# MINIMALLY INVASIVE OZAKI TECHNIQUE

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Implantation of a mechanical or biological graft remains the gold standard in treatment of patients with aortic valve pathology. However, the necessity of taking anticoagulants, the problem of graft durability, the risk for thromboembolic and haemorrhagic complications, prosthetic infective endocarditis impel surgeons to search for and develop new technologies. One of such new techniques is prosthetic repair of the aortic valve using autologous pericardium according to the S. Ozaki operation. This procedure makes it possible to form an aortic valve with excellent haemodynamic characteristics and low frequency of re-do operations in both the early and remote periods.

Current trends are towards exponential growth of minimally invasive cardiosurgical interventions. Upper partial sternotomy is one of the most commonly used techniques in surgery of the aortic valve. The results of previous studies demonstrated that a minimally invasive approach apart from a good cosmetic effect has a series of advantages over full sternotomy by the in-hospital and remote outcomes. On the other hand, a minimally invasive access is associated with limited surgical exposure and tight operative field and is therefore technically more complicated than the operation via full sternotomy.

In our retrospective study we compared the clinical outcomes of the minimally invasive Ozaki technique (Ozaki Mini Group, n=30) and full sternotomy (Ozaki Full Group, n=112). Because of differences between the groups by the clinical and demographic parameters in order to ensure maximum comparability we conducted computer-assisted propensity score matching, resulting in formation of 2 groups consisting of 30 patients each.

The primary outcome measures of the study were 30-day all-cause mortality and postoperative major adverse cardiac events (myocardial infarction, stroke). As additional categorical outcomes we examined new-onset atrial fibrillation and renal failure, resternotomy, prolonged (>24 h) assisted artificial pulmonary ventilation, mediastinitis/sternal instability. Secondary outcome measures were as follows: the duration of the operation, duration of myocardial ischaemia and artificial circulation, blood loss, requirement for transfusion of donor blood components.

Key words: mini-access, aortic valve prosthetic repair, pericardium, minimally invasive cardiac surgery.

#### INTRODUCTION

The development of a minimally invasive access as an alternative to prosthetic repair of the aortic valve (AV) via full sternotomy was necessary in order to reduce surgical trauma, and, as shown by previous studies, has a series of advantages by in-hospital outcomes as compared with full sternotomy. Apart from a small incision, good cosmetic effect and less pronounced pain syndrome, the mini-access ensures less blood loss and lower requirements for blood component transfusion, decreasing the incidence of new-onset atrial fibrillation and renal insufficiency, influencing the duration of artificial pulmonary ventilation (APV) and length of in-hospital stay [1, 2]. However, minimally invasive prosthetic repair of the AV is associated with a reduction the working space and poor exposure, thus making the procedure technically more difficult. Complicated implantation requires longer duration of the operation, artificial circulation (AC) and myocardial ischaemia, which may on the whole deteriorate the postoperative outcomes.

Recent years have witnessed ever increasing popularity of the AV prosthetic repair using autologous pericardium, developed by S. Ozaki and co-authors [3]. This procedure makes it possible to form an AV with excellent haemodynamic characteristics and is associated with a low rate of re-do operations both in the early and remote periods.

We performed for the first time the Ozaki operation via a J-sternotomy with thoracoscopic harvesting of the pericardium in March 2016. In the available literature we retrieved only one group of authors who had also reported performing the Ozaki operation thorough a mini-access [4, 5]. However, the available literature appeared to contain no works comparing the results of the minimally invasive Ozaki procedure with those of full sternotomy.



Fig. 1. Anatomical landmarks for performing skin incision – jugular fossa of the sternum and the 3rd intercostal space

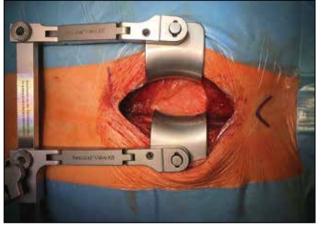


Fig. 2. J-ministernotomy performed through the  $\operatorname{\mathbf{3}rd}$  intercostal space

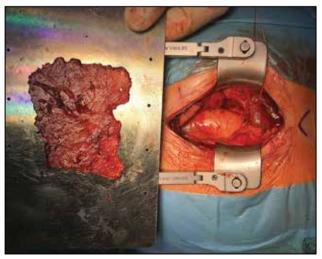


Fig. 3. Autologous pericardium harvested

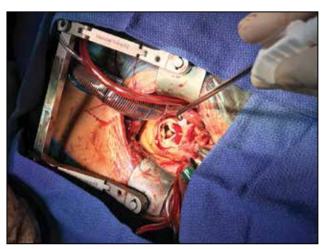


Fig. 4. Central connection of heart-lung machine (HLM), beginning of selective cardioplegia

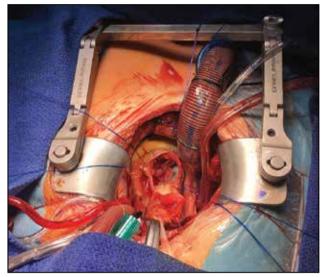


Fig. 5. Autopericardial valve formed

# **STUDY DESIGN**

Our retrospective observational study included a total of 142 patients subjected between October 2015 and December 2017 to reconstruction of the AV using autologous pericardium according to the Ozaki technique. Of these, 30 patients underwent surgery through a Jministernotomy (Study Group - Ozaki Mini) and 112 endured intervention via a full sternotomy (control group – Ozaki Full). A criterion for inclusion was the presence of AV pathology without or in a combination with an ascending aortic aneurysm. Exclusion criteria were as follows: the necessity of performing coronary artery bypass grafting, correction of pathology of the mitral and tricuspid valves, radiofrequency ablation, repeat operation on the heart. Due to differences between the groups in clinical and demographic parameters in order to ensure maximum comparability of the groups we performed their computer-aided adjustment by means of propensity score matching (PSM), resulting

Variables	Ozaki Mini, N=30	Ozaki Full, N=112	Difference	р
Age (years), Me [IQR]	54 [40; 65.75]	61.5 [55; 67]	5 [0; 13]	0.054
Female gender, n (%) [95% CI]	18, 60 [42; 75]	67, 60 [51; 68]	1.01 [0.41; 2.53]	1
BMI, kg/m², Me [IQR]	25.75 [22.93; 28.32]	28.7 [24.77; 32.92]	2.78 [0.32; 4.9]	0.022
LVEF, %, Me [IQR]	62.5 [55; 68.75]	62.5 [55.75; 68.25]	1 [-3; 5]	0.695
Grade III-IV AV calcification, n (%) [95% CI]	18, 60 [42; 75]	86, 77 [68; 84]	0.46 [0.18; 1.18]	0.102
AV defect aetiology: Degenerative, n (%), [95% CI] IE, n (%), [95% CI]	27, 90 [74; 97] 3, 10 [3; 26]	106, 95 [89; 98] 6, 5 [2; 11]	1.18 [0.29; 6.92] 1.95 [0.3; 9.87]	0.4 0.4
Diabetes mellitus, n (%), [95% CI]	6, 20 [10; 37]	14, 13 [8; 20]	1.74 [0.5; 5.48]	0.374
Peripheral artery lesion, n (%), [95% CI]	0, 0 [0; 11]	9, 8 [4; 15]	0 [0; 1.86]	0.204
AH, n (%), [95% CI]	20, 67 [49; 81]	77, 69 [60; 77]	1.74 [0.5; 5.48]	0.828
COPD, n (%), [95% CI]	1, 3 [1; 17]	2, 2 [0; 6]	1.89 [0.03; 37.45]	0.512
PICS, n (%), [95% CI]	1, 3 [1; 17]	6, 5 [2; 11]	0.61 [0.01; 5.35]	1
ACI/TIA, n (%), [95% CI]	1, 3 [1; 17]	10, 9 [5; 16]	0.35 [0.01; 2.68]	0.458
CKD (creatinine ≥ 200 mg/dl), n (%), [95% Cl]	4, 13 [5; 30]	12, 11 [6; 18]	1.28 [0.28; 4.69]	0.746
NYHA III-IV, n (%), [95% CI]	12, 40 [25; 58]	59, 53 [44; 62]	0.6 [0.24; 1.46]	0.304
EuroSCORE I Add., Me [IQR]	5 [3; 6]	5 [3; 7]	0 [-1; 1]	0.407
EuroSCORE I Log., Me [IQR]	3.315 [2.27; 6.17]	4.6 [2.27; 7.7]	0.49 [-0.66; 1.75]	0.356

Note: Me [IUR] – median [interquartile range]; CI – confidence interval; BMI – body mass index; LVEF – left ventricular ejection fraction (by Simpson's method); IE – infective endocarditis'; AH – arterial hypertension; COPD – chronic obstructive pulmonary disease; PICS – postinfarction cardiosclerosis; ACI/TIA – acute cerebral ischaemia/transitory ischaemic attack; CKD – chronic kidney disease; NYHA – functional class of heart failure according to the NYHA classification.

in formation of 2 groups, each consisting of 30 patients.

## SURGICAL TECHNIQUE

A minimally invasive access involved a 7–10-cm-long skin incision from the jugular fossa (Fig. 1) and partial J-ministernotomy with a lateral saw-cut to the right at the level of III–IV intercostal space (Fig. 2). In the control group we performed standard full sternotomy. Sternotomy was followed by harvesting of the autologous pericardium (Fig. 3). The excised pericardium was then fixed on a plate and placed into a 0.6% solution of glutaraldehyde for 10 min. The aldehyde-treated autologous pericardium was rinsed 3 times in normal saline for 6 min. We performed cannulation of the aorta and right atrium with a two-stage cannula for connection of the heart-lung machine, drainage of the left ventricle (LV) through the superior pulmonary vein (Fig. 4). The myocardium was protected by antegrade nonselective or selective crystalloid cardioplegia with Custodiol solution. Aortotomy was followed by applying 3 felt-

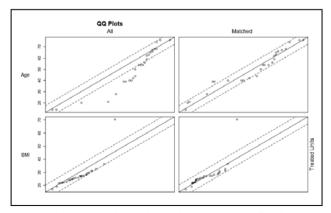


Fig. 6. The greater the number and more symmetrically relative to the central axis the points fall within the dotted line, the more balanced the groups are

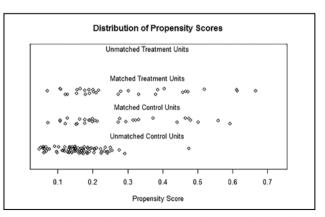


Fig. 7. In the baseline data, the PSM values were distributed unequally in the study and control groups. In the mini-access group a great number of patients had a score above 0.3. After matching, the distribution of the PS values was corrected

Table 2 Preoperative comparative characteristics of patients by the groups depending on the main clinical and demographic parameters after matching						
Variables	Ozaki Mini, N=30	Ozaki Full, N=30	р			
Age (years), Me [IQR]	54 [40; 65.75]	57 [38.75; 62.75]	0.912			
Female gender, n (%) [95% CI]	18, 60 [42; 75]	22, 73 [56; 86]	0.412			
BMI, kg/m², Me [IQR]	25.75 [22.93; 28.32]	25.3 [22.2; 31.78]	0.941			
LVEF, %, Me [IQR]	62.5 [55; 68.75]	64 [58; 69]	0.477			
Grade III-IV AV calcification, n (%), [95% CI]	18, 60 [42; 75]	17, 57 [39; 73]	1			
AV defect aetiology: Degenerative, n (%) IE, n (%), [95% CI]	27, 90 [74; 97] 3, 10% [3; 26]	28, 93 [79; 98] 2, 7% [2; 21]	1 1			
Diabetes mellitus, n (%), [95% CI]	6, 20 [10; 37]	3, 10 [3; 26]	0.472			
Peripheral artery lesion, n (%), [95% CI]	0, 0 [0; 11]	4, 13[5; 30]	0.112			
AH, n (%), [95% CI]	20, 67 [49; 81]	21, 70 [52; 83]	1			
COPD, n (%), [95% CI]	1, 3 [1; 17]	1, 3 [1; 17]	1			
PICS, n (%), [95% CI]	1, 3 [1; 17]	1, 3 [1; 17]	1			
ACI/TIA, n (%), [95% CI]	1, 3 [1; 17]	3, 10 [3; 26]	0.612			
CKD (creatinine ≥200 mg/dl), n (%), [95% Cl]	4, 13 [5; 30]	2, 7 [2; 21]	0.671			
NYHA III-IV, n (%), [95% CI]	12, 40 [25; 58]	13, 43 [27; 61]	1			
EuroSCORE   Add., Me [IQR]	5 [3; 6]	5.5 [3; 6.75]	0.714			
EuroSCORE   Log., Me [IQR]	3.315 [2.27; 6.17]	4.565 [1.82; 7.39]	0.673			

USA) and programme RStudio 0.99.879 - © 2009-2016 RStudio, Inc., USA, 250 Northern Ave, Boston, MA 02210- 844-448-121) in the language R (R Core Team (2015). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria).

Quantitative variables were assessed in order to check the conformity with the normal distribution law according to the Shapiro–Wilk test. Due to a small number of the parameters consistent with the normal distribution in the studied groups, non-parametric criteria were used for comparison.

The descriptive characteristics are expressed as the median (Me) [first quartile; third quartile] for continuous numerical data, percentage [lower limit – 95% CI; upper limit – 95% CI] for binary

pledged U-sutures onto each commissure for better exposure of the AV. After excision of the damaged AV we measured the distance between the commissures by means of the original sizing apparatus and the cusps were trimmed using an original template in accordance with the measurements obtained. The cusps were sequentially implanted into the AV position with uninterrupted blanket suture with Premilene 4/0 thread starting from the right coronary cusp then left coronary cusp and ending with the non-coronary cusp (Fig. 5). Formation of commissures was performed with separate U-shaped sutures on felt pledgets with 4/0 Premilene threads. If necessary, the ascending aortic portion was repaired.

# END POINTS

The primary end points of the study were 30-day all-cause mortality and major postoperative adverse events (myocardial infarction, stroke). As additional categorical outcomes we examined new-onset atrial fibrillation (AF) and renal failure (creatinine  $\geq$ 200 mg/ dl), resternotomy, prolonged (>24 h) APV, mediastinitis/ instability of the sternum. The secondary end points were as follows: duration of the operation, duration of myocardial ischaemia and AC, blood loss, requirement for transfusion of donor blood components.

# STATISTICAL ANALYSIS

The obtained data were statistically processed using the programme SPSS version 21 (SPSS, Chicago, IL, data with calculation of the limits of confidence intervals (CI) according to the Wilson formula.

The hypotheses on equality of numerical characteristics of sample distributions in the compared groups were statistically tested using unpaired Mann-Whitney U-test, calculating the bias of distributions with construction of 95% CI for the bias. The exact two-tailed Fisher test was used to compare binary and categorical parameters. The statistical hypotheses were tested at a critical level of significance p=0.05, i. e., the difference was regarded as statistically significant if p<0.05.

In preoperative comparative characteristic by the main clinical and demographic parameters statistically significant differences were determined for the body mass index, as well as close to significant differences by age (Table 1).

In order to minimize the bias of the results and to ensure maximum comparability of the groups the latter were adjusted by means of pseudorandomization (propensity score matching, PSM). 16 variables which could potentially influence the choice of a surgical access and the outcomes of treatment were included into the logistic regression model to perform PSM: age, female gender, body mass index (BMI), diabetes mellitus, arterial hypertension, peripheral artery disease, chronic obstructive pulmonary disease (COPD), a history of MI, a history of acute cerebral ischaemia/ transitory ischaemic attack (ACI/TIA), chronic kidney disease (CKD), NYHA functional class III–IV heart failure, LV ejection fraction, grade III–IV AV

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Variables	Ozaki Mini (n=30)	Ozaki Full (n=30)	р
Duration of the operation, min, Me [IQR]	303 [263.5; 333.25]	260 [230.25; 288]	0.007
Duration of AC, min, Me [IQR]	139 [121.75; 177,25]	126 [111; 147,25]	0.024
Myocardial ischaemia time, min, Me [IQR]	111 [97.75; 129]	106 [88.25; 123,75]	0.206
Blood loss in the operating room, ml, Me [IQR]	400 [300; 500]	350 [300; 437.5]	0.253
Blood loss in the ICU, ml, Me [IQR]	250 [200; 300]	600 [462.5; 700]	<0.001
Total blood loss, ml, Me [IQR]	650 [562.5; 787.5]	965 [850; 1087.5]	<0.001
Volume of transfused donor blood in the operating room, ml, Me [IQR]	288 [0; 536]	278 [0; 511.25]	0.698
Volume of transfused donor blood in the ICU, ml, Me [IQR]	0 [0; 0]	0 [0; 0]	0.734
Total volume of transfused donor blood, ml, Me [IQR]	351.5 [0; 553]	306.5 [233; 548]	0.952
Number of blood packs per patient, Me [IQR]	1 [0; 2]	1 [1; 2]	0.945
30-day mortality, n, %, [95% CI]	1, 3 [1; 17]	1, 3 [1; 17]	1
MI, n, %, [95% CI]	1, 3 [1; 17]	2, 7 [2; 21]	1
AIC/TIA, n, %, [95% CI]	1, 3 [1; 17]	1, 3 [1; 17]	1
Resternotomy, n, %, [95% Cl]	1, 3 [1; 17]	1, 3 [1; 17]	1
Atrial fibrillation, n, %, [95% Cl]	0, 0 [0; 11]	1, 3 [1; 17]	1
Renal failure, n, %, [95% Cl]	0, 0 [0; 11]	0, 0 [0; 11]	1
AC duration, min, Me [IQR]	350 [287.5; 520]	310 [265.8; 523.8]	0.539
Prolonged APV (>24 h), n, % [95% Cl]	2, 7 [2; 21]	1, 3 [1; 17]	1
AV-block requiring implantation of a pacemaker, n, %, [95% Cl]	1, 3 [1; 17]	0, 0 [0; 11]	1
Mediastinal instability/mediastinitis, n, %, [95% CI]	0, 0 [0; 11]	0, 0 [0; 11]	1
Length of stay in the ICU, days, Me [IQR]	2 [2; 2]	2 [2; 2]	0.239
Long stay in the ICU (≥ 3 days and more), n, %, [95% CI]	5, 16.67 [7; 34]	6, 20 [10; 37]	1
Length of postoperative hospital stay, days, Me [IQR]	7 [5; 9]	7 [6; 9.75]	0.565

## RESULTS

The characteristics of the intraoperative and early postoperative periods in the matched groups are shown in Table 3.

As can be seen from Table 3, there were no significant differenced between the groups by 30-day mortality and major postoperative adverse events (MI, stroke). The duration of operation and AC was more in the miniaccess group (303 min vs 260 min, p=0.007 and 139 vs 126 min, p=0.024, respectively). The groups did not differ by the time of myocardial ischaemia. The mini-access group patients were found to have lower blood loos in the ICU and total blood loss (250 ml vs 600 ml, p<0.001 and 650 ml vs 965 ml, p<0.001, respectively). However, by the number of packs of transfused donor blood per patient there were no significant differences between the groups. Neither were there significant differences in the duration of APV and prolonged (>24 h) APV, the length of stay in the ICU and hospital after surgery. In the mini-access group there were no cases of conversion to full sternotomy.

#### DISCUSSION

According to the literature data, the main advantages of repairing the AV through J-ministernotomy

Note: AC – artificial circulation; MI – myocardial infarction; ACI/TIA – acute cerebral ischaemia/transitory ischaemic attack; APV – artificial pulmonary ventilation; ICU – intensive care unit.

calcification, AV defect actiology (degenerative, infective endocarditis), risk of intervention by the EuroSCORE I Add. and EuroSCORE I Log. Pseudorandomization was performed by the 16 mentioned covariates. Each case from the study group was matched with a pair from the control group, i. e. a patient having the closest value of PS (one-to-one nearest neighbour method). The value of the PS portion equalling 0.2 of the standard deviation of the PS logit was sufficient to ensure the propensity score-matching of observations in the pair by the existing set of confounders.

After PSM, from the control group we selected 30 patients not differing from the study group by the age and BMI, as well as by the rest clinical and demographic characteristics (Fig. 6 and 7, Table 2).

include lower volume of blood loss and requirement for donor blood components transfusion, shorter duration of APV, lower incidence of postoperative AF and renal failure, shorter length of stay in the ICU and in hospital [1, 2]. However, 30-day mortality and long-term survival in both mini access and full sternotomy were comparable [6–9]. Our study also demonstrated that performing the Ozaki operation through a J-ministernotomy proved to be a safe procedure associated with a low 30-day mortality rate and postoperative complication rate.

The patients subjected to the minimally invasive Ozaki operation were found to have lower blood loss after the operation and total blood loss, however by the volume and the number of packs of transfused donor blood per patient no significant differences between

the groups were observed. Our findings are consistent with the results of meta-analysis by M. Brown, et al. [1], in which according to the results from 17 studies blood loss after aortic valve replacement from a mini-access was averagely by 73 ml [95% CI 23-136] less than that for full sternotomy. The frequency of resternotomies for haemorrhage in the present work amounted to 3% in both groups. D. Gilmanov, et al. [10] also reported the absence of significant differences by the frequency of resternotomies between mini- and full sternotomy (4.4 versus 6%, p=0.63), however, the patients in full sternotomy required larger amounts of donor blood (2 blood transfusion packs per patient versus 1 pack, p=0.046). N. Furukawa, et al. [11] reported that the frequency of resternotomies was identical in both groups (6%). However, in the work by D. Merk, et al. [12] the incidence of resternotomies and requirement for donor blood transfusion (more than 3 packs per patient) were higher in the mini-access group (4.2 versus 1.5%, p=0.009 and 28.1 vs 19.7%, p=0.002, respectively). Decreased blood loss in mini-access may be associated with a reduced surgical trauma. It is important to mention that the discharge through drainages after the operation is not, as a rule, pure blood. Also, the protocols of donor blood components transfusion significantly differ in clinics. Therefore, these end points, except resternotomy, are relatively tentative.

The majority of studies and meta-analyses report longer duration of operation, AC and myocardial ischaemia while performing AV reconstruction through a mini-access [1, 2, 8-11], with the time of AC and myocardial ischaemia in mini-access being averagely by 10 minutes longer compared with full sternotomy [1]. In our study, the mini-access group patients demonstrated longer duration of the operation (303 min versus 260 min, p=0.007) and AC (139 vs 126 min, p=0.024), however there were no significant differences in the time of myocardial ischaemia between the groups (111 min vs 106 min, p=0.206). Longer duration of AC and myocardial ischaemia might be conditioned by more technically difficult operation via the mini access and limited exposure, however this did not lead to increased frequency of unfavourable outcomes. A distinctive peculiarity of this study from the work by D. Nguyen, et al. [4, 5] is that exposure and preparation of the pericardium were carried out after performing J-sternotomy prior to initiating AC. Since it takes approximately 30 minutes to prepare autologous pericardium, the duration of AC was diminished averagely by this time.

Longer duration of the operation is, probably, also determined by technically more difficult procurement of the autologous pericardium via a mini access.

In our study, there were no significant differences between the groups by the duration of APV (350 min vs

310 min, p=0.539) and prolonged APV (7 vs 3%, p=1). However, authors of many studies report shorter time of APV and lower incidence of respiratory insufficiency during AV reconstruction through the mini-access. S.-E. Shehada, et al. [8] reported that APV time in the miniaccess group was significantly shorter as compared with full sternotomy (420 min vs 480 min, p=0.01). According to the findings of the meta-analysis by M. Brown, et al. [1], in using mini-access the APV time was shorter averagely by 2 hours (95% CI 1.30-2.95 h), however, in metaanalysis of only randomized studies the differences in duration of APV were inconsiderable (0.96 hour; 95% CI 0.01–1.93). Shorter APV time in mini-access might be explained by the increased stability of the thoracic cage, less traumatic nature and degree of pain syndrome, which allow the patients to be mobilized earlier. These factors may play an important role in reducing the risk of respiratory infections and wound complications [8].

Many investigators reported that the difficulty of removing air from the heart chambers at the end of the operation is one of the major concerns about minimal access aortic valve replacement procedures [13]. However, in our study there were no significant differences by the frequency of cerebrovascular and coronary events between the groups. The conventional use of  $CO_2$ insufflation into the operative field during the operation and transoesophageal echocardiography control make it possible to attain thorough removal of air from cardiac chambers. By the frequency of the development of newonset AF, implantation of a pacemaker, and instability of the sternum, the groups did not differ significantly, which is consistent with the data of the majority of studies and meta-analyses [1, 2, 6, 8].

The use of mini-access in AV reconstruction diminishes the length of stay in the ICU averagely by 11 h and in-hospital postoperative stay by 1 day [1]. However, in the work of S.-E. Shehada, et al. [8] the length of stay in the ICU and in hospital did not differ between the groups (3 days versus 4 days, p=0.35 and 9 days vs 10 days, p=0.23, respectively). Similar results were obtained in our study.

Studies of S. Ozaki [3, 14] and our previous studies [15, 16] demonstrated excellent immediate and remote results of AV reconstruction using autologous pericardium treated with glutaraldehyde. A combination of this method and a minimally invasive access is a simple and feasible procedure, does not increase mortality and incidence of major postoperative complications.

#### LIMITATIONS

This is a retrospective and observational study of patient data collected from our database; thus, it reflects a single-centre experience only. The miniaccess group was represented by a small sample of patients. Significant differences by the body mass index and age were noted in the overall cohort of patients. To decrease the effect of potential confounding factors on the results we performed the procedure of propensity score matching (PSM) by 16 parameters. This analysis decreased the risk of the effect of clinical and demographic differences on the results. However, a series of important unaccounted factors could have influenced the choice of the surgical approach and the results. Nevertheless, we believe that the method of propensity matching which included the most significant confounders is an adequate statistical method making it possible to minimize the bias of outcomes. In the present work we carried out no questionnaire survey among our patients concerning the degree of pain syndrome, which would have been highly interesting.

#### CONCLUSION

The findings of our study demonstrated that AV reconstruction using autologous pericardium according to the Ozaki technique may be performed through a J-ministernotomy without increasing the risk of mortality and other major complications. Besides, the mini-access was accompanied by less blood loss after the operation and total blood loss.

#### Conflict of interest: none declared.

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