Ministernotomy	131 (41.7)
Minithoracotomy	9 (2.9)
Concomitant CABG	94 (29.9)
No. of distal anastomoses	1.78 ± 0.88
Prosthesis size	
Small	37 (11.8)
Medium	135 (43.0)
Large	126 (40.1)
Extra large	16 (5.1)
Overall series	
Aortic crossclamping time (min)	43 ± 20
Aortic crossclamping time <30 min	79 (25.2)
Cardiopulmonary bypass time (min)	73 ± 28
Cardiopulmonary bypass time <60 min	105 (33.4)
Isolated AVR	
Aortic crossclamping time (min)	39 ± 15
Aortic crossclamping time <30 min	64 (29.1)
Cardiopulmonary bypass time (min)	66 ± 23
Cardiopulmonary bypass time <60 min	93 (42.3)
Combined procedure	
Aortic crossclamping time (min)	52 ± 26
Aortic crossclamping time <30 min	15 (16.0)
Cardiopulmonary bypass time (min)	88 ± 32
Cardiopulmonary bypass time <60 min	12 (12.8)

Continuous variables are reported as mean ± standard deviation; dichotomous variables are reported as counts and percentages in parentheses. AVR, Aortic valve replacement; CABG, coronary artery bypass grafting.

II (Figure 1); thus, the euroSCORE II was dichotomized according to a cutoff value of 10%. In the overall series, in-hospital mortality was 2.8% in patients with a euroSCORE II less than 10% and 4.0% in those with a euroSCORE II 10% or greater ($P = .558$): 2.0% and 0% ($P = .243$), respectively, in those who underwent isolated AVR, and 4.8% and 12.9% ($P = .158$), respectively, in those who underwent concomitant CABG.

Aortic crossclamping time was a determinant of in-hospital mortality in the overall series (area under the curve, 0.712; 95% CI, 0.550-0.874; adjusted for euroSCORE II, $P = .005$; odds ratio [OR], 1.033; 95% CI, 1.010-1.056) and in patients who underwent concomitant CABG (area under the curve, 0.758; 95% CI, 0.581-0.934; adjusted for euroSCORE II, $P = .027$; OR, 1.031; 95% CI, 1.004-1.059), but not among those who underwent an isolated procedure (area under the curve, 0.459; 95% CI, 0.323-0.596; adjusted for euroSCORE II, $P = .658$; OR, 1.033; 95% CI, 0.901-1.068).

Octogenarians had a higher in-hospital mortality than younger patients (5.2% vs 2.0%, $P = .125$), but this was not statistically significant. Similar findings were observed in patients who underwent isolated AVR (2.7% vs 0.7%,

TABLE 3. Postoperative data on patients who underwent aortic valve replacement with the Perceval S sutureless aortic valve bioprosthesis

Postoperative outcomes	No. (%)
Implantation success	313 (99.7)
Intraoperative paravalvular leak	
None	274 (87.3)
Mild	38 (12.1)
Severe	2 (0.6)
Prosthesis dislodgment	1 (0.3)
Conversion to conventional AVR	2 (0.6)
Stroke	6 (1.9)
De novo dialysis	5 (1.6)
Pacemaker implantation	25 (8.0)
Reoperation for bleeding	8 (2.5)
Intensive care unit stay (d)	3.2 ± 3.4
In-hospital stay (d)	13.4 ± 6.5
In-hospital/30-d mortality	10 (3.2)
After isolated procedure	3 (1.4)
After combined procedure	7 (7.4)
Prosthesis-related early mortality	0 (0)

Continuous variables are reported as mean ± standard deviation; dichotomous variables are reported as counts and percentages in parentheses. AVR, Aortic valve replacement.

$P = .223$) and patients who underwent concomitant CABG (9.5% vs 5.8%, $P = .491$).

Echocardiographic data were available in 305 patients. The mean peak transvalvular gradient was 27 ± 11 mm Hg, and the mean gradient was 14 ± 6 mm Hg.

Full Sternotomy Versus Ministernotomy/Minithoracotomy

Patients undergoing full sternotomy had a lower euroSCORE II than those undergoing ministernotomy/

minithoracotomy (mean, $8.2\% \pm 10.2\%$ vs $9.1\% \pm 6.3\%$, $P < .0001$). Full sternotomy was associated with significantly shorter aortic crossclamping time (35.6 ± 16.3 minutes vs 41.1 ± 14.3 minutes, $P = .003$) and cardiopulmonary bypass duration (58.2 ± 21.7 minutes vs 71.0 ± 22.2 minutes, $P < .0001$) compared with ministernotomy or minithoracotomy access. Full sternotomy was associated with a similar mortality risk compared with ministernotomy or minithoracotomy access (1.3% vs 1.4%, when adjusted for age, creatinine clearance, left ventricular ejection fraction, pulmonary disease, systolic pulmonary pressure, and prior cardiac surgery: $P = .921$; OR, 0.886; 95% CI, 0.064-12.346, when adjusted for euroSCORE II: $P = .844$; OR, 1.284; 95% CI, 0.107-15.376).

Intermediate Outcome

The overall follow-up included 366.3 patient/years with a median follow-up interval of 0.9 years (mean, 1.1 ± 1.0 ; interquartile range, 0.08-3.02 years). One-year and 2-year survivals were 90.5% and 87%, respectively (Figure 2). At the same intervals and including the operative events, freedom from valve-related mortality was 99.0% and 98.0%, freedom from stroke was 98.1% and 98.1%, freedom from endocarditis was 99.2% and 99.2%, and freedom from reoperation was 98.3% and 98.3%, respectively. Peripheral thromboembolism was not observed in any of these patients.

DISCUSSION

The results of this multicenter study suggest that the use of the sutureless Perceval S aortic valve bioprosthesis is associated with excellent early results. These findings are

FIGURE 1. Observed in-hospital mortality rates according to euroSCORE II quartiles after AVR with the sutureless Perceval S valve bioprosthesis (Sorin Biomedica Cardio Srl, Saluggia, Italy). The predicted mortality rates are according to the mean euroSCORE II in each quartile. The observed/expected mortality ratio in each euroSCORE II quartile is shown. euroSCORE, European System for Cardiac Operative Risk Evaluation; O/E, observed/expected.

FIGURE 2. Kaplan–Meier estimate of intermediate survival after AVR with the sutureless Perceval S aortic valve bioprosthesis.

of particular importance in light of the patients with high operative risk as indicated by the increased age and high euroSCORE II. Indeed, 37% of the patients were octogenarians and 30% of the patients underwent concomitant CABG, both factors having a marked impact on the risk of postoperative adverse events. We did not compare the results with a cohort of patients undergoing AVR with conventional bioprosthesis or TAVR. Therefore, the evaluation of the efficacy and safety of this sutureless bioprosthesis relied on the comparison between the observed in-hospital mortality and the mortality estimated by euroSCORE II. The Brier score suggested that this risk scoring method is a good predictor of mortality in these patients, even if its value and the observed-expected mortality ratio increased in the patients with the highest quartiles of euroSCORE II (Figure 1). The euroSCORE II has been shown to have a good observed–predicted ratio in patients undergoing conventional AVR^{10–12} and TAVR.^{13–16} In the present study, however, the euroSCORE II significantly overpredicted the mortality risk of these elderly patients with numerous comorbidities and undergoing AVR with the Perceval S sutureless valve bioprosthesis. We speculate that this discrepancy between observed and predicted mortality is due to the significant reduction of the myocardial ischemia time and duration of cardiopulmonary bypass, and possibly to the benefits of removal of the aortic valve with low rates of paravalvular leakage. Indeed, previous TAVR series reported on patients with a mean euroSCORE II similar to that in the present series, but with results significantly poorer despite a similar euroSCORE II predicted mortality.^{13–16} The beneficial effects of sutureless valve implantation were particularly evident in patients in the 3 highest quartiles of the euroSCORE II (ie, >4%) (Figure 1) and patients undergoing isolated AVR (mean euroSCORE II, $8.7\% \pm 7.9\%$). When comparing our results with the data on conventional

AVR from a pooled analysis of 176 recent studies reporting on approximately 700,000 patients,¹⁷ the operative mortality after conventional AVR with or without CABG was 4.3% (3.3% after isolated AVR and 5.5% after concomitant CABG), which is markedly higher than that observed in the present series. In that study, meta-regression indicated that patients approaching 80 years of age have a mortality risk of approximately 4% to 5% after isolated conventional AVR and approximately 6% after concomitant CABG.¹⁷ These figures increase to 7% and 10%, respectively, among octogenarians.^{18,19} The relatively high rate of implantation of permanent pacemakers observed in our study is worth noting. At this stage, it is not clear whether this could be related to the risk profile of these patients or the need for dilatation of this sutureless prosthesis, which may damage the conduction system.

This study showed that patients requiring concomitant CABG might benefit less from AVR with this sutureless valve bioprosthesis compared with patients requiring isolated AVR. It is well established that concomitant CABG can be associated with a somewhat higher risk of adverse events and poorer late outcome.¹⁷ To some extent, this can be explained by the presence of coronary artery disease and the need for longer aortic crossclamping time. The large difference in operative mortality (1.4% after isolated AVR and 7.4% after concomitant CABG, $P = .009$), in the absence of a marked increase in operative risk (euroSCORE II: 8.8% vs 9.5%, $P = .047$), suggests that alternative less-invasive approaches, such as TAVR and percutaneous coronary intervention, should be considered. A recent meta-analysis showed that a series reporting on TAVR with or without concomitant PCI reported a pooled rate of 6.3% operative mortality.²⁰

Adjusted analysis showed that a minimally invasive approach was associated with similar operative mortality

compared with a full sternotomy approach. These results cannot be considered conclusive because this series was not powered to allow such a comparison. However, as indicated in previous series,²¹ a minimally invasive approach may not allow a crossclamping time as short as 30 minutes, and this may jeopardize the benefits related to the implantation of this sutureless bioprosthesis. In the present series, a full sternotomy allowed us to perform an isolated procedure with a significantly shorter aortic crossclamping time (35.6 ± 16.3 minutes vs 41.1 ± 14.3 minutes, $P = .003$) and cardiopulmonary bypass time (58.2 ± 21.7 minutes vs 71.0 ± 22.2 minutes, $P < .0001$). However, some of the reported benefits with minimal access surgery²² may become more evident with increasing experience, which in turn may be confirmed as a valid alternative to TAVR.²³

Survival data from this series showed that this sutureless bioprosthesis may be as durable as the conventional stented bioprosthesis or TAVR prostheses in the short run (Figure 2). Therefore, the benefits of implanting a Perceval S prosthesis may not be limited to the early postoperative period, but we speculate may be durable over time. However, this series is characterized by a short follow-up, which is mostly due to the recent experience with the prosthesis in some of the centers involved in this multicenter study. The lack of data on the durability of the Perceval S prosthesis prevents its use in patients with a long life expectancy.

Study Limitations

The retrospective nature is the major limitation of this study. This series included patients mostly treated on an elective basis and with preserved left ventricular function. Therefore, the results may not necessarily apply to patients with impaired left ventricular function or requiring urgent/emergency operation, that is, patients with the highest operative risk. The lack of a control group, such as patients undergoing AVR with conventional prostheses or TAVR, prevents more conclusive results on the benefits associated with the use of this sutureless valve. However, the experience with this prosthesis is rather limited, and this study was mainly focused on the evaluation of the feasibility and safety of this method in several European centers. Further studies are needed to clarify the clinical outcomes and the incidence of paravalvular leakage during follow-up.

CONCLUSIONS

This multicenter retrospective study showed that the use of the sutureless Perceval S aortic valve bioprosthesis is associated with excellent early postoperative outcomes. The benefits of a short period of myocardial ischemia seem more pronounced in patients undergoing isolated AVR and patients with a high euroSCORE II. A longer follow-up is needed to define the structural and clinical durability of this bioprosthesis. Further data are needed

on the potential benefits of this approach in patients requiring coronary revascularization or any other cardiac procedure.

References

1. Lindroos M, Kupari M, Heikkilä J, Tilvis R. Prevalence of aortic valve abnormalities in the elderly: an echocardiographic study of a random population sample. *J Am Coll Cardiol*. 1993;21:1220-5.
2. Stewart BF, Siscovick D, Lind BK, Gardin JM, Gottdiener JS, Smith VE, et al. Clinical factors associated with calcific aortic valve disease. Cardiovascular Health Study. *J Am Coll Cardiol*. 1997;29:630-4.
3. Carrel TP, Dembitsky W, Dreyfus G, Champsaur G, Deklunder G, Flameng W, et al. Early treatment of aortic stenosis will prevent poor outcomes and save thousands of lives. *J Thorac Cardiovasc Surg*. 2013;146:4-5.
4. Rizzoli G, Bejko J, Bottio T, Tarzia V, Gerosa G. Valve surgery in octogenarians: does it prolong life? *Eur J Cardiothorac Surg*. 2010;37:1047-55.
5. Vinco G, Bergamini C, Pighi M, Golia G, Vassanelli C, Biancari F. Meta-analysis of the outcome of patients with low gradient severe aortic stenosis and preserved left ventricular ejection fraction. *Int J Cardiol*. 2013;168:5076-8.
6. Carrel T, Englberger L, Stalder M. Recent developments for surgical aortic valve replacement: the concept of sutureless valve technology. *Open J Cardiol*. 2013;4:4-1.
7. Nissinen J, Biancari F, Wistbacka JO, Peltola T, Lopenon P, Tarkkiainen P, et al. Safe time limits of aortic cross-clamping and cardiopulmonary bypass in adult cardiac surgery. *Perfusion*. 2009;24:297-305.
8. Nashef SA, Roques F, Sharples LD, Nilsson J, Smith C, Goldstone AR, et al. EuroSCORE II. *Eur J Cardiothorac Surg*. 2012;41:734-44.
9. Brier GW. Verification of forecasts expressed in terms of probabilities. *Monthly Weather Review*. 1950;78:1-3.
10. Barili F, Pacini D, Capo A, Ardernagni E, Pellicciari G, Zanobini M, et al. Reliability of new scores in predicting perioperative mortality after isolated aortic valve surgery: a comparison with the society of thoracic surgeons score and logistic EuroSCORE. *Ann Thorac Surg*. 2013;95:1539-44.
11. Spiliopoulos K, Bagiatis V, Deutsch O, Kemkes BM, Antonopoulos N, Karangelis D, et al. Performance of EuroSCORE II compared to EuroSCORE I in predicting operative and mid-term mortality of patients from a single center after combined coronary artery bypass grafting and aortic valve replacement. *Gen Thorac Cardiovasc Surg*. 2014;62:103-11.
12. Permanyer E, Estigarribia AJ, Ysasi A, Herrero E, Semper O, Llorens R. St. Jude Medical Trifecta™ aortic valve perioperative performance in 200 patients. *Interact Cardiovasc Thorac Surg*. 2013;17:669-72.
13. Durand E, Borz B, Godin M, Tron C, Litzler PY, Bessou JP, et al. Performance analysis of EuroSCORE II compared to the original logistic EuroSCORE and STS scores for predicting 30-day mortality after transcatheter aortic valve replacement. *Am J Cardiol*. 2013;111:891-7.
14. Stähli BE, Tasnady H, Lüscher TF, Gebhard C, Mikulicic F, Erhart L, et al. Early and late mortality in patients undergoing transcatheter aortic valve implantation: comparison of the novel EuroSCORE II with established risk scores. *Cardiology*. 2013;126:15-23.
15. D'Onofrio A, Salizzoni S, Agrifoglio M, Cota L, Luzi G, Tartara PM, et al. Medium term outcomes of transapical aortic valve implantation: results from the Italian Registry of Trans-Apical Aortic Valve Implantation. *Ann Thorac Surg*. 2013;96:830-5.
16. Watanabe Y, Hayashida K, Lefèvre T, Chevalier B, Hovasse T, Romano M, et al. Is EuroSCORE II better than EuroSCORE in predicting mortality after transcatheter aortic valve implantation? *Catheter Cardiovasc Interv*. 2013;81:1053-60.
17. Biancari F, Martin M, Bordin G, Vettore E, Vinco G, Anttila V, et al. Basic data from 176 studies on the immediate outcome after aortic valve replacement with or without coronary artery bypass surgery. *J Cardiothorac Vasc Anesth*. November 27, 2013 [Epub ahead of print].
18. Vasques F, Luceteforte E, Paone R, Mugelli A, Biancari F. Outcome of patients aged ≥ 80 years undergoing combined aortic valve replacement and coronary artery bypass grafting: a systematic review and meta-analysis of 40 studies. *Am Heart J*. 2012;164:410-8.
19. Vasques F, Messori A, Luceteforte E, Biancari F. Immediate and late outcome of patients aged 80 years and older undergoing isolated aortic valve replacement: a systematic review and meta-analysis of 48 studies. *Am Heart J*. 2012;163:477-85.
20. Messori A, Trippoli S, Biancari F. Early and intermediate survival after transcatheter aortic valve implantation: systematic review and meta-analysis of 14 studies. *BMJ Open*. 2013;3.

21. Gilmanov D, Miceli A, Bevilacqua S, Farneti P, Solinas M, Ferrarini M, et al. Sutureless implantation of the Perceval S aortic valve prosthesis through right anterior minithoracotomy. *Ann Thorac Surg*. 2013;96:2101-8.
22. Glauber M, Miceli A, Gilmanov D, Ferrarini M, Bevilacqua S, Farneti PA, et al. Right anterior minithoracotomy versus conventional aortic valve replacement: a propensity score matched study. *J Thorac Cardiovasc Surg*. 2013;145:1222-6.
23. Santarpino G, Pfeiffer S, Jessl J, Dell'aquila AM, Pollari F, Pauschinger M, et al. Sutureless replacement versus transcatheter valve implantation in aortic valve stenosis: a propensity-matched analysis of 2 strategies in high-risk patients. *J Thorac Cardiovasc Surg*. 2014;147:561-7.

Discussion

Dr Vinod H. Thourani (*Atlanta, Ga*). My disclosure is that I am a researcher in the pivotal trial for the Perceval (Sorin Biomedica Cardio Srl, Saluggia, Italy) system here in the United States.

I thank the Association for the privilege to discuss this important and timely presentation, and I congratulate you for an excellent presentation and your multinational study group for their contribution.

Without rehashing the entire conclusions, the authors report on 94 patients undergoing AVR + CABG and 220 patients undergoing isolated AVR. On the basis of a euroSCORE II of 9, I would consider this to be more of a medium-risk population than a high-risk population. I have 3 questions for you.

You didn't talk about this much as far as resource use, but the proposed advantage in some ways to the sutureless valve platform is decreased aortic crossclamp time, which you have shown, and this should transpose to some decreased intensive care unit (ICU) and length of stay. Did you see that in your sutureless valves, did you see a decreased length of stay, and what was your length of stay for the ICU and overall length of stay?

Dr Antonino S. Rubino. We believe that reducing crossclamping and cardiopulmonary bypass time may positively influence the immediate postoperative outcomes. However, one of the major limits of our study is that it is multicentric, and we have no uniform policy in the different centers about when to discharge, for example, patients from the ICU. So it could be difficult to generalize on this topic.

Dr Thourani. In your article, you show that the overall length of stay was 13 days and ICU stay was 3 days. So I think we need to be cautious when transposing sutureless valve technology to overall decreased resource use.

The second question is with your results, and looking specifically at the AVR + CABG population, especially in those patients with a euroSCORE greater than 10, have you stopped using the Perceval valve in those patients in whom you are showing a relatively higher mortality in all respects?

Dr Rubino. No, we don't stop performing this procedure. We all know that the need for associated CABG increases the operative risk in this cohort of patients, and that the use of a sutureless prosthesis might improve postoperative outcomes. We have also shown in this presentation that the use of this prosthesis might be more beneficial in those patients with a high-risk profile. So we still keep on performing associated CABG.

Dr Thourani. The last question is more of a philosophical question. I know that you also do transcatheter aortic valves. After seeing these data, which patients would receive a stented valve,

a sutureless valve, or a transcatheter valve, because now we have 3 different options for our patients?

Dr Rubino. This allows me to give you a wider opportunity to answer you. Again, I cannot answer about the policies in the other centers elsewhere but only about the policy in our center in Catania. We also do transcatheter valves, and we started with the transaortic and transapical approach.

We discuss the cases of high-risk patients with our cardiologists. We do not believe that the cutoff should be pointed out only by the euroSCORE, because there are some patients referred to TAVI from local cardiologists who come back to our surgical cohort, and there are some patients from the surgical cohort who we send for TAVI. For an indication, we don't have to rely only on the age, for example, or the euroSCORE but also on other severe comorbidities, such as severe neurologic dysfunction, malignancies, or poor expected life. In these last situations, we send them to the TAVI cohort.

We are happy to have these sutureless options, because this allows us to widen the therapeutic options for our population. In normal-risk patients, a standard conventional procedure should be the optimal solution. The sutureless valve allows us to increase the volume of a minimally invasive approach, which is also one of the most frequent reasons that the cardiologists have when they propose a TAVI, which is actually minimally invasive, to a patient. So this prosthesis allows us to improve the minimally invasive program in the center, and those patients who are at high surgical risk independently from the mere euroSCORE are sent to TAVI.

Dr Thourani. Congratulations. This is a great article.

Dr Harold L. Lazar (*Boston, Mass*). I know you don't have any controls, but would you estimate how much crossclamp time, based on your own series of isolated AVRs, you save with this technique?

Dr Rubino. In the standard conventional procedure, it is 40 minutes. If you put in stitches, you will need approximately 35 or 40 minutes of crossclamping. We tried and are implanting some prostheses with running sutures that also allow us to reduce the crossclamping time significantly. With this sutureless prosthesis, our mean crossclamping time is approximately 23 minutes in our center. So there is a significant reduction. But one of the key messages is that realistically with this prosthesis we can move toward a minimally invasive approach.

Dr Lazar. Briefly, what technical tricks have you learned as far as putting these valves in, especially with debriding the annulus?

Dr Rubino. This valve is particularly useful in those cases when you do not want to manipulate the aorta. We have 2 cases of almost porcelain aorta. We just did a transverse aortotomy approximately 1.5 cm above the sinotubular junction, more or less at the level of the fat pad. We removed the valve, and we put the valve in straight without touching the calcium.

To achieve a perfect and complete adhesion of the valve to the annulus and to the root, apart from the respect of the geometric relationship I showed before, it is more important to create an almost perfect circular geometry. In our center we try to decalcify the annulus almost completely, but what is really important with this valve is to create a circular geometry. In the past before the XL was available, we had cases of rescue surgery after TAVI, and the annulus was large. So we performed a partial decalcification, but we recreated a circular anatomy and put an L inside, and the patient went home without any paravalvular leak.