

# Pioneering transcatheter aortic valve Implant (Inovare<sup>®</sup>) via transfemoral

*Implante pioneiro de valva aórtica transcater (Inovare<sup>®</sup>) por via transfemoral*

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## *Abstract*

We present a patient with severe aortic valvular bioprosthesis dysfunction implanted for 11 years, presenting with acute pulmonary edema due to severe valvular insufficiency with severe systolic dysfunction (EF <30%) and comorbid conditions that amounted operative risk (STS score > 10). We carried out the transcatheter aortic valve implantation (Inovare<sup>®</sup> - Braile Biomedica), which was implemented successfully by transfemoral access and good patient outcomes.

**Descriptors:** Heart valve prosthesis. Aortic valve/surgery. Heart valve prosthesis implantation. Aortic valve insufficiency.

## *Resumo*

Apresentamos o caso de paciente com disfunção de bioprótese valvar aórtica implantada há 11 anos, apresentando quadro de edema agudo pulmonar em decorrência de insuficiência valvar grave. Apresentava disfunção sistólica grave (FE < 30%) e comorbidades que elevavam seu risco operatório (STS score > 10). Realizou-se o implante de valva aórtica transcater Inovare<sup>®</sup> - Braile Biomédica, por acesso transfemoral. O implante foi realizado com sucesso e o paciente apresentou boa evolução.

**Descritores:** Próteses valvulares cardíacas. Valva aórtica / cirurgia. Implante de prótese de valva cardíaca. Insuficiência da valva aórtica.

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Abbreviations, acronyms & symbols	
TAVI	transcatheter aortic valve implantation

## INTRODUCTION

The transcatheter aortic valve implantation has become a therapeutic option for patients with symptomatic severe aortic stenosis and high risk for conventional valve replacement surgery. Although balloon valvuloplasty have been the first option for less invasive treatment using percutaneous technique in critically ill patients, its long-term results have shown high rates of restenosis as well as not improving the clinical condition of the patients<sup>1</sup>, which makes this procedure only as an option for a bridge in emergency surgery. More recently the indication of transcatheter aortic valve implantation has been increased as repair of failed biological aortic prostheses in high risk for operation<sup>2</sup>.

## CASEREPORT

75-year-old male patient presenting biological valve prosthesis in the aortic position number 25 placed 11 years ago. He was admitted in the coronary care unit of University Hospital, Federal University of Mato Grosso do Sul with pulmonary edema and acute severe aortic valve failure. Comorbidities such as renal failure not on dialysis, chronic obstructive pulmonary disease, severe left ventricular systolic dysfunction (ejection fraction 30%) made him a high-risk patients with Euroscore > 20%.

It was then performed transcatheter implantation of an aortic valve prosthesis: Braile Biomedica's INOVARE.

The inner diameter of aortic prosthesis (22 mm) was previously measured using echocardiography and angiography of multiple detectors. Therefore, we used a 24- prosthesis. The surgery was designed so that the implants were performed by transapical approach, however due to the team's experience with transfemoral access due to the endovascular treatment of aortic diseases, we chose to implant this device via tranfemoral in a pioneer way. We used a femoral sheath Gore Dry Seal 24 Fr where the prosthesis together with its delivery balloon was introduced via the right femoral artery and carried using an extrastiff guide through the aorta until the level of the aortic prosthesis' ring; under the guidance fluoroscopic and transesophageal echocardiography was expanded at the ring of the bioprosthesis. The echocardiographic images (Fig. 1) demonstrated the correction of severe aortic regurgitation without significant transvalvular gradient (15.20 mmHg) allowing, together with fluoroscopy (Fig. 2),

to ensure the exact position of the prosthesis release and prove the effectiveness of the procedure when comparing the preoperative and postoperative images. After the procedure the patient was transferred to the coronary care unit, where he remained hospitalized for 2 days and discharged after three days of hospitalization.

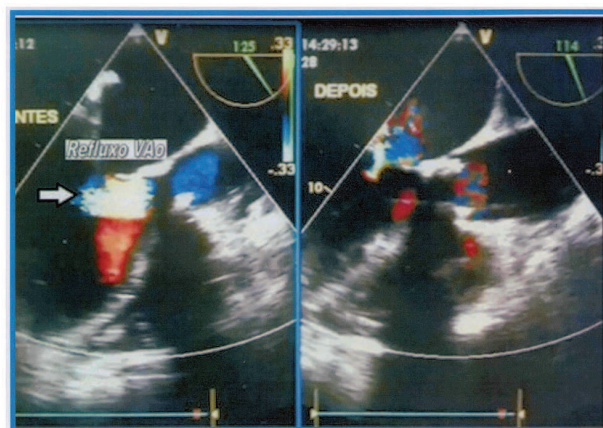


Fig. 1 - Image showing transesophageal echocardiogram demonstrating the presence of aortic valve regurgitation preoperatively and in the absence of imaging performed after transcatheter aortic valve implantation by transfemoral via

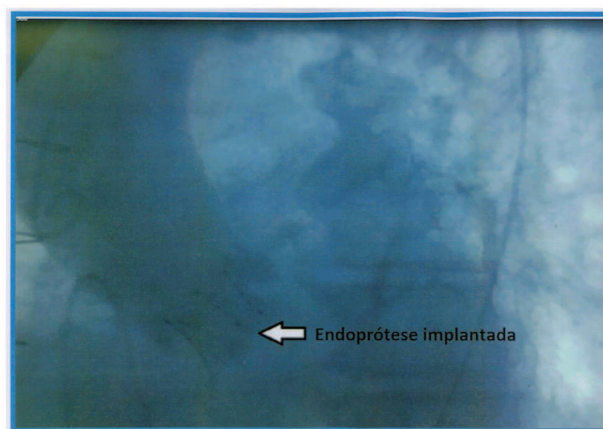


Fig. 2 - Image of fluoroscopy demonstrating the absence of reflux and the positioning of the transvalvular aortic valve prosthesis after transcatheter implantation by transfemoral via. Note also the maintenance of the left coronary trunk perfusion

## DISCUSSION

Due to high mortality of severe symptomatic aortic stenosis especially in high surgical risk patients the possibility of less invasive intervention using transcatheter

aortic valve implantation, either femoral or apical via, has become an attractive alternative.

The first description of the catheter valve implant was made by Davies<sup>3</sup>, 1965. Only in 2002, Cribier et al. [4] proposed the transcatheter aortic valve implantation (TAVI) to treat severe aortic stenosis in symptomatic patients with high surgical risk.

Partner Trial (Placement of Aortic Transcatheter) [5], the first “Trial” in its group B randomized trial, which compared medical therapy with transcatheter valve implantation, demonstrated superiority of the intervention, both in terms of mortality and quality of life. In group A the “trial” of transcatheter aortic valve implantation showed no inferiority when compared to open surgery in a year of follow-up of patients with critical aortic stenosis without surgical conditions.

In our environment Gaia et al<sup>6</sup> reported a 30-day mortality found in 18.18% and overall mortality (42.42%) mainly attributed to infectious complications postoperatively. The fact that 39.39% of these patients underwent surgery in the presence of decomposition and prolonged hospitalization, induces a greater risk of colonization and infection. Survival after hospital discharge was quite favorable (90.7%), demonstrating that after the initial phase the result is sustained.

We believe that the idea of a new procedure is the trend that its appointment is reserved for exceptional cases, but it may cause a negative bias in the analysis of mortality. The accomplishment of this procedure in end stage of heart failure of clinically decompensated patients, surely contributes to the emergence of postoperative complications, perhaps these extremely critical patients could benefit only from balloon valvuloplasty as a bridge to either the transcatheter valve implantation.

The implant by transapical approach is often chosen due to the incompatibility with sheaths of larger caliber and decreases the possibility of peripheral vascular complications. However the development of endovascular materials, such as stents and introducers are allowing greater ease in using the femoral approach, this would

minimize the harmful effects of thoracotomy on respiratory mechanics of these severe patients, which is known to be a risk factor for postoperative pulmonary infections. Further studies with larger samples are needed to define the safety of the procedure along with the sedimentation of technical learning in the future may allow this procedure be recommended for less critical and more electives patients.

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