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Percutaneous Treatment of Septal Defects; A Single-Center Experience

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ABSTRACT

Introduction: Atrial septal defect (ASD) is the most common congenital anomaly in adults. The aim of this study was to assess the operation success of percutaneous closure of ASD and patent foramen ovale (PFO) and the short-term results based on our experience.
Patients and Methods: Patients with ASD and PFO in whom percutaneous intervention was performed were evaluated retrospectively. Minor and major complication rates, success rate and short-term outcomes of the procedure were assessed.
Results: The overall success rate of the procedure was 96.9%. The minor complication rate was 2.7%. There were no major complication and in-hospital deaths. Left atrium volume and pulmonary artery pressure were decreased significantly after the closure of the septal defects. Two patient in whom percutaneous ASD closure was performed had a residual shunt. One patient developed minimal pericardial effusion and one had mild fever following the procedure.
Conclusion: The results of our series confirm that percutaneous closure of septal defects is an effective and safe technique according to the short term results and complication rates when it is performed in selected patients.
Key Words: Atrial septal defect; patent foramen ovale; percutaneous closure technique

Septal Defektlerin Perkütan Yolla Kapatılması; Tek Merkez Deneyimi

ÖZET

Giriş: Atriyal septal defekt (ASD), erişkinlerde en sık görülen konjenital kardiyak anomalidir. Bu çalışmanın amacı, kendi deneyimimize dayanarak perkütan yöntemlerle ASD ve patent foramen ovale (PFO) kapatılan hastaların işlem başarısı ve erken dönem sonuçlarını değerlendirmektir.
Hastalar ve Yöntem: Perkütan girişim yapılmış ASD ve PFO hastaları retrospektif olarak değerlendirilmiştir. Minör ve majör komplikasyon oranları, işlem başarısı ve erken dönem sonuçları değerlendirilmeye alınmıştır.
Bulgular: İşlem başarısı %96,9 olarak değerlendirilmiştir. Minör komplikasyon oranı %2,7 olarak ölçülmüştür. Majör komplikasyon veya hastane içi ölüm görülmemiştir. Septal defektlerin kapatılması sonrası sol atriyum bolümü ve pulmoner arter basıncı anlamlı olarak düşmüştür. Perkütan girişimle ASD kapatılmış olan iki hastada rezidüel şant tespit edilmiştir. Bir hastada minimal perikardiyal efüzyon ve bir hastada da işlem sonrası hafif ateş tespit edilmiştir.
Sonuç: Uygun hastalarda septal defektlerin perkütan yolla kapatılması, kısa dönem sonuçları ve komplikasyon oranları değerlendirildiğinde, etkili ve güvenilir bir yöntemdir.
Anahtar Kelimeler: Atriyal septal defekt; patent foramen ovale; perkütan kapama

INTRODUCTION

Percutaneous treatment of septal defects became the first therapeutic choice by the improvement in interventional techniques, therefore, lower complication rates, if the defect is amenable according to the current guidelines. Altough closure of atrial septal defects (ASDs) are well documented, closure of patent foramen ovale (PFO) still carries many questions.

Among congenital cardiac defects, ASD is 10%[1]. The American College of Cardiology (ACC)/American Heart Association (AHA) guidelines recommend ASD closure for patients with right atrium (RA) and right ventricular (RV) enlargement, regardless of symptoms (Class I)[2]. If the ASDs left without treatment, long-term complications can occur in up to 10% of patients[3]. Percutaneous closure requires an adequate septal rim 5 mm of septal tissue from the ASD to the superior and inferior vena cava, right upper and lower pulmonary veins, coronary sinus, and mitral/tricuspid valves[4].

Permanent closure of the foramen ovale is usually completed within the first year of life. Approximately in 20% of humans, the foramen ovale flap fails to fuse in which leads to persistent patency. It has been suggested that PFO may be associated with

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increased risk of stroke. The estimated risk of developing a stroke in someone with a PFO is 1 in 1.000/year. There are approximately 140.000 cryptogenic strokes /year in the United States, and 50% of them have a PFO. Also, the recurrence rate of stroke is approximately 2% annually. However, higher stroke rates (15%) have been associated with the presence of an atrial septal aneurysm (ASA). ASA may permits greater flow and therefore increases the chance of a thrombus passing from the venous to the arterial circulation[5-7]. Nonetheless, it is also possible for a large stroke to occur with a small PFO. Stroke volume on magnetic resonance imaging and PFO size on cardiac echocardiography was found loosely correlated[8]. Evolving of the design of the devices and enhancement in experiences make the device closure of ASD a safe and efficacious alternative to surgery. According to the data from the Nationwide Inpatient Sample, 15.482 secundum ASD/patent foramen ovale closures identified between 1988 and 2005. Of these, 5.495 were percutaneous, 10.278 were surgical, and 1.196 were unspecified or undetermined type[9].

Transcatheter ASD closure has a low complication rate which suggests that it is a safe procedure. Major complications include device embolization, erosion, pericardial effusion with tamponade, device thrombus, stroke, and endocarditis. Minor complications include excessive inflammatory reactions (perhaps due to nickel allergy), cardiac arrhythmias, and femoral access site complications. Several reports reveal a 1.2% to 2.5% major complication rate and 3.4% to 6.1% minor complication rate[10-12].

The aim of this study was to assess the short-term results of the percutaneous closure of ASD and PFO in a single cardiology and pediatric cardiology reference center.

PATIENTS and METHODS

This was a retrospective study based on data collected prospectively for a database of congenital heart disease. All patients with septal defects were treated by a percutaneous approach. Demographic data, minor and major complication rates, success rate and short-term outcome were assessed. Success was defined as the implantation of a closure device in a stable position without causing functional alterations or anatomical obstruction, and with no significant residual shunt. Major complications were defined as events resulting in death or significant morbidity during the procedure.

All patients underwent prior clinical assessment that included laboratory tests, electrocardiogram and echocardiography. Closure of ASD was performed under general anesthesia and with intraprocedural TEE in 81 patients and with TTE and fluoroscopic guidance in 45 patients. After femoral access was achieved, anticoagulation was begun with 100 U/kg heparin, to obtain an activated clotting time (ACT) >250 s. All patients were catheterized and an 18, 24 or 34 mm balloon catheter was passed through the septal defect coaxially with a guidewire positioned in a pulmonary vein (usually the left superior). The maximum diameter of the defect after balloon inflation was measured by TEE (except in patients with PFO) and fluoroscopy. The balloon was inflated until a waist was visible to make the decision on the size of the device during the procedure. In most patients the Cardi-O-Fix ASD Occluder (Starway Medical Technology Inc. Beijing, China) was used. The AMPLATZER™ PFO Occluder device (AGA Medical Corporation, USA) was used in 16 patients with PFO. Positioning and stability of the device and elimination of the shunt were confirmed by fluoroscopy using the "Minnesota wiggle" maneuver. All patients were reassessed clinically the following day by chest X-ray, ECG and TTE before they discharge and were prescribed on low-dose aspirin for life. Clopidogrel continued for a total of 3 months.

Statistical Analysis

Discrete variables are presented as counts and percentages of the total. Continuous variables were expressed as means and standard deviation. The measurements before and after procedure were compared by Student's t test. The statistical analysis was performed using SPSS version 15.

RESULTS

126 patients were treated and followed for 1 month in our center. The demographic properties of patients were demonstrated in Table 1. All patients with ASD (n=110) were presented right ventricular overload. Most of the symptoms of the patients were dispne and palpitation. Indications for closure in the population with PFO were cryptogenic ischemic stroke in 16 adult patients.

The overall success rate of the procedure was 96.9% in ASD and PFO. Two patient with ASD had a residual shunt detected by echocardiography but without hemodynamic significance. The other unsuccessful cases were due to the device not being released because of unstable position, the existence of an additional ASD, or interference with the mitral valve or the pulmonary veins. The minor complication rate was 2.7%. One patient developed minimal pericardial effusion and one had mild fever. There was no device embolization and no need for urgent surgery. Also, there were no in-hospital deaths. There was not any major complication.

Table 1. Demographic data of the patients

	Patients (n=126)
Age (years)	36±13 (Mean ± SD)
Gender (male-n)	82
BMI	24±4 (Mean ± SD)
Hypertension	16%
Diabetes Mellitus	5%
Hyperlipidemia	8%
CAD	13%
COPD	2%
Smoking	13%
Comorbid disease	22%

n: number, SD: Standart Deviation, BMI: Body mass index, CAD: Coronary artery disease, COPD: Chronic obstructive pulmonary disease

The left ventricular systolic and diastolic diameters were remained unchanged after 1 month of the procedure. However, left atrium (LA) volume and pulmonary artery pressure were decreased significantly after the device closure of the septal defects (p=0.009 and p=0.002, respectively.) The main results were presented in Tables 2 and 3.

DISCUSSION

The transcatheter approach is now the preferred strategy for ASD closure if the defect is amenable. The success rate for the device closure of ASD was reported as 96% to 98%[10,13,14]. In our study, we observed a success rate of 96.9%, which is in keeping with the literature. Also, LA volume and pulmonary artery pressure were decreased significantly after the device closure of the septal defects (p=0.009 and p=0.002, respectively).

During transcatheter closure of septal defects, careful evaluation of anatomy and adjacent structures is important. Echocardiographic imaging (TEE or intracardiac echocardiography) plays a significant role for guidance during closure and its mandatory for achieving optimal results. If a large-sized device used for closure, it may cause late complications by impinging on surrounding structures[15]. It has been reported that a major complication rate between 0.2% and 1.5% for procedural-related death, hemorrhage requiring transfusion, cardiac tamponade, and fatal pulmonary emboli. Minor complications including peri-procedural atrial arrhythmias, device arm fractures, device embolization, thrombosis, and femoral hematomas range from 7.9% to 11.5%[16].

Table 2. Percutaneous closure technique results of the patients

ASD (%)	85%
Defect Size (mm)	15±6
Posterior Rim (mm)	14±6
Aortic Rim (mm)	5±3
SVC Rim (mm)	10±5
IVC Rim (mm)	15±5
Qp/Qs	1.8±0.7
Heart Rate (per minute)	76±12
Success Rate (%)	96.9%
Minor complication	2.7%
Major Complication	None
Hospitalisation (day)	3±2

n: number, ASD: Atrial septal defect, SVC: superior vena cava, IVC: Inferior vena cava

Table 3. Echocardiographic evaluation of the patients before and after percutaneous closure of the septal defects

	Pre-procedure Mean±SD	Post-procedure Mean±SD	P value
LV diastolic diameter (mm)	46±5.7	46±5.2	0.716
LV systolic diameter (mm)	30±5	29±6	0.075
LA volume (mL)	34±5	31±5	0.009
PAP (mmHg)	38±9	24±16	0.002

n: number, SD: Standart Deviation, LV: Left ventricle, LA: Left atrium, PAP: pulmonary artery pressure

The first study comparing transcatheter approach to surgery in patients with ASD is the the amplatzer septal occluder (ASO) pivotal study. It was a multicenter nonrandomized trial performed in 29 pediatric cardiology centers from with 442 patients enrolled in the device group and 154 patients in the surgical group which compared the safety, efficacy, and clinical utility of the ASO for closure of secundum ASD to surgical closure. In this study, device closure group had lower major and total adverse events than the surgical group. The overall complication rate was 7.2% for the device group and 24% for the surgical group with a mortality of 0% for both groups. The major adverse event rates were 1.6% for the device group and 5.2% for the surgical group[10]. Another multicenter nonrandomized trial that compared the safety and efficacy of the helex septal occluder (HSO) with the surgical repair of secundum ASD was the HSO pivotal study. This trial was performed in 14 U.S. medical centers from with 119 patients enrolled in the device group and 128 patients in the surgical group. The major adverse event rate was 5.9% for the device group and 10.9% for the surgical group and these rates were not statistically different[11]. There are many other studies present that have confirmed the pivotal studies' safety outcomes[17,18]. The rate of major adverse events was 2.2% in 137 patients in the continued access study for the HSO[19]. A recent HSO report showed a major adverse event rate of 5.8%[20]. In this study, the minor complication rate was 2.7%. There were no in-hospital deaths and was not any major complication after the procedure.

Transcatheter closure of PFO in patients with stroke is not cleary known. In trial CLOSURE I (Evaluation of the STARFlex Septal Closure System in Patients With a Stroke or TIA Due to the Possible Passage of a Clot of Unknown Origin Through a Patent Foramen Ovale) which was consisted of 909 patients randomized at 87 sites across the United States and Canada tested whether PFO closure using STARFlex device (NMT Medical, Boston, Massachusetts) plus medical therapy to medical therapy alone for preventing recurrent stroke or TIA in patients with stroke or TIA and a PFO[21]. PFO device closure plus medical therapy (6 months of aspirin and clopidogrel followed by 18 months aspirin) failed to demonstrate superiority over best medical therapy (24 months warfarin or aspirin or combination).

Three other trials are PC-Trial (Patent Foramen Ovale and Cryptogenic Embolism), RESPECT (Randomized Evaluation of Recurrent Stroke Comparing PFO Closure to Established Current Standard of Care Treatment), and REDUCE (GORE HELEX Septal Occluder for Patent Foramen Ovale Closure in Stroke Patients). According to the recently reported in PC-Trial, closure of a patent foramen ovale for secondary prevention of cryptogenic embolism did not result in a significant reduction in the risk of recurrent embolic events or death as compared with medical therapy[22]. Likewise, according to the RESPECT Trial, in the primary intention-to-treat analysis, there was no significant benefit associated with closure of a patent foramen

ovale in adults who had had a cryptogenic ischemic stroke. However, closure was superior to medical therapy alone in the prespecified per-protocol and as-treated analyses, with a low rate of associated risks[23]. The REDUCE trial is still on going.

Percutaneous PFO closure is a relatively safe procedure. Major and minor complications are lower with newer percutaneous devices and smaller catheters. At the present time, none of the available PFO closure devices have been approved by the FDA. However, the FDA has approved several devices for closure of ASDs that can be used effectively to close a PFO off-label.

Distinctly to PFO, unrepaired ASD can lead to right ventricular volume overload with resultant right heart failure, elevated pulmonary vascular resistance, systemic embolism, and atrial arrhythmias. But also there are numerous potential device- or procedure related adverse events. In the FDA's MAUDE database, the most prevalent adverse event were the device embolizations that can be related to undersized device, inadequate or floppy rim, operator related technical issues such as malposition during the Minnesota maneuver . Amplatzer nitinol wire frame filled with polyester fabric and the Helex nitinol wire covered by an ultra-thin membrane of expanded polytetrafluoroethylene may also be thrombogenic. An analysis of the MAUDE database showed that 2.5% device related thrombus[24]. In our study there were no device embolisation during the procedure.

As with all implanted devices there remains a risk of infection. The FDA analyses of the MAUDE medical device reports showed 0.8% of the infection or endocarditis. In our center, one patient had a mild fever after procedure, however, there was not any infection or endocarditis.

Erosion is a rare but potentially fatal complication subsequently came to light. The motion of the device relative to the heart causes erosions, even with undersized devices if there was a tip-disk protrusion into the aortic root. In short term, there were no erosions in our cases.

A tendency toward atrial arrhythmias appears to increase with device closure. Atrial tachyarrhythmias or heart block, both transient and permanent and bundle branch block in patients with large ASD can be seen. The most important concern is that device closure of ASD may preclude future electrophysiology procedures that require transseptal access.

The use of nitinol-containing devices can pre-dispose to nickel allergy 2 days up to 1 month after implantation and manifested as headaches, rash or urticaria, difficulty in breathing, fever, or pericardial effusion. There were no allerjic reactions after the procedures in our center but one patient had minimal pericardial effusion which was resorbed spontaneously and one patient had a mild fever which was not recurred by paracetamol. In our population the success rate was high. Most of the complications were minor and had no significant consequences. The results of our series confirm that percutaneous closure of septal defects is an effective and safe technique in the short term when it is performed in selected patients.

CONCLUSION

Percutaneous closure of septal defects was shown to be a safe and effective technique and should be considered as the first treatment choice for amenable patients.

CONFLICT of INTEREST

The authors reported no conflict of interest related to this article.

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