

# Off-pump transapical balloon-expandable aortic valve endoprosthesis implantation

## *Implante transapical de endoprótese valvada balão-expansível em posição aórtica sem circulação extracorpórea*

Diego Felipe GAIA<sup>1</sup>, José Honório PALMA<sup>2</sup>, José Augusto Marcondes de SOUZA<sup>3</sup>, José Cícero Stocco GUILHEN<sup>4</sup>, Andre TELIS<sup>5</sup>, Claudio Henrique FISCHER<sup>6</sup>, Carolina Baeta Neves Duarte FERREIRA<sup>7</sup>, Enio BUFFOLO<sup>8</sup>

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### *Abstract*

**Objective:** The aortic valve replacement is a routine procedure, and involves replacement of the native valve/prosthesis. In most of the patients who undergo such procedure the risk is acceptable, but in some cases, such risk can justify contraindication. The minimally invasive transcatheter aortic valve implantation without cardiopulmonary bypass (CPB) has been shown to be viable, with lower morbidity and mortality. The aim of this study was to develop a catheter-mounted aortic bioprosthesis for implantation without CPB.

**Methods:** After developing in animals, three patients with high EuroSCORE underwent implantation. Case 1: patients with bioprosthesis dysfunction; Case 2: severe aortic stenosis; Case 3: dysfunction of aortic bioprosthesis. After minithoracotomy and under echocardiographic and fluoroscopic control, a balloon catheter was placed on aortic position and inflated. After, a second balloon with valved endoprosthesis was positioned and released under high ventricular rate. Echocardiographic and angiographic controls were performed and the patients were referred to ICU.

**Results:** In the first case, implantation without CPB was possible with appropriate results. The patient evolved with improvement of ventricular function. After, this patient developed bronchopneumonia, tracheoesophageal fistula and died due to mediastinitis. Autopsy confirmed proper valve positioning and leaflets preservation. The second case showed the device migration after inflation of the balloon, with the need for urgent median sternotomy, CPB and conventional valve replacement. This patient evolved well and was discharged from the ICU on the 14<sup>th</sup> postoperative day without complications. This patient developed respiratory infection, septic shock and died on the 60<sup>th</sup> postoperative day. The patient from the third case underwent successful implantation.

**Conclusion:** The off-pump transapical implantation of catheter-mounted bioprosthesis was shown to be a feasible procedure. Technical details and learning curve require further discussion.

**Descriptors:** Aortic valve. Cardiopulmonary bypass. Heart catheterization.

1. Master's Degree (Physician of the Cardiovascular Discipline)
2. Full Professor (Head of the Cardiovascular Surgery Discipline at UNIFESP)
3. PhD in Medicine (Hemodynamicist of UNIFESP)
4. Cardiovascular Surgeon (Resident Physician at UNIFESP)
5. Cardiovascular Surgeon (Resident Physician at UNIFESP)
6. PhD in Medicine (Echocardiographer at UNIFESP)
7. Master's Degree. Anesthesiologist. Anesthesia, Pain and Intensive Therapy Discipline – UNIFESP)
8. Titular Professor of Cardiovascular Surgeon (UNIFESP)

This study was carried out at the Federal University of São Paulo - UNIFESP, Sao Paulo, SP, Brazil.

Correspondence address:  
Diego Felipe Gaia - Rua Napoleão de Barros, 715 – 3º Andar – Cirurgia Cardiovascular – Vila Clementino - São Paulo, SP, Brazil.  
E-mail: drgaia@uol.com.br

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### Resumo

**Objetivo:** A troca valvar aórtica é procedimento rotineiro, envolve substituição da valva nativa/prótese. Na maioria destes pacientes o risco é aceitável, porém, em alguns casos, o risco predito pode justificar contra-indicação. O implante de valva aórtica minimamente invasivo transcater e sem circulação extracorpórea (CEC) tem se mostrado viável, com menor morbi-mortalidade. O objetivo deste trabalho foi desenvolver bioprótese aórtica, montada em cateter, para implante sem CEC.

**Métodos:** Após desenvolvimento em animais, três pacientes com EuroSCORE elevado foram submetidos ao implante. Caso 1: portador de bioprótese com disfunção; Caso 2: estenose aórtica grave; Caso 3: disfunção de bioprótese aórtica. Após minitoracotomia e sob controle ecocardiográfico e fluoroscópico, cateter-balão foi posicionado sobre posição aórtica e insuflado. Após, segundo cateter-balão, com endoprótese valvada, foi posicionado e liberado sob alta frequência ventricular. Controles angiográficos e ecocardiográficos foram realizados e pacientes encaminhados para UTI.

**Resultados:** No primeiro caso foi possível implante sem CEC com resultados adequados. Evoluiu com melhora da função ventricular. Cursou com broncopneumonia, fistula traqueo-esofágica e óbito por mediastinite. Necropsia confirmou bom posicionamento valvar e preservação dos folhetos. O segundo caso apresentou migração do dispositivo após insuflação do balão, necessidade de esternotomia mediana de urgência, CEC e troca valvar convencional. O paciente evoluiu bem, recebendo alta da UTI 14 dias após procedimento e sem complicações. Cursou com infecção respiratória, choque séptico e óbito no 60º pós-operatório. O terceiro caso foi submetido a implante com sucesso.

**Conclusão:** O implante de bioprótese transapical montada em cateter sem CEC mostrou ser procedimento factível. Detalhes técnicos e a curva de aprendizado demandam discussão.

**Descritores:** Valva aórtica. Ponte cardiopulmonar. Cateterismo cardíaco.

## INTRODUCTION

The aortic valve replacement in elderly patients is a routine procedure that usually involves replacement of the damaged native valve or replacement of its prosthetic impaired substitute by a bioprosthesis of different performances and models. In most of these patients, the surgical risk associated with the procedure is acceptable and appropriate long-term outcome is well established [1].

The expected result can still be quite acceptable even in octogenarians [2]. However, in some cases and especially in reoperations, the risk predicted by various scores can reach levels that justify the contraindication of the procedure, up to 6% -15% [3].

In search of alternatives for this group of high-risk patients, the minimally invasive transcatheter implantation and without use of cardiopulmonary bypass has been shown to be, in experimental and clinical series, a viable alternative with lower morbidity and mortality for patients with high surgical risk with the possibility of performing such procedure even in reoperations [4].

Some devices such as CoreValve (CoreValve, Paris, France) and Edwards Sapiens (Edwards Lifescience Inc, Irvine, CA, USA) are under study, but no of them are widely available in our country in addition to the high cost of using.

Thus, it became necessary to develop national technology in this field in order to facilitate the production and use of this new knowledge. After the experimental phase

of development and training in experimental animals, it was possible to obtain a safe device, easy to implant and with performance similar to that found in porcine bioprostheses currently available in our market (Figure 1).

Based on these results, it was possible to perform the transapical implantation of a catheter-mounted balloon-expandable bioprosthesis without cardiopulmonary bypass in three high surgical risk patients.



Fig. 1 – Final model of aortic bioprosthesis for mounting on balloon catheter

## CASE REPORTS

### Case 1

64-year male patient, hypertensive and carrier of biological prosthesis in aortic position (second prosthesis: the first 30 years and the second 20 years ago, without outpatient follow-up) was admitted to our emergency service with atrial flutter with high ventricular response. After control and reversal of arrhythmia, the patient remained under observation at the Chest Pain Unit. After a few hours he presented cardiogenic shock, evolving to functional class IV (*New York Heart Association*) and propaedeutic compatible with severe aortic insufficiency.

The transesophageal echocardiogram showed severe aortic insufficiency by rupture of the bioprosthesis leaflet, moderate pulmonary hypertension, mild-to-moderate mitral regurgitation and moderate left ventricular dysfunction and severe right ventricle dysfunction.

In a few hours, the patient evolved with presentation refractory to vasoactive drugs, lung congestion, oliguria, worsening of renal function and need for invasive mechanical ventilation. The operative risk estimated by the logistic EuroSCORE was of 54%.

It was decided to perform the valve-in-valve transcatheter transapical implant without cardiopulmonary bypass, based on experience acquired in centers that already used to perform the procedure, and experimental development of a satisfactory national device tested in experimental animals. Furthermore, meeting of consensus among the specialties involved has occurred, informed consent from those responsible for the patient and approval by the Research Ethics Committee were obtained.

The implant was performed in high technology hybrid operating room, with the presence of various devices (hemodynamics, echocardiography, cardiopulmonary bypass support in addition to materials and surgical equipments and usual anesthetics).

After anesthetic induction, a small antero-lateral thoracotomy in the fifth left intercostal space was performed to expose the left ventricular apex. Then a double purse-string suture supported in a Teflon felts was performed. A 6F vascular introducer was positioned with the aid of a guidewire by puncturing in the center of the suture under echocardiographic and fluoroscopic vision.

With the aid of a hydrophilic guidewire and a pigtail catheter was possible to get through the aortic valve into the descending thoracic aorta.

The initial aortography confirmed the aortic insufficiency and favored the identification of the prosthetic aortic valve ring and the position of the coronary ostia.

The aortic valve annulus was measured by transesophageal echocardiography, with an internal diameter of 19 mm. A balloon-expandable stainless steel

catheter-mounted bioprosthesis with “oversize” of 20% was selected and placed on the ring of the impaired bioprosthesis through a 24F introducer (Figure 2).

Cardiac output was reduced with the aid of temporary epimyocardial pacemaker, and then the balloon was inflated with maximum pressure of 5 atmospheres (atm) and the prosthesis was released (Figure 3).

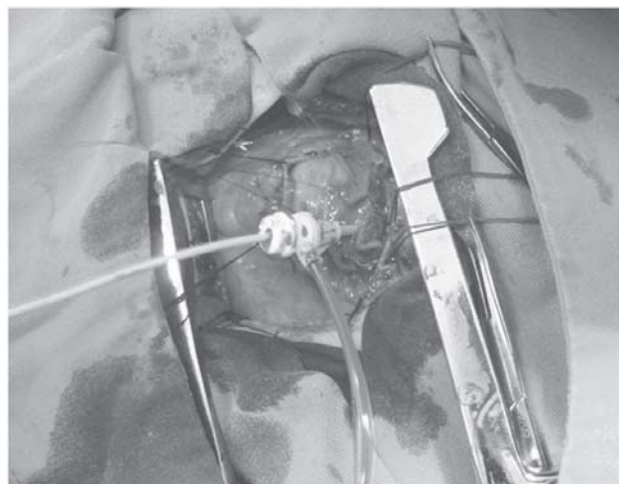


Fig. 2 – Left Antero-lateral minithoracotomy with exposure of the left ventricular apex. Introducer positioned

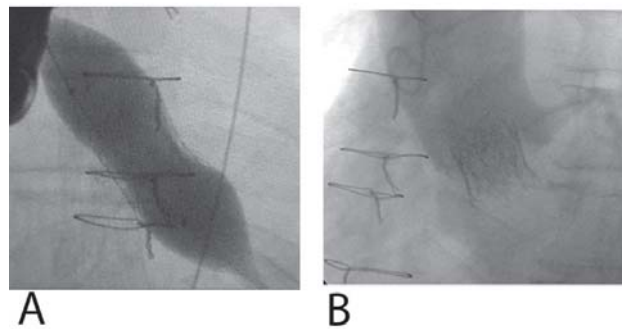


Fig. 3 - A: Balloon inflated with expansion of the prosthesis. B: Prosthesis positioned. Control aortography without aortic insufficiency and free coronary ostia

After the recovery of heart rate and blood pressure, echocardiography confirmed the absence of significant aortic insufficiency and the control aortography showed good prosthetics apposition and free coronary ostia (Figure 3).

The patient improved his ventricular function and the possibility of mechanical ventilation disconnection on the 2nd postoperative day. On the 30<sup>th</sup> postoperative day,

presented with bronchopneumonia, need for tracheostomy, tracheo-esophageal fistula and died due to mediastinitis. Necroscopic finding confirmed good positioning and maintenance of valve leaflets (Figure 4).



Fig. 4 - Necroscopic finding with good apposition between the prosthesis and the preserved leaflets. Free coronary ostia (identified by metal forceps)

Echocardiogram performed at the 30<sup>th</sup> postoperative day showed no dysfunction or leak, with a maximum aortic gradient of 39 mmHg.

### Case 2

81-year-old female patient, carrier of severe aortic stenosis with aortic maximum gradient of 72 mmHg and an ejection fraction of 42% was admitted in the emergency service with decompensated heart failure and need for use of vasoactive drugs.

The patient remained in heart failure with severe pulmonary congestion and the need for non-invasive mechanical ventilation despite optimized medical therapy.

The logistic EuroSCORE was 60%. After obtaining the written informed consent, the patient underwent transapical implantation of a balloon-expandable aortic valve.

Using the same technique described in case 1, a catheter-balloon was inflated up to its maximum pressure (5 atm) in order to relieve the aortic stenosis. A stent with 22 mm in diameter was expanded to its limit on the native ring under reduction of the cardiac output by using a pacemaker.

After expansion, it could be noted by fluoroscopic view the migration of the device into the aortic arch. Following, it has been chosen by median sternotomy and conversion to conventional procedure with cardiopulmonary bypass

for salvage of the prosthesis and aortic valve replacement.

The patient evolved satisfactorily and was discharged from the intensive care unit on the 14<sup>th</sup> postoperative day. However, on the 20<sup>th</sup> postoperative day, presented with respiratory infection, renal failure, septic shock and death on the 60<sup>th</sup> postoperative day.

### Case 3

84-year-old male patient, with aortic bioprosthesis for 16 years, hypertensive and with nondialytic chronic renal failure, admitted in the emergency service with congestive heart failure in functional class IV (New York Heart Association). Transthoracic echocardiogram showed rupture of the bioprosthesis leaflets with aortic insufficiency and severe left ventricular dysfunction (ejection fraction of 42%).

The cineangiogram showed no coronary lesions and aortography confirmed the aortic insufficiency.

The logistic EuroSCORE was 64%. After obtaining the written informed consent, transapical intervention was indicated.

Using the technique described in case 1, under echocardiographic, transesophageal and fluoroscopic control, a catheter-mounted balloon bioprosthesis was positioned on the impaired bioprosthesis and, during reduction of cardiac output, the bioprosthesis was expanded by balloon on the impaired bioprosthesis.

After recovering of cardiac output, echocardiography showed the correct apposition of the prosthesis without significant systolic gradient (25 mmHg) or central or perivalvular aortic insufficiency. The aortography confirmed such findings and the absence of interference with the coronary ostia.

The patient was disconnected from mechanical ventilation in the operating room and referred to intensive care unit. In the immediate postoperative period, the renal failure has become more acute, with need for temporary dialytic therapy.

The patient is currently stable in ward. Control echocardiogram without dysfunction, left ventricular ejection fraction of 57%, pulmonary artery pressure of 40 mmHg, aortic transvalvular gradient of 16 mmHg and without central or periprosthetic leak. Hospital discharge was scheduled on the 10<sup>th</sup> postoperative day.

### DISCUSSION

The transcatheter aortic valve implantation is a new technique and under study in various centers around the world [4-6]. The main objective of the procedure is to provide a satisfactory technical quality with lower morbidity and mortality when compared to the conventional approach, especially by avoiding the use of cardiopulmonary bypass, median sternotomy and aortic clamping.



Preliminary results have been encouraging, with mortality at 30 days around 8% [4]. In addition to implants on native valves, implants on impaired bioprostheses are also reported [7].

Various prosthetic devices have been tested in different centers, but the greater world experience focuses on the Edwards Lifesciences prosthesis, which is under investigation in a multicenter study (Partner trial- Placement of AoRTic traNscathetER valve).

This study may demonstrate the development of a prosthetic device of national technology, as well as other previous national experiences, such as cardiopulmonary bypass circuits, biological valve prostheses and aortic stents, an outcome of the interaction between industry and academia.

The local development of these technologies makes possible the disclosure of high technology procedures on our country, also allowing its access by the Unified Health System

The three cases reported herein highlight important points related to the procedure: its applicability and possibility of accomplishment, with immediate success in valve-on-valve implant and failure in implant on native prosthesis.

Failure on implantat on native prosthesis possibly occurred due to a learning curve in the expansion of the balloon, which was partially within the introducer, thus ejecting the prosthesis into the ascending aorta.

The experience proves to be essential the interaction between different specialties, demanding cardiovascular surgeon, hemodynamicist, echocardiographer and anesthesiologist specially trained and involved in the procedure. It is also necessary a hybrid surgical environment capable of integrating surgical and endovascular technologies with the presence of device for fluoroscopic images acquisition (with capacity of real-time reproduction of images) and transesophageal echocardiogram, in addition to surgical material adapted for radiosopic use [8].

The transapical route was selected instead of the transfemoral due to reports of increased mortality at 30 days and increased occurrence of stroke by this approach [9].

There were no vascular complications related to the access - a concern in the handling of the ventricular apex in the elderly patients - stroke or atrioventricular block, a complication reported specially with the self-expandable devices [10].

This little initial experiment does not allow us to suggest so reliable results of survival or complications because it deals with an initial procedure and also considering the learning curve of the procedure.

The evaluation of each of the devices, including the reported herein, is imperative in order to determine the

correct profile of patients candidates to the procedure. Analysis of maintenance of results, often considered suboptimal, especially when compared to conventional valve replacement is also essential.

Another point of discussion are the criteria used to define the severity of the selected patient, as the EuroSCORE and the STS score. Some authors have reported rates below the predicted rate in respect to the complication and mortality in aortic valve replacement in high-risk patients [2].

## CONCLUSION

Minimally invasive transapical implant of catheter-mounted balloon-expandable aortic bioprosthesis is a viable technique. There is significant learning curve and need for a team from multiple specialties in order to favor the procedure. The long-term result, and the correct selection of patients remain unresolved.

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### Comment

Initially I would like to thank the opportunity to comment on this study and congratulate Dr. Diego and the cardiovascular surgery team of UNIFESP for this pioneering initiative in our country.

In addition to reporting the first three cases of implantation of transapical aortic valve in Brazil, this study has the merit of developing together with a national company, a device that, like many others, may allow and expand its use in our country. Currently, CoreValve (which is a self expandable valve), recently acquired by Medtronic, is available for clinical use in Brazil and approved by ANVISA, and probably - at the time of submission of this article - it has not been released for commercialization yet. The other transapical valve available (Edwards Sapien) has not yet been released by ANVISA. Both can be implanted either via transfemoral and transapical approach.

The study, although reporting only 3 cases, shows the feasibility of using the device and its clinical application. The aortic valve implantation via catheter is a new procedure and was introduced in clinical practice a few years ago.

As emphasized in this study, in addition to the learning curve, the interaction between the cardiovascular surgeon, the interventional cardiologist, the echocardiographer and anesthesiologist is essential to the success of these procedures. Ideally, the procedure should be performed in a hybrid operating room with all surgical supplies, such as lights, surgical instruments, heart lung machine and image equipments such as transesophageal echocardiography, hemodynamic equipment with high-quality fluoroscopy and carbon fiber table. As this is a procedure in its early clinical experience and under evolution, the improvement of the devices by the industry should provide better conditions for positioning and also repositioning of the prosthesis, resulting in increased safety for these high-risk patients undergo conventional surgery.

I believe that the discussion on the comparison between transapical and transfemoral approaches could be explored further. The main advantages of the transapical approach are: antegrade insertion, associated with minimal manipulation of the ascending aorta and arch, and lower incidence of stroke when compared with the transfemoral approach. Furthermore, there is no problem in vascular approach and the positioning is more accurate. On the other hand, the transapical approach requires a mini-thoracotomy that can be a disadvantage, specially in patients with severe pulmonary disease and those too weak.

After these collocations, I propose 4 questions:

1) What is the opinion of the group on the placement of a guide wire in the femoral vein, in addition to access to the femoral artery (that is already used for the placement of the pigtail for angiographic control)? According to the group of Leipzig, Mohr et al, who recently published the experience of 1 year with 50 patients, this strategy allows for cardiopulmonary bypass in 2 to 3 minutes, and it has been used successfully in a patient with occlusion of the left coronary trunk by the prosthesis (strategy called "safety net").

2) Regarding the type of device used. A balloon expandable valved stent was used. What are the advantages and disadvantages in relation to self-expandable?

3) It is known that the occurrence of aortic insufficiency after these valvular procedures by catheter is high. What is the impression of you on the mid-term outcome such as the possibility of heart failure, hemolysis and endocarditis?

And finally:

4) In cases with contraindications for conventional surgery in aortic

stenosis, when should the transfemoral approach be indicated instead of transfemoral transapical approach?

I thank once again the opportunity to comment on this study.

**Eduardo Keller Saadi**  
*esaadi@terra.com.br*

### Answer

1) Due to the fact that it deals with initial experience of the group and judging essential the presence of the "safety net" strategy aiming at improving the safety of the procedure in eventualities and emergency conversions to a conventional or accident rescue procedures, we used in all cases the mounted and ready cardiopulmonary bypass circuit, in addition to the femoral artery and vein cannulated and prepared for introduction of perfusion under full heparinization.

Probably, with the progress of the experiment we may only allow the placement of guide-wires, without definitive cannulation.

2) The development in experimental animals of our device consisted, initially, of a self-expandable device. The manipulation and opening show to be more complex when compared to balloon-expandable. Furthermore, the literature shows that self-expandable devices may present a higher incidence of navigation failure, in addition to not allowing the "valve-in-valve" strategy used in some cases. Thus, we selected the balloon-expandable device for our initial experience. Certainly, comparative studies of longer duration may clarify which device is more safety and with better profile.

3) The transcatheter procedure definitely presents a suboptimal results when compared to conventional intervention. Most of these leaks are a result from incomplete coaptation of the device to the valve annulus. There are no data of long-term follow-up capable of predicting the outcome for comparison between these insufficiencies. We can assume that due to the severity of the selected cases, mild or mild-to-moderate insufficiencies with repercussions can be tolerated.

4) Although there is no consensus about the best access route, it is clear that the transfemoral route seems to be less aggressive and less invasive than ventricular apical approach.

On availability of low profile devices with introducers below 22F or 20F, favorable femoral iliac system, or that is, without large amount of atherosclerosis/tortuosity and in the absence of plaques/ulcers in the aortic arch, the transfemoral route seems to be more appropriate. However, the profile of these patients is exactly the opposite of this situation. Thus, we could affirm that the transapical route is most favorable to the great majority and the transfemoral one for selected cases in the current state-of-the-art of the devices. Clinical improvement was found but it was not significant in the mid-term follow-up.

It is reasonable to believe that the same way we have clinically noted patients with such insufficiency in native valves, we may act the same way in this selected group. The presence of severe hemolysis, refractory cardiac insufficiency or endocarditis certainly need to be approached conventionally in face of the predicted high risk for such interventions.