

Original Article

A comparative study on the efficacy of transthoracic minimal invasive closure and surgery in pediatric patients with ventricular septal defect

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Abstract: Objective: This study compared the efficacy of transthoracic minimal invasive closure and surgery in pediatric patients with ventricular septal defect (VSD). Methods: 93 pediatric patients diagnosed with VSD in our hospital were retrospectively analyzed and divided into 2 groups by random sampling. The control group (n=46) received surgery while the observation group (n=47) was treated by transthoracic minimal invasive closure. The 2 groups were compared for postoperative VSD diameter, success rate, indexes of cardiac function, incidence of complications, postoperative recovery and platelet aggregation rate. Results: After treatment, the observation group was lower in VSD diameter ($P<0.05$), incidence of complications (8.51% versus 23.91%) ($P<0.05$), ICU monitoring time and LOS ($P<0.05$), and higher in one-time successful rate (89.36% versus 86.96%) ($P<0.05$), medical expenses ($P<0.05$) and instant platelet aggregation rate ($P<0.05$). However, no significant difference was observed between the 2 groups in various indexes of cardiac function. Conclusion: Though both methods have achieved good efficacy in pediatric patients with VSD, the transthoracic minimal invasive closure is more acceptable in children when compared with surgery as it is minimally invasive and contributes to reduced complications and fast recovery. However, to ensure the long-term effects, active anticoagulant therapy and continuous follow-up after the surgery are necessary according to the study.

Keywords: Pediatric VS, transthoracic minimal invasive closure, surgery, treatment, efficacy

Introduction

Pediatric VSD is one of the congenital heart diseases (CHD) accounting for most of the major defects and mortality of neonates [1] with an incidence approaching 1/5. Its causes have not been ascertained clinically but suggested to be closely associated with electromagnetic radiation, environment, virus, heredity and drugs [2, 3].

VSD is a result of underdeveloped interventricular septum in embryonic period, which leads to abnormal left and right channels and shunting flow in chambers. Some pediatric patients may concurrently suffer from complex cardiac malformation [4, 5]. In early stages, the pediatric patients will not be compromised in hemodynamics but show manifestations such as fatigue, palpitations, and asthma, with a high risk of pulmonary infection, which may, in

severe cases, affect normal development, and result in arrhythmia and cardiac enlargement, or infectious endocarditis, and even heart failure [6, 7]. Clinical treatment against pediatric VSD focuses on intervention and surgery, and transthoracic closure, of which, surgery has the longest history, most experience and extensive indications. However, it is disadvantaged by obvious traumas affecting aesthetics, which limits its clinical popularization and implementation [8, 9]. As study goes further, medical materials and technologies improve, research and development of VSD occluders have made remarkable progression, while, so far, transthoracic minimal invasive closure has become a major method for clinical treatment of pediatric VSD.

In this study, 93 pediatric patients with VSD were retrospectively analyzed to specifically explore the application values of transthoracic

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minimal invasive closure, in order to find more effective and safe methods for the treatment of pediatric VSD.

Materials and methods

Materials

93 pediatric patients diagnosed with VSD in our hospital were included as the study objects, retrospectively analyzed and divided into the observation group (n=47), with age between 1-7, weight of 8-31 kg, and VSD diameter of 2-15 mm, and the control group (n=46), with age range between 2 and 7, weight of 10-31 kg and VSD diameter of 3-15 mm. (1) Inclusion criteria: patients included have satisfied the diagnosis criteria of pediatric VSD [10], and were not found of severe pulmonary hypertension, auricular fibrillation, liver and kidney dysfunction in perioperative period and other diseases which may affect treatment. (2) Exclusion criteria: patients were excluded if they reported concurrent diseases such as aorticopulmonary fistula, atrial septal defect, mild pulmonary hypertension, mild tricuspid regurgitation, abnormal number of platelets in perioperative period, history of using aspirin or antiplatelet drugs, or sensitive to aspirin. This study was approved by the Ethics Committee of The Affiliated Jiangxi Provincial Children's Hospital of Nanchang University.

Methods

Control group: patients lied on back flatly with chests bolstered up by 15-20°. Both upper extremities were naturally placed and close to the lateral chest wall to expose the incision completely. Under general anesthesia, single lumen endotracheal tube intubation was performed while the smaller tidal volumes (VTs) and high frequency ventilation were maintained. In the whole process of the surgery, degree of blood oxygen saturation was subject to close monitoring. An incision was opened at the middle sternum according to the sequence of skin and subcutaneous muscle. Assisted respiration was disconnected before it was recovered after sawing off the sternum. In front of the right phrenic nerve, pericardium was cut open obliquely to dissociate the venae cava superior and venae cava inferior, to expose the root of ascending aorta. Next step is selecting the appropriate veins and arteries for incubation to establish extracorporeal circulation.

Purse string suturing was performed at the combined arteries and roots of venae cava superior and venae cava inferior, to dissociate the nearby tissues. After heparinization to vertically cut apart the V. W. of aorta in purse string suture, tubes were intubated into the arcus aortae vessels. Incubation of the venae cava superior and venae cava inferior was done by the same methods. Purse string suturing was performed again with cold perfusion needles. After transfer and cooling down, cold perfusion needles were inserted into the root of aorta ascendens and connected to the perfusion tubes to reduce perfusion of extracorporeal circulation, while the aorta ascendens at the distal end of inserting cold perfusion needle was blocked. Through perfusion needles cardioplegia liquid is infused to stop heart beating. Next, the right atrium was cut open along and parallel to the atrioventricular sulcus to completely expose the VSD site. Autologous pericardium was sutured in a continuous manner with 6.0 slide wire to repair the VSD at the membrane 40. After lung dilation, the atrium dextrum was sutured, cold perfusion needles were removed from the aorta ascendens, and the operation table was lowered to keep the heat at low position. Both hands were used to press the heart and the root of aorta ascendens to keep the left atrium filled with blood and air exhausted. Next, the upper incision of the right atrium was sutured to open the venae cava superior and the venae cava inferior. As the body temperature resumed to a satisfactory level, all tubes were removed relying on extracorporeal circulation and knotted at the root of right auricular appendix. Blood at the pericardial margin was stopped with an electric coagulation knife. In succession, pericardial incision was intermittently sutured, and a drainage tube was reserved in anocelia and pericardium respectively. The chest was then closed by layers according to routine procedures.

Observation group: the pediatric patient lied on the back flatly in a general anesthesia status. The skin was cut apart by 3-5 cm at the 1/3 position below the middle sternum. As the lower sternum section was removed, the chest was braced to create a channel into it for incision and suspension of pericardium to expose the ventriculus dexter. The most trembling point was found by gently touching the antetheca of ventriculus dexter with fingers, and the specific size and position of VSD were determined

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based on transesophageal echocardiography to identify the right ventricular wall with the most suitable VSD angle, shortest distance and without coronary artery. Purse string suturing was performed at the puncturing point with 4.0 wire with pads, and puncturing was done at the suture trap. 100 U/kg heparin was intravenously injected, and a wire was inserted under the guides of transesophageal echocardiography. It first went through the membranous ventricular septal defect to enter the left ventricular cavity and then brought the sheathing canal into the same place before withdrawing without error. Next, a properly dimensioned occluder was placed into the left ventricular cavity along the sheathing canal to release the superficial umbrella therein orderly under the guides of echocardiogram, and then retrieved to the left ventricular side of VSD. After confirming a satisfactory position and morphology of side umbrella in echocardiogram, transmission of sheathing canal and guide wire was done before withdrawing the sheathing canal again to open the right side umbrella of the occluder. Where the transesophageal echocardiography indicated that there was no residual shunting in the VSD and the aortic valves can open and close normally, the superficial umbrella of the right ventricular cavity was then released. If the occluder at a satisfactory position was confirmed and there was no residual shunting or aortic regurgitation or abnormality in intracardiac structure based on transesophageal echocardiography, the retainer at the back end of delivery catheter was released and the handlebar was rotated counter-clockwise to fix the delivery catheter and slowly deliver sheathing canal in order to release the occluder. Hemostasis by compression was given as the sheathing canal was removed. After removing the transmission device, the incision was sutured and the tubes were knotted, while a drainage tube was reserved in anocelia and pericardium respectively. The pericardium was then sutured and the chest was closed according to routine procedures.

Observation indexes

(1) VSD diameter: VSD diameter was measured in the 2 groups before and after treatment by color Doppler flow imaging. (2) Success rate: The 2 groups were compared for one-time success rate. (3) Cardiac function: The 2 groups

were measured for indexes of cardiac function, including LVEDP, LVEDD, LVESD, LVEDV, LVESV and LVEF before and after the surgery by ultrasonic cardiogram. (4) Incidence of complications: The 2 groups were compared for postoperative wound bleeding, aortic and tricuspid regurgitation, conduction and abnormal heart rhythm, and incidence of hemolysis. (5) Postoperative recovery: The 2 groups were compared for operation time, ICU monitoring time, LOS and medical expenses. (6) Platelet aggregation rate: 5 ml of venous blood was taken before and immediately after the surgery, and collected into a tube containing the anticoagulant of sodium bromated. After thoroughly mixing, it was centrifuged at low speed under room temperature. The liquid supernatant was reserved and added with 0.5 mmol/L adenosine diphosphate (ADP). A blood coagulation tester was used to measure the maximal platelet aggregation rate. All operations were carried out in strict accordance with the requirements.

Statistical analysis

SPSS22.0 was used for statistical analysis. Measurement data are expressed as mean \pm standard deviation, and independent-samples T test was used for inter-group result comparison. Enumeration data are expressed as [n (%)], and X^2 test was used for inter-group result comparison. ANOVA was used for analysis of multi-point comparisons within groups. $P < 0.05$ indicated that the difference was statistically significant.

Results

Comparison between the observation group and the control group for general materials

Comparison between the observation group and the control group revealed no statistical differences in proportions of male and female patients, mean age, average VSD diameter and mean weight ($P > 0.05$) (**Table 1**).

Comparison between the observation group and the control group for VSD diameter

Without statistical difference before treatment ($P > 0.05$), both groups attained decreases in the VSD diameter after treatment ($P < 0.05$), which was more significant in the observation group ($P < 0.05$, **Table 2**).

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Table 1. Comparison between the observation group and the control group for general materials ($\bar{x} \pm sd$)/[n (%)]

Materials		Observation Group (n=47)	Control Group (n=46)	t/ χ^2	P
Gender	M	26 (55.32)	24 (52.17)	0.093	0.761
	F	21 (44.68)	22 (47.83)		
Age (y)		4.12 \pm 2.19	4.16 \pm 2.21	0.088	0.930
VSD Diameter (mm)		10.23 \pm 2.16	9.86 \pm 2.17	0.824	0.412
Weight (kg)		20.25 \pm 5.67	21.43 \pm 5.49	1.019	0.311

Table 2. Comparison between the observation group and the control group for VSD diameter ($\bar{x} \pm sd$, mm)

Group	n	Before Treatment	After Treatment	t	P
Observation Group	47	10.23 \pm 2.16	5.02 \pm 1.16	14.568	0.000
Control Group	46	9.86 \pm 2.17	6.87 \pm 1.25	8.098	0.000
t		0.824	7.400		
P		0.412	0.000		

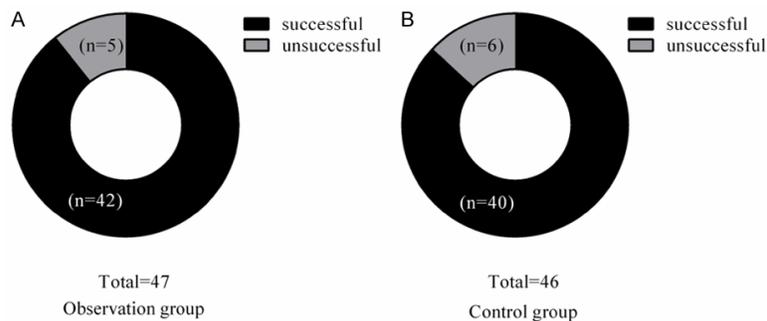


Figure 1. Comparisons between the observation group and the control group for one-time successful rate.

Comparison between the observation group and the control group in one-time success rate

There was no statistical difference between the 2 groups in one-time successful rate as 42 patients in the observation group were successfully treated by one time, with a one-time successful rate of 89.36%, while in the control group, the reported data were 40 and 86.96% ($\chi^2=0.129$, $P=0.720$, **Figure 1**). There was no difference between the observation group and the control group in one-time successful rate and one-time unsuccessful rate ($P>0.05$).

Comparison between the observation group and the control group for cardiac function

LVEDP, LVEDD, LVESD, LVEDV, LVESV and LVEF were 7.15 \pm 2.61 mmHg, 38.26 \pm 5.68 mm, 28.46 \pm 6.39 mm, 85.69 \pm 6.35 ml, 34.16 \pm

4.28 ml, and 51.08 \pm 3.38% in the observation group, 7.28 \pm 2.34 mmHg, 36.84 \pm 5.42 mm, 26.57 \pm 5.21 mm, 83.26 \pm 8.27 ml, 32.39 \pm 3.28 ml and 49.78 \pm 3.38% in the control group before the surgery.

LVEDP, LVEDD, LVESD, LVEDV, LVESV and LVEF were 7.52 \pm 2.63 mmHg, 37.59 \pm 5.24 mm, 28.94 \pm 6.53 mm, 86.34 \pm 6.29 ml, 34.28 \pm 4.21 ml, and 52.29 \pm 3.56% in the observation group, 7.28 \pm 2.19 mmHg, 36.86 \pm 4.98 mm, 27.86 \pm 5.92 mm, 85.76 \pm 5.39 ml, 33.84 \pm 4.19 ml and 51.46 \pm 3.82% in the control group.

Before the surgery, there was no significant difference in cardiac function between the observation group and the control group ($t=0.253, 1.233, 1.561, 1.591, 1.969, 1.854, P=0.801, 0.221, 0.122, 0.115, 0.052, 0.067$). After the surgery, there was no significant difference in cardiac function between the observation group and the control group ($t=0.478, 0.688, 0.835, 0.477, 0.505, 1.084, P=0.634, 0.493, 0.406, 0.635, 0.615, 0.281$). After the surgery, the cardiac functions in observation group were not significantly different from those before the surgery ($t=0.685, 0.594, 0.360, 0.500, 0.137, 1.690, P=0.495, 0.554, 0.720, 0.619, 0.094, 0.891$). After the surgery, the cardiac functions in control group were not significantly different from those before the surgery ($t=0.021, 0.018, 1.214, 1.718, 1.621, 1.936, P=0.983, 0.985, 0.228, 0.089, 0.109, 0.056$) (**Figures 2, 3**).

Comparison between the observation group and the control group for incidence of complications

There was no difference between the control group and the observation group in incidence

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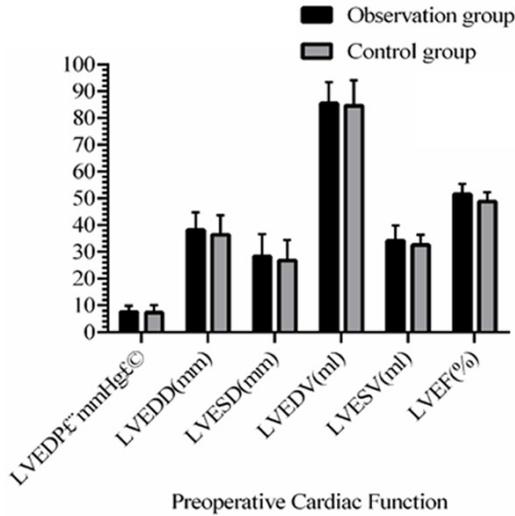


Figure 2. Comparisons between the observation group and the control group for preoperative cardiac function.

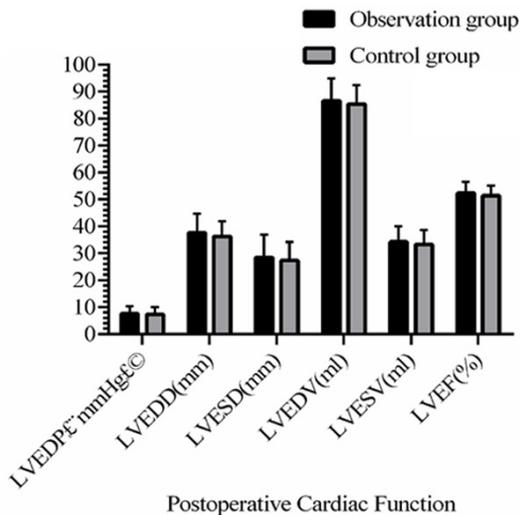


Figure 3. Comparisons between the observation group and the control group for postoperative cardiac function.

of complications such as wound bleeding, aortic and tricuspid regurgitation, conduction and abnormal heart rhythm and hemolysis ($P>0.05$). For total number of patients with complications, the observation group reported less as compared with the control group ($P<0.05$). After surgery, the number of complications such as wound bleeding, aortic and tricuspid regurgitation, conduction and abnormal heart rhythm, and incidence of hemolysis were 0, 2, 1, 1 with an incidence of 8.51% in the observation group, and 2, 1, 4 and 4 with an incidence

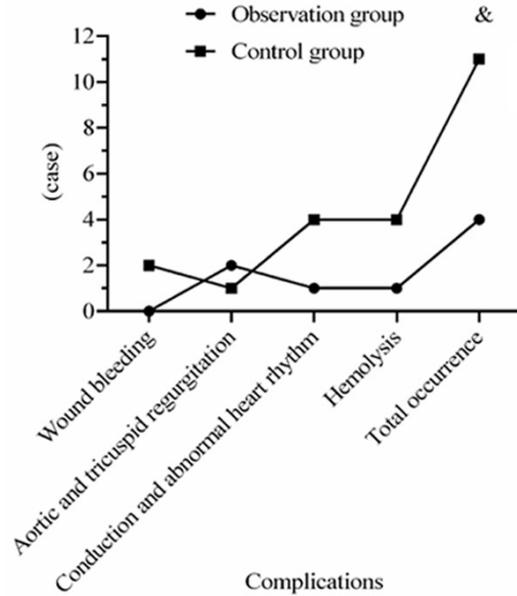


Figure 4. Comparisons between the observation group and the control group for incidence of complications. & indicates $P<0.05$ for comparison between the 2 groups in total number of patients with complications.

of 23.91% in the control group ($\chi^2=4.077$, $P=0.043$, **Figure 4**).

Comparison between the observation group and the control group for postoperative recovery

The observation group yielded shorter operation time, ICU monitoring time and LOS but paid higher medical expenses as compared with the control group ($P<0.05$, **Table 3**).

Comparison between the observation group and the control group for platelet aggregation rate

Without statistical difference before treatment ($P>0.05$), an increase in platelet aggregation rate was observed in both groups immediately after the surgery, which was significant in the observation group ($P<0.05$) but not in the control group ($P>0.05$), and after which, the observation group was higher than the control group obviously ($P<0.05$, **Table 4**).

Discussion

Transthoracic minimal invasive closure, more specifically, the transthoracic minimal invasive closure of ventricular septum defect by puncture of ventriculus dexter, is a minimally inva-

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Table 3. Comparison between the observation group and the control group for postoperative recovery ($\bar{x} \pm sd$)

Group	n	Operation Time (min)	Postoperative ICU Monitoring Time (d)	LOS (d)	Medical Expense (RMB 10,000)
Observation Group	47	48.25 ± 20.16	1.23 ± 0.28	5.28 ± 1.16	5.23 ± 1.19
Control Group	46	140.16 ± 35.81	7.51 ± 2.64	10.42 ± 2.85	3.52 ± 0.67
<i>t</i>		15.294	16.217	11.435	8.514
<i>P</i>		0.000	0.000	0.000	0.000

Table 4. Comparison between the observation group and the control group for platelet aggregation rate ($\bar{x} \pm sd$)

Group	n	Before Operation	Immediately after Operation	<i>t</i>	<i>P</i>
Observation Group	47	0.57 ± 0.06	0.77 ± 0.08	13.711	0.000
Control Group	46	0.55 ± 0.08	0.59 ± 0.09	2.267	0.026
<i>t</i>		1.366	10.199		
<i>P</i>		0.175	0.000		

sive technique applied clinically in recent years and has changed the clinical treatment strategy for VSD [11]. As it is applied in more cases with developed sophistication, experience in this field is abundant [12]. Compared with surgery, transthoracic minimal invasive closure is advantageous and safer in preoperative period that the patients recover quickly after the surgery according to a lot of researches [13, 14].

In the present study, comparative analysis indicated that the observation group, after transthoracic minimal invasive closure, had no significant difference in efficacy from the control group who received surgical treatment only based on one-time success rates of 89.36% and 86.96% respectively ($P > 0.05$). Furthermore, no statistical difference was observed between the 2 groups for preoperative and postoperative indicators of cardiac function, indicating that both methods can protect cardiac function in pediatric patients with VSD from any injury. However, compared with the control group, the observation group achieved significant reduction in other factors, including VSD diameter ($P < 0.05$), incidence of complications to 8.51%, lower than that of the control group which was 23.91% ($P < 0.05$), and platelet aggregation rate immediately after surgery ($P < 0.05$), indicating that transthoracic minimal invasive closure can more effectively reduce the VSD, incidence of complications, and platelet aggregation in pediatric patients with VSD. In addition, the observation group reported

shorter operation time, postoperative ICU monitoring time, and LOS but higher medical expenses as compared with the control group ($P < 0.05$), making clear that transthoracic minimal invasive closure can promote postoperative recovery at a higher cost beyond the financial capacity of some patients,

which shall be one of the reasons of its limited popularization.

Through analysis of the difference between surgery and transthoracic minimal invasive closure in application values, Zhou Yi et al and Fang J et al [15, 16] found that the 2 methods differed in blood transfusion which is required in the first case due to the large wound for extracorporeal circulation, complicated procedures, high demands of heparin and obvious bleeding, while in case of transthoracic minimal invasive closure, such conditions together with tissue injury, cardiac reperfusion injury, and obvious injuries to nearby tissues are avoided, or even tissues bleed, it can be stopped easily, further ensuring patients' safety [17, 18]. El-Saiedi SA et al [19] found in their study that transthoracic minimal invasive closure can be an alternative to surgery in the treatment of some simple CHDs, while according to Azhar AS et al [20], it can achieve more preferred efficacy in closure of atrial septum defect via right atrium and closure of aorticopulmonary fistula.

To sum up, the advantages of transthoracic minimal invasive closure include less difficult operation complexity, possibility of preventing operation wound and extracorporeal circulation, and postoperative complications which may affect patients' psychological status [21]. As the surgery is performed subject to TEE monitoring, the location of VSD, perivalvular tissues and postoperative regurgitation can be

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discovered from time to time, based on which, the treatment efficacy can be evaluated, and any problems can be solved immediately [22, 23]. The method is also applicable, feasible, safe and tolerable in infants and children as intubation of arteria cruralis and femoral vein, and myocardial perfusion are not required. Though the closure fails in the process, it can be changed into surgical treatment by extending the wound [24, 25].

In conclusion, both transthoracic minimal invasive closure and surgery can achieve better efficacy in pediatric patients with VSD. But in comparison, the first method is minimally invasive with less complications, accelerated recovery and elevation acceptance in pediatric patients despite its limitations in application, including conduction block after operation and high incidence of residual leakage, which demands strict anticoagulant therapy at a higher cost. Therefore, it is held in the present study that, to ensure the long-term effects, active anticoagulant therapy and continuous follow-up after the surgery are necessary. But, as a retrospective study, it failed to screen study objects in advance while study objects included were disadvantageous in number and age range, rendering the study results less comprehensive and the results less representative. Future studies shall be forward looking based on larger sample sizes and more aspects, in order to obtain scientific and representative conclusions to provide more guides for the treatment of pediatric VSD.

Disclosure of conflict of interest

None.

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