Clinical Investigation

Sutureless versus Conventional Aortic Valve Replacement:

Outcomes in 70 High-Risk Patients Undergoing Concomitant Cardiac Procedures

Muhammet Onur Hanedan, MD
Mehmet Ali Yuruk, MD
Ali Ihsan Parlar, MD
Ugur Ziyrek, MD
Ali Kemal Arslan, MD
Ufuk Sayar, MD
Ilker Mataraci, MD

In elderly, high-risk surgical patients, sutureless aortic valve replacement (AVR) can often be an alternative to conventional AVR; shorter aortic cross-clamp and cardiopulmonary bypass times are the chief advantages. We compared the outcomes of sutureless AVR with those of conventional AVR in 70 elderly patients who underwent concomitant cardiac surgical procedures.

We retrospectively analyzed the cases of 42 men and 28 women (mean age, 70.4 ± 10.3 yr; range, 34–93 yr) who underwent cardiac operations plus AVR with either a sutureless valve (group 1, n=38) or a conventional bioprosthetic or mechanical valve (group 2, n=32). Baseline patient characteristics were similar except for worse New York Heart Association functional status and the prevalence of diabetes mellitus in group 1.

In group 1, the operative, cross-clamp, and cardiopulmonary bypass times were shorter (all P=0.001), postoperative drainage amounts were lower (P=0.009), hospital stays were shorter (P=0.004), and less red blood cell transfusion was needed (P=0.037). Echocardiograms before patients' discharge from the hospital showed lower peak and mean aortic gradients in group 1 (mean transvalvular gradient, 8.4 ± 2.8 vs 12.2 ± 5.2 mmHg; P=0.012).

We found that elderly, high-risk patients who underwent multiple cardiac surgical procedures and sutureless AVR had better hemodynamic outcomes and shorter ischemic times than did patients who underwent conventional AVR. ***(Tex Heart Inst J 2018;45(1):11-6)***

Key words: *Aged; aortic valve insufficiency/surgery/therapy; heart valve prosthesis implantation/adverse effects/instrumentation/methods/mortality; hemodynamics; prospective studies; prosthesis design; risk factors; sutureless surgical procedures/adverse effects/instrumentation/methods; time factors; treatment outcome*

From: *Department of Cardiovascular Surgery, University of Health Sciences, Ahi Evren Thoracic and Cardiovascular Surgery Research and Education Hospital, 61040 Trabzon, Turkey*

Address for reprints: *Muhammet Onur Hanedan, MD, Ahi Evren GKDC Egitim ve Arastirma Hastanesi, Soguksu Mah. Vatan Cad. No:9, 61040 Trabzon, Turkey*

E-mail: *ohanedan@hotmail.com*

In the treatment of severe aortic stenosis, replacement of native aortic valves (AVs) with biological or mechanical prostheses has been the gold standard.[1] Because people are living longer, the need for AV replacement (AVR) has grown[2]; in many, concomitant cardiac surgical procedures are also necessary.[3] The use of sutureless AVs has increased,[4] and extending their use in patients with concomitant mitral disease might be of substantial benefit.[5]

Transcatheter AVR (TAVR) has been used to treat isolated AV disease in high-risk patients who are not eligible for surgery involving cardiopulmonary bypass (CPB). Moreover, the durability of TAVR is uncertain; it is associated with paravalvular leak (PVL) and neurologic events, and it increases risks during pacemaker implantation.[6] In addition, percutaneous approaches typically do not enable treating concomitant cardiac conditions. In this study, we compared the outcomes of sutureless AVR with those of conventional bioprosthetic and mechanical AVR in elderly patients who underwent concomitant cardiac surgical procedures.

Patients and Methods

We enrolled 70 elderly patients into this retrospective, nonrandomized study; all had been treated at our hospital from October 2009 through August 2016. We included 42 men and 28 women (mean age, 70.4 ± 10.3 yr; range, 34–93 yr). Inclusion criteria were severe symptomatic AV disease, New York Heart Association (NYHA) functional class II or worse, and planned surgical AVR with concomitant cardiac surgical procedures. The patients were divided into 2 groups: 38 underwent sutureless AVR (group 1), and 32 underwent conventional bioprosthetic or mechanical AVR (group 2). Written informed consent to participate was obtained from all patients except for those treated under emergency status. Our local ethics committee approved the study protocol.

Table I shows the preoperative data. The mean logistic EuroSCORE was 8.63 ± 1.86 in group 1 and 8.08 ± 0.63 in group 2 (P=0.093). The groups were comparable except for worse NYHA functional status and more patients with diabetes mellitus in group 1.

In group 1, we implanted an Edwards INTUITY valve (Edwards Lifesciences Corporation) in 27 patients and a PERCEVAL™ S valve (SORIN, part of LivaNova PLC) in 11 patients. In group 2, we placed a SORIN SOPRANO™ valve (LivaNova) in 10 patients, a SORIN FREEDOM SOLO™ (LivaNova) in 9, a Trifecta™ (St. Jude Medical, Inc.) in 5, and a St. Jude Medical mechanical valve in 8. Follow-up evaluation included analysis of outpatient clinical data and postoperative echocardiograms.

Operative Technique

The same surgeon operated on all the patients. After induction of general anesthesia, orotracheal intubation, and full sternotomy, all patients were placed on CPB. Myocardial protection was achieved via the antegrade administration of cold-blood cardioplegic solution on induction and was continued via antegrade or selective osteal doses of cold-blood cardioplegic solution every 20 min, in accordance with our hospital's protocol. A final warm-blood dose preceded release of the aortic cross-clamp. Transverse aortotomy was performed approximately 1 cm above the sinotubular junction for the PERCEVAL S valve and in standard fashion for the Edwards INTUITY valve. The native AV was excised and the annular calcifications were removed. Intraoperative transesophageal echocardiography (TEE) was used to evaluate the prosthesis.

The PERCEVAL S and Edwards INTUITY valves are approved for clinical use in Europe and Turkey, and we have used them often.[7,8]

Statistical Analysis

Statistics were analyzed by using SPSS version 16.0 (SPSS Inc., an IBM company). Data were expressed as mean ± SD for quantitative variables and as number and percentage for categorical variables. The groups were compared by means of the Student t test for continuous variables and the χ^2 or Fisher exact test for categorical variables. Cumulative survival curves were computed in accordance with the Kaplan-Meier method. The log-rank test was used to compare survival outcomes. Multivariate analysis was performed by using a binary logistic regression model to identify independent risk factors for 30-day death. Survival outcomes were further evaluated after multivariate Cox regression analysis. A P value <0.05 was considered statistically significant.

Results

Table II shows the operative and postoperative results. In group 1, we observed significantly shorter operative, CPB, and cross-clamp times. In-hospital mortality rates and lengths of intensive care unit stay were similar between the groups; in contrast, group 1 patients had significantly less need for drainage and red blood cell transfusions, and shorter hospital stays. The chief concomitant procedure was coronary artery bypass grafting (CABG), for 76.3% of patients in group 1 and 65.6% in group 2 (Table III).

TABLE I. Preoperative Demographic and Clinical Characteristics of the 70 Patients

Variable	**Group 1** (Sutureless AVR) (n=38)	**Group 2** (Conventional AVR) (n=32)	***P* Value**
Age (yr)	71.2 ± 8.9	69.5 ± 11.8	0.507
Male	19 (50)	23 (71.9)	0.063
NYHA functional class	2.7 ± 0.6	2.2 ± 0.4	0.001
LV ejection fraction	0.56 ± 0.11	0.55 ± 0.11	0.802
Body surface area (m^2)	1.75 ± 0.15	1.77 ± 0.27	0.696
Smoking	16 (42.1)	9 (28.1)	0.224
Diabetes mellitus	11 (28.9)	3 (9.4)	0.039
Carotid artery disease	4 (10.5)	5 (15.6)	0.722
Peripheral vascular disease	3 (7.9)	2 (6.3)	0.999
Renal failure	1 (2.6)	1 (3.1)	0.999
COPD	8 (21.1)	3 (9.4)	0.181
Logistic EuroSCORE	8.63 ± 1.86	8.08 ± 0.63	0.093

AVR = aortic valve replacement; COPD = chronic obstructive pulmonary disease; LV = left ventricular; NYHA = New York Heart Association

Data are expressed as mean ± SD or as number and percentage. P <0.05 was considered statistically significant.

Table IV shows the patients' pre- and postoperative echocardiographic results. The mean postoperative aortic gradients were 8.4 ± 2.8 mmHg in group 1 and 12.2 ± 5.2 mmHg in group 2 (P=0.012). Neither the postoperative nor the follow-up gradients differed between patients with the PERCEVAL and INTUITY valves.

Patients were monitored for 789.1 ± 634.3 days. The mean durations were 507.5 ± 350.8 days (range, 6–1,054 d) in group 1, and 1,123.4 ± 732.1 days (range, 1–2,486 d) in group 2. We observed no difference in survival outcome (P=0.065) (Fig. 1).

Our model revealed no independent risk factor that predicted 30-day death.

The only predictor of midterm death was CPB time (hazard ratio=1.05; 95% CI, 1.017–1.084; P=0.002). For cross-clamp time, the hazard ratio was 0.963 (95% CI, 0.927–1.0; P=0.052).

Because of substantial PVL in one patient, we performed early prosthesis explantation and implanted a different prosthesis 3 days later. We detected no moderate or severe PVL in any other patient.

Discussion

Several types of sutureless AVs have been introduced into clinical practice. Sutureless AVR can be the first-

TABLE II. Comparison of Operative and Postoperative Results

Variable	**Group 1** (Sutureless AVR) (n=38)	**Group 2** (Conventional AVR) (n=32)	***P* Value**
Operative time (min)	253 ± 76	350 ± 85	0.001
Cross-clamp time (min)	78 ± 28	122 ± 38	0.001
CPB time (min)	119 ± 42	166 ± 50	0.001
Ventilator dependence (hr)	9.4 ± 3.5	11.6 ± 7.8	0.134
Intensive care unit stay (d)	4.2 ± 3.7	4.9 ± 4.8	0.462
Drainage (mL)	396 ± 153	1,010 ± 1,208	0.009
Re-exploration for bleeding	2 (5.3)	2 (6.3)	0.999
Red blood cell transfusion (U)	2.2 ± 1.8	3.4 ± 3	0.037
FFP transfusion (U)	2.2 ± 1.9	2.9 ± 3.4	0.262
30-day hospital death	2 (5.3)	5 (15.6)	0.234
Hospital stay (d)	9.3 ± 5.1	13.6 ± 6.6	0.004

AVR = aortic valve replacement; CPB = cardiopulmonary bypass; FFP = fresh frozen plasma

Data are expressed as mean ± SD or as number and percentage. P <0.05 was considered statistically significant.

TABLE III. Comparison of Concomitant Procedures

Variable	**Group 1** (Sutureless AVR) (n=38)	**Group 2** (Conventional AVR) (n=32)
CABG	29 (76.3)	21 (65.6)
CABG + ascending aortic surgery	3 (7.9)	1 (3.1)
CABG + mitral ring annuloplasty	1 (2.6)	2 (6.3)
CABG + mitral valve replacement	1 (2.6)	1 (3.1)
Ascending aortic surgery	3 (7.9)	2 (6.3)
Mitral ring annuloplasty	0	2 (6.3)
Mitral valve replacement	1 (2.6)	1 (3.1)
Tricuspid annuloplasty	0	1 (3.1)
Atrial septal defect repair	0	1 (3.1)

AVR = aortic valve replacement; CABG = coronary artery bypass grafting

Data are presented as number and percentage.

TABLE IV. Comparison of Pre- and Postoperative Echocardiographic Findings

Variable	**Group 1** (Sutureless AVR) (n=38)	**Group 2** (Conventional AVR) (n=32)	***P* Value**
Preoperative			
LV ejection fraction	0.56 ± 0.11	0.55 ± 0.11	0.802
LV end-diastolic diameter (mm)	49.8 ± 5.9	50.4 ± 9	0.744
LV end-systolic diameter (mm)	32.3 ± 7.5	33.6 ± 9	0.514
IVST (mm)	12.9 ± 2.2	13.7 ± 2.1	0.135
Posterior wall thickness (mm)	12.3 ± 1.8	13.2 ± 1.7	0.039
Peak aortic gradient (mmHg)	62.4 ± 22	72.5 ± 20	0.059
Mean aortic gradient (mmHg)	37.4 ± 13.9	47.6 ± 12.7	0.003
Postoperative			
LV ejection fraction	0.55 ± 0.12	0.53 ± 0.11	0.584
LV end-diastolic diameter (mm)	49 ± 5.6	50.6 ± 8.9	0.428
LV end-systolic diameter (mm)	32.1 ± 7.5	34.6 ± 8.2	0.256
IVST (mm)	12.7 ± 2.1	13.0 ± 2	0.617
Posterior wall thickness (mm)	12.3 ± 2	12.4 ± 1.6	0.828
Peak aortic gradient (mmHg)	19.9 ± 6.5	23.6 ± 8.1	0.087
Mean aortic gradient (mmHg)	8.4 ± 2.8	12.2 ± 5.2	0.012

AVR = aortic valve replacement; IVST = interventricular septal thickness; LV = left ventricular

Data are expressed as mean ± SD. $P \ll 0.05$ was considered statistically significant.

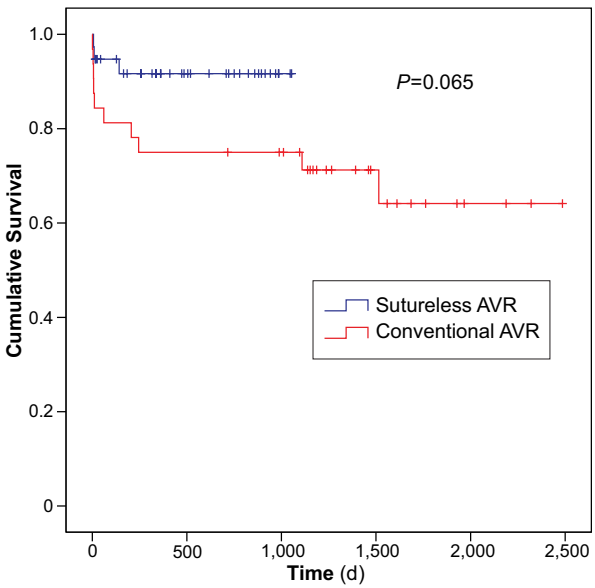

Fig. 1 *Kaplan-Meier survival curve shows similar survival outcomes for both aortic valve replacement (AVR) groups.*

line treatment for isolated AVR in elderly patients who have severe comorbidities, delicate aortic wall conditions (such as calcified root, porcelain aorta, or those resulting from repeat procedures), the need for time-consuming concomitant operations, or small aortic roots. The benefits of sutureless-valve technology include easy and rapid implantability; easy repositioning; shorter cross-clamp and CPB times; complete removal of the stenotic native AV; favorable hemodynamic performance (a larger orifice area); the ability for concomitant procedures to be performed; lower rates of vascular complications, stroke, and PVL; and less need for permanent pacemakers.

Authors of published series[9-14] on isolated AVR in high-risk elderly patients reported operative mortality rates of 0 to 3% for sutureless AVR and 4% to 10% for conventional AVR. In comparison, the operative mortality rates in our cohort were 5.3% and 15.6%, respectively—higher, we speculate, because patients in both groups underwent complex concomitant procedures.

Lengthy aortic cross-clamp and total CPB times have been associated with poor clinical outcomes in AVR. In a retrospective analysis of 979 patients who had undergone surgical AVR,[15] cross-clamp time independently predicted severe cardiovascular morbidity (increased risk, 1.4% per 1-min increase). Consistent with an earlier report,[16] the shorter CPB and cross-clamp times in our group 1 patients resulted in less drainage, less need for red blood cell transfusion, and shorter hospital stays.

In both our groups, AVR brought substantial symptomatic improvement and reduced transvalvular pressure gradients. Before our patients' discharge from the hospital, echocardiograms showed lower aortic gradients in group 1, which is consistent with other reports.[5,17,18]

Paravalvular Leak

Optimally, sutureless procedures permit full removal of the native AV and enable thorough annular decalcification, thereby lowering the risk of PVL. Nevertheless, PVL often influences the outcomes of sutureless AVR. Chief contributory factors are stenotic remnants of the native AV, residual annular calcification, intrinsic valve design, and operative variables such as incorrect sizing or positioning.[11] Preprocedural echocardiographic analysis is crucial to determine anatomic contraindications to sutureless AVR, such as aortic root dilation, an annular-to-sinotubular junction ratio >1:3, and an aortomitral curtain <5 mm thick in concomitant mitral valve replacement.

Intraoperative TEE detects moderate-to-severe PVL so that it can be corrected immediately. Severe postprocedural PVL has been correlated with poor patient outcomes.[19,20] In sutureless AVR, the incidence of PVL has ranged from 1.6% to 15.8%[21,22]—significantly lower than that after TAVR but still greater than that after conventional AVR. Substantial PVL occurred in only one of our patients.

Order of Surgical Procedures

When multiple procedures are planned, we recommend performing mitral valve intervention and left circumflex coronary artery bypass first, to minimize cardiac retraction and the consequent distortion or inadequate positioning of a sutureless AV. When the PERCEVAL S valve is used in association with CABG, the surgeon should ensure enough aortic length for proximal anastomoses. In addition, both procedures should be performed during the same aortic cross-clamp period. Because of prosthesis design, we recommend using the Edwards INTUITY valve if ascending aortic replacement is planned.

Bicuspid Aortic Valves. In the Sievers surgical classification of bicuspid AVs,[23] type 0 has no raphe, type 1 has one raphe, and type 2 has 2 raphes. Types 1 and 2 usually feature leaflets of unequal size, and the larger leaflet typically has a central raphe (or ridge) consequent to the fusion of 2 adjacent leaflet commissures. We have used sutureless valves in cases of bicuspid AV but think that the Edwards INTUITY is better. An annular diameter <25 mm might yield good results in type 0.[24] We increase the number of guiding sutures according to the situation.

The Gray Zone. It is debated whether TAVR or surgical AVR is better for patients in the "gray zone" of AV disease. The ideal candidate for sutureless AVR is an elderly patient who needs multiple interventions (such as CABG, multiple-valve surgery, or reoperation) and has several comorbid conditions that affect the choice between surgical AVR and TAVR. Muneretto and colleagues[25] compared the results of TAVR, conventional surgical AVR, and sutureless AVR in patients who were at intermediate-to-high risk. These authors suggested that, at 24 months, patients who underwent TAVR had more perioperative complications and less freedom from major adverse cardiac events and prosthesis dysfunction than did patients who underwent surgical or sutureless AVR. D'Onofrio and colleagues[26] compared early clinical and echocardiographic outcomes of patients who underwent surgical AVR, sutureless AVR with use of PERCEVAL valves, and transapical AVR. The authors reported lower 30-day mortality and postoperative aortic regurgitation rates in the surgical group than in the TAVR group, and no difference in mortality rates between the sutureless and TAVR groups.

Study Limitations

The limitations of this study are its single-center nature, small sample size, and nonrandomized design. This study focused on early hemodynamic and midterm survival outcomes, so long-term follow-up data from randomized clinical trials will be needed to evaluate durability, clinical outcomes, and sequelae.

Conclusion. Although proposing final conclusions would be premature, our results show that sutureless AVR provides favorable results and can be the first option for elderly, high-risk patients who need AVR and concomitant cardiac surgical procedures.

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