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Transcatheter aortic valve implantation: results of the current development and implantation of a new Brazilian prosthesis

Implante transcateter de valva aórtica: resultados atuais do desenvolvimento e implante de um nova prótese brasileira

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Abstract

Objective: **Aortic valve replacement is a routine procedure with acceptable risk, but in some cases, such risk can justify contraindication. Minimally invasive transcatheter aortic valve implantation has emerged as an alternative, with lower morbidity and mortality. The aim of this study was clinical, safety and efficacy assessment.**

Methods: **Thirty-three high risk patients underwent transcatheter balloon expandable aortic valve implantation. Mean Logistic EuroScore risk was 39.30% and STS score 30.28%. Eight patients presented with dysfunctional bioprosthesis, remaining ones presented calcified aortic stenosis. Procedures were performed in a hybrid OR under fluoroscopic and echocardiography guidance. Using a left minithoracotomy the prosthesis were implanted trough the ventricular apex under rapid ventricular pacing or hemorrhagic shock. Echocardiographic and angiographic controls were performed.**

Results: **Implant was feasible in 30 cases. Three conversions occured. There was only one case of operative death. Median transvalvular aortic gradient reduced from 43.58 mmHg to 10.54 mmHg. Left ventricular function improved in the first 7 postoperative days. Paravalvular aortic regurgitation was mild and present in 30.30%. One case presented major vascular complication and another one permanent pacemaker implant. One major stroke case occurred. Overall 30-day mortality was 18.18%.**

Conclusion: **The transapical implantation of catheter-mounted bioprosthesis is a safe procedure with acceptable midterm results. Long term follow-up with increased sample power is mandatory in order to access hemodynamic, life quality and survival.**

Descriptors: **Aortic valve. Cardiopulmonary bypass. Heart catheterization.**

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Resumo

Objetivo: **A troca valvar aórtica é procedimento rotineiro com risco aceitável. Em alguns casos, a mortalidade é elevada, contraindicando o procedimento. O implante minimamente invasivo transcateter de valva aórtica parece ser alternativa, reduzindo a morbimortalidade. A avaliação dos resultados clínicos, segurança e eficácia do procedimento são o objetivo desse estudo.**

Métodos: **Uma prótese transcateter, balão expansível foi utilizada em 33 casos de alto risco. EuroScore médio foi de 39,30% e STS score de 30,28%. Oito pacientes apresentavam disfunção de bioprótese e o restante, estenose aórtica calcificada. Os procedimentos foram realizados em ambiente cirúrgico híbrido, sob controle ecocardiográfico e fluoroscópico. Através de minitoracotomia esquerda, as próteses foram implantadas pelo ápice ventricular, sob estimulação de alta frequência ou choque hemorrágico. Foram realizados controles clínicos e ecocardiográficos.**

Resultados: **A correta liberação da prótese foi possível em 30 casos. Três conversões ocorreram. A mortalidade operatória foi de um caso e a mortalidade em 30 dias, 18,18%. O gradiente médio reduziu de 43,58 para 10,54 mmHg. A fração de ejeção apresentou aumento significativo após o 7º pós-operatório. Insuficiência aórtica residual esteve presente em 30,30% dos pacientes. Ocorreu uma complicação vascular periférica e um caso de bloqueio atrioventricular total. Um paciente apresentou acidente vascular cerebral. A mortalidade em 30 dias foi de 18,18%.**

Conclusão: **O implante transapical de valva aórtica transcateter é procedimento seguro e com resultados de médio prazo satisfatórios. São necessários estudos de longo prazo com maior poder amostral no intuito de determinar resultado hemodinâmico, qualidade de vida e sobrevida em longo prazo.**

Descritores: **Valva aórtica. Ponte cardiopulmonar. Cateterismo cardíaco.**

INTRODUCTION

The degenerative calcification of the aortic valve is considered the most common cause of aortic stenosis in developed countries, the most frequent indication for aortic valve replacement [1-5]. Standard treatment involves replacing of the valve by a prosthetic device (biological or mechanical) with operative mortality around 4% [6.7].

Despite these results some patients present morbimortality very high. Age advanced coronary grafts pervious, extensive thoracic irradiation, porcelain aortas, previous operations, biological fragility and neediness symptomatology well documented are factors that increase surgical risk. The conjunction these factors can determine contraindication procedure within 30% cases despite symptomatology or presence of structural cardiac commitment [8.9].

Recently, several groups have proposed alternative therapies aiming to reduce morbimortality associated with conventional intervention. Aortic valvuloplasty balloon was one these first interventions. Unfortunately after short improves, patients return showing symptoms and mortality comparable with pharmacological treatment [10]. In recent years implantation of one bioprosthesis aortic through catheters has been proposed with same goal, but more consistently [11.12]. Improvement of these devices, like reducing caliber introducers and structural improvements has provided increment significant result [13]. The Partner Trial (Placement of Aortic Transcatheter) randomized study comparing transcatheter clinical therapy demonstrated superiority of last both regarding mortality as quality life [14].

Despite encouraging results exists large discrepancy among results of different groups especially due heterogeneity of patients assessed with different risk scores and selection criteria [15.16].

Two devices are available commercially for transcatheter implantation in the aortic valve: Edwards Sapien (expandable balloon) (Edwards Lifesciences, CA, USA) and CoreValve (self expandable) (Medtronic Corporation MN, USA) both with distinct structural characteristics. In our environment it was developed one expandable balloon prosthesis with encouraging initial results [17.18].

Assessment of clinical outcomes, safety and efficacy of the procedure performed with this new prosthesis are the aim of this study.

METHODS

Patient Selection

Between June 2008 and January 2011, 33 patients underwent transcatheter aortic valve implantation, after agreeing with written informed consent and approval by the Ethics Committee (CEP 1116/08).

Patients were selected by one multidisciplinary group. Patient selection involved, beyond multidisciplinary query and criteria inclusion and exclusion, consideration of aspects such as high surgical risk, expectation, life quality and assessment of biological fragility. Biological Frailty was evaluated based analyzing multiple factors like mobility, strength, capacity of perform activities of daily life, nutritional status and presence of cognitive deficits. The EuroSCORE and STS score were used in order to provide

quantitative analysis of the individual risk involved in procedure.

Patients underwent clinical, laboratory, echocardiogram, cineangiocoronariography (when clinical condition permitting) and Doppler ultrasonography examinations of the iliac femoral and carotid system.

Inclusion and exclusion criteria are referred in another publication [18].

Demographic and comorbidities of the patients are listed in Table 1.

Table 1. Demographic characteristics and comorbidities.

Characteristics	n=33
Age in years (mean/range)	75.51/34-88
Female (n/%)	17/51.51
Systemic Arterial Hypertension (n/%)	31/93.93
Diabetes (n/%)	7/21.21
Dyslipidemia (n/%)	20/60.60
Glomerular filtration rate < 50 mL/min (n/%)	26/78.78
Renal dialysis	2/6.06
Restrictive/obstructive lung disease (n/%)	11/33.33
Pulmonary arterial hypertension (n/%)	9/27.27
Operated in the presence of hospitalization for decompensation (n/%)	13/39.39
Atrial fibrillation (n/%)	9/27.27
Functional type – NYHA (n/%)	
II	4/12.12
III	11/33.33
IV	18/54.54
Comorbidities	
Coronary artery disease (n/%)	18/54.54
Previous coronary angioplasty (n/%)	8/24.24
Prior cardiovascular surgery (n/%)	16/48.48
Peripheral arterial disease (n/%)	17/51.51
Previous stroke (n/%)	2/6.06
Cancer (n/%)	1/3.03
Porcelain aorta (n/%)	6/18.18
Chagas (n/%)	1/3.03
Sickle cell anemia (n/%)	1/3.03
Biological vulnerability (Frailty) (n/%)	15/45.45
"Valve-in-valve" (n/%)	8/24.24
Logistic EuroSCORE (%) (mean/range)	39.30/5.85-90.3
STS score (%) (mean/range)	30.28/4.8-62.9
Peak aortic gradient (mean ± standard deviation)	75.41±22.64
Mean aortic gradient (mean ± standard deviation)	43.58±14.67
Left ventricular ejection fraction (mean ± standard deviation)	49.23±13.50

NYHA – New York Heart Association

Device and Procedure

The implant of transapical aortic valve was performed according technique described previously [18]. Was used in all cases expandable transcatheter balloon bioprosthesis (Braile Biomédica, São José do Rio Preto, Brazil), in sizes 20 to 26 mm in diameter, as the aortic valve or the inner diameter of the bioprosthesis dysfunction, considering one on the size 10% (Figure 1).

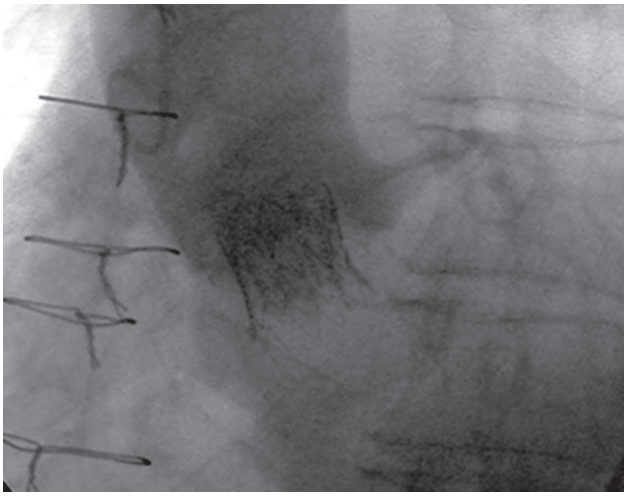


Fig. 1 - Aortography control, demonstrating the correct positioning of the prosthesis in relation to the valve annulus, coronary ostia patency and absence of aortic insufficiency

Intraoperative transesophageal echocardiographic controls were performed after valve implantation and hemodynamic stabilization in order checking correct prosthetic valvar functioning as well as its hemodynamics. In cases where it was verified perivalvar aortic insufficiency it was performed a new ballooning prosthesis with induced-hypotension. Aortography control was only performed in cases of doubt on echocardiographic valvar functioning or suspected interference with coronary ostia.

After the procedure, all patients were maintained on protocol of double antiaggregation using acetylsalicylic acid and clopidogrel.

Follow-up and Outcomes

Procedural success was defined as a correct implant, with satisfactory hemodynamic profile and absence of significant valvar and perivalvular leaks and absence of major immediate complications.

Patients were followed serially in the postoperative follow-up: 1 day, 7 days, 30 days, 6 months, 12 months, 18 months and 24 months. Clinical and echocardiographic assessments were performed.

The outcomes evaluated were all-cause mortality (30 days, and overall post-discharge), major cardiovascular events, rehospitalization for prosthetic valve dysfunction or clinical deterioration, functional class, stroke, vascular complications, renal failure and bleeding.

Stroke and AMI were defined according recommendations of the Valve Academic Research Consortium [19].

Statistical analysis

Statistical analysis was performed using SPSS version 11. The confidence level 0.05 was used as significant. Comparison between averages used testing of Friedman after verification of normal distribution of the values. Mean and standard error were used to express analyzes, unless specified otherwise. Kaplan-Meyer curve was used for analyzes of adequate survival outcomes.

RESULTS

Procedure

All cases were performed in the institution in hybrid surgical room. The valvar implant was successfully possible in 30 cases. Three immediate conversions occurred: two by migration of the prosthesis and one by hemodynamic deterioration after implantation.

Mean time of implantation was 183.21 ± 78.19 minutes. Mean time of fluoroscopy was 13.23 ± 6.01 minutes. Averaged quantity of contrast used was 27.87 ± 39.98 mL, while in second half of the casuistry it was 4.70 ± 13.28 mL. Operative mortality was of one case. There was no need of implant over one valve in the same patient. Major vascular complication occurred in one case (rupture of iliac vein during femoral cannulation requiring minilaparotomy). Two cases of definitive pacemaker occurred: one by atrial fibrillation of low ventricular response at day 15 of postoperative still in the hospital phase and one due to total atrioventricular block after discharged on the 45th postoperative day.

Table 2. Operative variables.

Variable	n=33
Procedural success (n/%)	30/90.91
Conversion to conventional replacement (n/%)	2/6.06
Defibrillation (n/%)	2/6.06
Intallation of CPB (excluding conversions)	1/3.03
Contrast (mL) (mean)	27.87
Fluoroscopy time (min) (mean ± standard deviation)	13.23±6.01
Procedure time (min) (mean ± standard deviation)	182.66±75.52

The following sizes of the devices were : 3 of 20 mm, 8 of 22 mm, 11 of 24 mm and 11 of 26 mm. Cases of valve-in-valve used prostheses: 2 of 20 mm, 4 of 22 mm and 2 of 24 mm.

The follow ran-up ranged from 1 to 21 months.

Operative Variables are listed in Table 2.

Mortality and rehospitalization

Mortality in 30 days was 18.18%. There were 12 hospital deaths (before discharge) these were due to following complications: bronchopneumonia (four cases: 32, 53, 112 and 418 days) tracheoesophageal fistula (one case: 392 days) sepsis with infection of bloodstream (five cases: 5 16 17, 21:31 days), AMI (one case: 54 days) and stroke (one case: 24 days). During post hospital discharge follow-up occurred two deaths: one case due to Influenza H1N1 (90

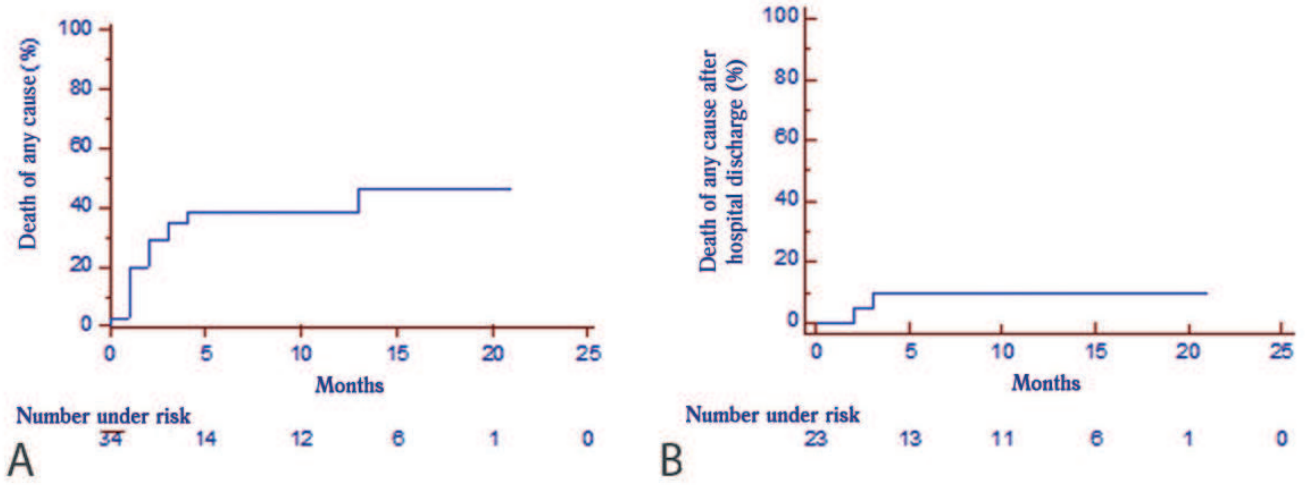


Fig. 2 - Kaplan-Meier curve for all-cause mortality and mortality after hospital discharge

days) and another by cardiogenic shock with normofunctioning prosthesis (52 days).

Survival at 6, 12 and 18 months calculated by the Kaplan-Meyer was respectively of 61.5%, 61.5% and 53.8%. Survival in patients discharged derived from Kaplan-Meyer curve at 6, 12 and 18 months was 90.7% (Figure 2).

Rate of rehospitalization was 15.15% while after sixth months occurred only one rehospitalization. Their causes were 1. Lobar pneumonia; 2. Left hemothorax probably secondary to apical ventricular bleeding requiring thoracic drainage; 3. Left pleural effusion requiring thoracentesis; 4. Aortic insufficiency with a new episode of valvar ballooning 5. Cardiogenic shock; 6. Total atrioventricular block, requiring definitive pacemaker.

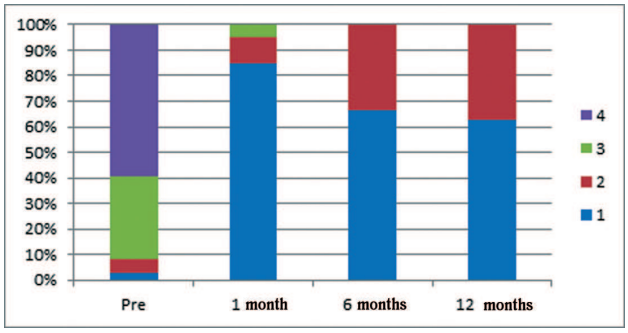


Fig. 3 - Evolution of NYHA functional class

Complications

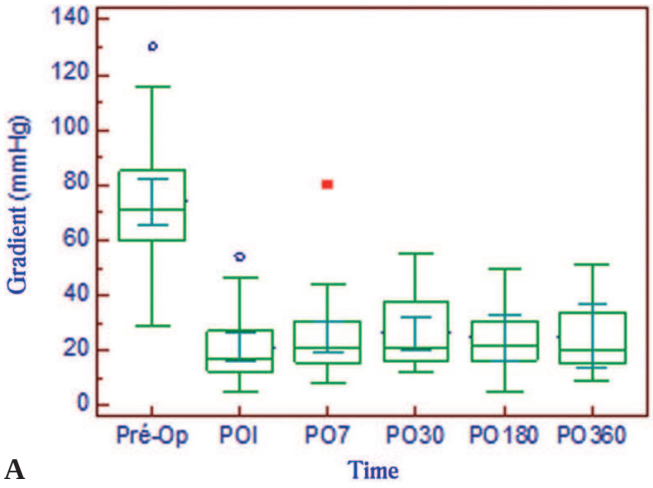
Other complications are related in Table 2.

Evolution of functional class

Functional class presented significant improvement comparing preoperatively with 1, 6 and 12 months (*P* <0.0001). Comparison between 1, 6 and 12 months did not demonstrate statistically significant difference (Figure 3).

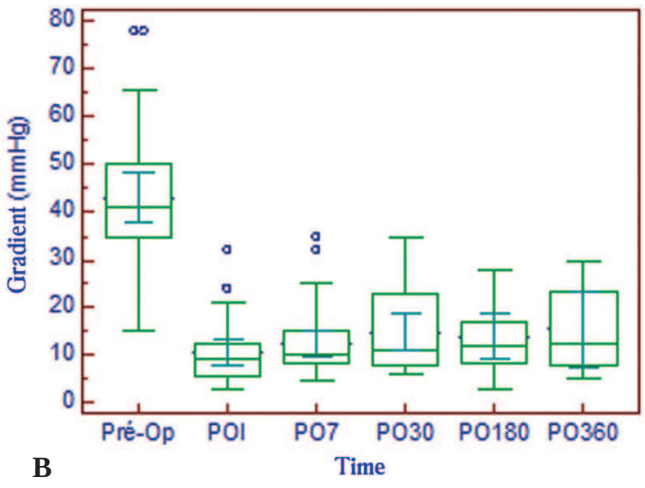
Echocardiographic evaluation

The hemodynamic results assessed by echocardiography was satisfactory, with significant reduction of peak gradient of 75.41 ± 22.64 21.32 ± 12.42 mmHg for the first postoperative day (*P* <0.001). Evolution demonstrated that this reduction gradient was maintained in subsequent exams without statistically significant between gradient obtained after implantation in the immediate postoperative (Figure 4). The gradient also demonstrated significant reduction 43.58 ± 14.67 mmHg to 10.54 ± 6.90 mmHg in 1st postoperative day (*P* <0.001). Evolution also demonstrated maintenance of this reduction (Figure 4).



A

Preoperative versus 1st postoperative – p<0.001
1st postoperative versus the subsequent days p>0.05



B

Preoperative versus 1st postoperative – p<0.001
1st postoperative versus the subsequent days p>0.05

Fig. 4 - A. Peak aortic transvalvular gradients in the pre-,1st, 7th, 30th, 180th, 360th postoperatively. B. Mean aortic transvalvular gradients pre-, 1st, 7th, 30th, 180th, 360th postoperatively

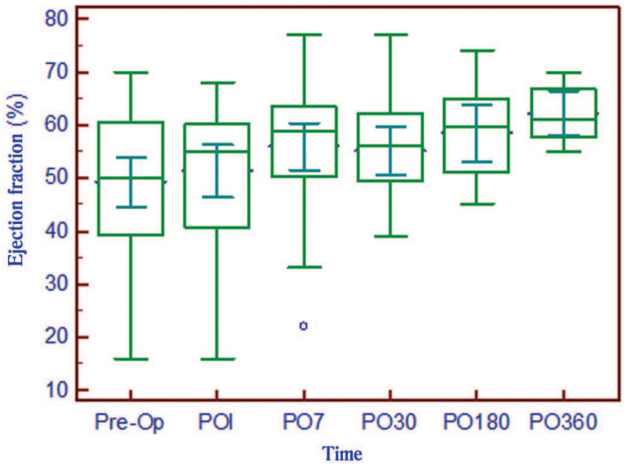


Fig. 5 – Left ventricular ejection fraction in the pre-,1st, 7th, 30th, 180th, 360th postoperatively.
Preoperative versus 1st postoperative day – P>0,05
Preoperative versus 7th postoperative day – P=0,01
Preoperative versus 30th postoperative– P<0,0001

Periprothetic aortic insufficiency in the immediate postoperative occurred in 10 (30.30%) cases being insufficiency 1 + in 15.15%, 2 + in 12.12% and 3 + 3.03%. Distribution and aortic regurgitation severity were maintained over the observation period and trending to decrease. In patients undergoing valve-in-valve implantation peri or transprosthetic aortic insufficiency did not occurr. One patient required reintervention, with a new episode of balloon inflation of the prosthesis on the 4th month of postoperative due to severe paraprosthetic regurgitation and resolution after the procedure, with no associated mortality.

Ventricular function measured by left ventricular ejection fraction by the method of Simpson presented improvement statistically significant 49.23 ± 13.50 for 55.93 ± 11.53 on the seventh days postoperative (P <0.01), sustained during the follow-up (Figure 5).

Intraoperative Variables are listed in Table 2.

DISCUSSION

Aortic valve replacement is the procedure of choice for patients with aortic valve stenosis or prosthetic dysfunction. In the majority of the population, the intervention has low risk and is able to promote functional improvement and increase the survival rate when compared to medical treatment [6]. Even in aged-advanced patients they may present acceptable risk in centers of great experience [20].

Despite these evidences, significant percentage of patients have their procedure denied either by risk considered unacceptable or technical conditions that make prohibitive the thoracic access, installation of CPB or aortic clamping. Among them the presence of aortas with calcifications extensive or in porcelain, presence of pervious coronary grafts, thoracic radiotherapy or existence of multiple comorbidities [8]. This population of carriers of aortic stenosis is not candidate to conventional procedure and therefore not included in most studies of operative risk which makes its evaluation doubtful.

Operative risk assessment based in risk scores has several limitations like non inclusion of some characteristics deemed as of risk: mediastinal irradiation, aortic porcelain, hepatic dysfunction, thoracic wall abnormalities and prior mediastinitis. One should regardless that individuals who served of basis for composition of scores were patients who effectively underwent surgery, limiting the inference in groups originally not considered candidates for interventional procedure [21].

Within this context, the possibility of less invasive intervention with the transcatheter aortic valve implant, both femoral or apical via, has become an attractive alternative. Several centers have published encouraging results, however, the mortality still remains significant, despite the seriousness of the patients and the advancement of the devices [14.18].

The population selected for initial evaluation of this novel device comprised individuals with risk score extremely high reaching a Logistic EuroScore of 90.3% and a STS score of 62.9%, with averages that outweigh most studies in the literature [22]. Although some cases present risk score below forecast inclusion criteria these patients were carriers of comorbidities not contemplated in such criteria and undescribed previously in individuals undergoing transcatheter treatment, such as Chagas disease and SCD. Multiprofessional evaluation justified its selection. Age was another factor of questioning showing that not only elderly individuals are candidates to the procedure.

Inclusion of young patient can arouse possibility of transcatheter intervention as bridge to stabilization until definitive therapy or even until as destination therapy.

Frequency of comorbidities as aorta porcelain, peripheral artery disease, coronary artery disease, previous surgery and renal dysfunction present in population of this study is higher than in SOURCE registry with consequent risk elevation [23].

The strategy of implante selected was via transapical for allowing compatibilization with introducers of larger caliber and decrease possiblity of peripheral vascular complications. Several studies have reported increased mortality with the transapical approach compared to the transfemoral, but mostly transapical access is reserved for

cases of failure in the femoral access, which makes the groups not comparable [23]. On the other hand, the transapical approach is the access of choice in some groups, to avoid excessive manipulation of the iliac femoral system and aortic arch, reducing vascular complications and stroke, factors known to be implicated in mortality [24].

Hospital mortality of the procedure is quite inconstant in the literature, but groups mostly are not comparable. The observed risk is smaller than predicted by risk scores despite several questionings about validity [22]. Another important point refers to fact that outcome mortality in 30 days may not explicit actual outcome of the patient since, as in our sample, many patients can survive initial procedure and perish after first months due to diverse complications, especially infectious of high mortality in this fragile group. Thus outcome of general mortality and its separation by mortality after discharged is fundamental for correct safety assessment and procedural efficacy.

Mortality found in 30 days is significant but similar to literature (18.18%) even considering greater gravity o four group [22]. And the global mortality (42.42%) is influenced negatively by infectious complications in the postoperative. In this sample 39.39% patients were operated under decompensation and hospitalized, arousing greater risk of infectious colonization. Conversely, survival after discharged is quite favorable (90.7%) demonstrating than that after initial phase the result is sustained and improvements in postoperative care as implementing of multiprofessional care are fundamental for success the of procedure [12].

The fact that the global mortality observed is similar to predicted EuroScore (39.30% versus 42.42%) should not mean that implantation of transcatheter aortic valve has similar result compared to conventional procedure since these scores were not calibrated for this population of patients. Patients selected for this study had their indication for conventional surgery denied for at least two surgeons. In groups like these the survival is unfavorable reaching in 1, 2 and 3 years only 50% 25% and 10% respectively [25].

Ye et al. [26] demonstrated in a 3-year follow-up, overall mortality rate of 42.25%, a result quite similar to that observed in our sample, and the 30-day mortality of 16.9%, despite the risk profile is more favorable with lower EuroSCORE and STS score.

The Partner Trial, recently published, demonstrated mortality and compound outcomes significantly lower in group undergone transcatheter therapy compared to clinical treatment in randomized samples with survival of 1 year of 69.3% for transcatheter group versus 49.3% with clinical treatment [14], a value similar to found in our sample (survival 1 years 61.5%).

Minors complications are event of relative frequency and affect negatively evolution, especially vascular complications [23]. In the group studied there was only one vascular complication (without mortality) which added to insufficient sample size it does not allow conclusions about impact of this complication in global mortality.

Failure in proper occlusion of the left ventricular apex is also reported in the literature, being potentially the cause of two cases of hemothorax requiring reintervention in first half of the casuistry. Reducing caliber of the introducer of 26Fr to 22Fr facilitated apical closing and there were no new cases of bleeding. Conversely, even with introducers of small caliber the apical occlusion can become challenging with great blood loss. The possibility of aid of CPB or rescue blood bsystems can be crucial in patient outcome.

There were two cases of need for renal replacement with hemodialysis therapy, although 78.78% of the patients had glomerular filtration rate below 50%. Possibly low use of iodized contrast collaborated in preservation of renal function (unused in 60.60% patients).

Structural valvar deterioration is still one parameter of difficult evaluation and comparison in the literature, given the small period of follow-up as well as small diversity of prostheses available. It is worrying the fact that valvar leaflets need compression and balloon expansion can theoretically cause their early structural deterioration. In our study it was not observed deterioration of valvar function in the leaflets during follow-up but one patient required new episode of ballooning due to aortic periprosthetic insufficiency with total resolution.

Atrioventricular block is a complication often described, reaching a third of patients, especially with the CoreValve [27]. Balloon expandable prostheses, such as Edwards Sapiens and Braile, present indices of need for permanent cardiac stimulation around 4.5% [14]. Only two cases need definitive pacemaker implantation being only one total atrioventricular block. Again, little power sample does not allow to estimate real incidence of disorder with this new prosthesis.

The need for conversion to the conventional approach, total cardiopulmonary support and valve replacement is reported as being around 3.5% [22]. In our sample, there were two (6.06%) conversions, and one patient died after 30 days due to bronchopneumonia and one is still alive without complications. Both causes of conversion were related to the learning curve, with migration of the valve during implantation. Problems related to valve embolization occur around 0.5% in trained staff [22]. Among the causative factors include incorrect assessment of the native valve (little calcification, asymmetric presence of calcium, imprecision of measurement of the annulus). The valve position during the release of the prosthesis is also a complicating factor, which may cause interference with mitral apparatus or obstruction of the coronary ostia, this complication is not present in this sample.

The echocardiographic evaluation and follow-up of patients undergoing transcatheter therapy is of paramount importance when comparing different devices and conventional aortic valve replacement. The performance and durability of these new prostheses need constant evaluation, considering the vast differences in valve design, their mode of implant and attachment mechanism. There are no long-term data on these variables. The hemodynamic profile of these devices is superior to traditional models, both mounted on a support or stentless model. The lack of major support structures contributes to the superiority, providing significant gains in effective orifice. Comparisons between the performance and evolution of hemodynamic improvement in ventricular function are markedly higher in patients who underwent transcatheter intervention when compared to the usual procedure [28,29].

Although the hemodynamic profile is higher, the persistence of varying degrees of aortic insufficiency after the procedure, mainly from perivalvar origin - usually mild to moderate - is present regardless of the type of prosthesis used [15]. The prevalence of failure is greater than the expected in conventional replacements [30]. Such leaks are secondary to the difficulty of perfect match between the prosthetic valve and irregular circumference of the aortic valve annulus after balloon valvuloplasty.

Data from Partner Trial evidenced 10.5% of moderate to severe periprosthetic aortic valve regurgitation in 1 year [14]. In present sample, incidence of severe or moderate aortic insufficiency was lower that found in literature. The availability of greater numbers of prosthetic diameters allow more precise selection of the appropriate model, capable of better coaptation compared to the native annulus. Patients undergoing aortic valve-in-valve implantation showed no perivalvar aotic insufficiency by coaptation, naturally more regularly between the two prostheses.

The transvalvular gradients after implantation showed a significant reduction compared to preoperative values †and remained low during follow-up, demonstrating a favorable hemodynamic profile of this device. This maintenance is similar to that found in other commercially available prostheses [29]. The reduction of the gradient was less pronounced, although significant in cases of valve-in-valve, suggesting that such a strategy may be more prone to generate mismatch, especially when the bioprosthesis dysfunction is of reduced diameter.

Ventricular function improves significantly as a result and as early as possible. On the seventh postoperative day, one can see significant increase. The rapid improvement may partly explain the differences in mortality observed between conventional and transcatheter procedures. The non-use of cardiopulmonary bypass and aortic clamping and cardioplegic protection in the presence of a lower afterload generated by transcatheter prostheses are possible causes [28,29].

The functional class of patients improved and remains stable in the follow-up. At 12 months, all patients are in functional class 1 or 2 (NYHA). Obviously, a larger sample may identify cases in a worse functional class, but the prevalence of mildly symptomatic patients should remain. Large studies that encompass assessment of parameters such as functional class and quality of life and exercise tolerance are needed to determine the real benefit.

The study has limitations such as small sample size and relatively short follow-up time. The learning curve is present especially in the correct selection of candidates for transcatheter treatment. Identify individuals with greater benefit with this strategy is only possible with more patients and long-term follow-up. Randomization facing the open clinical treatment and replacement can confirm the findings.

CONCLUSION

Transcatheter treatment of aortic stenosis and dysfunction of the bioprosthesis with this new valve is able to provide benefits with cardiac structural and functional improvement. It is mandatory a further follow-up, with the aim of measuring the benefits, complications and to improve selection criteria.

The conventional intervention remains the gold standard for low risk patients, but this new strategy can be recommended for selected groups, with contraindications to traditional procedure.

REFERENCES

1. Otto CM, Lind BK, Kitzman DW, Gersh BJ, Siscovick DS. Association of aortic-valve sclerosis with cardiovascular mortality and morbidity in the elderly. N Engl J Med. 1999;341(3):142-7.

2. Oliveira Júnior JL, Fiorelli AI, Santos RHB, Pomerantzeff PAM, Dallan LAO, Stolf NAG. A doença coronária aumenta a mortalidade hospitalar de portadores de estenose aórtica submetidos à substituição valvar? Rev Bras Cir Cardiovasc. 2009;24(4):453-62.

3. Segalote RC, Pomerantzeff PMA, Brandão CMA, Stolf NAG. Cirurgia de preservação da valva aórtica em idosos com estenose aórtica. Rev Bras Cir Cardiovasc. 2008;23(4):519-23.

4. Bonini RCA, Palazzi EM, Chaccur P, Sousa LCB. Correção cirúrgica da estenose aórtica supravalvar com modificação da técnica de Sousa. Rev Bras Cir Cardiovasc. 2010;25(2):253-6.

5. Feguri GR, Macruz HMS, Bulhões D, Neves A, Castro RM, Fonseca L, et al. Troca valvar aórtica com diferentes próteses. Existem diferenças nos resultados da fase hospitalar? Rev Bras Cir Cardiovasc. 2008;23(4):534-41.

6. Edwards FH, Peterson ED, Coombs LP, DeLong ER, Jamieson WR, Shroyer ALW, et al. Prediction of operative mortality after valve replacement surgery. J Am Coll Cardiol. 2001;37(3):885-92.

7. Saadi EK. Implante percutâneo de valva aórtica: mito ou realidade? Rev Bras Cir Cardiovasc. 2008;23(1):93-6.

8. Iung B, Cachier A, Baron G, Messika-Zeitoun D, Delahaye F, Tornos P, et al. Decision-making in elderly patients with severe aortic stenosis: why are so many denied surgery? Eur Heart J. 2005;26(24):2714-20.

9. Schueler R, Hammerstingl C, Sinning JM, Nickenig G, Omran H. Prognosis of octogenarians with severe aortic valve stenosis at high risk for cardiovascular surgery. Heart. 2010;96(22):1831-6.

10. Cribier A, Savin T, Saoudi N, Rocha P, Berland J, Letac B. Percutaneous transluminal valvuloplasty of acquired aortic stenosis in elderly patients: an alternative to valve replacement? Lancet. 1986;1(8472):63-7.

11. Cribier A, Eltchaninoff H, Bash A, Borenstein N, Tron C, Bauer F, et al. Percutaneous transcatheter implantation of an aortic valve prosthesis for calcific aortic stenosis: first human case description. Circulation. 2002;106(24):3006-8.

12. Walther T, Falk V, Kempfert J, Borger MA, Fassl J, Chu MW, et al. Transapical minimally invasive aortic valve implantation; the initial 50 patients. Eur J Cardiothorac Surg. 2008;33(6):983-8.

13. Webb JG, Altwegg L, Boone RH, Cheung A, Ye J, Lichtenstein S, et al. Transcatheter aortic valve implantation: impact on clinical and valve-related outcomes. Circulation. 2009;119(23):3009-16.

14. Leon MB, Smith CR, Mack M, Miller DC, Moses JW, Svensson LG, et al; PARTNER Trial Investigators. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. New Engl J Med. 2010;363(17):1597-607.

15. Al-Attar N, Himbert D, Descoutures F, Iung B, Raffoul R, Messika-Zeitoun D, et al. Transcatheter aortic valve implantation: selection strategy is crucial for outcome. Ann Thorac Surg. 2009;87(6):1757-62.

16. Walther T, Falk V, Borger MA, Kempfert J, Ender J, Linke A, et al. Transapical aortic valve implantation in patients requiring redo surgery. Eur J Cardiothorac Surg. 2009;36(2):231-4.

17. Gaia DF, Palma JH, Souza JA, Guilhen JC, Telis A, Fischer CH, et al. Off-pump transapical balloon-expandable aortic valve endoprosthesis implantation. Rev Bras Cir Cardiovasc. 2009;24(2):233-8.

18. Gaia DF, Palma JH, Ferreira CB, de Souza JA, Agreli G, Guilhen JC, et al. Transapical aortic valve implantation: results of a Brazilian prosthesis. Rev Bras Cir Cardiovasc. 2010;25(3):293-302.

19. Leon MB, Piazza N, Nikolsky E, Blackstone EH, Cutlip DE, Kappetein AP, et al. Standardized endpoint definitions for transcatheter aortic valve implantation clinical trials: a consensus report from the Valve Academic Research Consortium. Eur Heart J. 2011;32(2):205-17.

20. Grossi EA, Schwartz CF, Yu PJ, Jorde UP, Crooke GA, Grau JB, et al. High-risk aortic valve replacement: are the outcomes as bad as predicted? Ann Thorac Surg. 2008;85(1):102-6.

21. Zajarias A, Cribier AG. Outcomes and safety of percutaneous aortic valve replacement. J Am Coll Cardiol. 2009;53(20):1829-36.

22. Yan TD, Cao C, Martens-Nielsen J, Padang R, Ng M, Vallely MP, et al. Transcatheter aortic valve implantation for high-risk patients with severe aortic stenosis: A systematic review. J Thorac Cardiovasc Surg. 2010;139(6):1519-28.

23. Thomas M, Schymik G, Walther T, Himbert D, Lefèvre T, Treede H, et al. Thirty-day results of the SAPIEN aortic Bioprosthesis European Outcome (SOURCE) Registry: A European registry of transcatheter aortic valve implantation using the Edwards SAPIEN valve. Circulation. 2010;122(1):62-9.

24. Johansson M, Nozohoor S, Kimblad PO, Harnek J, Olivecrona GK, Sjögren J. Transapical versus transfemoral aortic valve implantation: a comparison of survival and safety. Ann Thorac Surg. 2011;91(1):57-63.

25. Kojodjojo P, Gohil N, Barker D, Youssefi P, Salukhe TV, Choong A, et al. Outcomes of elderly patients aged 80 and over with symptomatic, severe aortic stenosis: impact of patient's choice of refusing aortic valve replacement on survival. QJM. 2008;101(7):567-73.

26. Ye J, Cheung A, Lichtenstein SV, Nietlispach F, Albugami S, Masson JB, et al. Transapical transcatheter aortic valve implantation: follow-up to 3 years. J Thorac Cardiovasc Surg. 2010;139(5):1107-13, 1113.e1.

27. Fraccaro C, Buja G, Tarantini G, Gasparetto V, Leoni L, Razzolini R, et al. Incidence, predictors, and outcome of conduction disorders after transcatheter self-expandable aortic valve implantation. Am J Cardiol. 2011;107(5):747-54.

28. Zhao Y, Lindqvist P, Nilsson J, Holmgren A, Näslund U, Henein MY. Trans-catheter aortic valve implantation—early recovery of left and preservation of right ventricular function. Interact Cardiovasc Thorac Surg. 2011;12(1):35-9.

29. Clavel MA, Webb JG, Pibarot P, Altwegg L, Dumont E, Thompson C, et al. Comparison of the hemodynamic performance of percutaneous and surgical bioprostheses for the treatment of severe aortic stenosis. J Am Coll Cardiol. 2009;53(20):1883-91.

30. Rallidis LS, Moyssakis IE, Ikonomidis I, Nihoyannopoulos P. Natural history of early aortic paraprosthetic regurgitation: a five-year follow-up. Am Heart J. 1999;138(2 Pt 1):351-7.