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Original Article

Comparison of the Outcome of Ventricular Septal Defect Closure Using GORE-TEX and Autologous Pericardial Patches

Ali SadeghPour Tabaei[1], MD; Masood Darayee[1*], MD; GholamReza Omrani[1], MD; Seyed Mohammad Mahdavi[1], MD

ABSTRACT

Background: Despite the recent experiences and technical advances in the repair of congenital ventricular septal defects (VSDs), there is still the possibility of postoperative complications and even death among patients undergoing treatment.
This study aimed to determine and compare the short-term complications of congenital anomaly (VSDs) repair using the pericardial patch and GORE-TEX patch.

Methods: This cohort study evaluated 100 patients undergoing VSD repair surgery in 2 repair groups of the pericardial patch (50 patients) and the GORE-TEX patch (50 patients) in Rajaie Cardiovascular Medical and Research Center between 2019 and 2020. All the patients' information was recorded in a checklist and analyzed using the SPSS software via the Mann–Whitney and χ^2 tests.

Results: There was a significant difference in the duration of aortic clamping between the pericardial patch and GORE-TEX patch groups (P=0.03). The rate of complications in the GORE-TEX patch group was significantly higher than that in the pericardial patch group (34% vs 14%; P=0.01). The cost of treatment was significantly higher in the GORE-TEX patch group than in the pericardial patch group (P=0.0001).

Conclusions: The lengths of surgery, cardiopulmonary bypass, and aortic clamping, as well as short-term complications and treatment costs, were lower in the pericardial patch group than in the GORE-TEX patch group. ***(Iranian Heart Journal 2022; 23(4): 13-19)***

KEYWORDS: Congenital heart defect, Ventricular septal defect, Pericardial patch, GORE-TEX patch

[1] Rajaie Cardiovascular Medical and Research Center, Iran University of Medical Sciences, Tehran, IR Iran.

***Corresponding Author:** Masood Darayee, MD; Rajaie Cardiovascular Medical and Research Center, Iran University of Medical Sciences, Tehran, IR Iran.
Email: Mdmdmd525@yahoo.com **Tel:** +989143016849

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Ventricular septal defects (VSDs) account for 37% of congenital heart disease cases.[1] The type of intervention required for treatment largely depends on the size and type of defects. Large VSDs with systolic pressure in the right ventricle and the pulmonary artery close to left ventricular and aortic systolic pressures require surgery.[2] The mortality rate in VSD reconstructive surgery is less than 3%.[3] Long-term complications following surgery include infrequent

residual shunts, increased pulmonary hypertension, heart blocks or sinus node dysfunction, and moderate aortic regurgitation.[4] Today, new surgical techniques make it possible to repair these congenital defects with the least incidence of postoperative complications.[5] A bovine pericardial patch with Glutaraldehyde was first used in 1977 to make an artificial heart valve.[6] Most biological materials are eventually lost due to calcification, degeneration, fibrosis, and immune responses. However, they have the potential to act as scaffolds, stimulating tissue growth and regeneration.[7] Although many safety and efficacy studies have confirmed the efficacy of this type of patch in VSD closure,[8-10] the results of this reconstructive surgery have always been controversial, with disagreements over the success rate of some minor side effects of shunting, heart blocks, aortic valve insufficiency, pericardial patch destruction, stiffness, contraction, and calcification.[9,11] Dacron and GORE-TEX synthetic patches are used to repair VSDs, but they are unfortunately associated with complications of vascular aneurysms and calcification.[12,13] It is necessary to employ the most biocompatible and durable tissue available for reconstructive surgery to improve the surgical results and lower the incidence of complications in this group of patients. Therefore, further studies are warranted on the advantages and disadvantages of each of the patches used. Given the hitherto contradictory results of the few studies conducted in this field in Iran, we sought to compare the early outcomes of congenital VSD repair.

Objectives

This study was to determine and compare the short-term complications of congenital anomaly (VSDs) using the pericardial patch and the GORE-TEX patch.

METHODS

The present study was a cohort study conducted after the approval of the Ethics Committee of Iran University of Medical Sciences. The study population was composed of pediatric patients who were diagnosed with congenital VSDs and who underwent repair surgery with the pericardial patch or the GORE-TEX patch between October 2016 and September 2020 in Rajaie Cardiovascular Medical and Research Center. The inclusion criteria consisted of a diagnosis of VSD, the absence of systemic diseases, and the provision of consent to participate in the study. The exclusion criteria were comprised of the presence of complex cardiac anomalies and refusal to participate in the study. The patients were divided into repair subgroups based on the type of patch used: either the GORE-TEX patch or the pericardial patch. The method of surgery was the generally accepted approach to congenital heart defects. For the repair of defects with the autologous pericardial patch, immediately after a sternotomy and a thymectomy, the autologous pericardial patch was cut in the appropriate size. Then, a nurse fixed the patch in a glutaraldehyde solution at a concentration of 0.6% for 5 minutes and washed it in a normal saline solution. Information, including age, sex, the type of VSD, the duration of ventilation, the duration of intensive care unit (ICU) stay, in-hospital mortality, and short-term postoperative complications following the use of the GORE-TEX patch and the pericardial patch, was obtained from the patients' files and recorded in a pre-designed checklist. Data analysis was performed using the SPSS software, version 23, via the Mann–Whitney statistical analysis and the χ^2 test. A *P* value of less than 0.05 was considered statistically significant.

RESULTS

The study population was composed of 100 pediatric patients undergoing congenital

(VSDs) repair surgery. The patients were divided into 2 groups: the pericardial patch group (n=50) and the GORE-TEX patch group (n=50). The most common type of congenital anomaly in both groups was perimembranous VSD (the pericardial patch group: 78% and the GORE-TEX patch group: 72%), while the least frequent type was septal inlet anomaly (the pericardial patch group: 4% and the GORE-TEX patch group: 8%). According to the results of the χ^2 test, there was no statistically significant difference between the 2 groups in terms of the type of VSD (*P*=0.83) (Table 1). Based on the results of the Mann–Whitney test, the duration of aortic clamping was statistically significantly longer in the GORE-TEX patch group (*P*=0.03). A significant difference was noted in the number of surgical complications between the pericardial patch and GORE-TEX patch groups (*P*=0.01), with the number of complications being higher in the latter group (Fig. 1). The cost of surgery was statistically significantly higher in the GORE-TEX patch group than in the pericardial patch group (*P*=0.0001) (Table 2). Based on the results of the χ^2 test, there was no statistically significant difference in terms of complications during hospitalization between the 2 groups (*P*=0.14) (Table 3).

Table 1: Comparison of the frequency distribution of the congenital type of VSD between the 2 groups of patients

Type of VSD	Pericardial Patch Group	GORE-TEX Patch Group
	Number (%)	Number (%)
Inlet septal	2(4)	4(8)
Muscular	5(10)	6(12)
Perimembranous	39(78)	36(72)
Subarterial	4(8)	4(8)
P value (χ^2 test)	0/83	

VSD, Ventricular septal defect

Table 2: Comparison between the 2 groups of patients in terms of age and the duration of cardiopulmonary bypass, aortic cross-clamping, surgery, and hospitalization in the intensive care unit, as well as complications of surgery and costs

Variables	Pericardial Patch Group	GORE-TEX Patch Group	*P* value (Mann–Whitney test)
	Median (interquartile range)	Median (interquartile range)	
Age (y)	22(12-44)	26(18-61)	Z= -1/93 *P*=0/6
Duration of cardiopulmonary bypass (min)	71(59/25-85)	80(67-92/75)	Z= -1/83 *P*=0/06
Duration of aortic cross-clamping (min)	38/50(33-45)	43/50(35-55/25)	Z= -2/12 *P*=0/03
Duration of surgery (min)	190(175-215)	302/50(180-225)	Z= 0/96 *P*=0/33
Duration of hospitalization in the intensive care unit (d)	4(3-6)	4(3-6)	Z= -0/73 *P*=0/46
Complications of surgery (N)	0(0)	0(0-1)	Z= -2/38 *P*=0/01
Costs (Rials)	329993363(2777013995-370771161)	270320801(2284644-32293757)	Z= -4/10 *P*=0/0001

Table 3: Comparison of the frequency distribution of the relationships between the types of complications during hospitalization between the 2 groups of patients

Type of Group / Type of Complications	Pericardial Patch Group	GORE-TEX Patch Group
	Number (%)	Number (%)
Aortic regurgitation	1(2)	1(2)
Heart block	0(0)	3(6)
Residual shunt	1(2)	5(10)
Valve stenosis	1(2)	0(0)
Stroke	1(2)	1(2)
Tricuspid regurgitation	3(6)	7(14)
Death	0(0)	0(0)
P value (χ^2 test)	0/14	

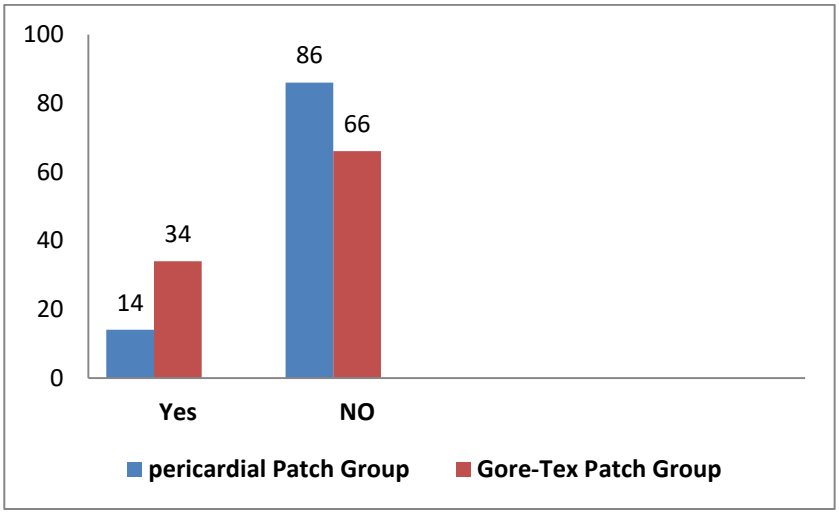

Figure 1: The image presents a comparison of the frequency distribution of the relationships between complications during hospitalization between the 2 groups of patients.

DISCUSSION

According to the results of the current study, the incidence of complications in patients undergoing VSD repair with the GORE-TEX patch was higher compared with the pericardial patch. None of the patients in the 2 groups died during hospitalization. The cost of surgery was higher in the GORE-TEX patch group than in the pericardial patch group, which is not far from the expected cost of treatment in this group due to the complications during hospitalization in the GORE-TEX patch group. Our results also showed the cost-effectiveness of the pericardial patch use compared with the GORE-TEX patch use. In contrast to our results, Lu et al[14] in 2020 reported a mortality rate of 6.5% at 8 months' follow-up in VSD repair with the GORE-TEX patch. The disparity in our respective results could be due to the lack of a long-term follow-up in the present study. Had we performed a follow-up of at least 6 months in our study, we might have had the same mortality rate.

Neethling et al[12] in 2013 evaluated the outcome of the pericardial patch use in the repair of congenital heart defects and reported 2 deaths in a 30-day period after surgery and 3 deaths in the first 6 months after surgery. The causes of the deaths were septicemia, hypoplastic aortic arch

pneumonia, coarctation, and large vessel displacement. Their 6 and 12-month echocardiographic evaluations showed anatomical and hemodynamic changes without any visible calcification. Their results are similar to ours in terms of the absence of death during hospitalization, although the outcomes and complications reported by Neethling et al are different from ours. Still, the results of both studies show significant complications in the pericardial patch use despite differences in the patient populations (patients with VSDs in the present study compared with patients with congenital heart anomalies such as atrial wall defects and tetralogy of Fallot in their investigation).

AL-Tae et al[15] in 2016 reported no in-hospital mortality among children undergoing autologous pericardium repair with glutaraldehyde during a 7-day hospital stay. Additionally, they eliminated 3 junctional rhythms in 1 week. One patient needed a pacemaker because of a complete heart block. We had 1 patient with the pericardial patch repair and 5 patients with the GORE-TEX patch repair, while Taei and colleagues had no such complications in their whole 6 months of follow-up. It seems that the difference in the mean age of our respective study populations and the coexistence of other disorders in their study caused the dissimilarities between our investigations.

The use of glutaraldehyde not only leads to the cross-linking of collagen molecules but also augments the pericardium; consequently, it maintains the approximate same shape and size of the pericardium when it is exposed to pressure.[15,16]

The results of a study by Bell et al[7] in 2018 are inconsistent with the results of our study. Their findings after a 24-month follow-up of the use of pericardial patches manipulated by tissue engineering showed the death of a patient within the first 30 days after surgery due to the displacement of large vessels and the need for surgical intervention in 10 patients in the first 12 months after surgery. In that study, there were no surgical complications during hospitalization due to tissue engineering manipulation to reduce cytotoxicity by removing residual lipids and cells, nucleic acids (DNA and RNA), and galactosyl. Moreover, glutaraldehyde monomeric manipulation was performed to maintain the strength and greater elasticity of the substance to reduce the likelihood of common biological tissue damage over time after reconstructive surgery.

The cross-linking of proteins with glutaraldehyde stabilizes collagen fibers and, while reducing antigenic strength, increases the strength and durability of the patch.[17] Most biological materials are eventually lost due to calcification, fibrosis, and immune responses. However, they have the potential for tissue growth and regeneration, suggesting the use of biological materials in the repair of congenital heart defects as a major advantage over synthetic materials.[18] The materials used for the synthetic patch should be such that they are biologically compatible and integrate with the patient's heart tissue and are mechanically strong, which according to the results of studies of synthetic materials is ideal for repairing congenital heart defects.[12] The failure of tissue replacement increases the likelihood of re-surgery and exposure to associated risks, with the use of GORE-TEX patches or other synthetic patches, leading to challenging discussions about the ability to replace biological patches to treat patients in the future.

One of the advantages of our study is the evaluation of patients with VSDs and without other concurrent cardiovascular disorders, making the results of our evaluation and comparison of the 2 techniques sufficiently accurate. Another strong point of the present investigation is

our comparative study of the implications of the 2 techniques for repairing ventricular wall defects with pericardial and GORE-TEX patches. Our study results revealed the superiority of the pericardial patch over the GORE-TEX patch in patients with VSDs, albeit in the short term.

CONCLUSIONS

The lengths of surgery, cardiopulmonary bypass, ventilation, and aortic clamping, as well as treatment costs, were low in our patients undergoing VSD repair with the pericardial patch compared with those undergoing the same surgery with the GORE-TEX patch. Additionally, higher residual shunts, heart blocks, and cusp valvular insufficiencies were observed in the group treated with the GORE-TEX patch.

Limitations

The results of the present study were retrospectively based on patients' records over a limited period, suggesting that it should be considered a clinical trial in the future. The lack of long-term follow-up of the consequences of congenital anomalous VSD surgery in both methods is another limitation of our study, suggesting that long-term follow-ups of at least 1 year should be considered in the future. Moreover, this study was performed in a single medical center, and its results are not generalizable to the whole community of patients undergoing congenital ventricular anomaly surgery. Future investigations should re-examine our results among larger patient populations in several medical centers.

REFERENCES

1. Dakkak. W, & Oliver, T. I. . Ventricular septal defect. StatPearls. 2020; 2020:https://www.ncbi.nlm.nih.gov/books/NBK470330/.
2. El-Sisi A, Sobhy, R., Jaccoub, V., & Hamza, H. Perimembranous Ventricular Septal Defect Device Closure: Choosing Between Amplatzer Duct Occluder I and II. . Pediatr Cardiol. 2017; 38(3):596–602. DOI 10.1007/s00246-016-1553-x.
3. Suligoj B, Cernic, N., Zorc, M., Noc, M., & Kar, S. Retrograde transcatheter closure of ventricular septal defect with Amplatzer Duct Occluder II. Postepy Kardiol Interwencyjnej. 2016; 12(2):177–8. DOI: 10.5114/aic.2016.59371.
4. Rao. PS, & Harris, A. D. . Recent advances in managing septal defects: ventricular septal defects and atrioventricular septal defects. Faculty Rev. 2018; 2018:1-20. doi: 10.12688/f1000research.4102.1.
5. Nordmeyer. S, Murin, P., Schulz, A., Danne, F., Nordmeyer, J., Kretzschmar, J., ... & Photiadis, J. . Results of aortic valve repair using decellularized bovine pericardium in congenital surgery. European Journal of Cardio-Thoracic Surgery. 2018; 54(6):986–92. doi:10.1093/ejcts/ezy181.
6. Ionescu MI, Tandon, A. P., Mary, D. A., Abid, A., & McGoon, D. C. Heart valve replacement with the Ionescu-Shiley pericardial xenograft. . Thorac Cardiovasc Surg. 1977; 7:31-42. doi:10.1016/S0022-5223(19)39979-9.
7. Bell. D, Prabhu, S., Betts, K., Justo, R., Venugopal, P., Karl, T. R., & Alphonso, N. Durability of tissue-engineered bovine pericardium (CardioCel®) for a minimum of 24 months when used for the repair of congenital heart defects. Interactive cardiovascular and thoracic surgery,. 2019; 28(2):284-90.doi:10.1093/icvts/ivy246.
8. Kang. S, Tometzki .,A, Caputo M, Morgan G, Parry A, Martin R. Longer-term outcome of perventricular device closure of muscular ventricular septal defects in children. Catheter Cardiovasc Interv. 2015;85:998–1005. doi:10.2/ccd.25821.
9. Li. D, Zhang .,Z, Li .,M. . Comparisons of periventricular device closure, conventional surgical repair, and transcatheter device closure in patients with congenital ventricular septal defects: a protocol for

systematic review. Medicine. 2020; 99:e18901. doi:10.1097/MD.0000000000018901.

10. Chowdhury. UK, Singh, S., George, N., Sankhyan, L. K., Chauhan, A., Avneesh, S., ... & Chowdhury, S. . Two Patch Repair of Rastelli's Type-A Complete Atrioventricular Septal Defect with Relief of Right Ventricular Outflow Tract Obstruction under Mild Hypothermic Extracorporeal Circulation and Cardioplegic Arrest: A Video Presentation. MedRead J Cardiol Res. 2020; 1(1): 1004. https://mail.med-read.org/uploads/article_pdf/1/scientific_1_942_20032020042526.pdf.

11. Deutsch. O, Bruehl, F., Cleuziou, J., Prinzing, A., Schlitter, A. M., Krane, M., & Lange, R. Histological examination of explanted tissue-engineered bovine pericardium following heart valve repair. Interactive CardioVascular and Thoracic Surgery. 2020; 30(1): 64-73. doi:10.1093/icvts/ivz234.

12. Neethling. WM, Strange, G., Firth, L., & Smit, F. E. Evaluation of a tissue-engineered bovine pericardial patch in paediatric patients with congenital cardiac anomalies: initial experience with the ADAPT-treated CardioCel® patch. Interactive cardiovascular and thoracic surgery. 2013; 17(4):698-702. doi: 10.1093/icvts/ivt268.

13. Us. MH, Sungun, M., Sanioglu, S., Pocan, S., Cebeci, B. S., Ogus, T., ... & Guler, A. A retrospective comparison of bovine pericardium and polytetrafluoroethylene patch for closure of ventricular septal defects. Journal of international medical research,. 2004; 32(2):218-21. doi:10.1177/147323000403200216.

14. Lu. T, Li, J., Hu, J., Huang, C., Tan, L., Wu, Q., & Wu, Z. Biventricular repair of double-outlet right ventricle with noncommitted ventricular septal defect using intraventricular conduit. The Journal of thoracic and cardiovascular surgery. 2020; 159(6):2397-403. doi:10.1016/j.jtcvs.2019.07.084.

15. AL-Tae. JJ. Experience with Autologous Pericardial Patch Closure of Ventricular Septal Defect. Iraqi Academic Scientific Journal. 2016; 15(1):58-60. https://www.iasj.net/iasj/download/5ea7556364f62f9f.

16. Bennink. G, HitchcockFJ, MolenschotM, Hutter P, SreeramN. Aneurymsal pericardial patch producing right ventricular inflowobstruction. AnnThoracSurg. 2001; 71:1346-47. doi:10.016/S0003-4975(00)02270-0.

17. Strange. G, Brizard CP, Karl TR, Neethling L. . An evaluation of Admedus' tissue engineering process treated (ADAPT) bovine pericardium patch (CardioCel®) for the repair of cardiac and vascular defects. . Expert Rev Med Devices. 2015; 12:135–41. doi:10.1586/17434440.2015.985651.

18. Golomb GERSHON, Schoen, F. J., Smith, M. S., Linden, J., Dixon, M., & Levy, R. J. The role of glutaraldehyde-induced cross-links in calcification of bovine pericardium used in cardiac valve bioprostheses. . Am J Pathol 1987; 127:122–30. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1899585/pdf/amjpathol00145-0127.pdf.