Analysis Of Hospital Data on Angioplasty and Infrainguinal Bypass for Chronic Critical Ischemia of The Lower Limbs in The Last 20 Years in Brazil

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ABSTRACT

Chronic Limb Ischemia (CLI) is a severe stage of peripheral arterial disease characterized by reduced blood flow to the extremities, often leading to amputations and high morbidity and mortality rates. Treatment options include open revascularization or endovascular techniques such as angioplasty, which is less invasive but requires more frequent reinterventions. This observational and retrospective study compares hospital data for open revascularization and infrainguinal angioplasty in Brazil from 2004 to 2023, using SIH/SUS and DataSUS. The analysis included costs, mortality, length of stay, character of service, and demographic distribution of procedures. During this period, 114,417 angioplasty procedures and 47,502 open revascularizations were performed, with a total expenditure of \$98.5 million. The number of deaths was 1,314 for angioplasty and 1,723 for revascularization, with mortality rates of 1.3% and 3.4%, respectively. The Northeast region stood out for having a higher ratio of angioplasty to open revascularization procedures.

Keywords: Critical Limb Ischemia, Angioplasties, Revascularization, Treatment

Introduction

Chronic Limb Ischemia (CLI), also known as critical limb ischemia, is an advanced manifestation of peripheral arterial disease (PAD), characterized by chronic reduction in blood flow to the limbs. This situation, as it results in inadequate tissue perfusion at rest, is associated with reduced quality of life, high morbidity and mortality (Kinlay, 2016; Farber, 2018; Conte *et al.*, 2019). The procedures proposed to treat this problem are angioplasty and open surgery. Many contemporary studies compare these two procedures, angioplasty has gained prominence in the last three decades, with the ability to reduce morbidity, mortality and expenses. However, many physicians argue in favor of revascularization surgery, arguing that surgery may be better in cases of extensive ischemia, has greater durability (patency) and lower cost, despite greater surgical risk (Tunis *et al.*, 1991).

CLI is predominantly associated with atherosclerosis and the ischemic symptoms range from lameness to critical limb-threatening ischemia and can progress rapidly in patients with aggravating risk factors such as smoking, diabetes, or renal failure (Becker *et al.*, 2011; Conte *et al.*, 2019)

The global prevalence of peripheral arterial disease (PAD) in the lower limbs varies between 3 and 12%, affecting approximately 202 million people worldwide in 2010. In Europe and North America, it is estimated that 27 million people are affected, resulting in approximately 413,000 annual hospitalizations attributed to PAD. The disease becomes more prevalent with advancing age, being a growing clinical problem due to the aging of the population. (Nehler *et al.*, 2014).

CLI exhibits a dismal prognosis in relation to amputation procedures, as evidenced by a study conducted in Oxfordshire, United Kingdom, where such procedures occurred in 43.4% of cases monitored over a five-year period (Howard *et al.*, 2015).

By-pass is the most traditional technique, using vascular grafts, with a higher patency rate and durability. However, this approach offers a high perioperative risk and difficulty in obtaining an adequate graft. Otherwise, endovascular therapy emerged as a less invasive option and, for this reason, has been preferred for high-risk patients, especially those lacking an adequate autogenous vein or whose lesion anatomy is unfavorable for an open surgical approach (TASC A, B, C). This type of surgery has been constantly evolving, with the development of new techniques such as percutaneous transluminal angioplasty (PTA) (Schanzer and Conte, 2010; Farber, 2018).

The first to be carried out was BEST-CLI, the study demonstrated lower rates of adverse effects, such as reintervention and amputation, for the group that underwent bypass surgery with an adequate saphenous vein (42.6% vs 57.4%) (Menard and Farber, 2014).

Subsequently, BASIL-2 was accomplished. The study demonstrated lower mortality in the last 30 days for patients undergoing angioplasty. However, patients also had a higher reintervention rate and lower amputation-free survival. Therefore, the study concludes that when performed with a viable saphenous vein, open revascularization has a better long-term outcome, otherwise angioplasty is preferable. Similar outcome to the American College of Cardiology Foundation/American Heart Association (Rooke *et al.*, 2011; Popplewell *et al.*, 2016).

Thus, what has been observed to date is that the choice between techniques must be individualized, considering life expectancy, functional status, the anatomy of the arterial disease, surgical risk and the surgeon's expertise. The objective is to only perform procedures in which the risk-benefit relationship is well balanced.

In this study, we will address the statistical analysis of the use of both treatment techniques in Brazil over the last 2 decades, considering the socio-economic conditions of different regions of Brazil, a country with continental extension and profound differences in the health system when analyzed separately.

Goals

Primary objective: To evaluate the statistical behavior of hospital data for hospitalization for infrainguinal bypass surgery in comparison with infrainguinal angioplasty.

Secondary objective: To analyze the distribution of hospital data on the outcome of infrainguinal bypass surgery and infrainguinal angioplasty compared by region.

Methodology

It is an observational, retrospective and descriptive study of secondary data, extracted from the Hospital Information System of the SUS – Sistema Único de Saúde - (SIH/SUS), available in the DataSUS

database of the Ministry of Health - Federal Government, referring to hospitalized patients in Brazil between the years 2004 and 2023, by place of residence, according to ICD-10 chapter: I70.2: atherosclerosis of the arteries of the extremities.

The data obtained was processed using Microsoft Excel software and tables and graphs were created relating to the data collected. This data can be verified through the TabNet portal, at the following access link: https://datasus.saude.gov.br/.

To describe hospitalizations for extremity angioplasty and infra inguinal bypass, the variables used were AIH (Hospital Admission Authorization) paid, total cost, average length of stay, death, mortality rate and type of care, with all costs converted to the dollar quoted at 5.15 on May 23, 2024. The demographic regions of Brazil (North, Northeast, Central-West, Southeast, South) were also evaluated, excluding the Federative Unit.

To calculate the average cost of AIH paid for extremity angioplasty and infra inguinal bypass between the years 2004 and 2023, the ratio was made between the number of the total cost and the number of AIH paid. Furthermore, the mortality rate extremity angioplasty and infra inguinal bypass between the years 2004 and 2023 was calculated, in which the ratio of the number of deaths to the number of hospitalized patients (AIH paid) was calculated.

As it is a public health database, analysis by the Ethics Committee was not required.

Results

Between 2004 and 2023, a total of 114,417 angioplasty interventions and 47,502 open revascularization procedures were documented in Brazil. Records indicate that the absolute number of deaths associated with angioplasty reached 1,314, while for revascularization cases, this number was 1,723, according to data from the DATASUS database.

Additionally, the fatality rate for these procedures was 1.3% and 3.4%, respectively, for angioplasty and bypass. A comprehensive analysis of the Brazilian national scenario over the nineteen years covered reveals an upward trend regarding the volume of angioplasties performed, contrasting with a decrease observed in the number of revascularization procedures.

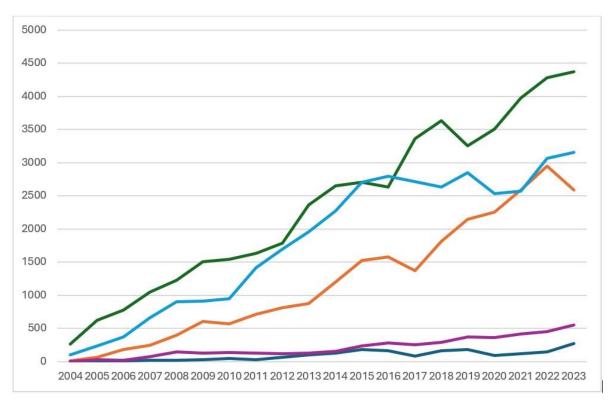
In examining the mortality figures, a noticeable increase in deaths related to angioplasty procedures was observed, accompanied by a significant decrease in fatalities associated with revascularization surgeries. Nevertheless, despite this increase, angioplasty still shows a lower number of deaths compared to revascularization, even though it is performed more frequently. Consequently, the mortality rate exhibited a decreasing trend in revascularization procedures (decreased from 4% in 2004 to 1.9% in 2023), in a magnitude higher than that observed in angioplasty (from 2.3% in 2004 to 1% in 2023), however the less invasive procedure still has a lower mortality rate.

When analyzed the parameters of average cost, length of stay and fatality rate, these remained relatively stable, lacking significant fluctuations. Regarding the nature of care, an additional analysis highlighted a notable number of urgent requests in both procedures, the average prevalence of urgent revascularization was 70% in relation to the total of open procedures and in the case of angioplasty, the average urgency prevalence was 66%.

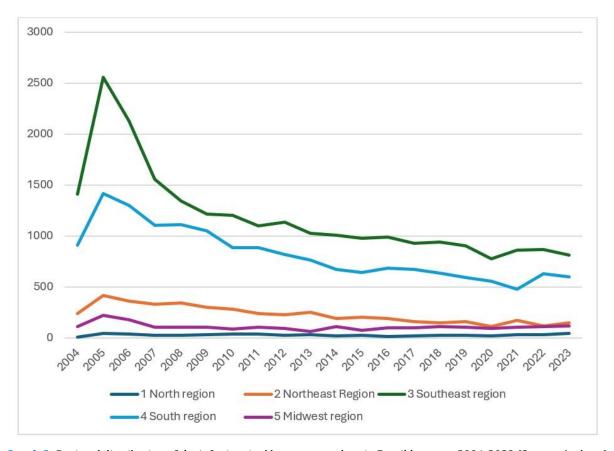
In the Southeast region, a significant number of hospitalizations were recorded for both procedures, totalling 47,561 (41.2% of the total) angioplasties and 23,730 (49.9% of the total) revascularizations. Subsequently, the South and Northeast regions emerge as important centers of medical care, with respective percentages of 31.9% and 34.5% for angioplasties and 21.4% and 9.7% for revascularizations.

Finally, the Central-West and North regions represent 5% and 1% of revascularizations and 4% and 2% of angioplasties, respectively. In absolute terms, there was a substantial 28-fold increase (from 389 to 10,939 during the analyzed period) in the number of angioplasty procedures over the analyzed period, while revascularization recorded a 1.5-fold reduction (leaving from 2,680 to 1,723, during the period analyzed) in the number of interventions carried out.

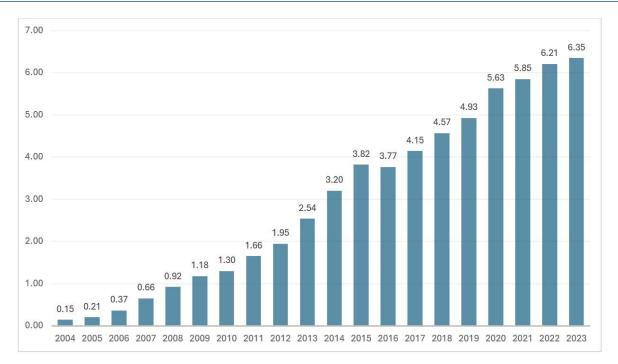
It is interesting to note that the Northeast region has a notably higher proportion of angioplasties in relation to revascularizations, with a rate of approximately 5.3 times, (with a total of 24,491 angioplasties against 4,594 revascularizations) significantly diverging from the other regions that maintain a comparable proportion in this aspect (angioplasty being 2 times more recurrent in the Center-West and South and 3.3 times more recurrent in the Southeast, in relation to revascularization). Graphs 1, 2 and 3 demonstrate the pattern explained.



Graph 1: Regional distribution of the infra inguinal angioplasty procedure in Brazil between 2004-2023 (Source: Authors).



Graph 2: Regional distribution of the infra inguinal bypass procedure in Brazil between 2004-2023 (Source: Authors).



Graph 3: Proportion of total AIH (hospital admission approval) approved for angioplasty and infra inguinal bypass in Brazil between 2004-2023 (Source: Authors).

Regarding the total financial expenditure attributed to each procedure, it appears that angioplasty accumulated a significant amount throughout the study period, with a total of US\$72,427,915, while revascularization required an expenditure equivalent to US\$ \$26,108,395. It is noteworthy that the Southeast region stands out as the epicenter of the largest financial disbursements in both procedures, with amounts of US\$31,500,127 (43.5% of the total) for angioplasty and US\$13,273,861 (50.8% of total) dollars for revascularization. For the less invasive procedure, the southeast region is followed by the south (33%), northeast (18%), central-west (4%) and north (1%). As for the by-pass: south region (34%), northeast (10%), mid-west (5%) and north (1%).

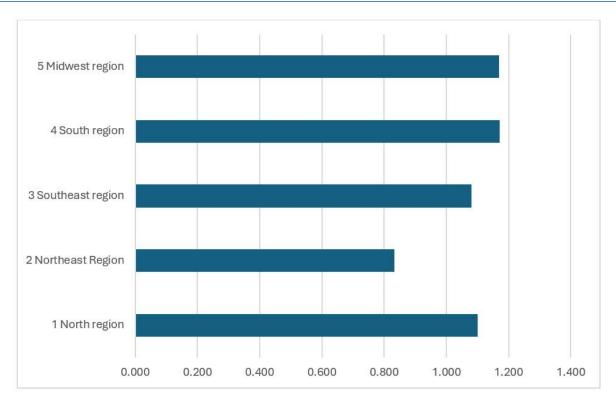
The average cost per angioplasty procedure, among the regions throughout the study period, is US\$ 627.7 dollars, with the Central-West standing out as the region with the highest average cost for such a procedure, reaching the mark of US\$693.5 dollars (10.5% increase compared to the average) while the Northeast records the lowest average cost, with US\$530.15 dollars (15% reduction compared to the average). Although slight variations have been observed over the years, it is pertinent to note that the North region stands out for presenting one of the most notable reductions, reaching a drop of 46% in comparison to 2004. On the other hand, revascularization reveals a consistent average cost compared to throughout the period under analysis, totaling US\$ 585.15 dollars, without significant disparities between the different regions having been identified, although a concentration of the lowest average cost in the North region,

fixed at US\$ 527.19 dollars (reduction of 10% of the total) and a greater concentration of cost in the Northeast with US\$605.8 (increase of 3.4% of the total).

The relationship between the average cost of angioplasty and revascularization reveals a tendency to decrease over the years in all regions, being less than 1 in all regions in the year 2023, except for the North, which presents a relationship of 1. 15. Furthermore, it is interesting to notice that the Northeast region is the one with the lowest ratio (0.7). When an average of this proportion was taken considering all the years analyzed, the only region in which angioplasty was less costly than revascularization was the Northeast with a ratio of 0.8, followed by the Southeast (1.1), North (1,1), Midwest (1.17) and South (1.17). Additionally, the average cost per procedure is variable depending on the nature of the care, so it is noticed that in angioplasty, the emergency procedure entails an additional cost of US\$104 (an increase of 16% compared to the elective procedure), while in revascularization, the emergency procedure translates into an additional US\$138, an increase of 27.2%. Graph 4 shows this relationship. Still analyzing the cost, the global guidelines for the management of chronic ischemia of the lower limbs present a prevalent practice in regions such as Latin America: the reuse of single-use medical devices, including sheaths, angioplasty balloons and guide wires. This strategy is adopted as a significant cost-saving measure, potentially reducing expenses associated with procedures by up to 50%. Although this practice does not represent the ideal standard of care, it allows greater access to endovascular treatments, contributing to the lower average cost of angioplasties in these regions.

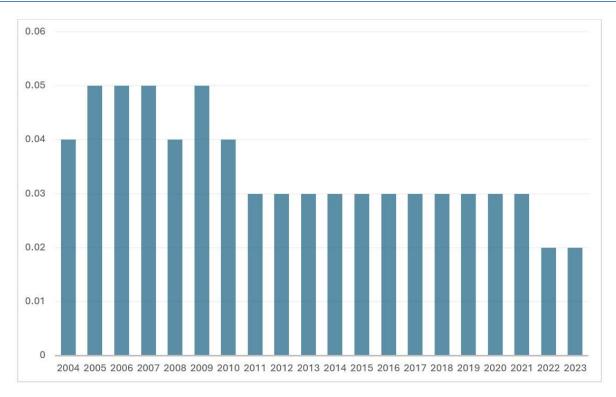
The average hospital stay associated with angioplasty in the Brazilian context, in 2004, was documented at 5.5 days, showing a slight tendency towards reduction over the years, stabilizing at an average of 4.7 days in 2023, a decrease of 15%. Although the average length of stay resulting from revascularization in 2004 was higher, and it was estimated at 11.4 days, a more pronounced decrease during the period was noticed, reaching an average of 8.8 days in 2023 (a reduction of 23%), without observe significant variation between different regions.

Notably, the average length of stay related to revascularization is approximately double that linked to angioplasty (ratio of 2.02). Furthermore, it appears that the average length of stay associated with angioplasty presents a substantial variation in relation to the nature of care. Patients undergoing emergency procedures tend to stay, on average, 2.2 days longer (69% longer) compared to those undergoing elective interventions, with a notable increase in time recorded in the North and Northeast regions, where the period of stay doubled. This pattern, however, is not significantly verified on revascularization, which exhibits a relatively smaller variation (an increase of 12.5%, when the procedure is urgent) in the average length of stay depending on the type of care received.

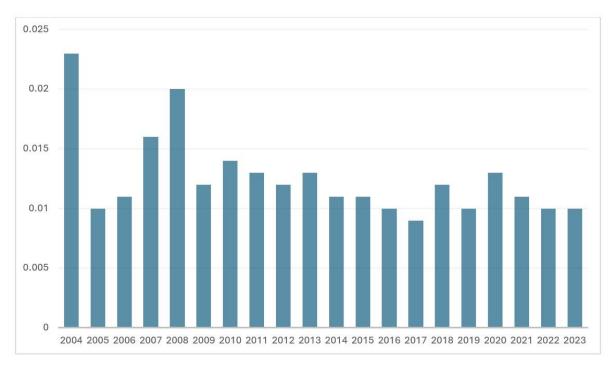


Graph 4: Relationship of the average amount spent for angioplasty on infra inguinal bypass according to the Brazilian region between 2004-2023 (Source: Authors).

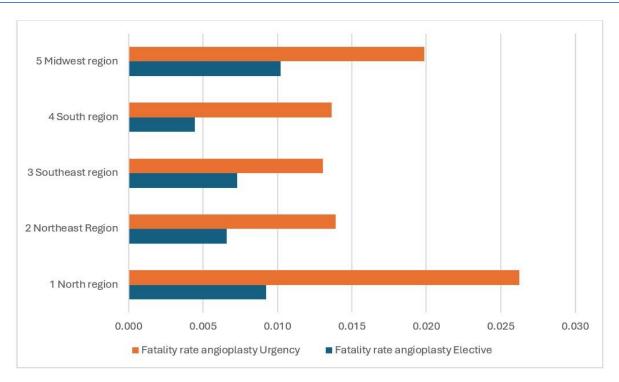
The mortality rate related to angioplasty has shown remarkable consistency over the years, while that relating to revascularization has shown a marked downward trend, starting from 4% in 2004 to reach the level of 2% in 2023. The analysis of the variation according to the care's nature showed that the fatality rate in angioplasty procedures performed in urgent situations was more than double (with a disparity of 2.3 times) that the rate observed in elective procedures. Such discrepancy was not noted in the sphere of revascularization, which was characterized by minimal variation in this aspect, except in the Northeast region, where a 1.86-fold increase in the fatality rate associated with emergency procedures was recorded. Comparing the regions, for the angioplasty procedure, the highest fatality rates were in the North and Central-West regions with approximately 1.8%, followed by the Southeast and South with approximately 1.1%, and the Northeast with the lowest rate of lethality, representing 1%, with no downward or increasing trend during the period analyzed. The analysis of the revascularization mortality rates according to the region showed that the regions with highest rate were the Northeast and Southeast with 4%, and the South, North and Central-West that presented 3%. Graphs 5, 6, 7 and 8 demonstrate this trend seen in the study.



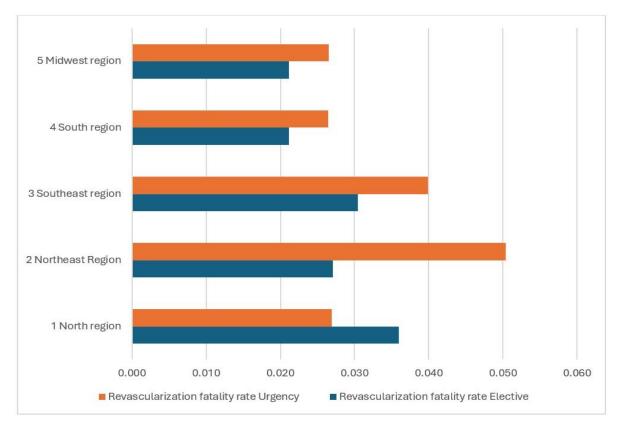
Graph 5: Fatality rate associated with infrainguinal bypass between 2004-2023 (Source: Authors).



Graph 6: Fatality rate associated with infra inguinal angioplasty between 2004-2023 (Source: Authors).



Graph 7: Fatality rate according to the nature of care associated with infra inguinal angioplasty between 2004-2023 (Source: Authors).



Graph 8: Fatality rate according to the nature of care associated with infra-onguinal bypass between 2004-2023 (Source: Authors).

The mortality rate showed a significant decline in both procedures, although it occurred in a higher magnitude in the context of revascularization, exceeding the rate observed in angioplasty by 2.7 times. It is observed that the variation in the mortality rate in angioplasty ranged between 2.31 and 1.04, while in revascularization it ranged from 3.99 to 1.92 throughout the analysis period. Comparing mortality rates between regions for the revascularization procedure, it was observed that the region with the highest rate is the North with 5.9%, followed by the Southeast region with 3.9%, Central-West and Northeast with 3.7%, finally the South region with 2.6%. For the angioplasty procedure, the North was again the region with the highest mortality rate (3.7%), but this time followed by the Central-West with 2.1%, then the Southeast with 1.3% and finally the South and Northeast regions with 1.2%.

The total number of elective angioplasty procedures was 36,968, in contrast to the 72,564 emergency procedures registered (a preponderance of urgency of 66%), while in the revascularization, elective procedures accounted for 9,714, compared to 23,320 urgent procedures (a preponderance of 71% in urgency procedures), showing a notable preponderance of emergency cases in both interventional contexts. Regarding the nature of care, it is noteworthy that the North region stood out by presenting a higher number of elective cases compared to emergency cases (52% of cases were elective in the angioplasty procedure and 60% in revascularization) in both procedures, a scenario that differs substantially from the trends observed in other regions.

Considering the distinction in nature of care, it appears that angioplasty performed in urgent situations leads to a mortality rate that is twice as high (1.39% when urgent and 0.65% when elective, revealing a disparity of 2.1 times) of that observed in elective procedures. This phenomenon is particularly evident in the North region, where this disparity almost triples (with a ratio of 2.9 times). On the other hand, in the context of revascularization, the discrepancy is less striking, representing only a 1.25-fold increase between elective and urgent procedures (3.5% for urgent and 2.8% for elective).

Discussion

During the period studied, it was noticed a growth and a significant preponderance of angioplasty compared to bypass, with angioplasty being performed twice as often. One explanation for this pattern would be the choice of a less invasive intervention measure, especially for high-risk patients - the main population that undergoes surgical intervention -, as this modality presents lower rates of morbidity and mortality. In addition to this factor, it is important to highlight that angioplasty has a higher rate of need for reintervention and its materials are more available, favoring its prevalence (Schanzer and Conte, 2010; Farber, 2018; Farber *et al.*, 2022).

Regarding regional distribution, a greater concentration of these procedures was noted in the Southeast region (41.2% of total angioplasties and 49.9% of total revascularizations), which is a populous and richest region that contains a reference center of advanced hospitals for the country, which has greater technological support, as demonstrated by the National Health Confederation (CNSaúde) in the 2021 to 2022 survey, in which the southeast region concentrates 41% of private hospitals in Brazil (Spichler *et al.*, 2020). Furthermore, another notable factor was a 5.3 times proportion of angioplasties compared to revascularization in the Northeast region, standing out from other regions, possibly because it has university reference centers that have stood out in recent years compared to other regions of the country (Queiroz *et al.*, 2021).

The high cost invested in both procedures over the 19 years analyzed demonstrates the notable relevance of PAD for the Brazilian health system. This factor confirms the need for better access to basic healthcare, as it is possible to reduce the number of cases of this problem with measures such as changing lifestyle habits and early diagnosis (Conte *et al.*, 2019; Pereira *et al.*, 2020). In this scenario, the discrepancy between the amount disbursed for angioplasty compared to revascularization expresses the greater availability of materials and professionals and consequently of procedures. Furthermore, the Southeast region again points to greater development of the tertiary health sector, as it is responsible for 43.5% and 50.8% of the figure applied to angioplasty and revascularization, respectively, according to the National Health Confederation (CNSaúde), in the 2021 to 2022 survey, on the hospital scenario in Brazil, it is shown that the southeast region concentrates 41% of private hospitals in Brazil (Spichler *et al.*, 2020).

In relation to the average cost of the procedure, there is a certain change in the scenario presented regarding the total cost, with the region that spent the most not being compatible with the region that has the most expensive procedure. Therefore, there is a noticeable difference between the cost of procedures depending on the region, such as the Northeast, which has the highest average cost for bypass (605.8 dollars) despite having the lowest average for angioplasty (530.14 dollars). This phenomenon can be answered according to how public spending is directed and the bidding for material that takes place in each state. The cost of each procedure varied little considering the period from January 2004 to December 2023, even more so when considering inflation of 281.75%, according to the Central Bank of Brazil.

Relating the cost between the two types of operation, the less invasive one was only slightly more expensive than the open one. Except in the Northeast region, where the ratio of the average cost of angioplasty compared to infra inguinal bypass was 0.8, so in this region it is less expensive to perform angioplasty. This again can be explained by the factors already mentioned above: according to the way in which public spending is directed and the bidding for material that takes place in each state.

Still considering the financial aspect of the procedures, the nature of the service is an important variable, which reinforces the importance of prevention not only to reduce risk, but also cost. When both procedures are performed urgently there is an increase of 16% and 27.2% for angioplasty and revascularization, respectively. This increase is closely related to the requirement for a longer hospital stay and assistance (Green and Wenzel, 1977).

Hospital stay is a very important factor to be analyzed before carrying out any procedure, the longer the time, the greater is the chance of infections and other problems (Green and Wenzel, 1977). In this sense, angioplasty has a considerably shorter duration than open revascularization, with a ratio of revascularization to angioplasty time of 2.02. Therefore, angioplasty becomes a good option for at-risk individuals, especially those more prone to hospital infections. Over the years, both procedures have shown a reduction in hospitalization time of 15% and 23% for angioplasty and revascularization, in the appropriate order. This demonstrates greater efficiency in the operation and post-operative care. Still in the data obtained, it was possible to identify a considerable drop in length of stay during the 2019-2022 pandemic, emphasizing major changes that this period generated in the entire health area. Hospital stays also show fluctuations according to the nature of the care, so when it is urgent there is a significant increase. In angioplasty, this increase in relation to the elective procedure is 69% or 2.2 days, whereas for infra inguinal bypass the increase is less prominent, 12.5% or 1.1 days. This difference in increase between interventions may be related to the open operation already having a long period of postoperative observation, while the less invasive one recommends a shorter hospital stay due to the very nature of the technique (Schanzer and Conte, 2010; Conte *et al.*, 2019).

When analyzed the mortality rate data, angioplasty continues to present a lower lethality rate, but the notable factor is the tendency for this rate to decline by 50% over the years in the revascularization procedure. This is mainly due to the learning and improvement of the team, but also the change in the patient profile, as over time angioplasty emerged as an alternative for high-risk patients (Rooke *et al.*, 2011). Furthermore, it was also noted the variation in lethality according to the type of care, with angioplasty being the modality that revealed the greatest increase in the lethality rate when the procedure was performed as an emergency, reaching 2.3 times higher. This data suggests the difficulty of using the angioplasty technique in emergencies, since in most regions, except for the Northeast region, the rate remained with minimal variation. Observing the regional distribution, the Northeast region stood out for having the lowest angioplasty lethality rate, both elective and urgent, while it has the highest lethality rate in revascularization, suggesting the region's preference for the angioplasty procedure.

As for the mortality rate, it is important to highlight a higher number in revascularizations, which presented an overall average of 3.4% compared to the endovascular approach with 1.3%. This data corroborates the fact that open surgery presents more surgical risks (Schanzer and Conte, 2010; Farber, 2018), however it proved to be considerably lower than the mortality in the last 30 days observed in BASIL-2, which was 6% and 3%, for open and endovascular surgery, respectively. However, although this is promising data, it must be interpreted with caution, due to the possibility of underreporting and errors in determining the cause of death. Analyzing the regional distribution, the North stood out with the highest mortality rate, fact that can be justified both by having fewer inhabitants, and by greater inexperience with the procedures, which are performed less frequently in this region, besides the lower availability of materials and fewer reference centers, according to CNSaúde.

Analyzing the nature of care, the preponderance of urgent procedures compared to elective procedures for both techniques is notable. This reflects the delay in intervention in those patients who require surgery (so the patient already appears in the medical center in an urgency state), as well as the delay in diagnosis resulting in higher rates of morbidity and mortality for these patients, especially in angioplasty. However, the North stands out for being the only region that presents a greater number of elective cases and almost triple the mortality rate in emergency angioplasty, probably because it does not have an adequate emergency center or because of underreporting of this modality in cases of urgency.

Finally, when we compared the data obtained with the BEST-CLI and BASIL-2 clinical trials, a scenario like the one described in BASIL-2 was noted, favoring the endovascular approach when analyzing the mortality rate and length of stay hospital. However, variables such as the use or not of the saphenous vein in revascularization and the rates of reintervention and amputation after the procedures weaken the analysis, not allowing a direct comparison. (Conte *et al.*, 2019; Bradbury *et al.*, 2023)

Our sample considered bypass or infra inguinal angioplasties as all procedures in the femoral-popliteal and distal popliteal territories because that is how it is in DataSUS database, even knowing that the prognosis and treatment of supra and infra patellar injuries are diverse, but unfortunately the basis of data does not differentiate these two topographies.

Despite being a descriptive study, information gaps in the Brazilian health data system make it difficult to provide a more accurate descriptive assessment for some study variables, which is its main limitation.

Conclusion

Angioplasty and open infrainguinal revascularization procedures are the two surgical interventions used to treat critical ischemia of the lower limbs. These procedures have been widely performed in Brazil with a total expenditure of 98,536,309.71 dollars during the period studied.

Both modalities have advantages and disadvantages, requiring an individual choice considering the variables of each patient and the surgeon's experience.

The data indicates a lower mortality rate and shorter hospital stay for angioplasty cases, which is currently the most widely adopted technique in Brazil. However, it is important to highlight that its main disadvantage, according to the literature, is the higher need for reintervention, which cannot be assessed due to the limitations of the DataSUS database, as discussed in the study's limitations.

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