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The cost of transcatheter aortic valve implantation according to different access routes*

O custo do implante por cateter de bioprótese valvar aórtica nas diferentes vias de acesso

El costo del implante por catéter de bioprótesis valvular aórtica en las diferentes vías de acceso

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ABSTRACT

Objective: Identifying the average direct cost of TAVI (Transcatheter Aortic Valve Implantation) for the different access routes. **Method:** This is a research with a quantitative, exploratory and descriptive approach carried out in a government teaching hospital in the state of São Paulo. **Results:** The average direct cost of TAVI procedures by the access routes resulted in R$82,826.38 (transfemoral route), R$79,440.91 (transaortic route) and R$78,173.41 (transapical route). The transcatheter valve cost represented a percentage variation between 78.47% and 83.14% of the total cost of the procedure. The Kruskal-Wallis test was used and presented a statistically significant difference between the three access routes: p=0.008. The Bonferroni test showed a difference in the association between transfemoral and transapical routes, while no statistically significant difference was observed in association with the transaortic route. **Conclusion:** The results are important for formulating adequate funding policies for the hospital network and understanding the costs according to the route facilitates rationalizing resources in order for them to be guaranteed for patients who present surgical contraindication to the valve implant.

DESCRIPTORS

Costs and Cost Analysis; Aortic Valve Stenosis; Heart Valve Prosthesis, Implantation; Cardiovascular Nursing.

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INTRODUCTION

Aortic valve disease is intimately influenced by advanced age and is present in between 3% and 5% of the population over 75 years[1].

Transcatheter Aortic Valve Implantation (TAVI) is indicated as a treatment choice for patients with aortic stenosis (AS) considered as inoperable, and it is an alternative strategy for patients with high surgical risk[2-3] comorbidities with the aim of minimizing mortality and morbidity associated with the profile of these patients[3]. With the improvement of socioeconomic conditions, medical support and medicine for the Brazilian population, life expectancy has increased[4]. Projections from the Brazilian Institute of Geography and Statistics (IBGE – *Instituto Brasileiro de Geografia e Estatística*)[5] indicate that the expectation of the contingent of elderly people (over 65 years) is expected to quadruple by 2050, representing 21.5% of the world population.

Population aging has a significant impact on public health policies[1,6] as age-related complications increase the use of health services, implying in increased probability of hospitalization, long-term health problems with more costly interventions, involving complex technologies[7].

TAVI has not yet been included in Brazilian Health Policies by the Unified Health System (SUS – *Sistema Único de Saúde*), nor, consequently, by the National Health Agency (ANS – *Agência Nacional de Saúde*). In the decision given by the National Commission for the Merger of Technologies (CONITEC – *Comissão Nacional de Incorporação de Tecnologias*) of 92[8], Ordinance No. 2 dated January 29, 2014, made the decision public of not incorporating it into the treatment of severe aortic stenosis in inoperable SUS patients. The CONITEC plenary considered the existence of a benefit, however, it stated that there were no long-term studies to prove the survival of these patients, as it was an innovation within the cardiology service and a very costly procedure with high costs, thus preventing its incorporation. The development of economic studies to analyze the procedure was suggested for its inclusion on the list of mandatory coverage[8].

TAVI has been suggested as a versatile technique that allows multiple access routes, which must be individualized according to the anatomy of each patient and the available devices[9]. The main insertion methods are the femoral artery technique, which includes transfemoral insertion (TF); iliac artery technique by transapical insertion (TAp); subclavian/axillary artery technique by transubclavian insertion (TS); transcarotid insertion technique (TC); and the transaortic insertion technique (TAo)[10].

Because it is a less invasive and totally percutaneous technique, the TF route has been considered the approach of choice in most centers and studies; however, either inadequate iliofemoral vessel characteristics or peripheral vascular disease impede its insertion in a large number of patients[10], highlighting the need for alternative approaches such as TAp, TAo and TS routes.

A recent study[11] compared the transfemoral and transapical routes, in which longer hospitalization time and slower recovery with higher morbidity and mortality were associated with the transapical procedure.

In one of the rare studies with an economic perspective, TAVI was pointed out as a viable strategy compared to conventional surgery for patients with TF access, however, regarding TAp access, future studies will be necessary to verify its cost-effectiveness[12].

Thus, considering the importance of TAVI for inoperable patients and the scarcity of national and international references regarding the procedural costs according to the different access routes, this study aims at identifying the cost of Transcatheter Aortic Valve Implantation among the different access routes used, according to a detailed direct cost calculation method.

It is known that the individualized costs of the procedures are the basis of the budgeting process for financing health facilities, and without this budgetary dimension the negotiation process is impossible. For this reason, obtaining these values/figures is an important step in order to enable future estimates[13].

METHOD

This is an exploratory, descriptive, retrospective and documentary study using a quantitative approach. For the development of this study, the absorption costing system per product to verify procedure costs proposed by Beulke and Bertó[14] was chosen as the method for calculating costs.

However, due to the research site not working with a costing system, and for this reason it does not implement an apportionment of indirect costs to the cost centers to calculate the average TAVI cost, therefore only direct costs of the procedures were considered per access route, which represents a limitation of the study.

The study was developed in a large specialized teaching-reference hospital which also deals with high-complexity cardiovascular diseases and is attached to the Direct Administration of the State Health Department of São Paulo (SES-SP – *Secretaria de Estado de Saúde de São Paulo*).

The hospital began performing TAVI in March 2012, when a hybrid room for catheter interventions was inaugurated in the surgical center joining together equipment with robotic systems for diagnostic imaging (angiography, echocardiography, tomography, among others) necessary for performing the procedure.

The study population corresponded to TAVI's elective procedures/surgeries between March 2012 and August 2015, totaling 108 procedures: 92 via TF, eight via TAo and eight via TAp.

The following data collection instruments were used: spreadsheets/tables regarding the surgical result, cost per hour of the medical gases and cost of the materials reprocessed by the Materials and Sterilization Center (CME – *Central de Materiais e Esterilização*); a table showing the average hourly cost of the professionals who participated in the procedures; equipment depreciation reports, preventive and corrective maintenance for equipment and the energy consumption of the equipment; in addition to monthly

statistics of the Surgical Center related to the production of the hybrid room.

For assessing each procedure, the independent variables that referred to the total of the following direct costs were considered: materials and medicines/solutions, usage time of medicinal gases, materials reprocessed by the CME, human resources time, equipment depreciation, preventive and corrective equipment maintenance, and finally, energy consumption.

The information collected was organized into a database in Excel format. A descriptive analysis of the data was performed through the SPSS program. The results were presented as tables and graphs. The Mann-Whitney Catheter Variable Test (Fisher's Exact Test) and the Continuous Variables Test (Kruskal-Wallis Test) were used for statistical analysis. The results, whose descriptive "p" (p values) presented values lower than 0.05, were considered statistically significant. The Bonferroni Correction Test (2x2 Test) was used to show the difference in the association between the access routes.

The currency used to calculate costs was the Brazilian real (R$).

The study was approved by the Research Ethics Committee (CEP) of the Escola de Enfermagem of the Universidade de São Paulo (EE/USP), CAAE 45451515.50000.5392 with Opinion number 1.180.524; and later by the Research Ethics Committee of the hospital under study according to CAAE 45421515.5.3001.5462 and protocol 4595.

RESULTS

Characterization of TAVI Procedures according to the Access Routes

The characteristics of TAVI procedures according to the access routes are shown in Figure 1.

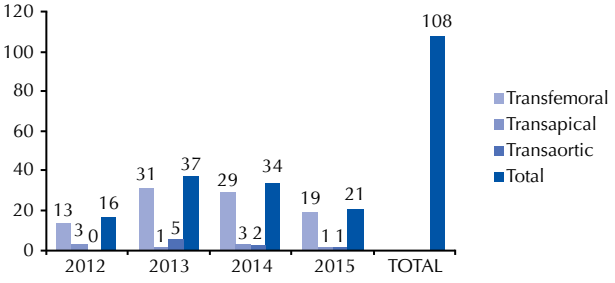

Figure 1 – Characterization of TAVI procedures by access routes regarding the period from March 2012 to August 2015 – São Paulo, SP, Brazil, 2017.

During the study period we can notice that: 92 (85.18%) of the 108 performed procedures were by transfemoral route, eight by transaortic route (7.41%) and eight by transapical route (7.41%).

In relation to the cost of materials, these were subdivided into five groups: hemodynamic materials, medications/solutions, consumable materials, surgical thread/suture and perfusion material, as shown in Table 1.

Table 1 – Average direct cost of materials used in TAVI procedures by access route regarding the period from March 2012 to August 2015 – São Paulo, São Paulo, Brazil, 2017.

Material	Transfemoral	Transapical	Transaortic	P. value
Hemodynamic	74,023.94[a]	67,610.92[b]	68,559.45[b]	*0.000
Medications/ solutions	234.36	266.85	246.25	*0.263
Consumables	1,089.43[a]	2,115.01[b]	1,505.03[b]	*0.000
Surgical thread/ suture	140.59[a]	737.99[b]	853.99[b]	*0.000
Perfusion	619.30[a]	1,036.62[b]	879.59[b]	*0.046
Total material and medication (cost)	76,107.64[a]	71,767.42[b]	72,044.29[b]	*0.004

* Continuous Variables Test - Kruskal-Wallis test. Bonferroni correction (a,b).

The average total direct cost with material and medicine was higher for transfemoral route (R$76,107.64), followed by transaortic route (R$72,044.29) and transapical route (R$71,767.42).

The mean direct cost with hemodynamic material had the highest value at R$74,023.94 via transfemoral route, R$68,559.45 by transaortic route, and R$67,610.92 by transapical route. The cost of the transcatheter valve at an amount of R$65,000.00 is allocated into hemodynamic materials and it has 85.40% representativeness of the total material and medicine (cost) by transfemoral route, 90.22% by transaortic route, and 90.57% by transapical route.

The second highest value was the average direct cost of consumables, which was R$2,115.01 by transapical route, R$1,505.03 by transaortic route, and R$1,089.43 by transfemoral route.

Based on the above data, we can verify that the average direct cost of hemodynamics was higher by transfemoral route. Regarding medication, consumable materials and perfusion materials, the average cost was higher by transapical route, while surgical thread/suture presented the highest average cost by transaortic route.

The Kruskal-Wallis Test – Continuous Variables Test was used, showing a statistically significant difference between the transfemoral, transapical and transaortic access routes for the following items: hemodynamic material (p=0.00), consumable materials (p=0.00); surgical thread/suture (p=0.00), perfusion material (p=0.04) and total material and medication (cost) (p=0.004). No statistically significant difference was found for the medications/solutions item.

Regarding hemodynamic materials, consumable materials, surgical thread/suture and total material and medicine (cost), the Bonferroni Correction test showed a difference in the association between the transfemoral x transapical and transfemoral x transaortic routes. No statistical difference was found regarding the transapical x transaortic association. All materials and medications presented the same statistical behavior according to the Bonferroni Test.

Table 2 shows the calculation of the total average direct cost for TAVI procedures by access route, accounting for the total costs related to material and medicine, HR, medical gases, reprocessed material, preventive and corrective maintenance of the hybrid room equipment, equipment depreciation and energy consumption by the equipment;

however, the table below does not show the variable of preventive and corrective maintenance of equipment, as an apportionment was calculated between all the procedures for calculating the cost and the cost was distributed equally regardless of the access route, resulting in a fixed average cost of R$409.93 per procedure.

Table 2 – Total average direct cost of TAVI procedures by access routes regarding the period from March 2012 to August 2015 – São Paulo, São Paulo, Brazil, 2017.

	Transfemoral	Transapical	Transaortic	P. value
Total material and medication (cost)	76,107.64[a]	71,767.42[b]	72,044.29[b]	*0.004
Human Resources	5,598.62	5,161.33	6,021.41	*0.169
Medical gases	31.66[a]	36.75[a,b]	45.02[b]	*0.002
Reprocessed material	284.07[a]	332.31[b]	335.34[b]	*0.000
Depreciation	323.49[a]	383.26[a,b]	483.99[b]	*0.001
Energy (consumption)	70.96[a]	82.38[a,b]	100.91[b]	*0.002
Total TAVI procedure (cost)	82,826.38[a]	78,173.41[b]	79,440.91[a,b]	*0.008

* Continuous Variables Test – Kruskal-Wallis test. *Bonferroni correction (a,b)*

The highest cost was total material and medicine, corresponding to R$76,107.64 by transfemoral route, R$72,044.29 by transaortic route and R$71,767.42 by transapical route, followed by the average direct cost of human resources with R$6,021.41 by transaortic route, R$5,598.62 by transfemoral route and R$5,161.33 by transapical route.

It was demonstrated that the total material and medicine (cost) represented the highest average cost in the transfemoral route; in contrast, costs of HR, medical gases, reprocessed materials, equipment depreciation, and energy consumed by the equipment used in the hybrid room represented a higher average cost in the transaortic route. Finally, the total cost of the procedure had a higher average cost by transfemoral route.

The Kruskal-Wallis test – Continuous Variables Test was used, showing a statistically significant difference between the transfemoral, transapical and transaortic access routes for the following items: total material and medication (cost) (p=0.004); medicinal gases (p=0.002); reprocessed material (p=0.000); equipment depreciation (p=0.001); energy consumption (p=0.002); total TAVI procedure (cost) (p=0.008). No statistically significant differences were found regarding the item total HR cost.

In relation to total material and medication and reprocessed material costs, the Bonferroni Test showed that a difference in the association between transfemoral x transapical and transfemoral x transaortic routes was observed, while no statistical difference was found for the transapical x transaortic association. Regarding medical gases, depreciation and energy consumption, a difference in the association between the transfemoral and transaortic routes was observed, while no statistical differences were found for the transfemoral x transapical and transapical x transaortic associations. Finally, the total TAVI procedure (cost) showed a difference in the association between the transfemoral and transapical routes, whereas no statistically significant difference was found in the association with the transaortic route.

DISCUSSION

This study showed that 85.18% of the procedures performed were by transfemoral route. This result confirms other studies[10,15] by referring that this route has been the first choice for being a less invasive technique and totally percutaneous, provided that the patients do not have any contraindication due to problems regarding iliofemoral vessels or peripheral vascular diseases that prevent placement by the transfemoral route.

However, the transfemoral route procedure had the highest average total direct cost in relation to the transapical and transaortic routes.

We emphasize that the input with the greatest impact on the procedural costs was the transcatheter valve at an amount of R$65,000.00, which represented 83.14% of the procedures performed by transapical route, 81.82% by transaortic route, and 78.47% of the cost by transfemoral route.

This study has shown that TAVI is a costly procedure, regardless of the implemented access route, which would reinforce the decision by the CONITEC plenary of not incorporating it[8], since the health system lacks resources and there is a financial limit that makes it impossible for this service to be provided by the SUS in its entirety, in accordance with the provisions of the Constitution of the Federative Republic of Brazil in 1988[16]. However, TAVI cannot be denied to those who really need it, since there are relevant findings in which patients with severe inoperable aortic stenosis have a very negative prognosis without valve replacement by TAVI[17-18]

Moreover, as this is an innovative procedure within Cardiology, TAVI requires new economic analysis studies that can not only compare the surgical procedure costs and TAVI, but also the long-term patient progression outcomes based on a reduction in the average hospitalization time and recurrent readmissions[5,19], improving the quality of life and integrating the patient into their daily activities more quickly.

Another factor to be considered given the results of this study regarding the high cost of the transcatheter valve is the need to develop public health policies for investments and industrial incentives at the national level, especially in the area of orthoses and prostheses, in order to increase production and competition of manufacturing companies, thereby providing lower values than those currently practiced.

CONCLUSION

The average direct cost of TAVI procedures by access routes resulted in R$82,826.38 by transfemoral route, R$79,440.91 by transaortic route and R$78,173.41 by transapical route. The Bonferroni test showed that the total cost of the TAVI procedure showed a difference in the association between the transfemoral and transapical routes; however, no statistically significant difference was found in association with the transaortic route. TAVI resulted in a high-cost procedure regardless of the access route implemented, and it is possible to conclude that its high cost was due to the transcatheter valve cost, around R$65,000.00, representing 78.47% of the total cost in the transfemoral route, 81.82% by transaortic route, and 83.14% by transapical route.

RESUMO

Objetivo: Identificar o custo direto médio do TAVI nas diferentes vias de acesso. **Método:** Trata-se de uma pesquisa com abordagem quantitativa, exploratória e descritiva, realizada em um hospital de ensino governamental do estado de São Paulo. **Resultados:** O custo direto médio dos procedimentos TAVI por vias de acesso resultou em R$ 82.826,38 (via transfemoral), R$ 79.440,91 (via transaórtica) e R$ 78.173,41 (via transapical). O custo da válvula transcateter representou uma variação de percentual entre 78,47% e 83,14% do custo total do procedimento. Foi utilizado o Teste de Kruskal-Wallis, apresentando diferença estatisticamente significativa entre as três vias de acesso: p = 0,008. No Teste de Bonferroni, apresentou diferença na associação entre as vias transfemoral x transapical, enquanto na associação com a via transaórtica não houve diferença estatisticamente significativa. **Conclusão:** Os resultados são importantes para formulações de políticas de financiamento adequadas para a rede hospitalar e o conhecimento dos custos por vias de acesso facilita a racionalização de recursos, a fim de que estes sejam garantidos para os pacientes que apresentam contraindicação cirúrgica para o implante valvar.

DESCRITORES

Custos e Análise de Custo; Estenose da Valva Aórtica; Implante de Prótese de Valva Cardíaca; Enfermagem Cardiovascular.

RESUMEN

Objetivo: Identificar el costo directo medio del TAVI en las diferentes vías de acceso. **Método:** Se trata de una investigación con abordaje cuantitativo, exploratorio y descriptivo, realizado en un hospital público de enseñanza del estado de São Paulo. **Resultados:** El costo directo medio de los procedimientos TAVI por vías de acceso resultó en R$ 82.826,38 (vía transfemoral), R$ 79.440,91 (vía transaórtica) y R$ 78.173,41 (vía transapical). El costo de la válvula trans-catéter representó una variación de porcentaje entre 78,47% y 83,14% del costo total del procedimiento. Se utilizó el test de Kruskal-Wallis, mostrando diferencia estadísticamente significativa entre las tres vías de acceso: p = 0,008. En la Prueba de Bonferroni, se presentó diferencia en la asociación entre las vías transfemoral x transapical, mientras que en la asociación con la vía transaórtica no hubo diferencia estadísticamente significativa. **Conclusión:** Los resultados son importantes para las formulaciones de políticas de financiamiento adecuadas para la red hospitalaria y el conocimiento de los costos por vías de acceso facilita la racionalización de recursos, a fin de que puedan garantizarse los mismos para los pacientes que presentan contraindicación quirúrgica para el implante valvular.

DESCRIPTORES

Costos y Análisis de Costo; Estenosis de la Válvula Aórtica; Implantación de Prótesis de Válvulas Cardíacas; Enfermería Cardiovascular.

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