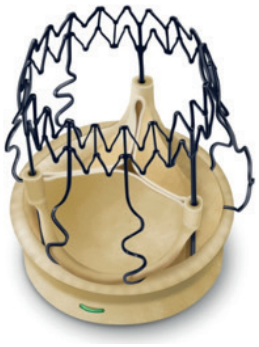
PERSPECTIVAS

SUTURELESS VALVE FOR AORTIC VALVE REPLACEMENT PERCEVAL´S DE SORIN® TO BE MARKETED SOON IN ARGENTINA



Aortic valve replacement with a sutureless prosthesis is an innovative option for the treatment of aortic stenosis, especially in patients with porcelain aorta or reoperations of severely calcified homografts in which it is impossible to suture the valvular prosthesis[1]. A systematic review of 1,300 patients revealed shorter implantation periods, mortality rates of 2.1% and 4.9% after 30 days and one year, a stroke incidence of 1.5% and paravalvular leak of 3.0%[2]. *Sutureless* prosthesis models include the Perceval S valve (Sorin Group, Saluggia), the 3F Enable valve (ATS Medical, Minneapolis), the Trilogy valve (Arbor Surgical Technologies, California) and the Edwards Intuity valve (Edwards Lifesciences, California). None of these models is currently available in the Argentine market but the Sorin® Perceval S valve, which is already used in Chile and is waiting for the authorization of ANMAT in Argentina, is expected to be launched locally soon. Although there are already many controlled clinical trials to evaluate the performance of these sutureless valvular prostheses for any kind of aortic valvular replacement by conventional surgery or by mini-sternotomy[3], the least controversial indications include its use when it is difficult to suture a new valve, as in the case of a severely calcified valve or a porcelain valve, or in homografts, autografts or xenografts with degenerative lesions[4], a technique that, in these latter cases, is similar to *valve-in-valve* implantation[5].

1. Santarpino G., Pfeiffer S., Fischlein T. Perceval sutureless approach in a patient with porcelain aorta unsuitable for transcatheter aortic valve implantation. Int J Cardiol 2012;155:168-70.

2. Phan K., Tsai Y. C., Niranjan N, et al. Sutureless aortic valve replacement: a systematic review and meta-analysis. Ann Cardiothorac Surg 2015; 4:100-11.

3. Shrestha M., Fischlein T, Meuris B., et al. European multicenter experience with the sutureless Perceval valve: clinical and haemodynamic outcomes upto 5 years in over 700 patients. Eur J Cardiothorac Surg 2016; 49: 234-41.

4. Folliguet T. A., Laborde F. Sutureless Perceval aortic valve replacement in aortic homograft. Ann Thorac Surg 2013; 96:1866-8.

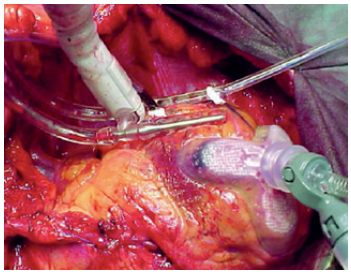
5. Villa E., Messina A., Cirillo M., Brunelli F, Mhagna Z., Dalla et al. Perceval sutureless valve in freestyle root: new surgical valve-in-valve therapy. Ann Thorac Surg 2013; 96:e155-7.

TRANSCATHETER AORTIC VALVE IMPLANTATION (TAVI) NOT COST-EFFECTIVE IN ARGENTINA

TAVI has begun to be less invasive than conventional surgery for patients at high operative risk. It improves the survival of patients that cannot undergo surgery; instead, for those eligible for surgery, TAVI has similar mortality rates but is associated with much more complications, such as stroke, paravalvular leaks and major vascular complications. Therefore, TAVI is cost-effective for patients that cannot undergo surgery and is not cost-effective for those who can be operated on[1-2]. This is consistent with the current evidence observed in many developed countries but is far from true in Argentina, where TAVI-related expenses are so high that in no case it is cost-effective. For a Medtronic® CoreValve for transfemoral implantation or for a Jenavalve® for transapical TAVI, the local funding system needs to pay between US$ 25,000 and 30,000, excluding procedure costs and hospitalization expenses. Instead, for surgical aortic valve replacement, the local funding system pays up to US$ 12,000 to 15,000, including the cost of the valvular prosthesis. Patients at high operative risk and possibly eligible for TAVI must meet the requirement of having a risk higher than 20% under the logistic EuroSCORE, or higher than 10% under the STS, or higher than 7% under the EuroSCORE II. Reaching such risk levels with these scores is very unusual, and sometimes it is surprising that patients offered TAVI are actually eligible for conventional surgery. For that reason, many funding entities deny to bear TAVI costs unless there is an express rejection by a cardiovascular surgeon contraindicating open surgery. On their part, surgeons are pressured by intervening cardiologists, or economically induced, to accept the indication of TAVI when, in fact, the patient does not meet the necessary requirements. Even worse, sometimes the family is convinced of the advantages of TAVI and it pressures the surgeon to take a decision with which he does not agree. The funders of the public and private health systems in Argentina should be aware of this to avoid such a dishonest maneuver from providers and the industry.

1. Sehatzadeh S., Doble B., Xie F., Blackhouse G., Campbell K., Kaulback K., et al. Transcatheter aortic valve implantation (TAVI) for treatment of aortic valve stenosis: an evidence-based Analysis (part B). Ont Health Technol Assess Ser 2012; 12:1-62.

2. Fairbairn T. A., Meads D. M., Hulme C., Mather A. N., Plein S., Blackman D. J., et al. The cost-effectiveness of transcatheter aortic valve implantation versus surgical aortic valve replacement in patients with severe aortic stenosis at high operative risk. Heart 2013; 99: 914-20.



OFF-PUMP CORONARY SURGERY NOT CHEAPER THAN ON-PUMP SURGERY

Some funders of private healthcare services in Argentina have decided unilaterally to pay lower rates when a coronary surgery without extracorporeal circulation is performed and also assume that coronary surgery can always be performed off-pump, unless a medical order or authorization indicates otherwise. Funders make two mistakes that need to be corrected soon to prevent market distortion. Globally, off-pump coronary surgery does not exceed 20% - 30% of total coronary surgeries performed in the country. Just as there are local centers that only promote off-pump surgery, other centers of equal prestige virtually do not perform it. In the United States, for example, the percentage of off-pump coronary surgery has dropped constantly over the last five years and nowadays it is performed in only 1 out of 5 patients[1]. On the other hand, non-randomized retrospective studies, prospective trials, systematic reviews and meta-analyses have not proved any significant short- and long-term mortality and morbidity advantages of off-pump surgery[2]. Even in those studies in which off-pump surgery showed improved results in the immediate postoperative period, such improvement did not continue on long-term follow-up[3]. Several studies have suggested that long-term survival can be reduced with off-pump surgery due to the usual incomplete revascularization derived from this technique, which has been associated with recurrent angina and the need for new revascularization. A meta-analysis of 22 studies including more than 100,000 patients related off-pump surgery to a worse survival rate after 5 years in comparison with on-pump surgery[4]. Regarding costs, a local study has already revealed that off-pump surgery costs are higher than those of the on-pump procedure, especially due to the costs of the stabilization system (Octopus®, Guidant®, Maquet®), which are three times higher than those of the pump-oxygenator, tubing and cardioplegia set used with extracorporeal circulation[5]. The improper resterilization and reuse of stabilizers should not be taken into account to determine procedure costs. Finally, several multisite studies evidenced that, after one year, off-pump surgery has the same[6] or higher costs than on-pump surgery[7]. In brief, off-pump coronary surgery does not seem to be better than on-pump surgery in the long term and, in addition, has at least the same cost.

THE NEED TO CREATE CENTERS AND TO TRAIN SURGEONS FOR THE TREATMENT OF ADULT CONGENITAL HEART DISEASES

Congenital heart diseases are the most common birth defect and reach 0.8% of live-born babies[1]. Argentina has the National Program of Congenital Heart Diseases of the National Ministry of Health, which guarantees surgical aid for all the children of the country with congenital heart disease diagnosis and without health insurance. In Argentina, about 7 thousand children are

1. Bakaeen F. G., Shroyer A. L. W., Gammie J. S., Sabik J. F., Cornwell L. D., Coselli J. S., et al. Trends in use of off-pump coronary artery bypass grafting: Results from the Society of Thoracic Surgeons Adult Cardiac Surgery Database. J Thorac Cardiovasc Surg 2014; 148:856-64.

2. Hattler B., Messenger J. C., Shroyer A. L., Collins J. F., Haugen S. J., García J. A-, et al. Off-pump coronary artery bypass surgery is associated with worse arterial and saphenous vein graft patency and less effective revascularization: results from the Veterans Affairs Randomized On/Off Bypass (ROOBY) trial. Circulation 2012;125: 2.827-35.

3. Hlavicka J., Straka Z., Jelinek S., Budera P., Vanek T., Maly M., et al. Off-pump versus on-pump coronary artery bypass grafting surgery in high-risk patients: PRAGUE-6 trial at 30 days and 1 year. Biomed Pap Med Fac Univ Palacky Olomouc Czech Repub 2016 Jan 5. doi: 10.5507/bp.2015.059.

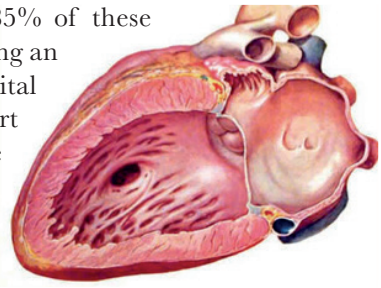
4. Takagi H., Umemoto T.; All-Literature Investigation of Cardiovascular Evidence (ALICE) Group. Worse long-term survival after off-pump than on-pump coronary artery bypass grafting. J Thorac Cardiovasc Surg 2014;148 1820-9.

5. Borracci R. A., Rubio M., Insúa J. T. Medical Cost Study of Off-pump Coronary Artery Bypass Grafting. Rev Argent Cardiol 2006;74: 289-96.

6. Lamy A., Tong W., Devereaux P. J., Gao P., Gafni A., Singh K, et al. The cost implications of off-pump versus on-pump coronary artery bypass graft surgery at one year. Ann Thorac Surg 2014; 98:1620-5.

7. Wagner T. H., Hattler B., Bishawi M., Baltz J. H., Collins J. F., Quin J. A., et al. On-pump versus off-pump coronary artery bypass surgery: cost-effectiveness analysis alongside a multisite trial. Ann Thorac Surg 2013; 96: 770-7.

born annually with this pathology and almost half of them needs surgery during the first year of life. Surgery and hemodynamics advances allow 85% of these children to reach adult age, thus creating an adult population with treated congenital heart diseases. These congenital heart diseases in adults constitute a separate chapter of Cardiology and Surgery that has acquired significance due to the increasing survival of these operated children, who still have sequels or present late evolution of their congenital disease. As for these adults, certain priority issues arise including heart failure in those operated for tetralogy of Fallot, indication of mechanical circulation support or transplant, evolution and treatment of patients with Fontan circulation, incidence of arrhythmias and sudden death, septal defects not treated in childhood, distant vascular complications following the treatment of aortic coarctation, distant results in the single ventricle, etc.[2-3]. In Argentina, 64% of cases of adults with congenital heart diseases die of pulmonary hypertension, heart failure or sudden death at an average age of 30[4], while in developed countries such adults reach the average age of 49[5]. A program to address this pathology should cover the following steps[6-7]: 1) knowing the number of adult patients with congenital heart diseases by creating a register; 2) determining by medical consensus the special needs of these patients; 3) estimating and training the medical-surgical work force needed to treat these patients; and 4) having the necessary number of centers available to guarantee these patients access to proper medical assistance. According to Maisuls HR[8], in Argentina 20 specialized centers would be needed for the treatment of such pathologies, i.e. 1 center every 2 million inhabitants. There are 55 centers in the United States, 15 in Canada and 70 in Europe. In the latter case, only 7.1% of 1.8 million adults with congenital heart diseases are assisted in specialized centers[9]. Maisuls HR also estimated that in Argentina there would be about 115,000 adult patients with congenital heart diseases: 54,000 with simple heart disease; 44,000 with moderate heart disease; and 17,000 with complex heart disease. A more realistic approach by other experts estimates that the total number of patients would reach 81,000. ■



1. Gurvitz M., Burns K. M., Brindis R., Broberg C. S., Daniels C. J., Fuller S. M., et al. Emerging Research Directions in Adult Congenital Heart Disease: A Report From an NHLBI/ ACHA Working Group. J Am Coll Cardiol 2016; 67:1956-64.

2. Ohuchi H. Adult patients with Fontan circulation: What we know and how to manage adults with Fontan circulation? J Cardiol 2016 Apr 28. doi: 10.1016/j. jjcc.2016.04.001.

3. Marzullo R., Bordese R., Bassignana A., Ferraro G., Dall'Orto G., Ferrarotti L., et al. Preliminary results and future perspectives of the Piedmont Adult Congenital Heart Disease Registry. G Ital Cardiol (Rome) 2016; 17: 225-33.

4. Cabrera M., Vega B., Juaneda E., Peirone A., Bruno E., Maisuls H., Alday L. "Realidad en Córdoba de los adultos fallecidos con cardiopatías congénitas". Rev Argent Cardiol 2010; 78(Supl 1): 52.

5. Verheugt C. L., Uiterwaal C. S., van der Velde E. T., Meijboom F. J., Pieper P.G., van Dijk A. P. J., et al. Mortality in adult congenital heart disease. Eur Heart J 2010;31:1220-9.

6. Webb G. D., Williams R. G. Care of the adult with congenital heart disease: Introduction. J Am Coll Cardiol 2001; 37: 1166-72.

7. Report of the British Cardiac Society Working Party. Grown-up congenital heart (GUCH) disease: current needs and provision of service for adolescents and adults with congenital heart disease in the UK. Heart 2002;88 Suppl 1:i1-14.

8. Maisuls H. R. "El adulto con cardiopatía congénita y los nuevos pacientes de la cardiología". Rev Argent Cardiol 2010; 78: 383-4.

9. Moons P., Meijboom F. J., Baumgartener H., Trindade P., Huyghe E., Kaemmerer on behalf of the ESC Working Group on Grown-up Congenital Heart Disease. Structure and activities of adult congenital heart disease programmes in Europe. Eur Heart J 2010; 31:1305-10.