Original Article

Comparison of Clinical Outcomes and Cost Between Surgical and Transcatheter Device Closure of Atrial Septal Defects in Singapore Children

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Abstract

Introduction: With advances in interventional catheterisation, transcatheter device closure of atrial septal defect (ASD) is now a feasible option to open heart surgery, especially in patients with isolated ASD. We aim to compare the outcomes, benefits and costs between device closure versus standard open-heart surgery for ASD in Singapore. Materials and Methods: This is a comparative study between 2 cohorts with isolated secundum ASDs who underwent closure of ASD either by surgery or device, at the Department of Paediatrics, National University Hospital (NUH). The clinical outcomes, complications, length of stay and total costs incurred were compared. Results: Surgical patients were at slightly greater risk of developing complications (RR=1.33; 95% CI, 0.30 to 5.95) than the device group. The median length of inpatient stay for the surgical group was significantly longer than that for the device group. Seventy percent of the patients in the device group did not need to be in ICU while 40% of patients in the surgery group stayed 2 or at least 3 days in ICU (*P* <0.001). The mean cost per successful procedure was $1511 (95% CI, -352 to 3375) higher for the device group patients despite a shorter length of stay in hospital. Conclusions: We concluded that transcatheter device closure is an effective and safe alternative to surgery in the treatment of suitable ASDs. Despite the high cost of the device, direct and indirect benefits for the patients and their families, who undergo device occlusion include less morbidity, better cosmesis, shorter length of stay in hospital, faster recovery and shorter time taken to resume normal activities.

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Introduction

Congenital heart defects (CHD), with an incidence of approximately 1 in 100 live births, are the most important and frequent congenital malformations.[1,2] It can cause significant morbidity and mortality in children as well as adults. Atrial septal defect (ASD) is one of the most common congenital heart defects in many countries, including Singapore. Conventional treatment with surgery through a median sternotomy using cardiopulmonary bypass is considered the gold standard for ASD for more than 45 years.[3] With recent advances in interventional cardiology, device closure through the transcatheter technique is now made possible. The first transcatheter device closure of an ASD was reported by King and Mills[4] in 1976 and was first introduced in Singapore in 1997.[5] Since then, many devices have been used, modified and/or discontinued. Of the many devices available in the market today, the Amplatzer septal occluder,[6-10] has been extensively deployed to close ASDs, and is currently one of the more established devices for the transcatheter treatment of ASD worldwide, given its safety profile. Today, advances in the field of minimally invasive surgical techniques and catheter-delivered devices have made these procedures a better alternative to surgery. Indeed, they are fast replacing open heart surgery, especially

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in isolated ASD. The perceived advantages compared with open surgery are shorter hospital stay, earlier return to normal activities, better cosmesis and fewer complications. Until now, no study has been done on cost comparison of transcatheter closure versus standard open-heart surgery in Singapore. We evaluate the outcomes, benefits and costs associated with these two methods of treating ASD.

Materials and Methods

Study Design

This was a retrospective study examining 2 cohorts of patients with isolated ASD, treated with surgery or device occlusion at a single centre. The clinical outcomes, complications, length of stay and costs of these 2 groups were compared.

Study population

Between August 2005 and December 2008, 25 consecutive patients underwent closure of an ASD in the National University Hospital (NUH). These were subjects who had isolated secundum ASDs. The diagnosis was confirmed on echocardiography, and all had evidence of right heart volume overloading, with a clinical indication for ASD closure. The suitability for transcatheter closure was assessed by echocardiogram, where particular attention was paid to the size of the defect as well as the adequacy of the rims surrounding the defect. The option of either open heart surgery or treatment with device was discussed with the patients' parents, who then decided on the choice of treatment. Open heart surgery was undertaken in those whose ASDs were considered not suitable for device closure because of very large defect or insufficient rims for device closure by the cardiologist or by parental choice.

Treatment

All transcatheter ASD closures were performed at one centre by the same paediatric cardiology team. The procedure was carried out under general anaesthesia, and venous access achieved through the femoral route. Oximetry of the right heart was performed, and the defect studied carefully using transesophegeal echocardiography (TEE). Based on the TEE, an appropriate sized device was chosen. This was delivered through a long sheath into the left atrium. The left atrial disc was deployed under TEE and fluoroscopic guidance (Fig 1). The system was then pulled back to straddle the atrial septal defect, and the long sheath withdrawn to deploy the waist and right disc of the Amplatzer septal occluder device (Fig 2). Once satisfactory position was confirmed on TEE, the device was then released and the sheath and connecting wire removed from the groin (Fig. 3). Haemostasis was secured, and the patient observed overnight and discharged the next day.

For those patients who underwent surgery, this was carried out by the same surgical team using the standard approach. Pericardial patch closure of the defect was performed under cardiopulmonary bypass, following which the sternum was closed. The patient was then brought to the intensive care unit before extubation, and then on to the general ward for recovery when their condition stabilised until discharged.

Complications

Complications were recorded, and classified as major or minor (Table 3).

Cost Estimation

Cost per case was calculated based on total hospitalisation that was reflected on the bill that patient would have paid, excluding any subvention. This means that it was a true reflection of the actual cost of treatment. The cost included hospital room charges, laboratory investigations, pharmaceutical charges, clinician and anaesthesia charges, facility and treatment charges, cost of surgery or device, for their respective length of stay. The bill was calculated based on a paying model in ward Class B1, this being closest to the actual cost incurred without taking into consideration any government subsidy. In so doing, we were able to

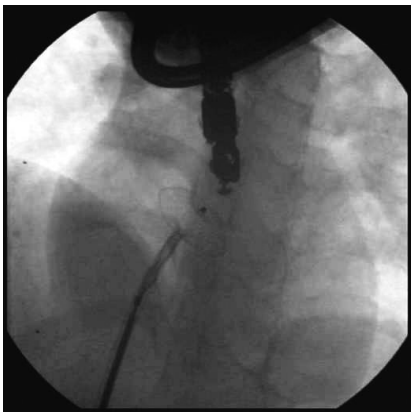

Fig. 1. Deployment of the left atrial disc

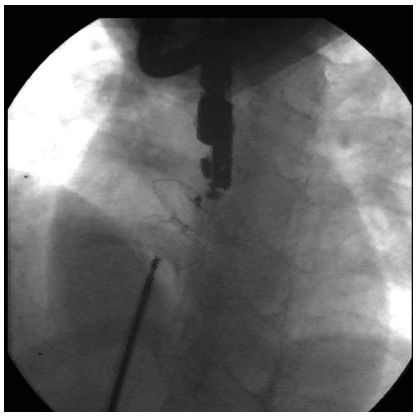

Fig. 2. Deployment of the right atrial disc.

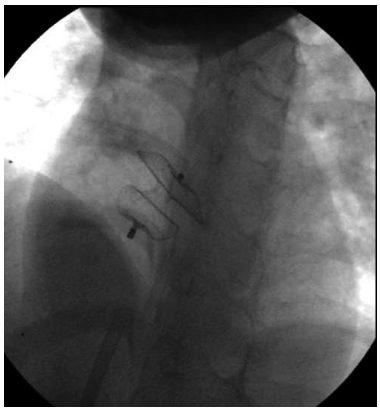

Fig. 3. Release of the device.

achieve a meaningful comparison of true costs incurred by each patient for either of the methods, which was the basis of our comparison. Although most of our patients chose the subsidised wards, Class B1 was used for computation of costs, since this made the comparison of the actual cost possible.

Statistical Analysis

Discrete categorical outcomes such as complications and number of days in ICU were compared between treatments using the Fisher's exact test. In the case of the length of hospital stay where the distribution was skewed, the duration of stay was compared using the Mann-Whitney U test. In addition, the cost outcomes were compared using the independent sample *t*-test. All statistical analyses were carried out using PASW Statistics 17.0.2, assuming a two-sided test at the conventional 0.05 level of significance.

Results

Study Population

The study population included 25 patients who were under 21 years old at the time of treatment intervention. Fifteen (8 males and 7 females) of them underwent closure by surgery and 10 (5 males and 5 females) underwent device closure. Patients on device tend to be older as compared to those with open surgery (median age 14 versus 9 years, respectively). The detailed demographic characteristics of the study population are shown in Table 1.

Clinical Outcomes and Complications

The clinical outcomes were excellent in both groups. All patients treated with device occlusion achieved successful closure of ASD. Small residual shunts after the procedure resolved on follow-up, as endothelisation took place over and around the device. The ASDs that were closed surgically also recovered well with no residual leak. The complications were minor, occurring in 4 of 15 (27%) surgical patients and 2 of 10 (20%) device patients (Table 2). Surgical patients were at slightly greater risk of developing complications (RR=1.33; 95% CI, 0.30 to 5.95) than the device group. The postoperative complications experienced by the surgical group included asymptomatic persistent tachycardia, hypertension (this may be pain-related), fever, as well as pneumopericardium and pneumoperitoneum. One patient in the device closure group developed urticaria due to oral Aspirin, which was discontinued and changed to Plavix while another developed a widespread rash probably due to intravenous cefazolin or contrast (Table 3). These were drug-related, but both did well, and the rash disappeared with treatment.

Table 1. Demographic Characteristics of Patients

	Total (n = 25)	**Surgery** (n = 15)	**Device** (n = 10)	***P* value**
Mean age (range), years	12 (2-20)	9 (2-19)	14 (6-20)	0.71
Gender (%)				0.596
Male	13 (52)	8 (53)	5 (50)	
Female	12 (48)	7 (47)	5 (50)	

Table 2. Outcomes of Study Patients

	Total (n = 25)	**Surgery** (n = 15)	**Device** (n = 10)	***P* value**
Complications (%)			0.545	
Nil	10 (40)	11 (73)	8 (80)	
Minor	15 (60)	4 (27)	2 (20)	
Total length of stay (days)				
Median (range)	5 (2-10)	6 (4-10)	2 (2-3)	< 0.001
No. of days in ICU (%)				< 0.001
0	7 (28)	0 (0)	7 (70)	
1	6 (24)	3 (20)	3 (30)	
2	6 (24)	6 (40)	0 (0)	
>= 3	6 (24)	6 (40)	0 (0)	
Total cost, mean (sd)	13,965 (2288)	13,361 (2686)	14,872 (1105)	0.107

Length of Stay and Costs

The median length of inpatient stay for the surgical group was 6 (range, 4 to 10) days. This was significantly longer than that for the device group (median 2; range, 2 to 3 days). In terms of the number of days the patient stayed in ICU, 70% of patients in the device group did not need to be in ICU, while the rest were monitored in ICU primarily because of their age. In contrast, all patients who had open heart surgery were required to be in ICU for at least 1 day, with 40% having to spend 2 or at least 3 days in ICU (P <0.001).

Table 3. Types of Complications

Surgical closure	**Device closure**
1. Asymptomatic junctional tachycardia and atrial ectopics – 1 patient (resolved spontaneously)	1. Allergy to aspirin – 1 patient
2. Hypertension and fever – 1 patient (resolved in 48 hours)	2. Allergy to cefazolin – 1 patient
3. Low grade fever – 1 patient (resolved in 48 hours)	
4. Pneumopericardium and pneumoperitoneum – 1 patient (resolved spontaneously)	

The mean cost per successful procedure was SGD$1511 (95% CI, -352 to 3375) higher for the device patients (Table 2). Although the cost of laboratory investigations, radiology and pharmaceutical charges were relatively higher for the surgery patients, the cost of the Amplatzer septal occluder device of approximately SGD$9000 weighed much heavier on the overall total charges despite a shorter length of stay.

Discussion

Device closure of ASD has increasingly become a feasible alternative of care to surgical closure in suitable ASDs, with the Amplatzer septal occluder being the most widely used device. The effectiveness of device closure has been well reported from case series and comparative studies,[11-21] although there has never been a truly randomised comparison of device versus surgical treatment for ASD. A randomised study would have been difficult, given that patients had the prerogative of choice in the treatment options available. The main aim of our study was to compare both techniques in terms of effectiveness and costs at the same tertiary centre in Singapore. We considered effectiveness in terms of procedural success, complications, length of hospital and including ICU stay, while realising that there were many other intangibles that were important enough to merit discussion. These would include post-procedural pain, cosmesis, opportunity costs and time away from school and/or work.

Apart from age and duration of hospitalisation, the 2 groups were comparable, with uncomplicated procedures and good outcomes. The age differences between our study groups indicated a slight bias towards surgical treatment for younger and smaller children. This could be explained as the tendency to surgical closure for younger patients were likely due to the technical limitations of the intervention and size of device.[22] It would be more complex and technically more challenging to implant a device in a smaller heart through the transcatheter route.

All patients had successful defect closure regardless of the method employed. However, more complications were seen in the surgical group, although these were largely minor. The median time to return to normal activities was significantly shorter in the device group since these patients required fewer days spent in the ICU and hospital. The implication of this would be that the children could go back to school and resume normal activities in a much shorter time frame. The longer hospital stay associated with surgery would also be more physically and mentally traumatic for a child and his/her parents during the recuperative process. Likewise, parents of these young patients would not need to take as much time-off from work. Although the data are not easily obtained, and therefore not factored into the cost equation, the savings in time and work-related issues would be expected to be substantial.

Another important consideration favouring device closure is the absence of surgical scar. It would take the form of a long central sternotomy scar as cardiopulmonary bypass is involved in open-heart surgery. This is a significant disadvantage in female patients, as the scar could be unsightly especially for those with a tendency to keloid formation. In contrast, the interventional route which uses femoral access would be entirely scar-free once the puncture marks heal over the groin in the next few days.

Importantly, there is a significantly better quality of life with less postoperative pain in the interventional method as compared to the pain experienced with a central sternotomy. Again, while not always discussed, this must be given due recognition, especially in a child who may be 'mentally' scarred by the experience as well. These are valid considerations for patients who may be faced with a choice of treatment, apart from the clinical considerations such as age, weight and size of defect.

In our analysis, costs were related to the local health management system and should not be viewed as an absolute, but rather as relative economic impact for both techniques. We did not take into consideration the reimbursement (subvention) system we have in place in Singapore. Costs of similar treatments will not be applicable to different hospitals as charges differ for both professional and facility fees, and hence these results may not be generalised to other hospitals. The higher overall costs in the device group were largely due to the high cost of the device. Nevertheless, in terms of resources in the hospital system, there is less utilisation of beds (shorter length of stay), and ICU facilities. This would free up resources, both in terms of facilities/equipment and manpower (doctors and nurses), which are absolute considerations in many of our public hospital settings where space and resources are operating at a premium.

Conclusions

We have reported the feasibility of transcatheter device closure as an alternative to surgery in the treatment of suitable atrial septal defects. This transcatheter technique is effective and safe for the treatment of ASD as compared with the conventional surgical method. Overall there were more complications in the surgical group than the device group, but all of these were minor and did not require much change in management. There were no cost savings with the newer transcatheter technique as compared to surgery despite a shorter hospital stay for patients undergoing ASD treatment in Singapore because of the high cost of device. However, there are major direct and indirect benefits for the patients who undergo device occlusion, such as less morbidity and less time spent in the hospital. This is the first study of its

kind comprehensively evaluating outcomes, costs and other facets in comparing treatment options. Additional studies with larger numbers of patients and longer term follow-up along these lines will be useful in further validating our observations and making recommendation for treatment guidelines of this condition.

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