

**Original Article** 

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# Outcomes of Valve-Sparing Aortic Root Replacement (David I Procedure) at a Single Center in Kazakhstan.

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#### Abstract

Valve-sparing aortic root replacement, commonly known as the David procedure, stands as a pioneering surgical technique aimed at addressing aortic root aneurysms while retaining the patient's native aortic valve. This procedure signifies a significant advancement in cardiac surgery, offering patients the potential for improved outcomes both in the short and long term.

**Aims.** The aim of the study was to analyze short- and long-term outcomes after valve sparing aortic root replacement operation using David I technique.

**Methods.** From January 2013 to November 2020 a total 124 David I procedures were performed. We analyzed survival and freedom from reoperation. Follow-up was performed 8 years postoperatively.

**Results.** Early mortality was 0.8% (n = 1). Mean age was  $48.25 \pm 17.42$ . The left ventricular ejection fraction (%) before discharge was significantly increased (p = 0.038) after surgery. The 1, 3, 6, 8 –year survival and freedom from reoperation rates were 99%, 99%, 98%, 87% and 99%, 98%, 95%, 91% retrospectively.

**Conclusion.** David procedure is a valuable option for treating aortic root aneurysms offering the potential for excellent long-term outcomes, especially when the native aortic valve can be preserved. The decision should be made on a case-by-case basis, considering the patient's individual factors and the expertise of the surgical team.

**Keywords:** Aortic root aneurysm, David procedure, valve-sparing aortic root replacement, aortic surgery.

## Introduction

The valve-sparing aortic root replacement, commonly known as the David procedure, is a surgical technique used to treat aortic root aneurysms or conditions affecting the aortic valve. This procedure is named after its pioneer, Dr. Tirone David, who introduced it in the 1990s as an alternative to traditional aortic valve replacement (AVR) with a mechanical or biological valve [1]. The aortic root, comprising the aortic valve and the beginning portion of the aorta, can sometimes become enlarged due to various reasons, such as genetic predisposition, connective tissue disorders like Marfan syndrome, or age-related degeneration [2]. This enlargement, known as an aortic root aneurysm, can lead to life-threatening complications like aortic dissection or rupture.

The David procedure was developed to address these issues while preserving the patient's native aortic valve whenever possible. Unlike traditional AVR, where the aortic valve is replaced along with the diseased aortic root, the David procedure aims to conserve the patient's own valve, thus potentially avoiding the need for long-term anticoagulation therapy and the risk of prosthetic valve-related complications [3]. In essence, the Valve-sparing aortic root replacement or David procedure represents a significant advancement in aortic root surgery, offering patients the possibility of preserving their native valve while effectively treating aortic root aneurysms, thereby enhancing their long-term prognosis and quality of life.

The aim of the study was to analyze both short- and long-term outcomes of patients who underwent valve-sparing aortic root replacement (David I procedure) at a single center in Kazakhstan. Specifically, the study focused on evaluating the survival rates and freedom from reoperation after this surgical technique was performed. The follow-up period for these patients extended up to eight years postoperatively to assess the effectiveness and durability of the procedure over time

## **Materials and Methods**

## Ethics

This study was conducted in accordance with the ethical standards of our institution and adheres to the principles outlined in the Declaration of Helsinki. As a retrospective study, it did not require institutional review board approval according to our institution's policies.

#### Study design

Between January 2013 and November 2020, 124 patients underwent the David procedure using the classical reimplantation method, known as the David I technique. We conducted a retrospective analysis of the outcomes for these 124 patients. The procedures included isolated David procedures as well as those involving aneurysms or aortic dissections. Additionally, some patients required coronary artery bypass grafting (CABG), as well as repair or replacement of the mitral or tricuspid valves.

Preoperatively, all patients routinely underwent transthoracic echocardiography (TTE) and computed tomography (CT) for lesion assessment. Coronary angiography was performed as indicated. Intraoperatively, transesophageal echocardiography (TEE) was utilized before surgery and again postoperatively to assess myocardial contractility, the degree of heart valves insufficiency and the nature of the lesion, the size of the heart chambers and aorta, and so on.

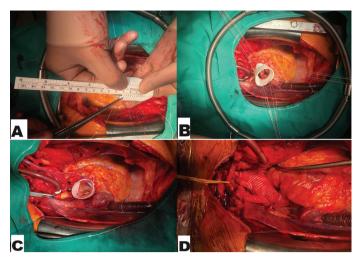
This retrospective study included follow-up data collected over an average of 8 years. We evaluated survival rates, freedom from reoperation, and various postoperative outcomes.

#### **Operative procedures**

We used standard David 1 technique for all patients, with vascular (Woven Polyester) graft (Figure 1). The procedure were performed through a standard full sternotomy approach. Patients received total anesthesia with endotracheal intubation. Aortic cannulation was executed higher than usual, closer to the aortic arch, and a two-stage cannula was used for venous return through the right atrium. Patient cooling was required during aortic arch replacement, followed by selective cerebral perfusion and circulatory arrest.

#### Statistical analysis

Descriptive statistics were used to summarize the baseline characteristics and perioperative data. Continuous variables were compared using Student's t-test or Mann-Whitney U test, as appropriate. Categorical variables were analyzed using the chi-square test or Fisher's exact test. Kaplan-Meier survival analysis was used to estimate overall survival and freedom from reoperation, with differences between subgroups assessed using the log-rank test. All data are presented as mean  $\pm$  standard



**Figure 1** – Reimplantation (David) procedure for the patient with acute aortic dissection. (A) Measuring the height of the neoaortic root. (B) Aortic valve reimplanted into a vascular graft. (C) Aortic valve cusps assessment. (D) Final view of operation

deviation with or without ranges, or the numbers and percentages were appropriate. A p-value <0.05 was considered statistically significant.

## **Results**

The study cohort (Table 1) had a mean age of 48.25 years, with a notable male predominance (57.2%). The high prevalence of arterial hypertension (76.6%) and ischemic heart disease (20.1%) indicates that these patients had significant cardiovascular risk factors.

#### Table 1 Patient Characteristics

Valuables	n = 124	
Age, years	48.25 ± 17.42	
Male sex	71 (57.2)	
Body mass index (kg/m <sup>2</sup> )	28.00 ± 5.86	
Body surface area (m <sup>2</sup> )	1.96 ± 0.22	
Height (cm)	172.08 ± 11.07	
Weight, (kg)	82.58 ± 17.35	
Arterial hypertension	95 (76.6)	
Diabetes	10 (8)	
Ischemic heart disease	25 (20.1)	
Atrial fibrillation	7 (5.6)	
Bundle branch block	3 (2.4)	
Chronic renal failure	5 (4.03)	
Multifocal atherosclerosis	11 (8.87)	
Pulmonary hypertension	8 (6.4 )	
Aortic dissection	17 (13.7)	
LVEF (%)	56.6 ± 7.0	
NYHA III–IV	46 (37.0)	
Mitral insufficiency	22 (17.7)	
Bicuspid AV	37 (29.8)	
Diameter of the aorta ascending (mm)	50.6 ± 5.8	
Diameter of the aortic root (mm)	44.8 ± 7.7	
Aortic valve insufficiency		
grade 0	7 (5.6)	
grade I	15 (12.0)	
grade II	28 (22.5)	
grade III	52 (41.9)	
grade IV	22 (17.7)	

Data presented as mean and standard deviation with or without ranges, or the numbers and percentages. LVEF, left ventricular ejection fraction; NYHA, New York Heart Association. The average cardiopulmonary bypass (CPB) time was 159.7 minutes, and the aortic cross-clamp time was 121.1 minutes (Table 2).

#### Table 2

Intraoperative characteristics

Type of operation	Total n = 124
Combined operation	56 (45.1)
Re-operation (redo)	0 (0,0)
Isolated David pr. and aorta ascending replacement	68 (54)
Combined surgeries David pr. and partial or total aortic arch replacement	20 (16)
David pr. and CABG	19 (15)
David pr. and MV reconstruction	10 (8)
David pr. and CABG + MV reconstruction	4 (3.2)
David pr. and MV+TV reconstruction	3 (2.4)
Size of prosthesis (mm)	28.9 ± 2.3
AV cusps intervention	45 (36.2)
CPB Time (min)	159.7 ± 37.1
Cross clamp time (min)	121.1 ± 25.3

Data presented as mean and standard deviation with or without ranges, or the numbers and percentages. CABG, Coronary artery bypass grafting; MV, Mitral valve; TV, Tricuspid valve; AV, Aortic valve; CBP, Cardiopulmonary bypass.

Low Cardiac Output Syndrome was in 3 (2.4%) cases. Arrhythmias requiring therapy was in 33 (26.6%) patients and pacemaker implantation was in 3 (2.4%) of patients. Reoperation for bleeding was 11 (8.8%) cases and cerebrovascular accidents/ stroke was in 1 (0.8%) patient. The 30-day mortality rate was 0.8% (Table 3).

Table 3

Postoperative characteristics

Complications	n = 124
Low cardiac output syndrome	3 (2.4)
Arrhythmias (requiring medical therapy/ cardioversion)	33 (26.6)
Pacemaker implantation	3 (2.4)
Reoperation for bleeding	11 (8.8)
Cerbrovascular accidents/Stroke	1 (0.8)
Renal failure	1 (0.8)
Gastrointestinal complications	3 (2.4)
80-day mortality	1 (0.8)
Number of days after surgery before discharge	8.60 ± 4.93
Aortic valve insufficiency	
grade I	19 (15.3)
grade II	0 (0)
Aortic valve stenosis	0 (0)

Data presented as numbers and percentages and mean and standard deviation with ranges.

The echocardiographic data (Table 4) before discharge and at follow-up provide critical insights into the procedure's effectiveness: gradient on aortic valve: the stability of the mean gradient was 6.45 mmHg before discharge to 6.88 mmHg at follow-up. Left Ventricular Ejection Fraction (LVEF%): significant improvement from 49.85% before discharge to 55.47% at follow-up (p = 0.038).

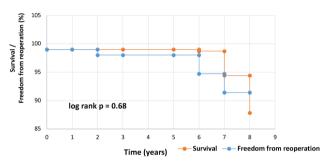


Echocardiagraphic data

Echocardiagraphic data	before discharge (n = 123)	follow-up (n = 95)	P value
Gradient on the aortic valve (mmHg)	6.45 ± 2.58	6.88 ± 3.72	0,1143
Left ventricular ejection fraction (%)	49.85 ± 9.60	55.47 ± 12.96	0,0384
Left ventricular end- diastolic volume (ml)	134.00 ± 33.57	146.36 ± 61.39	0,5516

Data presented as mean and standard deviation with or without ranges, or the numbers and percentages.

The long-term survival rates (99% at 1 and 3 years, 98% at 6 years, and 87% at 8 years) and freedom from reoperation (99% at 1 year, 98% at 3 years, 95% at 6 years, and 91% at 8 years) are indicative (Figure 2).



**Figure 2** – Kaplan-Meier curves for the entire cohort patients. Survival curve and freedom from aortic valve-related reoperation

## Discussion

The outcomes of the David procedure at the National Scientific Medical Center in Astana, Kazakhstan, affirm its efficacy and safety for treating aortic root aneurysms in our center. This discussion analyze the implications of these findings, compares them with existing literature, and addresses the limitations and future directions for this surgical technique.

The primary objective behind the David procedure is to maintain the functionality of the patient's natural valve while correcting the aneurysmal dilation of the aortic root. This technique involves replacing the dilated portion of the aorta while preserving the native aortic valve and reimplanting it into a Dacron graft, which acts as a support structure for the repaired aortic root.

The enduring success of the David procedure manifests over the long term, offering several advantageous outcomes. Previous studies showcase the sustained durability of the preserved aortic valve over an extended period, often circumventing the necessity for additional interventions due to valve dysfunction [4].

The relatively young age of patients in our study suggests that the David procedure is often chosen for younger individuals who may benefit from valve preservation over the long term, avoiding the complications associated with prosthetic valves. The David procedure success hinges on meticulous surgical technique and intraoperative management. These durations of procedure are comparable to other complex cardiac surgeries in our department and reflect the technical demands of the procedure (Table 2). Despite these challenges, the absence of redo surgeries within the cohort suggests that the initial surgeries were performed with high precision and effectiveness.

The long-term survival rates (Figure 2) are acceptable for us in this study. These outcomes affirm the procedure's durability and ability to provide sustained benefits without additional interventions. This aligns with other studies demonstrating similar long-term success rates for the David procedure [5, 6]. Long-term observations indicate lower occurrences of complications typically associated with neo-root (prosthetic), such as infections, thrombotic events, or structural valve deterioration [7].

Patients undergoing successful valve-sparing procedures typically enjoy an improved quality of life compared to those necessitating mechanical valve replacements. This is attributed to avoiding lifelong anticoagulation and retaining the functionality of their native valve [8-12].

These outcomes underscore the clinical efficacy and promise of the David procedure in mitigating complications, enhancing patient well-being, and extending longevity by preserving the native aortic valve. However, individual variations, surgical techniques, and post-operative care profoundly impact these outcomes, emphasizing the necessity for diligent patient monitoring and adherence to medical guidance for optimal results.

Retaining the native aortic valve offers significant benefits, such as a lower risk of thromboembolic events, which are more common with mechanical valve replacements. This can lead to better hemodynamics and potentially improved long-term quality of life compared to those receiving prosthetic valves [13-17].

The rate of postoperative arrhythmias (26.6%) is in line with other cardiac surgeries in our clinic. Arrhythmias are common after heart surgery and often manageable with medication or intervention. Pacemaker implantation (2.4%): This low rate suggests that the procedure does not significantly disrupt the heart's electrical conduction system in this study. This is also a procedure demonstrated low rates of postoperative complications such as low cardiac output syndrome (2.4%), cerebrovascular accidents (0.8%) and low incidence of reoperation for bleeding (8.8%)

These rates are consistent with reported in other studies, indicating that this procedure is not only effective but also safe for most patients [18-23].

The echocardiographic data (Table 4) indicates that the valve function is well-maintained postoperatively and left ventricle function demonstrates enhanced cardiac function, likely due to the relief of aortic valve regurgitation and improved ventricular mechanics in the long term. Similar studies have reported comparable improvements in LVEF, reinforcing the benefit of valve preservation over replacement [17].

One of the significant findings of this study is the improvement in left ventricular ejection fraction (LVEF) postoperatively, from 49.85% before discharge to 55.47% at follow-up, comparable to preoperative data. Here we can assume that despite the decrease in ejection fraction after surgery, taking into account myocardial ischemia and traumatism of the operation, myocardial function is restored in the long term.

The continual advancement of cardiac surgical techniques holds promise for further refining outcomes and expanding the horizons of patient care in the realm of aortic root aneurysm management.

It's important to note that the decision to perform the David procedure depends on the specific characteristics of the patient's condition, and not all patients may be suitable candidates. The choice between the David procedure and other aortic surgery techniques is made based on individual factors and the surgeon's expertise.

The outcomes of this study are comparable with those reported in other centers performing the David procedure. For instance, a study by Kvitting et al. reported 5 years, the survival rate was  $98.7\% \pm 0.7\%$ , and at 10 years, it was  $93.5\% \pm 5.1\%$ . The freedom from reoperation on the aortic root for any cause at 10 years was  $92.2\% \pm 3.6\%$ , with three reoperations due to structural valve deterioration. The freedom from structural valve deterioration at 10 years stood at  $96.1\% \pm 2.1\%$  [12], which is consistent with the results observed in our study.

The survival rates of 99% at 1 and 3 years, 98% at 6 years, and 87% at 8 years are impressive and align with findings from other centers performing this procedure. The freedom from reoperation rates also remained high, with 99% at 1 year, 98% at 3 years, 95% at 6 years, and 91% at 8 years. These results affirm the procedure's long-term efficacy and its potential to provide sustained benefits without the need for further surgical interventions.

The success of the David procedure heavily relies on careful patient selection and the expertise of the surgical team. Patients with a structurally intact aortic valve, free from significant sclerosis or calcification, are ideal candidates. The decision to proceed with the David procedure should be individualized, considering the patient's specific anatomical and clinical characteristics. Furthermore, the proficiency of the surgical team in performing this technically demanding procedure is crucial for achieving optimal outcomes.

#### Limitations

This study has several limitations that should be acknowledged. Firstly, it is a retrospective study, which limits the collection of additional data. Secondly, the follow-up period, although averaging 4.6 years, may not be sufficient to capture all long-term complications or reoperations.

Considering that the operations were performed on patients from all over the region of Kazakhstan, follow-up examinations in our clinic were limited due to the time and financial burden. It would also be useful to assess the quality of life.

Additionally, the study was conducted at a single center, which may limit the generalizability of the findings to other populations or healthcare settings.

## Conclusion

The outcomes of the David procedure have shown promising results. Studies indicate favorable survival rates and reduced incidences of valve-related complications, making it an attractive option for eligible patients with aortic root pathology.

By preserving the native aortic valve, this procedure reduces the need for lifelong anticoagulation therapy and enhances patient quality of life. Considering our relatively limited experience careful patient selection are essential for achieving the best possible outcomes, and ongoing research is needed to continue improving and expanding the use of this valuable technique in Kazakhstan.

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