Comparison of results and economic analysis of surgical and transcatheter closure of perimembranous ventricular septal defect

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Methods: A total of 345 consecutive patients who underwent isolated perimembranous ventricular septal defect closure were identified between July 2009 and July 2011 in our institution. A total of 157 patients with perimembranous ventricular septal defect (45.5%) underwent percutaneous closure and the remaining 188 patients (54.5%) were treated surgically.

Results: In the percutaneous closure group, 156 patients (99.4%) had immediate complete closure and 186 (98.9%) in the surgical group were treated successfully (P = 0.671). The surgical group was significantly younger (P = 0.000) and larger in size (P = 0.000). One case of irreversible complete atrioventricular block and one death occurred in the surgical group. There was no significant difference in terms of hospital stay between the two groups. The total medical cost in the percutaneous closure group was lower compared with that in the surgical group (P = 0.005). Charges for medication, bed occupancy and nursing care of patients undergoing surgical closure were greater than those for patients undergoing transcatheter closure (P = 0.000, P = 0.000, P = 0.000, respectively). None of the patients in the percutaneous closure group required blood transfusion during hospitalization. Charges for radiography, lab and ultrasound in the percutaneous closure group were higher compared with those in the surgical group (P = 0.000, P = 0.000, respectively).

Conclusions: Compared with surgical repair at our institution, the superior clinical outcomes and economic benefits of percutaneous closure are inspiring. Percutaneous closure is a valuable alternative to surgery and allows more patients to be effectively treated in China.

Keywords: Ventricular septal defect · Catheterization · Surgery · Cost

Introduction

Ventricular septal defect (VSD) is a common congenital heart disease in childhood, occurring in 20% as an isolated lesion [1]. According to our knowledge, ~75–80% of VSD are a type of perimembranous VSD. Surgical treatment is a widely accepted procedure and has been associated with minimal mortality. Unfortunately, it also carries potential risks of complete atrioventricular block (cAVB), postpericardiotomy, wound infection, neurological sequelae after cardiopulmonary bypass (CPB) and so on. In addition, formation of scar tissue after surgery is also a common concern for many patients. In 1988, Lock et al. [2] first reported their attempt at transcatheter closure of perimembranous VSD using a Rashkind double-umbrella device.

Nowadays, percutaneous closure (PC) is considered as an alternative to surgical closure for some suitable lesions at many institutions [3–6]. Regrettfully, there is inadequate literature about the comparison of clinical outcomes and economic analysis between surgical treatment and transcatheter closure of perimembranous VSD in China. Our institution embarked on a comparison of clinical outcomes and economic evaluation of surgical treatment and transcatheter closure using a modified double-disk occluder with symmetric and asymmetric left disks during hospitalization.

Materials and Methods

Patient selection

A total of 345 consecutive patients who underwent isolated perimembranous VSD closure with either transcatheter closure or
surgical treatment were identified from July 2009 to July 2011. The clinical characteristics of the patients were reviewed. Standard 12 lead electrocardiography and transthoracic echocardiography (TTE) were performed before the procedure. All patients were screened with TTE in the long axis parasternal view and apical five-chamber view to evaluate the rim under the aortic valve and in the short axis parasternal view to measure the rim from the tricuspid valve to the defect. The ejection fraction of left ventricular and flows through the mitral, tricuspid and aortic valve were all measured. Some serious complications during hospitalization were also noted.

Patients were not randomized to treatment group. Inclusion and exclusion criteria had been set before the research. Inclusion criteria for transcatheter closure were (i) age >3-years or weight >10 kg; (ii) maximum diameter ≤16 mm by TTE; (iii) defect located at 9–11 o’clock positions of an analogue clock in the short axis parasternal view; (iv) left to right shunt and (v) pulmonary pressure <70 mmHg by TTE. Surgery was performed on patients who were unsuitable for PC or suitable but opted for surgery. Patients with aortic valve prolapse, severe aortic or tricuspid regurgitation, right to left shunt, severe cyanosis, pulmonary pressure ≥70 mmHg and cardiac function class were excluded. No patient with post-infarction or postoperative residual VSD was included. The Ethics Committee of our hospital approved the study, and the choice of closure was discussed with the patients and consents were obtained.

**Occluder device and percutaneous device implantation**

The device used in the PC group was a new modified double-disk occluder (MDVO, Shanghai Shape Memory Alloy Ltd., China), which was designed based on the Amplatzer occluder and had been widely used in China. The occluder was made of flexible nitinol wire (0.01 mm) covered in a polyester fabric, which was sutured to the nitinol wire and fixed into a double-round shape. The modified double-disk occluder was approved by the State Food and Drug Administration (SFDA) of China. Unlike the Amplatzer occluder, there are two types of modified double-disk occluders: symmetric and asymmetric. The right disk of both symmetric and asymmetric occluders is similar to the Amplatzer occluder. The only difference is the shape of the left disk. In the symmetric occluder, which was used for those defects with rim ≥2 mm under the aortic valve, the left disk is symmetric. The diameter of the left disk is 4, 6 or 8 mm larger than that of the waist, respectively (A2B2, A3B2 or A4B2 occluder). The waist length of both A2B2 and A3B2 occluders is 2 mm and that of A4B2 is 2.5 mm. In the asymmetric occluder, which was used for those defects with <2 mm rim under the aortic valve, the diameter of the left disk is 6 mm larger than that of the waist. The left disk extends towards the apex and no superior margin extends towards the aorta. Thus, it is also named the zero eccentricity occluder. The waist length of asymmetric occluder is 2 mm.

Percutaneous device implantation was performed under local anaesthesia for children ≥10 years and adult patients. Children <10 years received ketamine basal anaesthesia. Heparin (100 IU/kg) was injected intravenously before the procedure. Diagnostic catheterization was performed to assess the ratio of pulmonary to systemic blood flow (Qp/Qs). Left ventriculography at 45–60° in the left anterior oblique and a 20–25° cranial tilt defined the location, shape and size of the VSD and the relationship between the aortic and tricuspid valves. A 5–10 French delivery sheath was placed in the left apex and a pigtail catheter was placed in the left ventricle for reference. The size of the occluder was selected at least 1–2 mm larger than the maximum diameter of the defect on the basis of ventriculography. The device was released only when its adequate position was obtained on the basis of aortic angiography, ventriculography and TTE evaluation. After the procedure, all patients were transferred to the general wards and administered aspirin 3–5 mg/kg per day for 1 month and then 100 mg per day for 5 months. Postoperative electrocardiography and TTE were performed routinely within 1 week after the procedure. Clinical symptom, physical examination, electrocardiography and TTE were routinely assessed for all patients at 1, 3, 6 months postoperatively at our outpatient clinic.

**Surgical treatment**

In the surgical group cardiac catheterization was required when the haemodynamic significance of VSD was questioned or when the assessment of pulmonary artery pressure was necessary. Surgical closure of perimembranous VSD was achieved through a mid-line sternotomy or right subaxillary slant incision thoracotomy by using moderate hypothermia at 32–34, CPB, aortic cross-clamping and cold crystalloid cardiopulmonary arrest. The defect was reached using an incision in the right atrium. Intraoperative temporary detachment of the tricuspid valve increased the exposure of the defect. Depending on the size of the defect and surgeon preference, the VSD was closed by direct suture or with a Dacron patch using an interrupted suture. After the surgery, patients were routinely transferred to the intensive care unit (ICU) for observation for 24–48 h. After discharge from the ICU, patients were monitored on a regular ward for ~2 days. Postoperative electrocardiography and TTE were also performed routinely within 1 week after the surgery. Patients were also followed at our outpatient clinic with physical examination, electrocardiography and TTE at 1, 3, 6 months postoperatively.

**Economic analysis**

In order to evaluate the economic analysis of this comparative study, data related to the length of hospital stay and ICU stay, operative and fluoroscopic time, time until return to a general diet and normal activity, cost for each charge and total medical cost were obtained from hospital records by two staff members. Our cost analysis compared only the direct medical economic burden (DMEB) in relation to the clinical success of the two procedures. DMEB included medication, blood transfusion, X-ray, ultrasound and laboratory tests, bed cost, nursing care, operation, device cost and so on.

**Statistical analysis**

Continuous variables were expressed as mean values and standard deviation. Univariate analysis was performed by the Student t-test
and chi-square test or Fisher’s exact test. Non-normal distribution of measurement data were analysed with Mann–Whitney U-test. P-value < 0.05 was considered statistically significant. The data were analysed with statistic software SPSS 17.0.

RESULTS

Demographic data and clinical characteristics

No procedure was aborted. 157 of 345 patients with perimembranous VSD (45.5%) were under percutaneous occlusion and the remaining 188 patients (54.5%) were treated surgically. The patients with surgical closure were significantly younger than those with PC (P = 0.000). Of 157 patients in the PC group, 156 (99.4%) had immediate complete closure and 186 of 188 patients (98.9%) in the surgical group were treated successfully (P = 0.671). In the PC group, nine patients (5.7%) younger than 3 years but with a body weight >10 kg were included and PC was performed on them successfully. In the surgical group, 180 of 188 patients (95.7%) were closed with a patch using an interrupted suture and the remaining 8 (4.3%) were closed by direct suture. The mean VSD diameter of the patients with surgical closure was larger than that of those with PC (P = 0.000). The size of the device used in the PC group ranged from 4 to 14 mm. There was no significance in the occurrence of residual shunt between the PC group and surgical group during hospitalization (P = 0.287). In the surgical group, one patient had a moderate shunt reported on TTE (Table 1).

Serious complications after closure

Complications during hospitalization were analysed: wound infection, arterio-venous fistula, irreversible cAVB and death. The incidence of wound infection was more common in the surgical group (1.1%) vs PC group (0%), including one case of incision fat liquefaction and another case of sternal dehiscence. Femoral arterio-venous fistula occurred in one case of the PC group (0.6%). The fistula was healed after simple observation for ~4 weeks.

Moreover, some serious postoperative complications occurred in three patients, including one case of serious tricuspid valve regurgitation requiring surgical repair, one case of irreversible cAVB and one case of death (Table 2). In the PC group, one device was not released during the procedure in a 13-year-old girl for the new-onset tricuspid regurgitation and the patient was converted to surgery. A 6-year-old girl in the surgical group developed permanent cAVB during the procedure and received a permanent pacemaker implantation after corticosteroid therapy for 3 weeks. A 4-year-old boy in the surgical group showed significant dysfunction of left ventricle and myocardial stunning weaning from CPB and finally died with a low cardiac output.

Clinical data and cost-effectiveness analysis of the two groups

Operating time was significantly longer in patients undergoing surgical closure (P = 0.000). No patient was transferred to the ICU after device deployment in the PC group, while all patients in the surgical group were transferred to the ICU with a mean time of 1.28 ± 0.57 days. The mean time of fluoroscopy in the PC group was 6.7 ± 4.0 min. Time until return to the general diet and normal activity was shorter in the PC group than that in the surgical group (P = 0.000). There was no significant difference in terms of hospital stay between the two groups (P = 0.054). The total medical cost in the PC group was lower than that in the surgical group (P = 0.005) (Table 3).

Charges for medication, bed occupancy and nursing care of patients undergoing surgical closure were greater than those of patients undergoing transcatheter closure (P = 0.000, P = 0.000, P = 0.000, respectively). None of the patients in the PC group required blood transfusion during hospitalization. Charges for radiography, lab and ultrasound in the PC group were higher compared with those in the surgical group (P = 0.000, P = 0.000, P = 0.000, respectively) (Fig. 1).

Postoperative follow-up

After discharge 149 patients (94.9%) in the PC group and 176 (93.6%) in the surgical group were followed up in our out-patient clinic and clinical examination, electrocardiography and TTE were performed on them. Mean duration of follow-up for patients who underwent surgical repair and transcatheter closure was 5.1 ± 1.2 and 5.2 ± 1.3 months, respectively (P = 0.436). No late deaths or cases of serious complications were reported. However, 10 cases (6.7%) of incomplete right bundle branch block occurred in the PC group. Twenty-six cases (14.8%) of incomplete right bundle branch block and 1 case (0.6%) of complete right bundle branch block occurred in the surgical group. No patients had left bundle branch block or cAVB. All residual shunts had either decreased or remained unchanged in both groups.
DISCUSSION

In this study, we compared the clinical and economic data of conventional surgery and PC with a modified double-disk occluder for all ages of patients of perimembranous VSD during hospitalization. Most cases of perimembranous VSD were treated successfully with a procedural success rate of 99.4% in the PC group and 98.9% in the surgical group. There were no significant differences of success rate between the two groups. Similar closure rate in patients with transcatheter closure has also been reported between 90 and 100% [7–9].

Serious complications during hospitalization

Postoperative TTE were performed after the procedure and there were no significant differences of occurrence of residual shunt between the two groups except for a case of moderate shunt in the surgical group. Excluding minor postoperative complications like wound infection, arterio-venous fistula, small pleural and pericardial effusion, minor arrhythmia and valve regurgitation, we listed three patients with serious complications during hospitalization.

In the PC group, one device was not released in a 13-year-old girl during the procedure because of interference with tricuspid valve motion. The VSD was perimembranous with an aneurysm. The defect was characterized by two exits with diameters of 4 and 4 mm. The symmetric occluder with a diameter of 9 mm was selected and echocardiography during the procedure showed serious interference with tricuspid valve closure. Therefore, the patient was converted to surgery and the defect was finally closed by a Dacron patch with a diameter of 18 mm. According to ventriculography, Qin et al. [10] classified the shape of defects into infundibular, aneurysmal, tubular and window-like. He pointed out that the aneurysmal defect particularly for multihole VSD, was more complex to close and the A4B2 symmetric occluder ought to be placed at the base of the aneurysm to close the inlet when the diameter of the inlet in the left side was <14 mm. Otherwise an asymmetric device placed at the inlet was the best selection.

cAVB is one of the most serious complications after closure. Occurrence of cAVB is reported in 1–5% [9, 11, 12] after surgical closure. The rate of cAVB caused by PC is reported as 0–8.7% [9, 13]. In contrast to literature previously reported, we found no case of permanent cAVB occurring within the first week after the percutaneous procedure. Permanent cAVB occurred in one patient during the surgical repair. After the treatment with corticosteroid, isoprenaline and temporary pacemaker implantation for 3 weeks, the patient did not recover and had to be treated with VVI pacemaker implantation. Ineffective therapy with corticosteroid for several weeks suggested that the physical injury of the conduction tissue or scar formation maybe the reason for the onset of conduction block. The reasons for the discrepant occurrence between the two groups are as follows. Firstly, the patients in the surgical group were significantly younger and had a larger size of defect. Butera et al. [9] suggested that age was significantly associated with the occurrence of cAVB and cAVB occurred only in subjects who were <6 years. Thus, the odds of affecting the conduction in the surgical group was higher. Secondly, the waist of the modified double-disk occluder was longer than that of the Amplatzer occluder (2.5–1.5 mm) so the strain of the septum might be smaller in the patients undergoing PC. Thirdly, improvement in preprocedural echocardiography played an important role in reducing the rate of serious arrhythmia. One of the most important inclusion criteria was the defect located at 9–11 o’clock positions of an analogue clock in the short axis parasternal view, which might be the key to achieving good results after PC. The zero eccentricity occluder was used for defects with a rim <2 mm under the aortic valve. Fourthly, appropriate device selection is important to avoid

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TR: tricuspid regurgitation; cAVB: complete atrioventricular block.

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complete heart block. The size of the occluder selected 1–2 mm larger than the largest measured diameter of VSD may be related with the lower incidence of cAVB in the PC group.

Mortality is close to zero for PC and although rare with cardiac surgery in the current era, it can still occur [14, 15]. Tucker et al. [16] reported the hospital mortality of 0.2% in the contemporary year, of 1315 patients after surgical repair. In our study, no deaths occurred in the PC group and one boy (0.5%) aged 4 died after surgical repair. His left ventricle showed significant dysfunction and myocardial stunning weaning from CPB. After treatment with dopamine, temporary pacemaker implantation, breathing machine for 2 h and defibrillation for three times, he died with in low cardiac output.

Clinical and economic advantages of percutaneous closure

Our analysis confirmed the described clinical and economic advantages of transcatheter closure in comparison with surgical closure, including an avoidance of extracorporeal circulation, ICU stay and blood transfusion, a shorter time of procedure, an earlier return to a general diet and activity and a lower medical cost. Although the hospital stay of the PC group appeared to be shorter than that of the surgical group, this difference failed to be statistically significant (7.09 ± 2.31 vs 11.00 ± 2.20 days; P = 0.054). Oses et al. [17] demonstrated the mean hospital stay for the PC group was 1.4 ± 1.2 and 10.6 ± 7.2 days for the surgical group (P < 0.001). Since cAVB usually occurred within the first week after transcatheter closure, the patients in our institution needed electrocardiographic monitoring for at least 1 week during hospitalization.

Most studies have shown an increased cost for PC in western countries because the cost of Amplazer device represents the main part of the total cost. In our institution, the cost of a modified double-disk occluder is $1902.80 and transcatheter closure proved about 10% cheaper in comparison with surgical closure ($3869.70 ± 343.11 vs 4582.74 ± 841.64 respectively, P = 0.005). The main parts of the charges in the surgical group were the cost of medication and stay in ICU. China’s per capita income is not comparable with that of Western countries and health care resources are limited, therefore, PC allows more patients in China to be effectively treated.

Limitations

Nevertheless, a limitation of the study is that it was a single-centre study and not randomized. Our institution could perform the transcatheter and surgical closure safely and effectively which attracted patients with congenital heart diseases from many places in China to our hospital. Therefore, the experiences of our institution may partly represent the situation of the treatment of perimembranous VSD in China.

Another limitation of the study is that it was a retrospective study during hospitalization. Follow-up of the patients is short and a few patients were not seen after the 6-month post-operative clinic visit. To our knowledge, studies on the safety and efficacy of transcatheter VSD closure with early-term and long-term follow-up have been previously reported and showed encouraging results. The key point of our study was to compare the clinical and economic data of the transcatheter and surgical closure during hospitalization. To thoroughly confirm the safety and effectiveness of the two procedures in a long-term follow-up, we would like to carry out a separate study in the future.

Asymptomatic patients with small VSD represent a controversial group for closure. There were some small VSD in the study that were closed not because of symptoms or haemodynamic changes. Patients with small VSD are at risk of infective endocarditis or progressive aortic valve prolapse leading to aortic insufficiency. Besides, patients with small VSD could suffer from psychological pressure on entering school, finding jobs or getting married in China. Therefore, we closed some small VSD in order to prevent the occurrence of infective endocarditis or reduce psychological pressure.

CONCLUSIONS

In experienced hands PC using a modified double-disk occluder is safe and effective for selected perimembranous VSD cases. Its advantages lie in its minimal invasiveness, an avoidance of ICU stay and blood transfusion, a shorter time of procedure, an earlier return to a general diet and activity, better clinical outcomes and economic benefits during hospitalization. Nowadays, PC is recommended as an effective and reliable procedure in China.

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