Editorial Comment

Indications and pitfalls of sutureless aortic valves: recommendations are welcome

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Sutureless aortic tissue valves have been introduced several years ago as an alternative to stented or stentless bioprostheses for the treatment of aortic stenosis. Initial reports and current evaluation of the clinical performance suggests that this new technology – after a carefully organized training phase - is safe and allows a quicker procedure with shorter cross-clamp and cardiopulmonary bypass duration. In addition, peri- and early postoperative complication rates are not higher than those observed after conventional surgical approach.

Until recently, three different models fabricated by three different companies (Enable® from ATS-Medtronic, Minneapolis, MN; USA, Perceval® from Sorin, Saluggia, Italy and Intuity® from Edwards Lifesciences, Irvine, CA, USA) have been on the market, but in November 2014, Medtronic issued a Field Safety Notice (FSN) to alert physicians regarding the risk of migration with the 3f Enable Aortic Bioprosthesis (Model 6000): the company modified the Instructions for use (IFU) to recommend the use of two tied-off guiding sutures. While the revised instructions in the FSN continue to show positive outcomes, the product has seen limited commercial adoption. Therefore, Medtronic has decided to discontinue the 3f Enable Aortic Bioprosthesis (Model 6000) and the related accessories as well as cease the training and proctoring of any new implanters. How could this happen? Some results were disappointing since complications like migration of the device and paravalvular leakage appeared instead of reducing cross-clamp and cardiopulmonary bypass duration due to rapid deployment. I had personally excellent clinical results with the 3-f Enable valve over the last 10 years (1,2) but I always advocated a careful proctoring and teaching of new centers as well as the establishment of a registry and the publication of a consensus regarding indications, potential pitfalls and unexpected events with this type of devices. In previous publications, there was a significant heterogeneity in outcomes such as paravalvular leaks and valve degeneration, which may reflect the varying degrees of technical experience between individual institutions and the divergent efficacy and safety between different types of sutureless valve types (3). Therefore, instead of improving the surgical outcome and facilitating the minimally invasive approach in higher risk patients, the results reported by some surgical teams were less than optimal and the devices remained controversially discussed and not adopted by a large number of surgeons.

For this reason, the present recommendations of an international consensus panel are welcome in order to clarify some practical issues and to further define the role of sutureless technologies in the broad field of surgical valvular devices (4). Among several interesting findings, the authors of this document exactly emphasize the fact that meticulous proctoring and training are mandatory for the sutureless technology, on both an institutional as well as individual level.

From a total of 1300 publications, only 80+ papers were cleared for the final appreciation. This is a classical finding in the cardiac surgical literature: this particular surgical domain lacks from randomized multicenter studies as compared with those available in interventional cardiology. For the purposes of this paper, the authors focus on observations in different institutions.

Which types of valvular replacement devices does the surgical community want to have available? The answer is rather simple: a valve easy for manipulation, reproducible during implantation, and proven good quality with stable long-term results. For special cases, e.g. those with a previous homograft in aortic position, sutureless technology might be the ideal alternative, because the device can be implanted once the degenerated leaflets of the homograft have been removed. The vascular part of the homograft stays in, of course. Another important indication may be for high-risk and multimorbid and/or older patients who need a combined procedure with anticipated longer ischemic time.

The work done by this international group of experts is the first step in the right direction. This paper has to be followed by additional work collected with increased experience with this type of valve.

As a cardiac valve substitute, sutureless prostheses avoid suturing after annular decalcification, thereby reducing aortic cross-clamp and cardiopulmonary bypass duration and facilitating a minimally invasive approach. While there is current data supporting reduced surgical operative times with sutureless AVR [5,6], whether the use of this technology results in improved clinical outcomes remains uncertain. Unfortunately, multiple outcomes are still not adequately reported, including resource-related outcomes such as intensive care unit stay, hospitalization duration, cost-effectiveness and quality of life outcomes (2). Such parameters are also of critical importance when considering SU-AVR as an alternative to conventional AVR and perhaps TAVI as well. The lack of randomization, blinding and comparators in the included studies indicates an inherent source of unaccounted bias, which may have skewed the presented results. Another major limitation of the current knowledge on sutureless valves is the absence of long-term data beyond 4 years. Long-term studies are also required to compare SU-AVR with conventional AVR and TAVI approaches, particularly in the setting of high-risk patients, to determine whether SU-AVR is safe and efficacious, and which approach offers more clinical advantages for each individual patient.

References

1. Aymard T, Kadner A, Walpoth N, Göber V, Englberger L, Stalder M, Eckstein F, Zobrist C, Carrel T. Clinical experience with the second generation 3f Enable sutureless aortic valve prosthesis. J Thorac Cardiovasc Surg 2010;140:313-316.

2. Englberger L, Carrel TP, Doss M, Sadowski J, Bartus K, Eckstein FF, Asch FM, Martens S. 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.

3. 3. Phan K, Tsai YC, Niranjan N, Bouchard D, Carrel TP, Dapunt OE, Eichstaedt HC, Fischlein T, Gersak B, Glauber M, Haverich A, Misfeld M, Oberwalder PJ, Santarpino G, Shrestha ML, Solinas M, Vola M, Yan TD, Di Eusanio M. Sutureless aortic valve replacement: a systematic review and meta-analysis. Ann Cardiothorac Surg. 2015;4:100-11.

4. Gersak B, Fischlein T, Folliguet T, Meuris B, Teoh K, Moten S et al. Sutureless rapid deployment valves and stented bioprotheses in aortic valve replacement: recommendations of an international consensus panel. Eur J Cardio-thorac Surg. 2015 in press.

5. Flameng W, Herregods M-C, 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. In 6 Edition. United States: Cardiac Surgery, Department of Cardiovascular Diseases, Katholieke Universiteit Leuven, Leuven, Belgium. willem.flameng@med.kuleuven.ac.be 2011; 1453-1457.

6. Shrestha M, Maeding I, Hoffler K, Koigeldiyev N, Marsch G, Siemeni T et al. Aortic valve replacement in geriatric patients with small aortic roots: are sutureless valves the future? Interact Cardiovasc Thorac Surg 2013; 17: 778-782; discussion 782.