NewsLetter
Scientific Newsletter · Year 7 · April-June 2016 · # 41

BRAILE BIOMÉDICA
Biologics & Solutions
Cardiovascular
Eletcromechanical
Endovascular
Oncology

INOVARE®
Transcatheter Prosthesis

The **INOVARE® Transcatheter Prosthesis** developed to enable the treatment of valvar diseases in patients considered to be at high or intermediate risk, is the first and only Brazilian cardiac valvular prosthesis for an implant via catheter.

In addition to the treatment of native valve diseases, it also enables valve-in-valve implants in the aortic and mitral positions, standing as an important alternative.

The **INOVARE®** prosthesis represents national technological excellence, with international projection in the minimally invasive cardiac surgery field.

In the last year were published three important scientific articles related to the **INOVARE® Transcatheter Prosthesis**.

NEW BRAILE INOVARE TRANSCATHETER AORTIC PROSTHESIS: clinical results and follow-up

adapted from Gaia *et al.*, 2015[1]

Gaia et al.[1] (2015) published in *EuroIntervention,* a high impact scientific publication, the main and most current clinical evaluation results of the **INOVARE® Transcatheter Prosthesis**, performed at the Paulista Medical School Hospital (UNIFESP).

The implants were performed, via transapical, in 90 patients with calcified aortic stenosis (Table 1).

The procedure's success was achieved in 87 cases (96.6%). There were three immediate conversions for open surgery (3.3%), two of them due to prosthesis migration and one due to the hemodynamic post-implant instability (Table 2).

Table 1: Patients' characteristics:

		n = 90
Mean age		77.3 (34-88)
Female		48 (53.3%)
Hipertensão arterial sistêmica		88 (97.7%)
Diabetes		29 (32.2%)
Dyslipidemia		67 (74.4%)
Glomerular filtration rate < 50 mL/min		65 (77.3%)
Dialytic renal insufficiency		8 (8.8%)
Restrictive/obstructive pulmonary disease		40 (44.4%)
Operated during hospitalization by decompensation		35 (38.8%)
Atrial fibrillation		18 (20.0%)
Functional Class - NYHA	II	7 (7.7%)
	III	35 (38.8%)
	IV	48 (53.3%)
Comorbidities		
Coronary arterial disease		58 (64.4%)
Prior cardiovascular surgery		39 (43.3%)
Peripheral arterial disease		61 (67.7%)
Prior Stroke		4 (4.4%)
Cancer		4 (4.4%)
Porcelain aorta		8 (8.8%)
Chagas Disease		1 (1.1%)
Sickle-cell disease		1 (1.1%)
Biological frailty		52 (57.7%)
Logistic EuroScore (mean)		39.3 (5.85-94.2)
Peak aortic gradient (mean)		75.6 ± 21.6
Medium aortic gradient (mean)		44.8 ± 15.3
LV ejection fraction (mean)		51.2 ± 15.2

NYHA: New York Heart Association; LV: left ventricle

Table 2: Surgical variables.

Variables	n = 90
Procedure sucess	87 (96.6%)
Conversion for conventional replacement	3 (3.3%)
Input in ECC (excluding conversions)	1
Contrast (mL) (mean)	29.0
Fluoroscopy time (min) (mean)	11.5 ± 4.9
Procedure time (min) (mean)	136.2 ± 81.8

ECC: extracorporeal circulation

There was only one case of surgical mortality, and mortality in 30 days was 13,3%. The survival at six, 12, 18, 24, 36 and 48 months, according to Kaplan-Meier's analysis, was 65.1, 62.7, 61.3, 58.3, 54.3 and 53.3%, respectively. Post-discharge hospital survival, according to Kaplan-Meier's analysis, in six, 12, 18, 24, 36 and 48 months was of 87, 85, 83, 83, 77.5 and 77.5%, respectively (Figure 1).

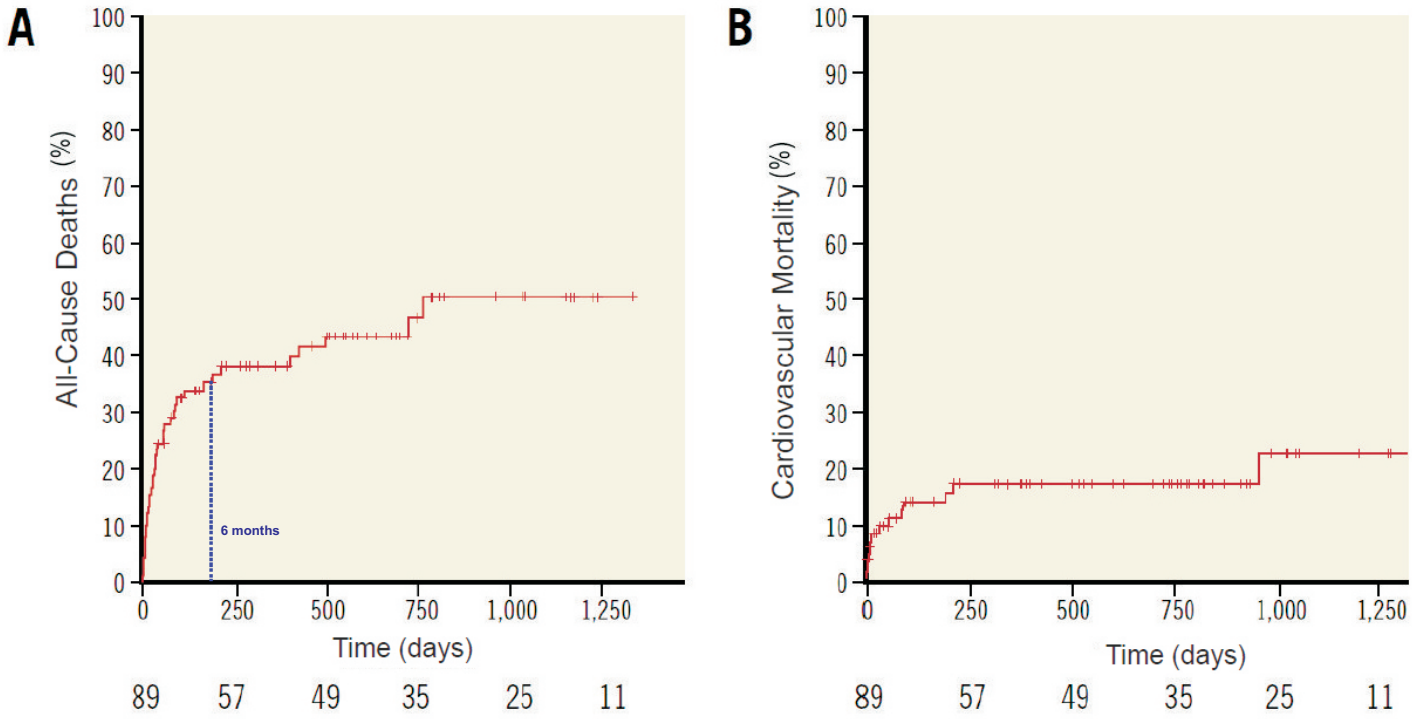


Figure 1: Kaplan-Meier's mortality curves.
A) All-cause mortality. B) Mortality by cardiovascular causes.

There was significant reduction of the peak aortic transvalvar gradient and the medium gradient obtained (75.6±21.6 to 27.4±14,6 mmHg, and 44.8±15.3 to 14.1±8.0 mmHg, respectively) in the first post-surgical evaluation (Figure 2).

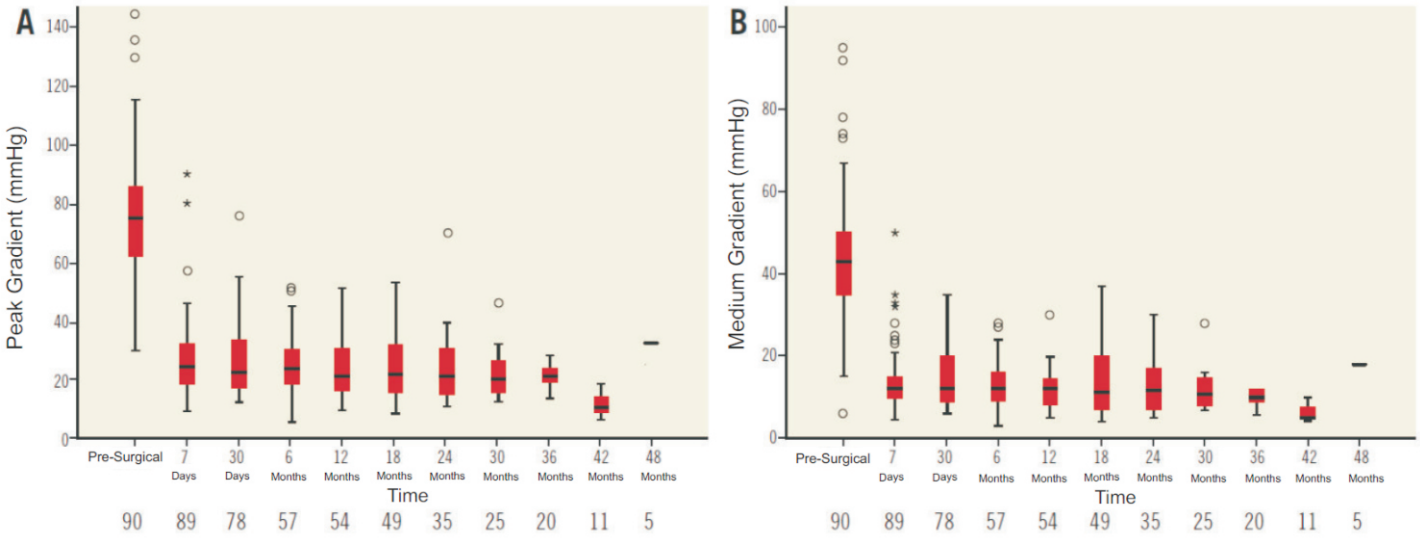


Figure 2: Aortic gradient.

A) Aortic gradient peak: Pre x 1st immediate post-surgical = p<0.001.
1st immediate post-surgical x subsequent post-surgical = p>0.05.
B) Aortic gradient mean: Pre x 1st immediate post-surgical = p<0.001.
1st post-surgical x subsequent post-surgical = p>0.05.

Th e left ventricular function improved in the first seven post-surgical days (Figure 3).

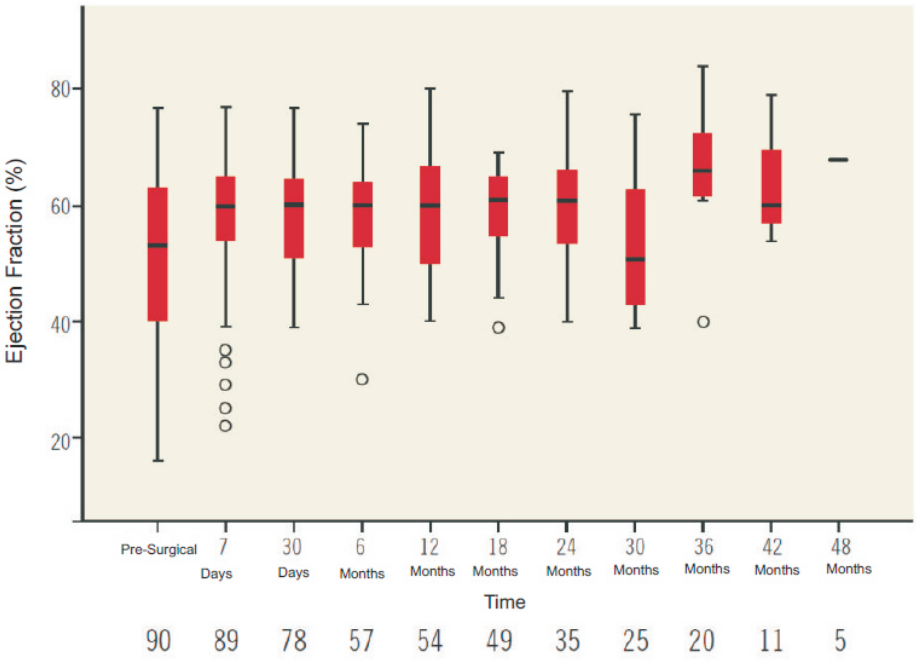


Figure 3: LV ejection fraction.

Pre-surgical x 7 days PS: p>0.05
Pre-surgical x 1 month PS: p=0.01
Pre-surgical x 6 months PS: p<0.0001
Pre-surgical x 12 months PS: p<0.0001
Pre-surgical x 18 months PS: p<0.0001
Pre-surgical x 24 months PS: p<0.0001
Pre-surgical x 30 months PS: p<0.0001
Pre-surgical x 36 months PS: p<0.0001
Pre-surgical x 42 months PS: p<0.0001

LV: left ventricle; PO: postoperative.

One case had a major vascular complication and there were two cases of a definitive pacemaker implant and two cases of stroke (Table 3).

TTable 3: Clinical results.

Variáveis	30 days	1 year
All-cause mortality	13.3%	37.3%
Acute stroke	2 (2.2%)	4 (4.4%)
Postoperative pacemaker	2 (2.2%)	3 (3.3%)
Acute bleeding	1 (1.1%)	1 (1.1%)
Acute vascular complications	1 (1.1%)	1 (1.1%)
Minor vascular complications	6 (6.6%)	6 (6.6%)
Postoperative dialysis	3 (3.3%)	3 (3.3%)

The functional class (NYHA) showed significantly improved with time, when compared to the pre-surgical level. After 24 months, almost all patients were in class I or II of the NYHA.

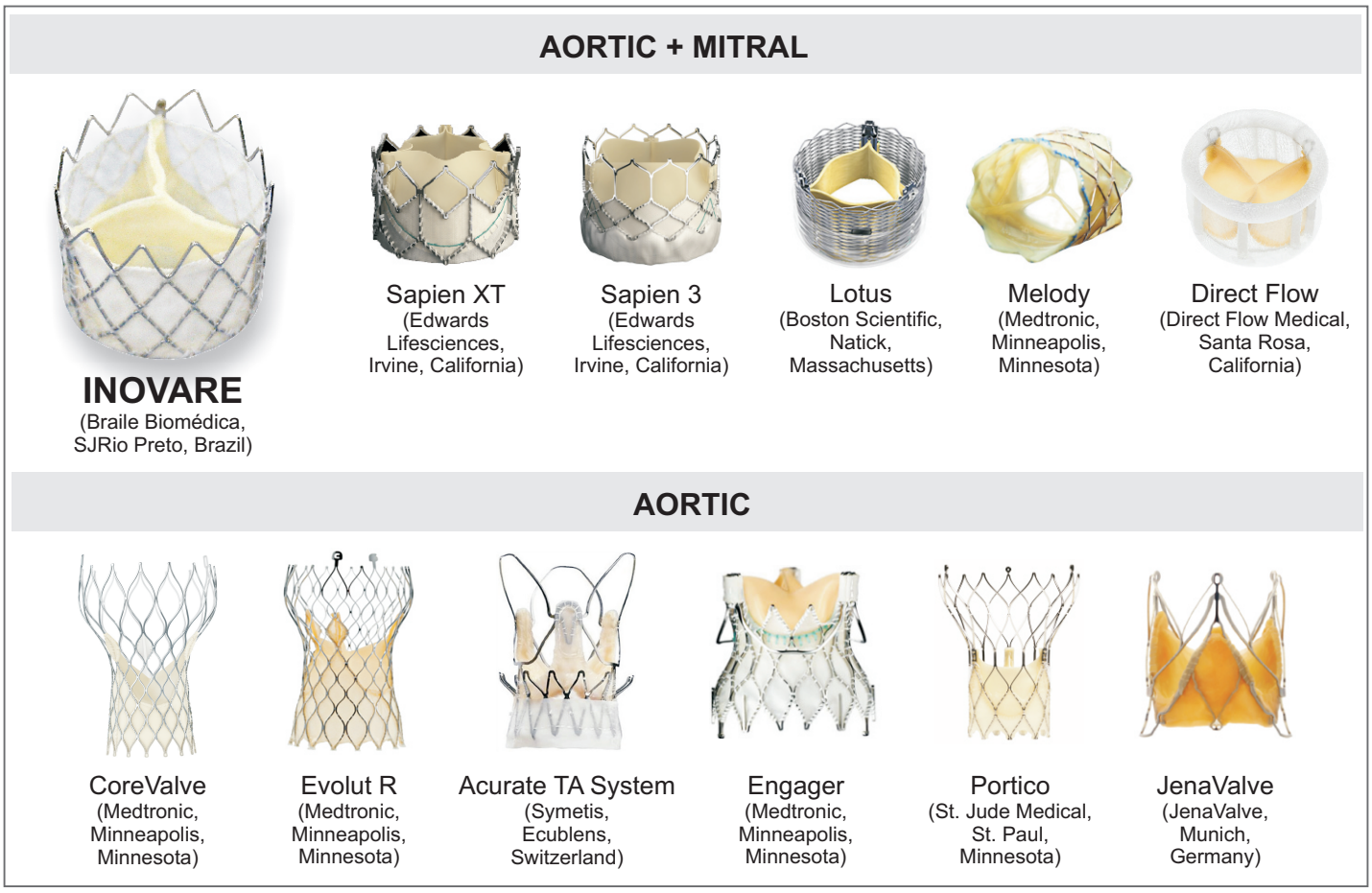
With a five-year follow-up, replacement of the aortic valve with the **INOVARE® Transcatheter Prosthesis** showed encouraging results, with significant structural and functional cardiac improvement.

Transcatheter Valve-in-Valve and Valve-in-Ring for Treating Aortic and Mitral Surgical Prosthetic Dysfunction

adapted from Paradis *et al.*, 2015[2]

In that second article, Paradis *et al.*[2] (2015) published a review on the *Journal of the American College of Cardiology (JACC)*, one of the most important international cardiology scientific publications.

The **INOVARE® Transcatheter Prosthesis** was highlighted, along with the main transcatheter prosthesis available in the global market, as viable for replacing degenerated bioprosthesis in aortic and mitral positions (Figure 4)[2].



adapted from Paradis *et al.*[2]

Figure 4: Transcatheter prosthesis for the valve-in-valve surgical technique.

COMMENTS

Considering that, despite the great benefits of the biological prosthesis, its durability is limited to around 15 years, depending on the patients' age and conditions. After this period, they should be replaced.

Currently, with the possibility of transcatheter intervention, we are able to implant a new valve inside the degenerated prosthesis (valve-in-valve), both in the aortic and mitral positions. This represents a new fact of great impact for the use of the biological prostheses, which have their durability extended for longer periods.

The study[2] showed a historical perspective review of the valve-in-valve transcatheter therapy, and addressed the technical challenges, the main risks, and the clinical results

Experimental Study and Early Clinical Application of a Sutureless Aortic Bioprosthesis

adapted from Gomes *et al.*, 2015[3]

Gomes *et al.*[3](2015) released in the *Brazilian Journal of Cardiovascular Surgery*, the results of the experimental evaluation results of the **INOVARE®** implanted via transaortic with extracorporeal circulation (ECC). The first clinical application of this technique with the device was also reported.

The authors[3] concluded that the transaortic implant with ECC of the **INOVARE®** valve was safe and effective, with reduced aortic and ECC clamping time, thus representing a new alternative to the conventional surgical procedure in patients with moderate to high surgical risk.

FINAL COMMENTS

In these three recently published studies, the **INOVARE® Transcatheter Prosthesis** was shown to be a safe and effective alternative for the treatment of valvar diseases, by minimally invasive implants, in patients for whom conventional surgery is not desired or is contraindicated.

REFERENCES

1. Gaia DF, Breda JR, Duarte Ferreira CB, Marcondes de Souza JA, Macedo MT, Gimenes MV, Couto A, Simonato M, Financi LF, Buffolo E, Palma JH. New Braile Inovare transcatheter aortic prosthesis: Clinical results and follow-up. EuroIntervention. 2015;11(6):682-9.

2. Paradis JM, Del Trigo M, Puri R, Rodés-Cabau J. Transcatheter valve-in-valve and valve-in-ring for treating aortic and mitral surgical prosthetic dysfunction. JACC. 2015;66(18):2019-37.

3. Gomes W, Leal JC, Jatene FB, Hossne Jr NA, Gabaldi R, Frazzato GB, Agreli G, Braile DM. BJCVS. 2015;30(5):515-9.

BRAILE BIOMÉDICA INDÚSTRIA, COMÉRCIO E REPRESENTAÇÕES LTDA
Pres. Juscelino K. de Oliveira Ave., 1505
CEP 15091-450 - São José do Rio Preto-SP - Brasil
Phone 55 17 2136-7000 | Fax 55 17 2136-7040
Service Customer 08007072050

www.braile.com.br