# FEASIBILITY ANALYSIS OF CHANGING THE DECISION-MAKING IN HEALTH MANAGEMENT WITH SCARCE RESOURCES

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## ABSTRACT

*Heart failure is the final pathway of most diseases that involve the heart, as a challenge in health management. Heart transplantation is a viable strategy for patients in end-stage disease. The donor shortage requires a process to ensure the appropriate selection of the recipient. In Brazil there is a single list of candidates in chronological order of arrival, the existence of a risk score could dynamically allocate these patients. The purpose of this analysis is to assess the feasibility of changing the allocation process of candidates for heart transplantation according to the IMPACT score. This research is prospective observational retrospective analysis of transplanted cohort at the National Institute of Cardiology. The study included 42 patients and IMPACT score of six or more is associated with the highest mortality after transplantation. Allocation of patients according to their IMPACT score can facilitate decision making about which candidate must be transplanted.*

**Keywords:** *decision making, heart transplantation, scarce resources, health management*

## 1. INTRODUCTION

The heart failure (HF) is the final pathway of most diseases that involve the heart, as one of the greatest current clinical challenges in health management area. The Heart Failure affects 2.4% of the adult population and more than 11% of the population over 80 years (Roger *et al.* 2012). It is an epidemic problem in progress. It is estimated that at least 400.000 new cases of heart failure are diagnosed each year in the United States and more than US$ 34 billion are spent per year to assist people with heart failure. The medical therapy ever more complex has reduced morbidity and mortality associated with heart failure . Despite of great developments, heart failure is the main cause of 40,000 deaths per year and a cause of more than 250,000 deaths per year in the United States. In 2007, HF was responsible for 2.6% of hospitalizations and 6,0 % of deaths recorded by the Brazilian Health System – Ministry of Health (SUS-MS) in Brazil (Revista Brasileira de Transplante,2014), consuming 3% of the total resources intended to be employed in all hospitalizations made by the system.

Once in place, the ventricular dysfunction systolic progresses, often, in an irreversible way (Dickstein *et al*, 2008) . The mortality in patients with HF occurs in a sudden way, because of progressive circulatory failure and other forms, including acute myocardial infarction (AMI), cerebral vascular accident and infections. As told by Allen *et al* (2012), the prognostic evaluation is important not only for the patient to plan his future and his relatives both for his doctor, that must pay attention to the best time to indicate higher cost therapies such as resynchronizers, defibrillators, mechanical devices and heart transplant.

The heart transplantation has emerged as a feasible therapeutic strategy for selected heart failure patients in end-stage disease, offering a better survival and quality of life. Patients with severe heart failure have a high mortality rate in a year, despite the advanced medical treatment. About 4,000 heart transplantations are made each year world-wide. In the United States, about 3,000 patients are waiting a transplant, but only 2,000 patients are submitted to any transplant annually due to the lack of viable donors. The long-term results after transplantation have improved with advancements made both in the assistance to donors and in the immunosuppressant treatment of recipients, besides a better selection of surgical techniques and postoperative cares. The present survival rate after heart transplantation was assessed as about 50% in 12 years by the International Society for Heart and Lung Transplantation (ISHLT) Registry. In practice, the better quality of life, exercise and longer survival in the medium and long term. The shortage of donors, which limits the heart transplants worldwide, as described above, highlights the alarming discrepancy between the number of patients with heart failure who could benefit from transplantation (about 25,000) and those who are fortunate to receive an adequate donor. These facts make it imperative to restrict the transplant option for patients with greatest need and you are likely to get the maximum benefit from transplantation. These facts make it imperative to restrict the transplant option for patients with greatest need and that are likely to get the maximum benefit from transplantation. Thus, recipient list's expansion beyond these seriously ill patients requires greater selectivity.

Candidates for transplantation are those with advanced disease, with severe and disabling symptoms without alternative treatment and high mortality rates in a year. One should pay attention to the removal of reversible or precipitating factors, including, coronary heart disease liable to surgical treatment; mitral insufficiency correction with ventricular remodeling; correction of congenital defects; but also meet the criteria for implantation of implantable defibrillators and ventricular resynchronization therapy.

Some criteria of indications and contraindications have been modified in recent years, particularly with regard to age, oxygen consumption during cardiopulmonary exercise testing, pulmonary vascular resistance, obesity, cancer, diabetes mellitus, renal failure, peripheral vascular disease, and drug addiction. Assessment of pulmonary vascular resistance, pulmonary artery pressure and transpulmonary gradient should be performed on all potential recipients. The oxygen consumption obtained from cardiopulmonary test with the patient reaching the maximum anaerobic threshold is a prognostic marker and has proven useful as stratifying risk and valuable as an auxiliary method in heart transplant indication in outpatients.

The donor shortage requires a very careful patient-selection process to ensure the appropriate selection of the receiver. Early referral to a specialist cardiologist in heart failure is recommended to evaluate for possible application properly. Some basic exams are necessary in the assessment process and include the right heart coronary cineangiography to evaluate the hemodynamic and, in particular, to assess the presence of any components of reversible pulmonary hypertension. Routine blood tests, including screening serology for cytomegalovirus, toxoplasmosis, Epstein, hepatitis B and hepatitis C, are also indicated. Since the inclusion and exclusion criteria are met, the patient will be listed.

According to the DATASUS, in Brazil, were carried out in 2012, 227 heart transplants, with an estimated need in 1,145. In the state of Rio de Janeiro, we conducted in 2012, 11 heart transplants, with a waiting list of at least 10 more patients waiting for an organ. In addition, we have only two hospitals performing heart transplantation, the National Institute of Cardiology and the Pró-Cardiaco Hospital, having already performed in total 34 transpants and one transplantation, respectively in these last three years.

Ambulatory stratification of patients with heart failure with objective criteria such as oxygen consumption peak exercise improved the ability to select appropriate adult patients for heart transplantation. The harmful effects of each condition in the post-transplant results should be weighed in order to determine the impact of comorbidities in each nomination for a heart transplant patient. However, most of the time we do not have a decision-making model that summarizes and simplifies this difficult task. Once listed, the patient enters a queue in chronological order, and changed only by some criteria of highest priority. In these cases top priority, we have patients in which there was a serious deterioration in health status. These are the patients who are at high risk of life in the traditional case wait queue. The urgent cases are, for example, patients who are on artificial mechanical support or inotropic vasopressor drugs- dependent. By looking at each risk criterion alone, just not weighing systematically together interference mortality of each and may allocate a scarce resource in a receiver with little chance of survival, leading to waste of this organ that could be benefiting other more viable patient. We must remember that in any situation related to allocation of this organ, we must always be in accordance with medical ethics, and weigh the costs of all these treatments for society as a whole.

Despite the existing risk scores in cardiac surgery, no score was validated anteriorly to evaluate postoperative heart transplant risk. Recently published by an American group a score: "index for mortality prediction after cardiac transplantation" (IMPACT). This score uses a scale of 50 points from 12 preoperative variables to evaluate the postoperative mortality in the first year after surgery (Kilic, Jeremiah & Weiss, 2013). As shown by Weiss *et al.* (2011), each 1 score point increases by 14% the risk of death at one year, that patients with more than 14 points have a survival rate of 60% in one year against 92.5% of patients with low scores in the patients tested in the original population.

The Brazilian guideline does not comment on the rules of allocation of receptors or donors. The Ministry of Health describes as a single list according to chronological order admissions in this (Ministério da Saúde, 2001). It is expected in this Brazilian rules, as stated earlier, the prioritization of patients with urgency criteria. For these reasons, a score that incorporates the immediate risks of heart transplantation, which is a scarce resource, could line up this shortage of organ with the best choice of the recipient. In the following section will describe the methodologies applied in this analysis, followed by discussion of the results and conclusion.

## 2. METHODOLOGY

The objective of this study is to analyze the feasibility of changing the allocation process of patients to heart transplantation already listed on the waiting list for transplantation according to the IMPACT risk score after heart transplant mortality. This is a prospective observational study of retrospective analysis of the transplanted patient cohort in INC. The included patients were all patients transplanted in the INC between 2008 and 2013. This study was conducted only with patients of the National Institute of Cardiology, which comprises all the transplant patients in the State of Rio de Janeiro. The inclusion criteria were adult patients (age> 17 years) transplanted for the first time. The exclusion criteria were patients who underwent combined transplants. General variables were collected from general files of the patient, including laboratory results obtained and summaries pre-trasnplant filed at the institute. The following variables were collected descriptively according to that was stated in the summary of pre-transplant of each patient: color (white or black); use of beta-blocker; hypertension (yes or no); diabetes mellitus (yes or no); Dyslipidemia (yes or no); smoking (yes or no); alcohol consumption (yes or no); previous cardiac surgery (yes or no). The following variables were collected quantitatively from the medical records of patients: Weight (kg); Creatinine clearance; total bilirubin. Calculation of IMPACT score was made for each patient individually according to sum of the points as described in Table 1.

The descriptive analysis presented in tables observed data, expressed as mean, standard deviation, median, minimum and maximum for numeric data, and frequency and percentage for categorical data and illustrative graphics. In order to check whether there is a significant relationship between the clinical and laboratory variables studied, with mortality after surgery, the following methods were applied:

i) for numerical data comparison was used the Student t test for independent samples or Mann-Whitney test (nonparametric);
ii) for categorical data comparison was used Fisher´s exact test or $\chi^2$; and
iii) logistic regression analysis was used to identify independent predictors of mortality.

The Kaplan-Meier curve was constructed to determine whether there is a significant difference in survival after surgery between Score Impact bands and compared by log-rank statistic.

Nonparametric methods were used because some variables were not normally distributed (Gaussian) due to asymmetry and rejection of the Shapiro-Wilks normality test. The significance adopted was the level of 5%. Statistical analyzes were performed using SAS ® statistical software version 6.11 (SAS Institute, Inc., Cary, North Carolina).

The project was submitted to the Research Ethics Committee of the Instituto Nacional de Cardiologia (INC), in compliance with the recommendations of the Resolution 466/2012 of the National Health Council. It was granted the release by the Research Ethics Committee of the consent form, since this is a retrospective observational study where data is extracted only from medical records of patients.

## 3. ANALYSIS OF RESULTS

Forty two patients were included with a mean body mass index of 23, a mean creatinine clearance of 60, the average total bilirubin of 2.23 and the average IMPACT score was 4.48. The mean survival of these patients evaluated in the study was 635 days. Table 2.1 shows the mean, standard deviation (SD), median, minimum and maximum for numeric variables and table 2. Shows the frequency (n) and percentage (%) of categorical variables in the total sample.

By analyzing the difference of variables between patients who survived and who died, we observed that age, renal function and weight were similar in these groups. However, bilirubin and IMPACT score could be used to differentiate the risk of death. The table 2.2 and 2.3 show the mean, standard deviation (SD), median, minimum and maximum number of variables in the subsamples of patients who died (n = 19) and lived (n = 23), respectively.

It was observed that the subgroup who died had Impact Score ≥ 6 points (42.1%) significantly (p = 0.014) greater than that subgroup who lived (8.7%), as shown in Figure 1. Therefore, it was held Logistic Regression including categorized Impact Score (≥ 6 points) and it was observed that only Impact score ≥ 6 (p = 0.020) was an independent predictor of mortality after surgery (table 4.2). The other variables showed no significant independent contribution, at the level of 5% in the presence of Impact Score ≥ 6. Graphs 2 and 3 illustrate the survival curve, according to the Kaplan-Meier method, in the overall sample and stratified by Impact Score ≥ 6 points, respectively. The curves were compared by the log-rank statistic which showed a significant difference in survival between the two subgroups of Impact Score (p = 0.004).

## 4. FINAL DISCUSSIONS

In this studied population, which represented all patients transplanted in the State of Rio de Janeiro in this period, we observed that the IMPACT score served to differentiate patients with increased risk of post heart transplantation death. Patients presenting IMPACT score of six or more has a mortality of over 70% in the first year post-transplantation. It can be suggested as the cutoff point of the feasibility of this procedure. In addition we know from studies of the population of origin of the IMPACT score, each point more in this score is related to higher mortality. Our cuttoff point of six is lower than that described in the original population. This is due to several factors inherent in the different realities between the State of Rio de Janeiro and the American origin population. The patients analyzed in our population have less severity criteria regarding the source population. In addition, our program still has around five years, which may suggest still be a learning curve, a fact that can not demonstrate in this study.For decision-making, know the real mortality of the population in which we find is very important for a realistic decision-making, avoiding bias in the selection of both the information for the decision as to patients and the ideal allocation of resources. In these circumstances, the doctor responsible for the transplantation waiting list will have to take a series of decisions. These decisions are made in the middle of factors constantly changing due to the dynamic characteristics of these patients with difficult information to be compared and often uncertain as to the result. This explains, in part, because many decisions are failures, contributing to the mortality of these complex patients, which in this case leads to the inefficient use of an organ, which is scarce in addition to the costs to society on the whole procedure which had a negative outcome (Silva, 2005).

In this context of high complexity, we are faced with a decision-making that requires a formal analysis of the frame. This decision is different from a programmed decision, which are widely used in simple situations where there is a lot of repetition and few alternatives to consider, or an instinctive decision, that is when we decided automatically, even not having previous experience, based on the repetition of the same decision. However, as in this case of heart transplantation, as the doctor is leading a number of factors that are difficult to compare, one end up making a decision more instinctive basis, ie decision based on their previous experiences. This occurs by several factors, including the urgency of decision making, the difficulty of comparison, as mentioned above, and because it is a decentralized decision that rests finally on the head of the transplant team. By incorporating in the single list for heart transplantation allocation of patients according to their IMPACT score would be simplifying decision making.In this new circumstance, we would have an order of patients according to their risk of death after transplantation, beyond which patient information the risk of the procedure makes it prohibitive. We know that sometimes, due to several logistical problems ended up having a marginal organ or sub-optimal for transplantation, in this case we could, for example, does not rule out the organ and evaluate the implant as compassionate therapy in patients at high risk of mortality. By doing these types of alignments, we are offering ethically objective parameters of viable organs for the most viable patients and for patients outside of possibilities would still offering any chance of survival. This change in allocation paradigm, would make the decision-making process in a programmed decision, as would become simple, according to the analysis of a single parameter of gravity provided by the score, reducing the interference of the intuitive analysis of several independent factors of mortality in this population. This logic is already done in the case of liver transplantation. In these cases, as described by Boin *et al.* (2008) patients are allocated in the single list of transplantation according to MELD scale (Model End-Stage Liver Disease). Thus, in the existence of an organ, patients are transplanted according to their risk of mortality and this model is regulated by the laws in force in Brazil being in full use.

## 5. CONCLUSION

We believe that the implementation of the IMPACT score as allocation criterion of patients candidates for heart transplantation is feasible, as demonstrated by our results obtained at the National Institute of Cardiology. The single list would be built from the risk at the time of the existence of a donor, meaning that would need to be always updated to be representative of reality at that time. If this were followed systematically, we would really considering the dynamicity of these complex patients candidates for heart transplantation. This dynamic allocation does not happen at this moment, so that the single list currently used in Brazil requires clause of patient on a priority as previously described. Associated with this, the current list of patients in priority presents objective parameters but not comparable objectively, hindering an audit of the results and justification of the allocation of all resources. Thus, by implementing this score in heart transplantation allocation process, we would be allocating a scarce resource in a reproducible manner in postoperative mortality expected these patients, according to medical ethics to ensure the most viable patient the best chance of survival. We observed the magnitude of the complexity of health management, once it is necessary to incorporate in its decision-making the best options for the patient, avoiding damage to this individual, besides the use of limited resources and costs imposed on the entire society. A limitation of this study was that it is only the state of Rio de Janeiro reality.

Thus, to implement this score in heart transplantation allocation process, we would be allocating a scarce resource in a reproducible manner in postoperative mortality expected these patients, in accordance with medical ethics to ensure the most viable patient the best chance of survival. Observe the magnitude of the complexity of health management, it is necessary to incorporate in its decision-making the best options for the patient, avoiding damage to this individual, and the use of limited resources and costs imposed on the entire society. A limitation of this study was that it is only the state reality of Rio de Janeiro, a sample of the various regions would be more emblematic of Brazilian reality. More studies are needed to assess the efficiency and effectiveness of this paradigm shift after implementation, if it occurs.

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Table 1. Table of impact score calculation

| **Impact** | |
|---|---|
| Variable | Punctuation |
| Age>60years | 3 |
| Serum bilirubin | |
| 0-0.99 | 0 |
| 1-1.99 | 1 |
| 2-3.99 | 3 |
| >4 | 4 |
| Creatinin clearance | |
| >50 | 0 |
| 30-49 | 2 |
| <30 | 5 |
| Dialysis | 4 |
| Female | 3 |
| Etiology of heart failure | |
| Idiopathic | 0 |
| Ischemic | 2 |
| Congenital | 5 |
| Others | 1 |
| Recent infection | 3 |
| IAB | 3 |
| Mechanical ventilation | |
| Race | |
| Caucasian<br>White | 0 |
| Black | 3 |
| Circulatory support | 7 |
| VAD | |
| Pulsatile | 3 |
| Continuous | 5 |
| HeartmateII | 0 |
| Total | 50 |

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Table 2.1. General descriptive of the numerical variables

| Variable | n | mean | SD | median | minimum | maximum |
|---|---|---|---|---|---|---|
| Age (years) | 42 | 46.6 | 9.6 | 47 | 20 | 62 |
| IMC (kg/$m^2$) | 42 | 23.0 | 3.6 | 22.5 | 14.4 | 32 |
| Creatinin clearance | 42 | 60.0 | 23.1 | 55.6 | 30.2 | 127.2 |
| Bt | 42 | 2.23 | 1.96 | 1.49 | 0.5 | 10.6 |
| Score Impact (points) | 42 | 4.48 | 2.44 | 4 | 1 | 10 |
| Survival (days) | 42 | 635.5 | 676.0 | 360.5 | 1 | 2293 |

SD: Standard Deviation

Table 2.2. General descriptive of the categorical variables.

| Variable | category | n | % |
|---|---|---|---|
| Sex | male | 33 | 78.6 |
| | female | 9 | 21.4 |
| Etiology | idiopathic | 13 | 31.0 |
| | Ischemic | 8 | 190 |
| | others | 21 | 50.0 |
| Death | yes | 19 | 45.2 |
| | no | 23 | 54.8 |
| CF (i) | CF II | 1 | 2,4 |
| | CF III | 31 | 73.8 |
| | CF IV | 10 | 23.8 |
| Colour | white | 34 | 81.0 |
| | black | 8 | 19.0 |
| Beta (i) | yes | 36 | 87.8 |
| | no | 5 | 12.2 |
| SAH | yes | 9 | 21.4 |
| | no | 33 | 78.6 |
| DM | yes | 5 | 11.9 |
| | no | 37 | 88.1 |
| Dyslipidemia | yes | 10 | 23.8 |
| | no | 32 | 762 |
| Obesity | yes | 2 | 4.8 |
| | no | 40 | 95.2 |
| Smoking | sim | 9 | 23.1 |
| | não | 30 | 76.9 |
| Alcoholism | yes | 8 | 20.0 |
| | no | 32 | 80.0 |
| Previous surgery | yes | 8 | 19.0 |
| | no | 34 | 81.0 |

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Table 2.3. General descriptive of numerical variables in the subsample who died

| Variable | n | mean | DP | median | minimum | maximum |
|---|---|---|---|---|---|---|
| Age (years) | 19 | 47.5 | 8.8 | 48 | 28 | 58 |
| IMC ($kg/m^2$) | 19 | 23.7 | 3.4 | 22.2 | 19 | 32 |
| Creatinin clearance | 19 | 52.7 | 18.3 | 52.8 | 30.2 | 112.2 |
| Bt | 19 | 2.95 | 2.53 | 1.9 | 0.5 | 10.6 |
| Score Impact (points) | 19 | 5.32 | 3.13 | 4 | 1 | 10 |
| Survival (days) | 19 | 157.5 | 242.4 | 48 | 1 | 862 |

SD: standard deviation

Table 2.4. General descriptive of the numerical variables in the subsample who lived

| Variable | n | mean | DP | median | minimum | maximum |
|---|---|---|---|---|---|---|
| Age (years) | 23 | 45.9 | 10.4 | 45 | 20 | 62 |
| IMC ($kg/m^2$) | 23 | 22.4 | 3.6 | 22.8 | 14.4 | 28.4 |
| Creatinin clearance | 23 | 66.0 | 25.2 | 59.9 | 33 | 127.2 |
| Bt | 23 | 1.64 | 1.06 | 1.4 | 0.5 | 4.6 |
| Score Impact (points) | 23 | 3.78 | 1.41 | 4 | 1 | 6 |
| Survival (days) | 23 | 1030.3 | 665.7 | 893 | 159 | 2293 |

SD: standard deviation

Graph 1. Score Impact ≥ 6 points versus mortality after surgery.

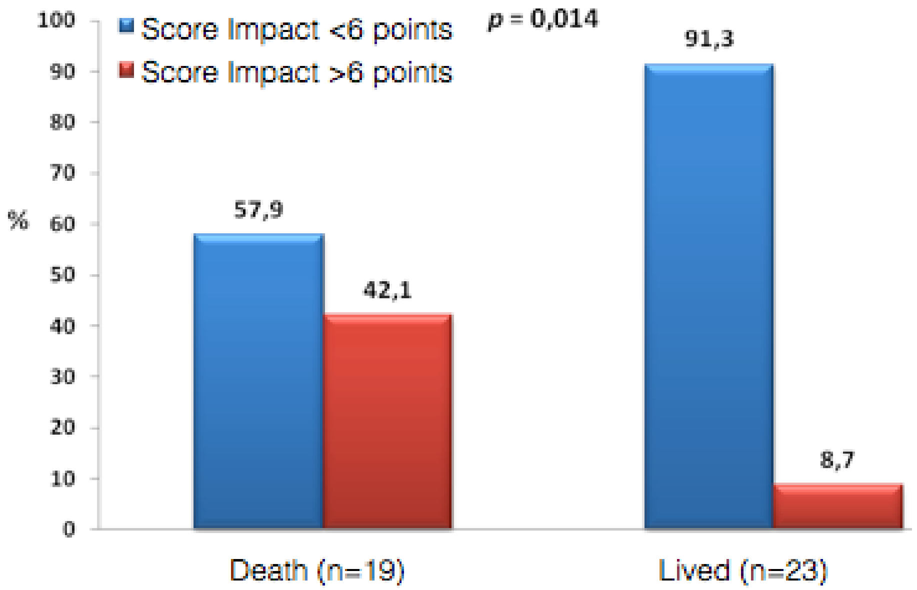


Table 4.2. Logistic regression for mortality after surgery with Impact Score ≥ 6

| | Significant variable | coeefficient | EP | p value | RR | CI de 95% |
|---|---|---|---|---|---|---|
| 1 | Score Impact ≥ 6 points | 2.0329 | 0.8738 | 0.020 | 7.64 | 1.38 - 42.3 |
| | Constant | -0.6466 | 0.3722 | 0.082 | | |

SE: standard error of the coefficient
RR: relative risk; CI of 95%: confidence interval of 95% for the relative risk.

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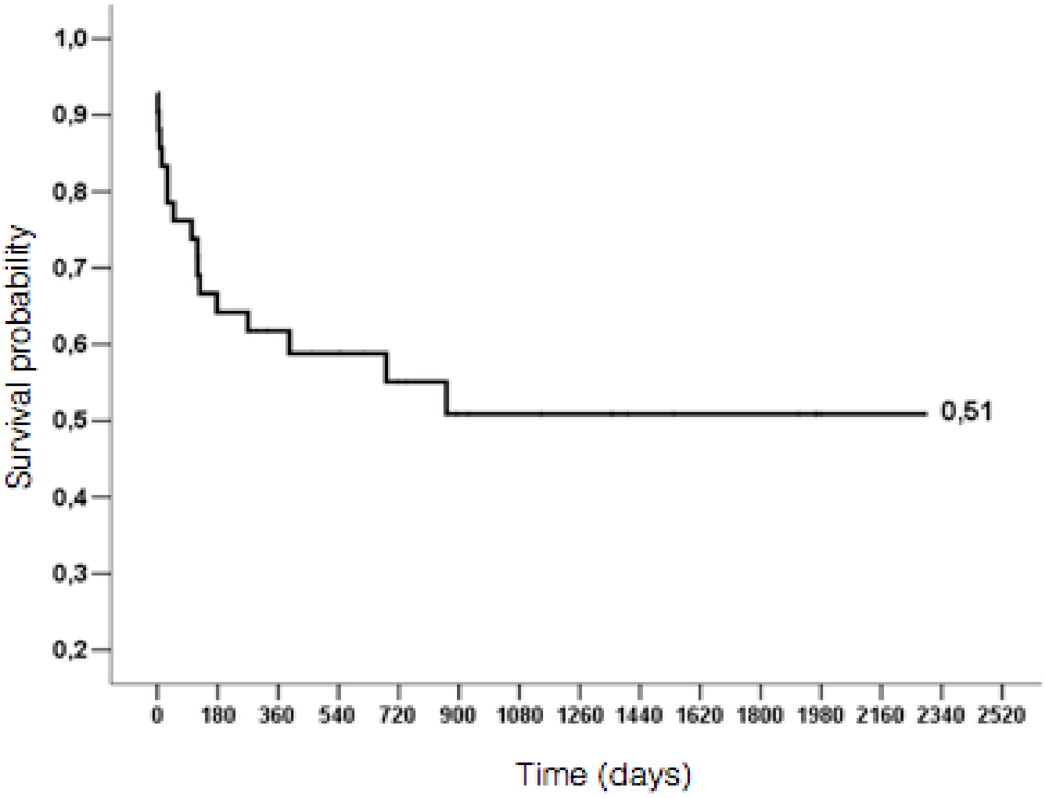
Graph 2. Survival curve in the general sample.




Graph 3. Stratified survival curve by Score Impact Impact .