Simple interrupted suturing increases valve performance after aortic valve replacement with a small supra-annular bioprosthesis

Minoru Tabata, MD, MPH,^a Kentaro Shibayama, MD,^b Hiroyuki Watanabe, MD,^b Yasunori Sato, PhD,^c Toshihiro Fukui, MD,^a and Shuichiro Takanashi, MD^a

Objective: A supra-annular aortic valve prosthesis is often used for aortic valve replacement in patients with a small aortic annulus. However, which suture technique provides the best valve performance has not been studied. We aimed to compare valve performance between 2 different suture techniques.

Methods: We reviewed 152 patients undergoing aortic valve replacement with a 19- or 21-mm Carpentier-Edwards Perimount Magna aortic bioprosthesis (Edwards Lifesciences, Irvine, Calif) between June 2008 and December 2010. Simple interrupted sutures were used in 102 patients (group A, 19-mm prosthesis in 47 patients and 21-mm prosthesis in 55 patients), and noneverting mattress sutures were used in 50 patients (group B, 19-mm prosthesis in 20 patients and 21-mm prosthesis in 30 patients). Transthoracic echocardiograms were performed at baseline and before discharge in all patients and 1 year after surgery in 141 patients. We compared the effective orifice area and incidence of prosthesis–patient mismatch (effective orifice area index $<0.85 \text{ cm}^2/\text{m}^2$) between 2 groups.

Results: The mean postoperative effective orifice areas were $1.41 \pm 0.32 \text{ cm}^2/\text{m}^2$ in group A and $1.30 \pm 0.28 \text{ cm}^2/\text{m}^2$ in group B ($P = .025$). The incidence of prosthesis–patient mismatch was 29% in group A and 56% in group B ($P = .002$). A multivariate analysis has shown that simple interrupted suturing is a negative predictor of prosthesis–patient mismatch (odds ratio, 0.33; 95% confidence interval, 0.13–0.83; $P = .018$). At 1 year, the incidence of prosthesis–patient mismatch was 27% in group A and 47% in group B ($P = .023$).

Conclusions: Simple interrupted sutures provide larger effective orifice areas and reduce the incidence of prosthesis–patient mismatch after aortic valve replacement with a small supra-annular bioprosthesis. This suture technique is preferred in those patients to maximize valve performance. (J Thorac Cardiovasc Surg 2014;147:321–5)

A supra-annular aortic valve prosthesis is often used for aortic valve replacement (AVR) in patients with a small aortic annulus. In these patients, it is desirable to obtain the largest possible effective orifice area (EOA) to avoid prosthesis–patient mismatch (PPM). The simple interrupted suture technique is one of the methods to prevent PPM.^{1,2} However, no quantitative analysis has been performed. We compared the valve performance between 2 different suture techniques: simple interrupted suturing and noneverting mattress suturing. We hypothesized that simple interrupted suturing increases the EOA and reduces the incidence of PPM after AVR with a 19- or 21-mm supra-annular bioprosthesis.

PATIENTS AND METHODS

Patients and Study Design

This study was approved by the institutional review board, and a waiver of informed consent was obtained. We reviewed 152 patients who underwent AVR with a 19- or 21-mm Carpentier-Edwards Perimount Magna Aortic Heart Valve (Edwards Lifesciences, Irvine, Calif) at Sakakibara Heart Institute between June 2008 and December 2010. Patients who underwent aortic root replacement or annular enlargement were excluded. Patients with low ejection fraction ($<40\%$), left ventricular outlet tract obstruction, or mitral valve prosthesis also were excluded because it is difficult to measure valve performance by echocardiography in these cases. Simple interrupted suturing was used in 102 patients (group A), and noneverting mattress suturing was used in 50 patients (group B). We initially used noneverting mattress sutures in every case, and we changed the suturing technique to simple interrupted sutures in the beginning of 2009 according to our department consensus, although there was some overlap period. Thus, the suturing technique was not chosen on the basis of surgeon's preference or patient characteristics.

Outcome measures included EOA, EOA index (EOAI), PPM (EOAI $<0.85 \text{ cm}^2/\text{m}^2$), and severe PPM (EOAI $<0.65 \text{ cm}^2/\text{m}^2$). EOAI was calculated by dividing the EOA by the body surface area. We compared these outcome measures and the incidence of paravalvular leak between 2 groups by univariate and multivariate analyses. Perioperative data were collected from the patients' medical records.

Surgical Procedure and Postoperative Anticoagulation

A median sternotomy or upper hemisternotomy was performed. Cardiopulmonary bypass was established with ascending aortic and right atrial/percutaneous femoral venous cannulation. A left ventricular vent was

From the Departments of Cardiovascular Surgery^a and Cardiology,^b Sakakibara Heart Institute, Tokyo, Japan; and Clinical Research Center,^c Graduate School of Medicine, Chiba University, Chiba, Japan.

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Address for reprints: Minoru Tabata, MD, MPH, Department of Cardiovascular Surgery, Sakakibara Heart Institute, 3-16-1 Asahi-cho, Fuchu-shi, Tokyo 183-0003, Japan, 81-42-314-3111 (E-mail: mtabata@post.harvard.edu).

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Abbreviations and Acronyms

AVR	= aortic valve replacement
EOA	= effective orifice area
EOAI	= effective orifice area index
PPM	= prosthesis–patient mismatch
TEE	= transesophageal echocardiography
TTE	= transthoracic echocardiography

placed through the right superior pulmonary vein. Cardiac asystole was obtained with a combination of antegrade and retrograde blood cardioplegia. The diseased valve was excised, and the annulus was carefully debrided of calcium deposits if the annulus was calcified. For the simple interrupted suture technique, 18 to 24 2-0 polyester sutures were used (Figure 1). For the noneverting mattress suture technique, 12 to 16 2-0 pledgeted polyester sutures were used (Figure 1). The prosthesis size was determined by using original valve sizers provided by the manufacturer. The sutures were passed through the sawing cuff of the prosthesis. The prosthesis was seated on the annulus, and the sutures were securely tied.

Aspirin and warfarin were started after surgery unless there was a contraindication. Warfarin was discontinued 3 months after surgery unless there was another reason for anticoagulation, such as atrial fibrillation.

Echocardiographic Evaluation

Transthoracic echocardiography (TTE) was performed in all patients before surgery and before discharge (mostly 1 week after surgery). Preoperative or intraoperative transesophageal echocardiography (TEE) also was performed in all patients. Of 152 patients, 141 (92.8%) underwent TTE 1 year after surgery. The annulus size was measured at the long-axis view using 2-dimensional TEE. The EOA was calculated using Doppler TTE and continuity equation. Paravalvular leak was assessed with TTE and defined as the presence of any regurgitant jet outside the prosthesis frame.

Statistical Analysis

For the baseline variables, summary statistics were constructed using frequencies and proportions for categorical data and mean and standard deviation for continuous variables. We compared patient characteristics using the Fisher exact test for categorical outcomes and unpaired *t* test for continuous variables, as appropriate. To adjust the effects of relevant covariates (sex, body surface area, ejection fraction, annulus size, and implantation of 19-mm prosthesis), multivariate analyses were performed with the incidence of PPM before discharge and at 1 year after surgery as the dependent variable. We selected clinically important covariates that are most likely to be related to the incidence of PPM. We used a generalized estimating equation¹ with compound symmetry as the covariance structure to adjust for cluster effects of the prosthesis size. All comparisons were planned, and the tests were 2 sided. All statistical analyses were performed by using PASW 18.0 (SPSS Inc, Chicago, Ill).

RESULTS

Patients' characteristics are shown in Table 1. In both groups, most patients had severe aortic stenosis. The annulus size was significantly smaller in group A than in group B. Operative data are also shown in Table 1. The ratio of female patients was significantly higher in group A than in group B; however, the mean body surface area was similar. A 19-mm prosthesis was more frequently used in group A than in group B (46% vs 40%), although the difference was not statistically significant. The prosthesis–annulus

size ratio was significantly larger in group A than in group B. There was no significant difference in cardiopulmonary and aortic crossclamp times.

Postoperative and 1-year valve performance data are shown in Tables 2 and 3, respectively. Postoperatively, group A had significantly larger mean EOA and mean EOAI than group B. The incidence of PPM was significantly lower in group A than in group B (29.4% vs 56.0%, $P = .002$). The incidence of severe PPM was 3.9% in group A and 6.0% in group B ($P = .684$). The incidence of paravalvular leak was 2.0% in both groups ($P = 1.000$), and all paravalvular leaks were graded as trivial. At 1 year after surgery, group A had a significantly larger mean EOAI. The incidence of PPM was significantly lower in group A than in group B (26.6% vs 46.8%, $P = .023$). The incidence of severe PPM was 3.2% in group A and 4.3% in group B ($P = 1.000$). The incidence of paravalvular leak was 3.2% in group A and 4.3% in group B ($P = 1.000$), and all paravalvular leaks were graded as trivial. Generalized estimating equations have shown that the simple interrupted suturing is independently associated with a lower incidence of PPM postoperatively (odds ratio, 0.33; 95% confidence interval, 0.27–0.39; $P < .001$) and 1 year after surgery (odds ratio, 0.37; 95% confidence interval, 0.17–0.81; $P = .013$).

DISCUSSION

The potential benefits of simple interrupted sutures have been described^{2,3}; however, no quantitative analysis has been performed. This study has indicated 2 potential benefits of simple interrupted sutures in AVR with a small supra-annular bioprosthesis.

First, compared with the noneverting mattress suture technique, the simple interrupted suture technique demonstrated a larger prosthesis–annulus size ratio. Because this result can be biased by our technical method, we cannot conclude that the simple interrupted suture technique enables a surgeon to implant a larger valve. However, this may be possible because noneverting mattress sutures with pledgets decrease the annulus size to some extent, whereas simple interrupted sutures do not.³ No study has proved these findings quantitatively; however, we often find that the maximal size of the prosthesis sizer that can be inserted into the annulus is smaller *after* than *before* placing mattress sutures.

Second, compared with the noneverting mattress suture technique, the simple interrupted suture technique is associated with a larger EOA and lower incidence of PPM independently of the prosthesis size (19 or 21 mm). In the subgroup analysis, there was no significant difference in EOA or EOAI in the subgroup with a 19-mm prosthesis probably because of small sample size. Noneverting mattress sutures tend to roll the annulus tissue beneath the prosthesis.² The annulus tissue often protrudes medially in the

FIGURE 1. A 21-mm Carpentier-Edwards Perimount Magna (Edwards Lifesciences, Irvine, Calif) aortic heart valve was implanted in the porcine heart with simple interrupted sutures (A) and noneverting mattress sutures (B). Prosthetic leaflets and aortic sinuses were removed after implantation. A1, Aortic view of simple interrupted sutures. A2, Ventricular view of simple interrupted sutures. B1, Aortic view of noneverting mattress sutures. B2, Ventricular view of noneverting mattress sutures.

prosthesis frame (Figure 1), which could disturb the blood flow through the prosthesis and reduce its EOA. On the other hand, no annulus tissue is rolled medially in the prosthesis frame after AVR with simple interrupted sutures (Figure 1).

A supra-annular aortic valve prosthesis often has been used in patients with a small aortic annulus because theoretically it provides a larger EOA and smaller pressure

gradient than an intra-annular or intrasupra-annular prosthesis. However, the actual advantage of the supra-annular prosthesis is controversial. Wagner and colleagues⁴ compared exercise hemodynamics 6 months after surgery among different prostheses in patients with a small annulus. They showed no significant association of the supra-annular design with better performance. In a randomized prospective comparison of 2 different mechanical prostheses, Guenzinger and colleagues⁵ showed no additional benefit of supra-annular positioning over intrasupra-annular valve positioning on hemodynamic performance. Noneverting mattress sutures were used for the valve implantation in both studies, which could be one reason for their negative

TABLE 1. Preoperative and operative data of patients

Variables	Group A (n = 102)	Group B (n = 50)	P value
Age (y)	76.3 ± 6.8	77.2 ± 5.1	.321
Woman	83 (81.4%)	29 (58.0%)	.003
Body surface area (m ²)	1.45 ± 0.17	1.49 ± 0.14	.154
Ejection fraction (%)	61.8 ± 6.5	60.4 ± 7.4	.259
Annulus size (mm)	20.5 ± 1.7	22.0 ± 2.1	<.001
Severe aortic stenosis	96 (94.1%)	44 (88.0%)	.210
19-mm prosthesis	47 (46.1%)	20 (40.0%)	.493
Prosthesis–annulus size ratio	0.98 ± 0.1	0.92 ± 0.1	<.001
Concomitant procedure	53 (52.0%)	27 (54%)	1.000
Coronary artery bypass surgery	37	17	
Aortic surgery	9	5	
Other valves	7	4	
Others	13	6	
Cardiopulmonary bypass time (min)	123 ± 71	113 ± 41	.296
Aortic crossclamp time (min)	89 ± 31	86 ± 33	.609

Frequencies and proportions for categoric data and mean and standard deviation for continuous variables are shown. The Fisher exact test was used for categoric outcomes, and the unpaired *t* test was used for continuous variables.

TABLE 2. Postoperative valve performance data

Variables	Group A (n = 102)	Group B (n = 50)	P value
Mean postoperative EOA (cm ²)	1.42 ± 0.32	1.30 ± 0.28	.025
19-mm prosthesis	1.25 ± 0.23	1.18 ± 0.25	.249
21-mm prosthesis	1.55 ± 0.32	1.38 ± 0.27	.014
Mean postoperative EOAI (cm ² /m ²)	0.98 ± 0.23	0.88 ± 0.19	.003
19-mm prosthesis	0.93 ± 0.17	0.83 ± 0.17	.032
21-mm prosthesis	1.03 ± 0.26	0.91 ± 0.19	.016
Postoperative PPM	30 (29.4%)	28 (56.0%)	.002
Postoperative severe PPM	4 (3.9%)	3 (6.0%)	.684
Paravalvular leak	2 (2.0%)	1 (2.0%)	1.000

Frequencies and proportions for categoric data and mean and standard deviation for continuous variables are shown. The Fisher exact test was used for categoric outcomes, and the unpaired *t* test was used for continuous variables. EOA, Effective orifice area; EOAI, effective orifice area index; PPM, prosthesis–patient mismatch.

TABLE 3. One-year valve performance data

Variables	Group A (n = 94)	Group B (n = 47)	P value
Mean 1-y EOA (cm ²)	1.44 ± 0.32	1.36 ± 0.45	.126
19-mm prosthesis	1.25 ± 0.23	1.21 ± 0.18	.426
21-mm prosthesis	1.60 ± 0.28	1.44 ± 0.35	.031
Mean 1-y EOAI (cm ² /m ²)	1.00 ± 0.25	0.92 ± 0.21	.045
19-mm prosthesis	0.93 ± 0.20	0.87 ± 0.13	.405
21-mm prosthesis	1.07 ± 0.23	0.95 ± 0.25	.036
1-y PPM	25 (26.6%)	22 (46.8%)	.023
1-y severe PPM	3 (3.2%)	2 (4.3%)	1.000
Paravalvular leak	3 (3.2%)	2 (4.3%)	1.000

Frequencies and proportions for categoric data and mean and standard deviation for continuous variables are shown. The Fisher exact test was used for categoric outcomes, and the unpaired *t* test was used for continuous variables. EOA, Effective orifice area; EOAI, effective orifice area index; PPM, prosthesis-patient mismatch.

results. A supra-annular prosthesis is more likely to be affected by the annulus tissue drawn underneath the valve by mattress sutures than an intrasupra-annular prosthesis because it generally has a small sewing cuff and there is no prosthetic structure that blocks the annulus tissue protrusion. In this regard, the simple interrupted suture technique is preferred for supra-annular prostheses to maximize their valve performance.

Some surgeons may be concerned that simple interrupted sutures could increase the risk of paravalvular leak. However, in our study there was no significant difference in the incidence of paravalvular leak between the 2 groups. All paravalvular leaks observed in both groups were trivial and did not affect hemodynamics or lead to hemolysis. None of the paravalvular leaks were complicated by infection. Those paravalvular leaks usually have a benign course.⁶ With the simple interrupted suture technique, the valve can be placed in the supra-annular or intra-annular position depending on how the valve is seated before tying the sutures. To avoid paravalvular leak due to a technical issue, it may be important to ensure that all parts of the prosthesis cuff are located in the same level (supra-annular or intra-annular level).

PPM has been shown to be associated with adverse outcomes, such as cardiac events and mortality.⁷⁻¹² In a meta-analysis reviewing 34 studies and 27,186 patients, Head and colleagues⁷ showed that both moderate PPM ($0.65 \leq \text{EOAI} < 0.85 \text{ cm}^2/\text{m}^2$) and severe PPM increased all-cause mortality and cardiac-related mortality over a long-term follow-up. They also showed that this association increases with the severity of PPM. In the current study, the incidence of severe PPM was low probably because our patients had a small body size (mean body surface area = $1.46 \pm 0.16 \text{ m}^2$). A 19- or 21-mm valve would result in a higher incidence of severe PPM in patients with a larger body size, and the advantage of simple interrupted sutures should have a greater impact in those patients. PPM also has been shown to be a risk factor of early structural valve

deterioration of aortic bioprostheses,¹³ although no structural valve deterioration was found in our patients during a 1-year follow-up. The simple interrupted suture technique may improve early and late clinical outcomes by reducing the incidence of PPM.

Pibarot and Dumesnil¹⁴ demonstrated that PPM can be avoided by using a simple strategy. In their study, they calculated the minimal EOA for each patient by multiplying his/her body surface area by 0.85 and selected the prosthesis with an expected EOA greater than the calculated one in the previous step.¹⁴ Most prosthesis types have their own EOAI chart provided by the manufacture. However, the EOAI chart based on a small echocardiographic cohort has been shown to be a poor tool for predicting and preventing PPM.¹⁵ We followed this strategy for all cases included in this study, and the incidence of PPM should have been zero if the expected EOA on the chart could be obtained in all cases. In reality, however, there was PPM in 38% of our patients who underwent AVR with a 19- or 21-mm supra-annular bioprosthesis. An EOAI chart should be used carefully to prevent PPM, especially when a small prosthesis is implanted.

Study Limitations

There are limitations of an observational nature. However, we minimized the bias by using multivariate regression models. We did not assess the association of the suture technique with clinical outcomes in this study because the sample size was relatively small and the follow-up period was short. However, because absence of PPM is a strong quality indicator of AVR that is associated with early and late clinical outcomes, our findings imply the positive impact of simple interrupted sutures on clinical outcomes.

CONCLUSIONS

The simple interrupted suture technique provides larger EOAs and reduces the incidence of PPM after AVR with a small supra-annular bioprosthesis. This suture technique is preferred in patients with a small annulus to maximize valve size and performance.

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