

# The Use of Preoperative Intra-Aortic Balloon in Myocardial Revascularization Surgery Associated to Severe Ventricular Dysfunction

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## OBJECTIVE

To evaluate the effectiveness of prophylactic intra-aortic balloon (IAB) in elective myocardial revascularization surgery (MRS), to prevent trans or post-operative infarction and reduce intra-hospital mortality in patients with low left ventricular ejection fraction.

## METHOD

Using a cohort study model, 239 patients with left ventricular ejection fraction  $\leq 40\%$ , submitted to elective MRS with extracorporeal circulation (ECC) were evaluated from March 1995 to February 2001.

## RESULTS

Of these, 58 patients received preoperative IAB and the remainder underwent surgery without circulatory assistance (control group). The two groups of patients had similar characteristics regarding factors associated to the pertaining outcomes. There were five demises (8.6%) in the group with IAB and 21 (11.6%) in the control group (non-significant difference). There were 2 (3.4%) infarctions in the IAB group and 28 (15.5%) in the control group ( $p < 0.05$ ), relative risk of 0.22 with an interval of confidence of 95% from 0.05 to 0.85.

## CONCLUSION

The use of pre-operative IAB can significantly reduce the risk of trans or post-operative acute myocardial infarction (AMI) in patients with decreased systolic function, without increasing vascular complications. In this same situation, the IAB does not significantly decrease mortality. Randomized studies are necessary to establish more precise conclusions.

## KEY WORDS:

intra-aortic balloon, ventricular dysfunction, myocardial revascularization

Improvements in medical assistance, especially in the ischemic cardiopathy area, with the development of pharmacological treatment and interventionist cardiology, resulted in an increased number of high-risk patients that need myocardial revascularization surgery (MRS)<sup>1-3</sup>. The stenosis of the left coronary trunk, surgical coronary reintervention, unstable angina and low ejection fraction of the left ventricle have been identified in previous studies, as risk factors for the worst post-operative prognosis<sup>4,5</sup>. However, patients with decreased left ventricle ejection fraction are among those that can benefit the most, in time, from the surgical treatment<sup>6</sup>.

The significant change in the type of patient who is submitted to myocardial revascularization surgery with extracorporeal circulation resulted in a considerable increase of the cost of the procedure, as well as in a relative increase of mortality<sup>7-10</sup>. It became necessary to institute measures to neutralize risk factors capable to attaining acceptable results at reasonable costs.

The intra-aortic balloon (IAB) counterpulsation produces hemodynamic effects that significantly benefit the cardiac outcome. These effects are due to the increase of oxygen flow to the myocardium and consequent improvement of diastolic perfusion, as well as by the reduction in oxygen consumption due to the decreased left ventricular post-load<sup>11</sup>. Patients with systolic dysfunction of ischemic etiology present an important reduction in the myocardial energetic reserve, and can benefit from the use of the intra-aortic balloon through the redistribution of blood flow to the ischemic myocardium<sup>12</sup>. This improvement in coronary flow, even for a reduced treatment period, can result in a higher energetic reserve for the transoperative ischemia period, resulting in improved hemodynamic recovery after extracorporeal circulation. It also reduces cardiac load, offering continuing circulatory support during and after surgery.

This study aims at verifying whether the preoperative use of intra-aortic balloon during elective myocardial revascularization surgery in clinically stable patients with poor left ventricular function can result in the reduction of perioperative mortality and morbidity.

## METHODS

We prospectively evaluated 239 patients by means of a study protocol; all patients presented severe ischemic cardiopathy, left ventricular dysfunction, characterized by left ventricular ejection fraction  $\leq 40\%$  defined by radioisotopic ventriculography at rest, with technetium-labeled red blood cells, indication of elective myocardial revascularization surgery and consecutively underwent surgery at *Hospital São Lucas/Pontifícia Universidade Católica do Rio Grande do Sul*, from March 1995 to February 2001. Patients with recent coronary event (less than 10 days before), associated surgical valvopathy, absolute contraindication for the

use of IAB, preoperative hemodynamic instability or formal indication for circulatory assistance by intra-aortic balloon were excluded from the study. Of the patients, 88 (36.8%) were females and 151 (63.2%) were males, with age ranging between 40 and 81 years, with mean of  $61 \pm 9$  years. Mean ejection fraction, according to the radioisotopic ventriculography, was  $31 \pm 6\%$ , ranging from 18% to 40%.

Although a decreased left ventricular ejection fraction represents an indication for the use of intra-aortic balloon in the pre-operative period of the revascularization surgery at the institution, the device implantation could not be accomplished for all patients included in the study, which resulted in patients being divided in two study groups:

Control group: included 181 patients (75.7%) who did not receive an intra-aortic balloon due to the device unavailability or the presence of a relative contraindication, such as peripheral vascular disease, aortic or iliac-femoral graft, moderate aortic regurgitation, tachyarrhythmia with ventricular frequency over 160 bpm, and contraindication to heparin or other intravenous anticoagulant drug.

IAB group: consisted of 58 patients (24.2%) who received an implant of intra-aortic balloon pump, between 2 and 24 hours before the moment of aortic clamping during cardiac surgery.

The patients' demographic characteristics are shown in Table 1

### *Implant and removal of the intra-aortic balloon*

The intra-aortic balloon was routinely implanted in one of the rooms at the hemodynamic laboratory of the hospital. Balloon-catheters were utilized, following the standard categorization, according to the individual anthropometrical data.

All patients underwent a percutaneous puncture of the femoral artery, with the insertion of a 10F arterial sheath and positioning of a balloon-catheter by radioscopy. After the implant of the intra-aortic balloon, the patients were anticoagulated with heparin and taken to the Intensive Care Unit (ICU), to await the myocardial revascularization surgery start. The counterpulsation equipment utilized was *Datascope*, adequately adjusted by the clinical staff of the surgical team.

The device was kept during the post-operative period for up to 48 hs, and its removal followed the clinical criteria of hemodynamic stability.

*Perioperative Care* – All patients were evaluated at the pre-operative period through laboratory findings, hemodynamic study (coronary arteriography and left ventriculography), electrocardiogram and radioisotopic myocardial ventriculography, which allowed the assessment of the left ventricular function.

The surgical myocardial revascularization was carried out through median sternotomy, hypothermic extracorporeal circulation (32°C), myocardial preservation

Table 1 – Basal demographical characteristics of the groups with and without prophylactic intra-aortic balloon

Variable	IAB (n=58)	No IAB (n=181)	Total	p
Male gender (%)	25 (43.1)	126 (69.6)	151 (63.2)	<0,001 <sup>[1]</sup>
Age (yrs)	61±9	60±10	60±10	0.57 <sup>[2]</sup>
Unstable angina (%)	25 (43.1)	77 (42.5)	102 (42.7)	0.99 <sup>[1]</sup>
Previous MRS (%)	2 (3.4)	8 (4.4)	10 (4.2)	0.99 <sup>[1]</sup>
Previous AMI (%)	31 (53.4)	109 (60.2)	140 (58.6)	0.45 <sup>[1]</sup>
LCT lesion > 60% (%)	14 (24.1)	36 (19.9)	50 (20.9)	0.61 <sup>[1]</sup>
RAD Ejection fraction	29±6	32±6	31±6	0.002 <sup>[2]</sup>
RAD Ejection fraction ≤ 30% (%)	37 (63.8)	72 (39.7)	109 (45.6)	0.006 <sup>[1]</sup>
ECC time ≤ 90 min (%)	26 (44.8)	58 (32.0)	84 (35.1)	0.11 <sup>[1]</sup>
LITA graft (%)	34 (58.6)	101 (55.8)	135 (56.5)	0.82 <sup>[1]</sup>
Incomplete MRS (%)	0 (0.0)	12 (6.6)	12 (6.6)	0.04 <sup>[1]</sup>

The data are presented as means±SD or frequency (%). IAB – intra-aortic balloon; MRS – myocardial revascularization surgery; AMI – acute myocardial infarction; LCT – left coronary trunk; RAD – radioisotopic ventriculography; ECC – extracorporeal circulation; LITA – left internal thoracic artery; [1] Chi-square test or Fisher exact test, when necessary; [2] Student's T test

by infusion of hypothermic crystalloid cardioplegic St Thomas II solution (4°C) and coronary bypass and/or internal thoracic artery implantation.

After surgery, the patients received routine care.

**Variables** – For correlation with patients' evolution, in addition to gender, age and left ventricular ejection fraction, the following pre-operative characteristics were selected: 1) unstable angina; report of more than 2 episodes of typical thoracic pain at rest, during oral pharmacological treatment, for more than 48 hs since the inclusion in the research protocol; 2) previous myocardial revascularization: history of coronary surgery; 3) previous myocardial infarction: history of infarction; pathological Q wave at electrocardiogram or ventriculography with compatible hypokinetic area; 4) left coronary trunk lesion: obstruction > 60%, identified at coronary arteriography. Surgical characteristics were also considered regarding the analysis of post-surgical evolution: 5) time of extracorporeal circulation > 90 min; 6) internal thoracic artery implantation; 7) incomplete myocardial revascularization: when the coronary bypass or internal thoracic artery implantation was not possible in a coronary artery with a lesion considered appropriate for revascularization by coronary arteriography.

**Outcomes** – The events capable of interfering with the post-operative evolution were considered as primary and secondary events, according to the degree of importance and consequence.

Primary outcomes were: 1) intra-hospital demise, which happened at the intra or immediate post-operative period, considered the hospital stay period, regardless of its cause; 2) myocardial infarction at the trans or post-operative period: infarction that occurred presumably during the period encompassing from the anesthetic induction to the hospital release from the ICU, following the diagnostic criteria of the occurrence of a new pathological Q wave or the left bundle branch block at the electrocardiogram, and serum creatine phosphokinase mb (CPKmb) > 50 mg/dl or CPKmb > 80 mg/dl in the absence of a new Q wave or left bundle branch block<sup>13</sup>.

The outcomes considered as secondary ones were: 1) low cardiac output, characterized by clinical or laboratory signs of reduced tissue perfusion, such as decreased urine output < 400 within 24 hs, increase of serum lactate > 3 mg/dl, arterial pH < 7.28 with sodium bicarbonate < 20 mEq/l; 2) use of vasopressor for a period > 24 hs, from the admission at the ICU; 3) mechanical ventilation by orotracheal intubation for period of time > 24 hs, from the admission at the ICU; 4) acute renal failure, having as criterion the elevation of serum creatine on the 2<sup>nd</sup> post-operative day to a value > 50% of the pre-operative control; 5) vascular complications, such as the ones attributable to the intra-aortic balloon, which needed surgical intervention in order to re-establish blood flow or that implicated in a permanent functional decrease of the limb, used for the insertion of the balloon-catheter.

This cohort study did not determine ethical implications or risk increase for the patients who participated in it. The fact that only part of the patients who had an indication for intra-aortic balloon due to reduced left ventricular fraction actually received the treatment, according to the routine of the institution where the study was carried out, did not depend on the decision of the researchers or the doctors who performed the therapeutic interventions, but on the moment's availability. The research project was analyzed by the Review Boards of the institutions where the study was carried out, and they approved the study.

The data collected were transcribed to contingency tables, with the quantitative data being shown as mean±standard deviation (SD), whereas the categorical variables are presented as percentages. Data processing was carried out by the SPSS software (release 11.0).

Group comparison was carried out by Student's T test, for quantitative variables, and Chi-square test for categorical variables.

For low frequency situations, Fisher exact test was used. To evaluate the power of association, the relative risk was used, with its respective confidence interval of 95%.

In order to adjust the effect of important risk factors in the relation between the use of intra-aortic balloon and the occurrence of considered outcomes, Cox proportional-hazards regression model was utilized.

An alpha of 5% was considered as level of significance, with higher significance levels being indicated.

## RESULTS

Regarding the significant differences in the characteristics of the patients distributed between the two groups, we observed a predominance of the male gender in the control group (69.9%), differently from the study group (43.1%,  $p < 0.001$ ). As for the mean ejection fraction, a higher value was observed for control group, when compared to the study group ( $32 \pm 6\%$  vs  $29 \pm 6\%$ ,  $p < 0.01$ , respectively). Regarding the percentage of patients with an ejection fraction  $\leq 30\%$ , it was significantly lower in the control group, when compared to the group that received the intra-aortic balloon (39.7% vs 63.8%;  $p < 0.01$ , respectively). Regarding the incomplete revascularization, it was observed in 6.6% of the patients in the control group, but it did not occur in any of the patients treated with intra-aortic balloon (0.0%,  $p < 0.05$ ).

Concerning the remaining variables, there were no significant differences between the two groups, as shown in Table 1.

There were 26 demises, which correspond to a global mortality of 10.9%. There were 21 demises in the control group (mortality of 11.7%) and 5 in the IAB group (8.6% of mortality). The 30% reduction in mortality related to the treatment with IAB was not significant, as shown in Table 2 and Figure 1.

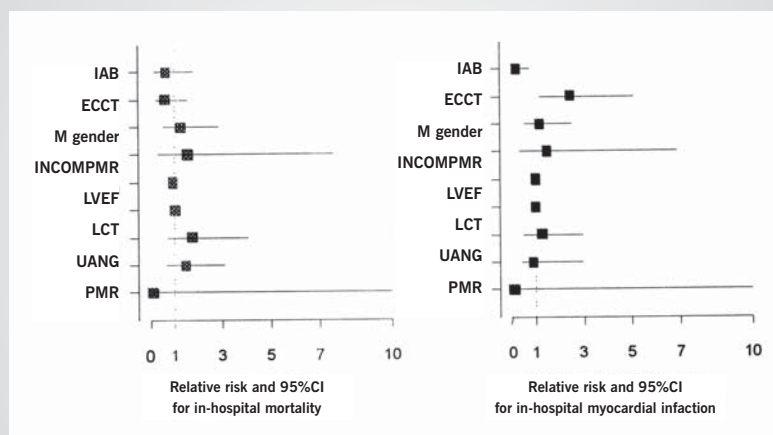
Acute myocardial infarction (AMI) occurred in 30 patients (18.9%). When the groups are considered, 28 patients (15.5%) from the control group suffered an AMI, whereas only 2 patients from the study group (3.4%) had the same complication, which is a statistically significant difference ( $p < 0.05$ ). The relative risk of myocardial infarction in a revascularization surgery was 0.22 for patients who received the intra-aortic balloon in the pre-operative period (confidence interval of 95%, with a value ranging from 0.05 to 0.85).

For a higher degree of confidence concerning the relation between the use of intra-aortic balloon and decrease of perioperative infarction risk, a multivariate analysis with Cox regression was carried out, controlling the following variables: age, gender, left ventricle ejection fraction, time of extra-corporeal circulation  $> 90$  min and incomplete myocardial revascularization, previous myocardial revascularization surgery, unstable angina and left coronary trunk lesion. As shown in Table 2, the protective effect of the intra-aortic balloon remained significant, after the variables were adjusted (Table 2).

**Table 2 – Comparison between the groups with and without intra-aortic balloon, regarding the occurrence of hospital mortality outcome and trans and post-operative acute myocardial infarction**

Outcome	IAB use		Univariate analysis			Multivariate analysis		
	Yes (n=58)	No (n=181)	RR <sub>b</sub>	IC95%	p	RR <sub>a</sub> *	IC95%	p
Hospital mortality	5 (8.6)	21 (11.7)	0.7	0.26 to 2.00	0.70	0.66	0.24 to 1.82	0.43
Trans and post-op AMI	2 (3.4)	28 (15.5)	0.22	0.05 to 0.85	0.029	0.19	0.04 to 0.80	0.02

*IAB – intra-aortic balloon; AMI – acute myocardial infarction; RR<sub>b</sub> – non-adjusted relative risk; RR<sub>a</sub> – relative risk adjusted in a regression model of Cox proportional hazards, including the terms: time of extracorporeal circulation  $\geq 90$  min, gender, incomplete myocardial revascularization, ejection fraction, left coronary trunk lesion  $> 60\%$ , age, previous myocardial revascularization surgery and unstable angina*



**Fig. 1 - Power of association of the intra-aortic balloon and variables of interest in primary outcomes. IAB – intra-aortic balloon; ECCT – extracorporeal circulation time  $\geq 90$  min; M gender – male gender; INCOMPMR – incomplete myocardial revascularization surgery; LVEF – left ventricular ejection fraction; LCT – left coronary trunk lesion; UANG – unstable angina; PMR – previous myocardial revascularization**

The variable extracorporeal circulation > 90 min showed to be associated to trans and post-operative myocardial infarction outcome in our sample. The remaining variables did not correlate to such outcome.

No significant differences were observed regarding the occurrence of secondary outcomes such as prolonged mechanical ventilation, acute renal failure, low cardiac output, prolonged vasopressor drug use, and in the occurrence of vascular complications in the two groups studied, as shown in Table 3.

## DISCUSSION

Previous studies that identified poor operative prognosis factors in MRS with extracorporeal circulation (ECC) indicated that the following factors are relevant: left coronary trunk lesion, unstable angina, previous MRS and systolic dysfunction of the left ventricle. The profile change in patients who were candidate to MRS was mainly characterized by a larger proportion of individuals with ventricular dysfunction<sup>2</sup>. In our study, we aimed at evaluating whether the beneficial hemodynamic effects of the IAB persisted as a protective factor for the MRS, when taking into account only the reduced ventricular function as a risk factor.

We used the left ventricle ejection fraction, measured by radioisotopic ventriculography at rest, as a criterion to define ventricular dysfunction, and therefore, high risk for the concerning outcomes. Previous multicentric studies<sup>14</sup> identified left ventricular failure as the main risk factor for sudden death and new coronary events in ischemic patients. In most of the reviewed studies, the criterion of ejection fraction was present at the definition of high operative risk. Associated to that, one can affirm that most of the remaining criteria mentioned somehow influence the myocardial contractile performance.

We considered 40% of the ejection fraction as the cut-off level to characterize high risk, as it was the most often used value in the reviewed studies.

As described by Antman<sup>12</sup>, trans and post-operative myocardial infarctions occur in 5 to 15% of MRS. Autopsy analyses indicate that most of the grafts performed were patent, so the physiopathological mechanism of the perioperative infarction seems to be related to the disproportion between oxygen offer and demand by the myocardium, and not to the occlusion

of the bypass grafts. This supports the idea that the prophylactic IAB can be beneficial in MRS.

According to our literature review, starting in 1992 with Georgeson and cols.<sup>15</sup> and mainly from the studies by Christenson and cols.<sup>16</sup>, the pre-operative prophylactic use of the IAB has shown to be important to prevent trans and post-operative complications in selected groups of patients.

In 1976, Cooper and cols.<sup>17</sup>, in a case series, reported that the prophylactic use of the balloon in revascularization surgery in the presence of left coronary trunk lesion was a safe strategy, with no increment of vascular complications. The surgical results were adequate and comparable to those obtained in lower risk surgeries.

Georgeson and cols.<sup>15</sup>, in a small review study, concluded that the pre-operative use of the balloon in non-cardiac surgery was beneficial, when the patients were classified as having higher risk (Goldman class IV).

In a 27-year review of the use of IAB, carried out at the Massachusetts General Hospital, mortality among patients who received pre-operative IAB at the myocardial revascularization surgery was 13.6%, whereas the mortality of patients who received trans or post-operative IAB was approximately 35%<sup>18</sup>.

The use of pre-operative IAB started to consolidate as a myocardial protection method for patients with increased risk in MRS as of the studies by Jan T. Christenson, initially published in 1997, producing a sequence of scientific work in this area until the recent publication in 2002<sup>19</sup>.

The series of articles produced by the team at Hospital Columbia de la Tour, led by Christenson, was the inspiration for our study. These studies concluded that the pre-operative use of the intra-aortic balloon in high-risk patients decreased the chance of infarction and death, reduced the hospital stay duration and was cost-effective.

They also defined, as the main risk factors for post-operative complications, left coronary trunk lesion, urgent surgery, unstable angina, reoperation and decreased ejection fraction, and that in the presence of two of these factors, the use of prophylactic IAB would be indicated<sup>20</sup>.

This study series showed the ideal time for pre-operative device implanting was between 24 and 2 hours

Table 3 – Comparison between the groups with and without IAB, regarding the occurrence of secondary outcomes

	With IAB (%)	Without IAB (%)	Total (%)	p
MV	6 (10,3)	15 (8,3)	21 (8.8)	0.83
LCO	0	9 (5)	9 (3.8)	0.11
VDU	15 (25,9)	32 (17,7)	47 (19.7)	0.24
ARF	4 (6,9)	15 (8,3)	19 (7.9)	1
Vasc. Comp.	2 (3,4)	4 (2,20)	6 (2.51)	0.061

IAB- intra-aortic balloon; MV – prolonged mechanical ventilation; LCO – low cardiac output; VDU – vasoactive drug use; ARF – acute renal failure; Vasc. Comp. – vascular complications

before the surgery<sup>21</sup>. It also demonstrated that the use of pre-operative IAB reduced the need for post-operative hemodynamic support and that the post-operative use of the balloon is an indication of poor prognosis<sup>22</sup>.

The results obtained by Christenson and cols were so remarkable that, in a letter to the Editor of the *Annals of Thoracic Surgery Journal* (2001) there was a discussion regarding the ethical aspect of conducting further randomized studies with a control group, considering the known great benefits of the pre-operative use of IAB for a selected group of patients<sup>23</sup>. However, it is noteworthy that a large number of patients from the samples studied by Christenson consisted of unstable patients, differently from our study, where all patients were clinically stable.

The results of our study point to a 30% decrease in mortality among patients treated with IAB, compared to patients from the control group. There was, however, no statistically significant difference. They also showed an important decrease in the risk of trans and post-operative myocardial infarction, of around 78%, which is statistically significant, with a relative risk for infarction of 0.22. After adjusting the results for the variables of interest, with the use of Cox multivariate regression, the reduction of the relative risk remained important and statistically significant.

Although there was heterogeneity between the two groups of patients, the differences in the sample indicated a tendency for more severe patients in the group with IAB, thus excluding the confusion bias in the results obtained.

For the correct analysis of our results, we identified variables, which in previous studies were related to the concerning outcomes, mainly trans and post-operative infarction, such as increased time of extracorporeal circulation<sup>24,25</sup>, left coronary trunk lesion<sup>26-28</sup>, and incomplete MRS<sup>29</sup>, in addition to variables already established as higher risk factors: age, unstable angina, and previous myocardial revascularization. These variables were controlled at the multivariate analysis, as well as the severity of the left ventricular dysfunction, expressed by the left ventricular ejection fraction.

There was no difference in the distribution of the increased extracorporeal circulation time variable (time of ECC  $\geq$  90 min) between the two groups of patients. However, this variable was significantly associated to a higher frequency of trans and post-operative acute myocardial infarction, in accordance to previous studies.

The incomplete myocardial revascularization variable was unevenly distributed between the groups of patients. All incomplete MRS cases occurred in the group without IAB. Likewise, there was no association between this variable with the concerning outcome.

The frequency analysis of the variables: prolonged mechanical ventilation, acute renal failure, low cardiac output and prolonged use of vasoactive drugs in the group

treated with IAB and the control group, were established as secondary outcomes, for being somewhat related to the left ventricular function.

The ischemia of lower limbs, related to the insertion site, and thrombocytopenia are the most frequent complications observed with the use of IAB<sup>30</sup>. These complications are mainly related to the diameter of the balloon-catheter, the time of counterpulsation use, prolonged hypotension periods and the presence of previous vasculopathy. An incidence of up to 20% of vascular complications with the use of IAB is mentioned in the literature<sup>31</sup>. These complications can be minimized if catheters  $<$  9.5 F are used, while thrombocytopenia is directly related to the time of counterpulsation use.

Regarding patients with vasculopathy and indication of IAB, the relation between the risks and the benefits of method must be assessed, as this situation is strongly associated to posterior vascular complications.

In our sample, vascular complications reached 2.51%, with no significant difference between the two groups of patients. The criterion used for vascular complication was the need for surgical measures to re-establish perfusion in the affected limb. Amputation was not necessary in any of the two groups of patients. Compared with the literature, in the same cohort study by Merharval with 911 patients, a frequency of 5.9% of vascular complications was observed using criteria that were very similar to ours.

Considering such results, some questions called our attention: if we used only the criterion of ejection fraction in elective surgery to define high risk, would the protective effects of the IAB remain? Would the results obtained in Europe be reproducible in our country?

As we observed on our study, there was a significant reduction in trans and post-operative infarction risk, but there was no significant reduction in mortality. Perhaps, if the risk criteria were stricter, the protective effects of the balloon would be more relevant, regarding intra-hospital death. However, the important reduction in the number of infarctions should probably reflect positively on the intra-hospital mortality<sup>13</sup>.

In face of these results, one must question whether it is possible to be flexible regarding the indication IAB use, using only the ejection fraction criterion, when one intends to prevent outcomes similar to those researched by Christenson. In order to do so, further randomized studies would be necessary, which, as mentioned previously, would need ethical analysis.

The results of this cohort study allow us to conclude that the use of pre-operative IAB in elective MRS in patients with ejection fraction  $\leq$  40% can significantly reduce the risk of trans and post-operative AMI without increasing vascular complications.

In this same situation, the use of the IAB does not significantly decrease intra-hospital mortality, as well as the need for vasoactive drugs, low cardiac output

frequencies, prolonged mechanical ventilation time and occurrence of acute renal failure. One must consider the fact that conclusions drawn from cohort studies

are indicative of a tendency. In order to establish the routine use of intra-aortic balloon in this situation, further randomized studies must be carried out.

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