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Transcatheter Closure of Secundum Atrial Defects with "Amplatzer Septal Occluder" Initial Experience in Jordan

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Objective: To evaluate the efficacy and safety of a new self centering device, the Amplatzer Septal Occluder (ASO) in closing secundum Atrial septal defects (ASD's) and to present our initial experience in Jordan.

Design: Cohort sample of consecutive 16 patients with ASD's selected to fulfill the criteria of measuring ≤2.2 cm with enough tissue rim > 5 mm surrounding the defect.

Setting: The cath lab of Queen Alia Heart Institute, Amman, Jordan.

Subjects: Sixteen patients (12 males, 4 females) with secundum ASD's , aged 2 - 37.1 years (median 5.25 years) with median weight of patients of 16.5 Kg (range 10-68 Kg).

Main outcome and measures: (1) Immediate success post delivery of the device as measured by the immediate degree of shunting assessed by pulmonary artery angiogram with levophase and Transoesophageal echocardiography. (2) Degree of shunting 1 day, 3 months after delivery of the device as measured by Transoesophageal echocardiography. (3) Recording any medical complications or any death upon clinical follow-up to the patients till 3 months post device delivery.

Results: There was immediate and complete (C) closure of ASD in 14/16 patients. One patient had trivial residual shunt (TS) and another one had small residual shunt (SS). There was no episode of device embolization or any need for blood transfusion. One patient developed transient neurologic deficit (right sided weakness) with near complete clinical recovery after few days.

Follow-up by Transoesophageal echocardiography (TEE) at 3 months showed residual shunting was not observed in any one of our patients. There was no incidence of endocarditis, wire fracture or further thromboembolism.

Interpretation and Conclusions: The ASO seems to be a promising device for the closure of ASD in children and adults. Further evaluation and long term data seem to be necessary before this new technique can be recommended.

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Transcatheter closure of secundum ASD has been attempted with a number of devices over the last 3 decades[1-10]. The bard clamshell device[1,11] (manufactured by USCI, Billerica, MA) was the most extensively evaluated device, however it had high rate of fatigue fractures and high incidence of residual shunts. Further devices such as the buttoned device[2,12-15] (manufactured by Custom Medical Devices, Amarillo, TX), the ASDOS[3-5,16-18] (Atrial Septum Defect Occluder System manufactured by Osypka Corp. Germany) and the self centering device (DasAngel Wings manufactured by Microvena,Vadnais, MN) appeared also to have their own drawbacks, namely; the unbuttoning, and the high incidence of residual shunting with the buttoned devices, and on the other hand, the complex multi-step placement and requirement of simultaneous arterial puncture, wire snaring across the defect and the large introducing system (12-13 Fr.sheath) needed to implant the (Das-Angel Wings) device across the ASD.

To overcome the limitations of the above devices, a new self-centering device (AMPLATZER™ SEPTAL OCCLUDER manufactured by AGA Medical Corp, Golden Valley, MN) has been developed recently by Amplatz and was evaluated in animal models[9] and a few human subjects[21] with ASDs.

Patient population

From 18 June 1997 to 3 July 1997, 16 patients (12 female/4

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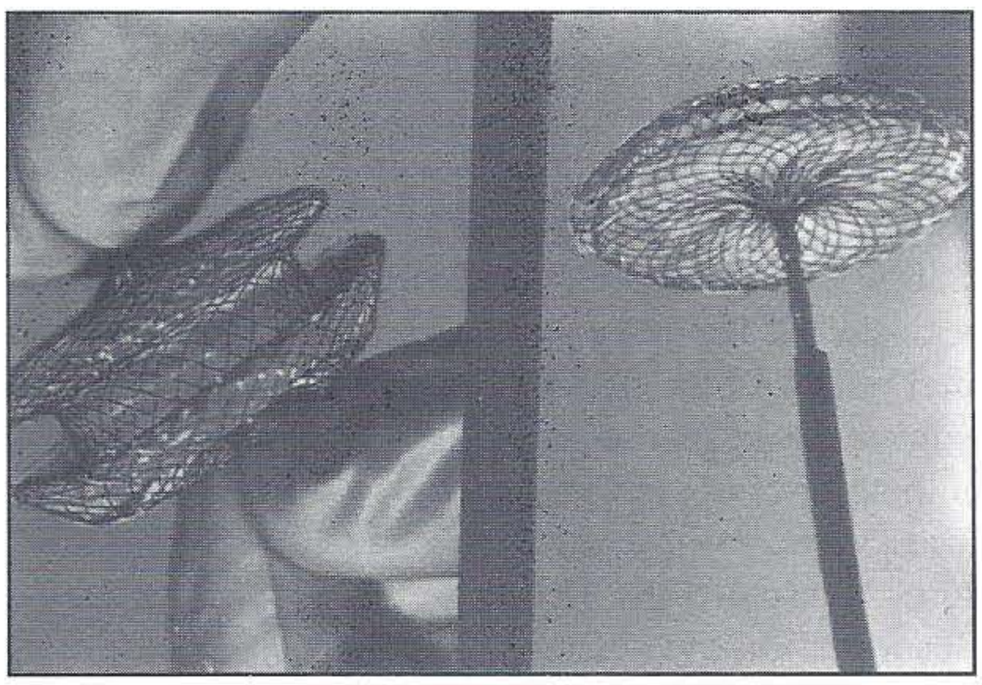
male) with clinical echocardiographic and angiographic evidence of ASD underwent an attempt at transcatheter closure using the ASO. Patients who had secundum type of ASD measuring 22mm with enough tissue rims (>5mm) surrounding the defect were eligible for the closure. The patients ages ranged from 2-37.1 years (median 5.25 year) and their weight ranged from 10-68 kg (median 16.5 kg). All patients except two were asymptomatic, patient # 10 and #14 were in NYHA class III. Informed consent was obtained from all patients or their guardians. All patients were followed up at 1 day after the ASO deployment by chest radiography, electrocardiography, and a transthoracic colour doppler echocardiogram (TTE) and in all patients a transesophageal echocardiography (TEE) was performed at 3 months follow up.

The Device (Fig 1)



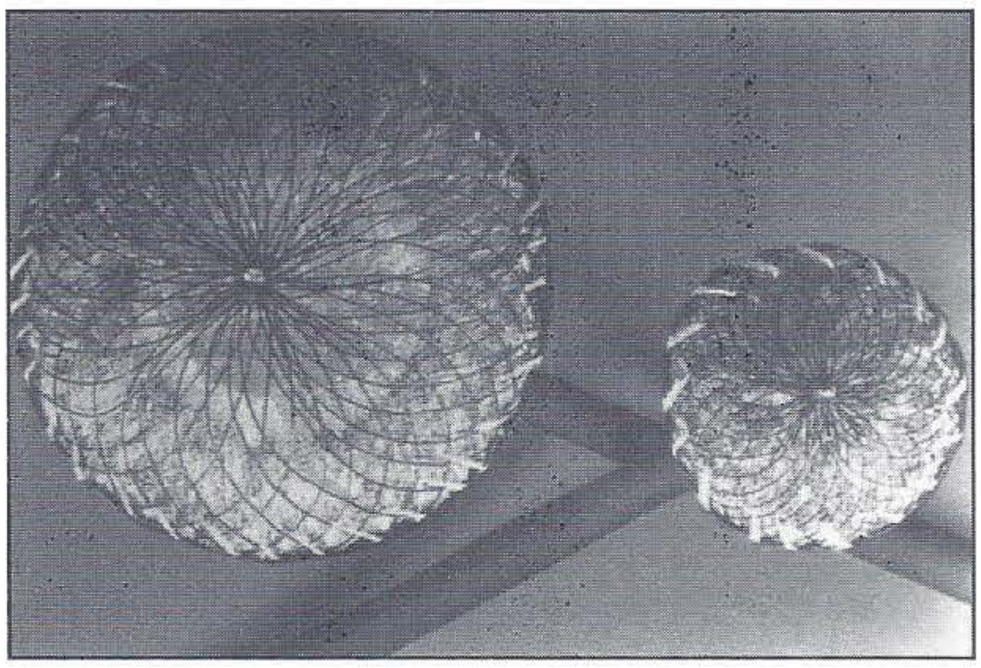


Figure1: Schematic view of the Amplatzer Septal Occluder

Nitinol a shape memory alloy composed of 55% nickel and 45% titanium, was used as the main material because of its unique super-elastic properties[22,23]. Owing to the high thrombogenicity, low inflammatory response, and time-tested safety profile of Dacron as a prosthetic material[16], fluffy Dacron threads (spun bonded polyester) were chosen as a filling material in the device to achieve rapid closure of the stented defect.

Taking into consideration the importance of device sizing relative to the defect, prosthesis were constructed in various sizes ranging from 4-26 mm in one mm increments (prosthesis size refers to the diameter of the waist which should be made identical to the measured balloon-stretched ASD diameter). The right atrial retention button was made slightly smaller, taking into account the uniformly present left to right pressure trans-atrial gradient.

Occlusion technique

For optimum device deployment, the closure was done under general endotracheal anesthesia and transesophageal echocardiography guidance was employed routinely. Full assessment of the defect, surrounding rims and the remaining cardiac structures was performed prior to catheter insertion. Standard right and left heart catheterization was performed via percutaneous puncture of the femoral vein and assessment of the degree of left-to-right shunt was done. Heparin was administered routinely in all patients. Angiography was performed in the right upper pulmonary vein in the hepatoclavicular projection in order to demonstrate the atrial communication. A balloon catheter is inserted over an exchange guide wire (J shaped) and introduced into the left atrium. The balloon catheter is inflated with various increments of contrast medium and pulled across the atrial communication. There should only be a slight deformity of the sizing balloon to determine the stretched diameter . Sizing of the defect was repeated more than once before selecting the occlusion device (Fig.2).

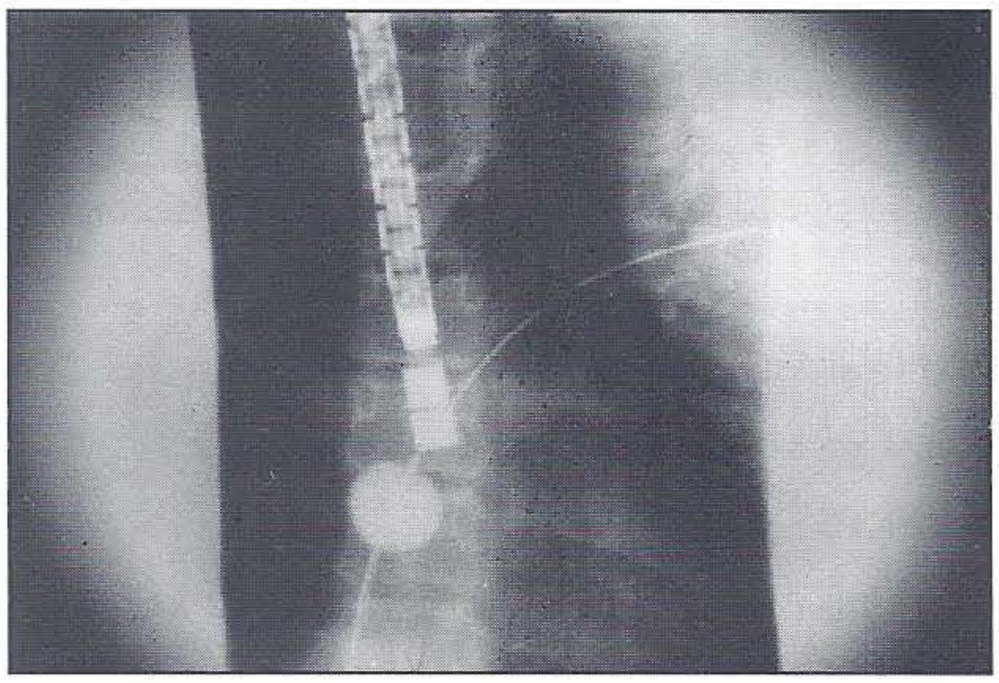


Figure 2: Balloon sizing of the atrial septal defect

The device size (waist diameter) chosen to be deployed was usually the same ± 1 mm as the stretched diameter of the defect. A long 7 F thin walled nontapered kink-resistant teflon sheath (AGA Medical Corp, Golden Valley, MN) was positioned in the left atrium. The delivery cable was passed through the loader and the proper size occlusion device was screwed clockwise into the tip of the delivery cable. The device and the loader were immersed in saline solution as the ASO was pulled into the loader . The loader was introduced into the delivery sheath and without rotation the device was advanced into the left atrium. The sheath was retracted until the left atrial disc was opened in the middle of the left atrium. The sheath with the delivery cable in it were pulled back as one unit close to the left atrial side of the septum. With further retraction of the sheath while maintaining constant tension on the delivery sheath and cable, the right atrial disc was deployed in the right atrium. To confirm correct placement, the delivery cable still attached to the device was pushed forward and pulled

backward "The Minnesota Wiggle manoeuver". Correct placement will be manifested by stable device position . TEE also was used to visualize both discs at their respective sides. If there was device misplacement , the device could be retracted back inside the delivery sheath and the steps were repeated. Once proper device position was confirmed, the device was released by turning the cable counter-clockwise using the pin vise. Assessment of device position and residual shunt after releasing the device was performed using both TEE and pulmonary angiogram with levophase (Fig 3,4). Hemostasis was assured and the patient was awakened to recover overnight at the hospital. Kefzol 50 mg /kg was given intravenously during the procedure and 2 doses 8 hours apart were given in the hospital.

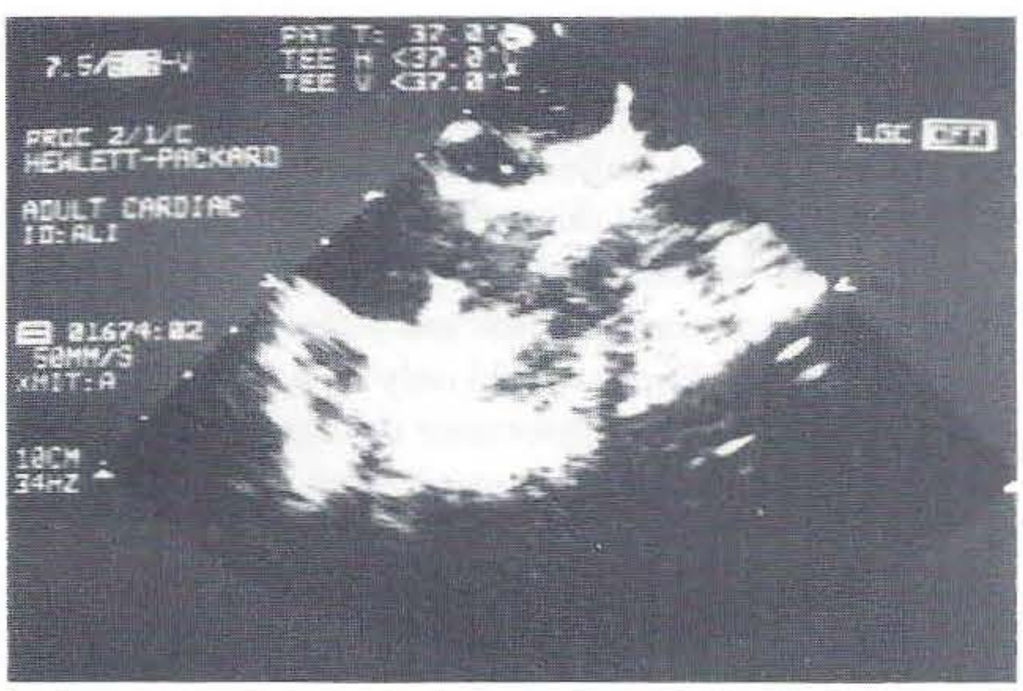


Figure 3: Transesophageal echocardiographic view after device release demonstrating both Discs and waist covering the defect.

Statistical Analysis

Results are expressed as median or mean ± SD.

RESULTS

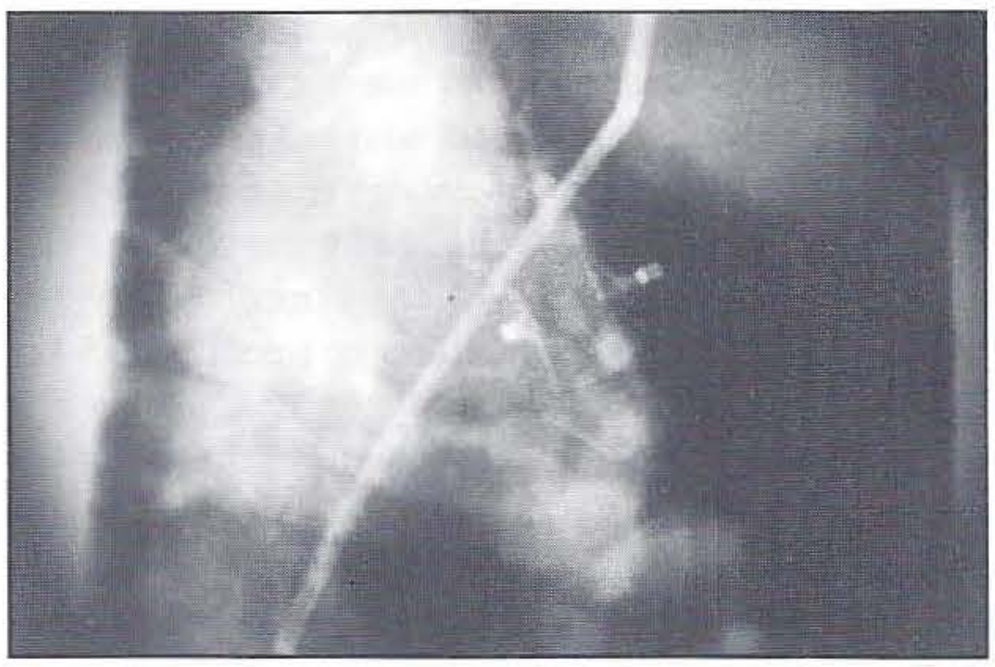


Figure 4: Final pulmonary angiogram with levophase revealing no residual shunt.

The clinical data is listed in table I . The median ASD diameter by TEE was 14.5 mm (range 12-22mm), and the median ASD balloon stretched diameter was 15.5 mm (range 13-25). The mean Qp/Qs was 1.78 ± 0.5. In none of the patients was anomalous drainage of pulmonary veins or pulmonary hypertension observed. In one patient #9 dextrocardia (situs inversus totalis) was an associated finding (Table 1). Patient #12 had Down syndrome. Sufficient occlusion of the defect was achieved in 15 of 16 patients after release of the device at the first attempt. One patient required device repositioning due to inadvertent deployment of both discs in the right atrium. The median device size (waist) used to close the defect was 17 mm (range 14-26 mm). As assessed by TEE there was immediate complete closure (C) of the defect in 14 patients, one patient # 10 had trivial residual shunt (TS= colour jet diameter <1 mm)and another one patient # 14 had small shunt (SS=colour jet 1-2mm). The median fluoroscopy time was 20 minutes (range 7-40 min) and the median total procedure time was 92 minutes (range 35-120 min). At one day, there was (C)

Table 1: Data on patients in whom the ASD was successfully closed with the Amplatzer[tm] septal occluder

No.	Age (year)	Sex	Weight Kg	ASD size TEE	Balloon	Device (mm)	QP/Qs	Degree of Shunt Imm(TEE)	Results(TTE) 1d	3m	Associated/ problems
1.	5.5	F	15	12	13	14	1.5	C	C	C	0
2.	5.2	F	16	15	16	17	1.9	C	C	C	0
3.	10.1	F	23	20	22	24	1.8	C	C	C	0
4.	2.5	M	16	19	21	22	1.6	C	C	C	0
5.	37.1	F	68	20	22	22	1.8	C	C	C	0
6.	30.2	F	60	14	15	16	2.3	C	C	C	0
7.	5.3	M	16	12	13	15	1.5	C	C	C	0
8.	9.1	F	23	19	20	22	1.7	C	C	C	CVA
9.	4.4	M	18	13	14	15	2.1	C	C	C	Dextrocardia SIT
10.	2.0	M	11	20	22	24	1.8	C	C	C	0
11.	5.1	F	17	13	14	15	1.6	TS	TS	C	0
12.	8.1	F	22	14	15	17	1.6	C	C	C	Down
13.	2.1	F	10	12	13	15	1.8	C	C	C	0
14.	5.2	F	16	22	25	26	1.7	C	C	C	0
15.	5.1	F	15	12	14	14	2.2	SS	SS	C	0
16.	13.1	F	40	16	19	19	1.5	C	C	C	0

*CVA - Cerebro Vascular Accident. SIT - Situs Inversus totalis. QP:QS - Pulm-to-systemic flow ratio; M-Male; F-Female; C- Complete closure; TS- Trivial shunt; SS - Small shunt; FT- fluoroscopy time; PT- Procedure time; Min- Minute; TEE-transesophageal echocardiography; TTE-Transthoracic echocardiography

of the ASD documented by TTE in 14/16 (88%) patients. The 2 previous patients in whom the immediate post procedural TEE showed TS, SS continued to have them. However at 3 months follow up, none of our patients showed any kind of residual shunt by TEE.

Complications

No deaths or severe complications necessitating surgery or causing significant morbidity occurred during this initial trial. Neither during implantation nor during a median follow up period of 4.5 months (range 4-4.5), were there any device embolizations, fractures of the implanted device or disruption, atrial perforations, pericardial effusions, obstructions of systemic or pulmonary veins, atrioventricular valve dysfunction, rhythm disturbances, episodes of endocarditis or other complications. However in one patient #8 transient right sided weakness was noticed on the second day of implantation. Brain CT scan showed evidence of ischemia in the left parietal region, however the patient was discharged on the eighth day of hospitalization after near normal clinical recovery. Follow up brain CT scan at 3 months proved to be completely normal. No blood transfusions were necessary in any patient.

DISCUSSION

In 1976 King and Mills[24-26] reported the first transcatheter closure of a secundum ASD in humans using a double-umbrella device. Since that time transcatheter closure of the ASD is gaining wider acceptance as an alternative to surgical closure. The latter requires a 6-to-8 day hospitalization, general anesthesia, thoracotomy, cardiopulmonary bypass, and postoperative monitoring in the intensive care unit, all of which carry risk as well as expense. In this paper we report our initial human experience using a new self-centering device, the AMPLATZER SEPTAL OCCLUDER, in an attempt to assess safety and efficacy of the system. The immediate closure rate documented by TEE and angiography was seen 14/16 patients (87.5%), however at 3 months follow up the (C) rate had increased 16/16 (100%), which todate, no other device had achieved such a high complete closure rate. Some of the patients with residual shunt had undergone spontaneous closure or decrease in the degrees of shunt with time, similar to patients who had other devices. Careful pre-selection of patients using TEE and the careful selection of device size seems very essential step in increasing the closure rates and minimizing the degree of residual shunting. The unique design features of this device are the connecting waist which in essence stents the defect, thus contributing to the immediate closure seen in the majority of patients, and the 200 wires woven with the presence of 3 layers of polyester patches (one layer in each disc and one in the waist) contributing to the increased thrombogenicity of the device. Furthermore other features such as the ease of implantation including total control and the ability to retract or reposition the device if misplacement occurs prior to release do characterize this new ASO device, resulting in 100% success rate of deployment (15/16 patients from first attempt, 16/16 in 2 attempts) with no episodes of device embolization immediately or on follow up.

CONCLUSION

We conclude therefore, that the ASO device can be implanted safely across the ASD and effectively via a 7F sheath even in small children, scoring high rates of complete closure with the least complications possible. We feel however that additional clinical trials are warranted to confirm the efficacy and safety of the device on the long term.

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