Suture technique does not affect hemodynamic performance of the small supra-annular Trifecta bioprosthesis

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Objective: The study objective was to evaluate whether aortic valve replacement with the Trifecta valve (St Jude Medical Inc, St Paul, Minn) using simple sutures produces better hemodynamic performance than valve replacement with noneverting pledget-reinforced sutures.

Methods: We analyzed prospectively acquired 1-year hemodynamic data of patients with small aortic annulus sizes who were enrolled in a multicenter trial of the Trifecta aortic valve bioprosthesis and underwent aortic valve replacement with a 19-mm or 21-mm bioprosthesis between August 2007 and November 2009. We compared preoperative clinical information and 1-year postoperative hemodynamic data for noneverting pledget-reinforced sutures (group 1) versus everting mattress sutures or simple sutures (group 2).

Results: A total of 346 patients underwent aortic valve replacement: 269 in group 1 and 77 in group 2. Preoperative demographic characteristics for the 2 groups were similar. For groups 1 and 2, the mean gradient was 10.4 ± 4.7 mm Hg and 11.1 ± 4.4 mm Hg for 19-mm valves, respectively, and 8.4 ± 3.5 mm Hg and 8.8 ± 3.6 mm Hg for 21-mm valves, respectively; the effective orifice area was 1.40 cm^2 and 1.25 cm^2 for 19-mm valves, respectively, and 1.57 cm^2 and 1.50 cm^2 for 21-mm valves, respectively. The rate of severe prosthesis–patient mismatch (indexed effective orifice area $\leq 0.65 \text{ cm}^2/\text{m}^2$) was 18.6% (n = 11) and 25% (n = 6) for 19-mm valves, respectively, and 10.9% (n = 20) and 16.3% (n = 8) for 21-mm valves, respectively.

Conclusions: The suture method did not affect hemodynamic performance of supra-annular bioprostheses in patients with small aortic annulus sizes. Choice of suture technique should be determined by surgeon experience and local anatomic features. (J Thorac Cardiovasc Surg 2014;148:1347-51)

Many variables may affect the hemodynamic performance of the aortic valve bioprosthesis, including stent and sewing ring design. The hemodynamic function of the third-generation supra-annular stented bioprosthesis is

generally similar to that of stentless valves.¹ Also, suture technique may affect the hemodynamic outcome of aortic valve replacement (AVR). In patients with a small aortic annulus (with or without augmentation), a slightly larger prosthesis may be possible when a simple suture technique is used instead of a mattress suture technique, which can reduce annular diameter by 1 mm or more.² Thus, use of simple sutures may decrease the likelihood of prosthesis–patient mismatch (PPM) in at-risk patients.

Some surgeons believe that noneverting mattress sutures with pledget reinforcement can further impair hemodynamic function of the prosthesis by drawing tissue toward the valve orifice and potentially contributing to transvalvular gradient and predisposing to pannus formation.^{3,4} In an analysis of 152 patients with small aortic annuli who underwent AVR with the Carpentier-Edwards Perimount Magna (Edwards Lifesciences Corp, Irvine, Calif) bioprosthesis, Tabata and colleagues⁴ reported that the simple interrupted suture technique yielded better hemodynamic function than noneverting sutures. To better understand the potential impact of suture method on prosthetic valve hemodynamics in North American and European populations, we reviewed the 1-year Doppler echocardiographic data of patients who underwent AVR with the 19-mm or 21-mm Trifecta bioprosthesis (St Jude Medical Inc, St Paul, Minn).

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Abbreviations and Acronyms

AVR	= aortic valve replacement
EOA	= effective orifice area
EOAI	= effective orifice area index
LVOT	= left ventricular outflow tract
PPM	= prosthesis–patient mismatch
TVI	= time-velocity integral

MATERIALS AND METHODS

We analyzed prospectively acquired data from the US Food and Drug Administration investigational device exemption study of the Trifecta aortic valve bovine bioprosthesis. Details of the multicenter study and participating sites have been published.⁵ We included patients who received a 19-mm or 21-mm valve and divided them into 2 groups by type of suture technique. Group 1 included patients in whom the aortic valve prosthesis was secured using noneverting pledget-reinforced mattress sutures; 12 to 16 pledgeted polyester sutures were passed from the ventricular side of the annulus through the aortic side and through the prosthetic valve sewing ring. Group 2 included patients who had their aortic valve prosthesis implanted using suture techniques that avoided gathering tissue beneath the valve (everting mattress sutures with or without pledgets, simple sutures, or continuous suture techniques). The Food and Drug Administration protocol did not prescribe an implant method, so the suture technique was determined by the implanting surgeon. Demographic and clinical information that was collected included the suture technique, late survival, reoperation, and reports of Doppler echocardiograms.

We compared preoperative demographic and hemodynamic data of the 2 groups and focused on 1-year postoperative Doppler echocardiographic data (eg, mean gradient, effective orifice area [EOA], and EOA index [EOAI]), which is computed by dividing the EOA by the body surface area. All Doppler echocardiograms were analyzed by an independent core laboratory. Mean aortic valve gradients were obtained from the echocardiographic instrument's software system using planimetry of the Doppler spectral envelope. EOA was calculated automatically from the continuity equation by using the left ventricular outflow tract (LVOT) area and the time-velocity integral (TVI) as $EOA = (CSA_{LVOT} \times TVI_{LVOT}) / TVI_{Ao}$, where CSA_{LVOT} is the cross-sectional area of LVOT, TVI_{LVOT} is the TVI of the LVOT derived from the pulsed-wave Doppler, and TVI_{Ao} is the TVI of the aortic valve (Ao), derived from software integration of transvalvular continuous wave Doppler.

We defined any degree of PPM as $EOAI \geq 0.85 \text{ cm}^2/\text{m}^2$ or less and severe PPM as $EOAI \geq 0.65 \text{ cm}^2/\text{m}^2$ or less. Also, we compared overall adverse event rates of the 2 suture techniques.

Statistical Analyses

Unless otherwise noted, categorical variables are summarized as number and percentage, and continuous variables are summarized as mean $\pm$ standard deviation. *P* values are based on the chi-square test or Fisher exact test, when appropriate, for categorical variables, and a 2-sample *t* test was used for continuous variables. No adjustments were made for multiple comparisons. Statistical analyses were generated using SAS software version 9.3 (SAS Institute Inc, Cary, NC).

RESULTS

A total of 393 patients with small aortic annuli underwent AVR with a 19-mm or 21-mm Trifecta valve bioprosthesis between August 2007 and November 2009. Of these 393

patients, 346 had 1-year echocardiographic examinations available for review.

Most (77.7% [269/346]) of these patients were in group 1 (aortic valve prosthesis secured using noneverting pledget-reinforced mattress sutures); 70 of the 269 patients had received a 19-mm prosthesis, and 199 patients had received a 21-mm prosthesis. Of the 77 patients (22.3%) in group 2 (aortic valve prosthesis implanted using everting mattress sutures or simple suture techniques), approximately more than one third ($n = 27$) had received a 19-mm prosthesis, whereas the rest ($n = 50$) had received a 21-mm prosthesis. The demographic characteristics of patients and their operative data are detailed in Table 1.

For patients who had received a 19-mm bioprosthesis, the peak and mean transvalvular gradients were similar for groups 1 and 2 (Table 2). However, there was a small but statistically significant difference in EOA that favored group 1 ($P < .05$). In patients receiving the 21-mm prosthesis, the peak and mean transvalvular gradients and the EOA and EOAI were similar between the 2 groups. Overall, the incidence of severe PPM was 12.8% (31/243) in group 1 and 19.2% (14/73) in group 2 (Table 3). The rate of severe PPM ($EOAI < 0.65 \text{ cm}^2/\text{m}^2$) in groups 1 and 2 was 18.6% ($n = 11$) and 25% ($n = 6$) for 19-mm valves, respectively, and 10.9% ($n = 20$) and 16.3% ($n = 8$) for 21-mm valves, respectively (Table 3).

DISCUSSION

In patients undergoing AVR, supra-annular positioning facilitates implantation of a prosthesis of suitable size with adequate EOAI. However, even supra-annular valve replacement may result in sizeable transvalvular gradients, especially in patients with small annuli. Tabata and colleagues⁴ recently reported that the method of securing the aortic prosthesis in the supra-annular position might affect hemodynamic performance. In their series of patients who underwent AVR with 19-mm or 21-mm Carpentier-Edwards Perimount Magna bioprostheses, EOAs were greater in those patients who had simple sutures than in those who had noneverting pledget-reinforced mattress sutures. Tabata and colleagues⁴ hypothesized that noneverting sutures gathered tissue (and pledget material) beneath the valve, placing it in the pathway of blood flow.

Our findings do not support the notion that suture technique influences hemodynamic performance of small aortic valve bioprostheses. Indeed, there was not even a trend toward better hemodynamics in patients who had simple or everting sutures compared with the hemodynamics in patients with noneverting sutures. The explanation for the difference between our findings and those of Tabata and colleagues⁴ is not immediately clear. In this series, all patients received the Trifecta bioprosthesis. The hemodynamic profile of this valve is good, as reflected by the average mean gradient in our patients of 10.6 mm Hg

TABLE 1. Characteristics of 346 patients with aortic valve replacement by valve size and suture technique*

Characteristic	19-mm prosthesis			21-mm prosthesis		
	Group 1: Noneverting suture (n = 70)	Group 2: Everting/simple suture (n = 27)	P value	Group 1: Noneverting suture (n = 199)	Group 2: Everting/simple suture (n = 50)	P value
Age, mean ± SD, y	78.1 ± 7.9	76.5 ± 7.1	.34	74.6 ± 8.5	74.9 ± 7.6	.80
Female sex	67 (95.7)	27 (100)	.56	120 (60.3)	30 (60)	.97
NYHA class III/IV	42 (60.0)	19 (70.4)	.34	103 (51.8)	28 (56)	.59
Previous CVS procedure	17 (24.3)	8 (29.6)	.59	36 (18.1)	16 (32)	.03
History of CAD	44 (62.9)	18 (66.7)	.73	102 (51.3)	31 (62)	.17
Hypertension	59 (84.3)	24 (88.9)	.56	163 (81.9)	44 (88)	.30
Diabetes mellitus	15 (21.4)	4 (14.8)	.46	57 (28.6)	10 (20)	.22
Smoking history	27 (38.6)	8 (29.6)	.41	99 (49.7)	25 (50)	.97
Isolated AVR	34 (48.6)	15 (55.6)	.54	94 (47.2)	14 (28)	.01
Concomitant CABG	26 (37.1)	8 (29.6)	.49	68 (34.2)	21 (42)	.30
CPB time, mean ± SD, min	102.7 ± 49.1	109.3 ± 48.5	.56	105.8 ± 48.3	115.6 ± 43.4	.19
CPB only AVR time, mean ± SD, min	79.9 ± 32.8	87.3 ± 42.3	.51	88.2 ± 32.9	76.4 ± 40.8	.23
ACC time, mean ± SD, min	79.8 ± 38.3	83.1 ± 36.6	.70	80.1 ± 36.6	87.9 ± 33.3	.17
ACC only AVR time, mean ± SD, min	61.7 ± 23.0	67.6 ± 34.6	.48	66.3 ± 24.1	56.1 ± 26.0	.15

ACC, Aortic crossclamp; AVR, aortic valve replacement; CABG, coronary artery bypass grafting; CAD, coronary artery disease; CPB, cardiopulmonary bypass; CVS, cardiovascular surgery; NYHA, New York Heart Association; SD, standard deviation. *Values are mean ± SD or number (percentage) unless indicated otherwise.

and 8.6 mm Hg for 19-mm and 21-mm prostheses, respectively, and these results are similar to those reported recently by Dell'Aquila and colleagues⁶ and Permanyer and colleagues.⁷ The EOAs in group 2 (n = 77) in our study are generally similar to those of patients who had simple suture techniques as reported by Tabata and colleagues⁴ (Figure 1), but the EOAI were lower, probably because of the higher body surface area of the patients in our Western population.

The Trifecta valve is a newer bioprosthesis with favorable hemodynamics, and it is possible that some aspect

of valve design may account for differences between our results and those of Tabata and colleagues.⁴ In the comparison of the Trifecta prosthesis with the Perimount Magna and Magna Ease prostheses (Edwards Lifesciences Corp, Irvine, Calif), Wendt and colleagues⁸ reported slightly lower mean gradients and higher aortic valve areas with the Trifecta prosthesis. However, multivariate covariance analysis showed no influence of prosthesis type on mean pressure gradient or aortic valve area because of differences in preoperative characteristics of the patients.

The design of our investigation differed slightly from that used by Tabata and colleagues,⁴ who compared only noneverting pledget-reinforced sutures and simple interrupted sutures. In contrast, we compared noneverting pledget-reinforced sutures with everting mattress sutures or simple sutures, because simple sutures were used in

TABLE 2. Comparison of echocardiographic findings in 346 patients 1 year after aortic valve replacement by valve size and suture technique*

Variable	Group 1: Noneverting suture	Group 2: Everting/simple suture	P value
Overall	(n = 269)	(n = 77)	
Peak gradient, mm Hg	17.2 ± 7.2	18.4 ± 7.4	.21
Mean gradient, mm Hg	8.9 ± 3.9	9.6 ± 4.1	.16
EOA, cm ²	1.53 ± 0.3	1.42 ± 0.3	.004
EOAI, cm ² /m ²	0.86 ± 0.2	0.8 ± 0.2	.007
Valve size 19 mm	(n = 70)	(n = 27)	
Peak gradient, mm Hg	19.5 ± 8.3	20.5 ± 7.7	.59
Mean gradient, mm Hg	10.4 ± 4.7	11.1 ± 4.4	.498
EOA, cm ²	1.40 ± 0.3	1.25 ± 0.2	.01
EOAI, cm ² /m ²	0.84 ± 0.2	0.74 ± 0.1	.01
Valve size 21 mm	(n = 199)	(n = 50)	
Peak gradient, mm Hg	16.4 ± 6.6	17.2 ± 7.1	.44
Mean gradient, mm Hg	8.4 ± 3.5	8.8 ± 3.6	.45
EOA, cm ²	1.57 ± 0.3	1.50 ± 0.3	.12
EOAI, cm ² /m ²	0.86 ± 0.2	0.83 ± 0.1	.20

EOA, Effective orifice area; EOAI, effective orifice area index. *Values are mean ± SD unless indicated otherwise.

TABLE 3. Distribution of prosthesis–patient mismatch at 1 year by valve size and suture technique*

Prosthesis–patient mismatch	Group 1: Noneverting suture	Group 2: Everting/simple suture	P value
Overall	(n = 243)	(n = 73)	
EOAI ≤ 0.85 cm ² /m ²	121 (49.8)	47 (64.4)	.03
EOAI ≤ 0.65 cm ² /m ²	31 (12.8)	14 (19.2)	.17
Valve size 19 mm	(n = 59)	(n = 24)	
EOAI ≤ 0.85 cm ² /m ²	30 (50.8)	20 (83.3)	.006
EOAI ≤ 0.65 cm ² /m ²	11 (18.6)	6 (25.0)	.52
Valve size 21 mm	(n = 184)	(n = 49)	
EOAI ≤ 0.85 cm ² /m ²	91 (49.5)	27 (55.1)	.48
EOAI ≤ 0.65 cm ² /m ²	20 (10.9)	8 (16.3)	.30

EOAI, Effective orifice area index. *Values are number (percentage) unless indicated otherwise.

FIGURE 1. Comparison of EOAs 1 year postoperatively in the present study with EOAs reported by Tabata and colleagues.⁴ Bars represent 1 standard deviation, and data are grouped by suture method and valve size.

relatively few patients. The everting mattress technique avoids bunching tissue beneath the valve, as does the simple suture technique. Indeed, before combining patients who had simple sutures with patients who had everting sutures in the same group, we performed a preliminary analysis and found almost identical early and 1-year hemodynamic results (Table 4). Thus, we believe that combining these patients is justified.

Although the impact of PPM on AVR outcomes has been debated,⁹ several authors have concluded that it is an important predictor of long-term mortality and morbidity, and thus may be an especially important consideration in young athletic patients and in patients with poor ventricular function.¹⁰⁻¹⁵ PPM may predispose to early failure of bioprostheses because of stenosis,¹⁶ and in severe PPM, higher transvalvular gradients impair left ventricular mass regression.^{3,10} Our findings indicate that suture technique does not affect the risk of PPM in patients undergoing AVR with the small Trifecta aortic valve bioprosthesis.

Over time, endothelialization of the valve sewing ring may occur, with the potential for fibrous ingrowth from the ventricular aspect that may reduce the EOA. Theoretically, this process may be initiated or accelerated by pledget material in the subaortic region. We found no evidence of this in Doppler echocardiographic data obtained 1 year postoperatively; however, further follow-up of these patients will be important to determine whether there are any late deleterious effects of subaortic pledgets in patients with small prostheses.

A potential advantage of using a continuous suture technique or a nonpledgeted suture technique is the

potential ability to accommodate a slightly larger diameter valve. Several series have demonstrated good results for this strategy, with low risk of perivalvular leakage.^{3,17-20} Likewise, when pledgets are used, the noneverting suture

TABLE 4. Comparison of simple and everting simple suture techniques at 1 year postoperatively*

Prosthesis-patient mismatch	Group 2A: Simple suture	Group 2B: Everting pledget-reinforced suture	P value
Overall	(n = 32)	(n = 20)	
Mean gradient, mm Hg	9.9 ± 4.0	10.1 ± 4.7	.92
EOA, cm ²	1.4 ± 0.27	1.43 ± 0.29	.71
EOAI ≤ 0.85 cm ² /m ² , No./total (%)	24/30 (80)	13/20 (65)	.24
EOAI ≤ 0.65 cm ² /m ² , No./total (%)	7/30 (23.3)	6/20 (30)	.24
Valve size 19 mm	(n = 15)	(n = 4)	
Mean gradient, mm Hg	11.2 ± 4.4	11.4 ± 6.6	.94
EOA, cm ²	1.24 ± 0.22	1.25 ± 0.04	.94
EOAI ≤ 0.85 cm ² /m ² , No./total (%)	13/14 (92.9)	4/4 (100)	>.99
EOAI ≤ 0.65 cm ² /m ² , No./total (%)	4/14 (28.6)	1/4 (25)	>.99
Valve size 21 mm	(n = 17)	(n = 16)	
Mean gradient, mm Hg	8.8 ± 3.4	9.7 ± 4.3	.51
EOA, cm ²	1.53 ± 0.24	1.47 ± 0.30	.54
EOAI ≤ 0.85 cm ² /m ² , No./total (%)	11/16 (68.8)	9/16 (56.2)	.47
EOAI ≤ 0.65 cm ² /m ² , No./total (%)	3/16 (18.8)	5/16 (31.2)	.69

EOA, Effective orifice area; EOAI, effective orifice area index. *Values are mean ± SD or number/total (percentage) unless indicated otherwise.

technique results in a supra-annular position and may allow a larger size valve than that achieved with the everting technique, which places the valve sewing ring within the annulus. Advocates of simple sutures point out that the technique does not require porous felt pledgets and multiple knots that can aid bacterial growth^{21,22} and further diminish the risk of thrombosis and embolus.^{17-19,22} However, other surgeons contend that pledget-reinforced mattress sutures decrease the risk of paravalvular leakage compared with that with simple or continuous sutures.²³ Indeed, in a multicenter report by Englberger and colleagues,²⁴ the risk of paravalvular leak was 1.7% (11/635) in patients with valves implanted with pledgeted mattress sutures, compared with 5.8% (10/172) in patients with other suture methods, and multivariate analysis showed suture technique to be independently predictive of paravalvular leak. Our study was relatively small, with follow-up data available for only 1 year, but we found no differences in the risk of paravalvular leakage by surgical method. The single case of major paravalvular leak occurred in a patient in whom noneverting pledget-reinforced sutures were used.

CONCLUSIONS

In patients with small aortic annuli, AVR can be safely performed with noneverting pledget-reinforced sutures, with results (ie, similar early postoperative gradients, valve orifice areas, and rates of PPM) comparable to those of other suture techniques.

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