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Historical analysis of the cost of acquiring a coronary stent and feasibility of the new ministry of health ordinance: a retrospective observational longitudinal study

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Abstract

Introduction: According to the World Health Organization (WHO), cardiovascular diseases (CVD) are the leading cause of death in the world. It is estimated that 17.7 million people died from CVD in 2015. According to data from DATASUS, in 2008, 44,138 coronary angioplasties were performed with or without stents. In 2016, 79,997 angioplasties were performed. The cost of orthoses, stents, and special materials for hospitals impacts the financial balance of the single health system (SUS). **Objective:** It was to carry out a cost analysis of stents for angioplasty from the perspective of the Brazilian Unified Health System. **Methods:** The present study followed a retrospective longitudinal observational model (STROBE). Data on stents about the years 2020 and 2021 and the cost assessment were carried out by searching the intra-hospital financial database of Santa Casa in the city of Jaú, São Paulo, Brazil, and the SUS table. The research was in the field of incomplete economic evaluation (cost analysis and brands of stents) through macro-costing of stent supply. The variables were presented as percentages, mean, and standard deviation. Comparisons of variables were performed using the Kruskal-Wallis test, with $p<0.05$, and Tukey analysis (ANOVA-One-Way) with $p>0.05$ with a statistical difference. Predictive logistic regression analysis was performed to better understand the trend in stent costs each year, with a significant $p<0.05$. **Results:** After analyzing the intra-hospital financial data and the SUS table, they showed a significant increase in the transfer value of stents from 2020 to 2021, with average values in reais of R$1,399 to R$2,478, respectively. This difference of R$1,079.00 can be justified by the period of the COVID-19 pandemic, as well as the increase in demand for stents. **Conclusion:** Lower average values for stent costs were observed in 2020 and 2021 compared to other stent values that were published in studies covering the same periods. However, the average cost of stents in this study in 2021 showed significantly higher values compared to 2020, which further burdened the budget of the Unified Health System. The future perspective is that a greater transfer of funds from the Federal Government for the Unified Health System, as well as a reduction in the cost prices of stents by manufacturers and suppliers in the post-COVID-19 period, to obtain a balance in public spending. Furthermore, it is expected that drug-eluting stents will be more widely used in the Unified Health System. Furthermore, it is necessary to establish public policies to standardize stent prices.

Keywords: Angioplasty. SUS. Stents. Costs. Historical analysis.

Introduction

According to the World Health Organization (WHO), cardiovascular diseases (CVD) are the leading cause of

death in the world. An estimated 17.7 million people died from CVD in 2015, representing 31% of all deaths worldwide, and more than 10 million are due to coronary artery disease (CAD) [1,2]. Furthermore, more than three-quarters, around 37%, of CVD deaths occur in low- and middle-income countries, and, in Brazil, CVD are responsible for around 384 thousand deaths per year [3].

In this scenario, interventional cardiology has evolved rapidly in the last 40-45 years, from the first balloon angioplasty in the 1970s to the implantation of the first coronary prosthesis (stent) to maintain the patency of the vessel in 1987. A few years later, stents underwent technological innovations, receiving polymers and drugs for release into the vessel walls [4].

In percutaneous coronary intervention (PCI), the success of treating a coronary lesion is mainly associated with its effective elimination through dilation and/or treatment using a percutaneous device. In the era of balloon angioplasty, reduction of diameter stenosis ≥ 20% associated with residual stenosis <50% at the lesion site at the end of the procedure was acceptable as a criterion for procedural success [5,6].

In this scenario, according to data from DATASUS, in 2008, 44,138 coronary angioplasties were performed with or without stents. Eight years later, 79,997 angioplasties were performed. With this significant increase in procedures (72.84%), an increase in cases of restenosis can be projected [7].

In Brazil, on average, more than 128 thousand procedures are performed per year related to acute myocardial infarction, such as angioplasties, catheterizations, and surgical interventions, among others. Every hour, at least 13 people die from a heart attack in Brazil, a sometimes silent disease that takes the lives of around 114,000 Brazilians per year. In the vast majority of these angioplasty procedures, it is necessary to unblock the vessels with coronary stent implantation in the acute setting or even in chronic cases [3,4].

In this context, the cost of OPME (orthoses, stents, and special materials) for hospitals impacts the financial balance of institutions and the feasibility of performing the angioplasty procedure, especially in the public health system (SUS) where financing tables are outdated constantly.

Therefore, the present study aimed to analyze the costs of stents for angioplasty from the perspective of the Brazilian Unified Health System (SUS).

Methods

Study Design and Data Collection

The present study followed a longitudinal observational retrospective model, following the clinical research rules of STROBE (Strengthening the Reporting of Observational Studies in Epidemiology, available at: https://www.strobe-statement.org/). Data on stents about the years 2020 and 2021 and the cost assessment were carried out by searching the intra-hospital financial database of Santa Casa in the city of Jaú, São Paulo, Brazil, and the SUS table.

Type of Research and Analysis

The research was in the field of incomplete economic evaluation (cost analysis and brands of stents) through the macro-costing of the supply of stents in the years 2020 and 2021. The cost evaluation was carried out by research in an intra-hospital financial database and the SUS table and agreements with the health manager.

Ethical Aspects

The present study only addressed research in terms of financial costs through an intra-hospital financial database and the SUS table, not involving patient data. Therefore, the research ethics committee does not apply.

Statistical Analysis

For data analysis, a database was built in a Microsoft Excel spreadsheet, which was exported to the statistical program Minitab 18® (version 18. Minitab. LLC. State College. Pennsylvania, USA). The variables were presented as percentages, mean, and standard deviation. Depending on the Gaussian distribution (normality test), comparisons of variables were performed using the Kruskal-Wallis test, with $p<0.05$ with the statistical difference in the 95% CI, and Tukey analysis (ANOVA-One-Way) with $p> 0.05$ with a statistical difference in the 95% CI between the variables of the present study in the 95% CI.

Results

The database was searched and general data on the total number and percentage of 2020 stents, with a total of n=395, and 2021 stents, with a total of n=153, were identified. About 2020, the Mult-Link brand stood out, with 231 (58.48%), and the supplier Nobre Medical, with 322 (81.51%). About the year 2021, the brand Xience Alpine was observed, with 81 (52.94%), and the supplier Nobre Medical, with 103 (67.32%).

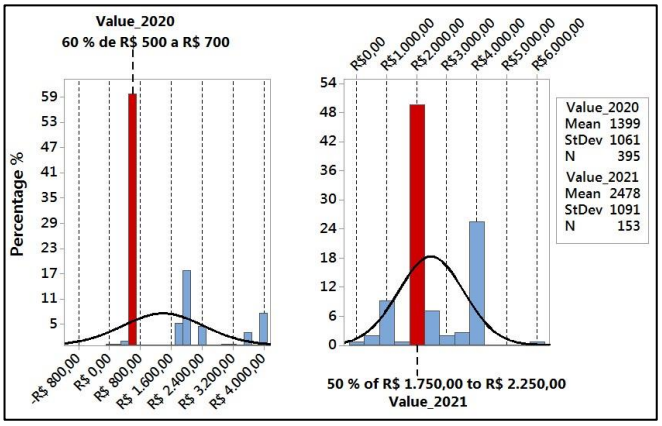
Table 1. General data on the total number and percentage of stents evaluated in this study, as well as the main brands and suppliers.

Brands/Suppliers/ *Stents*	*Stents* 2020, n (%)	*Stents* 2021, n (%)
N total	395(100%)	153(100%)
Brand: Mult-Link	231(58.48%)	15(9.80%)
Brand: Xience Alpine	56(14.17%)	81(52.94%)
Supplier: Nobre Medical	322(81.51%)	103(67.32%)
Supplier: Somma	42(10.63%)	22(14.37%)
Supplier: Scitech	19(4.81%)	25(16.35%)

Source: Own Authorship.

After analyzing the history of hospital costs by searching the intra-hospital financial database and the SUS table, a significant increase in the transfer value of stents from 2020 to 2021 was evidenced, with average values in reais of 1,399 (60% from R$500.00 to R$700.00) to 2,478 (50% from R$1,750.00 to R$2,250.00), respectively, as shown in Figure 1.

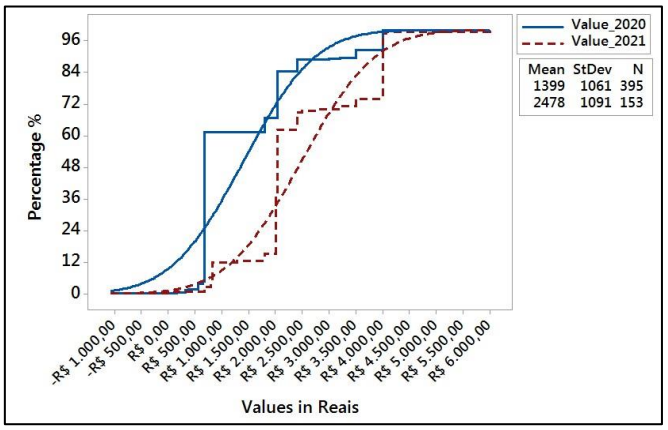
Figure 1. Histogram showing the historical distribution of stent costs in 2020 and 2021. The values were presented in reais (R$), the Brazilian currency.



Source: Own Authorship.

Figure 2 compares the cumulative distribution of stent value data from 2020 and 2021 with a known distribution, and estimates the percentages. Regarding the comparison between stent values, the sigmoidal curve (red color) referring to the year 2021 showed a greater shift towards increasing stent values than the year 2020, highlighting two values with higher frequencies, R$2,000, 00 (50%) and R$4,000.00 (24%). In 2020, only one more frequent value was observed, R$650.00 (60%). The difference between the average values of each prosthesis cost in 2020 and 2021 was R$1,079.00.

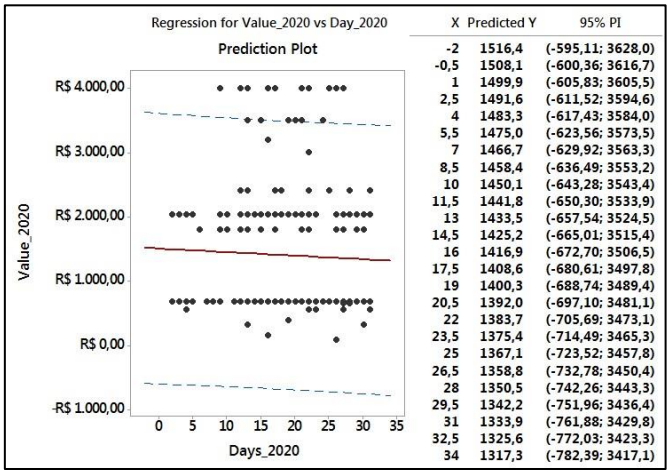
Figure 2. Empirical graph showing the comparative distribution between stent value data from 2020 and 2021 from this study with a known distribution. The values were presented in reais (R$), the Brazilian currency.



Source: Own Authorship.

Figure 3 presents the predictive logistic regression analysis of the trend in variation in stent costs in the year 2020. The analysis showed a trend in the reduction of stent costs as the days progressed in that year, with a statistical significance of p<0,05.

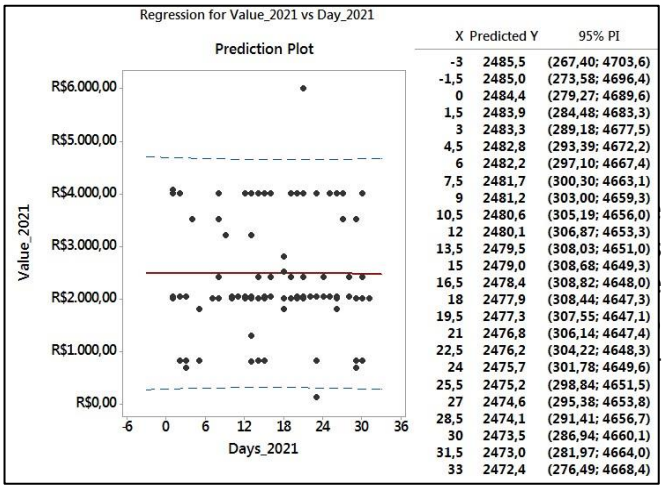
Figure 3. Graph showing the predictive logistic regression analysis of the trend in stent cost variation in 2020, within the 95% confidence interval. The values were presented in reais (R$), the Brazilian currency.



Source: Own Authorship.

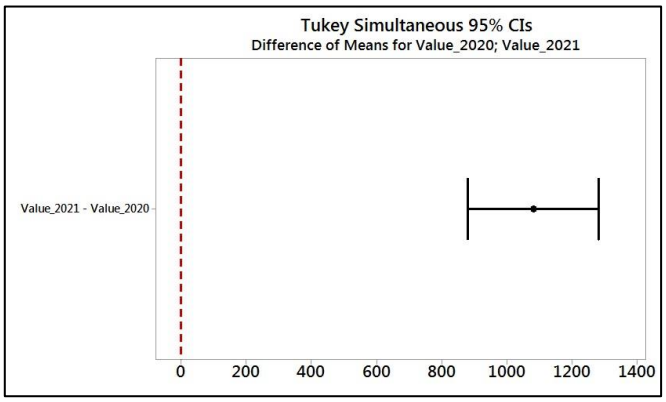
Figure 4 presents the predictive logistic regression analysis of the trend in variation in stent costs in the year 2021. The analysis did not show a trend in the reduction of stent costs as the days progressed in that year, without statistical significance, p>0.05. The cost values of stents showed little variation, demonstrating the maintenance of a higher value of stents.

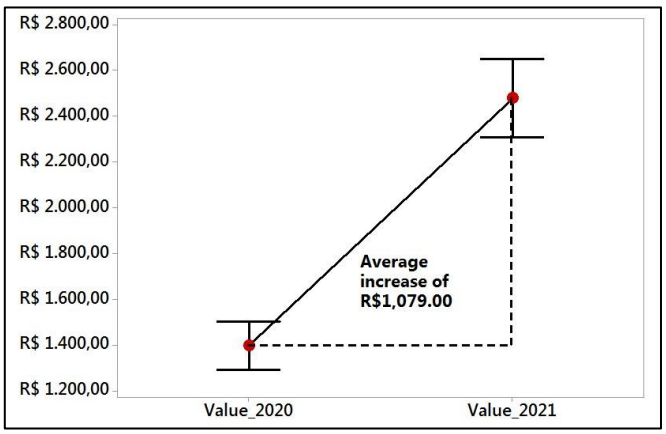
Figure 4. Graph showing the predictive logistic regression analysis of the trend in stent cost variation in 2021, within the 95% confidence interval. The values were presented in reais (R$), the Brazilian currency.



Source: Own Authorship.

Figure 5. Graph showing Tukey analysis (One Way - ANOVA) between the average values of stent costs in 2020 and 2021, with a 95% confidence interval (CI 95%).





Variables	Difference between means	95% CI	p-value
Value_2021 - Value_2020	1079	(879; 1279)	0.870

Source: Own Authorship.

Discussion

The results of the present study, after analyzing intra-hospital financial data and the SUS table, showed a significant increase in the transfer value of stents from 2020 to 2021, with average values in reais of R$1,399 to R$2,478, respectively. This difference of R$1,079.00 can be justified by the period of the COVID-19 pandemic, as well as the increase in demand for stents. Furthermore, the scaling established by the SUS compared to that considered ideal by the interventional cardiology team causes an increase in the number of coronary stent implantation procedures and, consequently, an increase in public spending [4].

Thus, the most frequent value for the year 2021 was R$2,000.00 (50%) versus R$650.00 (60%) for the year 2020, with a statistically significant difference (p=0.870>0.05). This difference became even more significant when, through predictive logistic regression analysis, a trend in reducing stent costs was evident as the days progressed in the year 2020 compared to the year 2021, whose cost values for stents showed small variation, showing the maintenance of a higher value of stents.

In this context of the present study, studies have presented technological advances in stent implantation and myocardial revascularization, demonstrating that the costs of initial hospitalization and two years after treatment of patients with multivessel coronary disease with multiple conventional stents versus myocardial revascularization were higher. advantageous for the stent group (27% reduction) [8,9].

In this sense, the budget impact analysis aims to assist in the decision of the Secretary of Health Care of the Ministry of Health, in the task of evaluating changes in the current system that establishes that coronary angioplasty with implantation of a double arterial intraluminal prosthesis should not exceed the total 20% of the total number of coronary angioplasties performed. In this regard, a published study showed that it generated 58 additional procedures, resulting in an expense of R$2,263.77 per procedure, and an additional cost of R$131,298.7. Thus, this strategy imposed by the SUS is not only uneconomical, but also limits the doctor's freedom to choose the best therapeutic approach for a given patient and, mainly, exposes them to more procedures than would be necessary, with their inherent risks [4].

In this scenario, an analysis of the impact of the drug-eluting stent on the SUS budget was carried out and it was observed that the use of a drug-eluting stent has an additional cost compared to the use of a conventional stent, in the first year of use in the SUS [10]. Therefore, research into new approaches and technology is an opportunity for cardiovascular health policymakers in the process of choosing between available alternatives, measuring the benefit for each cost unit, and estimating the return to society from incorporating new modalities. diagnostic and therapeutic [4].

Therefore, the use of drug-eluting stent (DES) compared to bare-metal stent (BMS) in percutaneous coronary intervention (PCI) reduced the percentage of restenosis, but without impact on mortality, with an increase in cost. The literature lacks randomized studies that economically compare these two groups of stents in the reality of the SUS.

A study estimated the incremental cost-effectiveness ratio (ICER) between DES and SNF in single-vessel coronary artery disease in SUS patients. Patients with symptomatic single-vessel coronary artery disease were randomized over 3 years to the use of DES or BMS during PCI, in a 1:2 ratio, with clinical follow-up of 12 months. Intra-stent restenosis (ISR), target lesion revascularization (TLR), major adverse events, and cost-effectiveness (CE) of each group were evaluated. In the SF group, of the 74 patients (96.1%) who completed follow-up, ISR occurred in 1 (1.4%), TLR in 1 (1.4%), and death in 1 (1.4%), without thrombosis. In the SMF group, of the 141 patients (91.5%), ISR occurred in 14 (10.1%), TLR in 10 (7.3%), death in 3 (2.1%), and thrombosis in 1 (0 .74%). In the economic analysis, the cost of the procedure was R$5,722.21 in the SF group and R$4,085.21 in the SNF group. The difference in effectiveness in favor of the SF group by ISR and RLA was 8.7% and 5.9%, respectively, with ICER of R$ 18,816.09 and R$ 27,745.76. In the SUS, the SF was cost-effective, by the EC threshold recommended by the World Health Organization [11]. In the same period of 2020, the present study showed a significantly lower average cost (R$1,399) for Santa Casa de Jaú services, showing that there is a discrepancy and non-standardization of prices for stent suppliers in Brazil.

Added to this, and knowing that in Brazil the SUS serves around two-thirds of the population, a study described the rates of carotid artery stent placement (CAS) and carotid endarterectomy (CE) performed between 2008 and 2019 in the country through publicly available databases. Between 2008 and 2019, 37,424 carotid bifurcation revascularization procedures were performed, including 22,578 CAS (60.34%) and 14,846 (39.66%) CE. There were 620 hospital deaths (1.66%), 336 after CAS (1.48%), and 284 after CE (1.92%) (p=0.032). Government reimbursement was $77,216,298.85 (79.31% of all reimbursements) for CAS procedures and $20,143,009.63 (20.69%) for CE procedures. The average cost per procedure for CAS was US$3,062.98 versus US$1,430.33 for CE (p=0.008) [12]. Therefore, in the same period of 2021 when COVID-19 predominated, the present study presented a lower average cost (R$2,478) for Santa Casa de Jaú services, and even with a smaller difference compared to the period of 2020, it also showed a discrepancy and non-standardization of prices by stent suppliers in Brazil.

Conclusion

It was concluded that based on the analysis of the costs of stents for angioplasty from the perspective of the Brazilian Unified Health System (SUS), lower average values of stent costs were observed in the years 2020 and 2021 compared to other stent values which were published in studies that covered the same periods. However, the average cost of stents in this study in 2021 presented significantly higher values compared to 2020, which further burdened the budget of the Unified Health System. This difference in stent costs between the years covered may be justified by the period of the COVID-19 pandemic, as well as the increase in demand for stents. Furthermore, the scaling established by the SUS compared to that considered ideal by the interventional cardiology team leads to an increase in the number of coronary stent implantation procedures and an increase in public spending. The future perspective is that there may be a greater transfer of funds from the Federal Government to the Unified Health System, as well as a reduction in the cost prices of stents by manufacturers and suppliers in the postCOVID-19 period, to obtain a balance of Public spending. Furthermore, it is expected that drugeluting stents will be more widely used in the Unified Health System. Furthermore, it is necessary to establish public policies to standardize stent prices.

Acknowledgement

Not applicable.

Ethical Approval

The present study only addressed research in terms of financial costs through an intrahospital financial database and the SUS table, not involving patient data. Therefore, the research ethics committee does not apply.

Informed consent

Not applicable.

Funding

Not applicable.

Data sharing statement

No additional data are available.

Conflict of interest

The authors declare no conflict of interest.

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