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Original Article

Subclavian Access for Transcatheter CoreValve® Aortic Prosthesis Implantation: Data from the Brazilian Registry

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ABSTRACT

Background: Transfemoral access is the preferred approach for transcatheter aortic valve implantation. However, some situations, such as the presence of peripheral vascular disease, preclude the use of such access. In these cases, subclavian access is an alternative approach for this procedure. This study aimed at evaluating the Brazilian experience using the subclavian approach for transcatheter CoreValve® prosthesis implantation. **Methods:** Aortic valve area < 1 cm², aortic valve ring ≥ 20 mm and ≤ 27 mm (26 mm and 29 mm CoreValve®), ascending aorta ≤ 43 mm and subclavian artery with a diameter ≥ 6 mm, without significant obstructive lesions, marked tortuosity and excess calcification were requisites for the procedure. The access through the subclavian artery was obtained by surgical dissection and, under direct vision, a subclavian artery puncture was performed. Once artery access was obtained, the standard technique was used. **Results:** Between January 2008 and April 2012, 8 patients with peripheral vascular disease underwent CoreValve® prosthesis implantation through the subclavian artery in 4 institutions. The procedure was successful in all cases with reduction of the mean transvalvular pressure gradient from 46.4 ± 17.5 mmHg to 9.3 ± 3.6 mmHg (P = 0.0018) and improvement of symptoms. At 30 days and after 275 ± 231 days of follow-up, 87.5% and 62.5% of the patients, respectively, were free from major adverse events (death, myocardial infarction, stroke and urgent cardiac sur-

RESUMO

Acesso pela Artéria Subclávia para Implante por Cateter da Bioprótese Valvar Aórtica CoreValve®: Dados do Registro Brasileiro

Introdução: A via de acesso transfemoral é preferencial para o implante por cateter de bioprótese valvar aórtica. Entretanto, algumas situações, como a presença de doença vascular periférica, impossibilitam a utilização desse acesso. Nesses casos, o acesso por dissecção da artéria subclávia é uma alternativa para a realização do procedimento. Nosso objetivo foi avaliar a experiência brasileira com a utilização da artéria subclávia como via de acesso para o implante por cateter da bioprótese CoreValve®. **Métodos:** Foram requisitos para o procedimento área valvar aórtica < 1 cm², ânulo valvar aórtico > 20 mm e < 27 mm (CoreValve® de 26 mm e 29 mm), aorta ascendente < 43 mm e artéria subclávia com diâmetro > 6 mm, isenta de lesões obstrutivas significativas, tortuosidade acentuada e calcificação excessiva. O acesso pela artéria subclávia foi obtido por dissecção cirúrgica e, sob visão direta, punção da artéria subclávia. Obtido o acesso arterial, empregou-se a técnica padrão. **Resultados:** Entre janeiro de 2008 e abril de 2012, 8 pacientes com doença vascular periférica foram submetidos a implante de prótese CoreValve® pela artéria subclávia em 4 instituições. O procedimento foi realizado com sucesso em todos os casos, com redução do gradiente transvalvar aórtico médio de 46,4 + 17,5 mmHg para 9,3 + 3,6 mmHg (P = 0,0018) e

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gery). **Conclusions:** In the Brazilian experience, the subclavian access was a safe and effective alternative for transcatheter CoreValve® implantation.

DESCRIPTORS: Aortic valve stenosis. Subclavian artery. Heart valve prosthesis.

melhora dos sintomas. Aos 30 dias e no seguimento de 275 + 231 dias, 87,5% e 62,5% dos pacientes, respectivamente, apresentavam-se livres de complicações maiores (óbito, infarto do miocárdio, acidente vascular cerebral e cirurgia cardíaca de urgência). **Conclusões:** Na experiência brasileira, o acesso pela artéria subclávia mostrou-se seguro e eficaz como via alternativa para o implante por cateter da bioprótese CoreValve®.

DESCRITORES: Estenose da valva aórtica. Artéria subclávia. Próteses valvulares cardíacas.

Transcatheter aortic valve implantation is a safe and effective procedure for the treatment of patients with symptomatic aortic stenosis that is either inoperable or that carries a high surgical risk.[1,2] For this procedure, the femoral approach is preferred, since it is less invasive. However, some situations, such as the presence of atheromatous disease, tortuosity, and calcification in the territories of the femoral and iliac arteries, prevent the procedure from being performed through the femoral artery. In these cases, alternative access routes can be used, such as the transapical and transaortic routes.[1,3,4] However, complications arising from the thoracotomy and the incision in the left ventricular apex are not uncommon with these techniques.[5,6] Access through dissection of the subclavian artery has been described as a less invasive option and therefore more attractive for the implantation of the CoreValve® bioprosthesis (CoreValve® Revalving System, Medtronic, Inc. – Minneapolis, USA).[7–11] In this study, the Brazilian experience with the use of the subclavian artery as an access route for CoreValve® bioprosthesis implantation is reported, with data obtained from the Brazilian Registry of Transcatheter Aortic Valve Bioprostheses Implantation.[12]

METHODS

Patient selection

Patients in whom the subclavian artery was used as an access for CoreValve® bioprosthesis implantation were selected for this study from the Brazilian registry. The subclavian artery was used only when there were contraindications to femoral access, and whenever possible, the left subclavian access was chosen. Patients considered to be suitable for the procedure were those with aortic valve area < 1 cm^2, annular aortic valve ≥ 20 mm and ≤ 27 mm (CoreValve® of 26 mm and 29 mm), ascending aorta ≤ 43 mm, and subclavian artery diameter ≥ 6 mm, free of significant obstructive lesions, severe tortuosity, and excessive parietal calcification.

The EuroSCORE and STS scores were used to estimate the risk of surgical mortality in this series of patients.[13,14]

Procedure

Preparation for the procedure consisted of antibiotic and antiplatelet therapy with aspirin and/or clopidogrel. The valve implantations were performed under general anaesthesia. Alternative access through the subclavian artery was obtained by surgical dissection. For the dissection, an infraclavicular incision was used. Under direct vision, the subclavian artery was punctured for the positioning of the 18 F sheath or, when the artery was deep, a Dacron graft was anastomosed to the artery and used for insertion of the 18 F sheath (Figure 1). After obtaining arterial access, the standard technique (Figure 2) was used for the CoreValve® bioprosthesis implantation, which consists of three porcine pericardium leaflets, mounted and sutured into an auto-expansible nitinol stent 5 cm in length. At the end of the procedure, the 18 F sheath was removed, and the subclavian artery was sutured.

Data collection and outcomes

Clinical data and information on complementary exams were collected during medical appointments or by telephone contact and entered into an electronic spreadsheet developed for the Brazilian Registry. All outcomes and complications followed the criteria established by the Valve Academic Research Consortium Consensus on Definition Event Event (VARC).[15]

Statistical analysis

Continuous variables are shown as the mean ± standard deviation, and categorical variables are shown as frequencies (number and percentage). For the comparative analysis of categorical variables, the chi-squared or Fisher's exact tests were used. For the sequential analysis of continuous variables in the same patient, a paired *t*-test was used. The significance level was set at 5% ($P < 0.05$).

RESULTS

Between January of 2008 and April of 2012, 277 patients with aortic valve stenosis and either contraindications for or high-risk for conventional surgical treatment underwent transcatheter CoreValve® bioprosthesis implantation in 12 centres, and were included in the Brazilian Registry. At four of these institutions,

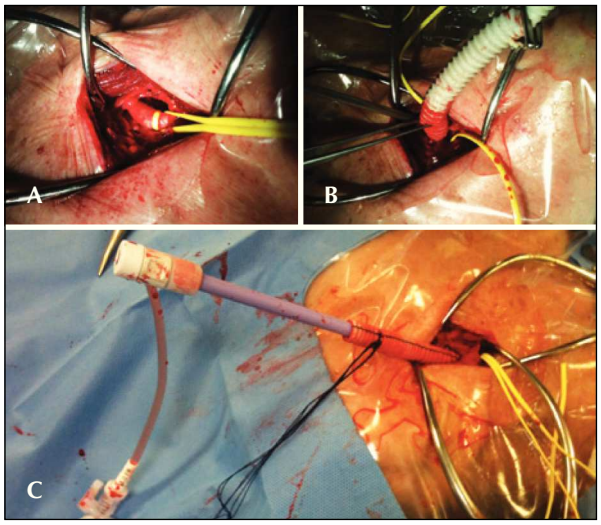

Figure 1 – In A, subclavian artery dissection. In B, Dacron graft anastomosis. In C, 18 F sheath positioning in the subclavian artery through the graft.

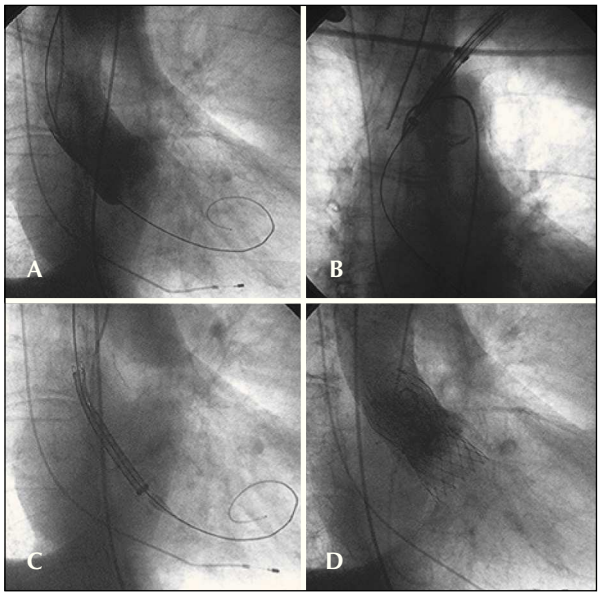

Figure 2 – In A, aortography and placement of a guidewire inside the left ventricle. In B, introduction of the CoreValve® prosthesis for the left subclavian artery. In C, a prosthesis positioned in the aortic annulus. In D, aortography demonstrating a well-positioned and competent CoreValve® prosthesis.

the subclavian access route was used for the treatment of eight (2.9%) patients: two (25%) through the right subclavian artery and six (75%) through the left subclavian artery.

The basal demographic and clinical characteristics of the eight patients receiving the CoreValve® bioprosthesis implant through the subclavian artery are described in Table 1. The high surgical risk in this group of patients was demonstrated by the EuroSCORE and STS risk scores, which were both above 30%. The contraindication for femoral access was the presence of peripheral vascular disease, and three (37.5%) of the patients also had an abdominal aortic aneurysm.

TABLE 1
Basal Demographic and Clinical Data

Characteristics	n = 8
Age, years (SD)	84 (7.3)
Male gender, n (%)	5 (62.5)
Logistic EUROSCORE, % (SD)	32 (16.4)
STS score, % (SD)	30.9 (23.4)
Functional Class (NYHA), n (%)	
I or II	0 (0)
III or IV	8 (100)
Diabetes, n (%)	3 (37.5)
Arterial hypertension, n (%)	5 (62.5)
Renal failure*, n (%)	6 (75)
Coronary artery disease, n (%)	5 (62.5)
Previous percutaneous coronary intervention	2 (25)
CABG	2 (25)
Cerebrovascular disease, n (%)	1 (12.5)
Peripheral vascular disease, n (%)	7 (87.5)
Chronic obstructive pulmonary disease, n (%)	2 (25)
Definitive pacemaker, n (%)	1 (12.5)

*Glomerular filtration rate < 60 mL/min.
SD = standard deviation; n = number of patients; NYHA = New York Heart Association; CABG = coronary artery bypass graft.

The mean hospital stay was 14 ± 12.9 days (one to 43 days). The mean follow-up of patients was 275 ± 231 days (one to 679 days). The one-month, one-year, and two-year follow-up data were available for seven (87.5%) patients, five (62.5%) patients, and one (12.5%) patient, respectively. There was no loss of clinical follow-up in any case.

Procedure

Data from the procedure are described in Table 2. Successful CoreValve® bioprosthesis implantation was achieved in 100% of the cases. In two (25%) cases it was necessary to perform post-dilation to properly expand the bioprosthesis and to reduce the intensity of the perivalvular insufficiency. Echocardiography detected the reduction of the mean and peak aortic transvalvular pressure gradients (Table 3). At the end of the procedure, there was mild periprosthetic aortic regurgitation in six (75%) cases.

Outcomes and complications

The transcatheter treatment of aortic valve stenosis was effective at alleviating the symptoms of heart failure. After 30 days and during follow-up, 85.7% of patients achieved functional class status I or II of the New York Heart Association (NYHA) criteria (P = 0.0007 vs. baseline).

Table 4 illustrates the complications that occurred within 30 days and during follow-up. During the procedure, one case of subclavian artery dissection occurred and was corrected with stenting, and one patient had bleeding that required a transfusion. One death from cardiovascular causes occurred one day after the procedure in a patient who developed refractory cardiogenic shock after valve implantation. Thus, mortality at 30 days was 12.5%. Two other deaths from non-cardiovascular causes occurred 43 and 679 days after the CoreValve® bioprosthesis implantation.

Two patients had renal failure after the procedure, one of which was associated with refractory cardiogenic shock and death, as previously described. None of the cases had a stroke, acute myocardial infarction (AMI), or the need for urgent heart surgery; thus, throughout the 275 ± 231 days of follow-up, five (62.5%) patients were free of major complications. In this series, excluding the patient who died one day after the procedure and one patient who was already using a pacemaker, two (33.3%) underwent implantation of a permanent pacemaker for advanced atrioventricular conduction disturbances.

TABLE 2
Procedure Data

Characteristics	n = 8
Proctor follow-up, n (%)	3 (37.5)
Transesophageal echocardiogram, n (%)	5 (62.5)
Anaesthesia, n (%)	
General	8 (100)
Sedation	0 (0)
Access route, n (%)	
Percutaneous	0 (0)
Surgical	8 (100)
Valvuloplasty, n (%)	5 (62.5)
Bioprosthesis, n (%)	
CoreValve® 26 mm	3 (37.5)
CoreValve® 29 mm	5 (62.5)
Post-dilation, n (%)	2 (25)
Device success, n (%)	8 (100)

n = number of patients.

DISCUSSION

The current versions of both devices available for clinical use, CoreValve® and Edwards SAPIEN (Edwards Lifesciences – Irvine, USA), with 18 F delivery systems (6 mm), allow the procedure to be performed through the femoral artery, as long as the arterial lumen diameter is at least 6 mm. However, in this population of patients of advanced age and with multiple comorbidities, it is not uncommon to find severe atheromatosis or excessive tortuosity, which prevent the procedure from being performed by this access route. In this case, access through the subclavian artery for CoreValve® bioprosthesis aortic implantation is a feasible, safe, and effective procedure, as demonstrated by several series and also by the present study with data from the Brazilian registry.[9–11] In international records, subclavian access is employed in approximately 5% of cases, and the patients have, in general, a higher surgical risk than patients in whom femoral access was used.[9–11,16–19] In the Brazilian Registry, only 2.9% of cases were treated using the subclavian artery, which is most likely due to the lower experience of centres with this alternative access route. As with the international series, patients from the Brazilian Registry treated through subclavian access had a very high surgical mortality risk, over 30%, demonstrating that the presence of peripheral vascular disease is also a marker of higher clinical and anatomic complexity.[20]

TABLE 3
Echocardiographic Data

	Basal (n = 8)	Post-implantation (n = 7)	P
Aortic valve area, cm^3 (SD)	0.7 (0.2)	NA	
Peak gradient, mmHg (SD)	73.6 (27.8)	17.8 (7.5)	< 0.001
Mean gradient, mmHg (SD)	46.4 (17.5)	9.3 (3.6)	0.0018
LVEF, % (SD)	58.7 (9.2)	63.4 (12.4)	0.175

SD = standard deviation; LVEF = left ventricular ejection fraction; n = number of patients; NA = not available.

TABLE 4
Adverse Events

	30 days	275 ± 231 days
Death, n (%)	1 (12.5)	3 (37.5)
Cardiovascular death	1 (12.5)	1 (12.5)
Stroke, n (%)	0	0
Myocardial infarction, n (%)	0	0
Acute renal failure, n (%)	2 (25)	2 (25)
Stage 1	1 (12.5)	1 (12.5)
Stage 2	0	0
Stage 3	1 (12.5)	1 (12.5)
Haemorrhagic complication, n (%)	1 (12.5)	1 (12.5)
Life-threatening, n (%)	0	0
Major, n (%)	1 (12.5)	1 (12.5)
Minor, n (%)	0	0
Vascular complication, n (%)	1 (12.5)	0
Major, n (%)	1 (12.5)	0
Minor, n (%)	0	0
Permanent pacemaker*, n (%)	2 (33.3)	2 (33.3)
Major-complication free**, n (%)	7 (87.5)	5 (62.5)
Complication-free***, n (%)	5 (62.5)	4 (50)

* Six patients with pacemaker risk.
** Death, stroke, AMI, and urgency heart surgery.
*** Death, stroke, AMI, urgency heart surgery, acute renal failure, and vascular and haemorrhagic complications.

As a positive point regarding access through the subclavian artery, it should be emphasized that it is easier to control the stent at the time of its release in the valvular annulus when compared with femoral access, as the shorter distance and less tortuous path allow better transmission of force to the distal system portion, allowing for a more accurate positioning. Moreover, in general, the subclavian arteries are less affected by atheromatosis than the iliac and femoral arteries.

When selecting access through the subclavian artery, there is a preference for the left artery because, intuitively, there would be less risk of stroke than when using the right subclavian artery, considering that the presence and manipulation of the prosthesis delivery device in the brachiocephalic trunk could cause embolization and limit flow into the right carotid. In this case, access through the right artery is feasible only when the diameter of the brachiocephalic trunk artery is > 7 mm and free of significant atheromatosis.

Another point in favor of using the left subclavian artery as the access route is the more favorable orientation of the bioprosthesis in the valve annulus at the implantation, similar to the positioning obtained by a femoral approach. Therefore, the right subclavian artery should be considered as a good alternative only in cases where the presence of atheromatous disease or tortuosity prevent implantation through the left subclavian artery, or in cases where the diameter of the left subclavian is < 7 mm in the presence of a patent internal thoracic artery graft to a coronary artery of major anatomical importance, due to the incapacity of accommodating the prosthesis-releasing device (6 mm) and maintaining blood flow to the graft. In the present study, following this recommendation, the right subclavian artery access was used in only 25% of cases.

More recently, the use of the subclavian artery for CoreValve® bioprosthesis implantation by totally percutaneous access and hemostasis obtained after the procedure with Prostar™ haemostatic devices (Abbott Vascular – Abbott Park, USA) or ProGlide™ (Abbott Vascular – Abbott Park, USA) has been reported.[21] However, validation of this approach also depends on the confirmation of its safety, since severe bleeding complications may result from the failure of the device to perform hemostasis.

CONCLUSIONS

In the Brazilian experience, transcatheter CoreValve® bioprosthesis implantation through the subclavian artery route was safe and effective for use in selected patients in whom femoral access was not feasible. This alternative access route allows for a larger number of patients to benefit from aortic valve bioprosthesis transcatheter implantation.

CONFLICT OF INTERESTS

See Appendix.

REFERENCES

1. Kodali SK, Williams MR, Smith CR, Svensson LG, Webb JG, Makkar RR, et al. Two-year outcomes after transcatheter or surgical aortic-valve replacement. N Engl J Med. 2012; 366(18):1686-95.
2. Makkar RR, Fontana GP, Jilaihawi H, Kapadia S, Pichard AD, Douglas PS, et al. Transcatheter aortic-valve replacement for inoperable severe aortic stenosis. N Engl J Med. 2012; 366(18):1696-704.
3. Wendler O, Walther T, Schroefel H, Lange R, Treede H, Fusari M, et al. Transapical aortic valve implantation: mid-term outcome from the SOURCE registry. Eur J Cardiothorac Surg. 2012 May 30. [Epub ahead of print]
4. Etienne PY, Papadatos S, El Khoury E, Pieters D, Price J, Glineur D. Transaortic transcatheter aortic valve implantation with the Edwards SAPIEN valve: feasibility, technical considerations, and clinical advantages. Ann Thorac Surg. 2011;92(2):746-8.
5. Lange R, Bleiziffer S, Piazza N, Mazzitelli D, Hutter A, Tassani-Prell P, et al. Incidence and treatment of procedural cardiovascular complications associated with trans-arterial and trans-apical interventional aortic valve implantation in 412 consecutive patients. Eur J Cardiothorac Surg. 2011;40(5):1105-13.

6. Bleiziffer S, Piazza N, Mazzitelli D, Opitz A, Bauernschmitt R, Lange R. Apical-access-related complications associated with trans-catheter aortic valve implantation. Eur J Cardiothorac Surg. 2011;40(2):469-74.
7. Bruschi G, Fratto P, De Marco F, Oreglia J, Colombo P, Botta L, et al. The trans-subclavian retrograde approach for transcatheter aortic valve replacement: Single-center experience. J Thorac Cardiovasc Surg. 2010;140(4):911-5, 915 e1-2.
8. Fraccaro C, Napodano M, Tarantini G, Gasparetto V, Gerosa G, Bianco R, et al. Expanding the eligibility for transcatheter aortic valve implantation the trans-subclavian retrograde approach using: the III generation CoreValve revalving system. JACC Cardiovasc Interv. 2009;2(9):828-33.
9. Modine T, Obadia JF, Choukroun E, Rioufoul G, Sudre A, Laborde JC, et al. Transcutaneous aortic valve implantation using the axillary/subclavian access: feasibility and early clinical outcomes. J Thorac Cardiovasc Surg. 2011;141(2):487-91, 491e1.
10. Moynagh AM, Scott DJ, Baumbach A, Khavandi A, Brecker SJ, Laborde JC, et al. CoreValve transcatheter aortic valve implantation via the subclavian artery: comparison with the transfemoral approach. J Am Coll Cardiol. 2011;57(5): 634-5.
11. Petronio AS, De Carlo M, Bedogni F, Marzocchi A, Klugmann S, Maisano F, et al. Safety and efficacy of the subclavian approach for transcatheter aortic valve implantation with the CoreValve revalving system. Circ Cardiovasc Interv. 2010;3(4): 359-66.
12. Brito Jr FS, Siqueira D, Sarmento-Leite R, Carvalho LA, Lemos Neto PA, Mangione JA, et al. Racional e desenho do registro brasileiro de implante de bioprótese aórtica por cateter. Rev Bras Cardiol Invasiva. 2011;19(1):145-52.
13. Hattler BG, Madia C, Johnson C, Armitage JM, Hardesty RL, Kormos RL, et al. Risk stratification using the Society of Thoracic Surgeons Program. Ann Thorac Surg. 1994;58(5):1348-52.
14. Roques F, Nashef SA, Michel P; EuroSCORE Study Group. Risk factors for early mortality after valve surgery in Europe in the 1990s: lessons from the EuroSCORE pilot program. J Heart Valve Dis. 2001;10(5):572-77; discussion 577-8.
15. 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. J Am Coll Cardiol. 2011;57(3):253-69.
16. Abdel-Wahab M, Zahn R, Horack M, Gerckens U, Schuler G, Sievert H, et al. Aortic regurgitation after transcatheter aortic valve implantation: incidence and early outcome. Results from the German transcatheter aortic valve interventions registry. Heart. 2011;97(11):899-906.
17. Bosmans JM, Kefer J, De Bruyne B, Herijgers P, Dubois C, Legrand V, et al. Procedural, 30-day and one year outcome following CoreValve or Edwards transcatheter aortic valve implantation: results of the Belgian National Registry. Interact Cardiovasc Thorac Surg. 2011;12(5):762-7.
18. Eltchaninoff H, Prat A, Gilard M, Leguerrier A, Blanchard D, Fournial G, et al. Transcatheter aortic valve implantation: early results of the FRANCE (FRench Aortic National CoreValve and Edwards) registry. Eur Heart J. 2011;32(2):191-7.
19. Gilard M, Eltchaninoff H, Iung B, Donzeau-Gouge P, Chevreul K, Fajadet J, et al. Registry of transcatheter aortic-valve implantation in high-risk patients. N Engl J Med. 2012;366(18):1705-15.
20. Sinning JM, Horack M, Grube E, Gerckens U, Erbel R, Eggebrecht H, et al. The impact of peripheral arterial disease on early outcome after transcatheter aortic valve implantation: results from the German Transcatheter Aortic Valve Interventions Registry. Am Heart J. 2012;164(1):102-10, e1.
21. Schafer U, Ho Y, Frerker C, Schewel D, Sanchez-Quintana D, Schofer J, et al. Direct percutaneous access technique for transaxillary transcatheter aortic valve implantation: "The Hamburg Sankt Georg approach". JACC Cardiovasc Interv. 2012;5(5):477-86.

APPENDIX
Conflict of interest

Nome	Participation in study[1]	Lecturer[2]	Consultant[3]	Normative committee[4]	Personal/ institutional aid[5]	Sponsored scientific texts[6]	Shareholder[7]
Dimytri Siqueira	No	No	No	No	No	No	No
Eberhard Grube	No	No	Yes	No	No	No	No
Fábio Sândoli de Brito Júnior	No	Yes	No	No	No	No	No
J. Eduardo Sousa	No	No	No	No	No	No	No
João Carlos Dias	No	No	No	No	No	No	No
José Armando Mangione	No	Yes	No	No	No	No	No
Luiz Antonio Carvalho	No	Yes	No	No	No	No	No
Marco Antonio Perin	No	Yes	Yes	No	No	No	No
Pedro Alves Lemos Neto	No	No	No	No	No	No	No
Rogério Sarmento-Leite	No	Yes	No	No	Yes	No	No
Teresa Cristina Nascimento	No	No	No	No	No	No	No

1: The author participated in clinical and /or experimental studies subsidised by the pharmaceutical industry or equipment related to the registry; 2: The author was a lecturer in activities or events sponsored by industry related to the registry; 3: The author was (is) a member of the advisory board of directors of pharmaceutical or equipment industries related to the registry; 4: The author participated in normative committees of industry-sponsored scientific studies related to the registry; 5: The author received personal or institutional aid from industry related to the registry; 6: The author wrote scientific articles in journals sponsored by industry related to the registry; 7: The author owns stocks of the industry related to the registry.