

# Initial Experience with Percutaneous Implantation of the Melody™ Valve in Brazil

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## ABSTRACT

**Background:** Transcatheter pulmonary valve implantation is an alternative for dysfunctional conduits. We report the first experience with the Melody™ valve implantation in Brazil. **Methods:** Patients with significant pulmonary stenosis or significant pulmonary insufficiency in conduits measuring 16 to 22 mm were enrolled. Standardized techniques were employed. The feasibility, safety and efficacy of this procedure were assessed. **Results:** From December 2013, ten patients (mean age and weight of 16.5 years and 49 kg, respectively) have undergone the procedure with a mean interval of  $11.9 \pm 8.6$  years since the last surgery. Pulmonary insufficiency was an indication for treatment in three patients, pulmonary stenosis in two, and mixed lesion in five. The Melody™ valve was successfully implanted in all cases. Mean right ventricular systolic pressure and right ventricle/left ventricle ratio decreased from  $49.2 \pm 15.9$  to  $35.8 \pm 5.7$  mmHg and from  $0.55 \pm 0.18$  to  $0.39 \pm 0.08$  mmHg ( $p < 0.01$  for both). Significant residual pulmonary stenosis or pulmonary insufficiency was not observed. One patient had a contained conduit tear requiring a covered stent and a second valve implantation. All patients were discharged within 72 hours. The valves were properly functioning in a mean follow-up of  $4.1 \pm 2.2$  months with no complications. **Conclusions:** Transcatheter Melody™ valve implantation was feasible, safe and effective in our environment and in line with previously published data. Although more patients and a longer follow-up are required, cost-effectiveness studies should be performed for possible incorporation in the Brazilian public health system.

**DESCRIPTORS:** Pulmonary valve stenosis. Pulmonary valve insufficiency. Tetralogy of Fallot. Prostheses and implants.

## RESUMO

### Experiência Inicial com o Implante Percutâneo da Válvula Melody® no Brasil

**Introdução:** O implante percutâneo da válvula pulmonar é uma alternativa para condutos com disfunção. Descrevemos aqui a primeira experiência com o implante da válvula Melody® no Brasil. **Métodos:** Foram selecionados pacientes com estenose ou insuficiência pulmonar significativa em condutos de 16 a 22 mm. Foram empregadas técnicas padronizadas. Factibilidade, segurança e eficácia desse procedimento foram avaliadas. **Resultados:** Desde dezembro de 2013, dez pacientes (média de idade e peso de 16,5 anos e 49 kg, respectivamente) foram submetidos ao procedimento com intervalo médio de  $11,9 \pm 8,6$  anos desde a última cirurgia. Insuficiência pulmonar foi indicação para o tratamento em três pacientes, estenose em dois e lesão mista em cinco. A válvula Melody® foi implantada com sucesso em todos os casos. A média da pressão sistólica do ventrículo direito e a relação ventrículo direito/ventrículo esquerdo diminuíram de  $49,2 \pm 15,9$  para  $35,8 \pm 5,7$  mmHg e de  $0,55 \pm 0,18$  para  $0,39 \pm 0,08$  mmHg ( $p < 0,01$  para ambos). Não observamos estenose e nem insuficiência pulmonar residual significativa. Um paciente teve extravasamento contido requerendo um stent coberto e um segundo implante valvular. Todos os pacientes receberam alta do hospital em 72 horas. As válvulas funcionaram adequadamente em um seguimento médio de  $4,1 \pm 2,2$  meses, sem complicações. **Conclusões:** O implante percutâneo da válvula Melody® foi factível, seguro e eficaz em nosso meio, e esteve de acordo com trabalhos previamente publicados. Apesar de mais pacientes e um maior tempo de seguimento serem necessários, estudos de custo-efetividade devem ser realizados para sua incorporação no sistema público de saúde brasileiro.

**DESCRIPTORIOS:** Estenose da valva pulmonar. Insuficiência da valva pulmonar. Tetralogia de Fallot. Próteses e implantes.

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Dysfunctions in the right ventricular outflow tract (RVOT) are common in the late postoperative period of connection surgeries between the right ventricle (RV) and pulmonary artery (PA).<sup>1</sup> In this context, pulmonary insufficiency (PI), especially when associated with pulmonary stenosis (PS), can result in progressive right-ventricular dilatation and dysfunction, exercise intolerance, potentially serious arrhythmias, and sudden death. Restoration of pulmonary valve function at an appropriate time can reverse this process, preserving or restoring ventricular function.<sup>2</sup> In general, valved conduits (for example, homograft's, valved ducts, bovine jugular vein, and bioprostheses) have a limited life span, requiring multiple reoperations, usually in less than ten years,<sup>3-6</sup> resulting in an accumulated incremental morbidity, especially considering the low age of the patients with these cardiac diseases. Percutaneous alternatives aiming to extend the life of RV-PA conduits included stenting, which relieved the obstruction, but entailed a complete PI, with its deleterious consequences on cardiovascular dynamics.<sup>7-9</sup>

Bonhoeffer et al.<sup>10</sup> were the first authors to report the percutaneous implantation of a valve in the pulmonary position, known as the Melody™ valve (Medtronic Inc., Minneapolis, United States). Hundreds of patients were treated by this method in Europe with excellent results,<sup>11</sup> which were later repeated in the United States.<sup>12</sup>

Despite the extensive documentation in the literature attesting to the safety and effectiveness with the use of this device,<sup>13-15</sup> the Melody™ valve was only approved by the Brazilian Health Surveillance Agency (Agência Nacional de Vigilância Sanitária – ANVISA) in February 2013. In this article, the initial Brazilian experience with percutaneous implantation of the Melody™ valve is described, with a preliminary assessment of its feasibility, safety, and efficacy.

## METHODS

### Study design and eligibility

This was a multicenter, prospective, longitudinal, observational, descriptive study of a cohort of patients who underwent percutaneous implantation of the Melody™ valve in the pulmonary position, in reference centers for interventional cardiology in Brazil, after approval by the relevant research ethics committees.

Inclusion criteria are specified in the Box. Patients surgically corrected with trans-annular flaps in RVOT, with dimensions > 22 mm without an appropriate anchorage point for prosthesis release, were excluded.

Demographic, clinical, and pre- and post-procedural hemodynamic data were prospectively collected.

### The Melody™ valve

Manufactured from a bovine jugular vein segmental patch with 18 mm diameter, the valve is sutured and mounted inside the silver-iridium Cheatham-Platinum (CP) stent, 34 mm long, and with 8 zigs of circumferential arrangement (NuMED Inc., Hopkinton, United States). This device is released by an Ensemble™ delivery system specifically designed for this purpose (Medtronic Inc., Minneapolis, USA United States). This system consists of a balloon-in-balloon catheter (BIB, NuMED Inc.) measuring 18, 20, or 22 mm diameter, and mounted in a retractable jacket. The system has a 22-F profile and, at its distal end, there is a blue plastic tip, which facilitates its passage through the skin and RVOT. A retractable plastic jacket covers the valved stent and, when retracted, allows for performing a control angiogram through its side arm (Figure 1).

### BOX

#### Indication criteria for percutaneous implantation of the Melody™ valve

Dysfunction of the right ventricle pulmonary artery conduit, since the right ventricular outflow tract has a minimum diameter of 16 mm and a maximum diameter of 22 mm in the presence of any of the findings by transthoracic echocardiography.

1. Patients with functional class II, III or IV, moderate or severe pulmonary insufficiency, and/or mean right ventricular outflow tract gradient  $\geq 35$  mmHg.

2. Patients with functional class I: severe pulmonary insufficiency with significant right ventricle dilation or dysfunction and/or mean right ventricular outflow tract gradient  $\geq 40$  mmHg.



**Figure 1** – Left, the Melody™ valve open, showing the arrangement of bovine jugular vein sutured inside the stent. Right, the Ensemble™ system, already with the prosthesis fitted, in its various stages for implantation.

## Procedure

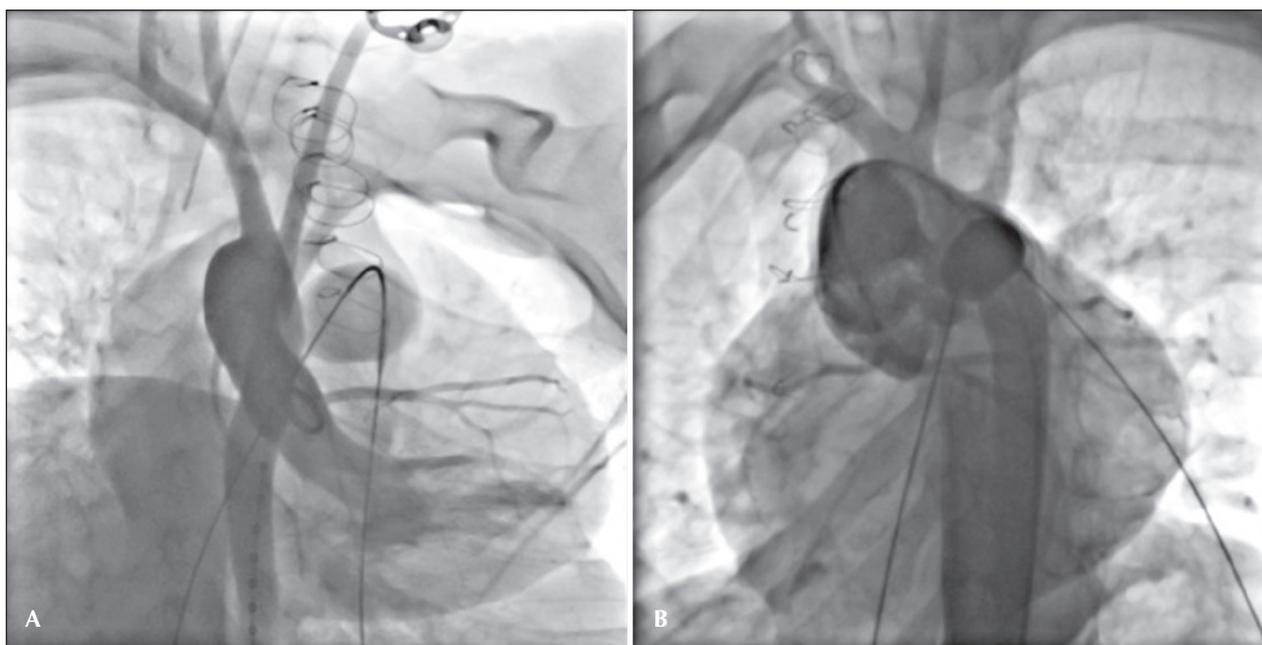
The technique employed for implanting the Melody™ valve was similar to those previously described.<sup>12</sup> The femoral venous approach was used in all patients. The vessel was previously prepared using two Perclose ProGlide™ (Abbott, Inc., Illinois, United States) percutaneous sutures. A high-profile DrySeal (Gore, Newark, United States) sheath (22 F, 28 cm long) was positioned to allow for multiple intravenous procedures through venous access. The arterial access was used for angiography procedures at the aortic root, or for selective coronary angiographies for defining coronary compression during a test inflation of the balloon at RVOT. Intravenous heparin was administered at a dose of 100 IU/kg and antibiotic prophylaxis was performed with cefazolin for 24 hours.

Right-chamber cardiac catheterization was followed by a RV and/or pulmonary artery angiogram in conventional projections. The length and diameter of the implant site were measured. An extra-hard guide wire (Lunderquist™; Cook Inc., Bloomington, United States) was positioned distally into PA, in order to allow for the coronary compression test, conduit preparation with stents, progression of the Ensemble™ system, and post-dilation, when necessary.

The conduit was previously dilated with progressive-diameter balloons. The initial balloon was chosen so that the smallest diameter had 80% of the conduit diameter. The balloons' diameter was increased, so that

the final balloon diameter was similar to the original diameter of the conduit, not exceeding 130-140% of this diameter. The coronary compression test was conducted by means of an angiogram of the ascending aorta, in several projections (Figure 2), while simultaneously inflating the larger-diameter balloon into the conduit. Coronary-flow reductions or a coronary proximity < 5 mm with respect to the conduit were considered as exclusion factors for the procedure.

The implant area was prepared with stent implantation, with dilation to a diameter close to that of the original conduit. Common stents Palmaz 4014 (Cordis Inc., Bridgewater, United States) or CP 8-zig of 34, 39, or 45 mm, mounted on BIB Max LD™ (NuMED Inc.) or Cristal (Balt, Montmorency, France) balloons were chosen. In cases where signs of dissection and/or contrast extravasation were observed after pre-dilation, a CP covered stent (NuMED Inc.) was used, instead of regular stents, as well as in cases with extensive conduit calcification. The conduit preparation was performed using long 14 F Mullins sheaths inside the DrySeal sheath. In those cases of valve implantation inside a bioprosthesis, no previous preparation was done.<sup>13</sup> In the case of stent elastic recoil > 2 mm, or of the presence of residual waists, a high-pressure Atlas balloon (Bard, Inc., Covington, United States) was used to a full expansion of the stent within the conduit. After each step in conduit preparation (pre-dilation with balloons, stent implantation, and post-dilation), control angiograms were performed.



**Figure 2** – Coronary balloon compression test. There was no detrimental effect to the left-coronary-artery filling in both tests. In B, an abnormality in the origin of coronary arteries, with a single ostium with a non-coronary sinus origin.

In general, the Ensemble™ system diameter was equal or up to 2 mm larger than the original conduit diameter. The steps for mounting the valve prosthesis in its delivery system were performed as recommended by the manufacturer, with special attention given to the proper orientation of the prosthesis in the balloon and in relation to the blood flow direction.

The DrySeal sheath was replaced by the Ensemble™, and the prosthesis was positioned within the previously prepared conduit, avoiding protrusion towards the pulmonary-artery bifurcation or the muscular portion of RVOT. When necessary, control angiograms were performed through the Ensemble™ side arm. After the retraction of the jacket into the Ensemble™ system, the BIB balloon was sequentially inflated, in order to release the valved stent. In cases of a short implantation zone (< 40 mm), especially if accompanied by a full PI, the conduit preparation and the Melody™ valve release were performed under a quick ventricular pacing with a RV-positioned pacemaker wire.

New pressure measurements and angiograms were obtained for evaluation of the result. According to availability, one intracardiac echocardiogram was obtained after implantation.

### Follow-up

Patients were observed for 72 hours in the hospital. A transthoracic echocardiogram (TTE) was performed before hospital discharge, as well as a chest X-ray and an electrocardiogram. All patients were instructed to use acetylsalicylic acid (ASA) 3 to 5 mg/kg/day (up to 100 mg/day) for 6 months. Outpatient follow-up was scheduled to return in 1, 6, and 12 months after the procedure. Patients were also instructed as to bacterial endocarditis prophylaxis for life.

### Definitions and variables for evaluation of outcomes

The feasibility of the procedure was defined by a successful implantation, with stent release for conduit preparation and prosthesis release with a proper final positioning.

The safety was assessed by the incidence of procedure- or prosthesis-related complications: mortality, conduit rupture, pulmonary-vessel perforations, a need for blood products, endovascular injury, impairment of pulmonary arterial flow, device embolization or fracture requiring reintervention, serious cardiac arrhythmias, and each and every complication putting the life or physical integrity of the patient at risk. The efficacy was assessed by the determination of a peak-to-peak pressure gradient < 25 mmHg of systemic blood pressure, with RV systolic pressure < 50% of systemic blood pressure, besides PI absence, or with a trivial residual presence of PI.

### Statistical analysis

Qualitative variables were expressed as absolute numbers and percentages, and quantitative variables were expressed as means and standard deviations, or medians and interquartile ranges, according to sample distribution. Student's *t*-test was used to evaluate changes in quantitative variables before and after the procedure. *P*-values < 0.05 were considered significant.

## RESULTS

### Patients

From December 2013 to June 2014, ten patients (seven men) with a median age of 16.5 years (11-31 years) and weighing 49 kg (32-85 kg) underwent implantation of the Melody™ valve (Table 1). Most patients (60%) had an initial diagnosis of tetralogy of Fallot, or its variants. Six patients underwent two or more previous surgeries, and the mean time since the last surgery was  $11.9 \pm 8.6$  years. One patient was in functional class III, four in functional class II, and the others in functional class I (50%). The patient in functional class III showed significant right ventricular dysfunction, QRS = 200 ms, and frequent episodes of non-sustained ventricular tachycardia in the 24 hours Holter monitor. The remaining patients showed good biventricular function without changes in cardiac rhythm (Table 1).

Five patients had a homograft in the pulmonary position, all  $\geq 16$  mm. The remaining patients had the following types of conduit: Contegra™ bovine jugular vein of 16 and 17 mm (Medtronic Inc., Minneapolis, United States) in two patients, one corrugated pericardium conduit of 18 mm, and a Epic™ bioprosthesis of 21 mm (St. Jude Medical, Inc., St. Paul, United States).

### Implantation success and technical aspects of the procedure

All patients, except one, underwent conduit preparation with stent, and Melody™ valves were properly implanted in the intended location. In one patient, two stents were necessary, due to an unequal expansion of the first stent and to the greater length of the conduit (homograft) to be treated. In another patient, a previous implantation with a covered CP stent was chosen, due to the extreme calcification associated to a severe conduit stenosis area.

In patients presenting lesions with prevalence of stenosis, or in mixed lesions (PI and PS), the relationship between right and left ventricular systolic pressures (RVSP/LVSP) was  $0.65 \pm 0.10$ , and the peak-to-peak gradient through the conduit was  $36.9 \pm 9.0$  mmHg. The original conduit mean diameter was  $19.4 \pm 2.4$  mm, and the mean for the smaller diameter found was  $15.5 \pm 3.6$  mm. One patient had bilateral pulmonary

**TABLE 1**  
**Clinical and laboratory characteristics**  
**before valve implantation**

	<b>n = 10</b>
Male gender	7
Age, years	16.5 (11-31)
Weight, kg	49 (32-85)
Underlying diagnosis	
Tetralogy of Fallot	4
Pulmonary atresia with ventricular septal communication	1
Pulmonary atresia with intact ventricular septum	2
Pulmonary stenosis	1
Double outlet right ventricle	1
Common arterial trunk	1
Type of conduit	
Homograft	5
Corrugated pericardial conduit	1
Contegra™	2
Bioprosthesis	1
Native output tract	1
Conduit diameter at the time of implantation, mm	15.5 (10-22)
Number of prior surgeries	2 (1-3)
Primary indication for valve implantation	
Stenosis	2
Failure	3
Mixed	5
Mean for maximum gradient in the conduit on echocardiography, mmHg	49.2 ± 20.2
Pulmonary insufficiency on echocardiography	
Absent	2
Mild	1
Moderate	1
Severe	6
MRI right ventricular ejection fraction,%	
Right-ventricular end-systolic volume (indexed), mL	57 ± 5
Right-ventricular end-diastolic volume (indexed), mL	49.2 ± 11.9

artery stenosis (Figure 3), and two others only exhibited stenosis in left PA (LPA). This entire group was successfully treated with stenting prior to valve implantation. The conduit pre-dilation was performed with balloons with a mean final diameter of  $20.8 \pm 2.9$  mm.

The mean diameter of the balloon used for pretreatment with stent was  $21.6 \pm 2.2$  mm, and the mean of the minor diameter of the stent was  $20.1 \pm 1.8$  mm. The stent was post-dilated with a high-pressure Atlas balloon in three patients (12, 16, and 20 atm, respectively), because of a persistent residual waist. The patient not subjected to the preparation had a calcified bioprosthesis in a semi-open position (Figure 4).

One patient, with tetralogy of Fallot and absence of right PA, was subjected to an off-label LPA implantation with the Melody™ valve. An important failure of the monocuspid device used in the RVOT transannular patch and a mild LPA stenosis (initial diameter, 16 mm) were observed, and the patient was considered as having a favorable anatomy for implantation of a conventional stent, which later served as an anchorage zone and, therefore, as a “conduit” to valve implantation.

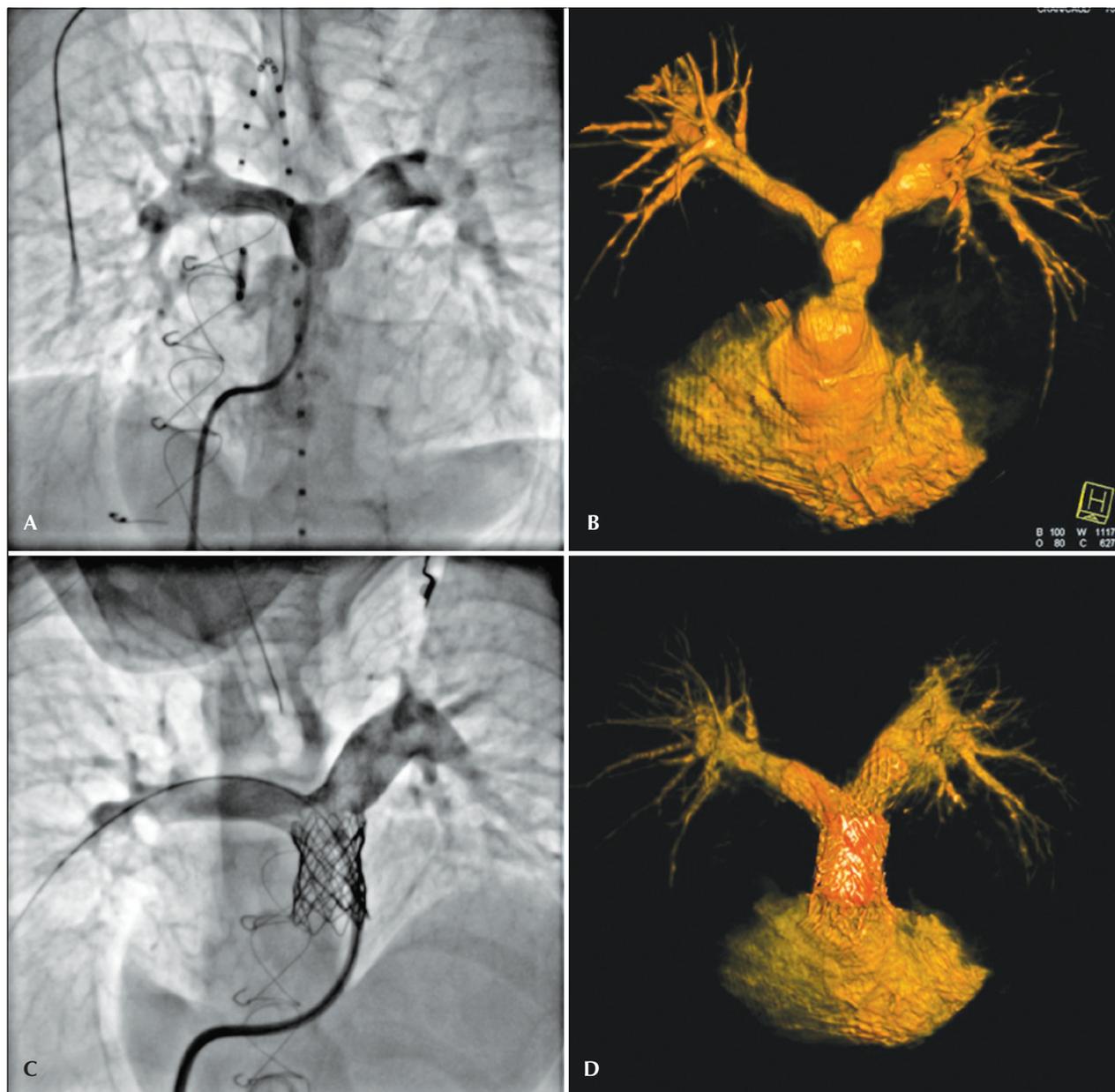
The Melody™ prosthesis was mounted on an 18-mm Ensemble™ system in a patient implanted with a stenotic Contegra™ (17 mm); and on an 20 mm Ensemble™ in two other patients – one of them implanted with an Epic™ bioprosthesis of 21 mm (internal diameter, 18 mm). In the remaining patients (70%), 22 mm Ensemble™ systems were used. The mean ratio between the diameter of the Ensemble™ system used and the conduit original diameter was 1.1 (0.95-1.35). No modification of the delivery system or of the prosthesis assembling technique was used.

### Efficacy

A significant reduction, in terms of post-treatment conduit obstruction, with the use of the Melody™ valve (Table 2) occurred. The PI detected by the control angiogram was not greater than trivial in any of the patients, a fact proven by the intracardiac echocardiogram performed in six patients. No post-implantation change in valve shape or performance, nor the occurrence of paravalvar leakage, was detected.

### Safety

A severe adverse event was observed in this cohort. After implantation, a patient with a homograft exhibiting significant calcification presented a contained extravasation of contrast in the distal portion of the conduit (Figure 5). No associated hemodynamic instability was noted. One covered CP stent was implanted, over-riding the implanted prosthesis, with immediate occlusion of the extravasation site, followed by implantation of a second Melody™ valve. This patient was transferred to the intensive care unit (ICU) after the procedure for monitoring, and was extubated within hours. The remaining patients were referred to their room after anesthetic recovery. In another patient, a Max™ LD balloon ruptured during conduit preparation. The rupture was circular, and the distal fragment of the balloon was rescued, using a loop catheter. No patient exhibited clinical or electrocardiographic changes consistent with coronary compression after treatment. There were no deaths and no need for an immediate surgical intervention. In two patients, during hospitalization a minor bleeding from the puncture site was observed, without formation of local hematoma and with no need for blood transfusions. All patients were discharged within 72 hours after treatment.



**Figure 3** – Conventional angiography studies in left anterior oblique projection with cranial angulation in A and C; and rotational angiography studies with three-dimensional reconstruction in B and D, in basal situation (A and B) and, after treatment of pulmonary arteries with stenting and a Melody™ valve implantation (C and D).

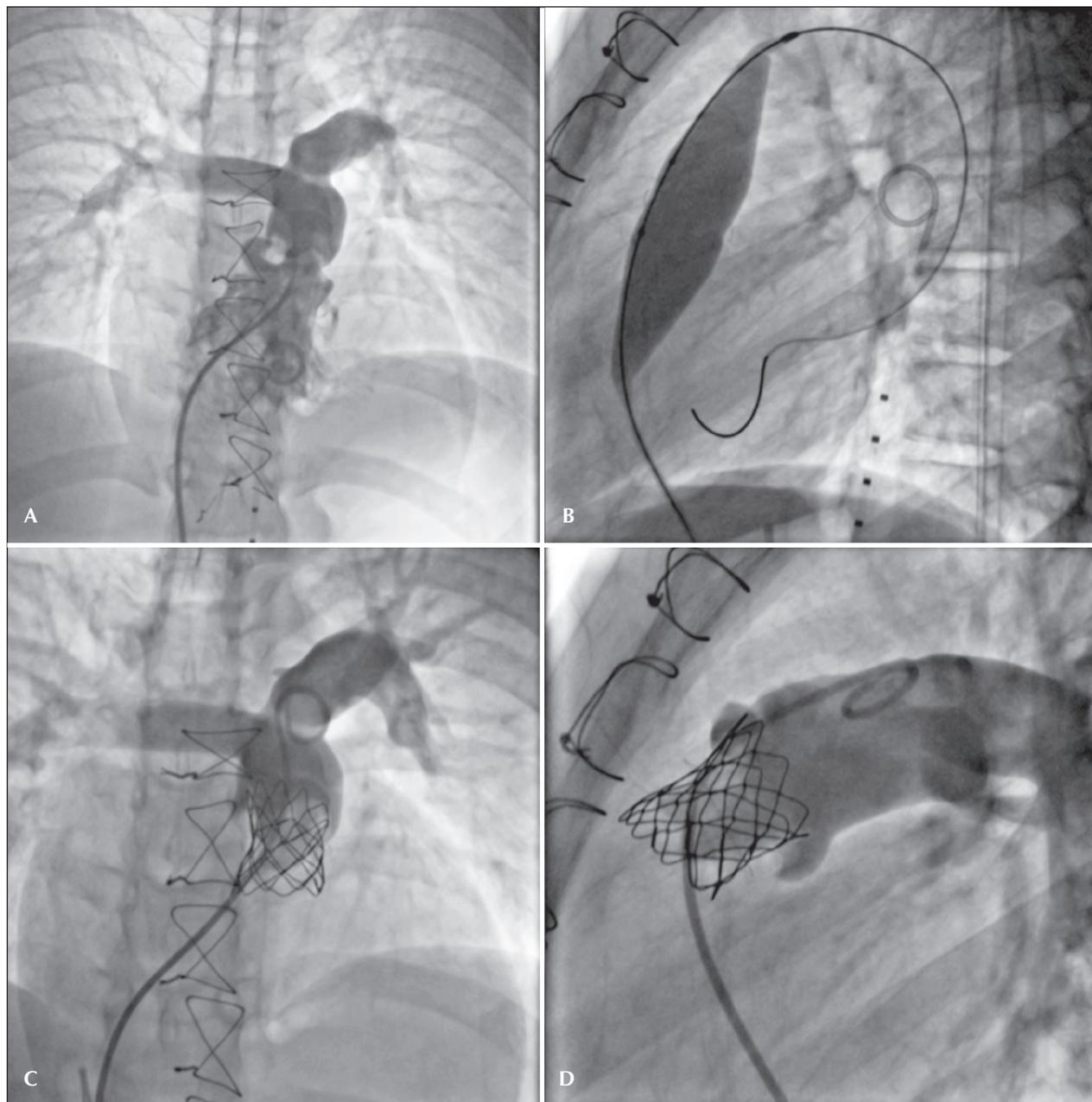
### Follow-up

All patients were followed as outpatients, with a mean of  $4.1 \pm 2.2$  months. No patient required re-intervention. One month after treatment, one patient (previously in functional class III) reported significant improvement in tolerance to daily activities. All treated patients noticed some improvement. TTEs performed 24 hours and 30 days after the procedure revealed that all patients presented mean gradients  $< 25$  mmHg through RVOT. In seven patients, no residual PI was observed;

and in two, PI was considered trivial. On chest radiography, no Melody™ valve fractures were noticed, and no clinical or echocardiographic signs of thrombosis or endocarditis were observed. There were no late complications associated with the venous access used.

### DISCUSSION

This study described the first Brazilian experience in Melody™ valve implantation. Its importance lies not only in its originality in this environment, but also in its



**Figure 4** – Melody™ valve implantation in patients carrying a bioprosthesis. In B, preparation of the implant site with ultra-high-pressure balloon, with a small residual central waist. In C and D, the final angiographic result in two orthogonal projections.

potential application for the future assimilation of this technology by the public health system. To this end, its feasibility, safety, and efficacy must be documented. This device comes at an opportune time, since, in this environment, there is a growing population with congenital heart disease in the late post-operative period of RV-PA conduits. In this small case series, nine of the ten treated patients had inclusion criteria similar to those classically used.<sup>14</sup> In the only off-label case, the anatomical substrate favored the realization of an LPA valve implantation, rather than in its commonly

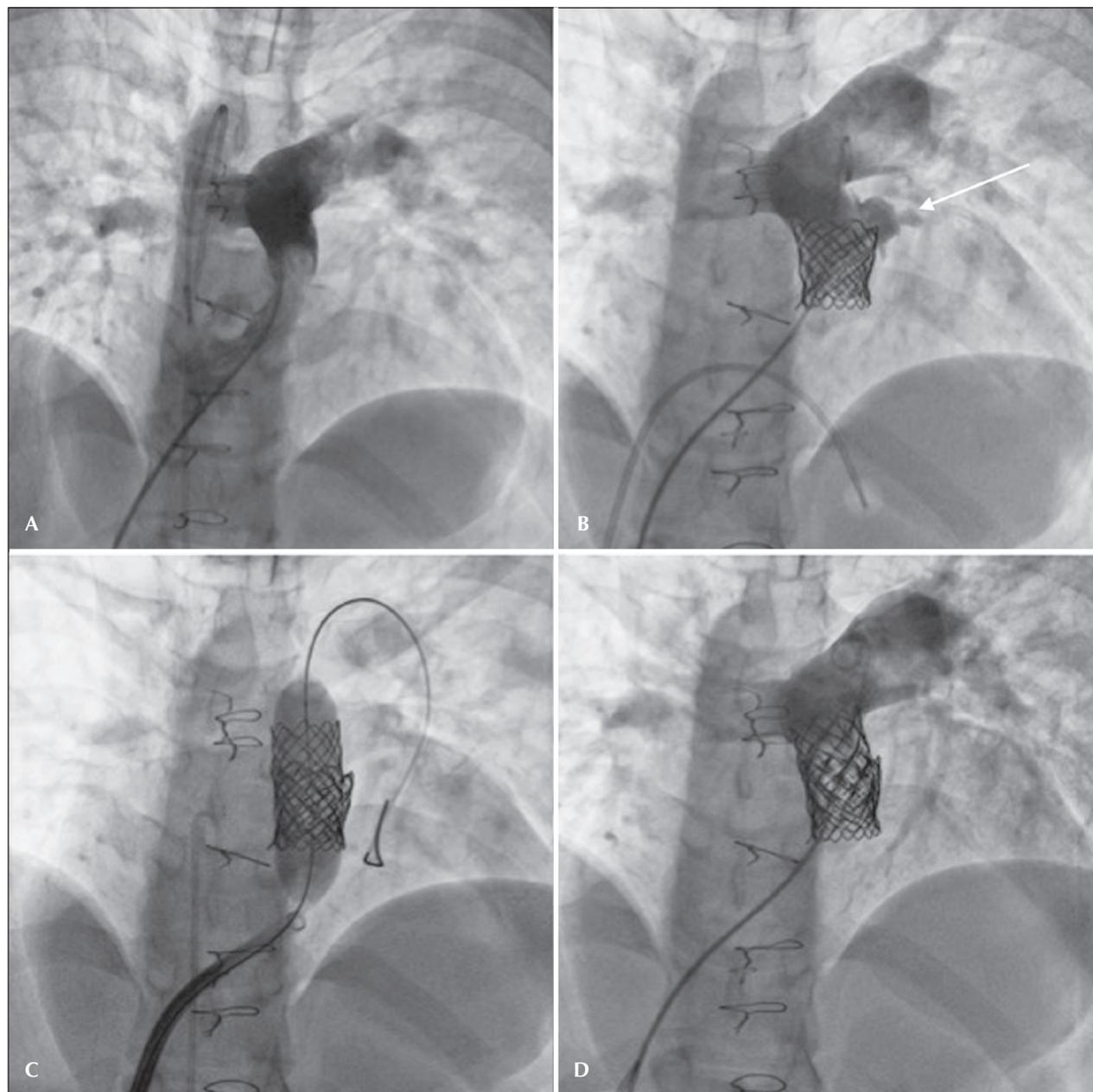
used place. In the literature, there are other reports of Melody™ valve implantation in pulmonary arteries of patients with complex anatomy, resulting in similar outcomes to those observed here.<sup>16,17</sup>

#### **Feasibility and technical aspects**

The procedure was successfully completed in all patients. Percutaneous implantation of the Melody™ valve proved to be an extremely labor-intensive task, requiring high technical differentiation. Should have a

**TABLE 2**  
**Immediate hemodynamic results**

	Basal value	Basal value	Post-implantation value	p-value
Right-ventricular systolic pressure, mmHg	49.2 ± 15.9	49.2 ± 15.9	35.8 ± 5.7	0.008
Right-ventricular/left ventricular pressure ratio	0.55 ± 0.18	0.55 ± 0.18	0.39 ± 0.08	0.002
Right-ventricle-pulmonary artery gradient, mmHg	25.1 ± 17.9	25.1 ± 17.9	7.0 ± 6.7	0.001



**Figure 5** – Contained leakage from the conduit after implantation of a Melody™ valve, identified by the white arrow (B). In C and D, the final angiographic result in orthogonal projections, after the implantation of a covered stent and a second Melody™ valve.

strong background in structural and congenital heart disease; moreover, they must be familiar with a wide

range of materials for percutaneous intervention in these diseases. Even in the hands of experienced surgeons,

the learning curve has a recognized impact on the progressive improvement of results.<sup>18</sup>

The smallest patient in our sample was 11 years old and weighed 32 kg; nevertheless, an American study has illustrated the feasibility of the procedure in patients weighing less than 30 kg, with five patients weighing less than 18 kg.<sup>19</sup> However, these authors observed a higher incidence of vascular complications in this subgroup. However, such a vascular access limitation can be overcome, even with still smaller patients, through the use of a periventricular access, as already described in the literature for a patient weighing 12 kg.<sup>20</sup>

The most labor-intensive step was not the Melody™ valve implantation itself, but the conduit preparation. The preparation of the conduit with stents dissipates the vector forces and the mechanical stress imposed on the Melody™ valve, reducing the incidence of fractures in the patients' follow-up.<sup>15</sup> These technical aspects are discussed below.

### **Efficacy**

The immediate hemodynamic improvement observed, with significant reduction in the degree of stenosis within the conduit and with pulmonary valve competence restoration, was similar to that found by European and American groups.<sup>11,12,14,21</sup> Gradients > 30 mmHg immediately after implantation are associated with lower durability of the valve and with less reintervention-free survival.<sup>13</sup> This observation justifies a more aggressive preparation of the conduit with the implantation of multiple stents, and the abolition of residual waists and gradients.

The follow-up is still in its early stages, but clinical and echocardiographic data obtained one month after the procedure confirmed the maintenance of valve competence in all treated patients, as well as the absence of residual obstruction. In the first evaluation after a month, all patients reported some clinical improvement, with less fatigue when exercising. Subjectively supporting these patient reports, some studies have shown that reduction of RVSP and/or improvement of volume overload after valvular treatment are associated with improved RV and septal strain,<sup>22</sup> culminating in an improved global biventricular function.<sup>23-25</sup>

This preliminary study did not compare the percutaneous versus surgical method, and the percutaneous treatment of cost-effectiveness was not analyzed. However, there are studies published in the literature pointing to percutaneous treatment as the best option in selected cases.<sup>26-29</sup>

### **Safety**

A major event in one patient was observed. There was a contained conduit extravasation, without hemodynamic consequences or need for transfusions. The

covered CP stent implantation resulted in an occlusion of the extravasation site. Such complication underscores the need to have covered stents of various lengths available in the room.

Together with a potential coronary compression, conduit rupture is the most severe complication that can occur in this type of procedure. However, the rupture of the conduit is more unpredictable; and, to avoid this complication some measures are recommended, such as a progressive dilation of the conduit and a serial angiographic study after each dilation and preparation with stents. The underlying rationale is the possibility of creating a lesion of lesser magnitude in the conduit wall, due to a more conservative and progressive dilatation, with less probability of a rupture that would result in extravasation into the mediastinum and in hemodynamic instability. The fibrosis adjacent to the conduit, secondary to previous surgeries, helps to minimize the occurrence of a catastrophic rupture.

In this regard, McElhinney et al.<sup>30</sup> studied the effects of the use of ultra-high pressure balloons compared to standard balloons in the dilation of these conduits. It was observed that the use of ultra-high pressure balloons results in lower residual gradients and in a larger diameter of the dilated site, in spite of the higher occurrence of dissection and small leakages. Such lesions caused by the balloons can be classified as therapeutic dissections (if < 3 mm), and contained and non-contained extravasations; the actual rupture with conduit avulsion is a very rare event.<sup>30</sup> In the American experience, in one patient the rupture of the conduit resulted in surgery.<sup>16</sup> In this same study, six patients were excluded because of the possibility of coronary compression. Although the authors have not experienced this possibility, this step of the procedure should merit special attention,<sup>7,12</sup> mainly due to the frequent changes in the origin and course of the coronary arteries associated with the presence of tetralogy of Fallot, and the transposition of the great arteries, among others, and also variations in the spatial location of the aorta and of the conduit.<sup>31-33</sup> Conversely, the occurrence of coronary artery compression in patients with bioprosthesis in the pulmonary position is unlikely, due to the rigidity of its metal ring. Even in this scenario, the compression test is mandatory.

Other serious complications, such as valve embolization, occlusion of pulmonary arteries, and distal perforation of pulmonary branches, were described in previous studies,<sup>11,12,14,18</sup> but are potentially preventable with the use of an impeccable technique and the accumulation of experience. In general, the percutaneous implantation of the Melody™ valve is a safe procedure, with low rates of severe associated complications or need for surgical intervention, as seen in this study.

One of the problems described in the follow-up was the occurrence of fractures of metal struts of the

CP stent, which surrounds the Melody™ valve, with rates of approximately 25% on a median follow-up of 13 months.<sup>16</sup> Several factors are associated with fractures, many of which are interconnected. Conduit blockage severity was associated with a decreased fracture-free survival, and also with a larger pressure gradient through the RVOT before and after valve implantation. Other predisposing factors were related to the vicinity where the prosthesis was implanted, including lower patient age, anterior chest-wall proximity, and signs of extrinsic vascular compression of the prosthesis.<sup>13</sup> Conversely, patients with bioprostheses are at lower risk for fractures in the metal mesh overtime.<sup>15,22</sup> The metal ring of the bioprosthesis probably acts as a shield against opposing vector forces, protecting the implant.

Despite the progressive increase in the prevalence of fractures over time a finding observed in several series,<sup>13-15,19,34-37</sup> less than half of these patients require reintervention.<sup>15</sup> It is estimated that about three years after implantation, approximately 85% of patients are free of new procedures.<sup>14-16</sup> Factors associated with an increased risk of reintervention were the same as those identified for an increased risk of fractures. The cases of prosthesis dysfunction can be safely and effectively treated with implantation of a new prosthesis (valve-in-valve), generally making the surgery unnecessary.<sup>13,14,35</sup> The present study did not observe the presence of fractures, probably due to the short follow-up time.

Recently, cases of late occurrence of Melody™ valve endocarditis were described.<sup>38</sup> Fever of unknown origin and a quick valvular function deterioration are clinical signs suggestive of the diagnosis. About 50% of these patients respond well to a long-term systemic antibiotic therapy; however, some patients require surgery for treatment. Apparently, there are no well-defined risk factors, but most patients with endocarditis were male, had previous episodes of endocarditis before implantation, and were intravenous drug users. In these scenarios, the implant should probably be contraindicated. Obviously, endocarditis prophylaxis should be recommended, as in conventional situations.

## CONCLUSIONS

In this preliminary study, percutaneous implantation of the Melody™ valve for restoration of pulmonary function in selected patients was feasible, safe, and effective in the short term. As there is extensive experience with this type of procedure in Europe and North America, it is speculated that the occurrence of potential adverse events may be even lower in the authors' practice, due to the neutralization of well-established risk factors. However, a larger number of patients and a longer follow-up time are needed for a better understanding of the durability of the implant and the incidence of complications in this environment.

## CONFLICTS OF INTEREST

Carlos A. C. Pedra occasionally receives medical fees from Medtronic Co. for lecturing at conferences and related events. John P. Cheatham is a consultant for Medtronic Co. and has received honoraria to work as tutor in the first five cases performed in this study.

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