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# The Application of On-Pump Beating-Heart Surgery for Partial Atrioventricular Septal Defect: A Report of 87 Cases

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### **ABSTRACT**

**Background:** Partial atrioventricular septal defect (P-AVSD) is a common congenital heart disease. Because of the presence of left and right atrioventricular valve deformities and the shift in the atrioventricular node and cardiac conduction bundle, the surgical repair of P-AVSD is difficult. This study was performed to compare the effects on the coronary sinus septum in the left versus the right atrium during surgical treatment for P-AVSD and report our experiences regarding the application of on-pump beating heart surgery under mild hypothermia for patients with P-AVSD.

Materials and Methods: The effects of on-pump beating heart surgery were analyzed retrospectively in 87 P-AVSD patients. Of the 87 total patients, 84 with anterior mitral leaflet cleft underwent valvuloplasty and 3 underwent mitral valve replacement. Seventy-seven patients underwent tricuspid valve annuloplasty, 2 underwent tricuspid valve replacement, and 1 underwent left superior vena cava ligation, and 3 patients with atrial fibrillation were treated with radiofrequency ablation. Patients with an ostium primum atrial septal defect underwent autologous pericardial modified Kirklin repair. Of these, 46 patients had their coronary sinus septum separated into the left atrium and 41 had their coronary sinus retained in the right atrium. Fingertip oxygen saturation was compared between patients in whom the coronary sinus was separated to the left atrium and those in whom the coronary sinus was retained in the right atrium.

**Results**: There was 1 postoperative early death (1.15%) due to respiratory failure, and 1 patient had a III degree atrioventricular block (1.15%) and underwent implantation of a permanent pacemaker. The fingertip oxygen saturation levels of the left atrium group were 96.81 ± 3.17 preoperatively,

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 $95.37 \pm 4.62$  at 7 days postoperatively, and  $94.53 \pm 4.95$  at 3 months postoperatively. Those of the right atrium group were  $98.53 \pm 2.84$  preoperatively,  $97.19 \pm 3.57$  at 7 days postoperatively, and  $96.89 \pm 4.19$  at 3 months postoperatively. During the follow-up period, which ranged from 3 months to 7 years, the cardiac function was adequately restored.

**Conclusions**: On-pump beating heart surgery under mild hypothermia is a safe and feasible method. The retention of the coronary sinus in the right atrium might maintain oxygen saturation.

### INTRODUCTION

Partial atrioventricular septal defect (P-AVSD) is a common congenital heart disease. Due to the presence of left and right atrioventricular valve deformities and the shift in the atrioventricular node and cardiac conduction bundle, the surgical repair of P-AVSD is difficult. Additionally, further knowledge of this disease is necessary due to potential heart block induced by the shift of the atrioventricular node and bundle [Minich 2010; Shinebourne 2011]. The purpose of this study was to describe 87 P-AVSD cases treated with on-pump beating heart surgery under mild hypothermia and compare the effect of the coronary sinus septum in the left versus the right atrium.

### **MATERIALS AND METHODS**

### Patient Characteristics

Eighty-seven P-AVSD patients, including 36 men and 51 women aged 3-52 years (18.58 ± 8.71 years) were enrolled in our study. Sixty-six patients had frequent colds, felt tired, and experienced shortness of breath on exertion. There were 82 patients with a precordial auscultation palpable tremor, P2 enhancement, and 3/6 systolic murmur in the 3-4 left border of the sternal intercostal and apical area. Chest x-ray examination revealed congestion of both lungs and an increased heart shadow. The electrocardiography and echocardiography results are shown in Tables 1 and 2. Congenital P-AVSD was diagnosed in these patients prior to the operation. Of these patients, 2 patients had comorbid dextrocardia, 3 had double-orifice mitral valve, and 16 had persistent left superior

Table 1. The Electrocardiography Data before or after Surgery\*

	Left Atrium Group (n = 46)		Right Atrium Group (n = 41)	
	Pre	10 Days Po	Pre	10 Days Po
Sinus rhythm	45 (97.83%)	45 (97.83 %)	39 (95.12%)	41 (100.00%)
Atrial fibrillation	1 (2.17%)	0	2 (4.88%)	0
Pacing rhythm	0	1 (2.17%)	0	0
Degree AVB	34 (73.91%)	33 (71.74%)	32 (78.05%)	30 (73.17%)
I Degree AVB	7 (15.21%)	3 (6.67%)	5 (12.19%)	3 (7.31%)
III Degree AVB	1 (2.17%)	1 (2.17%)	0	0

<sup>\*</sup>Data are presented as the no. of cases (%). Pre indicates preoperatively; Po, postoperatively; AVB, atrioventricular block.

vena cava (including 2 patients with blood flow back into the left atrium and 14 with flow back into the coronary sinus). Patients were divided into the left atrium group (coronary sinus septum separated into the left atrium) and the right atrium group (coronary sinus retained in the right atrium), according to the manner in which the coronary sinus was surgically altered. This study was in compliance with the Helsinki Declaration and was approved by the Ethics Committee of Xinqiao Hospital. The protocol was approved by the Review Board of Xinqiao Hospital. We obtained written informed consent from all study participants.

### Surgical Procedures

Surgery was performed while patients were under general intravenous anesthesia. Median sternotomy was performed, an aortic perfusion tube and superior and inferior vena cava drainage tubes were inserted conventionally, and the left atrium drainage tube was placed in the right superior pulmonary vein. Then, extracorporeal circulation was established

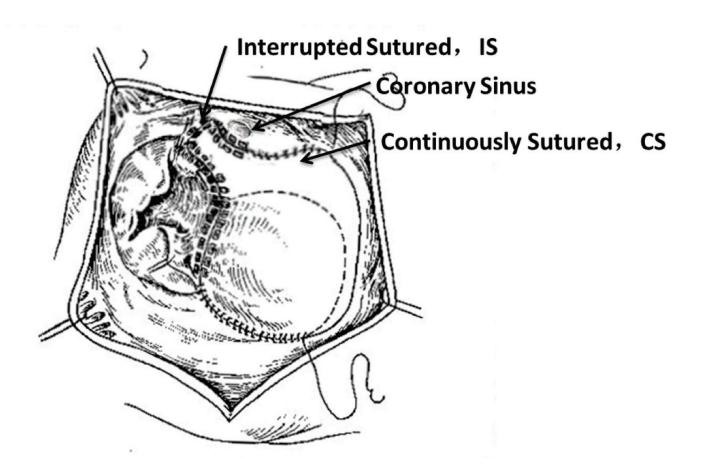
and the on-pump beating heart technique was performed under mild hypothermic conditions. During the operation, the nasopharyngeal temperature was reduced and maintained at  $32^{\circ}$ C ±  $1^{\circ}$ C, which obstructed only the superior and inferior vena cava without aortic cross-clamping and potassium cardioplegia, and perfusion pressure of approximately 60 mmHg was maintained. The patients of both groups underwent surgery to treat the mitral valve disease first. Of these patients, 84 had interrupted suture of the anterior mitral leaflet cleft, but the valvuloplasty effect of the other 3 adult patients with mitral annular calcification was unsatisfactory, resulting in mitral valve replacement. Three patients with left atrioventricular dual valve required careful protection of the valve bridge to prevent postoperative regurgitation. The primum atrial septal defect was treated next. Of these patients, 46 in the left atrium group underwent repair of the primum atrial septal defect using an autologous pericardial patch according to the modified Kirklin method, and the coronary sinus was separated into the left atrium. The 41 patients in the right

Table 2. Echocardiography Results before and after Surgery\*

	Left Atrium Group (n = 46)		Right Atrium Group (n = 41)	
	Pre	10 Days Po	Pre	10 Days Po
Anterior mitral leaflet cleft				
1	2 (4.35%)	0	2 (4.87%)	0
II	10 (21.74%)	0	9 (21.95%)	0
III	34 (73.91%) <sup>†</sup>	0	30 (73.17%) <sup>†</sup>	0
Mitral regurgitation				
Mild	4 (8.67%)	11 (23.91%)	3 (7.32%)	9 (21.95%)
Moderate	19 (41.30%) <sup>†</sup>	3 (6.52%)	16 (39.02%) <sup>†</sup>	2 (4.87%)
Severe	16 (34.78%)†	1 (2.17%)	17 (41.46%) <sup>†</sup>	1 (2.43%)
Tricuspid regurgitation				
Mild	8 (17.39%)	10 (21.74%)	7 (17.07%)	8 (19.51%)
Moderate	17 (36.96%) <sup>†</sup>	4 (8.67%)	14 (34.15%) <sup>†</sup>	3 (7.32%)
Severe	21 (45.65%)†	1 (2.17%)	20 (48.78%)†	1 (2.43%)

<sup>\*</sup>Data are presented as the no. of cases (%). Pre indicates preoperatively; Po, postoperatively.

 $<sup>^{\</sup>dagger}P$  < 0.05 relative to postoperative findings.



The root of the tricuspid valve was sutured with interrupted 3-0 Ethibond everting mattress sutures with a pledget, continuously sutured with 2-3 sutures at the junction between the septum valve and posterior valve, then transferred to the right atrium and sutured with interrupted everting sutures. When the top of the coronary sinus was sutured, the sutures were sewed at the top of the orifice of the coronary sinus by purl stitch, then sutured continuously with 4-0 Prolene sutures while retaining the coronary sinus in the right atrium.

atrium group underwent surgery according to the modified Kirklin method as follows. The root of the tricuspid valve was sutured with interrupted 3-0 Ethibond everting mattress sutures with a pledget, continuously sutured with 2-3 sutures at the junction between the septum valve and posterior valve, and then transferred to the right atrium and sutured with interrupted everting sutures. When the top of the coronary sinus was sutured, the sutures were sewed at the top of the orifice of the coronary sinus by purl stitch, then sutured continuously with 4-0 Prolene sutures while retaining the coronary sinus in the right atrium (Figure). With regard to the 2 patients with persistent left superior vena cava reflux into the left atrium, 1 patient was directly ligatured without influencing the reflux, whereas another patient showed significant facial swelling after snaring with tightening and separation into the right atrium using autologous pericardium. With regard to the 14 patients with persistent left superior vena cava flow back into the coronary sinus, the disease was retained in the right atrium. Seventy-seven patients with moderate-to-severe regurgitation of the tricuspid valve underwent tricuspid valve annuloplasty with DeVega techniques, including 12 patients

for whom a rigid ring was used. Two patients with serious tricuspid valve lesions that were difficult to repair underwent tricuspid valve replacement. Three patients with atrial fibrillation underwent radiofrequency ablation using an Atricure bipolar radiofrequency ablation device according to the method described by Sims and Roberts [Sims 2006] (Table 3). The epicardial pacemaker was retained conventionally after the operation to avoid arrhythmia.

### Measurement of Peripheral Oxygen Saturation

Early oxygen treatment after the operation and the fingertip oxygen saturation levels of the 2 groups before the operation, 7 days postoperatively, and 3 months postoperatively were analyzed.

#### Statistical Analysis

The Statistical Package for the Social Sciences (SPSS) version 17.0 was utilized for data analysis. The count data were assessed by the 2 test. All data were reported as mean  $\pm$  standard deviation (SD). P < 0.05 was considered statistically significant.

Table 3. Operation Data\*

	Left Atrium Group (n = 46)	Right Atrium Group (n = 41)
Time of CPB, min	86.7 ± 19.5	87.1 ± 21.3
Time of snaring the vena cava cannulas, min	65.5 ± 16.2	66.7 ± 17.7
Ventilation time, h	$8.2 \pm 4.7$	$7.7 \pm 5.5$
Drainage, mL	210.5 ± 76.5	$186.7 \pm 89.5$
Anterior mitral valve cleft treatment, n (%)		
Interrupted suture	44 (95.65%)	40 (97.56%)
Valvular replacement	2 (4.35%)	1 (2.44%)
Tricuspid valve treatment, n (%)		
Tricuspid valvuloplasty	34 (73.91%)	33 (80.49%)
Valvular replacement	2 (4.35%)	0
Ablation of atrial fibrillation	1 (2.17%)	2 (4.88%)

<sup>\*</sup>Data are presented as the mean  $\pm$  SD or no. of cases (%). CPB indicates cardiopulmonary bypass.

### **RESULTS**

As shown in Table 4, 12 patients had complications, with no statistical difference between the 2 groups. One 52-yearold patient had a III degree atrioventricular block (1.15%). The patient with sinus bradycardia before the operation had a 50 bmp, II degree atrioventricular block, P:QRS 2:1 conduction, and a complete right bundle branch block. During the operation, the mitral valve had a III degree cleft with severe mitral regurgitation and valve calcification. After implantation of an artificial mechanical valve, atrioventricular dissociation occurred and a temporary pacemaker was implanted. After the patient's condition was stable, a permanent pacemaker was implanted. One patient died early during surgery (1.15%) because of respiratory failure. During the follow-up period, ranging from 3 months to 7 years, one patient died after 6 months and 3 patients required valvular reoperation due to severe reflux, including 2 cases of mitral valve replacement and 1 case of tricuspid valve annuloplasty. Five patients developed moderate mitral regurgitation and 20 patients developed mild mitral regurgitation. Seven patients had moderate tricuspid regurgitation and 18 patients had mild tricuspid regurgitation. The quality of life of these patients was good and was observed continuously. Three patients with atrial fibrillation maintained sinus rhythm, and the electrocardiography and echocardiography results were as shown in Tables 1 and 2. The peripheral oxygen saturation levels of patients in the right and left atrium groups are shown in Table 5. There was no statistical difference between the preoperative and postoperative levels in the right atrial group. The preoperative, 7-day postoperative, and 3-month postoperative fingertip oxygen saturation levels were 96.53% ± 2.84%,  $97.19\% \pm 3.57\%$ , and  $96.89\% \pm 4.19\%$  for patients in the right atrium group and 96.81% ± 3.17%, 95.37% ± 4.62%, and  $94.53\% \pm 4.95\%$  for patients in the left atrium group. The 3-month postoperative levels were lower than

Table 4. Complications and Mortality Early after Surgery\*

	Left Atrium	Right Atrium
	Group	Group
	(n = 46)	(n = 41)
Repeat thoracotomy	0	1 (2.43%)
Infectious endocarditis	1 (2.17%)	0
Hemoglobinuria	1 (2.17%)	1 (2.43%)
Low cardiac output syndrome	1 (2.17%)	2 (4.87%)
Respiratory failure	3 (6.52%)	1 (2.43%)
Atrioventricular block	1 (2.17%)	0
Early death	1 (2.17%)	0

<sup>\*</sup>Data are presented as no. of cases (%).

Table 5. Fingertip Oxygen Saturation Comparison between the Left and Right Atrium Groups\* (Mean ± SD)

	Left Atrium	Right Atrium
	Group	Group
	(n = 46)	(n = 41)
Preoperatively	96.81 ± 3.17	$96.53 \pm 2.84$
7 Days postoperatively	$95.37 \pm 4.62$	97.19 $\pm$ 3.57 $\ddagger$
3 Months postoperatively	$94.53 \pm 4.95^{\dagger}$	96.89 ± 4.19‡

<sup>\*</sup>Data are presented as the mean  $\pm$  SD.

the preoperative levels in the left atrial group, but there was no statistical difference between the preoperative and 7-day postoperative levels. Compared to the left atrial group, the levels of fingertip oxygen saturation in the right atrial group were higher at 3 months postoperatively, but there were no statistical differences between the preoperative and 7-day postoperative levels.

#### **DISCUSSION**

P-AVSD repair surgery is difficult due to the left and right atrioventricular valve deformities and the shift in the atrioventricular node and cardiac conduction bundle. Additionally, surgery can easily lead to conduction block and is associated with a high risk of the need for reoperation. Therefore, understanding P-AVSD is important [Minich 2010; Shinebourne 2011]. In our study, 87 P-AVSD patients underwent on-pump beating heart surgery under mild hypothermia. We demonstrated that this technique could prevent the occurrence of conduction block and had unique effects on left atrioventricular valve plasty [Xiao 2001].

# Application of On-Pump Beating Heart Surgery under Mild Hypothermia in P-AVSD

EXPOSURE OF THE SURGICAL FIELD: When the cardiopulmonary bypass temperature was dropped to 32°C ± 1°C, onpump beating heart surgery could obstruct only the superior

 $<sup>^{\</sup>dagger}P$  < 0.05 relative to postoperative findings.

 $<sup>^{\</sup>ddagger}P$  < 0.05 relative to the left atrium group.

and inferior vena cava, without aortic cross-clamping and potassium cardioplegia, to maintain coronary perfusion and the myocardial blood supply. When the aortic valve had no lesions, good closure without regurgitation was enabled. Intraoperative bleeding primarily originated in the coronary sinus and pulmonary vein. The drainage tube was inserted into the left portion of the heart across the right pulmonary vein opening and was placed in the left ventricle across the mitral valve to maintain communication with the atmosphere. This technique completely drained the return blood of the pulmonary vein and the coronary sinus, thus resulting in beneficial effects without affecting the operation. Additionally, due to the low temperature, the aortic perfusion pressure was approximately 60 mmHg, the heartbeat was slow, and the myocardium was soft and easy to pull; the surgical exposure was sufficient to complete the operation [Xiao 2001].

# Using the Comprehensive Sequential Exhaust Method to Improve the Exhaust during Surgery

Complete exhaust airflow is a key technology used to avoid air embolism and is one of the most important concerns of cardiac surgeons. A set of comprehensive and sequential methods to ensure complete exhaust, including a draft tube placed in the left ventricle through the mitral orifice, was established after exploration and research in clinical practice. Using this method, the continuous left ventricular drainage and maintained mitral opening caused the left atrial and left ventricular pressure to be similar to the atmospheric pressure. The aortic perfusion pressure was approximately 60 mmHg, the aortic valve was closed tightly, and the gas did not enter the systemic circulation. Prior to closing the atrial septum, the operating table was set at a low position and leaned to the left at 30° to 45°; the left ventricular drainage was stopped and the heart was squeezed after the left atrium and left ventricle filled with blood, which was conducive to expelling the gas retained in the pulmonary vein. A Y-type tube was inserted in the root of the aorta and drained continuously. With this procedure, the microbubbles in the aorta were expelled thoroughly [Xiao 2001]. In our study, because the gas was removed thoroughly, patients did not develop complications such as cerebral air embolism.

### Myocardial Protection

The on-pump beating heart operation has been proposed as an effective technique for myocardial protection in cardiac surgery. During cardiopulmonary bypass without interruption of the coronary blood flow, the myocardium continues to receive oxygenated blood and ischemia-reperfusion injury is minimal. Therefore, the on-pump beating heart procedure has been widely accepted [Mo 2011; Xiao 2001]. In our study, only 3 patients (3.45%) developed low cardiac output syndrome following this operation. One of these patients had severe pulmonary hypertension before operation and 2 patients presented with moderate or worse mitral regurgitation in the early postoperative period. We observed that the predictors of low cardiac output syndrome included severe pulmonary hypertension or residual mitral regurgitation in the early postoperative period.

### **Existing Problems**

There are still some aspects of the on-pump beating heart technique that can be improved. Due to the performance of cardiopulmonary bypass without interrupting the coronary blood supply, increased blood return to the surgical field and increased suction tube application may lead to blood damage and a high incidence of hemoglobinuria during the early post-operative period. In our study, 2 patients developed hemoglobinuria (2/87, 2.3%); however, this symptom dissipated after 2 hours without apparent damage.

### Surgical Strategy for Atrioventricular Valve Deformity

Treatment of atrioventricular valve deformity is the key problem in P-AVSD, which is also the main reason for the need for reoperation [Xiao 2001; Tekin 2007; Padala 2008; Chowdhury 2009; Shinebourne 2011]. The incomplete fusion of the upper and lower endocardial cushion leads to primum atrial septal defect and clefts of the mitral and tricuspid valves in most patients with mitral and tricuspid insufficiency. The mitral valve cleft was previously placed at the junction of the ventricular valve. With the molding operation, mitral stenosis may occur postoperatively; therefore, the cleft was not treated or was sutured only partially during the operation. Longterm follow-up studies have shown that the main reason for reoperation is the postoperative residual mitral regurgitation induced by valves without treatment or with incomplete treatment. However, reasonable valvuloplasty techniques do not cause new and forward orifice stenosis [Padala 2008; Stulak 2010]. Recently, Padala et al. reported that the treatment of mitral valve cleft should perfectly correct the defect and be reasonably effective. In patients with left atrioventricular dual valves, the valve bridge should be protected carefully during the operation due to the presence of 2 valves with 1 papillary muscle and cable and 1 fibrous tissue bridge between the main valve and the additional valve. Injury or resection could lead to serious insufficiency. Additionally, for most adult patients with tricuspid valve developmental defects and insufficiency, improvement of the tricuspid valve lesion using modified De Vega techniques and mechanical rings is also important [Shinebourne 2011].

In our study, left atrioventricular valvuloplasty was performed using on-pump beating heart surgery under mild hypothermia. The valve was closed and opened with cardiac rhythm during the operation to maintain the natural physiological state. Compared to arrested surgery, this method is conducive to observation and judgment of the function of the valve opening and closing and adjustment of the valvuloplasty according to the findings of the investigation.

# Improvement in Atrial Septal Defect Repair and Prevention of Atrioventricular Block

In P-AVSD, the primum atrial septal defect is usually large. Due to the location of the defect, the orifices of the coronary sinus, atrioventricular node, and cardiac conduction bundle are shifted downward, and this bundle is displaced downward along the septal crest line [Minich 2010; Shinebourne 2011]. Recently, the 2 major atrial septal defect repair methods have included the McGoon method and the Kirklin

method. The latter method is used widely owing to the significantly lower incidence of atrioventricular block relative to that of the former method, although the coronary sinus is separated into the left atrium in this procedure, which could lead to a right-to-left shunt [Shinebourne 2011]. Chowdhury et al [Chowdhury 2009] reported that in their studies supraventricular arrhythmias were observed in 11.3% of patients after surgery, and complete and permanent atrioventricular dissociation occurred in 1.5% of patients. These patients required permanent pacemaker implantation. El-Najdawi et al reported that complete atrioventricular block occurred in 9 patients (3%), and permanent pacemakers were implanted in 11 patients (3.29%) [El-Najdawi 2000]. Mavroudis and Backer reported that postoperative permanent pacemakers were implanted in 2% and 4% of patients after surgery for atrioventricular septal defect [Mavroudis 2004].

In our study, we adopted a modified Kirklin method combined with the on-pump beating heart technique to repair primum atrial septal defects. The defect repair was successful, without postoperative residual leakage, because the residual leakage could be easily checked after atrial septal patching and was repaired in time. Additionally, atrioventricular block might have been prevented by electrocardiography and observation of the heartbeat during the operation. In our study, during repair of the primum atrial septal defect, 7 patients developed complete atrioventricular block when their sutures were transferred quickly from the right atrioventricular valve to the right atrium. The block gradually recovered after the sutures were removed and the 2-3 sutures were added with a pledget forward to the posterior tricuspid valve and transferred to the right atrium to avoid conduction block. These results illustrate that the on-pump beating heart technique is superior to other methods. In our study, 1 patient developed permanent III degree atrioventricular block (1.15%) that was not related to the operation itself. This 52-year-old patient had sinus bradycardia and II degree atrioventricular block with a P:QRS of 2:1 prior to surgery and intended to undergo permanent pacemaker implantation. A third degree mitral valve was noted, with severe mitral regurgitation and valvular calcification. It was difficult to perform mitral valve valvuloplasty, and a mechanical prosthetic mitral valve replacement was completed. After valve replacement surgery, atrioventricular dissociation appeared and an epicardial pacemaker was implanted; a permanent pacemaker was then implanted after 8 days and the patient recovered well.

### Treatment of Coronary Sinus Flow

During P-AVSD surgery, a modified Kirklin method should be used to reduce the occurrence of conduction block. Generally, the coronary sinus ostium should be separated into the left atrium. However, separation into the left atrium will inevitably lead to iatrogenic right-to-left shunting. In our study, compared to the left atrial group, the levels of the fingertip oxygen saturation in the right atrial group were higher at 3 months postoperatively. This showed that a coronary sinus retained in the right atrium might maintain oxygen saturation. As for patients with P-AVSD, if the persistent left superior vena cava is present, it should be treated. If there is

large innominate vein traffic and resistance without venous reflux disorders, it can be ligated. If there is no traffic vein, whether reflux flows into the left or right atrium or back into the coronary sinus ostium, the orifice of the coronary sinus should be separated into the right atrium. Otherwise, massive amounts of venous blood flow back into the left portion of the heart, and iatrogenic cyanosis might occur after surgery. The primum atrial septal defect repair method of separating the coronary sinus vein into the right atrium is often used in the McGoon method. To avoid bundle injury, a pericardial patch is sutured on the lower left atrioventricular valve and the lower edge of the defect [Shinebourne 2011]. However, this method was not absolutely effective. In our study, 1 patient underwent surgery according to the McGoon method. When the lower left atrioventricular valve and the lower edge of the defect were sutured, the heartbeat was suddenly stopped; after the thread was removed, the heart resumed beating. For this condition, we used a modified Kirklin method in which the straight edge of the pericardial patch was sutured on the root of the right atrioventricular valve with interrupted 3-0 Ethibond everting mattress sutures and a pledget. The lower edge was located at the junction of the right lower lobe and the adjacent lateral leaflets, which was sutured interruptedly by sutures with a pledget at the back of the right atrium and the top of the coronary sinus orifice, then the right margin of the sinus orifice was sutured continuously using a 4-0 Prolene line. Combined with the on-pump beating heart technique, electrocardiography, and heartbeat observation, atrioventricular node and cardiac conduction bundle injury and atrial septal defect residual leakage did not occur in the 41 patients who underwent this operation.

### CONCLUSION

The coronary sinus retained in the right atrium might maintain oxygen saturation. On-pump beating heart surgery under mild hypothermia is a safe and feasible method, and the application of this technique in P-AVSD patients might prevent atrioventricular block.

## **AUTHOR CONTRIBUTIONS**

LC is the senior author of the paper and undertook patient procedures and was the primary writer of the manuscript. YBX is the guarantor of the integrity of the entire study. XFW and BCC carried out patient procedures. RYM, JH, and WC took care of patients, conducted an extensive literature search, spoke with the patients, and contributed significantly to the intellectual content of the report. CQ carried out the data analysis.

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