The Egyptian Heart Journal 70 (2018) 249–253

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Contents lists available at ScienceDirect

The Egyptian Heart Journal

journal homepage: www.elsevier.com/locate/ehj

Original Article

Short-term outcomes after surgical versus trans catheter closure of atrial septal defects; a study from Iran

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ARTICLE INFO

Article history:
Received 11 June 2018
Accepted 2 September 2018
Available online 17 September 2018

Keywords:
ASD
Trans catheter closure of ASD
Surgical closure of ASD
Results of ASD closure
Complications of ASD closure

ABSTRACT

Objectives: Atrial Septal Defect (ASD) accounts for 10% of congenital cardiac defects. The purpose of this retrospective study was to compare the short-term outcomes of surgical versus trans catheter closure of secundum atrial septal defect.

Methods: This is a single-center retrospective cohort study in patients who had surgical or trans catheter ASD closure. ASD closure outcomes such as hospital cost, length of hospital and ICU stay, residual ASDs, complications, readmission, hospital and three month mortality were recorded and compared.

Results: Between March 2010 and March 2016, total of 102 secundum ASD patients were treated in our center (71 patients surgical ASD closure and 31 patients trans catheter ASD closure). About 13.9% of patients (5/36) in the device group had failed procedural attempt for various reasons and these patients underwent surgery closure. Complete closure was observed in 26 of 31 patients (83.9%) in the device group and in 70 of 71 patients in the surgery group (98.6%). The mean length of hospital stay was 5.56 days for surgical group and 2.06 days for device group. The procedure cost for surgery was found to be 5.7% lower than trans catheter closure (patient payment). The complication rates were 18.3% for surgical group and 25.8% for the device group. Readmission after discharge was more common in surgery group (11.2 vs 6.4%). Hospital and three months mortality in both groups were zero.

Conclusions: Both trans catheter and surgical procedure are good methods of successful ASD closure. Considering that the surgical group patients were higher risk patients, mean total hospital cost of patient's procedures were significantly higher in device closure group, failed intervention rate and residual ASD were more common in device group and complications of device group were more serious; thus, appropriate patient selection is an important factor for successful device closure.

1. Introduction

Atrial septal defect (ASD) is a common form of congenital heart disease, accounting for about 10% of all congenital heart defects in children.[1] Secundum type ASDs are the most common form of all ASDs, approximately 80%.[2] Survival to the age of 18 years for secundum atrial septal defect is 97.0% (90.0% to 99.0%).[3]

If atrial septal defects (ASD) left untreated, lead to chronic right-sided volume overload and right-sided chamber enlargement. Therefore, all patients with hemodynamically significant ASD should undergo ASD closure, in order to prevention of long-term complications.[4]

Techniques of ASD closure included: surgical closure and device closure. Surgical closure of ASD has been performed for over 60 years and techniques have steadily improved.[5] Device closure as an alternative technique was first practiced in 1976.[6] Device closure is relatively less invasive technique and has fewer post procedure complications, lower risks of anesthesia, shorter hospital stay, and has been widely used in recent years.[7]

Conversely, there were controversies about hospital costs[8–10] and complete closure.[11] Also surgical closure of ASD is technically simple and does not require specialized long-term follow-up but operator's experience is important factor for successful device closure and after trans catheter closure, patients should remain under permanent surveillance to detect potentially serious long-term complications.[11,12]

Nevertheless, despite increasing use of device closure of ASD and no any comparison of efficacy, morbidity and complications of two techniques in our country, we present a retrospective

Peer review under responsibility of Egyptian Society of Cardiology.

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https://doi.org/10.1016/j.ehj.2018.09.003
1110-2608/

comparison of short-term (three months) results for trans catheter and surgical closure of 102 ostium secundum ASD patients in seyed al shohada heart center.

2. Methods

Between March 2010 and March 2016, 192 patients admitted in our center (seyed al shohada heart center) with ASDs, who had undergone surgical or trans catheter closure of the ASD.

Exclusion criteria's from the study were those who had other types of ASD (foramen premium or sinus venousus or PFO), concomitant surgery with exception for tricuspid valve repair and incomplete medical recordings.

The suitability for trans catheter closure was assessed by echocardiography, according to the size of the defect as well as the adequacy of the rims surrounding the defect. Open heart surgery was undertaken for ASDs that were considered not suitable for device closure because of large defect or insufficient rims for device closure by the cardiologist. Patients more than 40 years old underwent diagnostic coronary angiography prior to the procedure.

Our primary variables were age, gender, weight, height, body mass index (BMI), concomitant comorbidities including: coronary artery disease, hypertension, diabetes, COPD (chronic obstructive pulmonary disease), CVA (cerebral vascular accident), hypothyroidism and echocardiography findings.

The procedure of trans catheter closure was performed under local anesthesia, guidance of trans esophageal echocardiography (TEE), heparinization (100 U/kg), balloon sizing of ASD with stop flow technique. The patients were put on dual antiplatelet therapy of aspirin (160 mg) and plavix (75 mg) for 3 months then following it aspirin (80 mg) therapy for at least 6 months. All patients were instructed on prophylaxis for infective endocarditis for about six months after device placement.

In all surgical procedures; under general anesthesia, the chest was opened by median sternotomy. After heparinization (300–400 U/kg), aortic and bicaval cannulation, cardiopulmonary bypass was instituted. Myocardial protection achieved by cold blood cardioplegic solution was given ante grade through the aortic root. After total cardiopulmonary bypass, oblique right atrial incision was made and the total anatomy and atrial septum was carefully checked. Direct closure or autologous pericardial patch reconstruction of the septal defect was chosen by the anatomy and surgeon's preference. After completing of operation, the patient was transferred to the intensive care unit before extubation.

Patients were discharged home after four to six days in the hospital, depending on their clinical condition.

Transthoracic echocardiography was performed after 24 h in trans catheter closure group and at discharge in surgical closure group and at three months follow-up in both groups. The patients were followed for three months.

ASD closure outcomes such as hospital cost, length of hospital and ICU stay, residual ASDs, complications, readmission, hospital and three month mortality were recorded.

Statistical analyses were performed using SPSS (version 20). Statistical significance was assessed at the 0.05 level. Characteristics of trans catheter patients and surgery patients were compared using chi-square tests.

3. Results

The total of 102 secundum ASD patients with complete medical records from the 192 patients who were treated for ASDs entered in the study. Overall 90 patients excluded due to other types of ASD (primum ASD or sinus venosus or PFO) (in 22 patients), concomitant surgery with exception for tricuspid valve repair (52 patients) and incomplete medical recordings (16 patients).

There were 71 patients who accepted surgical ASD closure, while 31 patients were treated with trans catheter ASD closure. They included 23 children (range 4–15 years) and 79 adults (range 15–60 years). 22 patients in surgery group and one patient in device group were under 15 years old.

The mean age for the device group was 36.3 years, whereas it was 26.4 years for the surgery group. Patients undergoing trans catheter ASD closure were more likely older (approximately 10 years, $p = 0.007$).

Of the 102 patients, 74 (72.5%) were female. There was no difference in gender between the two procedures ($p = 0.273$).

The mean body weight was 66 kg for the device group, whereas it was 58 kg for the surgery group. Body mass index (BMI) and height was higher in device group ($p < 0.05$).

The prevalence of comorbidities including hypertension, diabetes, chronic lung disease, CVA, and hypothyroidism were not significantly different between the two group ($p > 0.05$).

Coronary angiography (CAG) was done in 21 patients in surgery group and 6 patients in device group (normal or minimal coronary artery disease), there was no difference between two groups (29.6% to 19.3%) ($P = 0.286$). Patient characteristics are summarized in Table 1.

The size of ASDs ranged from 7 to 38 mm (median = 18 mm). Mean defect diameter in all patients: in the device group, was 18.5 mm and for surgical group 18.7 mm. Whereas, in patients older than 15 years old, it was 18.3 mm versus 19.7 mm respectively ($p > 0.05$). In our study, pericardial patch was used in all cases.

Pulmonary hypertension was more common in surgery group but RV (right ventricle) size, RV function and valve problems were not significantly different between two groups.

Echocardiographic findings are summarized in Table 2.

Patients who underwent a trans catheter ASD closure had a shorter length of stay (2.06 days vs 5.56 days, $p = 0.001$).

ASD device closure had a non-significant cost difference with surgery (5.7% higher).Mean patient payment (almost 10% to 20% of total cost) for operative closure was 438 dollars versus 463 dollars for trans catheter closure that was not significantly differ between two groups ($p = 0.841$) (see Table 3).

The mean total hospital cost (including hospital room charges, laboratory investigations, pharmaceutical charges, clinician and anesthesia charges, facility and treatment charges, cost of surgery or device) in surgical closure and trans catheter closure was 2886 and 3641 dollars respectively ($p < 0.05$). The ratio of operation room or catheterization laboratory (cath lab) costs into total costs were 66% for surgical closure and 94.5% for trans catheter closure. Amplatzer and delivery system cost solely was 65.5% of total trans catheter closure costs The ratio of hoteling into total costs was 19% for surgical closure and 3.4% for trans catheter closure.

The total complications were non significantly fewer in surgery group than device group (18.3% vs. 25.8%) ($p = 0.394$). The most common minor complication was pericardial effusion in the surgery group and access site hematoma in the percutaneous group.

Hematoma in the femoral region was observed in three patients (9.7%) in the device group. There were no cases of erosions, ischemic stroke, cardiac perforation, late embolization, thrombus formation, or malposition of the device after ASD percutaneous closure. Cardiac arrhythmias that require pacemaker placement or long term anti-arrhythmia medication were not observed.

The major complications were in one patient in each groups. Post operation bleeding in surgery group and massive hemoptysis in device group ($p = 0.547$).

Table 1
Demographic characteristics of the patients.

Characteristics		Surgery group	Device group	P value
Number of patients		71(69.6%)	31(30.4%)	–
Mean age		26.43	36.36	0.007
Gender no., %	Male	21(29.6%)	7(22.6%)	0.273
	Female	50(70.4%)	24(77.4%)	
Mean weight (kg)		45.67 ± 23.01	65.92 ± 10.64	0.001
Mean height (cm)		143.42 ± 32.54	163.10 ± 7.83	0.003
BMI		20.11 ± 5.39	25.39 ± 3.72	0.001
CAG		21(29.6%)	6(19.3%)	0.286
Hypertension		5(7%)	1(3.2%)	0.456
Diabetes		2(2.8%)	1(3.2%)	0.912
Chronic lung disease		1(1.4%)	1(3.2%)	0.547
CVA		2(2.8%)	0	0.350
Hypothyroidism		1(1.4%)	1(3.2%)	0.547
smoking		5(7%)	0	0.132
Colon surgery		1(1.4%)	0	0.611

Table 2
Echocardiographic findings.

Characteristics		Surgery group	Device group	P value
Mean EF		51.07% ± 7.46	53.55% ± 5.03	0.143
Pulmonary hypertension (MPAP > 25mmhg)		45(63.4%)	11(35.5%)	0.021
Severe RV enlargement		38(53.5%)	19(61.3%)	0.702
Severe RV dysfunction		33(46.5%)	19(61.3%)	0.565
Valve problems	No or trivial	12(16.9%)	5(16.1%)	0.965
	Mild or moderate MR	5(7%)	1(3.2%)	
	Mild or moderate TR	14(19.7%)	5(16.1%)	
	Mild or moderate MR and TR	33(46.5%)	20(64.6%)	
	More than moderate TR	7(9.9%)	0	
ASD size (mm)	All patients	18.7	18.5	0.355
	older than 15 yrs.	19.7	18.3	
Mean EF postop		50.76% ± 9.73	55.19% ± 4.45	0.018
Severe RV enlargement postop		13(17.3%)	6(19.4%)	0.902
Severe RV dysfunction postop		14(18.7%)	5(16.1%)	0.672

Table 3
Outcomes and complications.

Outcome	Surgery group	Device group	P value
Length of hospital stay (days)	5.56 ± 1.75	2.06 ± 0.77	0.001
Length of ICU stay (days)	2.66 ± 0.70	0	–
Mean patient payment (dollars)	438 ± 61	463 ± 52	0.841
On table deferred for surgery	–	5/36 (13.9%)	–
Residual ASDs (<2 mm)	1(1.4%)	5(16.1%)	0.003
Total complications until 3 months:	13(18.3%)	8(25.8%)	0.394
Arrhythmias(atrial)	3(4.2%)	2(6.4%)	
Postoperative bleeding	1(1.4%)	0	
Pericardial Effusion	4(5.6%)	1(3.2%)	
Hemoptysis	0	2(6.4%)	
Significant femoral hematoma	0	3(9.7%)	
Transient cerebral	2(2.8%)	0	
Respiratory	3(4.2%)	0	
Readmission within 3 months	8(11.2%)	2(6.4%)	0.457
Readmission reasons	Pericardial effusion (4) Atrial arrhythmias (1) Transient cerebral (2) Pneumothorax (1)	Massive hemoptysis (1) Atrial arrhythmias (1)	–
Hospital mortality	0	0	–
Mortality after discharge until 3 months	0	0	–

The infection of the surgical site was not observed. There were not any permanent cerebral complication, prolonged intubation, renal failure and other complications.

Tricuspid annuloplasty (TAP) was performed in 7 cases (9.9%) in patients with moderate or severe TR.

The mean cardiopulmonary bypass time was 61.9 min and the aortic cross-clamp time was 35 min.

Only one type of devices (amplatzer) were used for all patients, because it is the only FDA approved available device in our hospital.

In our study, 13.9% of patients (5/36) in the device group had a failed procedural attempt for various reasons and these patients underwent surgery closure.

During the follow-up period, complete closure was observed in 26 of 31 patients (83.9%) in the device group and in 70 of 71 patients in the surgery group (98.6%) (p = 0.003).

There was a significant decrease in RV dimension during 3-month of follow up, so Severe Right ventricle dilatation significantly decreased (from 53.5% and 61.3% to 18.3% 19.4% respectively).

Also RV dysfunction significantly improved in postoperative period (46.5% and 61.3% decreased to 19.7% and 16.1% respectively).

There was no significant change in LV ejection fraction as estimated by echocardiography (preop. 51.07% and 53.55% to postop. 50.76% 55.19% respectively).

Readmission was reported in 8 patient in surgery group (11.2%) and 2 patient in device group (6.4%) (p 0.547).

In regarding to the outcomes, there was no mortality in-hospital and three months follow up in both groups.

4. Discussion

Trans catheter closure of ASD with septal occluder devices has become an alternative to surgical techniques in patients with suitable secundum ASDs. Its principal benefits include fewer complications, the absence of incisional and scar problems, shorter length of hospital stay and less discomfort for the patients. The efficacy of percutaneous device closure has been well reported from most comparative studies.[13–15]

In our study, there was no difference in gender or comorbidities between the two procedures and the age disparity explains the differences in body weight and height and BMI. In patients older than 15 years, body weight, height and BMI was not significantly differ between two groups (p > 0.05).

Earlier discharge encourages patients and parents to return to work more quickly. Post-discharge, surgical patients will need even more time at home to recover from their sternotomy. Length of hospital stay was significantly longer in the surgery group, which is in agreement with other comparative studies.[13,15]

Shorter length of hospitalization and lack of intensive care unit stays in trans catheter group results in relatively lower cost.[8] But, in our country (Iran) the price of occluder device(amplatzer) is expensive and total cost of procedure in catheterization ward including amplatzer and delivery system is more than surgery in operation room (3440 vs 1905 dollars). Although total hospital cost in device group was significantly higher than surgery group, because of more subsidization payment by the Iranian government for intracardiac devices (around 1/2 of total device price), mean patient's payment (almost 10% to 20% of total cost) for operative closure was 438 dollars versus 463 dollars for trans catheter closure that was not significantly difference between two groups. Although we found that surgical costs were on average lower than trans catheter costs, this difference is various in hospitals and countries, and was sometimes viseversa. In some studies from developing countries such as Pakistan and Iran surgical costs were on average lower than trans catheter costs,[9,10,16] and in most studies from developed countries, surgical costs were on average higher than trans catheter costs.[8,15] Hospitalization days and hoteling costs are significantly lower in developing countries. In our study, the ratio of hoteling cost to total surgical closure costs were only 19%.

There are increasingly more frequent reports of serious complications of device ASD closures, including fatalities or major events that need surgical intervention. Complications leading to surgery can occur even after percutaneous closure of small ASDs with small devices and do not necessarily occur early in the catheterization ward or even during the same hospitalization, so in almost one-third of cases they occurred late. Therefore surgical backup for percutaneous ASD closure must be available in the hospital to deal with potentially lethal acute complications.[12,17,18]

Once a surgical complication does occur, its management is associated with significant mortality, which is higher than primary surgical closure of ASDs (in comparison, operative mortality of 5.4% versus 0.36% for all unselected cases of surgical ASD reported in the EACTS Congenital Database during the same time period).[12]

The most cases of embolization occur during the early learning curve of the operators. This complication reduces with increasing of operator experience and the use of TEE during implantation.[19]

In our study, complication rates with both of treatment modalities were reported to be low.

We think that use of TEE in all patients, operator experience and exact decision to on table deferred for surgery were important in results with low major complication. In our study, failed procedural attempt for device closure in 13.9% of patients (5/36) was due to anatomical conditions such as insufficient rims or the presence of anomalous pulmonary drainage. This is similar to previous study in Iran.[20] We didn't have any cases with urgent transfer to operation room.

One advantage of surgical closure versus device closure of ASD is simplicity of surgical technique so all cardiac surgeons are able to perform that easily. While appropriate patient selection and operator's experience are important factors for successful device closure.

In some series, complete closure (with no residual shunt) was achieved less often by the percutaneous method.[20,21] Similarly, in our study, the success rate of device closure was lower than surgical closure.

Tricuspid valve repair is recommended for significant TR in patients undergoing surgical ASD closure.

The patients with more than moderate and persistent tricuspid insufficiency after ASD closure have poor prognosis.[22,23] In our 7 patients with more than moderate TR that underwent TV Repair, tricuspid regurgitation severity became trivial to mild in postoperative period.

After trans catheter closure, patients should remain under permanent surveillance to detect potentially serious long-term complications. While, patients who have had successful surgical ASD closure do not require specialized long-term follow-up.[12] In our study, there was not any re-intervention in three months but readmission rate within 3 months due to complications was higher in surgery group (11.2%vs 6.4%).

Preoperative severe right ventricle dilatation and dysfunction significantly decreased in postoperative period and there was no significant change in LV ejection fraction in both groups. This is similar to other studies.[24,25]

The mortality in both groups of patients was zero. This is in accordance with the previous reports in the current era.

The first limitation of this study is that the design was not a randomized trial. Initially, patients were chosen for device closure then residual of patients were referred to surgery. Although we thought that a clinical trial is necessary to compare strategies but it is impossible to perform a randomized study for ASD closure because of many logistic and ethical reasons. Also the limited number of cases and short follow up period were other study limitations.

In conclusion, our results demonstrate that the length of hospital stay was shorter for device closure in comparison with surgical closure, but in overall the surgical group patients were higher risk patients due to higher PAP, concomitant Tricuspid valve problems and larger ASDs.

The mean total hospital cost of patient's procedures was significantly higher in device closure group. Of course we should consider that the patients payments in any procedures is depend on the insurance coverage and each centers policy so have no important role in cost-benefit ratio assessment.

On the other hand, failed intervention rate in the device group was around 13.9% and during the follow-up period, about 16% of patients in Amplatzer group had residual ASD that may lead to pulmonary artery hypertension and another procedure in a near future.

Total complications were non-significantly different in two groups, but complications of device group were more serious (massive hemoptysis & failed operation) than the surgery. We didn't have any re intervention but readmission rate within 3 months was higher in surgery group.

Conflict of interest

There are no conflicts of interest to disclose.

Acknowledgements

The present study was supported by the Research Vice Chancellors of Urmia University of Medical Sciences, Urmia, Iran. The authors are grateful to reza karimi and mrs tahereh miraliashrafi for her efforts in editing of the manuscript.

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