TRANSCATHETER CLOSURE OF SECUNDUM ATRIAL SEPTAL DEFECT, AS NON SURGICAL ALTERNATIVE TREATMENT"

Thesis
Submitted In Partial Fulfillment Of
The MD Degree In Cardiology

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2005

Introduction

The incidence of congenital heart defects is 0.8% of liveborn infants. Atrial septal defects (ASDs) are congenital abnormalities characterized by structural deficiency of the atrial septum. ASDs account for 10% of all congenital heart disease, with a 3:2 female/male ratio. The most frequent type of atrial septal defect is in the ostium secundum (fossa ovalis) location.

The physiological consequences of an atrial septal defect depend on the magnitude and duration of the shunt, and on the response of the pulmonary vascular bed. In large defects with significant left-to-right shunts, the right atrium and right ventricle are volume-overloaded, and the augmented volume is ejected into a low-resistance pulmonary vascular bed. Pulmonary vascular occlusive disease and pulmonary arterial hypertension may then develop in adulthood.
Survival is limited in young adults who develop progressive pulmonary hypertension. Even these patients, however, may live to reach their 40's. In their 50's, these patients experience increasingly frequent atrial arrhythmias, which represent a common precipitating cause of heart failure. 1

Patients diagnosed as having secundum ASDs with a significant shunt defined as a pulmonary blood flow to systemic blood flow ratio (Qp/Qs) of > 1.5) are

operated upon ideally before 5 years of age or whenever a diagnosis is made in later years.

Cardiac surgery requires cardiopulmonary bypass equipment to achieve closure through a right atriotomy. Small defects are sutured shut, and larger ones are patched with either pericardium,polyester, or Goretex (1).

The mortality reported in 1968 was as high as 12.5% this has been progressively reduced to 6%, to 3.3% , and currently to less than 1%. The presence of significant residual shunts has been reported in as many as 17% of patients undergoing repeat catheterization, and in the current era only 2% of patients undergo repeat cardiac surgery for residual shunts. (1)

Transcatheter closure has developed into a significant alternative for surgery including Clamshell™ Device (2), Buttoned Device (3) , Angel Wings™ Device and Atrial Septal Defect Occluder System Devic in the treatment of atrial septal defects (ASDs).

New techniques and devices have revolutionized the transcatheter techniques used to secundum Atrial Septal Defect.

The advantages, compared to surgery, are the avoidance of a thoracotomy, postoperative pain and morbidity, a long hospital stay.

Before the choice can be made between the two treatment options, patients should be selected who have a septal defect that is suitable for catheter closure,

The decision of the appropriate closure technique often depends on the size and location of the defect, as well as patient and physician preference.

Aim of the work

The purpose of this work is to compare the efficacy, safety And complication of transcatheter closure of secundum atrial septal using Amplatzer Septal Occluder versus surgical closure to carefully assess the immediate results as well as a period of 3 months after closure of the defect by both techniques.

Patients and Methods

50 Patients presenting to Ain Shams University hospital and
National Heart Institute with congenital heart disease, secundum Atrial Septal Defect Will be admitted to this study.
A written Consent will be signed for the group performing Transcatheter intervention .

Inclusions Criteria:

Patients with Isolated Ostium secundum atrial septal defect , the maximum size of the defect is 25 mm , with adequate septal margins I,e width of superior, inferior, anteroinferior or posterior septal rims are not less than 5 mm .

Exclusion Criteria:

Patients will be excluded from the study if one of the following diagnosis is associated :

- **Ostium primum atrial septal defects.**
- **Sinus venosus atrial septal defects .**
- **Partial anomalous pulmonary venous drainage .**
- **Patients with right and/or left ventricular decompensation with ejection fraction of less than 30%**

General Exclusion Criteria:

- **Sepsis (local/generalized)**
- **History of repeated pulmonary infection**
- **Any type of serious infection < 1 month prior to procedure**
- **Malignancy where life expectancy; is < 2 years**
- **Demonstrated intracardiac thrombi on echocardiography (especially left atrial or left atrial appendage thrombi)**
- **Inability to obtain informed consent**
- **Patients with gastritis, gastric ulcer, duodenal ulcer, bleeding disorders etc., and other contraindications to aspirin therapy unless other**

anti-platelet agents can be administered for 6 months.

Methods

All patients will be subjected to the followings :

1. **Full history taking and meticulous physical examination.**
2. **Chest X-Ray to assess the cardiovascular ratio and pulmonary vasculature.**
3. **12 Lead surface ECG .**
4. **Transthoracic Two dimensional and color Doppler echocardiography;**

The diameters of ASD and the atrial septal lengths in the transverse and longitudinal axis, and the width of the superior, inferior, anteroinferior, and posterior septal margins will be measured .

The shape and location of the ASD and the adequacy of the septal margins for anchoring occluding devices were determined.

Right ventricular function and paradoxical septal Motions will be determined .

ALL Patients will be divided into two equal group as followings:

***First Group : (Transcatheter closure Procedure*)**

25 Patients will undergo Transcatheter closure of secundum Atrial Septal Defect using Amplatzer septal Occluder .

AMPLATZER Septal Occluder .

The Amplatzer Septal Occluder is a self-expandable, double disc device made from aNitinol (Nickel-Titanium Alloy) wire mesh. The two discs are linked together by a short connecting waist corresponding to the size of the ASD. To increase its thrombogenicity, the device's discs and waist are filled with polyester patches. The polyester patches are securely sewn to the wire frame with polyester threads.

The Amplatzer Septal Occluders are provided in a kit containing devices ranging in size from 4-34mm. The delivery system consists of a delivery cable, sheath, loading devise, pin vise, and sizing template. Sheath sizes range from 6F to 12F.

Transoesphageal Echocardiography will be performed , patients will be intubated and placed under general anaesthesia. Percutaneous puncture of the femoral vein , complete hemodynamic evaluation will be performed with pressure and saturation measurements to be taken in all cardiac chambers .

Pulmonary arteriogram will be performed in a 35 left axial oblique projection with 35 cranial angulation (four chamber view) with Berman angiographic catheter to rule out anomalous pulmonary venous drainage.

Contrast injection will be injected at the junction of the left atrium with the right pulmonary vein to delineate the anatomy of the ASD.

A 7 F balloon-tipped end hole catheter to be manipulated through the ASD into the left upper or lower pulmonary vein .Using an exchange 260 cm , J-tipped guidewire 27 mm ,
100 –cm occlusion balloon catheter to be introduced into the left atrium . The balloon catheter will be inflated with various increments of contrast medium and pulled across the ASD under fluoroscopic and transesophageal echocardiographic observation . A slight deformity of the sizing balloon to be used as a stretched diameter .
The sizing balloon then to be removed , reinflated with the same amount of contrast medium and passed through the calibrated openings in a sizing plate to determine the stretched diameter . The Amplatzer's size to be chosen to be equal to or 1 mm less than the stretched diameter of the connecting waist

The device to be screwed to the tip of the delivery cable , immersed in normal saline and drawn into the loader. A Y connector to be applied to the proximal end of the loader to allow flushing with saline. A 7 F , long guiding sheath and dilator to be advanced over the guidewire through the communication into the left atrium . The correct

position of the delivery sheath is verified by test injection of the contrast medium . The loader with the collapsed device advanced into the guiding catheter by pushing the delivery cable. Under Fluoroscopy and transesophageal echocardiography first the left atrial disk to be deployed and pulled gently against the atrial septum .Using gentle tension on the delivery cable , the sheath is pulled back and right atrial disk to be deployed .
To and fro motion of the delivery cable ensured a secured
Position across the ASD .
After device deployment Transeosphageal echocardiography examination will be carefully check for presence of residual shunt , possible obstruction to systemic or pulmonary venous return and impairment of the atrioventricular valves.

Once its position is optimal the device will be released by counterclockwise rotation of the delivery cable .
After release of the Amplatzer both color Doppler echocardiography and pulmonary angiography performed to detect any residual shunt .
Intravenous antibiotics will be delivered (ampicilline 200 mg/Kg body weight and gentamycin 5 mg/Kg) immediately after placement of the prosthesis and repeated at 8 and 16 hours for a total of 3 doses .
Patients will be discharged on the day after the procedure

With instructions to take aspirin 3 to 5 mg / Kg daily for 3 months.

Following up by chest radiograph , 12 lead ECG and transthoracic color Doppler echocardiographic recording to be performed 24 hours after the procedure and at 1 and 3 months later.

Cases which has Unachieved Implantation of Amplatzer Septal Occluder will be sent for surgical repair.

Second Group : Surgical closure of secundum ASD
25 patients will undergo surgical closure of secundum ASD .

Patients who undergo surgical treatment will be subjected
For evaluation of residual shunt , hospital stay then will do
Following up by chest radiograph , 12 lead ECG and transthoracic color Doppler echocardiographic recording to be performed 24 hours after the procedure and at 1 and 3 months later.
A meticulous recording of cardiac and nocardiac complications will be reported and evaluated.

Statistical analysis ; Results will be expressed as mean value
SD , with confidence intervals given where applicable .
The standard t test will be used to compare results of both
Transcatheter and surgical closure of secundum Atrial Septal Defect .

Results will be compared with other literature.

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Dedication

This work is an ambitious attempt to give a peace in minds and hearts of mothers and fathers who trusted to place in the workers hands of this study, their most precious in their life, their lovely kids !!!!!!!!!!