How many sutures should a sutureless valve need?

Michael John Byrom, PhD,^{a,b} Yogeesan Sivakumaran, MBBS,^c Michael Patrick Vallely, PhD,^{a,b}
Michael Keith Wilson, MBBS,^{a,b} and Paul Gerard Bannon, MD, PhD^{a,b,d}

See related article on pages 1052-7.

Aortic valve replacement (AVR) has undergone significant transformation during the last 15 years. Minimally invasive approaches have led to a reduction in intensive care unit stay, postoperative ventilator support, and duration of hospital admission¹⁻⁴ while expanding the range of patients for whom an operative approach to aortic valve disease may be considered. At the least-invasive end of the spectrum, transcatheter aortic valve implantation (TAVI) provides catheter-based delivery of a bioprosthesis loaded within a self-expanding or balloon-expandable stent. In contrast to valve replacement, however, TAVI provides valve *implantation* within the native stenotic valve, the leaflets of which are merely pushed to the side. A number of potential sequelae may result, including coronary orifice obstruction, perforation of the aortic wall by calcium, paravalvular leak, and (at a significant rate) permanent pacemaker implantation.⁵⁻⁸ Nevertheless, for high-risk patients TAVI provides an extremely useful option and can be performed with high procedural success and low mortality.^{5,9,10}

An alternative to TAVI, minimally invasive AVR, provides a number of benefits relative to traditional AVR by full sternotomy, including reductions in pain, bleeding, wound infection, and atrial fibrillation, as well as an enhanced cosmetic result because of the smaller incision.^{1,2,11,12} This procedure is performed through either a ministernotomy or a right anterior thoracotomy, yet it still yields the benefits of true aortic valve *replacement*, including resection of the stenotic leaflets to maximize the available aortic annulus, the option of AVR for aortic regurgitation as well as stenosis, and the potential use of both mechanical and biologic valve prostheses. The reduced operative access, however, can lead to longer cardiopulmonary bypass and crossclamp times than those associated with AVR through a full sternotomy. Sutureless aortic valves rely on radial forces for stability within the débrided aortic annulus,^{13,14}

reducing operative times by substituting the placement and tying of multiple annular sutures with the deployment of a stented valve prosthesis. Methods of deployment include balloon expansion^{13,15} (Edwards Intuity; Edwards Lifesciences Corporation, Irvine, Calif), placement with an insertion tool¹⁶ (Trilogy Aortic Valve System; Arbor Surgical Technologies, Irvine, Calif), and self-expansion^{13,17} (Sorin Perceval S; SORIN SpA, Milan, Italy; and Medtronic 3f Enable; Medtronic, Inc, Minneapolis, Minn), with guiding sutures often used to facilitate valve orientation and annular location. With neither annular sutures to achieve fixation (AVR) nor the heavily calcified native valve leaflets to provide a firm landing zone (TAVI), however, valve migration after deployment has been reported to lead to tilting or partial to complete displacement from the intended location.¹⁸⁻²² Although valve migration has been reported for all available sutureless aortic valves, including the 3f Enable,^{17,20,21,23-25} Perceval S,^{19,22,26,27} Trilogy Aortic Valve System,¹⁶ and the Edwards Intuity Valve System,^{15,28,29} it remains a rare phenomenon. Reported rates for valve migration range from 0.5% to 2.5% at experienced centers, with most case identified and corrected during the same operation.^{19-21,26}

The article in this issue of the *Journal* by Vola and colleagues³⁰ describes the experience of 2 European centers (one of which proctored the other) with the implantation of the Medtronic 3f Enable sutureless aortic bioprosthesis through a right anterior minithoracotomy during a period 1.5 years. Seventy-one patients (median age of 78 years; median logistic euroSCORE of 7.0) with symptomatic severe aortic stenosis received prostheses ranging in size from 19 to 27. Procedural success was 100%, although 4 patients required reclamping for paravalvular leak of at least grade 1 (mild), with 2 requiring valve repositioning and 2 requiring valve exchange for the next larger size. Among the patients, 5.6% received a permanent pacemaker; interestingly, however, a change in insertion technique by moving the guiding suture after the first quartile of experience resolved this problem, and pacemaker requirement was 0% thereafter. Although follow-up is short (median of 7 months), valve-related mortality remains low, and importantly there is preservation of hemodynamics with specifically no new paravalvular leak, the leak at discharge (mild or less, occurring in 5.6% of patients) remaining stable, and no patient requiring reoperation. Use of a sutureless prosthesis resulted in a 35% reduction in crossclamp time relative to placement of a sutured prosthesis through a right anterior minithoracotomy and

From the Institute of Academic Surgery,^a Royal Prince Alfred Hospital, Sydney, Australia; The Baird Institute,^b Sydney, Australia; Concord Repatriation General Hospital,^c Sydney, Australia; and the University of Sydney,^d Sydney, Australia.

Disclosures: Authors have nothing to disclose with regard to commercial support. Received for publication Dec 22, 2014; accepted for publication Dec 22, 2014; available ahead of print Jan 24, 2015.

Address for reprints: Paul Gerard Bannon, MD, PhD, University of Sydney, Sydney Medical School (E-mail: pgbannon@gmail.com).

J Thorac Cardiovasc Surg 2015;149:1058-1004
0022-5223/\$36.00

Copyright © 2015 by The American Association for Thoracic Surgery
<http://dx.doi.org/10.1016/j.jtcvs.2014.12.050>

achieved times similar to placement of a sutured prosthesis through a full sternotomy in both centers. Importantly, Vola and colleagues describe the importance of avoiding a second guiding suture, because they believe that this would impair the distribution of radial force around the nitinol frame, possibly resulting in increased paravalvular leak.

In Australia, the Therapeutics Goods Administration issued a Hazard Alert in November 2014 for the Medtronic 3f Enable in response to concern regarding postimplantation valve migration, despite only 17 events reported globally (0.55% occurrence rate).³¹ This has resulted in the manufacturer issuing updated Instructions for Use including the recommendation of 2 tied-down guiding sutures at opposite sides of the annulus instead of the previously advised single suture,³¹ potentially impairing radial force distribution and leading to increased paravalvular leak. Continued methodologic and technologic refinement is crucial for sutureless AVR to achieve the criterion standard that is seen with AVR with a sutured prosthesis; however, the excellent results reported by Vola and colleagues demonstrate the need for regulatory agencies to demonstrate restraint in response to rare complications.

References

- Gilmanov D, Bevilacqua S, Murzi M, Cerillo AG, Gasbarri T, Kallushi E, et al. Minimally invasive and conventional aortic valve replacement: a propensity score analysis. *Ann Thorac Surg*. 2013;96:837-43.
- Glauber M, Miceli A, Gilmanov D, Ferrarini M, Bevilacqua S, Farneti PA, et al. Right anterior minithoracotomy versus conventional aortic valve replacement: a propensity score matched study. *J Thorac Cardiovasc Surg*. 2013;145:1222-6.
- Iribarne A, Easterwood R, Chan EY, Yang J, Soni L, Russo MJ, et al. The golden age of minimally invasive cardiothoracic surgery: current and future perspectives. *Future Cardiol*. 2011;7:333-46.
- Malaisrie SC, Barnhart GR, Farivar RS, Mehall J, Hummel B, Rodriguez E, et al. Current era minimally invasive aortic valve replacement: techniques and practice. *J Thorac Cardiovasc Surg*. 2014;147:6-14.
- Bourantas CV, Serruys PW. Evolution of transcatheter aortic valve replacement. *Circ Res*. 2014;114:1037-51.
- Klein AA, Skubas NJ, Ender J. Controversies and complications in the perioperative management of transcatheter aortic valve replacement. *Anesth Analg*. 2014;119:784-98.
- Laborde JC, Brecker SJ, Roy D, Jahangiri M. Complications at the time of transcatheter aortic valve implantation. *Methodist Debaquey Cardiovasc J*. 2012;8:38-41.
- Masson JB, Kovac J, Schuler G, Ye J, Cheung A, Kapadia S, et al. Transcatheter aortic valve implantation: review of the nature, management, and avoidance of procedural complications. *JACC Cardiovasc Interv*. 2009;2:811-20.
- Seco M, Martinez G, Bannon PG, Cartwright BL, Adams M, Ng M, et al. Transapical aortic valve implantation—an Australian experience. *Heart Lung Circ*. 2014;23:462-8.
- Smith CR, Leon MB, Mack MJ, Miller DC, Moses JW, Svensson LG, et al; PARTNER Trial Investigators. Transcatheter versus surgical aortic-valve replacement in high-risk patients. *N Engl J Med*. 2011;364:2187-98.
- Glauber M, Miceli A, Bevilacqua S, Farneti PA. Minimally invasive aortic valve replacement via right anterior minithoracotomy: early outcomes and midterm follow-up. *J Thorac Cardiovasc Surg*. 2011;142:1577-9.
- Miceli A, Murzi M, Gilmanov D, Fugà R, Ferrarini M, Solinas M, et al. Minimally invasive aortic valve replacement using right minithoracotomy is associated with better outcomes than ministernotomy. *J Thorac Cardiovasc Surg*. 2014;148:133-7.
- Carrel T, Englberger L, Stalder M. Recent developments for surgical aortic valve replacement: the concept of sutureless valve technology. *Open J Cardiol*. 2013;4:1-21.
- Goldstone AB, Joseph Woo Y. Minimally invasive surgical treatment of valvular heart disease. *Semin Thorac Cardiovasc Surg*. 2014;26:36-43.
- Haverich A, Wahlers TC, Borger MA, Shrestha M, Kocher AA, Walther T, et al. Three-year hemodynamic performance, left ventricular mass regression, and prosthetic-patient mismatch after rapid deployment aortic valve replacement in 287 patients. *J Thorac Cardiovasc Surg*. 2014;148:2854-61.
- Breitenbach I, Wimmer-Greinecker G, Bockeria LA, Sadowski J, Schmitz C, Kapelak B, et al. Sutureless aortic valve replacement with the Trilogy Aortic Valve System: multicenter experience. *J Thorac Cardiovasc Surg*. 2010;140:878-84. e1.
- Aymard T, Kadner A, Walpoth N, Göber V, Englberger L, Stalder M, et al. Clinical experience with the second-generation 3f Enable sutureless aortic valve prosthesis. *J Thorac Cardiovasc Surg*. 2010;140:313-6.
- Concistré G, Miceli A, Chiamonti F, Glauber M. Delayed dislocation of a sutureless aortic bioprosthesis: the first case. *Interact Cardiovasc Thorac Surg*. 2012;14:892-3.
- Dalén M, Biancari F, Rubino AS, Santarpino G, De Praetere H, Kasama K, et al. Ministernotomy versus full sternotomy aortic valve replacement with a sutureless bioprosthesis: a multicenter study. *Ann Thorac Surg*. December 4, 2014 [Epub ahead of print].
- Eichstaedt HC, Easo J, Härle T, Dapunt OE. Early single-center experience in sutureless aortic valve implantation in 120 patients. *J Thorac Cardiovasc Surg*. 2014;147:370-5.
- Permyer E, Estigarribia EJ, Ysasi A, Herrero E, Semper O, Llorens R. The 3f Enable sutureless bioprosthesis: early results, safeguards, and pitfalls. *J Thorac Cardiovasc Surg*. October 15, 2014 [Epub ahead of print].
- Rubino AS, Santarpino G, De Praetere H, Kasama K, Dalén M, Sartipy U, et al. Early and intermediate outcome after aortic valve replacement with a sutureless bioprosthesis: results of a multicenter study. *J Thorac Cardiovasc Surg*. 2014;148:865-71; discussion 871.
- Englberger L, Carrel TP, Doss M, Sadowski J, Bartus K, Eckstein FF, et al. Clinical performance of a sutureless aortic bioprosthesis: five-year results of the 3f Enable long-term follow-up study. *J Thorac Cardiovasc Surg*. 2014;148:1681-7.
- Martens S, Ploss A, Sirat S, Miskovic A, Moritz A, Doss M. Sutureless aortic valve replacement with the 3f Enable aortic bioprosthesis. *Ann Thorac Surg*. 2009;87:1914-7.
- Martens S, Sadowski J, Eckstein FS, Bartus K, Kapelak B, Sievers HH, et al. Clinical experience with the ATS 3f Enable® Sutureless Bioprosthesis. *Eur J Cardiothorac Surg*. 2011;40:749-55.
- Santarpino G, Pfeiffer S, Jessl J, Dell'Aquila AM, Pollari F, Pauschinger M, et al. Sutureless replacement versus transcatheter valve implantation in aortic valve stenosis: a propensity-matched analysis of 2 strategies in high-risk patients. *J Thorac Cardiovasc Surg*. 2014;147:561-7.
- Santarpino G, Pfeiffer S, Schmidt J, Concistré G, Fischlein T. Sutureless aortic valve replacement: first-year single-center experience. *Ann Thorac Surg*. 2012;94:504-8; discussion 508-9.
- Kocher AA, Laufer G, Haverich A, Shrestha M, Walther T, Misfeld M, et al. One-year outcomes of the Surgical Treatment of Aortic Stenosis with a Next Generation Surgical Aortic Valve (Triton) trial: a prospective multicenter study of rapid-deployment aortic valve replacement with the Edwards Intuity Valve System. *J Thorac Cardiovasc Surg*. 2013;145:110-5; discussion 115-6.
- Schlömicher M, Haldenwang PL, Moustafine V, Bechtel M, Strauch JT. Minimal access rapid deployment aortic valve replacement: initial single-center experience and 12-month outcomes. *J Thorac Cardiovasc Surg*. October 5, 2014 [Epub ahead of print].
- Vola M, Albertini A, Campisi S, Caprili L, Fuzellier J-F, Favre J-P, et al. Right anterior minithoracotomy aortic valve replacement with a sutureless bioprosthesis: Early outcomes and 1-year follow-up from 2 European centers. *J Thorac Cardiovasc Surg*. 2015;149:1052-7.
- Medtronic Limited. *Urgent field safety notice: 3f Enable™ Aortic Bioprosthesis Model 6000 labelling update*. London: Medicines and Healthcare products Regulatory Agency; 2014. Available at: <http://www.mhra.gov.uk/home/groups/fsn/documents/fieldsafetynotice/con477290.pdf>. Accessed December 15, 2014.