

Percutaneous aortic valve Replacement: myth or reality?

Implante percutâneo de valva aórtica: mito ou realidade?

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Abstract

Aortic valve replacement with mechanical or biological prosthesis with extracorporeal circulation is the gold-standard for the treatment of calcific aortic stenosis. Although the results are excellent with the conventional approach some elderly patients, with multiple high-risk comorbid conditions, reoperations and severe left ventricular dysfunction have high surgical risk. During the last years percutaneous techniques have been developed. The present study aim to analyse the literature, since the experimental development until clinical application of this novel treatment in patients with high surgical risk aortic stenosis. Percutaneous implantation of aortic valve prosthesis is being done in some centers and the cardiovascular surgeon that treats valve disease should be involved in this development.

Descriptors: Aortic valve stenosis. Aortic valve. Stents.

Resumo

A substituição valvar por prótese metálica ou biológica com o auxílio de circulação extracorpórea é o procedimento padrão-ouro para o tratamento da estenose aórtica calcificada. Embora os resultados sejam excelentes com a cirurgia convencional, alguns pacientes com idade avançada, doenças associadas, reoperações e disfunção ventricular esquerda grave apresentam alto risco cirúrgico. Nos últimos anos, técnicas de tratamento percutâneo foram desenvolvidas. A presente revisão tem por objetivo analisar a literatura desde o desenvolvimento experimental até a aplicação clínica desta nova modalidade de tratamento para pacientes com estenose aórtica grave e alto risco cirúrgico. O implante percutâneo de valva aórtica hoje vem sendo realizado por alguns centros e o cirurgião cardiovascular envolvido no tratamento das doenças valvares deve fazer parte deste desenvolvimento.

Descritores: Estenose da valva aórtica. Valva aórtica. Contenedores.

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INTRODUCTION

Calcific aortic stenosis affects 2% to 5% of elderly individuals. It is the leading cause of surgical valve replacement in the United States and Europe. Cardiac surgery using cardiopulmonary bypass and aortic valve replacement by either mechanical or biological prosthesis is the procedure of choice in these cases. Aortic valve replacement with cardiopulmonary bypass support presents very low mortality and low morbidity and only in special occasions presents high surgical risk. Conventional surgery provides symptomatic improvement and increased survival in most patients with low surgical risk [1]. This procedure is the gold-standard for stenosis and or aortic valve insufficiency. However, in elderly patients with associated diseases, undergoing reoperation and presenting with severe ventricular dysfunction, mortality can reach up to 50% [2,3].

In the last decade, new attempts with less invasive procedures have arisen, such as left ventricle apex bypass for aorta and aortic valvoplasty with a balloon catheter in attempting to treat high-risk surgical patients [4-7].

Percutaneous treatment of aortic valve diseases with implantation of valves by catheter with stents has been tested as an alternative method [8-13].

After having used with relative success the dilation balloon catheter to treat neonatal aortic stenosis, it was attempted in patients with calcific aortic stenosis with poor outcomes and was practically abandoned.

From then on, the concept of nonsurgical valve replacement has evolved. Initially, it was applied to the pulmonary valve due to its easy access and because it tolerates more easily not so perfect results as aortic valve. After a short-period of animal experimentation [9], the first stent implants using pulmonary valve were reported by Bonhoeffer et al. [14], in 2000, in patients with right ventricle conduit dysfunction for pulmonary artery. Currently, more than 100 patients have been treated by the abovementioned authors with only one death related to the procedure and with good outcomes in this pediatric group of patients [15,16].

Cribier et al. [17], in 2002, performed the first human implantation of a balloon-expandable prosthetic aortic valve in patients with severe aortic stenosis who were considered inoperable due to associated comorbidities. Since then, reports describing this new technique have been shown the feasibility of this procedure [18-22].

In the first procedures, the valves mounted within the stent were released into the aortic ring through an antegrade transseptal approach, but technically speaking, this procedure was difficult, especially to place the valve adequately into the aortic ring; it has been abandoned.

The retrograde access via femoral artery seems more logical, but one important limitation has been related to the condition of arterial access. Initially, 24F (French) sheaths or bigger

were necessary to release the prostheses. Currently, in the 3rd-generation of these devices, 18F introducers already exist. The peripheral vascular access in these elderly patients with aorto-iliac atherosclerotic occlusion or thin femoral-iliac vessels is one of the problems to be overcome. Other problems related with the method are as follows: risk of calcic embolization during aortic valve pre-dilation, coronary artery ostia impairment, valved stent migration, paravalvular leak, hemolysis, low cardiac output in the moment of dilation and release, and low prosthesis durability.

It is difficult for all surgeons who have experience with patients presenting calcific aortic stenosis to imagine that it is possible pre-dilate these petrified valves. However, oppositely to surgical logic, in the last three years some experimental studies have been published and early clinical experience showed that this is a feasible procedure and can be extended to the mitral valve [23,24].

One alternative to retrograde arterial access has been the transapical catheter antegrade release by left ventricle through a beating-heart minithoracotomy. The University of British Columbia Group, Vancouver, Canada, published a clinical experience with excellent outcomes using this technique [25].

Naturally, due to the rapid expansion and development of this field, much controversy has been brought up. With the purpose of establishing the real state-of-the-art and to normalize the indications to percutaneous valve implantation the *Society of Thoracic Surgeons* (STS) and the *American Association for Thoracic Surgery* (AATS) together with the *Society for Cardiovascular Angiography and Interventions* (SCAI) have issued an official position statement [26]. This text alerts for precautions that should be taken in order to avoid these procedures indiscriminating use, pointing out that many critical questions remain unanswered, including the durability of the devices. It has been stressed that experimental technologies are not justifiable in patients in whose, there are no established and published guidelines with clear indication, or in situations of prophylactic surgery until effective and security data are being published in well-designed clinical trials.

Even with the abovementioned exceptions, the method has been used in some centers, employing experimental clinical protocols in patients with no condition to undergo conventional surgery, where two cardiovascular surgeons sign the term contra-indicating the open surgery.

The outcomes have been reasonable and with a great interest and investment from the companies, the fast technological advance in manufacturing valves and catheters should facilitate the procedure and improve the indications. Most valves are composed of three equine or bovine pericardium leaflets mounted onto balloon-expandable or self-expandable stainless steel stents or nitinol. Currently, more than 20 companies develop these

valve replacements and Cribier-Edwards® as well as CoreValve® are already being used in clinical series regularly, either percutaneously or transapically.

Self-expandable prosthesis system presents several potential advantages over balloon-expandable devices. Besides being theoretically associated to a lower paravalvular leak incidence, it allows to treat patients with aortic valve insufficiency as well. Another potential advantage would be the greater prosthesis durability, once the trauma caused to the valve leaflets related to the balloon dilation would be eliminated [18,20,21].

In December 2005, Lamarche et al. [27] performed a percutaneous aortic valve implantation in Montreal, Canada, in a patient with critical aortic stenosis, ventricular dysfunction, and pulmonary fibrosis with contra-indication for conventional surgery. A self-expandable CoreValve (Paris, France) was implanted via arterial retrograde with femorofemoral CPB support. The patient had an uneventful course and the authors directed our attention to the importance of the multidisciplinary approach in these cases. In 2006, Grube et al. [28] reported a series of 25 consecutive patients undergoing percutaneous aortic valve implantation with femorofemoral cardiopulmonary bypass support. In this study, the patients with symptomatic aortic stenosis and aortic valve area lower than 1 cm were considered for enrollment. CoreValve implantation was performed under general anesthesia with femorofemoral CPB support. Clinical follow-up and echocardiography were performed after the procedure and at 15 and 30 days after device implantation to evaluate short-term outcomes. A total of 25 symptomatic patients with several comorbidities (median logistic EuroScore, 11%) were enrolled. Procedural success was achieved in 21 (84%) patients. Successful device implantation resulted in a marked reduction in the aortic valve gradients ($p < 0.0001$). Major in-hospital cardiovascular and cerebral events occurred in 8 patients (32%), including mortality in 5 patients (20%). Among 18 patients with device success surviving to discharge, no adverse events occurred within 30 days after leaving the hospital.

The authors concluded that percutaneous implantation of the self-expanding CoreValve aortic valve prosthesis in high-risk patients is feasible and, when successful, results in a marked reduction in the aortic valve gradients and clinical improvement in short-term.

In 2007, a series with 50 consecutive patients treated percutaneously during 1 year-follow-up was published showing good outcomes in this period of time and greater therapeutic success in the last 25 cases, demonstrating the importance of a learning curve and a fast improvement of the devices [29].

Currently, based on the aforementioned studies, we can assure that percutaneous aortic valve implantation is a procedure which is being applied, but it is still in the

evaluation phase. In Brazil, the National Health Surveillance Agency (Anvisa) did not release any of these products yet. Much remains to be done, but this is a procedure that has come to become the fashion. What we can discuss are the indications and which is the real space these less invasive procedures should occupy in clinical therapy of valve diseases. Despite the excellent outcome of the conventional valve surgery, science is advancing fast. We are living in exponential times. Cardiovascular surgeons involved in the treatment of valve diseases should be open to the introduction of groundbreaking methods, technologies, ideas, etc. Also, he/she should not get carried away and should always analyze the results in the light of well-conducted short and long term clinical trials. It is obviously that we must exert science rigorously to keep patients' safety. On the other hand, this is one more medicine field where the strict collaboration between the cardiovascular surgeon and the interventional cardiologist is critical to the patient's well-being.

REFERENCES

1. Rajamannan NM. Calcific aortic stenosis: a disease ready for prime time. *Circulation*. 2006;114(19):2007-9.
2. Roques F, Nashef SA, Michel P, Gauducheau E, de Vincentis C, Baudet E, et al. Risk factors and outcome in European cardiac surgery: analysis of the EuroSCORE multinational database of 19030 patients. *Eur J Cardiothorac Surg*. 1999;15(6):816-23.
3. Culliford AT, Galloway AC, Colvin SB, Grossi EA, Baumann FG, Esposito R, et al. Aortic valve replacement for aortic stenosis in persons aged 80 years and over. *Am J Cardiol*. 1991;67(15):1256-60.
4. Cooley DA, Lopez RM, Absi TS. Apicoaortic conduit for left ventricular outflow tract obstruction: revisited. *Ann Thorac Surg*. 2000;69(5):1511-4.
5. Sweeney MS, Walker WE, Cooley DA, Reul GJ. Apicoaortic conduits for complex left ventricular outflow obstruction: 10-year experience. *Ann Thorac Surg*. 1986;42(6):609-11.
6. Renzulli A, Gregorio R, De Feo M, Ismeno G, Covino FE, Cotrufo M. Long-term results of apico-aortic valved conduit for severe idiopathic hypertrophic subaortic stenosis. *Tex Heart Inst J*. 2000;27(1):24-8.

7. Vassiliades TA Jr. Off-pump apicoaortic conduit insertion for high-risk patients with aortic stenosis. *Eur J Cardiothorac Surg.* 2003;23(2):156-8.
8. Andersen HR, Knudsen LL, Hasenkam JM. Transluminal implantation of artificial heart valves: description of a new expandable aortic valve and initial results with implantation by catheter technique in closed chest pigs. *Eur Heart J.* 1992;13(5):704-8.
9. Bonhoeffer P, Boudjemline Y, Saliba Z, Hausse AO, Aggoun Y, Bonnet D, et al. Transcatheter implantation of a bovine valve in pulmonary position: a lamb study. *Circulation.* 2000;102(7):813-6.
10. Boudjemline Y, Bonhoeffer P. Steps toward percutaneous aortic valve replacement. *Circulation.* 2002;105(6):775-8.
11. Boudjemline Y, Bonhoeffer P. Percutaneous implantation of a valve in the descending aorta in lambs. *Eur Heart J.* 2002;23(13):1045-9.
12. Sochman J, Peregrin JH, Pavcnik D, Timmermans H, Rosch J. Percutaneous transcatheter aortic disc valve prosthesis implantation: a feasibility study. *Cardiovasc Intervent Radiol.* 2000;23(5):384-8.
13. Cribier A, Eltchaninoff H, Borenstein N. Transcatheter implantation of balloon expandable prosthetic heart valves: early results in an animal model. *Circulation.* 2001;104:II-552.
14. Bonhoeffer P, Boudjemline Y, Saliba Z, Merckx J, Aggoun Y, Bonnet D, et al. Percutaneous replacement of pulmonary valve in a right-ventricle to pulmonary-artery prosthetic conduit with valve dysfunction. *Lancet.* 2000;356(9239):1403-5.
15. Khambadkone S, Coats L, Taylor A, Boudjemline Y, Derrick G, Tsang V, et al. Percutaneous pulmonary valve implantation in humans: results in 59 consecutive patients. *Circulation.* 2005;112(8):1189-97.
16. Attmann T, Quaden R, Jahnke T, Muller-Hulsbeck S, Boening A, Cremer J, et al. Percutaneous pulmonary valve replacement: 3-month evaluation of self-expanding valved stents. *Ann Thorac Surg.* 2006;82(2):708-13.
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(24):3006-8.
18. Cribier A, Eltchaninoff H, Tron C, Bauer F, Agatiello C, Sebah L, et al. Early experience with percutaneous transcatheter implantation of heart valve prosthesis for the treatment of end-stage inoperable patients with calcific aortic stenosis. *J Am Coll Cardiol.* 2004;43(4):698-703.
19. Bauer F, Eltchaninoff H, Tron C, Lesault PF, Agatiello C, Nercolini D, et al. Acute improvement in global and regional left ventricular systolic function after percutaneous heart valve implantation in patients with symptomatic aortic stenosis. *Circulation.* 2004;110(11):1473-6.
20. Webb JG, Chandavimol M, Thompson CR, Ricci DR, Carere RG, Munt BI, et al. Percutaneous aortic valve implantation retrograde from the femoral artery. *Circulation.* 2006;113(6):842-50.
21. Cribier A, Eltchaninoff H, Tron C, Bauer F, Agatiello C, Nercolini D, et al. Treatment of calcific aortic stenosis with the percutaneous heart valve: mid-term follow-up from the initial feasibility studies: the French experience. *J Am Coll Cardiol.* 2006;47(6):1214-23.
22. Grube E, Laborde JC, Zickmann B, Gerckens U, Felderhoff T, Sauren B, et al. First report on a human percutaneous transluminal implantation of a self-expanding valve prosthesis for interventional treatment of aortic valve stenosis. *Catheter Cardiovasc Interv.* 2005;66(4):465-9.
23. Ma L, Tozzi P, Huber CH, Taub S, Gerelle G, von Segesser LK. Double-crowned valved stents for off-pump mitral valve replacement. *Eur J Cardiothorac Surg.* 2005;28(2):194-9.
24. Boudjemline Y, Pineau E, Borenstein N, Behr L, Bonhoeffer P. New insights in minimally invasive valve replacement: description of a cooperative approach for the off-pump replacement of mitral valves. *Eur Heart J.* 2005;26(19):2013-7.
25. Lichtenstein SV, Cheung A, Ye J, Thompson CR, Carere RG, Pasupati S, et al. Transapical transcatheter aortic valve implantation in humans: initial clinical experience. *Circulation.* 2006;114(6):591-6.
26. Vassiliades TA Jr, Block PC, Cohn LH, Adams DH, Borer JS, Feldman T, et al. The clinical development of percutaneous heart valve technology: a position statement of the Society of Thoracic Surgeons (STS), the American Association for Thoracic Surgery (AATS), and the Society for Cardiovascular Angiography and Interventions (SCAI). *Ann Thorac Surg.* 2005;79(5):1812-8.
27. Lamarche Y, Cartier R, Denault A, Basmadjian A, Berry C, Laborde JC, et al. Implantation of the CoreValve percutaneous aortic valve. *Ann Thorac Surg.* 2007;83(1):284-7.
28. Grube E, Laborde JC, Gerckens U, Felderhoff T, Sauren B, Buellesfeld L, et al. Percutaneous implantation of the CoreValve self-expanding valve prosthesis in high risk patients with aortic valve disease: the Siegburg first-in-man study. *Circulation.* 2006;114(15):1616-24.
29. Webb JG, Pasupati S, Humphries K, Thompson C, Altwegg L, Moss R, et al. Percutaneous transarterial aortic valve replacement in selected high-risk patients with aortic stenosis. *Circulation.* 2007;116(7):755-63.