# The Influence of Time on the Characteristics and Risk Factors for Patients Submitted to Myocardial Revascularization

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**Objective:** To compare the clinical and surgical profile between two groups of patients submitted to Myocardial Revascularization (MCR) surgery at the Instituto de Cardiologia of Rio Grande do Sul with a ten year interval, to observe its influence upon MCR hospital mortality and to verify the predictability of this result using the risk score.

**Methods:** A retrospective cohort study involving 307 patients who underwent MCR surgery within a six month period during 1991/92 (INITIAL group, n=153) or 2001/02 (CURRENT group, n=154). Demographic characteristics, heart disease, comorbidities and surgical events were analyzed to compare the groups and to define the hospital mortality risk score (based on the Cleveland Clinic method).

**Results:** The CURRENT group was older, had more severe heart condition (functional class, incidence of heart failure and number of vessels with severe lesions) and a greater prevalence of comorbidities. The INITIAL group had a higher prevalence of nonelective surgery. Both groups had similar mean risk scores (2.8 $\pm$ 3.1 for INITIAL and 2.2 $\pm$ 2.5 for CURRENT) and hospital mortality rates (3.3% and 1.9% respectively). These figures are comparable to those for reported by Cleveland Clinic (for a risk score of 3 the predicted mortality range between 2.0 %; using a confidence level of 95% the predicted mortality is between 0 and 4.3%; and actual mortality confirmed by the study was 3.4%).

**Conclusion:** Patients currently submitted to MCR are older and in worse clinical condition (heart and systemic) than those operated on ten years ago; however, the risk scores and hospital mortality rates were slightly higher in the INITIAL group. The higher number of nonelective surgical interventions could have contributed to this. A risk score can be used to identify patients that require a higher level of care and to predict surgical outcomes.

**Key words:** Heart surgery, myocardial revascularization, risk factors.

The treatment of ischemic heart disease has undergone significant modifications that involve the natural history of the disease as well as indications for surgical intervention[1-5]. Some therapeutic interventions, pharmacological or invasive such as percutaneous transluminal coronary angioplasty (PTCA), contribute to a better clinical evolution and facilitate or delay myocardial revascularization (MCR) surgery requirements[6,7]. Limiting surgery requirements in high risk situations (such as cardiogenic shock secondary to an extensive myocardial infarction that did not permit reperfusion therapy) or emergency situations (such as unstable angina, that could be alleviated with PTCA) has contributed to the improvement in global statistical data for surgical outcomes along with the development of surgical techniques, technological equipment advances (such as oxygenators or mechanical heart stabilizers for surgery without extracorporeal circulation), a better selection of grafts and a greater availability of circulatory support[1,8].

However, whenever a surgical indication is postponed there is always a possibility that a higher risk surgical intervention will be required in the future on an older patient with new or deteriorated comorbidities, coronary disease that is more advanced (often accentuated by catheter manipulation) and with diminished left ventricle function (particularly in the case of ischemic events)[1,2,6].

The deterioration of ischemic disease in surgical patients should increase MCR morbidity and mortality rates. However, over the past twenty years it has been observed that advances in preoperative care by means of surgical risk factor identification and the development of measures to neutralize their harmful influence as well as advances in postoperative care have resulted in reduced surgical morbidity and mortality rates is a logical supposition[1,2,4,9].

The objectives of this study are to define profiles of patients submitted to MCR in the current period and ten years ago

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in order to identify modifications that could have influenced surgical risk and to evaluate whether or not the Cleveland Clinic risk score can predict surgery outcomes.

## Methods

*Patients* - Retrospective cohort study involving 307 patients who underwent MCR surgery or MCR surgery in conjunction with either a left ventricle aneurysmectomy or carotid endarterectomy at the Instituto de Cardiologia do Rio Grande do Sul/Fundação Universitária de Cardiologia (IC/FUC). The patients were divided into two groups, INITIAL: 153 patients operated on between October 1991 and April 1992 and CURRENT: 154 patients that consecutively underwent the same surgical procedure between October 2001 and April 2002. Patients who underwent MCR surgery in conjunction with cardiac valve reconstruction or replacement were excluded from the study. The surgical indications were based on the criteria of the latest revision of the American College of Cardiology/American Heart Association Clinical Practice Guidelines[10], using the recommendations for Class IIa, level of evidence C.

*Hospital mortality risk factors* - Patient characteristics recognized as possible factors to increase hospital risk[11-17] were classified as follows:

- Demographic Characteristics: factors associated to the patients, but not determined by the disease, such as age, gender, race, obesity (body mass index greater than 30; normal value: 18.5 to 24.9) hematocrit and serum creatinine levels.

- Heart Disease: determined by factors that identify the extent and impact of the coronary disease or that can have a direct influence on heart performance such as clinical manifestations (grading stable or unstable according to the Canadian Society of Cardiology and New York Heart Association functional classes I to IV), left ventricular function (severe ventricular dysfunction considered as left ventricular ejection fraction less than 30%) systemic hypertension (diastolic blood pressure $\geq$ 90 mmHg in successive readings or specific medication required for this condition), dyslipidemia (total cholesterol greater than 200 mg/dl and triglycerides greater than 150 mg/dl), presence of heart failure ( symptoms, clinical signs and evidence in at least one test such as a chest X-ray, echocardiogram or cardiac catheterization) distribution of severe coronary lesions (occlusion or blockage greater than 70% of the vessel lumen), and previous events such as acute myocardial infarction (AMI) or PTCA with or without intracoronary stent implantation.

- Comorbidities: prior diseases not directly related to the heart disease such as smoking, diabetes mellitus (DM, evidenced by treatment with oral hypoglycemic medication or insulin), peripheral vascular disease (PVD, characterized by symptoms and an obstructive lesion of a systemic artery > 70 %), cerebrovascular disease (CVD, evidenced by a clinical picture indicative of vascular obstruction or failure, stroke, or disease of the carotid and of intracranial vessels defined in a specific investigation), renal insufficiency (RI, serum creatinine $\geq$ 1.6 mg/dl), and chronic obstructive pulmonary disease (COPD with diagnosis confirmed by the clinical examination and chest X-ray).

- Surgical variables: surgical indication criteria (elective or nonelective or emergencial), prior MCR (repeat operation), duration of the extracorporeal circulation, duration of the aortic clamping, number of grafts implanted in the coronary arteries and use of the internal thoracic artery. Use of the intra-aortic balloon pump and nitroglycerin in the pre-operative stage were also considered.

*Risk score attribution* - Clinical characteristics that are recognized as factors influencing the surgical morbidity and mortality rates as defined by the Cleveland Clinic risk score[17] were identified in the patients from both groups. The pertinent score established for each characteristic is shown in table I and figure 1. The scope of the study did not include patients with a diagnosis of mitral regurgitation or aortic valve stenosis, although the original Cleveland Clinic score included weights for these diagnoses. The mean score established for each group corresponds to a hospital mortality estimative.

Hospital mortality was expressed as the percentage of deaths registered in each of the populations, considering those that occurred between the time of the operation and release from the hospital.

*Outcomes* - The demographic and surgical characteristics as well as those that defined the severity of the heart disease and comorbidities were expressed as absent or present (for dicotomic variables) or by intensity (for continuous variables) in order to distinguish the two populations and identify significant distribution differences, so as to determine possible modifications in the clinical profiles of the two populations submitted to MCR within the ten year period.

Comparisons were made between the average scores of the two groups in relation to the Cleveland Clinic scale distribution.

| Clinical Characteristic | Score |
|---|---|
| Age | |
| 65-74 years | 1 |
| > 75 years | 2 |
| Cerebrovascular disease | 1 |
| Previous vascular surgery | 2 |
| Chronic pulmonary disease | 2 |
| Anemia (hematocrit < 34%) | 2 |
| Renal insufficiency | |
| Serum Creatinine 1.6 – 1.8 mg/dl | 1 |
| Serum Creatinine > 1.9 mg/dl | 4 |
| Left Ventricle Ejection Fraction <35% | 3 |
| Mitral regurgitation with surgical indication* | 3 |
| Aortic valve stenosis with surgical indication* | 1 |
| Repeat operation | 3 |
| Emergency Surgery | 6 |
| Diabetes Mellitus | 1 |

** Characteristics not considered in the study.*

**Table 1 - Cleveland Clinic Risk Score[17]**

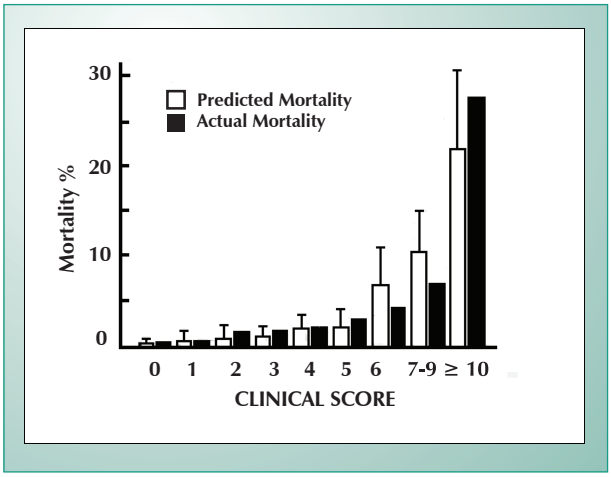


***Fig. 1*** *- Hospital mortality risk score for myocardial revascularization surgery based on the Cleveland Clinic score[17]. Confidence intervals of 99.4%, are calculated in regard to predicted mortality.*

The end result used to define MCR success was surgical mortality or in other words the actual mortality rate of each group in comparison to the rate predicted by the risk score.

*Ethical considerations* - This study was registered with the Research Department of the Instituto de Cardiologia do Rio Grande do Sul/Fundação Universitária de Cardiologia and approved by the Institution's Research Ethics Committee. The study is retrospective and based on research of patient records and therefore no risk was anticipated regarding violation of patients' rights. All medical information was treated confidentially.

*Data collection and statistical analysis* - Patient information was collected in a medical log and registered in contingency tables for statistical analysis using the program SPSS. Numerical data are expressed as averages and standard deviations. Comparative tests included the Student's t-test, the chi-square test and variance analysis. The significance level was considered as a critical $\alpha$ of 5%, referred to as $p< 0.05$, and lower p values are identified. Predicted mortality, based on the Cleveland Clinic risk score, was expressed with a confidence limit of 99.5%, in accordance with the confidence level reported in medical literature[17].

## Results

*Group Profiles* -

a) Demographic Characteristics (Tab. 2)

Demographic comparisons between the groups revealed statistical differences for age and obesity. The CURRENT population was older (58.9 years versus 62.7 years, $p<0.01$) and obesity was more prevalent in the INITIAL group (20.9% versus 9.7%, $p<0.001$). The pre-operative laboratory tests revealed that in comparison to the INITIAL group, the CURRENT group had lower hematocrit values (38.1% versus 40.6%, $p<0.01$) and higher creatinine levels (1.14 mg/dl versus 1.01 mg/dl, $p<0.05$).

b) Heart Disease (Tab. 2)

For heart disease symptoms, the INITIAL group had a higher prevalence of unstable angina than the CURRENT group (88.7% versus 66.2%), but the CURRENT group had more patients in the NYHA functional classes II, III and IV (INITIAL and CURRENT respectively, 3.3% versus 15.6% for class II, 2% versus 13% for class III and 1.3% versus 3.9% for class IV, $p<0.01$). Gender distribution was similar and both groups had a higher percentage of male patients (77.8% in INITIAL and 71.4% in CURRENT).

There was a higher prevalence of diagnoses for heart failure, systemic hypertension and dyslipidemia in the CURRENT group, however there was no significant difference in comparison with the INITIAL group.

For previous events, we only found a significant difference for PTCA stent implantation which was higher in the CURRENT group (4.8% versus zero, $p<0.01$). The CURRENT group also had a higher prevalence of myocardial infarction (56.5% versus 49.0%), but with no significant difference.

A cinecoronariography revealed that the average number of vessels with severe lesions was higher in the CURRENT group than in the INITIAL group (2.76 vessels versus 2.42 vessels, $p<0.01$). The mean ejection fraction value was higher for the CURRENT group than the INITIAL group (68.3% versus 60.4%, $p<0.01$), even though the average was within the normal range for both groups (EF> 55%).

c) Comorbidities (Tab. 2)

For comorbidities the CURRENT group, in comparison to the INITIAL group, had a higher incidence of diabetes mellitus (36.4% versus 21.6%; $p<0.01$), peripheral vascular disease (16.2% versus 5.2%; $p<0.001$), cerebrovascular disease (10.4% versus 4.6%; $p<0.05$) and renal insufficiency (8.4% versus 0%, $p<0.001$).

d) Surgical Variables (Tab. 2)

The INITIAL group had a higher incidence of nonelective surgery than the CURRENT group (30.7% versus 9.1%, $p<0.01$). Only five patients from the CURRENT group (3.2%, $p<0.05$) had an intra-aortic balloon pump implanted before surgery.

Surgical data such as the duration of extracorporeal circulation, duration of myocardial ischemia and the number of grafts used (INITIAL group - average of $3.0 \pm 1.1$ grafts/patient and CURRENT - $3.0 \pm 0.8$) were similar for the two groups. The use of the internal thoracic artery graft was the only variable that was higher in the CURRENT group when compared to the INITIAL group (74% versus 39.9%, $p<0.01$).

*Surgical mortality and risk score (fig. 2)* - Surgical mortality rates were near similar for the two groups, that is, 3.3% for the INITIAL group and 1.9% for the CURRENT group ($p=0.358$, n.s.).

The characteristics of the populations evaluated established an average Cleveland Clinic score of $2.8 \pm 3.1$ for the INITIAL group and $2.2 \pm 2.5$ for the CURRENT group, with no significant difference ($p=0.054$, n.s.). To compare the scores, the values were rounded off to 3, which according to the Cleveland Clinic risk score predicts a mortality rate of 2.0% or using a maximum confidence limit of 99.4% the upper predicted mortality rate is 4.3%, which corresponds to the historic surgical mortality rate at this institution of 3.6%. If patients with a score of 2 were considered, the upper predicted mortality rate was 3.4%[17]. The

| Characteristics | INITIAL Group | CURRENT Group | p < |
|---|---|---|---|
| Sample (n) | 153 | 154 | - |
| **Demographics** | | | |
| Mean age (years) | 58.86 ± 8.87 | 62.71 ± 9.36 | 0.001 |
| Obesity | 32 (20.9%) | 15 (9.7%) | 0.01 |
| Laboratory evaluation | | | |
| Hematocrit (%) | 40.61 ± 3.82 | 38.05 ± 3.98 | 0.01 |
| Creatinine (mg/dl) | 1.01 ± 0.25 | 1.14 ± 0.46 | 0.05 |
| **Heart Disease** | | | |
| NYHA | | | 0.001 |
| Class I | 140 (91.5%) | 104 (67.5%) | |
| Class II | 5 (3.3%) | 24 (15.6%) | |
| Class III | 3 (2%) | 20 (13%) | |
| Class IV | 5 (3.3%) | 6 (3.9%) | |
| Dyslipidemia | 22 (14.4%) | 44 (28.6%) | 0.01 |
| **Previous Events** | | | |
| Stent Implant | 0 (-) | 9 (5.8%) | 0.01 |
| **Comorbidities** | | | |
| Diabetes Mellitus | 33 (21.6%) | 56 (36.4%) | 0.001 |
| PVD | 8 (5.2%) | 25 (16.2%) | 0.001 |
| CVD | 7 (4.6%) | 16 (10.4%) | 0.05 |
| Surgical | | | |
| Surgery Timeframe | 1991-1992 | 2001-2002 | - |
| Nonelective Surgery | 47 (30.7%) | 14 (9.1%) | 0.001 |
| Pre-operative BiAo | 0 | 5 (3.2%) | 0.05 |
| Left ITA graft | 61 (39.9%) | 114 (74.0%) | 0.001 |

*NYHA – New York Heart Association; PVD – Peripheral Vascular Disease; CVD – Cerebrovascular Disease; BiAo – Intra-aortic Balloon; ITA – Internal Thoracic Artery.*

**Table 2 - Characteristics of the patients considered in the study that revealed significant differences between the patient populations submitted to myocardial revascularization surgery with a ten year interval**

applicability of the Cleveland Clinic mortality score to estimate risk levels for surgical patients in our institution was proven, as shown in figure 2.

## Discussion

*Risk factors and surgical characteristics* - In agreement with medical literature[1], this study indicates that patients currently submitted to MCR are older. This appears to be a consequence of the documented lower surgical mortality rates for this subgroup of patients and the advances in caring for high risk patients, who to a large extent are older people[16,18]. Since the risk for elderly patients varies greatly, risk evaluations should be preferentially determined on an individual basis[19]. Studies using data banks confirmed the predominance of male patients[20,21]. Surgical indications for women are generally postponed due to conditions such as equivocal symptom interpretations and therefore a late diagnostic process. Women are also older when revascularization procedures are considered, have a higher number of comorbidities, a higher incidence of mechanical complications with acute coronary syndrome (ventricular septal rupture, severe acute mitral regurgitation)[20] as well as higher hospital mortality rates and higher cardiac morbidity rates[22,23]. Nevertheless, the benefits of interventions for ischemic diseases appear to be the same for both men and women[20].

The deteriorated clinical condition of patients currently submitted to surgery, depicted by the higher prevalence of heart failure comorbidities (such as diabetes mellitus, systemic blood pressure and peripheral vascular disease), the higher functional class (such as NYHA class III) and multi-vessel disease is confirmed in various studies based on large data banks[24,25] and can be explained by the referral of lower risk patients for PTCA procedures that usually include stent implantation[11,12,25]. In our study, no patients in the INITIAL

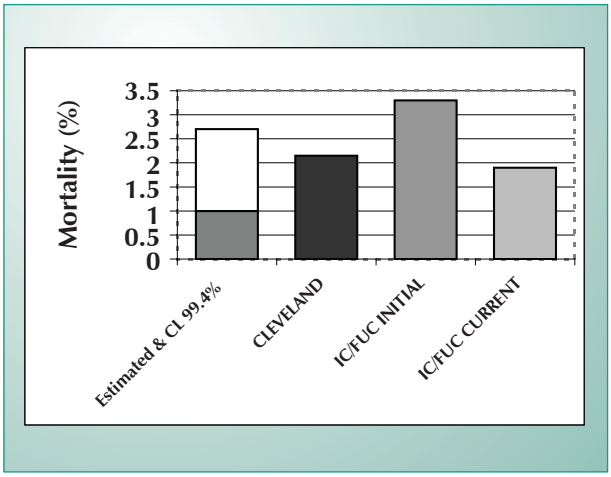


***Fig. 2*** *- Mortality estimate with a maximum confidence limit (CL) of 99.4%, for the Cleveland Clinic score 3, predicted mortality rate for the patients of this institution[17] and actual mortality for the INITIAL and CURRENT groups operated on at the Cardiology Institute (IC/ FUC).*

group had had a stent implant before the surgery, since the technique had not been developed at the time; however, we did not find any significant difference between the groups in relation to balloon angioplasty procedures before surgery (Tab. 2). We expected that the number of patients in the CURRENT group who had undergone PTCA procedures before surgery would be greater than the INITIAL group, however this was not the case. It is known that the risk of a new procedure after a primary PTCA has been reduced and that the risk of primary angioplasty patients requiring a new revascularization procedure is low. In the 1990's the two year risk was 33.6% which was reduced to 12.4% in the 2000's and can be applied to this study[7]. As such, only the angioplasty patients with a higher risk to develop atherosclerosis returned for MCR procedures and were included in the surgical case study.

Despite the deteriorated clinical condition of the patients operated on in 2001/02, we did not find a greater number of patients with an EF lower than 30%. Cardiac catheterization revealed a higher mean EF for the patients in the CURRENT group than for those operated on in 1991/92, even though this variation was not statistically significant (respectively, 60.45±15.9% and 68.3±15.9%, n.s.). These results differ from those observed in a European Clinic study on cardiac surgery tendencies that indicated a progressive reduction in the EF for patients operated on in three consecutive triennials, that began in 1993, of roughly 4% per triennial (57.4%, 55.8% and 53.5%, respectively) even though there was no statistical significance[26]. The authors did not consider this reduction in the EF to have a great impact on hospital mortality (and morbidity) and only emphasized the role of age and the presence of hospital comorbidities. Recalling that the CASS study showed significant benefits of MCR for patients with a low ejection fraction and multiple coronary artery disease[27], the expectation arises that patients who begin to present left ventricular dysfunction should automatically be indicated for surgery.

Although the mortality rate for the CURRENT group was lower than the INITIAL group, there was no statistical difference between the values. The lower hospital risk for MCR patients has been observed in various medical literature studies that have indicated mortality reductions in the range of 23 to 63%[2,4,24,25]. Factors that could have contributed to the increased mortality rate in the INITIAL group include the prevalence of unstable angina, a lower mean EF obtained by cardiac catheterization (even though it was close to normal) and more importantly the greater prevalence of nonelective surgery which is a known risk factor. The direct effect of percutaneous coronary interventions was not investigated but it is possible that the increase in the number of these procedures has had a positive effect on the current surgical results, if it is responsible for reducing the number of nonelective surgeries performed more recently. This is due to the fact that possible emergency or nonelective MCR candidates can have their coronary lesions effectively alleviated and not require surgery during an acute ischemic process (whether unstable angina or acute myocardial infarction evolution). Factors that could have contributed to the reduction in nonelective surgery indications for the CURRENT group include the increasing use of the intra-aortic balloon pump during the preoperative stage (although not a routine procedure at our institution), the widespread use of thrombolytics, the use of statins and the continuation of beta-blocker medication during the pre-operative stage.

It is difficult to establish if the surgical mortality result would be affected by MCR procedures without extracorporeal circulation, although recent studies have proven that this technique produces positive results in regard to morbidities[28,29]. A recent study questions the applicability of the risk scores developed for conventional MCR in relation to MCR procedures without extracorporeal circulation[30].

*Risk score validity* - It should be noted that the clinical profile deterioration in the CURRENT surgical group did not present an increase in the mean risk score (2.2 $\pm$ 2.5), when compared to the INITIAL group (2.8 $\pm$ 3.1; p=0.054; n.s.), considering the numerical criteria established by the Cleveland Clinic for characteristics that can predict hospital mortality (Tab. 1). This current reduction in the mean risk score of the population submitted to MCR is reflected in the hospital mortality rate that, as mentioned earlier, was reduced from 3.3% in the INITIAL group to 1.9% in the CURRENT group (p=0.358, n.s.).

The lower prevalence of nonelective surgery in the CURRENT group (9.1%) when compared to the INITIAL group (30.7%) could be the main justification for the reduction in the mean risk score even though the criterium considered to establish the score was emergency surgery (calculated using the highest risk value - 6). In our study, all nonelective surgical indications were included within the nonelective situations. Another characteristic that is associated with increased surgical risk was the high prevalence of chronic obstructive pulmonary disease (value 2) in the INITIAL group in comparison to the CURRENT group (respectively 11.8% and 6.5%, p=0.08; n.s.). Other characteristics that were considered by the Cleveland Clinic score to influence hospital risk such as the prevalence of mitral regurgitation (value 3) and aortic stenosis (value 1), were not considered, since they are part of patient exclusion criteria for the purposes of this study. Consideration of these factors could have led to the inclusion of a predominant

number of patients in one group or another which would be reflected in a higher surgical mortality rate.

The reduced risk score variation can be justified by the lower numeric values attributed to the 15 known influential factors on surgical mortality as defined by the Cleveland Clinic risk severity score (varying from 1 up to a maximum of 6, with a predominance of value 1 characteristics, which represented one third of the total characteristics and value 2, which represented 4/15$^{th}$ of the total), and the reasonable amplitude accepted for the intensity of some of these characteristics before they are considered as a risk factor, for example creatinine plasma levels, left ventricular dysfunction severity and average hematocrit.

The favorable surgical mortality result of roughly 2% obtained in this study, represents, as mentioned earlier, an expression of the low risk scores for the surgical patients. Figure 1 clearly indicates that surgical risk in relation to both mortality and morbidity rates, increases drastically when the score is higher than 6. Patients in this classification should have compromised clinical and cardiac conditions. Occasionally, some of these factors can be neutralized (as long as nonelective surgery is not necessary). Improvements in renal function, treatment of anemia or heart failure compensation can result in a lower surgical risk. This is, in fact, the most significant reason for using a risk score – to identify patients with risk factors and neutralize them before operating in order to improve surgical outcomes.

Other recognized risk scores such as the Veterans[2], Personnet[31], Northern New England[32], and EuroScore[14] studies consider demographic characteristics, comorbidities and heart disease with different weights. It should be noted that no risk score is able to make an absolute prediction since they are based on the results found in data banks, which compromises precision. As already noted, parameter selection for the different risk stratification systems varies greatly. At one extremity of this scale there are precise systems, that are based on a large number of risk factors that have been compared to results from a large data bank, such as EuroScore[14]. Establishing individual risk from this system could become a complex task due to the large amount of information, the sophisticated statistical calculations, and the requirement of information that is not always registered at all hospitals. On the other hand, simpler systems based on few risk factors are too inaccurate to determine individual patient risk[33], and are unable to provide a risk score for a patient that resists having surgery. Some suggestions have been presented recently in order to improve the risk score systems[34].

Our option to consider the Cleveland Clinic risk score as an acceptable method to predict surgical mortality and to identify some of the conditions that could be neutralized in order to improve the surgical result, is due to the fact that this scale uses accessible factors and a simple mathematical analysis. Our surgical result comparisons and those predicted by the risk score used, demonstrates that this was a suitable choice and is supported by a recent publication regarding the use of different risk scores for surgical patients in an American community hospital[35].

Patients that are currently submitted to MCR are older and have a worse clinical condition (heart and systemic) than those operated on ten years ago. Risk scores and mortality rates were similar for the two groups although a reduction in surgical mortality has been observed recently. The higher prevalence of nonelective surgery in the INITIAL group could have contributed to the higher risk score, even though this group had a lower prevalence of comorbidities.

### Potencial Conflict of Interest

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

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