Prospective Risk Analysis in Patients Submitted to Myocardial Revascularization Surgery

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Objective

To perform a stratified risk analysis in Myocardial Revascularization Surgery (MRS).

Methods

814 patients were prospectively studied by applying two prognostic indexes (PI): Parsonnet and Modified Higgins. The Higgins PI was modified by substituting the variable "cardiac index value" by "low cardiac output syndrome" at the Intensive Care Unit (ICU) admission. The discriminatory capacity for morbimortality of both indexes was analyzed by ROC (receiver operating characteristic) curve. Logistic reaction identified the associated factors, independently from the events.

Results

Mortality and morbidity rates were 5.9% and 35.5%, respectively. The Modified Higgins PI, which analyzes pre- and intra-operative and physiological variables at the ICU admission showed areas under the ROC curve of 77% for mortality and 67% for morbidity. The Parsonnet PI, which only analyzes pre-operative variables, showed areas of 62.2% and 62.4%, respectively. Twelve variables were characterized as independent prognostic factors: age, diabetes mellitus, low body surface, creatinine levels (>1.5 mg/dL), hypoalbuminemia, non-elective surgery, prolonged time of extracorporeal circulation (ECC), necessity of post-ECC intra-aortic balloon, low cardiac output syndrome at the ICU admission, elevated cardiac frequency, decrease in serum bicarbonate concentrations and increase of the alveolar-arterial oxygen gradient within this period.

Conclusion

The Modified Higgins PI showed to be superior to the Parsonnet PI at the surgical risk stratification, showing the importance of the analysis of intraoperative events and physiological variables at the patient's ICU admission, when prognostic definition is achieved.

Keywords

myocardial revascularization surgery, prognostic indexes, morbidity and mortality

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Received on 12/22/03 • Accepted on 03/04/05

The results of myocardial revascularization surgery (MRS) are influenced by the clinical characteristics of patients, as well as by the aspects that are inherent to the surgical procedure and extracorporeal circulation[1,2].

The prognostic definition, through pre-operative clinical parameters, is important for the surgical indication; however, it does not always reflect the prognosis, when the patient is admitted to the Intensive Care Unit (ICU). Such fact has called our attention to the possibility of applying the ICU Admission Score for Predicting Morbidity and Mortality Risk of Coronary Artery Bypass Grafting, developed in 1997 by DR Thomas Higgins at the Cleveland Clinic, which analyzes pre-operative and intra-operative factors and physiological variables when the patient is admitted at the ICU, and which has, in theory, a broader prognostic range[3].

There was, however, a significant problem regarding its use for all patients submitted to MRS, represented by the variable "cardiac index value at the ICU admission", whose measurement required bedside hemodynamic monitoring.

In an attempt to simplify it and amplify its use, we substituted the variable represented by the cardiac index $< 2.1\ 1.min^{-1}/m^{-2}$, at the patient's admission to the ICU[3], by "low cardiac output syndrome", characterized by arterial pressure < 60 mmHg; need for vasoconstrictor (noradrenaline) when trying to keep the mean arterial pressure > 60 mmHg or the need for dopamine at a dose > 6 μg/kg/min.

We then named this score "Modified Higgins prognostic index".

Methods

The present study was developed at Instituto Dante Pazzanese de Cardiologia, between March 5, 2002 and June 3, 2003.

Two prognostic indexes (PI) were prospectively applied: the Parsonnet PI (Tables I and II)[4] , which analyzes only pre-operative variables and the Modified Higgins[3] PI (Tables III and IV).

Data collection was carried out by the main investigator during the pre-operative period through the perfusion record analysis and surgical description, and collection of the patient's physiological parameters in the first 20 minutes of his/her ICU admission.

Death due to all causes as well as all severe complications[3] were considered dependent variables, in addition to those with a lower prognostic significance such as atrial fibrillation (AF), bronchospasm, bypass surgery scar infection and others. The outcomes, mortality and morbidity were analyzed within a period that went from the surgical ward admission up to 30 days of post-operative evolution.

A sample of 814 patients was calculated based on the clinical experience and retrospective data, with an estimated incidence of deaths and complications of 15%, considering an absolute precision of 2.5% and a level of significance of 0.05%.

Sensitivity and specificity assessment of Parsonnet and Modified Higgins PI was carried out by ROC (receiver

Table I - Parsonnet[4] Prognostic Index (PI)

Variables	Value
Female sex	1
Morbid Obesity(> 1.5 times the ideal weight)	3
Diabetes mellitus	3
Arterial Hypertension (AP > 140 mmHg x 90 mmHg)	3
Ejection Fraction (%)	
Good (> 50)	0
Regular (30-49)	2
Poor (< 30)	4
Age (yrs)	
70-74	7
75-79	12
> 80	20
Reoperation	
First	5
Second	10
Intra-aortic balloon at pre-operative period	2
Left ventricle aneurysm	5
Emergency surgery post-transluminal coronary angioplasty or hemodynamic study	10
Catastrophic states (acute structural defect, cardiogenic shock, acute renal failure)	10-50
Other situations (paraplegia, pacemaker dependency, congenital adult cardiopathy, severe asthma)	2-10
Mitral valve surgery	5
Pressure at pulmonary artery > 60 mmHg	8
Aortic valve surgery	5
LV-Ao Gradient > 120 mmHg	7
Myocardial revascularization + valve surgery	2

AP- arterial pressure; mmHg- millimeters of mercury; LV-Ao- left ventricle-aorta

Table II - Mortality predicted by the Parsonnet PI

Score	Predicted mortality (%)
00-04	1
05-09	5
10-14	9
15-19	17
> 20	31

Table III - Modified Higgins Prognostic Index

Variable	Value
Pre-operative factors	
Low body surface area (< 1,72 m^2)	1
Previous cardiac surgery	
Once	1
Twice or more	2
History of operation or angioplasty for peripheral vascular disease	3
Age ≥ 70 yr	3
Pre-operative creatinine ≥ 1.9 mg/dl	4
Pre-operative albumin < 3.5 mg/dl	5
Intra-operative factors	
Time of extra-corporeal circulation > 160 min	3
Use of intra-aortic balloon post extra-corporeal circulation	7
Physiological parameters at ICU admission	
(A-a) O_2 Gradient ≥ 250 mmHg	2
Cardiac frequency ≥ 100 bpm	3
Low cardiac output syndrome	3
Central venous pressure ≥ 17 mmHg	4

m^2 - square meter; mg/dl - milligrams per deciliter; O2 - oxygen; mmHg - millimeters of mercury; bpm - beats per minute

Table IV - Morbidity and mortality predicted by Higgins PI

Score	Morbidity (%)	Mortality (%)
0-5	5	1
6-9	12	2
10-13	25	8
14-20	42	14
> 20	81	40

Table V - Post-operative morbidity

Variable	n / Total	(%)
Low cardiac output syndrome (evolution)	130/807	16.1
Vasoactive drugs (≥ 40 hs)	180/807	2.3
Acute myocardial infarction	53/807	6.6
Prolonged ventilatory support (≥ 72 hs)	49/814	6.1
Acute respiratory failure	74/814	9.2
Neurological complications		
Type 1 (major)	30/807	3.7
Type 2 (minor)	60/807	7.4
Coma (≥ 72 hs)	13/807	1.6
Acute renal failure		
Dialytic	11/807	1.4
Non-dialytic	23/807	2.9
Severe infections	25/807	3.1
Other complications	161/807	20.0

n - number of patients; (%) - percentage of patients

operating characteristic) curve. The discriminatory capacity of both indexes for mortality and morbidity was obtained by calculating the area under the curve.

All risk factors included in the prognostic indexes as well as others considered pertinent by the authors, were analyzed. Initially, the association of each variable with mortality was evaluated, and the statistically significant ones were identified ($p < 0.100$).

The qualitative variables were evaluated by Chi-square test and the quantitative ones by Student's T-test.

Subsequently, the selected variables ($p < 0.100$) were analyzed together through a logistic regression model (odds ratio), in order to determine their prognostic weight[5-9].

Results

The studied patients' age ranged from 30 and 85 years, with a mean age (mean ± SD) of 61.8 ± 10.2 yrs. Of the 814 individuals studied, 557 (68.4%) were male and 34.6% were diabetic patients.

Regarding ejection fraction, 71.5% of them presented 50% or higher, 22.5% had between 30% and 49% and 6% had lower than 30%; the mean was 62%.

Of the procedures that were carried out, 677 (83.2%) were considered elective, 89 (10.9%) were characterized as urgent procedures and 48 (5.9%) were emergency procedures. Only two (0.2%) were characterized as post-accident emergencies at the hemodynamics laboratory.

Most of the surgical procedures consisted of revascularization of 2 to 4 coronary arteries. The data regarding the morbid events that took place in the ICU are shown in Table V.

The occurrence of only one morbid event meant an increase of 50% in hospital stay duration. Morbidity after hospital release was basically restricted to healing problems of the bypass surgery scar, such as localized edema, local inflammatory reaction or minor infectious processes.

ICU stay duration varied broadly, from one hour (early death) to 1,730 hours (chronic patients). In the absence of complications, this time is represented by a median of 44 hours. Hospital stay duration, when measured in days starting from the day of the surgical procedure, was in average 8 days, ranging from 1 day (early death) to a maximum of 173 days (chronic patients).

There were 48 deaths during the first 30 days of evolution, representing a mortality rate of 5.9%.

Low cardiac output syndrome was the main factor responsible for death in 26 (54.2%) patients. In 75% of the times, death occurred prematurely, within the first 48 hours of post-operative evolution. Acute transoperative myocardial infarction was the triggering factor in 30% of the cases.

The deaths that occurred during the late hospital phase were related to a wider range of factors. Its main representative was severe stroke or cerebral vascular

accident. The extra-hospital deaths were represented exclusively by sudden death. The causes of death are shown in Table VI.

Table VII shows the mortality predicted by the Parsonnet[4] PI at the different risk stratification groups and the one obtained for the studied population.

Table VIII shows the mortality predicted by the Higgins[3] PI and the one obtained for this study with the use of the Modified Higgins PI.

At a second phase, the discriminatory capacity of Parsonnet PI and Modified Higgins PI was evaluated when predicting mortality and morbid events, through the ROC (receiver operating characteristic) curve.

Regarding mortality, the area under the ROC curve of the Modified Higgins PI presents a value of 77% (CI 95%, 68.2-86.0), whereas this value for the Parsonnet PI is 62.2% (CI 95%, 51.8-72.6).

Table VI - Cause of Death

Cause of Death	n	(%) of Death	(%)Total
Low cardiac output syndrome	26	54.2	3.2
Stroke - coma	5	10.4	0.6
Bronchopneumonia + septicemia	4	8.3	0.5
Sudden death	3	6.2	0.4
Severe ventricular arrhythmia	3	6.2	0.4
Hemorrhagic shock /bleeding	1	2.1	0.1
Coagulopathy	1	2.1	0.1
Complete atrioventricular block	1	2.1	0.1
Dissecting Aneurysm of the aorta (ruptured)	1	2.1	0.1
Intra-operative aorta rupture	1	2.1	0.1
Early-phase ventricular fibrillation	1	2.1	0.1
Pulmonary thromboembolism	1	2.1	0.1
Total	48	100	5.8

Table VII - Parsonnet Prognostic Index and Mortality (predicted and real)[4].
814 patients were analyzed

Risk stratification score	Mortality Predicted by Parsonnet (%)	Deaths/ patients per Group	(%) of deaths / group
0-4	1	14(281)	5.0
5-9	5	6(232)	2.6
10-14	9	12(164)	7.3
15-19	17	7(82)	8.5
≥ 20	31	9(55)	16.4

Table VIII - Modified Higgins Prognostic Index and mortality (predicted and real)[3].
787 patients were analyzed

Risk stratification	Mortality predicted by Higgins (%)	Deaths (patients per group)	(%) of deaths / group
0-5	1	7 (287)	2.4
6-9	2	5 (303)	1.7
10-13	8	13 (128)	10.2
14-20	14	9 (60)	15.0
> 20	40	6 (9)	66.7

The areas under the ROC curve have, respectively, the values of 67% and 62.4%, with confidence intervals ranging from 62.9 to 71.0 for the Higgins PI and 58.2 to 66.6 for the Parsonnet PI.

The x^2 test was used in search for an association between the qualitative variables and death, and Student's T test was used to compare the means of each quantitative variable value between the patients who died and those who survived.

With the objective of simplifying the analysis, the quantitative variables were categorized in two classes, according to a cutoff chosen based on clinical criteria, literature data and statistical analysis (ROC curve and x^2 test). This cutoff remained unaltered for serum albumin values in the pre-operative period and body surface area, and showed altered values regarding the original PI for age (≥ 70 yrs to 65 yrs), creatinine (1.9 mg/dL to 1.5 mg/dL), time of extra-corporeal circulation (≥ 160 min to > 100 min), cardiac frequency (≥ 100 bpm to > 110 bpm) and alveolar-arterial pulmonary gradient (≥ 250 mmHg to 320 mmHg). Therefore, they were re-categorized.

Among the variables with statistical significance, 12 were selected for analysis through logistic regression (Tables IX and X). The exclusion criterion of a variable was based on the variable's low incidence, its characterization as a post-operative complication or for being redundant in relation to the others. The following were excluded: catastrophic states, types of grafting used during the surgical procedure, need for sympathomimetic amines for a prolonged period in the post-operative period, acute perioperative myocardial infarction, and reoperation in the early phases of the post-operative period, major neurological complications, and persistent coma.

Variables such as serum albumin measurement, time of extra-corporeal circulation, low cardiac output syndrome at ICU admission and sodium bicarbonate measurement at the initial post-operative gasometry present a high prognostic value for mortality. When analyzing morbidity, these same variables are identified as having high statistical significance, adding to others such as the patient's age and cardiac frequency at the ICU admission.

Discussion

A higher mortality and morbidity was observed in the urgency/emergency surgeries with a relative risk of 1.17 (relative risk of 1.17 (CI 95%, 0.55-2.46; p = 0.844) for mortality and 0.99 (IC 95%, 0.62-1.57; p = 0.955) for morbidity.

The surgeries that were carried out exclusively with venous graft (15.1%) presented a higher morbimortality than those carried out with at least one arterial graft (left internal thoracic artery[10], right left internal thoracic artery and/or radial arteries). It has been shown, right in the early phases of the post-operative period, a beneficial effect of using arterial grafts, which is not restricted to the use of

Table IX - Logistic regression- mortality

Variable	OddsRatio	CI 95%	p Value
Age > 65 yrs	1.51	0.73-3.14	0.265
Diabetes mellitus	1.17	0.55-2.46	0.687
Body surface < 1.72 m^2	1.35	0.66-2.77	0.405
Creatinine > 1,5 mg/dl	1.37	0.55-3.42	0.503
Albumin ≤ 3,5 mg/dl	2.38	1.07-5.35	0.036
Surgery priority (urgency/emergency)	1.09	0.45-2.64	0.844
Time of extra-corporeal circulation	2.68	1.32-5.46	0.006
Intra-aortic balloon post- extra-corporeal circulation	2.56	0.71-9.29	0.152
Low cardiac output syndrome	5.78	2.58-12.96	< 0.001
Cardiac frequency > 110 bpm	1.09	0.50-2.36	0.833
Alveolar-arterial gradient of O^2	1.60	0.70-3.63	0.266
Sodium bicarbonate ≤ 19 mmol/l	3.09	1.46-6.56	0.003

CI 95% - confidence interval of 95%; m^2 - square meters; mg/dl - milligrams per deciliter; min - minutes; bpm - beats per minute; mmHg - millimeters of mercury; mmol/l - millimol per liter

Table X - Logistic regression - morbidity

Variable	Odds Ratio	CI 95%	p Value
Age > 65 yrs	1.78	1.27 - 2.47	0.007
Diabetes mellitus	1.15	1.15-1.62	0.439
Body surface < 1.72 m^2	1.17	0.83 - 1.65	0.360
Creatinine > 1,5 mg/dl	1.42	0.85-2.35	0.179
Albumina < 3.5 mg/dl	2.67	1.74 - 4.10	< 0.001
Surgery priority (urgency/emergency)	0.99	0.62 -1.57	0.955
Time of extra-corporeal circulation > 100 min	1.69	1.19 - 2.40	0.003
Intra-aortic balloon post-extra-corporeal circulation	1.96	0.35 - 10.89	0.442
Low cardiac output syndrome (ICU admission)	1.53	5.42 - 24.54	< 0.001
Cardiac frequency > 110 bpm	1.40	0.96-2.03	0.079
Alveolar-arterial gradient of O^2> 320 mmHg	0.93	0.66-1.30	0.652
Sodium bicarbonate ≤ 19 mmol/l	1.54	0.98-2.42	0.059

CI 95% - confidence interval of 95%; m2 - square meters; mg/dl - milligrams per deciliter; min - minutes; bpm - beats per minute; mmHg - millimeters of mercury; mmol/l - millimol per liter

the left internal thoracic artery, but also includes the use of the right left internal thoracic artery and radial arteries.

Comparing the ROC curves for mortality and morbidity, we observed that the Modified Higgins PI has a higher discriminatory capacity when compared to Parsonnet PI, which is accentuated when mortality is analyzed.

Patients older than 65 yrs[1,11-13] and diabetic ones[14-17] have a poorer evolution prognosis. Another important risk factor is the low body surface (<1.72m^2)[3,18,19]. It generates a relative risk of 1.35 (CI 95%, 0.66-2.77; p=0.405) for mortality and 1.17 (CI 95%, 0.83-1.65; p = 0.360), for morbidity.

The importance of the presence of renal dysfunction prior to the surgical procedure as an independent prognostic factor was confirmed (serum creatinine levels > 1.5 mg/dL[3]). Similarly, pre-operative albumin levels are associated to a higher morbimortality, justified by its association to complications such as cardiac failure, acute respiratory failure, acute renal failure, longer periods of mechanical ventilation support, higher incidence of gastrointestinal bleeding and nosocomial infections[3,19-22]. The hypoalbuminemic patients (17.7%) presented a relative risk of 1.37 (CI 95%, 1.07-5.35; p = 0.0360) for mortality and 2.67 (CI 95%, 1.74-4.10; p = 0.179), for morbidity.

The prolonged extra-corporeal circulation predisposes to post-operative complications, and the need for intra-aortic balloon reflects the presence of accentuated hemodynamic instability. It was observed that an extra-corporeal circulation time > 100 min characterized as an independent factor for morbimortality. The need for intra-aortic balloon (IAB), however, occurred in a small number of patients (2.1%). Mortality in this group was 47.8%, against 5% who did not need it (p< 0.001). This mortality rate above the one predicted in the literature (30 to 40%) is justified by the resistance to its early indication, making its use restricted to extremely severe situations.

The low cardiac output syndrome at the ICU admission can be transitory and respond to measures such as volemic replacement and short periods of inotropic support. Its duration beyond 24 hours rules out the possibility of being connected to the effects of stunned myocardium and systemic inflammatory response syndrome, which, in theory, have been reverted and is correlated with a high mortality (39%)[24].

The low cardiac output syndrome, identified at the ICU admission through the previously mentioned clinical criteria, has a high capacity to predict death, even when the syndrome is transitory. This group of patients presented a mortality of 27.3%, compared to 2.7% in the rest of the group. Therefore, low output manifestations,

even when at its initial post-operative phases, generated a high relative risk of 5.78 (CI 95%, 2.58-12.96; $p < 0.001$) for mortality and 11.53 (CI 95%, 5.42-24.54; $p < 0.001$), for morbidity.

Higgins and cols[3] considered as prognostic factors five physisological variables measured at ICU admission: arterial-alveolar pulmonary gradient, cardiac frequency, cardiac index, central venous pressure, and arterial blood sodium bicarbonate measurement. Of these, the cardiac index was substituted by the variable "low cardiac output syndrome" and the central venous pressure did not show statistical significance when analyzed.

The arterial-alveolar pulmonary gradient is increased during the initial phases of the post-operative period due to alterations such as increase of the pulmonary vascular permeability, accumulation of interstitial liquid and increase of intrapulmonary shunt, secondary to the appearance of atelectasias. The gradient was considered increased when its values were > 320 mmHg. It was demonstrated that patients with an increased arterial-alveolar pulmonary gradient presented a relative risk of 1.60 (CI 95%, 0.70-3.63; $p = 0.266$) for mortality and 0.93 (CI 95%, 0.66-1.30; $p = 0.652$), for morbidity.

Cardiac frequency was considered a risk factor when it was > 110 bpm and it confers a relative risk of 1.09 (CI 95%, 0.50-2.36; $p = 0.833$) for mortality and 1.40 (CI 95%, 0.96-2.03; $p = 0.787$), for morbidity[23]. Tachycardia in the early phases of the pre-operative period generates an increment in energy consumption and oxygen consumption by the myocardium.

Serum bicarbonate levels ≤ 19 mmol/L generated a relative risk of 3.09 (CI 95%, 1.46-6.56; $p = 0.003$) for mortality and 1.54 (CI 95%, 0.98-2.42; $p = 0.059$), for morbidity[25]. Its decrease, ultimately, means the presence of tissue hypoxia.

Although it was not our primary objective, some post-operative complications showed to be important development interferences. Among them we cite persistent left ventricular dysfunction, characterized by the need for sympathomimetic amines for a period of time ≥ 40 of post-operative phase; acute transoperative myocardial infarction[26-28], and the type 1 or major neurological complications, plegias, stupor and coma[29-32]; respiratory failure[33] and the need for prolonged mechanical ventilation (time ≥ 72 hs); acute renal failure[34-38]; severe infections of the surgical wound, extensive pneumonias and sepsis[39-42]. The patients who presented one of these complications has an elevation in their mortality rate ($p< 0.001$).

Other complications, such as bypass grafting site infections, urinary tract infections and atrial fibrillation[43] did not show interference in mortality; however, they are noteworthy due to fact that they increased hospital stay duration.

Global morbidity was 35.5%, which is a higher rate than that found in the literature that ranges from 15% to 30%[44,45]. This is related to the fact that we identified post-operative complications as a whole. When we analyzed what was the significance of the occurrence of a single complication, regardless of its severity, we obtained an increase of 50% in hospital stay duration as a result.

Most of the studies in literature describe a hospital mortality of around 1%, which ranges from 1% to 6%. In a recent report, Almeida and cols[46] described a post-surgical mortality of 11.3%.

One can affirm, based on such data, that the predicted mortality for low-risk patients submitted to elective surgery is 1%. Nevertheless, it can depend on factors such as the presence of co-morbidities and transoperative complications.

The mortality rate identified up to 30 days of post-operative evolution in this study was 5.9%. Although high, it is acceptable, justified by the great incidence of complications and for a long period of post-operative follow-up, which lasted thirty days.

The mortality rates obtained for the different groups of risk stratification deserve a few comments.

Regarding the Parsonnet PI, a higher mortality is observed in patients stratified as being low-risk. In the other groups, it is observed a lower mortality than the predicted one. However, when the obtained stratified mortality is compared to the one predicted by the Higgins PI, we observe that the values are close to the predicted ones, with a slight increase in patients classified as being high-risk.

The higher mortality found in low-risk patients that were stratified by the Parsonnet PI, was due to the elevated incidence of cerebral vascular accident and coma in this group.

The higher mortality observed among the patients stratified as being high-risk by the Modified Higgins PI serve as an alert for the need to conduct a more aggressive initial approach in this group.

Finally, we observed that 0.9% of the deaths occurred in the surgical ward and were linked to severe left ventricular dysfunction. The early hospital deaths (39.6%) occurred all at the ICU and their main cause was the low cardiac output syndrome. Late hospital deaths (41.6%) were due to a broader range of factors and their main factors were: cerebral vascular accident, severe infections and uncontrollable arrhythmias. The extra-hospital deaths (0.2%) were exclusively linked to sudden death.

The main cause of deaths, when analyzed as a whole, was low cardiac output syndrome.

We conclude that the Modified Higgins PI was superior to the Parsonnet PI at surgical risk stratification. It is noteworthy, through a comparative analysis of both indexes and the individualized study of prognostic factors, the importance of intra-operative events and the physiological variables at the patient's ICU admission. Hence, the Modified Higgins PI characterizes as a concrete and viable alternative for the stratified risk analysis in patients submitted to MRS, when he or she is admitted to the ICU. It is worth mentioning that the current prognostic indexes used in general intensive care (APACHE, SOFA, MPM), present severe limitations to their use in patients who undergo MRS.

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