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Transcatheter Atrial Septal Defect Device Closure - A 2.5 Years Single Center Study

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Abstract

Background: Atrial septal communications account for approximately 6-10% of congenital heart defects, with an incidence of 1 in 1,500 live births. The atrial septal defect (ASD) is among the most common acyanotic congenital cardiac lesions, occurring in 0.1% of births and accounting for 30-40% of clinically important intracardiac shunts.

Transcatheter device closure is advised for all symptomatic patients and also for asymptomatic patients with a Qp: Qs ratio of at least 2:1 or those with right ventricular enlargement. The timing for elective closure is usually after the 1st yr and before entry into school. Closure carried out at open heart surgery is associated with a mortality rate of <1%. Repair is preferred during early childhood because surgical mortality and morbidity are significantly greater in adulthood.

Aim of Study: Is to evaluate 2.5 years experience in transcatheter device closure of secundum atrial septal defect at the Pediatric Cardiology Unit, Assiut University Children Hospital.

Patients and Methods: The study was conducted on 62 patients [56 (90.4%) children and 6 (9.6%) adults] who underwent transcatheter secundum ASD device closure, at Pediatric Cardiology Unit of Assiut University Children Hospital from March 2014 till September 2016.

Results: Transcatheter closure of secundum ASD in children adolescents and adults has a high success rate (98.3%) regarding the efficacy (successful closure of the defect without residual shunt) and safety (no death or major complications as cerebral embolism, cardiac tamponade, device embolization or dislodgement requiring open cardiac surgery and infectious endocarditis) during procedure, immediate and short to midterm follow-up.

Conclusion: Transcatheter closure of secundum ASD in children adolescents and adults has a high success rate (98.3%) regarding the efficacy (successful closure of the defect without residual shunt) and safety (no death or major complications as cerebral embolism, cardiac tamponade, device embolization or dislodgement requiring open cardiac surgery and infectious endocarditis) during procedure, immediate and short to midterm follow-up.

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Key Words: *Atrial septal defect – Transcatheter device closure.*

Introduction

ATRIAL septal communications account for approximately 6-10% of congenital heart defects, with an incidence of 1 in 1,500 live births [1]. The atrial septal defect (ASD) is among the most common acyanotic congenital cardiac lesions, occurring in 0.1% of births and accounting for 30-40% of clinically important intracardiac shunts [2]. The patent foramen ovale (PFO) is more common and is present in greater than 20-25% [3].

Guidelines for the comprehensive assessment of the interatrial septum (IAS) have the potential to reduce variation in the quality of echocardiographic studies, guide the complete characterization of defects, standardize the measurements and techniques used to describe the anatomy and physiology, and improve the assessment of suitability for surgical and transcatheter therapies [4].

Patients and Methods

Research design: A retrospective descriptive study conducted on patients who underwent transcatheter closure of atrial septal defect at Pediatric Cardiology Unit of Assiut University Children Hospital, 2.5 Year from March 2014 to September 2016.

Inclusion criteria:

All patients that underwent transcatheter ASD device closure and were suitable for this maneuver as they had significant ASD (QP/QS ›_ 1.5/1) with

Abbreviations:

ASD: Atrial Septal defect.
IAS : Interatrial septum.
PFO : Patent foramen ovale.
TTE : Transthoracic echocardiography.
TEE : Transesophageal echocardiography.

right ventricular volume overload and suitable for device closure (suitable septal rims of at least 4 mm for children and 5mm for adults); according to the guidelines of American Heart Association (AHA) for cardiac catheterization and intervention in pediatrics [5].

Defects were defined as small (>3mm to <6mm), moderate (>or=6mm to <12mm), or large (>or= 1 2mm).

Exclusion criteria:

Patients with ASD that were unsuitable for device closure due to:

- Large ASD size in relation to the weight of the patient, especially in children (10-15kg) in whom the ratio of device/body weight was >1.5; or large ASD >34mm or deficient rims [6].
- ASD types other than secundum type.
- Abnormal venous drainage.
- Associated complex cardiac anomaly.
- Severe pulmonary hypertension with ASD bi-directional or right to left shunting.
- Newborns or children below one year of age or less than 10Kg with asymptomatic small ASD.

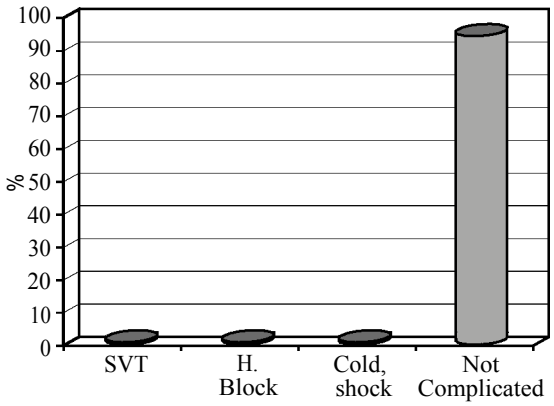

Fig. (1): Complications during the ASD device closure.

Results

The study was conducted on 62 patients [56 (90.4%) children and 6 (9.6%) adults] who underwent transcatheter secundum ASD device closure, at Pediatric Cardiology Unit of Assiut University Children Hospital from March 2014 till September 2016.

The patients were grouped according to age into four groups; three children groups: From 1-6 years, 7-12 years, 13-18 years and one adult group from 19-50 years.

Table (1): The demographic data of studied patients (n=62).

Demography (n=62)	Number	%
Age (years):		
1–6	37	59.7
7–12	11	17.7
13–18	8	12.9
19–50	6	9.7
Sex:		
Male	30	48.4
Female	32	51.6
Residence:		
Rural	38	61.3
Urban	24	38.7

Table (2): ECG and Chest X-ray and findings in the studied patients (n=62).

Investigations (n=62)	ECG			Normal	Chest X-ray	
	RVH	RAD rsR'	RVH+Rt axis deviation		Cardiomegaly	Normal
No.	8	3	5	4	42	25	37
%	12.9	4.9	8	6.4	67.7	40.3	59.9

RVH: Right ventricular hypertrophy. RAD: Right atrial dilataion. rsR': Pattern in V1- V3.

Table (3): The comparison between the (mean ± SD) ASD sizes (mm) measured by TTE and TEE.

Age groups (ys)	Children			Adults
ASD size	1–6 (n=37)	7–12 (n=11)	13–18 (n=8)	19–50 (n=6)
TTE:				
Range (mm)	(4-24)	(6-25)	(12-22)	(12-32)
Mean ± SD (mm)	13.9±4.8	13.5±6.1	14.8±3.8	21.8±7
TEE:				
Range (mm)	(6-35)	(8-26)	(17-32)	(15-38)
Mean ± SD (mm)	16.8±6.3	17.5±6.4	23.3±6.5	26.4±8.4
p-value	0.029*	0.149	0.007*	0.327

TTE: Transthoracic echocardiography. TEE: Transesophageal echocardiography.

Table (4): Cases with or without cardiomegaly on chest X-ray in relation to the ASD size measured by TTE.

ASD size TTE	Cardiomegaly by CXR			
	Cases with		Cases without	
	No.	%	No.	%
Small (<5mm) (n=2)	None	0	2	100
Moderate (6-12mm) (n=15)	7	46.6	8	53.4
Large (>12 mm) (n=45)	37	82.2	8	17.8

Table (5): Some important procedure characteristics.

Procedure characteristics	ASD size (mm)		Device size (mm)	Device/ defect ratio	Delivery sheath diameter (Fr)	Procedure time (min)	Fluoro time (min)
	TTE	TTE					
Range	4–32	6–38	9–40	1.2–1.6	6–12	10–45	3.2–24
mean ± SD	15.7±5.6	18.3±6.9	24.1±6.6	1.53± 0.11	9.3± 1.6	32.7± 12.1	8.4±4.5

Table (6): Relation between ASD size measured by TEE, TTE and the device closure size.

	ASD size by TEE	ASD size by TEE
ASD size by TEE		
r-value		
p-value		
ASD size by TTE		
r-value	0.854	
p-value	0.000*	
Device closure size		
r-value	0.764	0.650
p-value	0.000*	0.000*

Discussion

We studied 62 patients with significant secundum ASD suitable for device closure [56 (90.4%) children and 6 (9.6%) adults], 30 males (48.4%) and 32 females (51.6%). The age of the studied patients ranged from 1-18 years (6.1±3.8 years) in children and from 19-50 years (26± 12.7 years) in adults. Most of the children patients 37/62 (59.7%) aged from 1-6 years, 11/62 (17.7%) aged from 7-12 years and 8/62 (12.9%) aged from 13-18 years in addition to six adults (9.7%) aged from 19-50 years.

Previous studies reported that transcatheter closure of ASD is efficient in children weighing ≤ 15Kg, and can be proposed as a first line of treatment in symptomatic patient [7,8]. Choi et al., [9] and Woods et al., [10] stated that device closure is a safer and more effective alternative to surgery, with valid advantages in very small children, including infants and those who weigh <10kg and there was no additional risk in such small babies for transcatheter ASD closure.

Rao and Harris [11] stated that small defects <5mm are likely to spontaneously close and do not need occlusion. Evidence for right ventricular volume overloading (dilatation of right atrium and right ventricle with flat or paradoxical interventricular septal motion) by echocardiogram is used by most cardiologists as an indication for closure. If cardiac catheterization is performed, QP: QS (pulmonary to systemic flow ratio) >1.5 is an indication for closure.

In the present study ASD size was measured by TTE before the procedure and by TEE within the procedure and under general anaesthesia. The mean ± SD ASD size in the patients was 15.7±5.6 mm (measured by TTE) and 18.3 ±6.9mm (measured by TEE). It was significantly higher when measured by TEE (13.9±4.8 and 14.8±3.8) than when measured by TTE (16.8 ±6.3 and 23.3 ±6.5) in the group of children aged (1-6) years and (13-18) years (p=0.029 and p=0.007 respectively). In addition, There was a significant positive correlation between the ASD size that was measured by TTE and that was measured by TEE (r=0.854, p =0.000). There were significant positive correlations between the ASD size that was measured by TTE and TEE and the size of the ASD device that were used to close the defects (r=0.764, p=0.000 and r=0.650, p=0.000 respectively).

In the present study, three types of ASD closure devices were used: Amplatzer septal occluder (ASO) in 57/62 (92%), Occlutech septal occluder (Figulla-Occlutech Device) (FOD) in 3/62 (5%) and Amplatzer multifenestrated septal oocluder (cribriform occluder) in 2/62 (3%). The mean device/defect ratio was [1.53 ±0.11, (range 1.2-1.6)]. Successful closure of secundum ASD was achieved in 98.3% (61/62) of patients regarding

the efficacy (successful closure of the defect without residual shunt) and safety (no deaths or major complications). In one case the device was removed because of complete heart block. Immediate and follow-up results of ASO implantations appear encouraging, with immediate complete closure.

Our results are keeping with Behjati et al., [12] who reported closure rate 94.7% in their study.

Generally our experience concludes that, closure of secundum ASD was a safe procedure as it was not complicated by death or any of major complications as cerebral embolism, cardiac tamponade, device embolization or dislodgement requiring open cardiac surgery and infectious endocarditis. The patients were discharged 24 hours after the procedure on Aspirin 5mg/Kg/day once daily for six months.

Conclusion:

Transcatheter closure of secundum ASD in children adolescents and adults has a high success rate (98.3%) regarding the efficacy (successful closure of the defect without residual shunt) and safety (no death or major complications as cerebral embolism, cardiac tamponade, device embolization or dislodgement requiring open cardiac surgery and infectious endocarditis) during, immediate and short to midterm follow-up.

It is a safe procedure in young children with small weight (age of 1 year and weight of 10kg), and in adults (age up to 50 years and weight up to 86Kg).

Our findings suggest that Amplatzer device closure of secundum ASD guided by TTE and/or TEE measurements and fluoroscopy could be the first option of management.

Recommendations:

We recommend further studies on larger number of patients with longer periods of follow-up.

Prompt measurements of ASD size and ASD rims length is achieved by using TTE.

Further studies on the efficacy of TTE as an only modality for assessment of such procedure.

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إغلاق الجيب بين الأذينين عن طريق القسطرة دراسة خلال عامين ونصف بمستشفى الأطفال الجامعى بأسيوط

تهدف هذه الدراسة الوصفية المرجعية إلى تقييم سنتين ونصف من الخبرة فى إغلاق الجيب بين الأذينين فى وحدة أمراض القلب للأطفال بمستشفى جامعة أسيوط من مارس ٢٠١٤ حتى سبتمبر ٢٠١٦.

كان المرضى المشمولين فى الدراسة هم الذين خضعوا لإغلاق الجيب بين الأذينين بواسطة جهاز القسطرة القلب وتم أستبعاد أولئك الذين يعانون من ثقب غير مناسب لإغلاقه بواسطة القسطرة وقد أجريت الدراسة من خلال جمع لبيانات التالية:

١- الديموجرافيا الخاصة بالمرضى مثل الأسم، السن، النوع، مكان أقامة المريض، والعلامات الحيوية، والفحص الشامل والقلبى للمريض.

٢- نتائج الأشعة السينية على الصدر، تخطيط القلب الكهربى، وصورة الدم الكاملة العد، أختبارات وظائف الكلى، الأيونات فى الدم، زمن وتركيز البروثرومبين وألتهاب الكبر الفيروسى C وB سيرولوجى.

تم تجميع البيانات الكاملة التى تم الحصول عليها عن طريق تخطيط صدرى بالدوبر الملون مثل حجم الثقب بين الأذينين ونوع الجهاز المستخدم فى إغلاق الثقب عن طريق القسطرة (أمبلتزر، أوكلولوتيك أو كريبريفورم) وحجم الجهاز. كماتم تسجيل وقت الإجراء، وقت التعرض للأشعاع، والمضاعفات ومتابعة المرض.

تم أستخدام ثلاث أنواع من أجهزة إغلاق الثقب: أمبلاترز الحاجز فى٧ ٦٢/٥ (٩٢٪)، أو كلوتيش الحاجز (جهاز فيغولا أو كلوتش) فى ٣/٦٢ (٥٪) وأمبلاترز متعدد الطبقات (كريبريفورم أوكلودر) فى ٢/٦٢ (٣٪).

تم تحقيق الإغلاق الناجح للثقب فى ٩٨.٣٪ (٦١/٦٢) من المرضى فيما يتعلق بالفاعلية (ناجح للخلل دون وجود ثقب متبقى) والسلامة (لا وفيات أو مضاعفات). فى حالة واحدة تم إزالة الجهاز بسبب أختلال دقات القلب الكامل.

وبصفة عامة فإن تجربتنا تخلص إلى أن أغلاق الثقب بين الأذينين هو إجراء أمناً لأنه لم يكن معقداً بسبب الوفاة أو أى من المضاعفات الرئيسية مثل الأنسداد الدماغى أو أنسداد الجهاز الذى يتطلب جراحة القلب المفتوح وألتهاب الشغاف المعدية. وقد خرج المرضى بعد ٢٤ ساعة من إجراء القسطرة على الأسبرين ٥/مجم /كجم/ يوم مرة واحدة يومياً يمدة ستة أشهر. نوصى بإجراء مزيد من الدراسات على عدد أكبر من المرضى مع فترة أطول من المتابعة.