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Results of Minimally Invasive Valve-Sparing Aortic Root Valve Surgery: Propensity Score Matching Analysis

Aim Evaluation of efficacy and safety of minimally invasive, valve-sparing interventions on the aortic root and a comparative analysis of outcomes versus a group of patients with a complete sternotomy intervention using the method of propensity score matching (PSM).

Material and methods From 2016 through 2019, 458 interventions on the aortic root were performed, including 160 (36.6%) interventions with mini-sternotomy. The study included 106 patients with the valve-sparing surgery (David procedure). Two groups of 30 patients each were formed using PSMC: group 1, complete sternotomy (CS) and group 2, J-shaped mini-sternotomy (MS). Immediate and long-term outcomes were evaluated at 13.8±10.3 (1–38 months (min-max) in the MS group and 42±21 (1–61 months (min-max) in the CS group.

Results Statistically significant differences in death rate, echocardiographic indexes, absence of reoperations and complications in the postoperative period were not observed. In group 2, durations of extracorporeal circulation ($p=0.04$) and period of myocardial ischemia ($p=0.004$) were increased. The same group showed decreased intraoperative blood loss ($p=0.001$), postoperative drainage losses ($p=0.0001$), extubation time ($p=0.0001$), duration of stay in resuscitation and intensive care units and in the department of reconstructive recovery cardiovascular surgery ($p=0,005$).

Conclusion The David procedure with mini-sternotomy is a safe and effective alternative to the traditional approach. This technique significantly reduces the time of rehabilitation and duration of patients' stay in the hospital without significant differences in the long-term period, which suggests advantages of this method. However, despite these promising results, the retrospective nature of this study, a small sample of patients, and a short follow-up period warrant further study.

Keywords Aortic root aneurysm; dissection; aortic valve? replacement; David procedure; mini-sternotomy; minimally invasive surgery; valve-sparing surgery

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The minimally invasive approach has become increasingly common in modern cardiac surgery. The background of experience and the results of large randomized trials have shown some advantages of minimally invasive access over the conventional approach, such as reducing surgical trauma and associated blood loss, decreasing pain intensity, and enabling rapid rehabilitation of patients. Current trends in minimally invasive surgery have spread to valve and coronary surgery and are gradually gaining ground in thoracic aortic repair.

Despite the appearance of a wide range of aortic root interventions, the replacement of the aortic root and aortic valve (AV) put forward by Bentall and DeBono in 1968 remains the gold standard in aortic root surgery [1]. However, interest in valve-preserving interventions is growing considerably, along with the desire to improve patients' quality of life after surgery. The best-known surgery with long-term, 25 year outcomes is the David procedure proposed by the author in 1992 [2]. Despite the apparent simplicity and utilization of the procedure, it is technically complex and requires adequate surgical experience [3]. It should also be noted that direct technical performance, wound exposition, and precision of execution directly affect the immediate and long-term outcomes and the function of the AV. For these reasons, the technique requires appropriate experience and clinical settings. That is why the main objective of this study was to compare the outcomes of patients undergoing the David procedure with those of patients undergoing complete sternotomy using propensity score matching (PSM), as well as to assess the safety and efficacy of minimally invasive, valve-preserving interventions on the aortic root based on hospital and midterm findings.

Material and Methods

In 2016–2019, more than 450 procedures on the ascending aorta (AAo) and the aortic arch were performed under the program of minimally invasive surgery of the thoracic aorta in the Russian Scientific Center of Surgery n.a. Academician B.V. Petrovsky [4]. In 106 cases, patients with aortic root aneurysm with/or without aortic insufficiency (AI) underwent valve-preserving reimplantation of a native AV into the vascular prosthesis in the original and modified David procedures [5] using thermal blood cardioplegia in all cases [6]. Thirty-five (33%) cases were minimal-access interventions. Aortic arch interventions were performed under antegrade cerebral perfusion, hypothermia, and circulatory arrest [7]. Inclusion criteria were aortic root and ascending aorta disease, primarily scheduled David procedure volume, and age ≤75 years. Exclusion criteria were repeated interventions, acute aortic dissection, and complex interventions on the aortic arch with or without a history of multivalve correction. The groups of complete sternotomy (CS; n=61) and mini-

Figure 1. Design of the comparative analysis using PSM between the groups of complete and mini-sternotomy using 1:1 nearest-neighbor matching

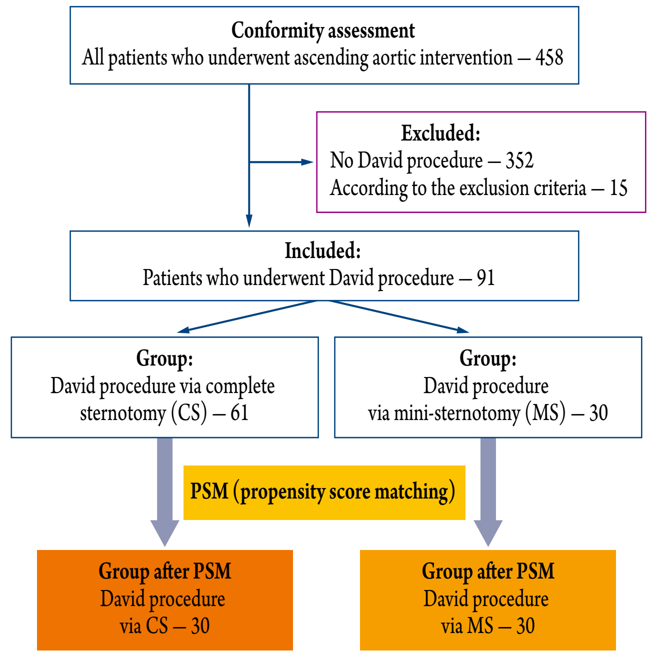

Table 1. Preoperative characteristics of patients included in the analysis (n=91) before and after PSM (n=60)

Показатель	Before PSM (n=91)			After PSM (n=60)		
	MS (%), (n=30)	CS (%), (n=61)	p	MS (%), (n=30)	CS (%), (n=30)	p
Age, years	44.4±15	51.5±9.8	0.007	44.4±14.5	48.6±15.8	0.224
Sex, male	24 (80)	45 (73)	0.608	24 (80)	25 (83)	1.000
BMI, kg/m²	28.5±5	26.7±9	0.311	28.5±5	25.6±5.1	0.068
Smoking	16 (53)	41 (67)	0.63	16 (53)	12 (57.1)	0.356
Bicuspid AV	3 (10)	5 (8.1)	1.000	3 (10)	3 (10)	1.000
COPD	4 (13)	21 (34)	0.046	4 (13)	7 (23)	0.506
LVEF, %	58±6	51±20	0.001	58±6	61±7	0.079
FC III-IV CHF	4 (13)	21 (34)	0.046	4 (13)	9 (30)	0.209
AF	2 (6.6)	12 (19.6)	0.1315	2 (6.6)	3 (10)	1.000
Diabetes mellitus	1 (3.3)	8 (13.1)	0.2622	1 (3.3)	2 (6.6)	1.000
CKD stage >II	2 (6.6)	15 (24)	0.047	2 (6.6)	4 (13)	0.6707
Leaflet prolapse	6 (20)	16 (26)	0.6082	6 (20)	4 (13)	0.7306
Aortic dissection type I	0	12 (19.6)	0.0073	0	2 (6.6)	0.4915
Aortic root and/ or ascending aortic aneurysm	30 (100)	49 (80)	0.0073	30 (100)	28 (93)	1.000
Marfan syndrome	5 (17)	15 (24.5)	0.4348	5 (17)	7 (23)	1.000
MR >2	3 (9.9)	6 (9.8)	1.000	3 (9.9)	2 (6.6)	1.0000

The data are expressed as absolute and relative rates — abs. (%) or the mean and the standard deviation (M±SD). | PSM, propensity score matching; MS, mini-sternotomy; CS, complete sternotomy; BMI, body mass index; AV, aortic valve; COPD, chronic obstructive pulmonary disease; LVEF, left ventricular ejection fraction; CHF, chronic heart failure; FC, functional class; AF, atrial fibrillation; CKD, chronic kidney disease; MR, mitral regurgitation.

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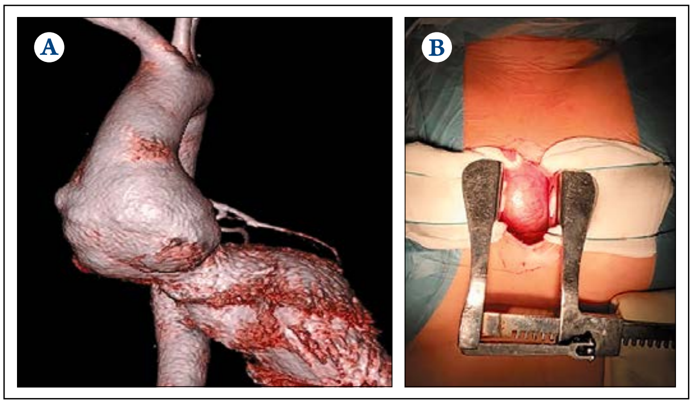
Figure 2. Initial pathology was aortic root and/or ascending aortic aneurysm



A: 3D-multislice computed tomogram with the reconstruction of root and ascending aortic aneurysm;
B: Intraoperative view of aneurysm from mini-sternotomy.

sternotomy (MS; n=30) were formed retrospectively from the general patient cohort. The mean age of patients was 44.4±15 years in the MS group and 51.5±9.8 years old in the CS group. Moreover, there were 19.6% of patients with DeBakey type I aortic dissection in the CS group, and no such patients in the MS group. Preoperative assessment showed many significant differences between the groups: age (p=0.0074), the presence of chronic obstructive pulmonary disease (p=0.0455), chronic heart failure (p=0.0455), chronic kidney disease (p=0.047), left ventricular ejection fraction (p=0.0007), and DeBakey type I aortic dissection (p=0.0073) (Table 1).

Фn intergroup PSM analysis was performed using 1:1 nearest-neighbor matching to remove the effect on the analysis of preoperative profiles (Figure 1). After

Table 2. Perioperative parameters and early postoperative outcomes

Parameter	Before PSM (n=91)			After PSM (n=60)		
	MS (%), (n=30)	CS (%), (n=61)	p	MS (%), (n=30)	CS (%), (n=30)	p
Combined interventions						
Aortic hemiarch replacement	1 (3.3)	5 (8.1)	0.6594	1 (3.3)	2 (6.6)	1.0000
Complete aortic replacement	2 (6.6)	14 (22.9)	0.0470	2 (6.6)	3 (9.9)	1.0000
CABG	0	8 (13)	0.0490	0	3 (9.9)	0.2373
MV reconstruction	3 (9.9)	6 (9.8)	1.000	3 (9.9)	2 (6.6)	1.0000
Intraoperative profile						
CPB duration, min	147±14	154±23	0.8884	147±14	134±31	0.0444
Aortic clamping, min	130±17	116±24	0.0364	130±17	115±21	0.0035
Blood loss, mL	710±171	1158±189	0.0001	710±171	1065±288	0.001
Drainage (2 days), mL	317±101	689±56	0.0001	317±101	647±300	0.0001
Early postoperative outcomes						
Postoperative mechanical ventilation time, h	5±1.9	9.2±1.3	0.0001	5±1.9	11.3±1.5	0.0001
Postoperative mechanical ventilation for more than 48 h	1 (3.3)	6 (9.8)	0.4185	1 (3.3)	4 (13)	0.353
Length of stay in ICU, days	1.2±0.4	2.6±1.1	0.0001	1.2±0.4	1.9±0.9	0.0003
Bed-days spent in hospital, days	8±2.6	13±2.5	0.0001	8±2.6	10.8±4.5	0.005
Death	1 (3.3)	1 (1.6)	1.0000	1 (3.3)	1 (3.3)	1.000
AR grade > 2	1 (3.3)	1 (1.6)	1.0000	1 (3.3)	0	1.0000
Neurological complications	1 (3.3)	2 (3.2)	1.0000	1 (3.3)	1 (3.3)	1.000
Tamponade	2 (6.6)	3 (4.8)	1.0000	2 (6.6)	1 (3.3)	1.000
Sepsis	1 (3.3)	1 (1.6)	1.0000	1 (3.3)	1 (3.3)	1.000
Repeat exploratory surgery for bleeding	0	4 (5.4)	0.3042	0	2 (6.6)	0.4915
Respiratory failure	1 (3.3)	6 (9.8)	0.4185	1 (3.3)	6 (9.8)	0.1028
Deep wound infection	2 (6.6)	1 (1.6)	0.2518	2 (6.6)	1 (3.3)	1.000

The data are expressed as the absolute and relative rates — n (%) or the mean and the standard deviation (M±SD).
PSM, propensity score matching; MS, mini-sternotomy; CS, complete sternotomy; CABG, coronary artery bypass grafting; MV, mitral valve; CPB, cardiopulmonary bypass; ICU, intensive care unit; AR, aortic regurgitation.

PSM, 30 pairs significantly comparable by preoperative profiles from each group were determined (see Table 1).

The David procedure was indicated for all patients with AV insufficiency, without severe aortic valve calcification or fibrosis, with annuloaortic ectasia and aneurysm or aortic root and AAo dilation (Figure 2), and patients with aortic root dissection if partial aortic root repair was impossible. The final choice was made after mandatory intraoperative evaluation of the AV function using transesophageal echocardiography and direct visual inspection during the revision of AV [8, 9]. The decision whether to perform the minimally invasive intervention was made in the preoperative period, after analyzing the findings of multislice computed tomography of the thoracic and abdominal aorta and the iliac-femoral lesion to assess the possibility of femoral cannulation and the technical feasibility of MS. Complete longitudinal sternotomy was a technique of choice for patients with indications for combined myocardial revascularization and rhythm-converting procedures.

The midterm analysis of survival, absence of repeat AV interventions, and recurrence of severe AI >2 degree was performed. The mean follow-up period was 13.8±10.3 (1–38 [min-max]) months and 42±21 (1–61 [min-max]) months in the MS and CS groups, respectively.

The study was approved by the local ethics committee. All patients signed informed consent.

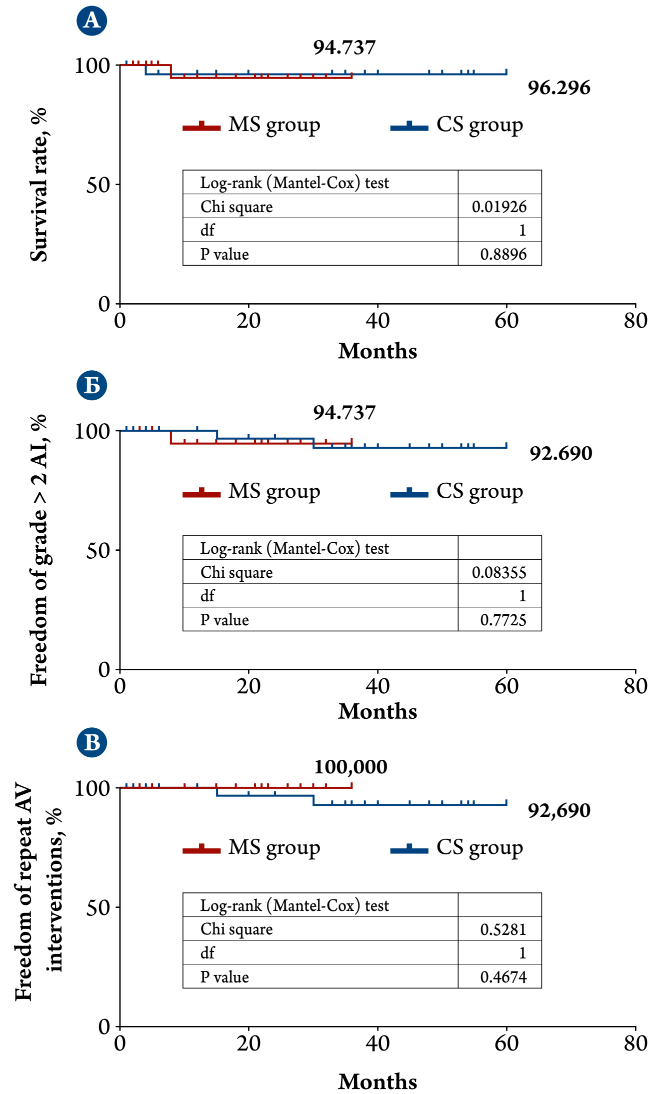
The findings were statistically processed using SPSS 23.0 and GraphPad Prism 7.0. The quantitative variables are expressed as the mean and the standard deviation (M±SD), and categorical variables are presented as the absolute values and the percentage of the total number. The categorical variables were compared using Pearson's $\chi 2$ test and Fisher's exact test. The Student t-test was used for the comparison of the quantitative variables. An intergroup PSM analysis was conducted using 1:1 nearest-neighbor matching to increase the significance of results, taking into account the preoperative profiles summarized in Table 1. The survival rate, absence of repeat interventions, and absence of severe AI were assessed using the Kaplan-Meier method.

Results

The perioperative profiles and direct outcomes are shown per study groups in Table 2.

Depending on the nature of the combination interventions, the groups did not differ significantly in the number of "half-arch" interventions and mitral valve reconstructions. It should also be noted that the combination complete replacement of the aortic arch

Figure 3. Midterm survival rate (A) of patients, the absence of grade >2 aortic insufficiency (B), and no need for repeat interventions (B) during the mean follow-up period of 13.8±10.3 (1–38) months and 42±21 (1-61) months in the MS and CS groups, respectively



Log-rank (Mantel-Cox) test, the logarithmic rank Mantel–Cox test used to compare two survival curves; Chi-square, the chi-square test; df, the number of degrees of freedom; p value, the measure of the probability.

(2 [6.6% vs. 14 [22.9%]; p=0.047) and myocardial revascularization (0 [0%] vs. 8 [13%]; p=0.049) were performed in significantly more cases before PSM in the CS group. However, these differences between the groups disappeared after PSM (p=1.000).

In the MS group, there were significant increases in intraoperative profiles after PSM: the duration of cardiopulmonary bypass (CPB) (147±14 vs. 134±31 min; p=0.0444) and aortic compression (130±17 vs. 115±21 min; p=0.0035). However, it should be noted that the minimally invasive approach had significant advantages in intraoperative blood loss (710±171 mL

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vs. 1065±288 mL; p=0.001), 48-hour postoperative drainage loss (317±101 mL vs. 647±300 mL; p=0.001), postoperative ventilation time (5±1.9 h vs. 9.2±1.3 h; p=0.0001), duration of stay in intensive care unit (ICU) (1.2±0.4 days vs. 1.9±0.9 days; p=0.003), and duration of hospitalization (8±2.6 days vs. 10.8±4.5 days; p=0.005).

In the MS group, one (3.3%) patient required intraoperative conversion due to emergency myocardial revascularization. The mortality in both groups was due to the development of prosthesis infection, sepsis, and multiple-organ system failure, and was equal to 3.3% (p=1.000). The groups did not differ significantly in the number of postoperative bleeding events requiring repeat wound revision (p=0.4915), the incidence of deep sternal infection (p=1.000), hemorrhagic tamponade (p=1.000), and respiratory failure (p=0.1028).

Midterm Outcomes

The mean follow-up period was 13.8±10.3 (1–38) months and 42±21 (1–61) months in the MS and CS groups, respectively. Midterm survival did not differ significantly between the groups, and was 94.7% vs. 96.3% (p=0.89) in the MS and CS groups, respectively (Figure 3A).

The two deaths in the CS and MS group occurred at 3 and 8 months, respectively, during hospitalization for the development of prosthetic valve infection, and are described above.

In the long-term period, one (3,3%) patient had grade >2 AI at 8 months in the MS group, associated with infectious endocarditis with the involvement of aortic and mitral valves. In the CS group, two patients (6.6%) had moderate AI. The number of cases with grade >2 AI did not differ significantly between the groups, and was 94.7% vs. 92.7% (p=0.77) in the MS and CS groups, respectively (Figure 3B). There were no repeat AV interventions in the MS group; two patients in the CS group required repeat surgeries due to the progression of annuloaortic ectasia and valve prolapse at 15 and 30 months. Thus, repeat intervention was not required in 100% and 92.7% of cases in the MS and CS groups, respectively (p=0.467) (Figure 3C).

Discussion

Cardiac surgery in its present stage shows a paradigm shift in the approach to the treatment of patients with severe thoracic aortic disease. This field of surgery, in its earliest days, prioritized saving the patient's life; now, after achieving the best-possible results and having gained sufficient experience, it puts the patient's quality of life and reducing surgical trauma first.

For example, Bentall-DeBono's surgery, which was suggested more than 50 years ago, remains the gold standard in aortic root and AAo surgery due to its consistent long-term results [10]. However, the rate of valve-preserving interventions has been increasing over the past 20 years. The desire to improve the patient's quality of life and eliminate complications associated with the use of warfarin is expressed in the long-term 20-year results confirming certain benefits of the David procedure [11].

The reduction of surgical trauma is another way to improve the outcomes of thoracic aortic surgery. The minimally invasive approach has certain advantages over the conventional approach: decreased blood loss, intensity and duration of pain syndrome, and duration of rehabilitation, as well as rapid readaptation to work [4, 8, 12, 13]. However, the David procedure is technically difficult to perform. The immediate and, most importantly, the long-term AV functional outcome directly depends on the quality of the procedure, which makes it impossible to use it routinely due to the limited operational field and poor exposition of the minimally invasive approach. When we began to use the minimally invasive approach for the David procedure, a sufficient number of conventional aortic root and AAo interventions had been performed in our hospital, including the David procedures (more than 100)—which, in our opinion, allowed eliminating the effect of the learning curve on the procedure outcome and obtaining comparable benefits with the CS group. Moreover, a PSM analysis was performed to assess the safety and efficacy of the technique and define the advantages over the conventional approach. The step-by-step approach allowed a comparable rate of mortality (3.3% vs. 3.3%; p=1.000), incidence of neurological complications (3.3% vs. 3.3%; p=1.000), repeat exploratory surgery for bleeding (0% vs. 6.6%; p=0.4915) in the MS and CS groups, respectively. In the MS group, only one (3.3%) patient required urgent conversion to CS due to emergency myocardial revascularization, which is consistent with the literature [14]. These findings demonstrate the safety of the minimally invasive approach, which is also due to the gradual step-by-step implementation of this approach as the surgical team gained sufficient experience.

Moreover, according to our data, the minimally invasive intervention increases significantly the duration of CPB (147±14 vs. 134±31 min; p=0.0444) and aortic compression (130±17 vs. 115±21 min; p=0.0035) in the MS group. This may be mainly because wound manipulations (clamping and installing a left ventricular drain tube in large aneurysms, pericardial drainage, suturing of external pacing leads, etc.) are partially performed before unclamping the aorta during CPB, as well as because of the limited exposure. However, recent papers have shown a significant decrease in intraoperative time as experience is being accumulated and the number of interventions increases [8, 14, 15]. The learning curve may also have an effect, which was shown in our previous works [4]. In the 3-year period of using the minimally invasive aortic root and AAo interventions in our center, the time of CPB and aortic compression decreased (147±8.7 vs. 141±3.6 min; p=0.581, and 12 8± 6,4 vs. 118±3,6 min; p=0.155, respectively), as did intraoperative blood loss (750±150 vs. 660±177 mL; p=0,007), as did the incision-to-suture time (5.15±2.97 vs. 4.27±0.5 min; p=0.5) during the David procedure.

As for the benefits of mini-sternotomy versus the conventional approach in our study, a significant reduction in blood loss, drainage loss, postoperative ventilation time, duration of stay in the ICU, and hospitalization ($p < 0.05$) should be highlighted.

The long-term rate of the absence of severe grade >2 AI and repeat interventions was 94.7% and 100% in the MS and CS groups, respectively ($p>0.05$). The long-term survival rate (94.7% vs. 96.3%; p=0.89) was also comparable and did not differ from similar studies of the minimally invasive David procedures [14–16]. The outcomes also show the high safety of the minimally invasive approach.

However, certain limitations of this study should be mentioned: different follow-up periods in the groups (13.8±10.3 months in the MS group and 42±21 months in the CS group), and the use of retrospective data in the CS group. The described differences and benefits may result from the David procedure learning curve, since the first interventions included in the study date back to 2014 in the CS group and 2016 in the MS group. Prospective randomized trials may be required in the future to obtain more significant benefits and disadvantages of minimally invasive, valve-preserving interventions.

Conclusion

The David procedure with mini-sternotomy is a safe and effective technique with low case fatality and complication rates. It can be used as a routine procedure in a hospital with extensive experience of conventional interventions. Our experience showed that, unlike conventional approaches, the minimally invasive technique is associated with a significant increase in the duration of cardiopulmonary bypass, myocardial ischemia, and decrease in blood loss, drainage loss, postoperative ventilation time, duration of stay in the intensive care unit and hospitalization ($p < 0.05$). However, prospective randomized trials are required to identify more reliable benefits and burdens of minimally invasive, valve-preserving interventions.

No conflict of interest is reported.

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