Analysis of >100,000 Cardiovascular Surgeries Performed at the Heart Institute and a New Era of Outcomes

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Abstract

Background: The current challenge of cardiovascular surgery (CVS) is to improve the outcomes in increasingly severe patients. In this respect, continuous quality improvement (CQI) programs have had an impact on outcomes.

Objective: To assess the evolution of the incidence and mortality due to CVS, as well as the current outcomes of the Hospital das Clínicas Heart Institute of the University of São Paulo Medical School (InCor-HCFMUSP).

Methods: An outcome analysis of CVSs performed at the InCor, between January 1984 and June 2019. We observed the surgical volume and mortality rates in 5 time periods: 1st (1984-1989), 2nd (1990-1999), 3rd (2000-2007), 4th (2008-2015) and 5th (2016-2019). The CQI program was implemented between 2015 and 2016. The analysis included the total number of surgeries and the evolution of the most frequent procedures.

Results: A total of 105,599 CCVs were performed, with an annual mean of 2,964 procedures and mortality of 5.63%. When comparing the 4th and the 5th periods, the average global volume of surgeries was increased from 2,943 to 3,139 (p = 0.368), bypass graft (CABG), from 638 to 597 (p = 0.214), heart valve surgery, from 372 to 465 (p = 0.201), and congenital heart disease surgery, from 530 to 615 (p = 0.125). The average global mortality went from 7.8% to 5% (p < 0.0001); in CABG surgery, from 5.8% to 3.1% (p < 0.0001); in heart valve surgery, from 14% to 7.5% (p < 0.0001) and in congenital heart disease surgery, from 12.1% to 9.6% (p < 0.0001).

Conclusion: In spite of a recent trend towards increased surgical volume, there was a significant decrease in operative mortality in the groups studied. After the implementation of the CQI program, the mortality rates were closer to international standards. (Arq Bras Cardiol. 2020; 114(4):603-612)

Keywords: Cardiovascular Surgical Procedures/trends; Quality Improvement; Patient Safety; Hospital Mortality; Database.

Introduction

Cardiovascular surgery has undergone transformations throughout its history, especially after the consolidation of large databases. These data helped reduce surgical mortality by implementing data-oriented improvements. At that time, this was the reality of only a few centers in the world.

In 1984, the Hospital das Clínicas Heart Institute of the University of São Paulo Medical School (InCor-HCFMUSP) database was structured with the purpose of defining and improving cardiovascular surgery outcomes. Thus, the InCor, one of the largest Cardiology centers in Brazil, took its first step into the virtuous cycle of outcome continuous improvement.

In this respect, a national analysis of cardiovascular surgery outcomes already showed a mortality of 8%, virtually twice as much than that in the best centers worldwide, although the data were obtained from an administrative database. There was a wide range of justifications, such as healthcare access difficulties, lack of adherence to protocols and socioeconomic conditions. In fact, it was quite difficult to identify the health service weaknesses, given the lack of clinical data available.

In InCor, limitations in variable definitions, regarding both data completeness and consistency, as well as the lack of reference parameters to follow the results caused the development of a data-driven culture over time, which was strengthened after the implementation and validation of the EuroSCORE I and the modified Parsonnet’s score. Afterwards, the InCor created the InsCor, becoming one of the few centers in the world to have its own risk model for prediction, planning and optimization of outcomes.

Over time, the InCor took the lead by establishing a partnership with the São Paulo State Department of Health, in order to build the Sao Paulo Registry of Cardiovascular Surgery (REPLICCAR). Next, the InCor established the Patient Safety and Quality Surgical Unit, which gave rise to the CQI Program, consolidated in 2016, whose initial mission was to reduce mortality rates in cardiovascular surgery.
The purpose of this study is to assess the evolution of the incidence and mortality of cardiovascular surgery, as well as the influence of the CQI Program in one of the centers of reference in cardiology in Brazil: the InCor-HCFMUSP.

Methods

Sample
An observational retrospective study from InCor database. We collected information on the surgical volume and mortality outcomes from January 1984 to June 2019. To facilitate this analysis, data were grouped into 5 periods: 1984-1989; 1990-1999; 2000-2007; 2008-2015 and 2016-2019. Thus, we analysed the surgical volume and mortality rates in general, as well as those related to the groups with the highest surgical volume and mortality rates (Coronary, Valvular, Congenital and Arrhythmias). In addition, the evolution of mortality rates in the last two periods (4th and 5th) for Aortic Valve Surgery, Mitral Valve Surgery, Aortic Valve Surgery + Mitral Valve Surgery, CABG + Valve Surgery (Aortic or Mitral) and Aortic Dissection Surgery was analysed in isolation.

Data collection, definition and organization
The InCor database (SI3)7 includes clinical and follow-up data of patients inside and outside the hospital. Filling out this register is compulsory and performed by employees from several healthcare areas. The data are placed online (http://si3/) with a personal password and user. Data completeness and veracity were validated by the Incor Hospital Medical Information Unit, by the Assistance Operations Management and by the Patient Safety and Quality Surgical Unit. Data of the first publication, “Evolution of Cardiovascular Surgery at the Instituto do Coracao: Analysis of 71,305 Surgeries”, were retrieved and analysed together.8 Surgical mortality was defined as any death occurring within 30 days after the main procedure, in or out of the hospital.

Inclusion Criteria
All cardiovascular procedures performed at the InCor, between January 1984 and July 2019.

Exclusion Criteria
For the analysis by procedure type, emergency or rescue procedures were excluded.

The CQI Program
Envisioning a new era of cardiovascular surgical outcomes, the new InCor management, led by Prof. Fábio Jatene, created, inside the Cardiovascular Surgery Division of Incor, the Patient Safety and Quality Surgical Unit (UCQSP). This unit aims at supporting the construction of a safety culture, by promoting transparency, standardizing training courses, improving staff work and monitoring performance. In order to converge these and other activities, the UCQSP established the CQI Program in Cardiovascular Surgery.9 To this end, an alignment with the Information Technology Service and the Hospital Medical Information Unit of the InCor was crucial to monitor the program implementation. Thus, the initial set of measures of the CQI Program was:

1) establish annual goals of surgical volume and outcomes;
2) public and monthly presentations of the outcomes;
3) implementation of a surgical Checklist and its propagation to 100% of the surgical procedures;
4) establishment of a clinical/surgical outpatient setting for all groups;
5) monitoring of adherence to the perioperative protocols established;
6) multidisciplinary approaches to all surgeries and/or patients at high risk;
7) assessment of the cause of operative mortality using the POCMA (Phase of Care Mortality Analysis) process;
8) requirement of quality improvement metrics for each area involved in healthcare;
9) development of Researches in Quality and Safety;
10) accurate indication and timing of surgery for urgency/emergency patients.

Statistical analysis
Regarding the mortality rates observed, the periods were compared using a two-tailed test for comparison of proportions. In 2019, it was observed that the second and the first semester had the same number of surgeries and average deaths. From 1984 to 2007, for the Arrhythmia group, only the annual mean of the number of surgeries performed in each period was available. Therefore, we considered that the number of surgeries carried out in each year was equal to the average of the period, in order to estimate the p-value. For the variable number of surgeries, the two-tailed Mann-Whitney test was used. The level of significance established was 0.05. The R software (version 3.5.3) was used for the analyses and graphs. The Excel software was used to consolidate the original basis.

Ethics and consent term
This Project was carried in the UCQSP, with the approval of the hospital management, as a study on quality improvement. It was a database study with no identification of patients. Therefore, the Free and Informed Consent Form was not required.

Results
A total of 105,599 CVSs were performed, with an annual mean of 2,964 procedures and mortality of 5.63%.

In the total volume analysis, there was an increase of 32.5% between the 1st and 2nd periods (p = 0.001) and of 35.3%, between the 2nd and 3rd periods (p = 0.0001). There was a decrease of 22.7% between the 3rd and 4th periods (p = 0.0006) and a slight increase of 6.7% between the 4th and 5th periods (p = 0.3677). In relation to CAGB surgery, there was an increase of 18.3% between the 1st and 2nd periods (p = 0.0145), and of 9.2%, between the 2nd and 3rd periods (p = 0.0293).
There was a decrease of 42.3% between the 3rd and 4th periods (p = 0.0002), and of 6.4%, between the 4th and 5th periods (p = 0.2141).

In valve surgeries, there was an increase of 8.5% between the 1st and 2nd periods (p = 0.1471), and of 37.6%, between the 2nd and 3rd periods (p = 0.0001). This increment decreased in the same proportion between the 3rd and 4th periods (p = 0.0009). However, there was an increase of 24.9% between the 4th and 5th periods (p = 0.2019).

In congenital surgeries, there was an increment of 23.4% between the 1st and 2nd periods (p = 0.0020), and of 37.8%, between the 2nd and 3rd periods (p = 0.0077). There was a decrease of 22.7% between the 3rd and 4th periods (p = 0.0312), and an increase of 16.1%, between the 4th and 5th periods (p = 0.1250).

In arrhythmia surgeries, there was an increase of 154.6% between the 1st and 2nd periods (p = 0.0001), 68% between the 2nd and 3rd periods (p = 0.0001), 12.6% between the 3rd and 4th periods (p = 0.0001), and of 1.6% between the 4th and 5th periods (p = 0.8081). (Table 1).

In the total mortality analysis, although there was a decrease in mortality of 1% between the 1st and 2nd periods (p = 0.0001), there was an increase of 0.1% between the 2nd and 3rd periods (p = 0.5227), and of 2.9% between the 3rd and 4th periods (p = 0.0001). However, there was a decrease of 2.8% between the 4th and 5th periods (p = 0.0001), which resulted in a decrease of 0.8% between the 1st and 5th periods (0.0051).

In relation to CABG surgery, there was a decrease in mortality of 0.1% between the 1st and 2nd periods (p = 0.7088), with an increase of 0.5% between the 2nd and 3rd periods (p = 0.1072), and of 1% between the 3rd and 4th periods (p = 0.0121). Nonetheless, there was a decrease of 2.6% between the 4th and 5th periods (p = 0.0001), achieving a decrease of 1.3% between the 1st and 5th periods (p = 0.0002).

In valve heart surgeries, there was an increase in mortality of 0.3% between the 1st and 2nd periods (p = 0.6693), of 0.5% between the 2nd and 3rd periods (p = 0.4174), and of 5.5% between the 3rd and 4th periods (p = 0.0001). However, there was a decrease of 6.5% between the 4th and 5th periods (p = 0.0001), ending up with a decrease of 0.2% between the 1st and 5th periods (p = 0.8946).

In congenital surgeries, there was a decrease in mortality of 0.9% between the 1st and 2nd periods (p = 0.1993), and of 2.7% between the 2nd and 3rd periods (p = 0.0001). Although there was an increase in mortality of 6.9% between the 3rd and 4th periods (p = 0.0001), there was a decrease of 2.5% between the 4th and 5th periods (p = 0.0017). When we compared the 1st and 5th periods, there was an increase in mortality of 0.7% (p = 0.3943).

In arrhythmia surgeries, there was a decrease in mortality of 1.2% between the 4th and 5th periods (p = 0.0001). We could not accurately retrieve the data on mortality of the arrhythmia surgeries performed in the 1st, 2nd and 3rd periods. (Table 2).

The graphs of global, coronary, valve, and congenital volume and mortality in > 35 years of the InCor are shown in Figures 1, 2, 3 and 4, respectively.

Additionally, we provided the annual volume (Table 3) and mortality (Figure 5) rates of the most complex and most frequently performed procedures in cardiovascular surgery since 2008: Acute Aortic Dissection, Congenital, Isolated CABG, CABG + Valve, Aortic Valve, Mitral Valve, and Aortic Valve + Mitral Valve.

For didactic purposes, we decided to compare these procedures in the 4th and 5th periods as well. Therefore, in Acute Aortic Dissection, the average annual volume increased 66% (p = 0.1060) and mortality decreased 11.2% (p = 0.0016). In CABG + Valve, the average annual volume decreased 22.4% (p = 0.1481) and mortality reduced 12.1% (p = 0.0001). In Mitral Valve surgery, the average annual volume increased 34.1% (p = 0.1535) and mortality reduced 6.4% (p < 0.0001). In Aortic Valve surgery, the average annual volume increased 14.6% (p = 0.1481) and mortality reduced 6.7% (p < 0.0001). In Mitral Valve surgery + Aortic valve, the average annual volume increased 22% (p = 0.2688) and mortality reduced 11.9% (p < 0.0001) (Figure 5).

We also analysed two procedures considered the state of the art in cardiovascular surgery: Off-pump CABG surgery (OPCAB) and Valve Repair, for periods 4 and 5. The annual average volume of OPCAB decreased 49.8% (p = 0.0040) and mortality increased 0.8% (p = 0.7018). Still, the annual average volume of Valve Repairs reduced 5.7% (p = 0.8081), but mortality reduced 3.8% (p = 0.0427).

### Discussion

We carried out a time series analysis of the volume and mortality in cardiovascular surgeries in > 35 of the InCor, one of the greatest intitutions in Latin America which, in 2016, established its CQI Program. These information were obtained

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**Table 1 – Number of Procedures per Surgical Group at the InCor during the 5 periods**

| Groups Selected | Period 1 | Period 2 | Period 3 | Period 4 | Period 5 |
|-----------------|----------|----------|----------|----------|----------|
| Total           | 2,122    | 2,812    | 3,806    | 2,943    | 3,139    |
| Coronary        | 856      | 400      | 856      | 400      | 856      |
| Valve           | 1,013    | 434      | 1,106    | 372      | 597      |
| Congenital      | 403      | 497      | 685      | 530      | 615      |
| Arrhythmias     | 238      | 606      | 1,018    | 1,146    | 1,165    |
Table 2 – Mortality Rates per Surgical Group of the InCor during the 5 periods

|                | Period 1 | Period 2 | Period 3 | Period 4 | Period 5 |
|----------------|----------|----------|----------|----------|----------|
| Total          | 5.79%    | 4.75%    | 4.86%    | 7.78%    | 4.99%    |
| Groups Selected|          |          |          |          |          |
| Coronary       | 4.44%    | 4.29%    | 4.79%    | 5.78%    | 3.14%    |
| Valve          | 7.63%    | 7.95%    | 8.44%    | 13.96%   | 7.47%    |
| Congenital     | 8.85%    | 7.94%    | 5.27%    | 12.13%   | 9.60%    |
| Arrhythmias    | 2.15%    | 0.94%    |          |          |          |

Figure 1 – Year-by-year graph of global surgical volume and mortality in > 35 years of the InCor.

from the InCor database, which was founded in 1984, at the same time that the New York State database was established.10 This is also the period when a series of risk scores began to arise all over the world, with the purpose of stratifying patients, adjusting risk and monitoring the outcomes.11

These initiatives came at a time when patients had more comorbid conditions and, at the same time, the most complex surgeries were influenced by the increase in life expectancy.12 It was the ideal scenario to start measuring the outcomes and optimizing the strategies. Perhaps one of the highest impact projects on outcomes continuous improvement has been the creation of the EuroSCORE13 and the STS score14 which, through the estimation of expected mortality, allowed us to plan, prepare and even look for new treatment alternatives for the patients. The adoption of these instruments in surgical practice enabled the phenomenon to develop. While the centers started to make their measurements, the outcomes observed continued to improve to the extent that the scores had to be recalibrated in order to survive.15

At the InCor, the measurements started to be taken in 2007 with the incorporation of the EuroSCORE and the 2000 Bernstein-Parsonnet model, for estimation of expected mortality.4 These models, which were validated first, were used by the INCOR to elaborate its own model: the InsCor.5 In the evolution of outcomes, this corresponds to period 4 of the present analysis. It was in this period that the culture of data and outcomes measurements began to consolidate, although a decrease in the surgical volume at the InCor, both in general surgery and in the subgroup ones, resulted in a proportional increase in surgical mortality rates. In addition,
Figure 2 – Year-by-year graph of volume and mortality in CABG surgery in > 35 years of the InCor.

Figure 3 – Year-by-year graph of volume and mortality in Valve Cardiac Surgery in > 35 years of the InCor.
although in this period there was the implementation of certain improvement initiatives, these were not convergent, and, consequently, could not be structured and far less sustainable.

The success of centers that had already started to work on the organization and structuring of improvement programs started to show results. In this respect, in 2012, the European Association for Cardio-Thoracic Surgery (EACTS) established its Quality Improvement Programme (QUIP) with the purpose of improving the outcomes, as well as integrating strategies for quality improvement.16

The Cardiovascular Surgery Division of the InCor started to create improvement initiatives through an organizational culture that focused on reducing mortality outcomes by following established goals. These goals at first followed historical data, which means improving one’s own results. This is one of the best ways to create progressive and sustainable results. Because it understood the importance of multicenter registries and of continuous and collaborative learning, the InCor, by means of a partnership with the SES-SP and the FAPESP, created, in 2013, the Paulista Cardiovascular Surgery Registry.6 After this initiative, the InCor gained a better understanding of the outcomes and could guide its strategies better. As a result, in 2016, the InCor, with the establishment of a data-driven culture, converged its improvement measures through the implementation of its CQI Program.9

This analysis was carried out with 105,599 cardiovascular surgeries and it is possible to observe that, since 1984, the
annual surgical volume has only increased, with the largest increase occurring in the 3rd period. The annual death rate was progressively increasing until the 4th period. The significant growth in surgical volume between the 2nd and 3rd periods (35%) caused the increase in mortality rate to be insignificant (0.1%). Nevertheless, the major decrease in surgical volume in the 4th period (22.7%) caused the mortality rate to increase significantly (2.9%). Although surgical volume growth between the 4th and 5th periods (6.7%) was not significant, the mortality rate reduced significantly (2.8%). Anyway, since its origins until the current period of the InCor, there has been a significant increase in surgical volume (47.9%), with a decrease in mortality rates (0.8%).

The significant decrease in the global surgical volume in period 4 was directly related with the significant decrease in surgical volume in all subgroups, excepted for the arrhythmia subgroup. This was more evident in the CABG group, most probably due to the boom in percutaneous procedures, such as coronary angioplasty. Moreover, new evidence changed the practice of cardiovascular disease treatment, with the advances in drug therapy and accurate indication for surgical intervention. Here, we highlight the role of Science in balancing and adjusting the scenario for the benefit of better patient outcomes.

The decreased volume of CABG was significant between the 3rd and 4th periods (42.3%). However, we can say that it stopped to decline, since between the 4th and 5th periods, there was a decrease of only 6.4% (p = 0.21). We can see that, even though the highest CABG volume occurred in the 3rd period, the mortality rate has also increased (0.5%). Although this was not significant, it shows an increase in the number of deaths in this period. As described before, the incorporation of risk scores into our practice only took place by the beginning of the 4th period, which may explain to some extent the outcomes observed. As a result, the reduction of 42.3% in CABG volume in the 4th period undoubtedly impacted the mortality rate, which reached 5.78% (p = 0.01). What is evident is that, even though the volume reduction was not significant, in the 5th period, the mortality rate reduced 2.6% (p = 0.0001). By examining Figure 2, we note that the mortality rate in CABG surgeries reached 1% in 2019, a historic achievement, which is very close to the results of the best centers in the world.

The volume of Valve Surgeries, which had been progressively increasing, suffered a significant reduction in the 4th period (37.6%), with a significant increase in mortality (5.5%). However, in the 5th period, the surgical volume increased 24.9% (p = 0.20), and there was a decrease of 6.5% in the...
cases of Acute Aortic Dissection Surgeries increased 66% because, in addition to a significant volume increase (389.5%), mortality reduced significantly (2.5%). This also reflects the continuous implementation of improvement measures by the staff and the cardiovascular surgery division which, by 2019, has already reduced mortality rates to 7% (Figure 4).

For arrhythmia surgery, the 5th period was quite satisfactory because, in addition to a significant volume increase (389.5%), there was a reduction in mortality of 1.2% (p = 0.0001).

On the other hand, in relation to the isolated procedures, which have been presenting an expressive increase since 2008, we compared the 4th and 5th periods. We observed that the cases of Acute Aortic Dissection Surgeries increased 66% (p = 0.1060), and mortality reduced 11.2% (p = 0.0016). In 2019, the results already reach 11% for a mean mortality in the best centers of >20%. It is important to mention that several protocols were structured taking into account the best moment for the surgical approach and the standardization of the surgical technique. In CABG + Valve surgeries, the average annual volume had a modest reduction of 22.4% (p = 0.1481).

However, there was a significant mortality reduction (12.1%). In 2018, the mortality rate was 8% and, in 2019, we still have not registered any deaths due to this associated procedure. In mitral valve surgery, the average annual volume increased 34.1% (p = 0.1535), with a reduction in mortality of 6.4% (p < 0.0001). Until the first period of 2019, mortality had already reached 2%. In aortic valve surgery, the mean annual volume increased 14.6% (p = 0.1481) and there was also a significant decrease in mortality (6.7%). In 2019, mortality also followed a downward trend and is already at 5%. In the combined mitral and aortic valve repairs, the average annual volume increased 22% (p = 0.2688) and mortality reduced 11.9% (p < 0.0001). The positive mortality outcomes of the valve group is also the result of strong efforts towards the establishment of a line of care, of a multidisciplinary outpatient surgery clinic and the standardization of surgical techniques. Besides, this is a population at high risk, with 56% of rheumatic disease patients, 75% of patients in functional classes III and IV and 31% of reoperations.

The purpose of this analysis is to show the evolution of cardiovascular surgery in one of the centers with the greatest operative volume in South America, where > 80% of the patients are assisted under Brazil’s Unified Health System (SUS), which makes it a reference hospital that receives all types of patient referrals for different procedures. Unquestionably, the decrease in surgical volume in the 4th period had an impact on mortality in a context that still focused on surgical volume, because evidence shows that the improvement in mortality outcomes due to volume were replaced by improvements resulting from the CQI programs, including at university hospitals, which would be our case, and in several parts of the world.

Within the package of measures developed by the InCor through its CQI program, previously mentioned, it is worth to highlight the implementation of the InCor Checklist. This project was initiated in 2014, but it was only after 2016 that it became compulsory for all surgeries. Research projects in the area of Quality and Safety have favoured partnerships financed by the FAPESP, such as the cooperation with the Fuwai Hospital, in China, and the partnership of the REPLICCAR II with the Harvard University Department of Public Health (www.repliccar.com.br).

Undoubtedly, the greatest challenge should be sustainability and, above all, the continuous outcomes improvement. To this end, strategies that aim at reducing morbidity, optimizing processes to reduce hospital stay time and that focus on improving patient experience are required. Programs like this could be spread in Brazil, focusing on standardization and continuous structuring of good quality practices, regardless of the surgical volume.

Limitations

We note 3 limitations: 1) This is a unicentric and retrospective study, which would hinder the generalization of our conclusions. However, the large surgical volume and the existence of an institutional registry that improves over time help minimize this bias. 2) The lack of patient stratification based on risk makes it difficult to understand whether the decrease in surgical mortality would be more associated with a greater proportion of patients at low risk. A subanalysis of more recent periods (from 2013 to 2019) was carried out and we found a significant decrease in mortality with no differences in the surgical volume or in the risk estimated by the EuroSCORE II. 3) The CQI program was consolidated in 2016, but improvement measures date back to 2007. In fact, isolated actions can be traced back to 2007, but the formulation and structuring of the CQI program were established between 2015 and 2016. In practice, we can say that the package of measures converged in 2016, which may explain the mortality reduction in all groups.

Conclusions

In spite of a recent trend towards increased surgical volumes, except for CABG surgery, a significant decrease in the general surgical mortality rate and in the groups studied was evident. The consolidation of the CQI program at the InCor has been associated with the progressive decrease in surgical mortality, which corroborates the evidences, regardless of the scenario or region. After the consolidation of the CQI program, the mortality rates were close to international standards.

Author contributions

Conception and design of the research: Mejia OAV, Lisboa LAF; Jatene FB; Acquisition of data: Mejia OAV, Lisboa LAF;
Arita ET; Analysis and interpretation of the data: Mejia OAV, Lisboa LAF, Caneo LF, Brandão CMA, Dias RR, Costa R, Jatene MB, Pomerantzef PMa, Jatene FB; Statistical analysis and Writing of the manuscript: Mejia OAV; Critical revision of the manuscript for intellectual content: Lisboa LAF, Caneo LF, Arita ET, Brandão CMA, Dias RR, Costa R, Jatene MB, Pomerantzef PMa, Jatene FB.

Potential Conflict of Interest
No potential conflict of interest relevant to this article was reported.

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