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

Murat Ugur, MD,[a] John G. Byrne, MD, MBA, FACC,[b] Joseph E. Bavaria, MD,[c] Anson Cheung, MD,[d] Michael Petracek, MD,[e] Mark A. Groh, MD,[f] Rakesh M. Suri, MD, DPhil,[a] Michael A. Borger, MD,[g] and Hartzell V. Schaff, MD[a]

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 $\pm$ 4.7 mm Hg and 11.1 $\pm$ 4.4 mm Hg for 19-mm valves, respectively, and 8.4 $\pm$ 3.5 mm Hg and 8.8 $\pm$ 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 cm^2/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 colleagues[4] 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).

From the Division of Cardiovascular Surgery,[a] Mayo Clinic, Rochester, Minn; Division of Cardiac Surgery,[b] Brigham and Women's Hospital, Boston, Mass; Division of Cardiovascular Surgery,[c] Hospital of the University of Pennsylvania, Philadelphia, Pa; Division of Cardiac Surgery,[d] St Paul's Hospital, University of British Columbia, Vancouver, British Columbia, Canada; Department of Cardiac Surgery,[e] Vanderbilt University Medical Center, Nashville, Tenn; Cardiovascular and Thoracic Surgery,[f] Mission Health, Asheville, NC; and Department of Cardiac Surgery,[g] Leipzig Heart Center, Leipzig, Germany.

The study was supported by St Jude Medical Inc (St Jude Medical Inc, St Paul, Minn).

Disclosures: The authors were investigators in the Food and Drug Administration–mandated clinical trial of the small supra-annular Trifecta (St Jude Medical Inc) aortic valve bovine bioprosthesis. Joseph E. Bavaria reports consulting fees from W. L. Gore and lecture fees from St Jude and Medtronic Vascular. Anson Cheung reports consulting fees from St Jude, Edwards, and Medtronic and equity ownership in Entourage Medicals and Neovasc Inc. Mark A. Groh reports consulting fees from St Jude. Rakesh M. Suri reports consulting fees from Sorin (Percival Trial PI and patent applications), and grant support from Edwards, Sorin, and St Jude. Michael A. Borger reports lecture fees from St Jude, Edwards, and Medtronic. All other authors have nothing to disclose with regard to commercial support.

The Mayo Clinic does not endorse the products mentioned in this article.

Received for publication Sept 12, 2013; revisions received Nov 15, 2013; accepted for publication Dec 5, 2013; available ahead of print Feb 8, 2014.

Address for reprints: Hartzell V. Schaff, MD, Division of Cardiovascular Surgery, Mayo Clinic, 200 First St SW, Rochester, MN 55905 (E-mail: schaff@mayo.edu).

0022-5223/$36.00

Copyright © 2014 by The American Association for Thoracic Surgery

http://dx.doi.org/10.1016/j.jtcvs.2013.12.006

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 0.85 cm^2/m^2 or less and severe PPM as EOAI 0.65 cm^2/m^2 or less. Also, we compared overall adverse event rates of the 2 suture techniques.

Statistical Analyses

Unless otherwise noted, categoric variables are summarized as number and percentage, and continuous variables are summarized as mean ± standard deviation. *P* values are based on the chi-square test or Fisher exact test, when appropriate, for categoric 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 cm^2/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 colleagues[4] 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 colleagues[4] 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 colleagues[4] 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

Download English Version:

https://daneshyari.com/en/article/2980388

Download Persian Version:

https://daneshyari.com/article/2980388

Daneshyari.com