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Quality control in cardiovascular surgery: a new paradigm

Controle de qualidade em cirurgia cardiovascular: um paradigma a ser atingido

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Abstract

The objective is to write a literature review of the relevant information related to quality control in cardiovascular surgery. The authors have studied several parameters to allow quality control in cardiovascular surgery: 1. Construction of a database as complete as possible to the similar ones of the Society of Thoracic Surgeons and the European Association for Cardio-thoracic Surgery; 2. To create a surgical risk model like the Euroscore; 3. To make an analysis of the different reasons for a poor surgical outcomes and try to correct them; 4. To study the human factor as an important element to the surgical outcome and discuss methods to avoid erros in an action similar to the ones used in aviation. Enabling a tight control of quality in cardiovascular surgery it is possible to obtain a major improvement in surgical outcomes.

Descriptors: **Quality control. Cardiac surgical procedures. Database.**

Resumo

O objetivo do trabalho é fazer uma revisão da literatura sobre o controle de qualidade em cirurgia cardiovascular. Os autores estudaram os diversos parâmetros necessários para um melhor controle de qualidade em cirurgia cardiovascular: 1. Criação de uma base de dados abrangente, utilizando-se como modelos as bases de dados da Society of Thoracic Surgeons e European Association for Cardio-thoracic Surgery; 2. Prever um escore de risco cirúrgico nos moldes do Euroscore; 3. Analisar os fatores que podem contribuir para um mau resultado cirúrgico e apontar meios de corrigi-los; 4. Analisar o impacto do fator humano sobre o resultado cirúrgico, fazendo um paralelo com a metodologia usada em aviação. Por meio de um controle rigoroso da qualidade em cirurgia cardiovascular, é possível se melhorar em muito o resultado cirúrgico.

Descritores: **Controle de qualidade. Procedimentos cirúrgicos cardíacos. Base de dados.**

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INTRODUCTION

Surgery quality control is necessary in order to obtain from a planed surgery the expected outcome in accordance with the current physician's knowledge [1].

Quality in surgery can be analyzed into several aspects: safety, efficiency, efficacy, equity, time, and patient. Regarding safety, we may understand that the treatment should be performed in a correct way, being efficiently implemented within the principles based in evidence. Surgical management should be effective, being cost-effective, without overdo diagnosis tests, without non-tested operations or complications that could raise hospital cost. By equity, we may understand that the surgical management should be provided to all the patients regardless the age, gender, ethnic group, health insurance or socioeconomic status. Surgical therapies present better outcomes when provided at the right and proper time without unnecessary delays. Surgical management should be performed aiming at the patient as an individual, analyzing risks and benefits focused in that particular patient [2].

DATABASE

The first step towards surgery quality control is the databases configuration. Each surgeon, surgery service, hospital unit, or health service should enter into database composition from which should be possible to analyze the outcomes and to reverse the quality of the services afforded.

Simple databases assess the postoperative patients analyzing the mortality outcomes and the most common complications. These databases can become increasingly more complex so as to allow a more pertinent inference on a certain type of surgical management. The myocardial revascularization surgery has been the most studied surgery in the history of medicine; extraordinary databases in American and European studies with both prospective and retrospective analyses over 30 years allow corroborating the efficacy of this surgical procedure.

An analysis of the information collected allows guiding the procedures to be achieved. In 1863, Florence Nightingale observed that the London in-hospital mortality was much superior (91%) than the regional city hospitals (52%). From these observations in simple databases, important therapeutic and sanitary measures could be taken by the English health authorities [3].

Data collection can be performed by a variety of manners. It can be made starting from administrative or clinical data. The studies by Godoy *et al*. [4] were performed from administrative data and by the analysis of authorization forms for hospital admittance (AIH) for Unified Health System (SUS). However, the clinical data collection seems to better represent the actual quality of the services provided, since it is taken into consideration the patients' clinical variability and presents minor bias in fulfilling data in comparison with the administrative data collection. Mack *et al*. [5], in 2005, showed the superiority of clinical data collection over the administrative data collection by comparing the expected outcomes with each one of these collections with the achieved outcome.

Data collection can be either mandatory or voluntary. Mandatory data collections are important in order to the health control services to evaluate the outcomes of the surgeries accomplished. The voluntary data collections are important in order to the surgeons to understand what they are doing and how to improve the outcomes. Certainly, a more surveillance on the services rendered must be done by health providers and controllers.

This data collection can be made by the surgical team itself or by independent collectors. The data collection by an independent staff can be made by a skilled health officer, what tend to be more reliable, yet more costly.

Data collection can be derived from the surgeon itself, from the hospital administrative services, from requirements of either medical societies or Health Ministry as well. Data should be collected in the pre, per, and postoperative. Surgeon should be trained to collect as much data as possible from the patients he operates including in-hospital mortality, morbidity, late outcome, and hospital costs since the beginning of his/her career. Only by doing so, the surgeon will be able to construct a sound experience based on authentic evidences. Hospitals need to have data from the procedures herein preformed in order to promote surgical outcome improvements, to correct structural and technical defects, and to reduce unnecessary hospital expenditures. Medical societies are the guardians of specialties and by means of data analysis can identify and correct the errors. Obviously, with data correctly obtained the Health Ministry can propose modifications in the national health policies, addressing resources to where they can be better used.

Surgical outcome evaluation was initially focused on in-hospital mortality only, i.e., that occurred until 30 days after the surgical procedure. Nevertheless, with the increasingly reduced mortality, other data became more relevant and began to be considered into the quality assessment.

In heart surgery, other important data in outcome assessment are as follows: 1. In-hospital infection incidence; 2. Stroke; 3. Sustained pulmonary ventilation; 4. Renal insufficiency; 5. Hospital length of stay; 6. Length of stay in the ICU; 7. Hospital costs; 8. Patient's age; 9. Gender; 10. Procedure emergency; 11. Reoperation; and 12. Facility where the procedure was carried out.

In order to interpret the attained data, it is very important to perform a well-done analysis. A *simple univariate* data analysis is the starting point. Thenceforth, varying statistical

resources allow a more comprehensive data analysis.

An adjustment of the mortality according to the surgical risk is crucial to assess the quality of the service rendered. Different surgical outcomes should be expected for patients with diseases of different complexities and with a number of comorbidities. The use of statistical resources such as multivariate analysis and logistic regression allow us to analyze a variable among the presence of several others. In a multivariate analysis, a new regression equation is formulated in which are included only the interested independent variables. Thus, it is possible to pinpoint the role of renal insufficiency as a risk factor for myocardial revascularization surgery among other concurrent variables (e.g., age, gender, respiratory insufficiency, etc) [6].

To risk stratification, the *Society for Thoracic Surgeons* uses the Bayes theorem, in which the positive and negative predictive values are created from diagnostic specificity, diagnostic sensitivity, and prevalence known data [7].

In 2002, Grunkemeir *et al*. [8] developed a propensity score to group distinctive patients who underwent the same surgery. Thus, a group of patients with different comorbidities, degrees of heart failure, and left ventricle sizes are put together into distinct groups by analyzing the late outcome of either mitral valve replacement or mitral valve reconstruction, for example.

In 2003, Kaempchen et al. [9] showed that the Kaplan-Meier actuarial curve is an adequate method to analyze the life table (also called mortality table or actuarial table), but to analyze valve prosthesis longevity, the actual curve is more adequate. The authors' conclusions were attained by analyzing the actual data observed with the extrapolated data from statistical analyses.

The major goals arising from these statistical studies are as follows: 1. To obtain a better surgical outcome; 2. To prevent the operative risk for both a particular procedure and patient; and 3. To allow specific actions to be taken to correct the existing errors.

Two major databases on heart surgery were developed to provide this information: the *STS Database* of the *Society for Thoracic Surgeons* (EUA) and the *EuroScore* of the *European Association for Cardio-thoracic Surgery* (Europe).

Database of the STS Database has reviewed 3 millions heart surgeries carried out in 771 participating centers since 1989. It was originally collected 400 data per patient and currently is collected 52 data per patient with 32 of these being clinical data arising from pre, per, and postoperative periods. These data have been extensively validated by clinical trials. The database analysis of the *STS Database* allowed the corrections to be performed and better outcomes obtained in the myocardial revascularization surgery [10].

The European database relies basically on preoperative data and intends to predict surgical outcomes for different risk factors. It was then created a score, the EuroScore, which identifies the surgical risk of a specific patient. This risk score was also extensively validated [11]. By means of a spreadsheet, it is possible to attain the operative mortality expected for a certain surgical procedure by plotting the patient's preoperative data. EuroScore can be used as either a pattern or as logistic regression. The latter is particularly important when dealing with critically-ill patients, since the data attained by logistic regression of the independent variables are closer of the reality observed. Data from EuroScore surgical forecast were also validated for Brazilian patients [12].

In 2007, the *European Association for Cardio-thoracic Surgery* published the evaluation result of 637,976 surgeries performed between 2004 and 2005, at 260 participating hospitals in 22 countries. This huge study was carried out by a contracted company – the *Dendrite Clinical Systems* – based on UK, which has helped to draw up a program to collect, gather, analyze the data attained and publish the outcomes. Analyzing these data, it was observed that the myocardial revascularization surgical mortality was 2.1% among men, 3.5% among women, 7.3% among patients aged 80 years or more, and 10% in patients with an ejection fraction <30%. From these data, many other information can be drawn, which contributes to surgical outcome improvement [7].

In 2003, the same company compiled the heart surgery outcomes performed in Great Britain and Ireland under the auspices of the Society of Cardio-thoracic Surgeons of Great Britain and Ireland. Data registration was initiated in 1977, and in 2003 it was already registered 646,292 surgical procedures, being possible to verify the surgeries carried out in each hospital and by each surgeon evaluated by the programme [13].

QUALITY CONTROL

Quality control in heart surgery depends on the surgical team, hospital unit, and health system.

Surgical staff quality control depends on everyone; however it is focused mainly on the staff leader, which is the surgeon. Basic and continuous training is important to improve the skills of the surgical staff members.

The most important factor to achieve quality control in surgery, depending on the surgical staff, is the human factor [14]. Human errors can be either minor or major, corrected or not. Minor errors can have severe consequences. Safety in surgery depends on anticipated acknowledgement of the potential problems that may happen as well as their preventive resolution. De Leval [15] showed the importance of the human factor by reporting three Jatene operations to correct transposition of the great vessels: in one, the coronary anastomosis was correctly performed; in another

one, the anastomosis was performed under tension, but in which the consequent myocardial ischemia was promptly correct; and eventually, the third operation in which there has been a myocardial ischemia, which has taken a long time to find and to correct. In the first case, the child was discharged from hospital after 7 seven days at a cost of US$ 24,000.00. In the second case, the postoperative period was troublesome requiring three-week ICU admission, five days of extracorporeal membrane oxygenation (ECMO), and recovery was achieved at a cost of US$ 94,000.00. In the third case, the child had a cardiac arrest at the ward postoperatively, recovering with neurologic damage at an excessively high cost, and with an unfortunate human outcome. This outcome differences depended on a human factor: a coronary anastomosis performed under stress and slightly angulated [15].

Hospital facilities should have quality undergraduate staff, once surgical outcome is directly dependent on the hospital facility where it is performed.

Analyzing our personal casuistry, we sought to classify the hospitals where it is possible to operate acute aortic dissection into *A, B,* or *C*. Angiotomograph, echocardiogram, and transesophageal echocardiogram; all the grafts and prosthesis required, fine blood bank, coagulation factors for transfusion, biological glue, autotransfusion system, and thromboelastogram all are available at the operating room in *A* hospitals. In these hospitals the surgeries can be easily performed any time of day or night. Our mortality rate was 16%, which is lower than that of the *International Registry for Aortic Dissection,* which is 26%, when operating acute aortic dissection in such *A* hospitals. *B* hospitals have only a few items abovementioned and the *C* hospitals are considered minor hospitals and have fewer items. Surgical mortality rate was higher when patients were operated in these facilities.

This hospital hierarchizing should be performed by the Health Secretariat, or by the Brazilian Medical societies, or by the Brazilian Hospitals Association, so that physicians and patients could be aware of where to get a better quality on surgical care.

Importantly, the surgical therapy quality should be the same at both private and public hospitals, a fact currently overlooked in Brazil. Nevertheless, this is a goal that should be achieved. In the United States, this concern caused the Congress to proclaim a Law in 1985 making mandatory to compare the adjusted risk among the surgical therapy outcome at the Veterans Administration Hospitals (VA), public hospitals, and private hospitals. This culminated with the creation in 1991 and 1994 of The National Veterans Administration Surgical Risk Study and The National Surgical Quality Improvement Program (NSQIP), respectively. As a consequence of these measures, between 1996 and 2006, there has been a decrease in both mortality and morbidity rates of 47% and 43%, respectively, in the Veterans Administration Hospitals paralleling with the surgical outcomes from the private sector hospitals [17].

Data correctly gathered from the surgical procedures carried out should be used by the public system, or by health provider unit services to correct distortions on the system and to improve the surgical therapy quality delivered.

The New York Health System provides to the layman via Internet, the mortality rate of the myocardial revascularization surgeries and the surgeons who performed these surgeries in the New York State [18]. In possession of these data, one could interfere in hospitals and surgical services in order to get better outcomes. The performance payment, i.e., a financial reward to those who operate with better outcomes is a consequence of the capitalism and the logic of these measures.

We should emphasize that this effort for better information is worthwhile only if the distortions are corrected. It is a waste of time to conclude that the increased in-hospital infection after the surgery is consequence of a sterilization device failure and do not take the necessary measures to fix or replace it.

In 1914, Codman [19] had already proposed some important principles of quality control in surgery, which are listed as follows: 1. Hospitals need to know the ultimate surgery outcomes performed; 2. Hospitals need to find their strong and weak points; 3. Hospital need to compare their outcomes with other hospitals; 4. Hospital need to make known not only their success, but also their failure; and 5. Facilities with better surgical outcomes should have a better payment for their services. This later statement is very important if we take into consideration that a surgical complication can increase hospital bill ten-, twenty-fold, or higher.

THE HUMAN FACTOR

The surgical act is a high-technology procedure. Immediately, it was sought to compare the techniques for an improvement of surgery quality with that one employed by the high-tech industries, such as aviation. Some of the principles used in aviation can be adopted by the surgical centers: 1. “Briefing” and “debriefing” – a judicious analysis by the surgeon together with all staff members regarding the surgery to be performed, and afterwards, an evaluation of all the circumstances involved in the surgery. Few surgeons do that and many attendant physicians are taken by surprise with unexplained correctly intraoperative procedures; 2. “Checklist” – it does not matter how many times a procedure is performed, the routine rereading as the pilots do before takeoff, certainly is beneficial. Any heart surgeon, once, could have initiated a cardiopulmonary bypass without heparinizing the patient because he/she

did not make a rereading of the routine; 3. Spare parts and equipment replacement are mandatory in order not to be taken by surprise in the middle of a surgery due to a severe failure of the equipment. When an electromagnetic motor from an extracorporeal circulation pump breaks throughout the surgery, this can be compared to when an airplane motor breaks in the middle of the Atlantic Ocean. There are solutions, but the quality is already compromised; 4. Black box – any incident, or accident, must be exhaustively investigated. Mortality and morbidity conferences, the Hospital Infection Control Commission studies, and the autopsy studies are considered the black boxes of the surgical procedure; 5. Near accidents - the analysis of near accidents, or incidents, is very important in aviation in order to prevent a real accident. In aviation it is a habit to report to everyone the mistakes and incidents in which you were involved. This habit must be widespread among surgeons in order to prevent new mistakes and to improve the outcomes.

The CTSnet, the cardiothoracic surgery Network from the *American Association for Thoracic Surgery, the Society for Thoracic Surgeons, and European Association for Cardio-thoracic Surgery,* developed a program to communicate surgical incidents and accidents, the *CTSnet Cardio-thoracic Study,* in the same patterns of the reporting systems in aviation employed by NASA (http://ascrs.nasa.gov/). Up to September 12, 2007, nine incidents and their solutions have been reported, and they were considered very instructive.

In aviation, the human factor is considered very important. In approximately 70% of the airplane accidents, a human error is likely to be involved. Airplane accidents have much more visibility than an accident at the surgical center, but also in a surgical center the human error is the cause of an important adverse outcome.

A crew Resource Management training system was developed in order to reduce human failure. Some frequent errors were identified by aerial accident analysis, such as: 1. To perform the memorized "checklist"; 2. To enter the wrong number on the onboard computer; 3. To misunderstand the flying altitude; 4. Fail to program the onboard computer; and 5. Unnecessary flight with bad weather. Corrections were proposed from these errors analyses.

Equivalent errors are found at in operating theatres, such as: 1. Failure to inform team of patient's problem; 2. Failure to discuss alternative procedures; 3. Leadership failure; 4. Conflicts between the surgeon and the anesthetist; 5. Fail to solve the unexpected adverse situations; and 6. Fail to monitor all the surgical procedure steps [20].

Crew training has reduced the airplane accidents in USA. This training was focused on participative leadership, "briefing" and "debriefing", and "checklist". The use of these principles in surgery should be encouraged. In an American hospital, the Concord Hospital, in New Hampshire, the introduction of preoperative discussion of all the cases with the surgical staff caused the heart surgery mortality rate in 650 consecutive patients to fall from 4.8% to 2.1%. The use of a "checklist" at John Hopkins Hospital ICU led to a reduction of patients' length of stay in the ICU by 2 days [21]. In 2007, the Mayo Clinic carried out the first symposium regarding Human Factors in Health Care, where practical applications to improve the patient's safety were discussed. This fact corroborates the theme's importance.

CONCLUSION

Quality control in surgery should be part of the surgeon's practicing. The adequate fulfillment of the operative data should be done by the surgeon itself because they are critical to further analyses. The surgeon must keep his/her database and seek to improve his/her results based on this information.

The surgeon, the health unit, and the public and private health systems must do all the efforts in order to carry out the surgeries with the maximum security as possible.

The surgeon's efficiency is judged by the results achieved.

Quality control in surgery is an important clinical action and it should not be seen as a corporative or police measure.

REFERENCES

1. Lohr KN, Schroeder SA. A strategy for quality assurance in Medicare. N Engl J Med. 1990;322(10):707-12.

2. Committee on Quality of Health Care in América Institute of

Medicine. Crossing the quality chasm: a new health system for the 21st century Washington DC:National Academia Press;2001.

3. Nightingale F. Notes of hospitals. 3rd ed. London:Green and Roberts;1863.

4. Godoy PH, Klein CH, Silva NAS, Oliveira GMM, Fonseca TMP. Letalidade na cirurgia de revascularização do miocárdio no Estado do Rio de Janeiro - SIH/SUS no período de 1999 - 2003. Rev SOCERJ. 2005;18(1):23-9.

5. Mack MJ, Herbert M, Prince S, Dewey TM, Magee MJ, Edgerton JR. Does reporting of coronary artery bypass grafting from administrative databases accurately reflect actual clinical outcomes? J Thorac Cardiovasc Surg. 2005;129(6):1309-17.

6. Norman GR, Streiner DL. Biostatistics. The bare essentials. 2nd ed. New York:Decker Hamilton;2000.

7. Keogh BE. Third European Adult Cardiac Surgery Database Report. Dendrite Clinical Systems, Oxfordshire;2007.

8. Grunkemeier GL, Payne N, Jin R, Handy JR Jr. Propensity score analysis of stroke after off-pump coronary artery bypass grafting. Ann Thorac Surg. 2002;74(2):301-5.

9. Kaempchen S, Guenther T, Toschke M, Grunkemeier GL, Wottke M, Lange R. Assessing the benefit of biological valve prostheses: cumulative incidence (actual) vs. Kaplan-Meier (actuarial) analysis. Eur J Cardiothorac Surg. 2003;23(5):710-3.

10. Ferguson TB Jr, Hammill BG, Peterson ED, DeLong ER, Grover FL, STS National Database Committee. A decade of change: risk profiles and outcomes for isolated coronary artery bypass grafting procedures, 1990-1999: a report from the STS National Database Committee and the Duke Clinical Research Institute. Society of Thoracic Surgeons. Ann Thorac Surg. 2002;73(2):480-9.

11. Nashef SA, Roques F, Hammill BG, Peterson ED, Michel P, Grover FL, et al; EuroSCORE Project Group. Validation of European System for Cardiac Operative Risk Evaluation (EuroSCORE) in North American cardiac surgery. Eur J Cardiothorac Surg. 2002;22(1):101-5.

12. Moraes F, Duarte C, Cardoso E, Tenório E, Pereira V, Lampreia D, et al. Avaliação do EuroSCORE como preditor de mortalidade em cirurgia de revascularização miocárdica no Instituto do Coração de Pernambuco. Rev Bras Cir Cardiovasc. 2006;21(1):29-34.

13. Keogh BE. Fifth National Adult Cardiac Surgery Database Report. Dendrite Clinical Systems;2004.

14. ElBardissi AW, Wiegmann DA, Dearani JA, Daly RC, Sundt TM 3rd. Application of the human factors analysis and classification system methodology to the cardiovascular surgery operating room. Ann Thorac Surg. 2007;83(4):1412-8.

15. de Leval MR. Beyond Flatland. J Thorac Cardiovasc Surg. 2003;125(1):12-9.

16. Hagan PG, Nienaber CA, Isselbacher EM, Bruckman D, Karavite DJ, Russman PL, et al. The International Registry of Acute Aortic Dissection (IRAD): new insights into an old disease. JAMA. 2000;283(7):897-903.

17. Khuri S, Henderson W. The patient safety in surgery study. J Am Coll Surg. 2007;204:1087-8.

18. Adult Cardiac Surgery in New York State 2004. Disponível em http://healta.state.ny.us/ Acesso em 8 de julho de 2007.

19. Codman EA. The product of a hospital. Surg Gynecol Obstret. 1914;18:491-6.

20. Helmreich RL. On error management: lessons from aviation. BMJ. 2000;320(7237):781-5.

21. Healy GB, Barker J, Madonna G. Error reduction though team leadershis applying aviation's CRM model in the OR. Bull Am Col Surg. 2006;91(1):11-5.