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Special Article

Transcatheter pulmonary valve implantation. Clinical treatment protocol and accreditation requirements for centers and interventionists in Brazil

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ABSTRACT

Transcatheter pulmonary valve implantation (TPVI) has evolved significantly since its introduction in the early 2000s. Currently, this technique is a safe and effective option for the treatment of severe valve dysfunction (stenosis and/or regurgitation) in bioprostheses or surgical conduits in pulmonary position, in several centers worldwide. In Brazil, the initial results with this procedure in reference centers were similar to those observed in the overall experience. TPVI was proven to be feasible, safe, and effective in trained hands in Brazil. However, prior to the widespread application of this technique to other centers in this country, it was necessary to establish some criteria for patient selection, implantation technique, and clinical follow-up, as well as for the training and accreditation of new interventionists and centers. The guidelines described here were determined by a group of experts with well-known experience in congenital heart disease and TPVI, and were referred to the *Conselho Federal de Medicina* (CFM, portuguese for Federal Council of Medicine). Representatives of the different medical societies were involved in the creation of this document, including the *Sociedade Brasileira de Cardiologia* (SBC, portuguese for Brazilian Society of Cardiology), the *Sociedade Brasileira de Hemodinâmica e Cardiologia Invasiva* (SBHCI, portuguese for Brazilian Society of Hemodynamics and Invasive Cardiology), and the *Sociedade Brasileira de Cirurgia Cardiovascular* (SBCCV, portuguese for Brazilian Society of Cardiovascular Surgery). The authors believe that strict adherence to the recommendations contained in this official document is crucial for patient safety and for optimal results to be achieved in both the short and long term. Once consolidated in Brazil, TPVI will open doors for the introduction of new valve therapies in congenital cardiopathies.

Implante transcateter da valva pulmonar. Protocolo clínico de tratamento e requisitos para credenciamento de centros e operadores no Brasil

Palavras-chave:
Diretrizes para o planejamento em saúde
Valva pulmonar
Cateterismo cardíaco

RESUMO

O implante transcateter da valva pulmonar (ITVP) evoluiu significativamente desde sua introdução, no início dos anos 2000. Atualmente, esta técnica é uma opção segura e eficaz para o tratamento das disfunções valvares graves (estenose e/ou insuficiência) em biopróteses ou condutos cirúrgicos em posição pulmonar, em vários centros do mundo. No Brasil, os resultados iniciais com este procedimento em centros de referência foram similares àqueles observados na experiência global. O ITVP tem se demonstrado factível, seguro e eficaz em mãos treinadas na nossa realidade. Porém, antes da aplicação disseminada desta técnica em outros centros em nosso país, houve a necessidade de se estabelecerem alguns critérios para a seleção do paciente, a técnica de implante e o seguimento clínico, assim como para o treinamento e o credenciamento de novos operadores e centros. As orientações aqui descritas foram determinadas por um grupo de especialistas com experiência renomada em cardiopatias congênitas e ITVP, tendo sido encaminhadas ao Conselho Federal de Medicina (CFM). Representantes das diferentes sociedades médicas foram envolvidas na preparação deste documento, incluindo a Sociedade Brasileira de Cardiologia

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(SBC), a Sociedade Brasileira de Hemodinâmica e Cardiologia Invasiva (SBHCI) e a Sociedade Brasileira de Cirurgia Cardiovascular (SBCCV). Acreditamos que a rígida aderência às recomendações listadas neste documento oficial seja crucial para a segurança do paciente e para que ótimos resultados sejam alcançados imediatamente e a longo prazo. Uma vez consolidado em nosso meio, o ITVP abrirá caminho para a introdução de novas terapias valvares em cardiopatias congênitas.

Introduction

Right ventricle (RV) outflow tract dysfunctions are frequently present in the late postoperative period of surgeries connecting the RV with the pulmonary artery (RV-PA) in patients with tetralogy of Fallot, pulmonary atresia, truncus arteriosus, or any other congenital heart disease in which pulmonary flow should be anatomically restored.[1] In this context, pulmonary insufficiency and, especially, its association with pulmonary stenosis (mixed pulmonary valve disease) may result in progressive right ventricular dilatation and dysfunction, exercise intolerance, potentially severe arrhythmias, and sudden death. Pulmonary valve function restoration at an appropriate time may reverse this process, restoring ventricular function and improving symptoms.[2,3]

There are several surgical options and techniques to treat pulmonary valve insufficiency, including the use of homografts from cadavers, synthetic valves, bovine jugular vein grafts, or a bioprosthetic valve implanted directly into the RV outflow tract. However, over time, all these options start showing varying degrees of dysfunction, characterized by stenosis, accompanied or not by regurgitation. It has been estimated that the probability of being free of conduit replacement in 10 years is only 50%, with even less favorable figures in young children.[4]

The group led by Bonhoeffer was the first to develop a transcatheter pulmonary valve, later renamed as the Melody® valve (Medtronic Inc., Minneapolis, USA).[5] After this initial report, hundreds of patients were treated in Europe, with excellent results;[5] later, these results were also observed in the United States,[6] culminating in the approval of transcatheter pulmonary valve implantation (TPVI) by the Food and Drug Administration (FDA) in 2010, within the humanitarian device exemption (HDE) regime.[7]

In 2011, the American Heart Association (AHA) issued a guideline for interventions in congenital heart disease,[8] in which the recommendation for TPVI was classified as IIa (Level of Evidence B), stating that "the transcatheter pulmonary valve implantation is indicated in patients with RV-PA conduit with moderate to severe stenosis or pulmonary insufficiency, considering the pre-established inclusion/exclusion criteria." In January 2015, the FDA definitively approved the commercialization and clinical use of the Melody® valve.

The safety and efficacy of this valve have been widely documented in the international literature.[9-15] In Brazil, the Melody® valve was approved for clinical use by the *Agência Nacional de Vigilância Sanitária* (ANVISA, portuguese for National Agency of Sanitary Surveillance) in February 2013 and the initial experience with this device, published in 2014, showed results that were similar to those previously published. In the national series, therapeutic success was obtained in all the first ten patients, with no severe complications in a short-term clinical follow-up.[16]

Botrel et al. published in the *Revista Brasileira de Cardiologia Invasiva* a systematic review of the literature on transcatheter pulmonary valve implantation involving 15 published studies, including 678 patients, in which they concluded that "TPVI is a safe and effective procedure in the treatment of dysfunctions (pulmonary stenosis, pulmonary regurgitation, or both) of homografts, bioprosthesis, and other valved conduits surgically implanted in the right ventricle outflow tract. Such functional recovery is achieved without the need for cardiopulmonary bypass, and is associated with good immediate and medium-term outcomes. Although there have been no studies comparing the percutaneous and the surgical techniques, current evidence in the literature suggests that this should be the first-choice procedure or, at least, a good therapeutic alternative for patients with dysfunctions in the conduits of right ventricle outflow tract."[17]

A recent study, comparing the percutaneous pulmonary valve treatment with the surgical alternative, observed approximately the same immediate cost, with a higher increase in the percutaneous group costs 5 years later.[18] In contrast, despite the higher cost, a preliminary European analysis concluded that its cost-effectiveness ratio is favorable,[19] especially considering that the study was carried out at an early stage of the learning curve, with higher reintervention rates than those currently observed.[18] Another consideration in favor of the percutaneous option for the treatment of the RV outflow tract (RVOT) is its positive socioeconomic impact, since it implies a shorter hospital length of stay (24 to 48 hours on average) and an early return to normal activities, both for patients and their parents, when compared with patients submitted to open heart surgery.[18] Increments resulting from better patient readaptation to his/her environment would probably also have a positive impact on the quality of life indexes in this population.[19] It is well known that patients with congenital cardiopathy with RV-PA conduit require long, difficult, and repeated surgeries for the reconstruction and maintenance of RVOT throughout their lives.

Defining the basic requirements for the training and accreditation of interventionists and centers is a fundamental step towards the consolidated implementation of this new and revolutionary technique in the country. For this purpose, this document was prepared by a board of experts, which included representatives from all medical societies directly involved in the care of target-patients in this therapeutic modality, namely: *Sociedade Brasileira de Cardiologia* (SBC, portuguese for Brazilian Society of Cardiology), *Sociedade Brasileira de Hemodinâmica e Cardiologia Invasiva* (SBHCI, portuguese for Brazilian Society of Hemodynamics and Invasive Cardiology), and *Sociedade Brasileira de Cirurgia Cardiovascular* (SBCCV, portuguese for Brazilian Society of Cardiovascular Surgery). The authors believe that adherence to the following recommendations is essential for this procedure to effectively become part of the Brazilian therapeutic armamentarium, in a consolidated and widespread manner, as part of a transcatheter valve implantation program.

Clinical protocol for percutaneous pulmonary valve implantation

The Melody® valve

It is made of a segmental flap of the bovine jugular vein mounted and sutured inside a 34 mm 8-zig Cheatham Platinum (CP) stent (NuMED Inc., Hopkinton, USA). The valve is released by a delivery sys-

tem called Ensemble®, specifically designed for this purpose (Medtronic Inc., Minneapolis, USA). It consists of a balloon-in-balloon (BIB) catheter (NuMED Inc. Hopkinton, USA), with 18, 20, or 22 mm diameter, mounted inside a retractable cover. The system has a 22 F profile and, at its distal end, a blue plastic tip is found, which facilitates the passage through the skin and the RVOT. The retractable plastic sheath covers the valve stent and, when retracted, allows control angiographies through its lateral arm.

Indications

Patients with indication for pulmonary valve replacement and candidates to TPVI are those in the postoperative period of RVOT reconstruction surgery through plasty, with a conduit or bioprosthesis implantation, and evidence of pulmonary dysfunction according to the following criteria:

- RV outflow tract with sufficient inner diameter for prosthesis anchoring (according to the manufacturer's recommendation and proven by the specific medical literature).
- Any of the following findings by transthoracic echocardiography:
  - In patients with class II, III, or IV (New York Heart Association - NYHA): moderate or severe pulmonary failure; or mean RVOT gradient equal to or greater than 35 mmHg.
  - In patients with class I (NYHA): severe pulmonary regurgitation with RV dilatation or dysfunction; or mean RVOT gradient equal to or greater than 40 mmHg.

The final decision on the procedure indication, as well as associated technical aspects, should be individualized and ideally carried out at a local multidisciplinary group meeting, consisting of the following professionals with acknowledged experience in congenital heart diseases: clinical cardiologist, interventional cardiologist, cardiovascular surgeon, and imaging professionals (echocardiographist and radiologist).

Any of the following conditions constitute a contraindication to the proposed treatment:

- Patient refusal and non-signing of the Free and Informed Consent Form (FICF) for the procedure.
- Coronary pathway adjacent to the RVOT with risk of compression after valve stent implantation. Such risk is assessed by an aortography or selective coronary angiography during maximum inflation of a balloon-catheter of a diameter similar to that of the valve prosthesis to be implanted inside the RVOT. Any change in coronary filling by contrast or electrocardiographic alteration suggestive of myocardial ischemia should be considered extrinsic coronary compression and, thus, a contraindication to valve implantation.
- Other criteria, such as: infectious diseases and/or active endocarditis; hemorrhagic or thrombophilic diathesis; severe or progressive non-cardiac systemic disease that implies a life expectancy of less than one year (*e.g.*, renal failure, liver failure, cancer, etc.); and women of childbearing age who have a positive urine or serum test for pregnancy prior to the procedure.

Therapeutic success criteria

They are defined by the resolution of the pulmonary conduit dysfunction, through the detection of a peak-to-peak pressure gradient of less than 25 mmHg and RV systolic pressure of less than 50% of systemic arterial pressure shortly after implantation, in addition to absence of pulmonary regurgitation or reduction in severity to a "mild" classification.

Definition of complications

Complications related to the procedure or prosthesis are defined as:

- **Acute (during the implantation and up to the first 24 hours after it):** death, conduit rupture, pulmonary vessel perforations, endovascular lesions, pulmonary arterial flow impairment (uni- or bilateral reduction), prosthesis embolization, severe cardiac arrhythmias, and any complications that put the patient's life or physical integrity at risk.
- **Late (during the clinical follow-up):** infectious endocarditis, device fracture (requiring reintervention), and valve thrombosis or calcification, as well as any other complication directly related to the device or procedure that puts the patient at risk or requires reintervention.

Clinical follow-up

Patients should undergo a transthoracic echocardiogram up to 24 hours after the procedure for the detection of cardiovascular complications. Intravenous antibiotic prophylaxis must be administrated for 24 hours after the procedure; the first dose must be infused at the beginning of the catheterization. Oral administration of acetylsalicylic acid (3 to 5 mg/kg daily, maximum dose of 100 mg daily) is also initiated, which should be maintained indefinitely due to the risk of thrombus formation on the prosthetic structures. If the patient is in good clinical condition and no severe complications have been detected, early discharge (24 to 48 hours afterwards) is recommended.

Outpatient follow-up should be performed 1, 6, and 12 months after implantation, and, thereafter, annually or at shorter intervals, at clinical discretion. The patient should be advised to maintain prophylaxis for infective endocarditis throughout life. In each of the outpatient returns, the following exams must be performed, with their respective objectives:

- **Posteroanterior and lateral chest X-ray,** to assess the integrity of the CP stent.
- **Electrocardiogram,** to detect cardiac rhythm or electrical conduction disturbances.
- **Transthoracic echocardiogram,** to evaluate the prosthesis positioning and determine possible obstruction to right ventricular ejection and/or pulmonary insufficiency, as well as to evaluate flow for both pulmonary branches.

Annually, a chest fluoroscopy should be performed in the left anterior oblique view with cranial angulation, left lateral and right anterior oblique with caudal angulation, to better assess the Melody® valve integrity.

Criteria for center accreditation

Regarding the hospital environment for the TPVI procedure performance, the requirements established in Annex IV of the Brazilian Ministry of Health Decree 210 of June 15, 2004, for the operation of High-Complexity Cardiovascular Units must be met. It is worth mentioning that the criteria defined below are in accordance with a document previously prepared by the SBHCI and discussed at a meeting of the technical chamber of the *Conselho Federal de Medicina* (CFM) specifically for this purpose, together with SBC and SBCCV.

A High-Complexity Cardiovascular Care Unit is a hospital unit with adequate technical conditions, physical facilities, equipment, and human resources to provide specialized care to any individual with cardiovascular disease. For the performance of the aforementioned procedure, these units, consisting of Services of High-Complexity Cardiovascular Care, must be integrated as described:

- Service of High-Complexity Care in Interventional Cardiology Procedures in Congenital Heart Diseases.
- Service of High-Complexity Care in Pediatric Cardiovascular Surgery that can provide adequate care (24 hours a day, 7 days a week) to procedures performed in cases of possible complications of percutaneous valve implantation. Additionally, it is the medical team surgeon's responsibility to establish the direct atrial or ventricular (transapical) surgical access, when this is the option for valve implantation.
- Continuous and specific preoperative and postoperative clinical follow-up in congenital heart diseases, in addition to urgency/emergency care in pediatric cardiology and congenital heart diseases of the adult.
- Anesthesiology team experienced in procedures performed in patients with complex congenital heart diseases.
- A team of professionals specialized in imaging methods (echocardiography, nuclear magnetic resonance, computed tomography, etc.) in the diagnosis of complex congenital heart diseases.

Institutional requirements

The institution must perform at least 150 cardiac catheterizations in congenital heart diseases a year. Of these, 75 should be interventional procedures, including (but not limited to) stent implantation into pulmonary arteries and/or RVOT. Additionally, the institution must also perform a minimum of 100 open surgical procedures in patients with congenital heart defects annually.

Cardiac catheterization laboratory requirements

The TPVI procedure should be performed in a conventional catheterization laboratory or in a hybrid operating room. The conventional catheterization room should be large enough to accommodate the anesthesia equipment and two instrumentation tables, as well as allowing easy movement of the entire multidisciplinary team involved in the procedure (interventionist and two assistants, anesthesiologist, nurse, and nurse technician, etc.), taking care to ensure surgical sterility, which is crucial to the adequate practice of the technique.

The cardiac catheterization laboratory must meet the general requirements for the practice of the usual interventional cardiology procedures, summarized below:

- Radiological angiography device, adequately fixed to the ground or ceiling, and motorized C-arm system.
- Architecture that allows the performance of axial projections with 40° of angulation and oblique projections with 90° of angulation.
- Examination table that supports patients weighing up to 200 kg, plus 100 kg imposed during resuscitation maneuvers, which ensures safety in emergency situations.
- High-voltage X-ray generator with a minimum power of 80 kW, for fast and sufficient radiation emission, to attain image contrast and sharpness, allowing, in these circumstances, the operation to be performed within the safe radiation limits for patient and interventionist.
- X-ray tube with a minimum thermal capacity of 1,700,000 HU.
- Pulsed fluoroscopy with rates of at least 30/15 pulses per second.
- Image intensifier with the highest possible conversion factor or flat-panel digital system.
- High-resolution video camera to ensure the quality of the fluoroscopy images and able to transform the analog signal into the digital angiography.
- High-quality digital image with a matrix of at least 512 × 512 × 8 bits at 30 frames per second.
- Long-term digital archiving in DICOM format.
- Polygraph with a record of at least three electrocardiogram channels and two pressure channels.
- High-precision contrast injection pump.
- Anticoagulation monitoring device through measurement of activated coagulation time.
- Radiation protection equipment.
- Anesthesia equipment appropriate for adults and children.

Specific materials for the transcatheter pulmonary valve implantation procedure

TPVI is a highly complex procedure and requires a wide variety of materials and catheters. The essential materials for the procedure are: short, high-profile sheaths (18 to 22 F); long, high-profile sheaths (10 to 14 F); hemostasis and endovascular suture devices; high-flow angiographic catheters; extra-rigid guidewires; temporary endocardial pacemaker electrode catheter; coronary and peripheral angioplasty balloon catheters of varying diameters, including high-pressure ones; conventional and covered balloon-expandable stents with large diameters; and vascular occlusion devices.

Clinical staff requirements

The institution must have a group of qualified professionals actively engaged in the treatment of congenital and structural heart diseases (Heart Team), with experience in the treatment of pulmonary valve conditions and RVOT. This group should consist of clinical cardiologist, invasive/interventional cardiologist, cardiac surgeon, echocardiographist, and radiologist. During the periodic clinical-surgical meetings, the Heart Team is responsible for the individualized discussion of cases that could benefit from the TPVI technique and the decision on the best approach for each patient.[20]

Specific roles of professionals in the transcatheter pulmonary valve implantation procedure: the Heart Team

Clinical cardiologist

Indication of the appropriate time for pulmonary valve replacement, adequate patient selection, and immediate and long-term postoperative care.

Imaging professionals (echocardiographist and radiologist)

Noninvasive selection of favorable cases and assessment of early and late results through the recommended imaging methods.

Interventionist

Indication of the appropriate time for pulmonary valve replacement, adequate patient selection, percutaneous procedures (feasible in almost all cases) and transapical procedures, as well as immediate postoperative care.

Cardiovascular surgeon

Indication of the appropriate time for pulmonary valve replacement, adequate patient selection, local surgical backup for possible complications,attainment of the transapical alternative access route, and auxiliary interventionist, in cases of transapical implantation.

Interventionist requirements

It is strongly advised that interventionists have extensive experience in percutaneous diagnostic and therapeutic procedures for congenital heart disease, especially pulmonary artery stent implantation. They are also required to master the coronary catheterization technique, as well as to know the anatomical association of the origins of the coronary arteries with the PA, since, in some cases, the release of the pulmonary bioprosthesis can lead to coronary occlusion, which would contraindicate the therapy.[20]

Furthermore, they are required to have specific knowledge of the general characteristics of the catheter-implantable valvular prosthesis; its adequate indication according to underlying congenital heart disease; anticoagulation control; and appropriate management of possible complications, such as coronary compression, cardiac or vascular perforation, partial or total rupture of the treated conduit, prosthesis embolization, prosthesis thrombus formation, infective endocarditis, and cardiac arrhythmias, among others.

The medical specialist should also be aware of the different surgical strategies employed in the reconstruction of RVOT necessary for the treatment of complex congenital heart diseases, such as tetralogy of Fallot, pulmonary atresia with ventricular septal defect, double RVOT with infundibular pulmonary stenosis, transposition of the great arteries with ventricular septal defect and infundibular pulmonary stenosis, and corrected transposition of the great arteries with pulmonary stenosis and common truncus arteriosus.

In turn, regarding the physicians' qualification, CFM Resolution n. 2.068/13, which addresses medical specialties and was published in the Brazilian Federal Register on January 3, 2014, establishes the following as prerequisites to obtain the Certificate of Expertise in Hemodynamics and Interventional Cardiology: a certificate in medical specialization in Cardiology and/or Pediatrics with qualification in Pediatric Cardiology, issued by the Brazilian Medical Association and/or the National Commission of Medical Residency. Therefore, the physician responsible for carrying out the TPVI must have the Certificate of Qualification in Hemodynamics and Interventional Cardiology duly registered at the *Conselho Regional de Medicina* (CRM, portuguese for Regional Council of Medicine) of the jurisdiction where he or she works, in accordance with the current regulations.

Therefore, the training of the physician in this new therapeutic modality will take place according to the requirements listed below, which is done in accordance with the recommendations of the main American medical societies involved (Society for Cardiovascular Angiography and Interventions – SCAI, American Association of Thoracic Surgery – AATS, American College of Cardiology Foundation – ACC, and Society of Thoracic Surgeons – STS):[20]

- The centers qualified for the formation, training, and mentoring of TPVI specialists must meet the following requirements:
  - To be part of the group of training centers in hemodynamics and interventional cardiology accredited by the Brazilian Medical Association, through the medical specialty societies and/or area of activity, or by the National Medical Residency Commission.
  - To verify the previous participation of the training center coordinator as the first interventionist in at least 100 cardiac catheterizations a year in congenital heart diseases, 50 of them with therapeutic purposes.
  - To verify the prior participation of the training center coordinator as the first interventionist, independently, in at least 10 TPVI procedures.
  - To perform at least 5 TPVI procedures a year, every year.
  - To have extensive experience in surgery and diagnostic and interventional catheterization for high-risk congenital heart diseases.
  - To be committed to a comprehensive multidisciplinary program in congenital heart diseases therapy.
- In turn, the training that needs to be offered to the interventional cardiologist for TPVI qualification should include:
  - Theoretical-practical course (with discussion of potentially favorable cases for TPVI), with a minimum workload of 24 hours.
  - Participation as an observer in at least 1 procedure in an accredited training center.
  - Performance, as the first interventionist, under the supervision of a trained interventional cardiologist (proctor), in a minimum of 3 procedures. Proficiency and autonomy in performing the procedure should be attested by the supervising physician.
- The participation of the supervisor (proctor) in TPVI procedures performed outside the jurisdiction of CRM, under which the supervisor is registered, must comply with the conditions required for live surgical demonstrations established by CFM Resolution 1.653/02.
- At the end of the specialist physician's training, a certificate of qualification in the TPVI procedure must be issued, according to the guidelines and regulations established by CFM Resolution number 2.068/13.

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Conflicts of interest

The authors declare no conflicts of interest.

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