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MINIMALLY INVASIVE AORTIC VALVE REPLACEMENT VS AORTIC VALVE REPLACEMENT THROUGH MEDIAL STERNOTOMY: PROSPECTIVE RANDOMIZED STUDY

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Standard surgical approach in an aortic valve treatment is medial sternotomy. In recent years minimally invasive procedures have been used more toward decrease of trauma and faster recovery of patients.

The aim of our study is a comparison of the preoperative, perioperative results and early mortality of patients in whom aortic valve replaced through mini- (Mini-AVR) or medial-sternotomy.

The study included 70 patients. Preoperative, intraoperative and early postoperative patients, and characteristics were analysed. Preoperative variables were homogenous. The euro-score value was significantly higher in medial sternotomy group ($p = 0.037$). The cross- clamp and cardiopulmonary bypass time were longer in mini-AVR group ($p < 0.001$). There was no difference in the incidence of postoperative myocardial infarction, stroke and acute renal failure. One patient in each group underwent surgical revision because of bleeding. There was no difference in hospital mortality between two groups. Postoperative blood loss was insignificantly lower in mini-AVR group ($p = 0.69$). Three patients had suffered from wound infection after medial sternotomy: 2 superficial infections and 1 deep infection ($p = 0.4$). The length of intensive care unit was similar in both groups. Patient in mini-AVR group had shorter hospital stay when compared with patient operated thought medial sternotomy (8 days (IQR 7-11) vs 7 days (IQR 7-9)).

The mini-AVR reduces tissue trauma and hospital stay and also promotes a patient's recovery. In high- risk patients with comorbidities like obesity, diabetes and elder patients reduces the prevalence of infection.

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Key words: *aortic valve, ministernotomy, aortic valve replacement, minimally invasive approach*

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Introduction

Standard surgical approach in aortic valve treatment is median sternotomy, which means complete longitudinal transection of sternal bone. Nowadays, minimally invasive procedures are in the focus of patients as well as physicians because of reduced trauma and faster recovery of patients (1). In aortic valve surgery, a lot of different approaches can be used: parasternal, infra-axillar, lower hemisternotomy, transverse sternotomy, but the most commonly used is partial upper "J" sternotomy. This technique implies small skin incision 8-10 cm long and sternal transection from jugular notch to 3th or 4th intercostals space, dependent on a patient's constitution (2). Many different studies showed that with this approach we achieve smaller skin incision which improves cosmetics effect. This includes less bleeding, faster respiratory function recovery after surgery, reduced wound and mediastinal infection, as well as the length of hospital stay (3). Other studies showed that minimally invasive aortic valve replacement (mini-AVR) has some disadvantages such as longer duration of cardio-pulmonary bypass and cross-clamp, less visibility of heart structures, worse myocardial protection and heart deareation (removal

of air from the heart chambers) (4). Newer studies about mini-AVR presented different results and conclusions which are still unclear.

Aim

The aim of our study is a comparison of the pre- and perioperative results and early mortality in patients in whom mini-AVR and conventional AVR were performed.

Materials and methods

This prospective randomized study was performed at the Cardiovascular Institute "Dedinje" from 11.02.2016. to 24.05.2017. The study included 70 patients in whom isolated aortic valve replacement was performed. The patients were randomized in two groups. In both groups, we had 35 patients. Surgical approach in the first group of patients was partial upper "J" sternotomy, in another group conventional sternotomy was performed. All the patients in whom aortic valve surgery was performed concomitant with other cardiac procedures were excluded from the study. Re-do AVR procedures were not included in the study.

Surgical technique

We performed mini-sternotomy through an 8 to 10 cm skin incision. The sternum is transected horizontally at the level of the 3rd or 4th intercostal space, taking care to avoid injury to the right internal mammary artery. Thymol fat is dissected, and pericardial sutures are placed and retracted to the dermis while the sternal retractor is temporarily removed, thereby exposing the aorta and operative field. The patient is fully heparinized, and the ascending aorta assessed for a safe cannulation site with manual palpation. We use a 22 or 24 Fr standard plastic right angle tip aortic cannula. For venous drainage, double stage venous cannula is used. Cardiopulmonary bypass is initiated, and the aorta is directly cross-clamped. Antegrade cardioplegia is given in ascending aorta.

Basic (descriptive) statistics included mediana, mean values and standard deviations. Furthermore, frequencies of certain features inside each group were determined. The difference in the distribution of frequencies of certain features among the tested groups was determined using the χ^2 or Fisher's Exact test. After the normality of the distribution of numerical variables had been tested using the Shapiro Wilk and Kolmogorov Smirnoff tests, the comparison between the groups was done using the Student T- and Mann Whitney test. A starting point of statistical significance was determined at the level $p \leq 0.05$. Data processing was done using statistical software SPSS 25.0 for Windows 10.

Results

The study included 70 patients, 28 males and 42 females, mean age 64.75 ± 8.05 years.

Table 1. Preoperative caracteristic of patients devided in two groups

Preoperative caracteristics	Medial Sternotomy n = 35	Mini Sternotomy n = 35	P value
Age	69.3 ± 7.7	65.71 ± 7.9	0.12
Female gender	19	23	0.9
BMI	27.8 ± 4.2	27.1±3.3	0.75
Hypertension	25	29	0.25
Hyperlipidemia	16	20	0.33
NYHA clasification	2	2	
Smoking history	16	14	0.63
Diabetes mellitus	10	7	0.4
Cerebrovaculare disease	3	3	1.0
Vascular disease	6	5	0.74
Ejection fraction	50.14 ± 11.4	54.4 ± 9.9	0.09
EF <30%	3	1	0.12
EF 30-50%	13	7	0.12
EF >50%	19	27	0.12
Aortic valve area (AVA)	0.66 ± 0.25	0.68 ± 0.20	0.77
Aortic valve pressure gradient	54.4 ± 23.7	63.1 ± 20.6	0.1
EuroScore	2.33 ± 2.03	1.53 ± 0.9	**0.037**

*BMI - body mass index, † EF- ejection fraction

The mean value of Euro-score in all patients was 1.93 %. Comparing gender, age and risk factors in groups we found that groups were homogenous ($p \geq 0.05$). Preoperative characteristic of the patients divided into separate groups were presented in Table 1.

In all of the patients sick aortic valve was replaced with a mechanical or biological prosthesis. Different types of artificial valve were used equally in both groups (mechanical valve - 20; biological valves - 15). The cardio-surgical procedures were performed by using the cardiopulmonary bypass support.

Analysis of the intraoperative data in groups showed statistically significantly longer duration of cardiopulmonary bypass and cross-clamp in mini - AVR group ($p < 0.001$). The other intraoperative results are presented in Table 2. Regarding the data statistically significant difference between groups was not registered.

Table 2. Intraoperative and postoperative characteristics of patients divided in two groups

Intraoperative and postoperative Caracteristics	Coventional Sternotomy n = 35	Mini sternotomy n =35	P value
CBP time, minutes	72.14 ± 14.63	94.11 ± 20.1	**0.001 <**
Aortic cross clamping time	52.17 ± 11.5	69.40 ± 13.3	**0.001 <**
Prothesis size	21	21	
Blood drainage (ml)	454.2 ± 458	415.71 ± 355	0.69
Ventilator time (hours)	13.03±4.4	13.46 ± 3.72	0.9
ICU length of stay, days	2	2	
Reintubation	1	0	1.0
Reexploration for bleeding	1	1	1.0
Blood transfusion, ml	164.2±208.2	235.43 ± 276.6	0.22
Postoperative IM	0	0	
Postoperative CVI	0	0	
New onset of AF	9	14	0.2
Atrioventricular block	0	0	
Hemodialysis	1	0	1.0
Wound infection	2	0	0.4
Mediastinitis	1	0	1.0
Intrahospital mortality	1	1	1.0

*CBP time- cardiopulmonary bypass time, †ICU- intensive care unit, ‡IM- infarction myocardial, ¥CVI- cerebrovascular insult, £AF- atrial fibrilation

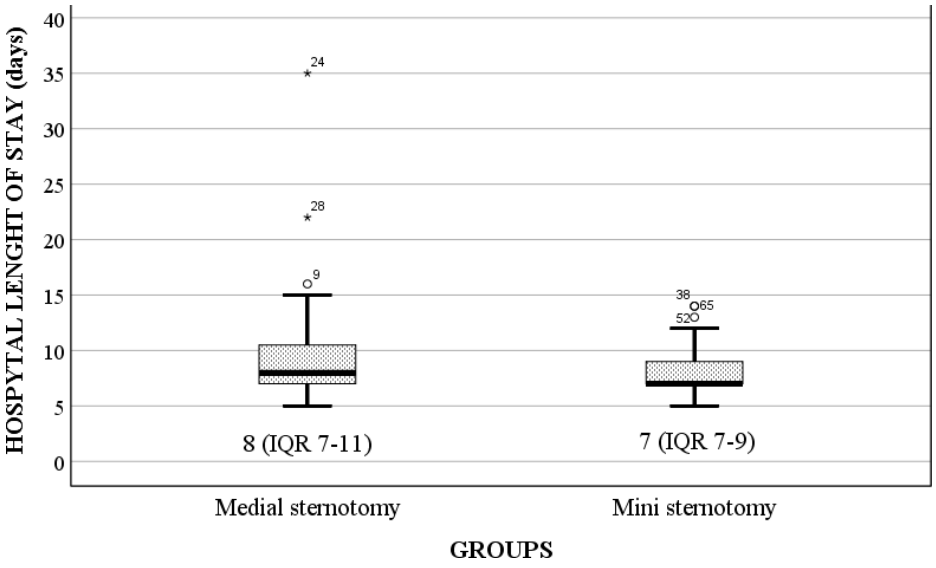

Figure 1. Hospital lenght of stay of our patients dependent on the used operative technique

One patient in whom AVR was done through the medial sternotomy, was reintubated and died during the early postoperative period. Conversion in full sternotomy was performed in one case because the patient was hemodynamically unstable and this patient also died. Presternal infection was detected in two cases in whom medial sternotomy was made but without statistically significant difference between groups. Mediastinitis was registered in one case in the same group. Presternal infection and mediastinitis weren't registered in mini-AVR group.

Patients in whom aortic valve was replaced through medial sternotomy were longer in hospital than patients in mini-AVR group (Figure 1).

Discussion

The standard surgical approach for aortic valve surgery is medial sternotomy. In recent years standard surgical approach has been replaced by the minimally invasive procedures. Mini-AVR represents a safe and efficient option for aortic valve treatment because it reduces the number of complications (5). The aim of this procedure is a smaller scar with less of bleeding, hospital stay, and cost of treatment (6). The special benefit can be seen in patients with significant comorbidities, like obesity, diabetes, chronic obstructive pulmonary disease and in seniors. In these high risk patients, mini-AVR reduces the incidence of wound infection and promotes respiratory function recovery (7). In our study, we followed an intraoperative and early postoperative period of patients in whom mini-AVR and conventional AVR was performed.

Our results showed no statistically significant difference in age, gender, NYHA and ejection fraction (EF) and indicate that groups were homogenous because of the performed randomization. The euroscore values had higher statistical significance in conventional sternotomy group. Cardiopulmonary bypass and cross-clamp times were statistically significant longer in mini -AVR group. The similar results were obtained in the other studies (8, 9). Longer duration of cardiopulmonary bypass didn't influence the morbidity and mortality rate during the early postoperative period in our patients, Ghanta et al. showed similar results in their study (4). By the time, we expect that duration of the cardiopulmonary and cross-clamp will be shorter with the better trained surgical team. Although there was less blood loss in the mini-AVR group, we could not demonstrate a statistically significant difference between groups. The most available studies showed less blood drainage in the mini-AVR group (9). Also, it should be noted that measurement of blood lost through drainage tube isn't precise, because fluid collection in the chest tube may be a combination of blood and other fluids, and therefore values can be variable. Bakir at al. showed that mini-AVR reduced rate of blood transfusion (10). In our study, less blood transfusion was used in the group of a medial sternotomy, but without statistically significant difference. We found many different results about the requirements for blood transfusion. Some studies showed that blood transfusion requirements were equal in both groups (11). Other studies report an important reduction of blood transfusion in the mini-AVR group (12). Murtaza et al. in their large study reported important reduction of blood loss in mini-AVR group (13). We didn't see any difference in reoperations because of bleeding. We found similar results in other studies (2, 10, 13). One of the problems of mini-AVR is difficult deaeration at the end of surgical procedures (14). Although, it is more difficult to make deaeration than in the procedures which were performed through the medial sternotomy, in our study, clinical signs of the bad preformed deaeration weren't noticed. Namely, postoperative CVI and increase blood rate of CK-MB were not registered during hospitality in our patients. Through our experience we can perform successful deareation in case of mini-sternotomy. Good results in deareation are being reached with the fulfillment of operative area with carbon dioxide because carbon dioxide is more soluble in blood than air.

Robert et al. said that in a group of patients with convention sternotomy higher rate of postoperative atrial fibrillation (POAF) was detected (2). Our results showed a higher number of POAF in mini-AVR group, but without significance. The results about POAF rate must be taken with reserve because their etiology is multifactorial (15). A significant advantage of the mini-sternotomy in comparison to the other minimally invasive procedures is the possibility of fast conversion in full sternotomy (2). The conversion is associated with significant morbidity and mortality, and the usual reasons for conversion are bleeding, ventricle dysfunction and bed exposition (9, 13). During our research, only one conversion was done because hemodynamic instability and this patient died in hospital. While some studies wrote about a shorter duration of the mechanical ventilation in a mini-AVR group (9, 13, 16), the analysis of our results showed no statistically significant difference.

Total intensive care unit stay was similar in our groups, but Brown et al. presented shorter intensive care stay in the mini-AVR group. Same studies presented that total intra-hospital stay was shorter for one day in patients in whom mini-AVR was performed (9). Our results were the same (Figure 1). Statistical significance difference between groups was not found when we were analysing presternal infection and mediastinitis, although in mini-AVR group presternal infection and medistinistis were not registered. We expect that a statistically significant difference will be proved in our further studies with higher number of included patients. One of the ideas, why we are doing this procedure at all, is better sternum healing and reduced frequency of SSI (surgical site infection). Santana et al. showed less frequency of wound infection in obese patients in whom partial upper sternotomy was performed (17). Welp et al. showed that partial upper sternotomy in high -risk patient didn't have significant benefit and the similar results were presented in the studies which included patients with lower risk(18).

The mortality rate was equal in both groups. Namely, in each group, only one patient died. Our results are similar with results in earlier presented studies which concluded that difference in mortality

between mini-AVR and conventional AVR group did not exist (9, 10). On the other hand, Raja et al. Presented less mortality rate in the mini-AVR group than in the medial sternotomy group but without statistical significance.

Conclusion

Our research showed that aortic valve replacement might be safely and effectively performed through the partial upper sternotomy. This surgical approach reduces tissue trauma and hospital stay, and also promotes the patient's recovery. In high-risk patients with comorbidities like obesity, diabetes and elder patients reduces the prevalence of infection. Partial upper sternotomy prolongs the duration of the operative treatment and cardiopulmonary bypass, and does not influence the morbidity and mortality rate. Mini-AVR is a good approach for aortic valve treatment but it requests perfect trained and experienced surgical team.

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MINIMALNO INVAZIVNA ZAMENA AORTNE VALVULE NASUPROT ZAMENI AORTNE VALVULE KROZ MEDIJALNU STERNOTOMIJU: PROSPEKTIVNA RANDOMIZOVANA STUDIJA

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Standardni pristup u lečenju aortne valvule je medijalna sternotomija. Proteklih godina se minimalno invazivne procedure sve češće upotrebljavaju u cilju smanjenja traume i bržeg oporavka bolesnika.

Cilj ove studije bio je upoređivanje preoperativnih, perioperativnih reziltata i ranog mortaliteta kod bolesnika kojima je učinjena zamena aortne valvule kroz ministernotomiju (Mini-AVR) i medijalnu sternotomiju.

Studija je uključivala 70 bolesnika. Analizirani su preoperativni, intraoperativni i rani postoperativni rezultati. Preoperativni rezultati bili su homogeni. Vrednosti euro-skora bile su statistički veće u grupi sa medijalnom sternotomijom ($p = 0,037$). Trajanje kardiopulmonalnog bajpasa i kleme bilo je duže u grupi sa mini-AVR ($p < 0,001$). Nije bilo razlike u pojavi postoperativnih infarkta miokarda, slogova i renalne insuficijencije. Po jedan bolesnik iz svake grupe hirurški je revidiran zbog krvarenja. Nije bilo razlike u hospitalnom mortalitetu između dve grupe. Postoperativni gubitak krvi beznačajno je bio niži u mini-AVR grupi ($p = 0,69$). Tri bolesnika imala su infekciju rane nakon medijalne sternotomije: dve površinske infekcije i jedna duboka infekcija ($p = 0,4$). Dužina boravaka u intenzivnoj nezi bila je slična u obe grupe. bolesnici sa mini-AVR imali su kraći boravak u bolnici u poređenju sa bolesnicima operisanim kroz medijalnu sternotomiju (8 dana (IQR 7-11) nasuprot 7 dana (IQR 7-9)).

Mini-AVR redukuje traumu tkiva, boravak u bolnici i takođe ubrzava oporavak bolesnika. Kod visokorizičnih bolesnika sa komorbiditetima, kao što su gojaznost i dijabetes i kod starijih osoba smanjuju prevalenciju infekcija.

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Ključne reči: *aortna valvula, ministernotomija, zamena aortne valvule, minimalno invazivni pristup*