# Use of glutaraldehyde-treated autologous pericardial patch in complete atrioventricular septal defect repair

O. DOYURGAN<sup>1</sup>, H. BALIK<sup>2</sup>

**Abstract.** – **OBJECTIVE:** Synthetic patch materials, such as polytetrafluoroethylene and knitted polyester, are commonly used for the repair of complete atrioventricular septal defects using the double-patch technique. In our study, we investigated the impact of glutaraldehyde-treated autologous pericardial patch on postoperative atrioventricular valve function.

PATIENTS AND METHODS: In this retrospective study, patients who underwent repair of complete atrioventricular septal defects using the double-patch technique between January 1, 2018, and May 15, 2023, at our pediatric cardiac center were included in the study. Patients were divided into two groups based on the type of patch used for the repair of the ventricular component of the atrioventricular septal defect: autologous pericardial patch (group 1) and polytetrafluoroethylene patch (group 2). Postoperative data of the patients were retrospectively analyzed.

RESULTS: Thirty-four patients (57.6%) were female, and 25 (42.4%) were male, with a median age of 7 (5-18) months. The median body weight at the time of surgery was 5.5 (4.1-10) kilograms. Down syndrome was present in 45 (76.3%) patients. The autologous pericardium was used for ventricular septal defect closure in 44 (74.6%) patients (Group 1), while polytetrafluoroethylene was used in 15 (25.4%) patients (Group 2). Permanent cardiac pacemaker placement was required in 4 (6.8%) patients due to postoperative atrioventricular block. Hospital mortality was 11.9% (n=7). Among these cases, 4 (6.8%) patients died from low cardiac output syndrome, and 3 (5.1%) patients died from sepsis. Postoperative echocardiographic evaluation revealed insignificant residual ventricular septal defects in 17 (28.8%) patients. No significant differences were observed between the groups in terms of mortality and postoperative atrioventricular valve insufficiency. The median follow-up duration for discharged patients was 5 months (7 days to 3.9 years). Throughout the follow-up period, there were no reoperations due to valve insufficiency or left ventricular outflow tract obstruction.

conclusions: Glutaraldehyde-treated autologous pericardium is a safe material that can be confidently used for the repair of the ventricular component of complete atrioventricular septal defects. This patch material does not adversely affect atrioventricular valve function and allows for the successful closure of ventricular septal defects.

Key Words:

Complete atrioventricular septal defect, Congenital heart surgery, Pericardium, Repair.

### Introduction

Since the first successful repair of complete atrioventricular septal defect (AVSD) in 1955, significant progress has been made in the operative management of these patients. In addition to advancements in cardiopulmonary bypass, myocardial protection, and postoperative intensive care, surgical repair techniques have continued to evolve. Repair methods for AVSD include classic single-patch, double-patch, modified single-patch, and, more recently, no-patch techniques<sup>1</sup>.

While early outcomes of primary AVSD repair in infants are favorable, the most common indication for reoperation is left atrioventricular (AV) valve insufficiency. Most reoperations on the left AV valve occur within the first year after correction. However, a persistent risk of late mortality during follow-up remains<sup>2,3</sup>. AV valve insufficiency, often caused by suture dehiscence, is attributed to factors, such as low body weight and delicate leaflet tissue<sup>4</sup>. Anchoring bridging leaflets onto a rigid synthetic patch may adversely affect the natural dynamics of the AV valves<sup>5</sup>.

We hypothesized that autologous pericardial patches, a natural material, could effectively harmonize with the delicate tissue of the AV valves. Therefore, we utilized autologous pericardial patches for

<sup>&</sup>lt;sup>1</sup>Department of Pediatric Cardiac Surgery, Dr. Gazi Yasargil Training and Research Hospital, Diyarbakir, Turkey

<sup>&</sup>lt;sup>2</sup>Department of Pediatric Cardiology, Gazi Yasargil Education and Research Hospital, Diyarbakir, Turkey

the repair of the ventricular component of AVSD. In this study, we evaluated the impact of glutaraldehyde-treated autologous pericardial patches on AV valve function and compared these results with patients who underwent closure of ventricular septal defects using polytetrafluoroethylene (PTFE) patches.

#### **Patients and Methods**

## **Patient Population**

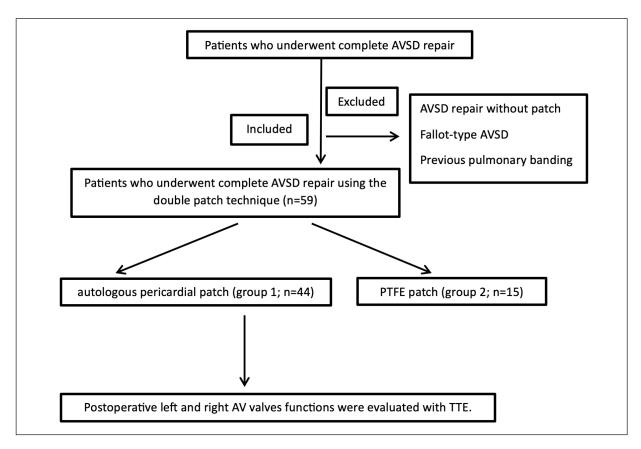
In this retrospective study, patients diagnosed with complete atrioventricular septal defect (AV-SD) who underwent repair using the double-patch technique with glutaraldehyde-treated autologous pericardium and polytetrafluoroethylene (PTFE) patches for closure of ventricular septal defects (VSD) between January 1, 2018, and May 15, 2023, at our pediatric cardiac center were included in the study. Patients with VSD components not closed with a patch, those with Fallot-type AVSD, and those who had previous pulmonary banding were excluded from the study. The flow diagram of the study is shown in Figure 1.

The study protocol was approved by the Health Sciences University, Gazi Yaşargil Training and Research Hospital Ethics Committee (Date: 23/6/2023, No: 446). Informed consent was obtained from each patient's parent or legal guardian and study was conducted in accordance with the principles of the Declaration of Helsinki.

#### Data Collection

During the retrospective analysis, data were collected from the hospital database, including age, gender, body weight at the time of surgery, associated genetic anomalies, cross-clamp and cardiopulmonary bypass durations, postoperative mechanical ventilation (MV) duration, length of stay in the intensive care unit (ICU), total hospital stay duration, vasoactive inotrope score, postoperative complications, and follow-up duration. Patients were categorized into two groups based on the type of patch used for the repair of the ventricular component of AVSD: autologous pericardial patch (group 1) and PTFE patch (group 2).

Postoperative transthoracic echocardiography was performed in the ICU to evaluate the function



**Figure 1.** Flow diagram of the study. AV, atrioventricular; AVSD, atrioventricular septal defect; PTFE, polytetrafluoroethylene; TTE, transthoracic echocardiography.

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of the left and right AV valves. AV valve function was classified as trivial/mild or moderate/severe insufficiency. After discharge, outpatient follow-up visits were scheduled at 1, 3, and 6 months and subsequently annually.

# Surgical Technique

Standard aortic-bicaval cannulation, moderate hypothermic cardiopulmonary bypass, and del Nido cardioplegia were employed for all patients. The standard AV valve was approached from the right atrium. Both leaflets of the AV valve were marked with sutures at common coaptation points. VSD closure was performed using a glutaraldehyde-treated autologous pericardial patch in 44 patients (74.6%) and PTFE patch in 15 patients (25.4%). A D-shaped patch of appropriate size was prepared based on preoperative echocardiography and intraoperative assessment. The convex side of the patch was continuously sutured to the ventricular crest using 6-0 polypropylene sutures. The flat side of the patch was attached to the bridging leaflets with individual U stitches using 6-0 polypropylene sutures. These stitches were also used to secure the atrial septal defect (ASD) patch to the AV valves. Care was taken to ensure that the VSD patch was not excessively wide or too narrow to create tension on the AV valves.

The mitral cleft was repaired using individual 6-0 polypropylene sutures. The mitral valve was tested by filling the left ventricle with saline. Subsequently, the right ventricle was filled to test the tricuspid valve, and commissuroplasty was performed if insufficiency was observed. In all patients, the primum ASD was closed using glutaraldehyde-treated autologous pericardial patch, leaving the coronary sinus in the right atrium; the foramen ovale was left open.

#### Statistical Analysis

Statistical analysis of the obtained data was performed using SPSS version 23.0 (IBM Corp., Armonk, NY, USA) software package for Windows. For continuous variables, parametric data were presented as mean  $\pm$  standard deviation (SD), while non-parametric data were presented as median (minimum-maximum) values. For the assessment of categorical variables in binary groups, the Chi-square test was used, while the independent samples Student's *t*-test was used for normally distributed measurements. The Mann-Whitney U test was conducted for continuous variables that did not exhibit a normal distribution. A value of p < 0.05 was considered statistically significant.

#### Results

Of the patients, 34 (57.6%) were female, 25 (42.4%) were male, and the median age was 7 months (5-18 months). The median body weight at the time of surgery was 5.5 kg (4.1-10 kg). Down syndrome was present in 45 patients (76.3%). Preoperatively, seven patients (11.9%) were admitted to the intensive care unit (ICU), and three of them (5.1%) required intubation. Preoperative moderate/severe AV valve regurgitation was present in 18 patients (30.5%). The distribution of Rastelli types was as follows: Type A, 59.3%, Type B, 10.2%, and Type C, 30.5%. Autologous pericardium (Group 1) was used for VSD closure in 44 patients (74.6%), and PTFE (Group 2) was used in 15 patients (25.4%). There were no significant differences between Groups 1 and 2 in terms of gender, age at surgery, body weight at surgery, and preoperative status (ICU admission and mechanical ventilation support). The demographic characteristics and preoperative data of the patients are presented in Table I.

The median cross-clamp time was 112 (74-199) minutes, median cardiopulmonary bypass time was 160 (113-265) minutes, median ICU stay was 8 (2-34) days, and median hospital stay was 12 (5-64) days. Additional surgical procedures included patent ductus arteriosus ligation in nine patients (15.2%) and closure of secundum atrial septal defect in 10 patients (18.6%). Analysis revealed no significant differences between the two groups in terms of cross-clamp time, cardiopulmonary bypass time, ICU stay, and hospital stay. The operative and postoperative data of the patients are presented in Table II.

Postoperative arrhythmia was the most common complication observed, with postoperative AV block occurring in 11 patients (18.6%). These patients left the operating room with temporary pacemakers. Of these, seven patients (11.9%) returned to sinus rhythm during ICU follow-up. Four patients (6.8%) who did not revert to sinus rhythm had permanent pacemaker implantation due to complete AV block. Supraventricular tachycardia occurred in two patients (3.4%) and was treated medically. Other frequently observed complications included sepsis in five patients (8.5%), acute renal failure requiring peritoneal dialysis in four patients (6.8%), low cardiac output syndrome in four patients (6.8%), and pneumonia in two patients (3.4%). Postoperative ICU complications are presented in Figure 2.

Hospital mortality was 11.9% (n=7). Among these patients, four (6.8%) died due to low cardiac

**Table I.** Demographic characteristics and preoperative data of the patients.

Characteristics	Autologous pericardial patch n=44 (74.6%)	PTFE patch n=15 (25.4%)	Total N=59	P
		, ,		
Age at repair, month	6 (5-18)	7 (5-12)	7 (5-18)	$0.32^{\dagger}$
Weight, kg	5.5 (4.1-10)	5.4 (4.5-7.4)	5.5 (4.1-10)	$0.98^{\dagger}$
Gender				
Female	25	9	34	$0.82^{\ddagger}$
Male	19	6	25	
Preoperative condition				
On ÎCU	4	3	7	$0.25^{\ddagger}$
MV support	2	1	3	$0.74^{\ddagger}$
Preoperative LAVVR				
Trivial/mild	31	10	41	$0.78^{\ddagger}$
Moderate/severe	13	5	18	
Preoperative RAVVR				
Trivial/mild	28	10	38	0.83‡
Moderate/severe	16	5	21	

<sup>†:</sup>Mann-Whitney U test; ‡:Chi-square test; PTFE, polytetrafluoroethylene; MV, mechanical ventilation; ICU, intensive care unit; LAVVR, left atrioventricular valve regurgitation; RAVVR, right atrioventricular valve regurgitation

**Table II.** Operative and postoperative data of patients.

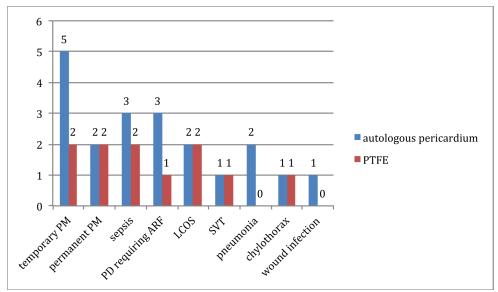
Variables	Autologous pericardial patch n=44	PTFE patch n=15	Total N=59	p
CPB time, min	159.5 (113-265)	166 (117-244)	160 (113-265)	0.708†
ACC time, min	110 (74-199)	118 (83-181)	112(74-199)	$0.486^{\dagger}$
Concomitant procedure				
Yes	14	5	19	0.91‡
No	30	10	40	
Rastelli AVSD types:				
A	28	7	35	$0.286^{\ddagger}$
В	3	3	6	
C	13	5	18	
Complication, n (%)	21	6	27	$0.60^{\ddagger}$
Permanent PM implantation	2	2	4	$0.24^{\ddagger}$
Mortality				
Early (<30 days)	5	1	6	$0.83^{\ddagger}$
Late	0	1	1	
Days on ventilator	2 (1-11)	3 (1-32)	3 (1-32)	$0.31^{\dagger}$
ICU length of stay, days	7 (2-30)	9 (4-34)	8 (2-34)	$0.34^{\dagger}$
Hospital length of stay, days	11.5 (6-42)	13 (5-64)	12 (5-64)	$0.76^{\dagger}$
Postoperative LAVVR				
Trivial/mild	31	11	42	$0.83^{\ddagger}$
Moderate/severe	13	4	17	
Postoperative RAVVR				
Trivial/mild	35	14	49	0.219‡
Moderate/severe	9	1	10	
Follow-up duration, days	200 (7-1414)	50 (9-547)	136 (7-1414)	$0.029^{\dagger}$

<sup>†:</sup>Mann-Whitney U test; ‡:Chi-squared test; PTFE, polytetrafluoroethylene; PM, pacemaker; CPB, cardiopulmonary bypass; ACC, aortic cross-clamp; PM, pacemaker; MV, mechanical ventilation; LAVVR, left atrioventricular valve regurgitation; RAVVR, right atrioventricular valve regurgitation.

output syndrome, and three (5.1%) died due to sepsis. The median follow-up period for discharged patients was 5 months (range: 7 days-3.9 years). During postoperative follow-up echocardiography, hemodynamically insignificant residual VSDs were detected in 17 patients (28.8%).

# Discussion

A contributing factor to the recent improvements in mortality and morbidity in complete atrioventricular septal defect (AVSD) repair is the utilization of novel and diverse patch materials prepared



**Figure 2.** Postoperative complications. PM, pacemaker; PD, peritoneal dialysis; ARF, acute renal failure; LCOS, low cardiac output syndrome; SVT, supraventricular tachycardia; PTFE, polytetrafluoroethylene.

through new techniques. Autologous pericardium offers several advantages as a patch material due to its non-prosthetic nature, lack of tissue reaction, flexibility facilitating ease of use, absence of sterilization requirement, and cost-effectiveness. In our study, we analyzed the impact of using glutaral-dehyde-treated autologous pericardial patches on perioperative and short-term follow-up outcomes in patients diagnosed with complete AVSD. Our findings suggest that glutaraldehyde-treated autologous pericardium could potentially be a suitable patch material for repairing AVSD.

After complete atrioventricular septal defect (AVSD) repair, surgical mortality has shown significant variations among institutions, with reported rates ranging from 3% to 21.7% in the literature<sup>6-9</sup>. In recent years, advancements in surgical techniques and preoperative/postoperative patient management have progressively contributed to the reduction in mortality. In our study, the overall mortality rate in our series was found to be 11.9%, consistent with the existing literature. Despite the decline in postoperative mortality, persistent challenges include left atrioventricular (AV) valve dysfunction, a common early and late complication, and left ventricular outflow tract obstruction, which continues to contribute to morbidity<sup>9</sup>.

Severe left AV valve regurgitation often necessitates reoperation, with initial mitral cleft dehiscence or suture detachment from the left AV valve being a major culprit<sup>1,5</sup>. Postoperative left AV valve regurgitation following complete AVSD

repair has been identified as a prominent risk factor for mortality as well<sup>10</sup>. Studies have reported the probability of not experiencing moderate or worse left AV valve regurgitation to be 68.7% by Xie et al<sup>11</sup> and 85% by Bell et al<sup>12</sup>. In our series, we did not encounter any cases requiring reoperation due to valve insufficiency or left ventricular outflow tract obstruction. The rate of moderate or more severe postoperative left AV valve regurgitation in our patients was 28.8%, consistent with the literature. There were no significant differences detected in terms of mortality and postoperative AV valve regurgitation between patients who received autologous pericardium and those who received polytetrafluoroethylene (PTFE) patches.

There is no universally accepted ideal patch material for the repair of complete atrioventricular septal defects (AVSD). The choice of patch material in surgery is generally determined by the surgeon's personal preference and the center's experience. Autologous pericardium (fresh or processed with glutaraldehyde), bovine pericardium, woven polyester, and polytetrafluoroethylene (PTFE) are commonly used patch materials<sup>5,13</sup>. Studies in the literature have not demonstrated the superiority of one of these patches over the others<sup>14</sup>. Prosthetic materials, such as woven polyester and PTFE, carry a risk of endocarditis<sup>15,16</sup>. On the other hand, fresh autologous pericardium patches may lead to aneurysm formation as the patient grows<sup>17</sup>. Schoof et al<sup>18</sup> reported that aneurysm formation is not solely attributed to the use of fresh autologous pericardium, but is also associated with the use of excessively large patches. In our study, to prevent aneurysm formation and facilitate surgical manipulation, we subjected the autologous pericardium to glutaraldehyde solution. Indeed, none of our patients exhibited aneurysm formation in the patch on the ventricular septum. The literature reports a rate of 1-3.5% for hemodynamically significant residual ventricular septal defects (VSDs)<sup>9,14,19</sup>. In our study, no hemodynamically significant VSDs were observed; however, 17 patients (28.8%) had residual VSDs smaller than 4 mm that were not hemodynamically significant. There was no significant difference in terms of residual VSDs between patients who received autologous pericardium and those who received PTFE patches.

Due to its flexibility and durability, autologous pericardium is a versatile material. Treatment of autologous pericardium with glutaraldehyde strengthens the collagen cross-links of the pericardium, stabilizes its structure, and reduces its elasticity<sup>20,21</sup>. This process strengthens the collagen cross-links of the pericardium, stabilizes its structure, and reduces its elasticity<sup>21</sup>. Glutaraldehyde-treated autologous pericardium is used in various areas of cardiac surgery, such as closing ventricular and atrial septal defects, reconstructing the aortic and mitral valves, the pulmonary artery, and the right ventricular outflow tract<sup>22-25</sup>. In this study, the early-term outcomes of glutaraldehyde-treated autologous pericardium and PTFE patches were compared using the double-patch technique for complete AVSD repair. Our study found no significant differences between the two patch materials in terms of mortality, re-interventions, or AV valve function. We did not encounter any patch-related complications, such as aneurysmal dilation, calcification, thrombosis, or vegetation in patients who received autologous pericardium, either during surgery or in the postoperative period.

The incidence of complete AV block after complete AVSD repair has been reported in various studies to range from 2.1% to 4.3%<sup>1,9,10,19</sup>. In our series, permanent pacemaker implantation was performed in 4 (6.8%) patients due to atrioventricular complete block following complete AVSD repair.

While reviewing the literature, we did not come across a comprehensive series using glutaraldehyde-treated autologous pericardial patches for the repair of the ventricular component of complete AVSD. Our study suggests that autologous pericardium could serve as a valuable patch material option for VSD repair in complete AVSD surgery using the double-patch technique. In times of

global issues such as the COVID-19 pandemic and international conflicts leading to disruptions in the supply chain, autologous pericardium could emerge as a viable alternative to expensive patches. The results of our study show that autologous pericardium with glutaraldehyde can be used successfully in AVSD repair, thus shedding light on future studies.

## Limitations of the Study

Our study has several limitations. Being a single-center and retrospective design constitutes the primary limitations of our study. The relatively small sample size and control group represent another constraint.

#### Conclusions

Glutaraldehyde-treated autologous pericardium is a reliable material for the repair of the ventricular component in complete AVSD. Fixation with glutaraldehyde enhances the usability of the pericardium and reduces the risk of aneurysmal dilation. The use of this patch allows for effective closure of the ventricular septal defect in complete AVSD without significant residual shunting. However, further studies are needed to evaluate its long-term efficacy.

## **Conflict of Interest**

The authors have no relevant financial or non-financial interests to disclose.

## Acknowledgments

The authors acknowledge the contribution of Osman Akdeniz, Yiğit Kılıç, Ahmet Kuddusi İrdem, and Bedri Aldudak.

#### Funding

The authors declare that no funds, grants, or other support were received during the preparation of this manuscript.

#### Authors' Contribution

All authors contributed to the study's conception and design. Material preparation, data collection, and analysis were performed by Onur Doyurgan. The first draft of the manuscript was written by Onur Doyurgan and Hasan Balık. Onur Doyurgan and Hasan Balık reviewed and edited previous versions of the manuscript. All authors read and approved the final manuscript.

## **Ethics Approval**

The study protocol was approved by the Health Sciences University, Gazi Yaşargil Training and Research Hospital Ethics Committee (Approval Number: 2023/446).

#### **Informed Consent**

Informed consent was obtained from the parents or legal guardians of all patients included in the study.

#### ORCID ID

Onur Doyurgan: 0000-0002-4198-3504 Hasan Balık: 0000-0002-3373-1585.

# **Data Availability**

The datasets generated during and/or analyzed during the current study are available from the corresponding author upon reasonable request.

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