

EDITORIAL

DIFFERENT APPROACHES TO AORTIC VALVE TREATMENT:
SUTURELESS-AVR *VERSUS* TAVISutureless aortic valve replacement
vs. transcatheter aortic valve implantation:
a review of a single center experienceGiuseppe SANTARPINO^{1,2*}, Renato GREGORINI¹, Luigi SPECCHIA¹,
Antonio ALBANO¹, Anna NICOLETTI¹, Theodor FISCHLEIN²¹Città di Lecce Hospital, GVM Care&Research, Lecce, Italy; ²Klinikum Nürnberg, Paracelsus Medical University, Nuremberg, Germany*Corresponding author: Giuseppe Santarpino, Città di Lecce Hospital, GVM Care&Research, Lecce, Italy.
E-mail: g.santarpino@libero.it

The most appropriate treatment strategy for old “intermediate and high risk” patients with aortic valve stenosis is still a matter of debate. According to the recent guidelines of the European Society of Cardiology on the management of valvular heart disease, aortic valve replacement (AVR) is recommended as first-line therapy in patients with severe symptomatic aortic valve stenosis to improve both symptoms and survival.¹

Transcatheter aortic valve implantation has emerged as an alternative treatment to conventional surgery for patients of advanced age who are deemed inoperable.^{2, 3} In particular after the publication of the Cohort A results of the PARTNER (Placement of AoRTic TraNscatheter Valve) Trial, there has been great debate regarding alternative therapeutic strategies such as transcatheter aortic valve implantation (TAVI) for high-risk patients with symptomatic severe aortic valve stenosis.⁴ However, studies comparing TAVI with conventional surgical aortic valve replacement in elderly patients showed that isolated advanced age per se should not be considered an indication for TAVI.⁵ On the other hand, transcatheter aortic valve implantation has become clinical routine

in most centers worldwide for the treatment of severe symptomatic aortic stenosis in inoperable or high-risk patients, with number of procedures surpassing conventional aortic valve surgery.⁶

From the dualism between the surgical and transcatheter approaches, a new option has emerged: recent studies have demonstrated better clinical and cosmetic results with minimally invasive techniques for AVR *versus* conventional surgery.⁷ The drawback of minimally invasive surgery is that it generally requires longer crossclamp and operative times. This may expose patients to potential additive risks, especially if the procedure is performed by surgeons who are not experts or are still on the learning curve. Although there are no data supporting this observation, a high level of surgical skills is required for these procedures because of the increasing use of technology, and a learning curve is unavoidable. More recently, sutureless AVR devices have been developed that enable short procedural times and also easy implantation of the aortic valve prosthesis when using a minimally invasive surgical approach.⁸⁻¹¹ In addition, the use of new sutureless aortic bioprostheses

that allow shorter cardiopulmonary bypass (CPB) and cross-clamp times¹² has proved to be associated with good outcome in octogenarians.¹³

In the Nuremberg University Hospital, from January 2010 to March 2012, 122 patients underwent minimally invasive sutureless aortic valve replacement, and 122 underwent TAVI. After propensity matching, 37 matched pairs were available for a clinical and echocardiographic analysis.¹⁴ Pre-discharge echocardiographic data showed higher paravalvular leak rate in the TAVI group. At mean follow-up, survival was significantly differed between groups (sutureless 97.3% vs. TAVI 86.5%; $P=0.015$). In the TAVI group, a significant difference in mortality was observed between patients with and without paravalvular leak. In other words, in our opinion, removal of the diseased native valve may enhance procedural quality by avoiding paravalvular leak.

However, these findings together suggest that recently developed surgical and interventional techniques may also be adopted in high-risk elderly patients. This issue has a significant economic relevance for health care systems, given the high costs of the new devices and the limited life expectancy of this patient population.

Keeping this goal in mind, we made a new analysis with a total of 626 patients were distributed between transcatheter aortic valve implantation (364) and sutureless (262) groups. Patients of both groups were not comparable for clinical and surgical characteristics, but many patients were in a “gray zone”; therefore, a new retrospective propensity score analysis was possible and performed. For the 102 matched pair samples, postoperative, follow-up clinical data, and costs data were obtained.¹⁵ Also in this second analysis with more patients and a longer follow up, paravalvular leakage occurred more frequently in patients in TAVI group (34% vs. 6.9%; $P<0.001$) with an impact on the survival rate. But the most interesting part of the results of this study is the costs: these costs associated to the 2 procedures are similar when the cost of the device was excluded. When included, the sutureless

approach resulted a cost saving (22,451 Euro vs. 33,877 Euro, $P<0.001$).

Although several unanswered questions remain over the clinical outcomes and the cost effectiveness of TAVI, there has been a change in access route choice over the years, which has resulted in the rapid rise in transfemoral (TF) procedures with respect to the transapical (TA) approach. The latter is generally perceived to be less invasive and associated with more complications, and usually tends to be performed in patients with significant comorbid conditions (*e.g.* vasculopathy) who cannot receive TF-TAVI.^{16, 17}

Given the increasing trend towards using the TF route and the ongoing debate regarding patients considered in the “gray zone” between TAVI and conventional surgery, in a third study we aimed at comparing TF-TAVI vs. elective isolated AVR with the sutureless Perceval S aortic valve bioprosthesis. Our results demonstrate that both minimally invasive AVR with the sutureless Perceval aortic valve and TF-TAVI are safe and effective in this cohort of the study. However, several differences emerged between the two techniques that deserve discussion: paravalvular leakage at discharge was present in 3.8% of the sutureless group and in 32.9% of the TF-TAVI ($P<0.001$). Consequently, survival rates were 97.5% and 84.8% in the sutureless vs. TF-TAVI group, respectively ($P=0.001$). We could conclude that both TF-TAVI and sutureless AVR are well standardized, safe and effective procedures for the treatment of patients with symptomatic severe aortic stenosis. However, TF-TAVI seems to be a valuable alternative to surgical AVR for frail patients. In patients with no concurrent disease (*e.g.* malignancy) and a favorable long-term survival outcome, minimally invasive AVR remains the procedure of choice in this cohort of the study population, as it is associated with better long-term results.

In conclusion, the most appropriate treatment strategy for this patient population remains to be clearly established and should include a multidisciplinary heart team approach. We believe that sutureless aortic valve prostheses have the potential to shorten the

surgical time, and future research will determine whether this advantage will also translate into better outcomes in high-risk patients. Sutureless aortic valve replacement has been shown to be associated with improved survival compared with transcatheter aortic valve implantation, owing to the lower or no rates of residual aortic regurgitation. Only randomized prospective studies comparing the two surgical techniques will allow definite conclusions to be drawn regarding this issue.

References

- Vahanian A, Alfieri O, Andreotti F, Antunes MJ, Baron-Esquivias G, Baumgartner H, *et al.* Guidelines on the management of valvular heart disease (version 2012): the Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS). *Eur J Cardiothorac Surg* 2012;42:S1-44.
- Leon MB, Smith CR, Mack M, Miller DC, Moses JW, Svensson LG, *et al.*; PARTNER Trial Investigators. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. *N Engl J Med* 2010;363:1597e1607.
- Popma JJ, Adams DH, Reardon MJ, Yakubov SJ, Kleiman NS, Heimansohn D, *et al.*; CoreValve United States Clinical Investigators. Transcatheter aortic valve replacement using a self-expanding bioprosthesis in patients with severe aortic stenosis at extreme risk for surgery. *J Am Coll Cardiol* 2014;63:1972e-1981.
- Reynolds MR, Magnuson EA, Wang K, Thourani VH, Williams M, Zajarias A, *et al.*; PARTNER Trial Investigators. Health-related quality of life after transcatheter or surgical aortic valve replacement in high-risk patients with severe aortic stenosis: results from the PARTNER (Placement of AORTic Transcatheter Valve) Trial (Cohort A). *J Am Coll Cardiol* 2012;60:548-58.
- Strauch JT, Scherner M, Haldenwang PL, Madershahian N, Pfister R, Kuhn EW, *et al.* Transapical minimally invasive aortic valve implantation and conventional aortic valve replacement in octogenarians. *Thorac Cardiovasc Surg* 2012;60: 335e342.
- Beckmann A, Funkat AK, Lewandowski J, Frie M, Ernst M, Hekmat K, *et al.* Cardiac surgery in Germany during 2014: a report on behalf of the German Society for Thoracic and Cardiovascular Surgery. *Thorac Cardiovasc Surg* 2015;63:258-69.
- Johnston DR, Atik FA, Rajeswaran J, Blackstone EH, Nowicki ER, Sabik JF III, *et al.* Outcomes of less invasive J-incision approach to aortic valve surgery. *J Thorac Cardiovasc Surg* 2012;144:852-8.e3.
- 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; discussion 115-6.
- 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.
- Santarpino G, Pfeiffer S, Schmidt J, Concistre G, Fischlein T. Sutureless aortic valve replacement: first-year single-center experience. *Ann Thorac Surg* 2012; 94:504-8; discussion 508-9.
- Santarpino G, Pfeiffer S, Concistré 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;96:77e81.
- Santarpino G, Pfeiffer S, Vogt F, Hinzmann M, Concistré G, Fischlein T. Advanced age per se should not be an exclusion criterion for minimally invasive aortic valve replacement. *J Heart Valve Dis* 2013;22:455e459.
- 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, Jessl J, Dell'Aquila A, Vogt F, von Wardenburg C, *et al.* Clinical Outcome and Cost Analysis of Sutureless Versus Transcatheter Aortic Valve Implantation With Propensity Score Matching Analysis. *Am J Cardiol* 2015 1;116:1737-43.
- Biancari F, Rosato S, D'Errigo P, Ranucci M, Onorati F, Barbanti M, *et al.* Immediate and intermediate outcome after transapical versus transfemoral transcatheter aortic valve replacement. *Am J Cardiol* 2016;117:245-51.
- Blackstone EH, Suri RM, Rajeswaran J, Babaliaros V, Douglas PS, Fearon WF, *et al.* Propensity-matched comparisons of clinical outcomes after transapical or transfemoral transcatheter aortic valve replacement: a placement of aortic transcatheter valves (PARTNER)-I trial substudy. *Circulation* 2015;131:1989-2000.

Conflicts of interest.—Giuseppe Santarpino is a consultant for Sorin Group Italia; Theodor Fischlein is a consultant for Livanova Group.

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