Complications in patients after percutaneous aortic valve replacement

Complicações em pacientes após substituição valvar aórtica percutânea

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Abstract

Objective: Identify the profile of patients undergoing percutaneous aortic valve replacement and check the main complications after the implantation, as well as the associated comorbidities and death.
Methods: This is a retrospective and quantitative study carried out at a Public Institution in the city of São Paulo. The inclusion criterion was patients undergoing percutaneous aortic valve replacement at Institution department of hemodynamics from 2009 to 2012. Our baseline sample consisted of 85 patients. We excluded 14 patients who underwent the implant in the hybrid operating room, which could present discrepancy between the results. Thus, from our sample of 71 patients, data collection was possible only on 65 individuals, because some of the medical records were not available at the time of collection.
Results: Patients' profiles were elderly, with a mean age of 82 ± 6.9 years, female, widowed, with low education, and retired. During implantation, arrhythmias were the major complication. In the immediate postoperative period, the most prevalent complications were vascular injury, psychomotor agitation, and confusional state. In late post-implantation, complications were vascular injury, skin injury by medical adhesive tape, hyperglycemia, loss of temporary pacemaker, 21.5% of the patients died.
Conclusion: The adoption of this new technology should be consolidated for elderly patients with formal contraindications to conventional surgery with the improvement of the implantation technique, better selection of candidates, and decrease of mortality.

Resumo

Objetivo: Identificar o perfil de pacientes submetidos à substituição valvar aórtica percutânea e verificar as principais complicações após o implante, assim como comorbidades associadas e morte.
Métodos: Estudo retrospectivo e quantitativo realizado numa instituição pública na cidade de São Paulo. O critério de inclusão considerou pacientes submetidos à substituição valvar aórtica percutânea no departamento de hemodinâmica da instituição, de 2009 a 2012. A amostra base consistiu de 85 pacientes. Quatorze pacientes que receberam o implante na sala de cirurgia híbrida foram excluídos, já que sua inclusão poderia causar discrepância entre os resultados. Assim, da amostra de 71 pacientes, a coleta de dados só foi possível para 65 indivíduos, porque alguns prontuários médicos não estavam disponíveis no momento da coleta.
Resultados: Os perfis dos pacientes foram idosos, com idade média de 82 ± 6,9 anos, sexo feminino, viúvos, com baixa escolaridade e aposentados. Durante o implante, arritmias foram as maiores complicações. No período imediatamente após a operação, as complicações mais prevalentes foram lesões vasculares, agitação psicomotora e estado de confusão mental. No período pós-implante tardio, as complicações foram lesões vasculares, lesões de pele por fita adesiva cirúrgica, hiperglicemia, perda de marca-passo provisório, e 21,5% dos pacientes morreram.
Conclusão: A adoção dessa nova tecnologia deve ser consolidada para pacientes idosos com contraindicações formais a cirurgias convencionais, à medida que, há aprimoramento da técnica de implante, melhor seleção de candidatos e diminuição de mortalidade.

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Introduction

The population's life expectancy has been increasing significantly over the years and it is observed the increase of various cardiovascular, specifically the valvular diseases, following the aging population. In Brazil, 8.6% are elderly and of these, 25% are aged 75 and over.[1] Aortic stenosis increases its prevalence with age and can be found in approximately 5% of the elderly. The treatment is the correction, which is done by valve replacement surgery, yet 33% of the patients do not have this recommendation due to the surgical risk and mortality.[2-6]

Approximately 30% to 40% of patients with advanced age and associated comorbidities (patent coronary grafts, extensive thoracic irradiation, porcelain aorta, previous operations, biological fragility) are rejected for surgery due to the high risk of perioperative mortality, reaching 50%.[2,3] Fewer invasive procedures for replacing the aortic valve were developed to meet the need of these patients contraindicated to classical surgery. The aortic balloon valvuloplasty was one of the first procedures proposed in 1986 by Cribier et al.[4] However, after a short trial period, it was noticed that patients had the symptoms back, and at the end of 12 months, only 40% of patients were free from reintervention, aortic valve replacement, atrioventricular block or death.[3,9]

A second option is the percutaneous aortic valve replacement (TAVI), which was successfully implanted for the first time in humans by Alan Cribier in 2002, [5] obtaining satisfactory immediate results, with a significant reduction in the transvalvular gradient, improved ejection fraction and clinical status of cardiogenic shock, initiating a new phase of interventional cardiology.[2,6-9] This technique corresponds to the implant of an expandable prosthetic valve by balloon or self-expanding stents, implanted by catheter via femoral, iliac, transthoracic, and apical arteries. Most valves have three bovine or equine pericardium leaflets mounted and sutured in a stent.[2,8]

The main arterial vascular access used is the femoral artery or iliac artery, which allows the introduction of a 18F sheath and other arterial access to the contralateral leg for 5F or 6F pigtail catheter, where the injection of contras tis performed to assist the positioning and the prosthesis release. During the procedure, the clinical and hemodynamic parameters of the patient are evaluated by contrasted aortography and transesophageal echocardiography.[2,10] The health personnel who stays inside the room are the heart surgeon, the hemodynamicist doctor, anesthesiologist, echocardiographist, nursing assistants and nurses.

This technique is constantly growing and spreading worldwide. It is reported as a safe and effective method for patients with severe aortic stenosis without the possibility of conventional surgery.[10,11] Taking into account the profile of patients submitted to the procedure, as high risk, we can consider that complications related exclusively to the method are relatively low. We achieved a success treatment rate greater than 75%.[10]

The PARTNER Trial (Placement of Aortic Transcatheter) was the first randomized trial carried out aiming to compare surgical treatment with percutaneous aortic valve replacement in a 2-year-follow-up period. It demonstrated the superiority of transcatheter aortic valve implantation over the medical therapy in those patients who have a contraindication for conventional surgical treatment, both in terms of mortality and quality of life.[12]

The characterization of this patient in the post-implant period is important to assist the nursing staff to plan the care assistance and avoid complications, contributing to the early hospital discharge. The objectives of this study were to identify the profile of patients undergoing percutaneous aortic valve replacement, and to check the main complications after implantation and associate them to comorbidities and death.

Methods

This is a retrospective and quantitative study carried out at a Public Institution in the city of São Paulo. The inclusion criterion was patients undergoing percutaneous aortic valve replacement at Institution department of hemodynamics from 2009 to 2012. Our baseline sample consisted of 85 patients. We excluded 14 patients who underwent the implant in the hybrid operating room, which could present discrepancy between the results. Thus, from our sample of 71 patients, data collection was possible only on 65 individuals, because some of the medical records were not available at the time of collection.

The researcher consulted the hospital records. The variables studied were sex, age, skin color, education, marital status, weight, height, profession, family history, origin, and risk factors (smoking, hypertension, diabetes, dyslipidemia, family history, sedentarism). Regarding complications after percutaneous aortic valve replacement, such as preoperative comorbidities, hypertension, dyslipidemia, body mass index (BMI), non-dialysis chronic kidney disease (CKD), heart failure (HF), and diabetes mellitus were adverse events presented in the Intensive Care Unit (ICU) and Ward.

For statistical measures, we described them by absolute (N) and relative (%) frequencies, and by means, standard deviations (SD), 25th and 75th percentiles (25% and 75%). For associations between death and comorbidities, the chi-square Pearson test was performed. The significance level was 5%, in other words, differences were considered significant when the descriptive level of the tests (p-value) was less than 0.05.

The selection of the patient involved the evaluation of the favorable anatomical and functional conditions for prosthetic implantation through imaging examinations, such as transthoracic color Doppler echocardiography, coronary angiography, and CT angiography, as required.[9,10]

In this study, we used the third generation of the aortic valve prosthesis CoreValve™, which consists of a three-leaflet stented pericardial porcine bioprosthesis, and a self-expanding nitinol stent. The valve smaller internal diameter is 21 mm, and the nitinol stent is laser cut to form a 50 mm-length tube. The prosthesis distal part has a high radial strength, which allows its expansion and exclusion from the calcified valve leaflets, and prevents its post-implant shrinkage. The prosthesis middle part supports the valve, and its architecture allows the atrioventricular orifices to remain free and accessible. The proximal part is enlarged, allowing its fixing and longitudinal stability. Previously the valve implantation, it is washed and cooled in ice cold, saline solution. Then, it passes through a series of vascular templates to reduce its profile. Next, it is crimped and fixed in a 18-French releasing system, which delivers the prosthesis after balloon aortic valvuloplasty.[2,7,9]

After the release of the prosthesis, there is no possibility of removal, thus it is necessary a prior evaluation of the patients undergoing the procedure, in order to determine the best access route and the prosthesis size to be used. The CoreValve™ System is currently available in 26 and 29 mm sizes for an aortic diameter range of 20-23 mm, and 24-27 mm, respectively. The smaller valve prosthesis has a 22 mm diameter and the largest has a 24 mm diameter. Currently, it is the only device approved by the National Health Surveillance Agency (ANVISA) for percutaneous aortic valve replacement.[7,10]

We used echocardiography and angiography for analysis of morphological and anatomical criteria of the aortic valve and the aorta. We also used the aortoiliac path and coronary angiography to exclude the presence of significant coronary disease.[7,11]

The night before the procedure, patients received a 200 mg loading dose of aspirin (Bayer®) in conjunction with 300 mg loading dose of clopidogrel (Sandoz®). At the time of implantation, patients are kept under general anesthesia and anticoagulation, using weight-adjusted unfractionated heparin (Hepamax®). At the beginning, a temporary cardiac pacemaker electrode (Medtronic®) is inserted through the jugular vein. The pacemaker (Medtronic®) provides cardiac pacing by increasing the frequency between 180 and 220 beats per minute to facilitate the positioning and prevent balloon movement during inflation.[2,7,10,11]

The dissection of the left inguinal region was the most used access pathway to insert the valve prosthesis (CoreValve®, Medtronic®) (67.8%), followed by the right inguinal region (25.4%), and by the right subclavian region. We also carried out a procedure for minithoracotomy, one by an apical route, and one by a retroperitoneal pathway as well.

The implant procedure lasted from one to four hours and 10 minutes on average. The 9F to 21F catheters (Medtronic®) and an average of 137 ml (130 ± 54.8) of contrast were used. At the beginning of the procedure, heart rate was 77 beats per minute, and the mean arterial pressure was 117 x 67 mmHg (120x66 ± 18x15). The average hospital length of stay was 16 days (11 ± 12.7).

The development of this study met standards of ethics in research involving human subjects *Certificado de Apresentação para Apreciação Ética (CAEE):* 13689613.6.0000.5462 (Brazil).

Results

The patients were aged between 61 and 93 years, mean age 82 ± 6.9 years; 44 (67.7%) were female and 21 (32.3%) were male. Most of them were widowed (56.5%), caucasian (93.3%), with low school level (64.4%) and retired (63.1%).

The main preoperative comorbidities presented by the patients were arterial hypertension (89.2%), dyslipidemia (63.1%), and high BMI (56.9%), non-dialysis CKD (38.5%), heart failure (38.5 %), Diabetes *mellitus* (35.9%), smoking (69,2), overweight (63,1%), sedentarism (29,2%), coronary artery disease (23,1%), carotid disease (18,5%), obstructive heart failure (18,5%), hypothyroidism (16,9%), myocardial revascularization (15,4%), acute myocardial infarction (12,3%), cerebrovascular accident (7,7%), chronic obstructive pulmonary disease (7,7%), stable angina (7,7%)l, syncope (7,7%), peripheral occlusive arterial disease (6,2%), prior coronary angioplasty (4,6%), auditory deficit (4,6%) e pulmonary hypertension (4,6%) (Tables 1, 2 and 3).

Table 1. Complications presented in the intensive care unit by patients undergoing percutaneous aortic valve replacement

Adverse events	n(%)
Vascular complication	26(40.0)
Agitation and mental confusion	21(32.3)
Injury caused by surgical tape	21(32.3)
Arrhythmia	18(27.7)
Hypotension	15(23.1)
Hypertension	14(21.5)
Accidental loss of TPM	12(18.5)
Blood transfusion	11(16.9)
Respiratory infection	9(13.8)
Hyperglycemia	8(12.3)
Prolonged mechanical ventilation	7(10.8)
Acute renal insufficiency	7(10.8)
Bony prominence (Hyperemia)	7(10.8)
Oliguria	7(10.8)
Pacemaker implantation	3(4.6)
Swelling of inferior members	3(4.6)
Pulmonary congestion	3(4.6)
Others	7(10.8)

TPM - temporary pacemaker

Table 2. Complications after late implant presented in the inpatient unit by patients undergoing percutaneous aortic valve replacement

Adverse Events	n(%)
Vascular complication	28(46.1)
Injury caused by surgical tape	17(28.3)
Hyperglycemia	5(8.3)
Loss of TPM	5(8.3)
Blood transfusion	5(8.3)
Permanent pacemaker	4(6.7)
Agitation and confusion	4(6.7)
Hypertension	3(5.0)
Acute renal insufficiency	2(3.3)
Hyptension	2(3.3)
Bony prominence (Hyperemia)	2(3.3)
Arrhythmia	2(3.3)
Others	11(18.3)

TPM - temporary pacemaker

Table 3. Association between comorbidities and mortality of the patients undergoing percutaneous aortic valve replacement

Comorbidities	p-value
Hypertension	0.632
Diabetes mellitus	0.061
Dyslipidemia	0.017
Coronary artery disease	0.378
Smoking	0.081
Sedentarism	0.469
Obesity	0.223
Stroke (cerebrovascular accident)	0.223
Carotid disease	0.06
COPD	0.01
Non-dyalisis CKD	0.025
Obstructive heart failure	0.747
Hypothyroidism	0.766
Myocardial revascularization	0.335
Acute myocardial infarction	0.507
Others	0.638

p-value <0.05; COPD - chronic obstructive pulmonary disease; CKD - chronic kidney disease

Discussion

A significant portion of elderly patients has the procedure denied by one of the following events: (1) surgical risk, which is considered unacceptable; (2) technical conditions that make the thoracic access prohibitive; (3) installation of cardiopulmonary bypass; and (4) aortic clamping.[3] TAVI emerged as a new technique in which the main goal is to improve the elderly's quality of life, with less morbidity and mortality when compared to the conventional treatment.[12]

In Brazil, the elderly statute provides that this population is prioritized in access to public and private services, including the right of access to healthcare. This therapy has been evaluated and incorporated in several countries. Although the technique has been available since 2008, with registration by the National Health Surveillance Agency (ANVISA), there is no forecast of mandatory coverage by the national health system, excluding significant portion of these elderly from scientifically appropriate treatment.[11] In this study, our results matched several case studies published, in which we could notice a a similar profile.[2,3,11,14]

The main pre-implant comorbidities presented by the patients were hypertension, dyslipidemia, high body mass index, non-dialysis chronic kidney disease, heart failure, diabetes mellitus, and current or former smokers. In previous studies, similar data were already found, highlighting the coronary artery disease, peripheral artery disease, prior cerebrovascular accident and prior coronary artery bypass grafting (CABG). In all studies, the high percentage of systemic arterial hypertension and heart failure were extremely relevant.[3,9,11,14]

In the PARTNER study, the profile found was as follows: women (57.8%), elderly people (83.6 ± 6.8) with comorbidities such as New York Heart Association (NYHA) class III or IV (94.3%), coronary artery disease (74.9%), chronic obstructive pulmonary disease (DPOC) (52.6%), peripheral vascular disease (43%), prior coronary artery bypass grafting surgery (42.6%), pulmonary hypertension (42.4%), atrial fibrillation (40.8%), previous angioplasty (34%), cerebrovascular accident (29.3%), previous acute myocardial infarction (26.8%), and definitive pacemaker (20%).

During TAVI, 60% of patients had some type of complication. Among them, arrhythmias were very frequent, occurring in 49.2% of the patients. The emergence of left bundle branch block was the most often associated factor to the total atrioventricular block in the evolution of patients undergoing TAVI, thus requiring permanent pacemaker.[2,11] In this study, only 7.8% had left bundle branch block on admission, evolving after percutaneous aortic valve replacement to 32.1%. During procedure, 6.2% of patients had ventricular fibrillation or complete atrioventricular block. The long-term complications caused by the percutaneous technique are related to the atrioventricular conduction disorders, vascular access, and embolic phenomena.[10]

During this period, all patients had at least one complication, especially vascular complications, psychomotor agitation, confusional state, and skin injury by medical adhesive tape, arrhythmias, hypotension, hypertension, and accidental loss of TPM.

Electrocardiograms were performed immediately after the procedure and daily until hospital discharge. Temporary pacemaker was kept according to the demand and when necessary, leading the heart rate to the reversal of bradyarrhythmia or permanent pacemaker implantation.[11]

In the late post-implant period, the patient remained in the ward for an average of 10 days and a maximum of 70 days, until their full recovery and discharge. During this period, complications occurred in 75% of patients. The most observed complications were vascular complication, skin injury by medical adhesive tape, hyperglycemia, and loss of TPM.

It was observed that vascular diseases were common in the immediate post-implant period. They are still a problem during the hospital stay in the late post-implant period, once they can cause local hematomas, which may lead to vascular surgical procedures.[15] The risk factor for vascular diseases is the issue of prosthesis navigability within the vessels. Good size femoral arteries with few tortuosities and without calcifications are necessary. Recently

published data have demonstrated the decrease of vascular conditions with a combination of newer generations of devices with a smaller diameter, integrated with a better screening of patients and increased performer's experience.[12,16,17]

Vascular complications followed-up from 30 days to one year after TAVI showed that the main complications were venous dissection (62.8%), vascular perforation (31.3%), local hematoma (22.9%), retroperitoneal bleeding (9.5%), pseudoaneurysm (3.4%), and gastrointestinal ischemia (1.6%). The most time-consuming procedures and those that used more contrast had major complications, besides increasing patients' length of stay. This study also showed that patients who had vascular disorders after 30 days, presented bleeding events (p = <0.0001) and dialysis renal failure (p = 0.003) significantly higher than the patients without vascular disorders. With regard to death from 30 days to one year, patients with vascular disorders had a higher mortality rate (p = <0.0001).[16]

The confusional state present in a large number of patients was solved after they were referred to the ward. No persistent case was reported. It was observed skin lesion caused by surgical tape after implantation, which was related to the need of compressive dressings after catheter removal for local hemostasis combined to the skin fragility of the elderly. Another outstanding complication, both in the ICU and the ward, were the arrhythmias that persisted, requiring a permanent pacemaker implant in 11.3% of patients. Several studies have also reported the need for a permanent pacemaker insertion as a complication from the procedure, varying between 67% and 6%, once the largest number of implants occurred in the early years of the procedure.[2,3,11,17]

The overall mortality found during the study was 21.5%. The main causes of death were septic shock, pneumonia, and death in the immediate post-implantation period in the ICU. A study of 33 patients showed a mortality rate of 36%, especially with complications related to bronchopneumonia and sepsis with bloodstream infection.[3] A study examining 1,521 TAVI records of 20 countries found a mortality rate of 10.3% in 30 days.[17]

The PARTNER study made a comparison between TAVI and conventional surgery. It showed 30-day mortality from various causes of 3.4% and from cardiac causes of 3.2%, while conventional surgery presented mortality from various causes of 6.5% and from cardiac causes of 3%. After one year, TAVI mortality rate from various reasons was 24.2% and 14.3% from cardiac causes, while surgery showed a varied cause of death of 26.8% and from cardiac causes of 13%. It has been shown that in the considered cases of high surgical risk, TAVI showed a mortality rate after one year similar to that obtained by surgical treatment, demonstrating that the implant catheter is an excellent treatment option for this population.[15]

In this study, from 2009 to 2010, the mortality rate found was 35.3% and in 2011 and 2012 was 6.5%, with p-value being considered statistically significant (P = 0.0047), demonstrating that the technical enhancement is connected with the procedure success rate.[12,15] It is believed that the procedure in decompensated patients with prolonged hospitalization induces the increased risk of infection and colonization, as well as major complications in the postoperative period.[18]

The statistical association between death and pre-implant comorbidities showed that dyslipidemia (p = 0.017), COPD (p = 0.01), and no-dialysis CKD (p = 0.025) were the major comorbidities presented by the patients who died during the study. This demonstrates that decompensated patients or those with chronic diseases have a higher risk of death.[19]

Conclusion

The main complications during implantation were arrhythmias. At the Intensive Care Unit, all the patients had at least one complication, especially vascular complications (hematoma, bleeding, and pseudoaneurysm), psychomotor agitation, confusional state, and skin injury by medical adhesive tape, arrhythmias, hypotension, hypertension, accidental loss of temporary pacemaker, and the need of blood transfusion.

In the late postoperative period, the main complications were vascular complications, skin injury by medical adhesive tape, hyperglycemia, and loss of permanent pacemaker. Comorbidities, such as dyslipidemia, Chronic Obstructive Pulmonary Disease, and non-dialysis, Chronic Kidney Disease was the ones that stood out in patients who died, demonstrating that the decompensated patients or those presenting chronic diseases had higher risk of death. With the improvement in the implantation technique and better selection of candidates, the adoption of this new procedure should be consolidated for elderly patients with formal contraindications to conventional surgery.

Collaborations

Bastos AS and Silva EV declare that they collaborated with the research design and planning, as well as data analysis and interpretation. She also collaborated with relevant critical review of the manuscript intellectual content, as well as the final manuscript version approval to be published. Beccaria LM, Barbosa TP and Werneck AL declare that they contributed with the writing and relevant critical review of the manuscript intellectual content, as well as the final manuscript version approval to be published.

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