

OUTCOMES IN MINIMALLY INVASIVE VALVE SURGERY IN ISCHEMIC PATIENTS (30-DAY-FOLLOW-UP)

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Abstract: *Minimally invasive techniques are increasingly used in cardiac valve surgery, with satisfactory results to date. The present study is important because it is an attempt to address these problems at the level of a single center, on a population of patients from 2018, who have benefited from the approach of the valvular pathologies through minimally invasive novel techniques. In this retrospective study, data were collected, in 2018 and 2019, in an observational, nonintervention study, for patients with minimally invasive cardiac valve surgery in 2018. There were 93 cases with minimally invasive valve surgery during 2018. There was only one death regarding the 30-day-follow up. In the group of patients who had minimally invasive valve surgery, in this particular center, in 2018, we conclude that the hybrid approach is safe.*

INTRODUCTION

Minimally invasive techniques are increasingly used in cardiac valve surgery, with satisfactory results to date. Although minimally invasive video-assisted techniques are proving to be more and more secure, however, few centers, at European and global level, are introducing such techniques, because of the costs, the learning curve, and the lack of long-term studies.

In the current guidelines, minimally invasive surgery does not have clear recommendations (1), especially in ischemic patients, because of the lack of multicentric prospective studies, and the fear of haemorrhagic risk, or stent thrombosis, when antiplatelet therapies are insufficient, though there are more and more series of cases presented in the literature starting from 2005, showing the safety of hybrid strategies both from the haemorrhagic risk, and stent thrombosis risk. Also, there are registries which started enrolling patients from several European centers, from 2017-2018, which will follow these kinds of patients for at least 5 years, and will thus have the objectivity of long term, prospective, multicentric studies.

The present study is important because it is an attempt to address these problems at the level of a single center, on a population of patients from 2018, who have benefited from the approach of the valvular pathologies through minimally invasive novel techniques

MATERIALS AND METHODS

In the European Hospital Poliano Sibiu, after obtaining the approval of the Ethical Council, for gathering the data of patients, in compliance with the rules in force, for an observational study, in which data are collected from the electronic files, retrospective data were collected, in 2018 and 2019, in an observational study, for patients with minimally invasive cardiac valve surgery in 2018 and the parameters under discussion, but these were completed in computer systems prospectively.

The types of procedures are: biological or mechanical mitral valve replacement; mitral valve repair; biological or mechanical aortic valve replacement.

The characteristics of the study population were

collected as follows: sex (M/F), age (years), presence/absence of arterial hypertension (HTA), presence/absence of diabetes mellitus, presence/absence of a history of cerebrovascular disease; presence/absence of peripheral artery disease, renal insufficiency, or myocardial infarction (MI) in the history.

An Excel format database was built, which included the following: type of procedure, clamping duration and cardiopulmonary bypass duration, need for prolonged ventilation (> 24h), type of associated procedures (including implantation of pacemakers), ischemic status was filled out as well as PCI/non-PCI; the number of days of hospitalization was filled out, the preoperative and postoperative ejection fraction at 5 and 30 days; cases with thoracic hemorrhagic complications, or digestive bleeding, or postoperative stroke have been identified; cases with postoperative myocardial ischaemia were noted; pulmonary complications defined as pneumonia, pneumothorax, pleural collection without drainage were noted; cases of death, and the need for coronary reintervention were recorded.

The evolution of these patients is recorded during the perioperative period, and at the re-evaluation after 30 days. The following subgroups were formed: minimally invasive aortic surgery (MIAS), minimally invasive mitral surgery (MIMS), and percutaneous coronary intervention (PCI) - stent procedure before valvular surgery, and NON-PCI.

Statistical analysis was performed using SPSS v.20 and Microsoft Excel programs from the Microsoft Office 2016 package. Fisher's Exact Test 2-sided was used to compare dichotomous variables, with the definition of statistically significant correlation if $p < 0.05$, and for the study and correlation of mean times (in minutes for the duration of aortic clamping and cardiopulmonary bypass; and in days for the average length of hospitalization), the ANOVA test was used, with $p < 0.05$ defined as statistically significant.

RESULTS

There were 93 cases with minimally invasive valve surgery during 2018, with an average age of 62, with 16 cases of PCI with preoperative stent implantation. MIAS with implantation of a biological valve - 31 cases, with implantation

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of a mechanical valve - 15 cases; MIMS with mechanical valve implant - 1 case, with biological valve implant - 4 cases, with mechanical valve implant - 14 cases, and with repair - 26 cases respectively. Of the 93 cases, 5 were with MI in personal history, and 15 were diabetic. 63 were with hypertension. 5 patients had peripheral artery diseases.

For cases with indication of permanent pacemaker implantation, it was decided to implant the VVI-type pacemaker in 6 cases, and of the DDD type in 7 cases, there were 10 cases with complete atrioventricular (AV) block, one case with slow atrial fibrillation (AF) rate, and another 2 cases with irreversible bradycardia with indication of pacemaker implantation.

There was only one death in the second postoperative day, by electromechanical dissociation, in a patient with aggravated renal insufficiency with a need for hemofiltration, and postoperative ejection fraction of 35% (with positive inotropic support). It should be mentioned that this case was not in the group of those with PCI.

In the total of 93 patients, there were 16 cases with stenting, of whom 3 suffered hemorrhagic complications, the other 4 being in the group of non-ischemic patients. Thus, two of the PCI patients had pericardial hemorrhagic effusion, with the need for reintervention, and the third haemothorax, with reopening at the chest level. Of the nonischemic patients, one was with pericardial hemorrhagic effusion, one with the evacuation of a pleural hemorrhagic effusion, one with intrathoracic collection with subsequent hemostasis, and one was with a mediastinal hematoma, without reintervention, with no statistically significant differences between the two groups ($p=0.095$).

There were 3 cases of postoperative stroke, all of them being ischemic, without a statistically significant correlation between the groups of PCI/non-PCI patients ($p=0.436$). There was no case of hemorrhagic stroke.

There were no documented cases of digestive bleeding.

There was no statistically significant correlation between stent ischemic disease status and chronic renal failure status.

There was no statistical correlation between the need for prolonged ventilation (> 24h) and the status of ischemic patient with prior stenting (2 cases) ($p=0.316$).

The average durations of cross clamping and extracorporeal circulation were lower in patients with a history of PCI than in those without, but the differences were not statistically significant ($p=0.145$ and $p=0.267$ respectively).

There were no statistically significant differences in the evolution of the left ventricular ejection fraction in this case series, nor are there differences between ischemic and non-ischemic ones.

If the case is analyzed according to the type of valve operated (mitral or aortic), the minimally invasive mitral intervention is statistically correlated with the risk of pulmonary complications ($p=0.038$).

DISCUSSIONS

Considering the primary end point, 30-day mortality (all cause), our result is comparable with other results from literature. In the case of more severe cases, with an increased operative risk, Leacche et al (2010) published a series of 39 patients with PCI + MIMS via right thoracotomy. Of these, 13% had acute coronary syndromes, 49% were with heart failure, 41% performed the hybrid emergency procedure, and 41% were reinterventions; 77% of all patients performed the single-stage hybrid procedure in the hybrid ward, while the others initially performed PCI and MIMS at 1-4 days. Operative mortality was

low, 1 patient alone, compared with Society of Thoracic Surgeons (STS) prediction of 16%.⁽³⁾ But with respect to the minimally invasive surgical approach at the level of the aortic valve, a number of studies had previously appeared, supporting the safety and efficacy of the minimally invasive approach in valvular surgery, at least in high-risk patients.

Santana O et al. publishes in 2011⁽⁴⁾ a series of 160 obese patients, and establishes that the minimally invasive approach has lower morbidity and mortality (no deaths in that series).

Regarding the hemorrhagic risk, the case series presented by us is statistically similar to the ones presented in the literature (George, 2015, Santana 2016-2017), and statistically there are no significant differences between the hemorrhagic risk in patients with previously PCI compared to those without.^(5,6) Also, in this series of cases, no patient with postoperative myocardial infarction or stent thrombosis was documented at 30 days, the data being in accordance with the literature.

Regarding the risk of postoperative stroke, in the analyzed case series, there are no statistically significant differences between the groups of minimally invasive ischemic/non-ischemic patients, there are 3 cases with ischemic stroke and no hemorrhagic stroke, these data are in accordance with the current literature⁽⁷⁾, also, from the point of view of the risk of renal failure, there is no statistically significant correlation, in accordance to the literature.

There were 2 cases of prolonged ventilation (not statistically significant), according to the data presented in the literature.⁽⁸⁻¹⁰⁾

In the case series analyzed by us, there were no cases of digestive bleeding, a result consistent with those presented since 2005.⁽¹¹⁾

The average durations of cross clamp and extracorporeal circulation were lower in the cases of patients with PCI, compared with those without, but the differences were not statistically significant, which showed that the operative times did not differ significantly, in previously stented patient, similar to the specialized literature.^(12,13)

There are no statistically significant differences in the evolution of the left ventricular ejection fraction in this case series, nor are there differences between ischemic and nonischemic ones, according to the literature data.^(14,15)

There are statistically significant differences regarding the risk of pulmonary infection ($p = 0.038$) in the patients with minimally invasive intervention at the mitral valve level, data consistent with those in the previously published literature.⁽¹⁶⁻¹⁸⁾

There is the need of continuing gathering data, prospectively, in multicentric studies.

CONCLUSIONS

In the group of patients who had minimally invasive valve surgery, in this particular center, in 2018, we conclude that the hybrid approach is relatively safe.

There is no increase in postoperative mortality in those with prior stenting, and minimally invasive surgical approach.

There is no statistically significant different hemorrhagic risk in patients with prior stenting, nor of acute coronary syndromes.

Digestive bleeding is not observed in this case series; there is no statistically significantly increase in the frequency of stroke, renal insufficiency or mechanical ventilation time.

There is no statistically significant difference between cross clamp times and extracorporeal circulation, in stented

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patients, compared with those without stenting, after minimally invasive valvular surgery.

There are no significant differences in left ventricular ejection fraction in the two categories of patients. Pulmonary complications in cases with MIMS are statistically significantly more frequently.

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