All other authors have nothing to disclose with regard to commercial support.

References

- Villa E, Messina A, Cirillo M, Brunelli F, Mhagna Z, Dalla Tomba M, et al. Perceval sutureless valve in freestyle root: new surgical valve-in-valve therapy. *Ann Thorac Surg*. 2013;96:e155-7.
- Folliguet TA, Laborde F. Sutureless Perceval aortic valve replacement in aortic homograft. *Ann Thorac Surg*. 2013;96:1866-8.
- Shrestha M, Folliguet T, Meuris B, Dibie A, Bara C, Herregods MC, et al. Sutureless Perceval S aortic valve replacement: a multicenter prospective pilot trial. *J Heart Valve Dis*. 2009;18:698-702.
- Santarpino G, Pfeiffer S, Pollari F, Concistrè G, Vogt F, Fischlein T. Left ventricular mass regression after sutureless implantation of the Perceval S aortic valve bioprosthesis: preliminary results. *Interact Cardiovasc Thorac Surg*. 2014;18:38-42.
- Folliguet TA, Laborde F, Zannis K, Ghorayeb G, Haverich A, Shrestha M. Sutureless Perceval aortic valve replacement: results of two European centers. *Ann Thorac Surg*. 2012;93:1483-8.
- Flameng W, Herregods MC, Hermans H, Van der Mieren G, Vercauteren M, Poortmans G, et al. Effect of sutureless implantation of the Perceval S aortic valve bioprosthesis on intraoperative and early postoperative outcomes. *J Thorac Cardiovasc Surg*. 2011;142:1453-7.
- Akins CW, Miller DC, Turina MI, Kouchoukos NT, Blackstone EH, Grunkemeier GL, et al. Guidelines for reporting mortality and morbidity after cardiac valve interventions. *J Thorac Cardiovasc Surg*. 2008;135:732-8.
- Beckmann A, Funkat AK, Lewandowski J, Frie M, Schiller W, Hekmat K, et al. Cardiac surgery in Germany during 2012: a report on behalf of the German Society for Thoracic and Cardiovascular Surgery. *Thorac Cardiovasc Surg*. 2014;62:5-17.
- Cribier A, Eltchaninoff H, Bash A, Borenstein N, Tron C, Bauer F, et al. Percutaneous transcatheter implantation of an aortic valve prosthesis for calcific aortic stenosis: first human case description. *Circulation*. 2002;106:3006-8.
- Magovern GJ, Cromie HW. Sutureless prosthetic heart valves. *J Thorac Cardiovasc Surg*. 1963;46:726-36.
- Totaro P, Nicolardi S, Zattera G, Viganò M. Old prosthesis with a modern concept: 41-year survival with a sutureless Magovern-Cromie aortic valve prosthesis. *Eur J Cardiothorac Surg*. 2011;39:789.
- 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.
- 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.
- Shrestha M, Folliguet TA, Pfeiffer S, Meuris B, Carrel T, Bechtel M, et al. Aortic valve replacement and concomitant procedures with the Perceval valve: results of European trials. *Ann Thorac Surg*. 2014;98:1294-300.
- Mazine A, Teoh K, Bouhout I, Bhatnagar G, Pelletier M, Voisine P, et al. Sutureless aortic valve replacement: a Canadian multicentre study. *Can J Cardiol*. 2015;31:63-8.
- Miceli A, Santarpino G, Pfeiffer S, Murzi M, Gilmanov D, Concistrè G, et al. Minimally invasive aortic valve replacement with Perceval S sutureless valve: early outcomes and one-year survival from two European centers. *J Thorac Cardiovasc Surg*. 2014;148:2838-43.
- Santarpino G, Pfeiffer S, Concistrè G, Grossmann I, Hinzmann M, Fischlein T. The Perceval S aortic valve has the potential of shortening surgical time: Does it also result in improved outcome? *Ann Thorac Surg*. 2013;96:77-81.
- Munieretto C, Bisleri G, Moggi A, Di Bacco L, Tespili M, Repossini A, et al. Treating the patients in the 'grey-zone' with aortic valve disease: a comparison among conventional surgery, sutureless valves and transcatheter aortic valve replacement. *Interact Cardiovasc Thorac Surg*. 2015;20:90-5.
- Biancari F, Barbanti M, Santarpino G, Deste W, Tamburino C, Gulino S, et al. Immediate outcome after sutureless versus transcatheter aortic valve replacement. *Heart Vessels*. January 9, 2015 [Epub ahead of print].

Key Words: Aortic valve replacement, sutureless heart valve prosthesis

EDITORIAL COMMENTARY

Encouraging durability results for sutureless aortic valve: The new gold standard for aortic valve replacement?

Mattia Glauber, MD, and Antonio Miceli, MD, PhD

See related article on pages 84-8.

From the Istituto Clinico Sant'Ambrogio, University and Research Hospitals, Gruppo Ospedaliero San Donato, Milano, Italy.

Disclosures: Mattia Glauber reports lecture fees, advisory boards, and proctorship from Sorin Group. The other author has nothing to disclose with regard to commercial support.

Received for publication April 17, 2015; accepted for publication April 17, 2015.

Address for reprints: Mattia Glauber, MD, Istituto Clinico Sant'Ambrogio, Gruppo Ospedaliero San Donato, University and Research Hospitals, Via Faravelli 16, 20100 Milano, Italy (E-mail: mattia.glauber@ftgm.it).

J Thorac Cardiovasc Surg 2015;150:88-90

0022-5223/\$36.00

Copyright © 2015 by The American Association for Thoracic Surgery

<http://dx.doi.org/10.1016/j.jtcvs.2015.04.047>

Aortic valve replacement using stented valves is the conventional standard approach in the treatment of aortic valve disease. Despite the excellent long-term results with biological stented valves, sutureless technology recently has been developed as an alternative to stented valves in high-risk patients to simplify the surgical implantation and reduce the operative times.¹⁻³

The Perceval S (Sorin Group, Milan, Italy) sutureless valve is new self-expanding prosthesis made of bovine pericardium mounted in a nitinol stent. Several studies

have reported excellent results in terms of postoperative outcomes, hemodynamic performances, and structural valve deterioration and freedom from reoperation at 1-year follow-up.⁴⁻⁷ However, there are no data on the long-term durability.

The pilot trial is the first clinical, prospective, non-randomized study conducted in 3 cardiac centers on 30 elderly (mean age, 80 years) high-risk patients who underwent aortic valve replacement between April 2007 and February 2008.³ It was designed to assess the safety of the Perceval S in terms of mortality and morbidity at 30 days and 1 year and to evaluate its hemodynamic performance up to 1-year follow-up. In this issue of the *Journal*, Meuris and colleagues⁸ report the 5-year clinical and hemodynamic outcomes of these patients, adding evidence for the safety and durability of these bioprostheses on midterm follow-up. Specifically, overall 5-year survival was 72.3%, and freedom from endocarditis and atrioventricular block was 90.7% and 91%, respectively. In addition, no dislodgment of the valve, structural valve deterioration, hemolysis, stroke, or valve thrombosis was observed within the 5-year follow-up. Finally, only 1 patient had moderate paravalvular leak at 1 year, and 2 patients had mild paravalvular leak at 1 and 5 years. Despite these promising results, the low sample size and the low number of patients at risk at 5-year follow-up limit this study. Nevertheless, Shrestha and colleagues⁹ recently confirmed these data, reporting the midterm clinical and hemodynamic results on 731 patients undergoing aortic valve replacement in 25 European centers. Most important, neither valve migration nor structural valve degeneration or thrombosis was observed at 5-year follow-up. In addition, the rate of major paravalvular leakage was 1.4% and 1% at early and late follow-ups, respectively, similar to data reported by the Placement of Aortic Transcatheter Valves (PARTNER) 1A trial for the stented valves (1.9 at 1 year and 0.9% at 2 years) and lower than for those undergoing transcatheter aortic valve implantation (7% at 1 year and 6.9% at 2 years).¹⁰ Paravalvular leak is now considered a negative outcome, because it has been demonstrated that even the presence of mild regurgitation is associated with lower survival at 5 years.¹¹ Finally, 26% of patients underwent a minimally invasive procedure, demonstrating the feasibility and safety of this bioprosthesis using this approach. Recently, we reported our experience of aortic valve replacement with the Perceval S through a right minithoracotomy or ministernotomy and showed that this approach is a safe and reproducible procedure associated with excellent hemodynamic results, postoperative outcomes, and 1-year survival.¹² To date, this is the largest study on minimally invasive aortic valve replacement using sutureless valves.

The learning curve is an important advantage of the sutureless technology. According to Meuris and colleagues,⁸ 2 proctored implants are advised for the Perceval S implantation through a standard sternotomy. Nevertheless, our CUSUM analysis has shown that a minimum of 10 procedures is required to implant the Perceval S through a right anterior minithoracotomy.¹³

Finally, from an economic point of view, compared with stented valves, the use of the Perceval S might be associated with savings, mainly related to a reduction of surgery costs for fewer complications and shorter intensive care and hospital length of stay.¹⁴

The Perceval S sutureless valve demonstrates excellent clinical outcomes and hemodynamic performance at 5-year follow up, requires a short learning curve, and facilitates minimally invasive approaches. Although more data are required and a longer follow-up is mandatory, these encouraging results indicate that the sutureless technology is a promising alternative to the standard biological valves and in the future might be the new gold standard for aortic valve replacement, especially in minimally invasive settings.

References

1. McClure RS, Narayanasamy N, Wiegerinck E, Lipsitz S, Maloney A, Byrne JG, et al. Late outcomes for aortic valve replacement with the Carpentier-Edwards pericardial bioprosthesis: up to 17 years follow-up in 1,000 patients. *Ann Thorac Surg*. 2010;89:1410-6.
2. ISTHMUS Investigators. The Italian study on the Mitroflow postoperative results (ISTHMUS): a 20-year, multicentre evaluation of Mitroflow pericardial bioprosthesis. *Eur J Cardiothorac Surg*. 2011;39:18-26.
3. Shrestha M, Folliguet T, Meuris B, Dibie A, Bara C, Herregods MC, et al. Sutureless Perceval S aortic valve replacement: a multicenter, prospective pilot trial. *J Heart Valve Dis*. 2009;18:698-702.
4. Flameng W, Herregods MC, Hermans H, Van der Mieren G, Vercalsteren M, Poortmans G, et al. Effect of sutureless implantation of the Perceval S aortic valve bioprosthesis on intraoperative and early postoperative outcomes. *J Thorac Cardiovasc Surg*. 2011;142:1453-7.
5. Folliguet TA, Laborde F, Zannis K, Ghorayeb G, Haverich A, Shrestha M. Sutureless Perceval aortic valve replacement: results of two European centers. *Ann Thorac Surg*. 2012;93:1483-8.
6. Santarpino G, Pfeiffer S, Schmidt J, Concistrè G, Fischlein T. Sutureless aortic valve replacement: first-year single center experience. *Ann Thorac Surg*. 2012;94:504-9.
7. Rubino AS, Santarpino G, De Praeter H, Kasama K, Dalèn 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.
8. Meuris B, Flameng WJ, Laborde F, Folliguet TA, Haverich A, Shrestha M. Five year results of the pilot trial of a sutureless valve. *J Thorac Cardiovasc Surg*. 2015;150:84-8.
9. Shrestha M, Fischlein T, Meuris B, Flameng W, Carrel T, Madonna F, et al. European multicenter experience with the sutureless Perceval valve: clinical and haemodynamic outcomes up to 5 years in over 700 patients. *Eur J Cardiothorac Surg*. March 6, 2015 [Epub ahead of print].
10. Miller DC, Blackstone EH, Mack MJ, Svensson LG, Kodali SK, Kapadia S, et al. Transcatheter (TAVR) versus surgical (AVR) aortic valve replacement: occurrence, hazard, risk factors, and consequences of neurological events in the PARTNER trial. *J Thorac Cardiovasc Surg*. 2012;143:832-43.
11. Mack MJ, Leon MB, Smith CR, Moses JW, Tuzcu EM, Webb JG, et al. 5 year outcomes of transcatheter aortic valve replacement or surgical aortic valve replacement for high risk surgical patients with aortic stenosis (PARTNER 1): a randomized controlled trial. *Lancet*. March 15, 2015 [Epub ahead of print].

12. Miceli A, Santarpino G, Pfeiffer S, Murzi M, Gilmanov D, Concistrè G, et al. Minimally invasive aortic valve replacement with Perceval S sutureless valve: early outcomes and one year survival from two European centers. *J Thorac Cardiovasc Surg.* 2014;148:2838-43.
13. Glauber M, Miceli A, Canarutto D, Ferrarini M, Farneti PA, Murzi M, et al. Early and long term outcomes of minimally invasive mitral valve surgery through right minithoracotomy: a ten year experience in 1604 patients. Presented at: 27th European Association for Cardio-Thoracic Surgery Meeting; Monday, October 13, 2014; Milan, Italy.
14. Pradelli L, Zaniolo O. Perceval Sutureless valves in isolated and concomitant AVR procedures: an economic model shows overall decrease of costs for isolated or combined operations. *Farmeconomia. Health Econ Ther Pathways.* 2012;13:159-74.