

Low-Risk Surgical Aortic Valve Replacement in the Era of Transcatheter Aortic Valve Implantation

Milos M. Jovanovic, MD¹; Slobodan V. Micovic, MD, PhD¹; Miodrag S. Peric, MD, PhD¹; Igor S. Zivkovic, MD¹; Stasa D. Krasic, MD²; Ognjen S. Milicevic, MD³; Stefan P. Stankovic, MD¹; Petar M. Vukovic, MD, PhD¹

¹Department of Cardiac Surgery, Dedinje Cardiovascular Institute, Belgrade, Serbia

²Department of Cardiology, Mother and Child Health Care Institute of Serbia, Belgrade, Serbia

³Department of Medical Statistics and Informatics, School of Medicine, University of Belgrade, Belgrade, Serbia

Open surgical aortic valve replacement (SAVR) is a viable alternative to transcatheter implantation in low-risk patients. In this light, we evaluated the safety and effectiveness of SAVR performed through conventional and less invasive surgical approaches in a high-volume center.

We retrospectively reviewed the records of 395 consecutive patients who underwent open SAVR from January 2019 through December 2019 in our center. We evaluated and compared the operative results and postoperative major adverse outcomes of 3 surgical approaches: full median sternotomy (n=267), upper ministernotomy (ministernotomy) (n=106), and right anterior thoracotomy (minithoracotomy) (n=22).

Overall, the 30-day all-cause mortality rate was 0.8% (3 patients). Stroke occurred in 8 patients (2%), disabling stroke in 4 patients (1%), myocardial infarction in 1 (0.2%), and surgical site infection in 13 (3.2%). There was no difference in 30-day mortality rate or incidence of postoperative major adverse events among the 3 surgical groups. Stroke and surgical site infection occurred more frequently, but not significantly so, in the full-sternotomy group. The mean hospital stay was longer after full sternotomy (9.1 ± 5.5 d) than after ministernotomy (7.5 ± 2.9 d) or minithoracotomy (7.4 ± 1.9 d) ($P=0.012$).

Our findings suggest that open SAVR performed in a high-volume center is associated with a low early mortality rate and that less invasive approaches result in faster postoperative recovery and shorter hospital stays. (Tex Heart Inst J 2022;49(1):e207435)

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Corresponding author:

Milos Jovanovic, MD, Department of Cardiac Surgery, Dedinje Cardiovascular Institute, Heroja Milana Tepica 1, 11000 Belgrade, Serbia

E-mail:

milos.wrc@gmail.com

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Therapy for severe aortic valve (AV) stenosis has evolved rapidly over the last 2 decades. Transcatheter AV implantation (TAVI), originally performed only in inoperable patients, is now widely accepted and considered first-line therapy for intermediate- and high-risk patients.^{1,2} Furthermore, the concept of the heart team has improved quality of care for patients undergoing TAVI. Open surgical AV replacement (SAVR) has also evolved, with development of less invasive approaches such as upper ministernotomy (ministernotomy) and right anterior thoracotomy (minithoracotomy).^{3,4} Consequently, SAVR has become a viable alternative to TAVI in low-risk patients.

In this study, we aimed to evaluate the safety and effectiveness of contemporary SAVR in a high-volume center by comparing the outcomes of conventional and less invasive surgical approaches and evaluating the role of sutureless valve implantation and reconstructive procedures in SAVR.

Patients and Methods

A total of 395 consecutive patients (232 males [58.7%]; mean age, 66.3 ± 11.3 yr) underwent isolated primary SAVR at our center from January through December 2019 (Table I). Demographic, clinical, surgical, and outcomes data were collected from medical records and reviewed retrospectively. The local ethics committee waived

the need for the written informed consent of patients because the study was retrospective.

The surgical approach in each patient depended on the surgeon's preference and proficiency: full sternotomy, ministernotomy, or minithoracotomy. Full sternotomy involved a 20-cm skin incision and a full-length median sternotomy. Ministernotomy involved a 6- to 10-cm incision and J-shaped division of the upper part of the sternum up to the third or fourth intercostal space. Minithoracotomy involved a 5- to 7-cm incision in the right second intercostal space. Regardless of approach, the incision was followed by arterial cannulation of the ascending aorta and venous cannulation of the right atrial appendage centrally through the surgical site (99.8% of cases); venting of the left ventricle through the right superior pulmonary vein; myocardial protection with cold blood cardioplegia; and flooding of the pericardial cavity with carbon dioxide.

In most cases, a standard stented AV prosthesis, either mechanical or biological, was implanted. In patients with a small aortic annulus or calcified aortic root, a sutureless bioprosthetic valve (Perceval S; LivaNova) was implanted, usually through either of the less inva-

sive approaches. Selected patients underwent the Ozaki procedure,⁵ in which all 3 AV cusps were reconstructed with autologous pericardium.

Primary endpoints were the 30-day all-cause mortality rate and 30-day incidence of major adverse events after SAVR. Major adverse events included stroke, myocardial infarction (MI), revision for bleeding, prolonged intubation, systemic inflammatory response syndrome, new-onset atrial fibrillation (AF), and surgical site infection. The secondary endpoint was the 30-day incidence of major adverse events after full sternotomy, ministernotomy, or minithoracotomy.

Statistical Analysis

All statistical analyses were performed with SPSS, version 17.0 (SPSS, an IBM company). Data were reported as mean \pm SD for continuous variables or as number and percentage for categorical variables. Preoperative, operative, and postoperative data were compared within and among groups by means of a one-way analysis of variance (ANOVA), with use of the Fisher least significant difference test for post hoc repeated measurements. Adjusted analyses were done with a 2-way ANOVA. Homoge-

TABLE I. Baseline Demographic and Clinical Characteristics of the 395 Patients

Variable	Surgical Approach				P Value
	Overall (N=395)	Full Sternotomy (n=267)	Ministernotomy (n=106)	Minithoracotomy (n=22)	
Age (yr)	66.3 \pm 11.3	66.2 \pm 10.9	65.6 \pm 13	70.2 \pm 7.1	0.22
Male sex	232 (58.7)	172 (64.4)	56 (52.8)	4 (18.2)	0.0001
History					
Smoking	155 (39.2)	101 (37.8)	44 (41.5)	10 (45.5)	0.67
Stroke	35 (8.9)	19 (7.1)	14 (13.2)	2 (9.1)	0.17
Hypertension	278 (70.4)	186 (69.7)	77 (72.6)	15 (68.2)	0.83
Diabetes	52 (13.2)	34 (12.7)	15 (14.2)	3 (13.6)	0.93
Coronary artery disease	64 (16.2)	46 (17.2)	16 (15.1)	2 (9.1)	0.57
Chronic renal disease	23 (5.8)	15 (5.6)	7 (6.6)	1 (4.5)	0.9
Peripheral artery disease	28 (7.1)	21 (7.9)	7 (6.6)	0	0.37
NYHA functional class					
I	34 (8.6)	25 (9.4)	7 (6.6)	2 (9.1)	0.68
II	287 (72.7)	191 (71.8)	80 (75.5)	16 (72.7)	0.77
III	69 (17.5)	47 (17.7)	18 (17)	4 (18.2)	0.9
IV	3 (0.8)	2 (0.8)	1 (0.9)	0	0.87
LVEF (%)	50.9 \pm 10.8	50.4 \pm 11.7	52.3 \pm 8.8	50.5 \pm 8.6	0.33
Aortic valve area (cm ²)	0.66 \pm 0.21	0.66 \pm 0.21	0.68 \pm 0.21	0.65 \pm 0.16	0.54
Mean gradient across aortic valve (mmHg)	59.6 \pm 18.6	60.1 \pm 19.1	59.2 \pm 17.9	56.2 \pm 16.3	0.63
EuroSCORE II (%)	1.91 \pm 2.04	1.99 \pm 2.25	1.69 \pm 1.59	2.08 \pm 1.21	0.41

LVEF = left ventricular ejection fraction; NYHA = New York Heart Association

Data are presented as mean \pm SD for continuous variables or as number and percentage for categorical variables. $P < 0.05$ was considered statistically significant.

neity of variance was evaluated with the Levene test; variables that had a P value <0.05 were log-transformed. Multivariate regression was used to determine the effect of surgical procedure type and preoperative and operative variables on the incidence of postoperative outcomes. Outcomes were modeled using linear regression for continuous variables and logistic regression for binary variables. The variables included in the logistic regression models were chosen by backward elimination through the Wald test, with an exclusion threshold of $P \geq 0.1$. Proportions were compared using the χ^2 test (or the Fisher exact test if the expected frequency of an outcome was < 5). P values <0.05 were considered statistically significant.

Results

Operative Results

Overall, the mean EuroSCORE II in our study population was $1.91\% \pm 2.04\%$, an indicator of low surgical risk (Table I). Full median sternotomy was performed in 267 of 395 patients (67.6%); ministernotomy, in 106 (26.8%); and minithoracotomy, in 22 (5.6%). Mechanical valves were implanted significantly more frequently ($P=0.001$) in the full-sternotomy group than in the other 2 groups (Table II). All 3 treatment groups were similar in terms of prosthesis size, aortic cross-clamp (ACC) time, and cardiopulmonary bypass (CPB) time. However, sutureless valves were implanted significantly more frequently ($P=0.001$) in the ministernotomy and minithoracotomy groups than in the full-sternotomy group. After adjustment for surgical approach, sutureless valve implantation was also found to be associated with shorter ACC time (49.2 ± 14 vs 64.8 ± 20.4 min;

$P=0.001$) and shorter CPB time (77.6 ± 18.6 vs 88.8 ± 27.6 min; $P=0.001$). In the full-sternotomy group, use of the Ozaki procedure was associated with longer ACC time (94 ± 20.7 vs 62.7 ± 19.1 min; $P=0.001$) and longer CPB time (119.6 ± 26.3 vs 86.1 ± 25.3 min; $P=0.001$).

Postoperative Major Adverse Events

Overall, 3 patients (0.8%) died within 30 days of surgery (Table III). The ratio of observed-to-expected all-cause deaths at 30 days was 0.39. (The expected risk was based on EuroSCORE II.) Other postoperative major adverse events included stroke in 8 patients (2%), disabling stroke in 4 patients (1%), and MI in one patient (0.2%). No patient experienced a deterioration in renal function that necessitated postoperative dialysis. Thirteen patients (3.2%) had a surgical site infection. One patient (0.2%), who underwent full sternotomy, had mediastinitis. The mean intensive care unit (ICU) stay was 2.1 ± 2.1 days, and the mean hospital stay, 8.6 ± 4.8 days.

Among groups, there was no difference in the 30-day mortality rate or incidence of postoperative major adverse events (Table III). The incidences of stroke, systemic inflammatory response syndrome, and surgical site infection were not significantly higher after full sternotomy. Sutureless valve implantation was not associated with a higher rate of pacemaker implantation (1.4% vs 0 ; $P=0.57$).

Multiple linear regression analysis revealed that longer ICU stay was associated with EuroSCORE II $>2.5\%$ as compared with EuroSCORE II $<2.5\%$ (2.57 ± 0.34 d vs 1.69 ± 0.19 d; $P=0.026$, adjusted for groups). The mean ICU stay was significantly shorter for patients who received mechanical valves than for those who did not (1.85 ± 1.56 d vs 2.36 ± 2.67 d; $P=0.007$). On the other hand, the mean hospital stay was significantly longer

TABLE II. Operative Results

Variable	Surgical Approach				P Value
	Overall (N=395)	Full Sternotomy (n=267)	Ministernotomy (n=106)	Minithoracotomy (n=22)	
Prosthesis type					
Mechanical	233 (59.0)	184 (68.9)	48 (45.2)	1 (4.5)	0.001
Bioprosthetic	110 (27.8)	65 (24.3)	43 (40.6)	2 (9.1)	0.001
Sutureless	42 (10.6)	8 (3)	15 (14.1)	19 (86.4)	0.001
Prosthesis size (mm)	21.7 ± 1.8	21.6 ± 1.8	21.9 ± 1.8	21.7 ± 1.5	0.48
Ozaki procedure	10 (2.3)	10 (3.7)	0	0	0.001
Aortic cross-clamp time (min)	63.14 ± 20.4	63.9 ± 20.1	62.7 ± 20.7	56.4 ± 23.1	0.24
CPB time (min)	87.7 ± 27.0	87.4 ± 26.0	88.5 ± 29.8	86.5 ± 25.4	0.92

CPB = cardiopulmonary bypass

Data are presented as mean \pm SD for continuous variables or as number and percentage for categorical variables. $P < 0.05$ was considered statistically significant.

TABLE III. Postoperative Outcomes

Event	Surgical Approach				P Value
	Overall (N=395)	Full Sternotomy (n=267)	Ministernotomy (n=106)	Minithoracotomy (n=22)	
All-cause death	3 (0.8)	2 (0.7)	1 (0.9)	0	0.897
Myocardial infarction	1 (0.3)	1 (0.4)	0	0	0.786
Stroke					
Any	8 (2)	8 (3)	0	0	0.141
Disabling	4 (1)	4 (1.5)	0	0	0.385
Revision for bleeding	23 (5.8)	13 (4.9)	10 (9.4)	0	0.333
Prolonged intubation	6 (1.5)	5 (1.9)	1 (0.9)	0	0.671
SIRS	7 (1.8)	6 (2.2)	1 (0.9)	0	0.56
New-onset AF	108 (27.3)	75 (28.1)	27 (25.5)	5 (22.7)	0.78
Surgical site infection	13 (3.3)	11 (4.1)	2 (1.9)	0	0.371
Pacemaker implantation	5 (1.3)	3 (1.1)	2 (1.9)	0	0.722
Length of stay					
ICU (d)	2.1 ± 2.1	2.2 ± 2.4	1.8 ± 1.3	1.6 ± 0.7	0.166
Hospital (d)	8.6 ± 4.8	9.1 ± 5.5	7.5 ± 2.9	7.4 ± 1.9	0.012

AF= atrial fibrillation; ICU = intensive care unit; SIRS = systemic inflammatory response syndrome

Data are presented as mean ± SD for continuous variables or as number and percentage for categorical variables. $P < 0.05$ was considered statistically significant.

after full sternotomy (9.1 ± 5.5 d) than after ministernotomy (7.5 ± 2.9 d) or minithoracotomy (7.4 ± 1.9 d) ($P=0.012$).

Multivariate logistic regression analysis of categorical postoperative outcomes showed that EuroSCORE II was a consistent covariate predictor of stroke, new-onset AF, surgical site infection, and pacemaker implantation (Table IV). Ministernotomy was not a significant covariate predictor of revision for bleeding, although the association did approach statistical significance ($P=0.069$). Female sex was not a significant covariate predictor of surgical site infection.

Discussion

This study of SAVR in a high-volume center included a low-risk group of patients with an overall mean EuroSCORE II of 1.91%. The low overall 30-day mortality rate (0.8%) suggests that experienced surgical teams in high-volume centers may achieve better results than predicted by a valid risk scoring system. In addition, the incidence of other severe adverse outcomes including postoperative MI and disabling stroke in our study population is consistent with those observed in recently published large-scale multicenter studies.⁶⁻⁸

In 2019, reports on the benchmark Evolut⁷ and PARTNER 3⁸ trials compared the results of SAVR versus TAVI in low-risk patients. However, both studies had important limitations. Both excluded younger

patients who needed mechanical valves and patients with bicuspid AVs because such patients were not considered good candidates for TAVI.^{7,8} Consequently, the results of both trials apply only to the populations studied. Only 6% of patients in the Evolut trial⁷ and 7% of patients in the PARTNER 3 trial⁸ were younger than 65 years, resulting in a relatively high rate of exclusion of low-risk patients who were initially screened for TAVI. Nevertheless, even in the era of TAVI, the possibility of implanting durable, hemodynamically efficient mechanical valves in low-risk patients has become an advantage in favor of surgical therapy. In our study population, a mechanical valve was implanted in 58.9% of patients. Closer analysis revealed that significantly more mechanical valves were implanted in the full-sternotomy group, suggesting that surgeons who rely on traditional median sternotomy may more often choose to implant a mechanical valve.

In recent years, the broad implementation of less invasive approaches to SAVR has been a focus of the surgical community. Potential advantages of minimal access AVR include reducing morbidity and mortality rates without sacrificing the excellent results obtained with the conventional procedure; improving cosmetic results; and shortening ICU and in-hospital stays.⁹ The major criticism so far has been that the small operating field created by less invasive approaches necessitates longer ACC and CPB times.¹⁰ In our study, we found no differences between full sternotomy and less invasive approaches.

TABLE IV. Logistic Regression Analysis of Predictors of Postoperative Outcomes

Outcome	Predictor	Effect	Odds Ratio (95% CI)	P Value
Death	Age (yr)	0.284	1.329 (1.024–1.588)	0.028
Stroke	EuroSCORE II	0.190	1.209 (1.039–1.407)	0.014
Revision for bleeding	Ministernotomy	0.794	2.12 (0.939–5.208)	0.069
Prolonged intubation	Hypertension	–1.586	0.205 (0.037–1.133)	0.069
New-onset AF	EuroSCORE II	0.114	1.120 (1.010–1.243)	0.032
Surgical site infection	Female sex	–2.497	0.082 (0.011–0.790)	0.028
	EuroSCORE II	0.207	1.230 (1.043–1.399)	0.007
Pacemaker implantation	EuroSCORE II	0.188	1.206 (1.020–1.427)	0.028

AF= atrial fibrillation

Effect is presented as regression coefficient. Odds ratio is presented as exponentiated effect. $P < 0.05$ was considered statistically significant.

This finding can best be explained by the high rate of sutureless valve implantation in the ministernotomy and minithoracotomy groups (Table II) and by our experience-based observation that sutureless valves are more easily and quickly implanted in a small operative field. Implanting a sutureless prosthesis, especially through a less invasive approach, is safe and results in excellent hemodynamic function.¹¹ Low 30-day mortality rates, reduced cross-clamp times, and lower incidences of adverse early and mid-term outcomes have been reported.^{11,12}

Our comparison of full-sternotomy and less invasive surgical approaches revealed no significant differences in postoperative major adverse outcomes. Of note, even though all stroke events occurred in the full-sternotomy group, the stroke rate did not differ significantly among the 3 surgical groups. The higher incidence of stroke in the full-sternotomy group may be related to patient-selection bias. Most of the patients who had signs of severe aortic calcification had undergone a full sternotomy.

A meta-analysis of propensity-matched studies comparing minimal access and conventional SAVR showed no differences in early mortality and stroke rates.¹³ However, a recently published report on a multicenter, propensity-matched study revealed an association between the minimal access approach and a reduced 30-day mortality rate.⁶ The investigators emphasized that, in previous retrospective studies and meta-analyses, the minimal access approach was never associated with an increased number of deaths and that associated morbidity rates often decreased. Yet, contrary to expectations, the less invasive approach was associated with an increased risk of reopening for bleeding and blood transfusions.⁶

In our study population, surgical site infection occurred slightly but not significantly more often in those who underwent full sternotomy than in those who underwent the less invasive procedures. This is consistent

with findings from a study that compared outcomes after conventional surgery and ministernotomy.¹⁴ In addition, hospital stays were shorter after less invasive SAVR, also consistent with reports by others.^{6,9,14} We hypothesize that the reduced surgical trauma to the chest wall and lower risk of infection afforded by less invasive procedures helped patients recover faster.

Complete AV replacement with autologous pericardium (Ozaki procedure) may be a better therapeutic choice in selected patients. Our results indicate that meticulous adherence to the surgical technique described by Ozaki and colleagues⁵ led to excellent early outcomes. No early aortic regurgitation was noted. Mid-term results of Ozaki surgery indicate a complete absence of stenosis and regurgitation on aortic valves made using autologous pericardium. The Ozaki procedure requires no foreign material, which is especially beneficial in patients with infectious endocarditis, and it is suitable for patients with small aortic annuli.⁴

Limitations

Our study had important limitations. First, it was a retrospective, observational, single-center study. Second, the choice of surgical approach was biased by the surgeon's preference and the patient's preoperative characteristics. No propensity-score matching was used to minimize the selection bias. Third, only early outcomes were analyzed. Follow-up data were unavailable. In light of these limitations, larger, prospective studies are warranted to corroborate our findings.

Conclusion

We found that AV surgery at our high-volume center is associated with a very low 30-day mortality rate and a

low observed-to-expected mortality ratio. Surgical invasiveness does not appear to affect the frequency of major adverse outcomes. However, less invasive surgery may result in faster postoperative recovery and shorter hospital stays.

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