

Feasibility of percutaneous closure of atrial septal defects in adults under transthoracic echocardiography guidance using the Figulla atrial septal defect occluder device



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Background: Closure of atrial septal defect (ASD) among adults under transthoracic echocardiography (TTE) guidance using devices other than the Amplatzer Septal Occluder has not been extensively tested.

Aim of work: Assessment of the safety and efficiency of secundum ASD closure using the Occlutech Figulla ASD Occluder under TTE guidance in adult patients with hemodynamically significant secundum ASD.

Methods: Twenty patients (mean age, 32.9 \pm 9.7, 75% of them females) were enrolled in the study. All patients underwent TTE and transoesophageal echocardiography (TEE) to assess the characteristics of the ASD prior to percutaneous closure. Procedures were performed using the Figulla Occluder device under both fluoroscopic and TTE guidance. Follow-up clinical and TTE examinations were done at 1, 3, and 6 months following the procedure.

Results: TTE estimated mean ASD size was 21.7 \pm 7.3 mm with adequate rims except for the aortic rim (deficient in one third of cases). Mean device size was 28.1 \pm 8.6 mm with mean procedure and fluoroscopic times of 46.2 \pm 16.4 and 15.7 \pm 5.4 minutes respectively. ASD was successfully closed in all patients. Two patients showed a small residual shunt immediately after the device placement that disappeared by the end of the 2nd followup TTE examination. Transient complications were detected in 2 patients. All patients were asymptomatic during the follow-up period.

Conclusion: Transcatheter closure of secundum ASD in adults under TTE guidance using the Occlutech Figulla ASD occluder device is safe and effective when performed in a tertiary center and by expert echocardiographers and interventional cardiologists.

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Introduction

Atrial septal defect (ASD) is one of the most commonly encountered congenital heart diseases in the adult population [1]. In a previous report from Egypt, ASD constitutes 20% of all congenital heart defects in adults and up to 25% of all acyanotic lesions among this population [2]. A higher prevalence was also detected in a large registry from Greece [3]. While the majority of ASDs are diagnosed during infancy and childhood in the western countries, hemodynamically significant ASD might be diagnosed for the first time during adulthood in developing countries [2]. If left untreated, patients with such defects may develop many complications including right ventricular (RV) failure, atrial arrhythmias, and systemic embolization [1]. Although surgical closure of ASD is associated with a high success rate and a low rate of complications, percutaneous device closure is considered currently as the method of choice for management of secundum ASD when applicable [1]. The percutaneous procedure is performed under either transesophageal (TEE) or intracardiac echocardiography. Recent studies, however, showed the safety and efficacy of ASD closure under transthoracic echocardiographic (TTE) guidance in children [4,5].

The most commonly implanted device used for ASD closure is the Amplatzer septal occluder. Many other devices are currently available and used for selected patients with suitable morphological and anatomical features such as the Figulla ASD occluder, the Gore HELEX septal occluder, and others [6–9]. The Occlutech Figulla device (Occlutech GmbH, Jena, Germany) is characterized by being flexible, able to self-center in the shunt, and easy to be handled and to be recaptured before disconnection from the delivery system [8]. In this study, we aimed to assess the safety and efficiency of ASD closure under TTE guidance using the Figulla ASD occluder in adult patients with hemodynamically significant left to right shunting.

Methods

Twenty adult patients (age >18 years) with hemodynamically significant left to right secundum ASD suitable for device closure as assessed by TEE and adequate TTE window were enrolled in this prospective cohort study. A hemodynamically significant shunt was evidenced by the presence of both the echocardiographic evidence of

Abbreviations

ACHD	Adult congenital heart disease
ASD	Atrial septal defect
ASO	Amplatzer septal occluder
ICE	Intracardiac echocardiography
IAS	Interatrial septum
IU	International unit
MVP	Mitral valve prolapse
PASP	Pulmonary artery systolic pressure
Qp/Qs	pulmonary flow/aortic flow
RA	Right atrium
RV	Right ventricle
TEE	Transesophageal echocardiography
TR	Tricuspid regurgite
TTE	Transthoracic echocardiography
2D-TTE	Two-dimensional transthoracic echocardiography

right-sided dilation and the catheter-derived pulmonary/systemic flow (Qp/Qs) ratio of ≥ 1.5 . The Qp/Qs ratio was calculated by dividing the product of flow through the pulmonary artery and pulmonary arterial diameter by the product of flow through the aorta and aortic diameter. Patients with complex ASD lesions, reversed right to left shunt, or left ventricular dysfunction were excluded from the study. Written informed consent was obtained from all patients, and the study was approved by the local ethical committee. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Echocardiography

Examinations were performed using commercially available Philips IE-33 (Philips Medical Systems, Andover, MA, USA) and Esaote MyLabTM 70 XVision (Esaote Medical Systems, Genoa, Italy). Electrocardiographic monitoring was included in all studies. TEE examinations were performed in all patients to assess the suitability for percutaneous closure. The following data were assessed in all patients prior to the procedure using both TTE and TEE: (1) the number of ASD, (2) ASD size, (3) ASD rims, (4) total septal length, (5) RV size and function, (6) velocity of tricuspid regurgitation (TR) and estimated pulmonary artery systolic pressure (PASP), and (7) any associated heart defects including assessment of the pulmonary venous drainage. The largest ASD diameter detected in any view in a given patient was chosen as the reference ASD diameter for selecting the optimal size of the device occluder.

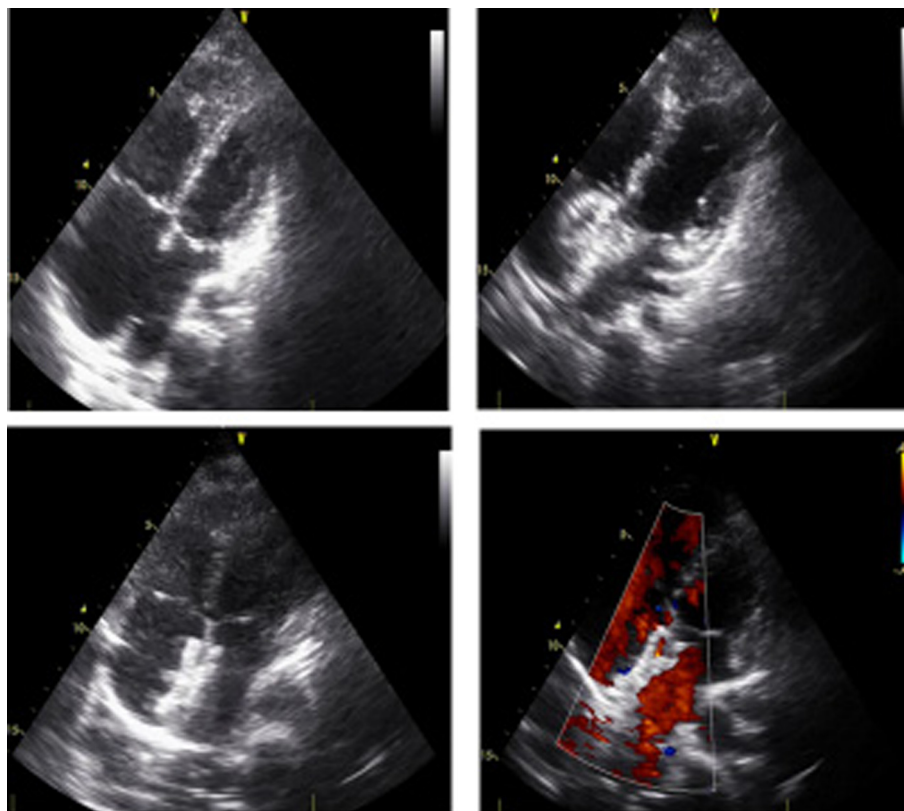


Figure 1. Two-dimensional and color Doppler TTE-modified apical view, performed during ASD device closure: before device deployment, during release of the right atrial disc, after device deployment, and after device deployment. ASD = atrial septal defect; TTE = transthoracic echocardiography.

Technique

All selected ASDs were percutaneously closed using the Figulla ASD occluder (Occlutech GmbH). The device consists of a nitinol mesh providing a smooth and flexible outer layer. The absence of a left atrial disc micro-screw minimizes the amount of material on the left atrial aspect and reduces the possibility of clot formation [8]. Procedures were performed under both TTE and fluoroscopic guidance. Patients received unfractionated heparin (100 IU/kg) to maintain activated clotting time of >200 seconds. Venous access was secured through the right femoral vein, and then a soft-tipped 0.035-inch guidewire was advanced in the left anterior oblique/cranial view through the defect and positioned in the upper left pulmonary vein. Next, an appropriate delivery sheath was advanced to the left atrial side over the guidewire. No balloon sizing was used. The occluder was subsequently loaded in a short Cook delivery sheath and advanced by means of the delivery system to the left atrial side. After opening the left atrial disc, the system was retracted until the left atrial disc was positioned opposite the left intera-

trial septum. The right atrial disc was deployed thereafter. Prior to device release, the cable was pushed forward and backward (“Minnesota wiggle”), and correct positioning was confirmed by means of fluoroscopy and TTE. Adequate device position was determined by the lack of movement of the device in either direction. A residual shunt was ruled out by color Doppler flow imaging (Fig. 1). Once the occluder was positioned properly, it was released by opening the locking mechanism (Fig. 2).

Follow-up

All patients were discharged on aspirin and clopidogrel daily (75 mg) for 6 months. Prophylaxis for infective endocarditis was recommended during the first 6 months. At follow-up, all patients were examined by TTE at 1 month, 3 months, and 6 months to evaluate the following: (1) proper device position and its relationship with the adjacent anatomic structures, (2) presence of residual shunt (trivial if the color jet width was ≤ 1 mm, small if it was >1 mm and ≤ 2 mm, moderate if it was >2 mm and ≤ 4 mm, and large if it was

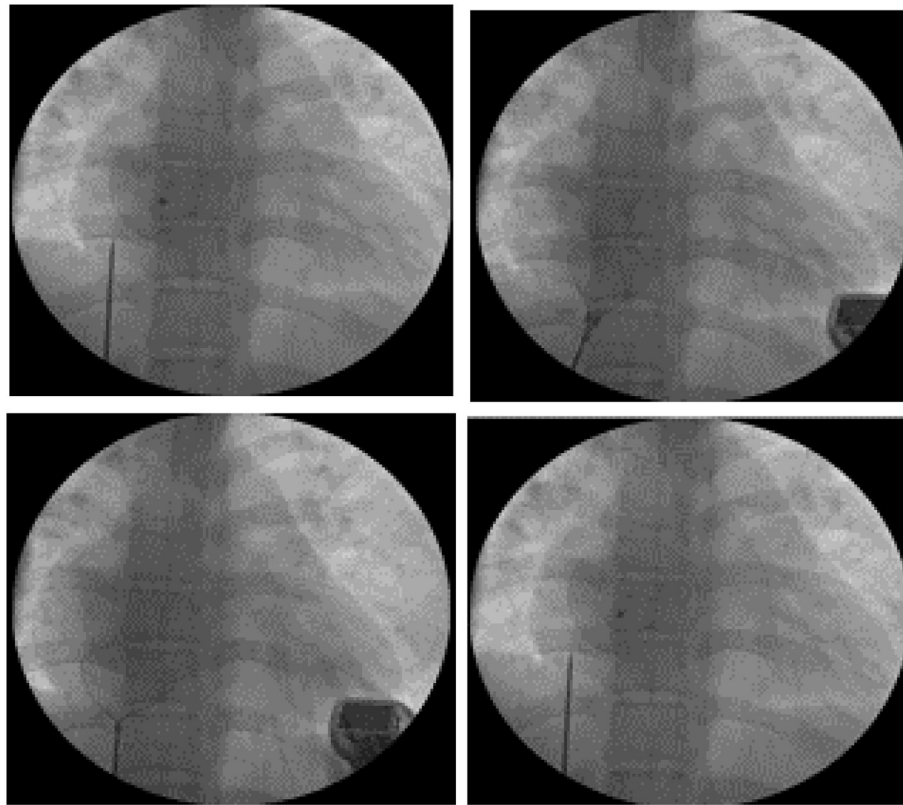


Figure 2. Angiographic views of the Figulla ASD occluder device showing release of the left atrial disc, release of the right atrial disc, Minnesota wiggle, and release of the device from the introducer. ASD = atrial septal defect.

>4 mm), (3) RV dimensions and systolic function, (4) TR velocity and estimated PASP, and (5) any thrombotic complications. The procedure was considered successful if no, trivial, or small residual shunt was present immediately after the procedure and in the absence of major complications such as death, stroke, device embolization, perforation, or pericardial effusion.

Statistical analysis

Data were analyzed using the Statistical Package for Social Sciences version 17.0 (SPSS Inc., Chicago, IL, USA). Numerical data were expressed

Table 1. Demographic and procedural characteristics of the studied population. Data given as mean \pm standard deviation, range, or number (percentage).

	Patients (n = 20)
Female sex, n (%)	15 (75%)
Age (y)	32.9 \pm 9.7 (19–52)
Weight (kg)	63.6 \pm 9.6 (44–81)
Fluoroscopy time (min)	15.7 \pm 5.4
Procedure time (min)	46.2 \pm 16.4
Successful implantation, n (%)	20 (100)
Complications, n (%)	2 (10%)

as mean and standard deviation, or median and range as appropriate. The paired *t* test was used for comparison of variables.

A *p* value of <0.05 was considered significant. Bland–Altman analysis was used to calculate the limits of agreement with the use of the statistical package MedCalc Software version 11.3.0 (MedCalc, Mariakerke, Belgium).

Results

The demographics and clinical data of patients are illustrated in Table 1. Preprocedural combined

Table 2. TTE findings of the studied population.

Variable	
ASD size (mm)	21.7 \pm 7.3
IAS length (mm)	44.3 \pm 3.9
ASD/IAS ratio	0.48 \pm 0.13
Deficient aortic rim	7 (35)
Qp/Qs ratio	2.4 \pm 0.4
RVEDD (mm)	34.9 \pm 7.0
Pulmonary hypertension, n (%)	8 (40)

Data given as mean \pm standard deviation or number (percentage). ASD = atrial septal defect; IAS = interatrial septum; Qp/Qs = pulmonary/systemic flow; RVEDD = right ventricular end diastolic diameter; TTE = transthoracic echocardiographic.

TTE and TEE revealed an isolated secundum ASD in all patients with evidence of right atrial and RV dilatation. Mid RV cavity size was 34.4 ± 7.0 mm. TR of moderate to severe degrees was observed in all patients. Five cases (25%) had associated mild mitral valve prolapse with no significant regurgitation. Eight cases (40%) have mild pulmonary hypertension with PASP ranging between 42 mmHg and 50 mmHg. There was a statistically significant difference between the sizing of the ASD using TTE and TEE, with larger sizes being measured by TEE ($p = 0.004$). The mean ASD size was 21.7 ± 7.3 mm (range: 9–32 mm, median: 22 mm) and 24.6 ± 7.7 mm (range, 9–36 mm, median: 24 mm) by TTE and TEE, respectively. The mean interatrial septal length was 44.3 ± 3.9 mm and 44.9 ± 4.7 mm by TTE and TEE, respectively. The mean ASD size/interatrial septal ratio was 0.48 ± 0.13 . The mean Qp/Qs ratio was 2.4 ± 0.4 . In all patients, all rims were adequate except the aortic rim, which was deficient in seven cases (35%; Table 2).

Procedure

All patients underwent transcatheter closure of ASD under TTE guidance and conscious sedation. TTE was performed during the procedure in apical 4 chamber and subcostal views to guide device placement and detect any residual shunts. TEE was performed many days before the procedure to all patients to confirm the diagnosis of secundum ASD, accurate measurement of defect size, and condition of septal rims. Right femoral vein access was achieved in all cases. All cases received parenteral heparin at a dose of 100 IU/kg during the procedure together with cefotaxime 1 g administered intravenously. The mean device size used was 28.1 ± 8.6 mm (range: 10.5–40 mm, median: 27 mm). Long and short sheath diameters ranged between 7 and 14 Fr. The mean procedure time was 46.2 ± 16.4 minutes. The mean fluoroscopic time was 15.7 ± 5.4 minutes. ASD was successfully closed in all 20 patients after 22 percutaneous attempts. Two patients needed two additional attempts to close the defect securely with device size of 36 mm and 40 mm. The device was placed successfully in all patients, and no case of embolization was recorded. A small residual flow was seen immediately after device placement in two cases (10%) and disappeared by the end of 3 months' follow-up. TTE is likely to miss small shunts that would be detected by transesophageal echocardiography. These shunts, however, are not clinically important, which can be mentioned at this instance.

Complications and follow-up

Two patients (10%) developed temporary periprocedural complications. One patient developed transient supraventricular tachycardia during the procedure, which recovered to sinus rhythm with the administration of verapamil. The second patient developed groin hematoma after sheath removal, which was resolved on the 4th postoperative day, as verified by Duplex examination. At 6 months' follow-up, all patients were asymptomatic. TTE showed securely closed and properly positioned devices. No related masses were seen. Patients with preprocedural echocardiographic evidence of elevated PASP showed normalization of the estimated PASP and regression of the TR severity.

The procedure was performed as an outpatient procedure. All patients were discharged on the 2nd postoperative day except one patient with groin hematoma, who was discharged on the 5th postoperative day.

Correlation between ASD size by TTE and TEE

The mean maximal diameter measured by two-dimensional TTE was 21.7 ± 7.3 mm, while the mean TEE was 24.6 ± 7.7 mm. This difference was statistically significant ($p = 0.004$). The mean difference between the values of the ASD diameter obtained by TTE and TEE was 2.9 ± 3.9 mm.

There was a good correlation between the TTE maximal defect sizing and TEE measurements ($r = 0.861$, $p < 0.001$; Fig. 3). By the linear regression analysis, $\text{ASD size by TEE} = 0.821 \times \text{ASD size by TTE}$

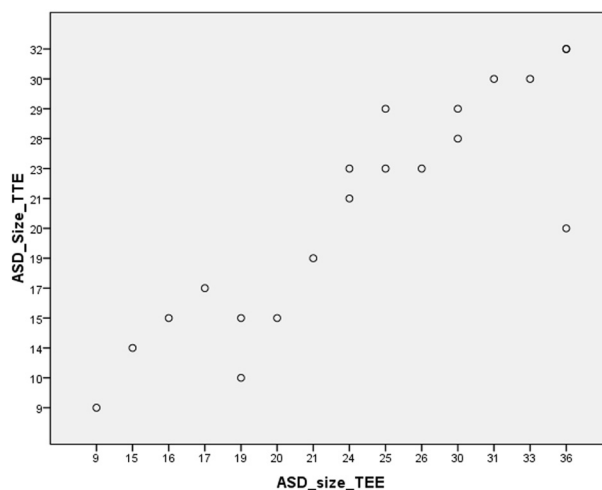


Figure 3. Linear regression analysis of ASD size by TTE and TEE. ASD = atrial septal defect; TEE = transesophageal echocardiography; TTE = transthoracic echocardiography.

TTE + 1.493; $r^2 = 0.741$. In 90% of the cases, TEE values were larger, and only in 10% they were similar to TTE.

The Bland and Altman plot showed agreement between the two measurements because the number of points laid out of the 95% range of agreement (± 1.96 SD) was less than 5% of all the observations (Fig. 4).

Discussion

The present study showed that secundum ASD can be safely and securely closed under TTE guidance using devices other than the widely used Amplatzer occluder device. This requires, however, proper preprocedural adequate TTE and TEE examinations and the presence of well-trained echocardiographers and interventional cardiologists in a tertiary center.

The implant procedure is similar in both devices; however, we believe that the use of the Occlutech Figulla device is less expensive while providing comparable and successful ASD closure, and this matter is crucial in developing countries and in centers with limited resources.

With the advances achieved in the field of adult congenital heart disease and the establishment of special dedicated centers concerned with the management of these patients, it is expected to encounter more patients with secundum ASD requiring closure. Although surgical closure of ASD is an uncomplicated surgery with a high success rate and a low complication rate, percutaneous ASD closure (when suitable) is currently the recommended method for secundum defect

closure [1]. One of the advantages of percutaneous closure is the absence of scar that may result in many psychological problems among females in whom the prevalence of ASD is higher.

Many ASD closure devices are currently available for clinical use. The Figulla ASD occluder was recently introduced and tested in previous studies showing its safety and efficacy in ASD closure [8,10]. The absence of a left atrial clamp reduces the amount of left atrial material and the chance of thrombus formation. The earliest study was conducted by researchers from Germany who studied the safety and efficiency of the device in closing both patent foramen ovale and ASD. The procedure was performed under both fluoroscopic and TEE guidance. All patients underwent successful closure, while one patient died due to myocardial infarction several days following the implantation of the device. Autopsy ruled out an embolic underlying cause and proved the absence of thrombi related to the occluder surface. Only one patient with patent foramen ovale showed residual shunt at 180 days' follow-up [8]. Two earlier reports were also published in 2008 and 2010 confirming the safety and efficiency of the Figulla occluder device [11,12]. These studies, however, closed the defects under TEE guidance, and little is known about the success of closure using the Figulla occluder under the guidance of TTE. Intraprocedural TEE (even without concomitant fluoroscopic guidance) provides adequate and accurate visualization of the defects and surrounding structures, and allows high implantation success especially among adults [13].

Recently, many reports showed the success of ASD closure under TTE guidance. These studies were performed mostly in children rather than the adult population. We believe that in patients with adequate acoustic windows, performing ASD closure under TTE guidance in a tertiary center by expert echocardiographers and interventionalists might be less costly, successful, and associated with comfort in more patients and fewer TEE/anesthesia-related complications, especially that these patients undergo routinely a full TEE study prior to the closure to give detailed anatomical, structural, and functional data. Pan et al. [4] studied the success and costs of ASD closure under TTE guidance without fluoroscopy in 127 patients (age: 2–18 years). They found that the procedure time, laryngeal complications, and costs were lower in patients who underwent TTE-guided ASD closure as compared with those who underwent the procedure under TEE guidance. The success rates in both groups of patients

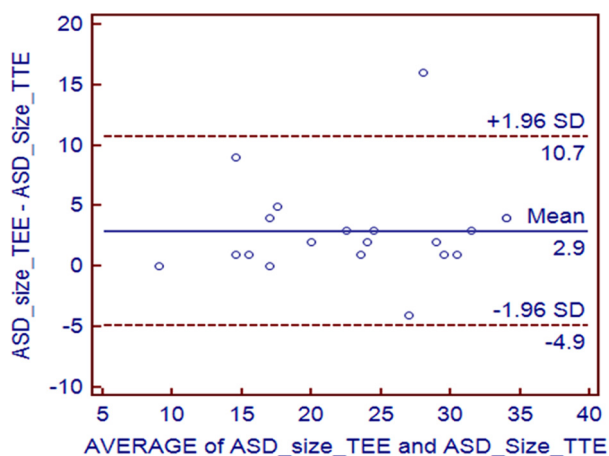


Figure 4. Bland and Altman plot for assessing agreement between ASD size by TTE and TEE. ASD = atrial septal defect; SD = standard deviation; TEE = transoesophageal echocardiography; TTE = transthoracic echocardiography.

were comparable. Similar beneficial results were also confirmed in an earlier study [5]. Erdem et al. [14] published their experience in closing the ASD using either TTE or TEE in a large number of patients including both children and adults. They used several devices including the Amplatzer septal occluder (129 patients), Figulla (7 patients), and others. Patients who underwent TTE were significantly younger and had smaller ASD size, shorter procedure and fluoroscopy times, and a lower complication rate. These findings were in accordance with earlier studies that showed safety and efficiency of TTE in guiding ASD closure procedure [15]. These studies used, however, the Amplatzer devices. Praz et al. [16] studied the safety and feasibility of percutaneous ASD closure using the Amplatzer Septal Occluder (ASO) device in many cases (217 patients, 44 of them being children). TEE guidance and general anesthesia were restricted to the children, while devices were implanted under fluoroscopic guidance only in the adults. Routine preprocedural TEE was performed in all adult patients. They reported that the success rate was 98.6% with a residual shunt rate of 10% at 2 years' follow-up with four adult patients undergoing implantation of a second device for a residual shunt. They also reported new-onset atrial arrhythmias in 9% of patients, all of whom were adults.

Conclusion

Transcatheter closure of secundum ASD in adults under TTE guidance using the Figulla ASD occluder device is safe and effective provided it is performed in a specialized center and in the presence of expert echocardiographers and interventional cardiologists. Larger studies including a large number of patients are still warranted.

References

- [1] Warnes CA, Williams RG, Bashore TM, Child JS, Connolly HM, Dearani JA, et al. ACC/AHA 2008 guidelines for the management of adults with congenital heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (writing committee to develop guidelines on the management of adults with congenital heart disease). *Circulation* 2008;118:e714–833.
- [2] Farouk H, Shaker A, El-Faramawy A, Mahrous A, Baghdady Y, Adel A, et al. Adult congenital heart disease registry at Cairo University: a report of the first 100 patients. *World J Pediatr Congenital Heart Surg* 2015;6:53–8.
- [3] Giannoglou GD, Antoniadis AP, Chatzizisis YS, Louridas GE. Adult congenital heart disease investigated with cardiac catheterization over a 20-year period. *Open Cardiovasc Med J* 2009;3:124–7.
- [4] Pan XB, Ou-Yang WB, Pang KJ, Zhang FW, Wang SZ, Liu Y, et al. Percutaneous closure of atrial septal defects under transthoracic echocardiography guidance without fluoroscopy or intubation in children. *J Interv Cardiol* 2015;28:390–5.
- [5] Bartakian S, El-Said HG, Printz B, Moore JW. Prospective randomized trial of transthoracic echocardiography versus transesophageal echocardiography for assessment and guidance of transcatheter closure of atrial septal defects in children using the Amplatzer septal occluder. *JACC Cardiovasc Interv* 2013;6:974–80.
- [6] Rao PS, Berger F, Rey C, Haddad J, Meier B, Walsh KP, et al. Results of transvenous occlusion of secundum atrial septal defects with the fourth generation buttoned device: comparison with first, second and third generation devices. International Buttoned Device Trial Group. *J Am Coll Cardiol* 2000;36: 583–2.
- [7] Sah SP, Bartakian S, El-Said H, Molkara DP, Printz B, Moore JW. Preprocedural transthoracic echocardiography can predict amplatzer septal occluder device size for transcatheter atrial septal defect closure. *Congenit Heart Dis* 2016;11:656–62.
- [8] Krizanic F, Sievert H, Pfeiffer D, Konorza T, Ferrari M, Hijazi Z, et al. The Occlutech Figulla PFO and ASD occluder: a new nitinol wire mesh device for closure of atrial septal defects. *J Invasive Cardiol* 2010;22:182–7.
- [9] Jones TK, Latson LA, Zahn E, Fleishman CE, Jacobson J, Vincent R, et al. Results of the U.S. multicenter pivotal study of the HELEX septal occluder for percutaneous closure of secundum atrial septal defects. *J Am Coll Cardiol* 2007;49:2215–21.
- [10] Cansel M, Pekdemir H, Yağmur J, Tasolar H, Ermis N, Kurtoglu E, et al. Early single clinical experience with the new Figulla ASD occluder for transcatheter closure of atrial septal defect in adults. *Arch Cardiovasc Dis* 2011;104:155–60.
- [11] Halabi A, Hijazi ZM. A new device to close secundum atrial septal defects: first clinical use to close multiple defects in a child. *Catheter Cardiovasc Interv* 2008;71:853–6.
- [12] Ilkay E, Kaçmaz F, Ozeke O, Turan RS, Firat S, Pampal K, et al. The efficiency and safety of percutaneous closure of secundum atrial septal defects with the Occlutech Figulla device: initial clinical experience. *Turk Kardiyol Dern Ars* 2010;38:189–93.
- [13] Ewert P, Berger F, Daehnert I, van Wees J, Gittermann M, Abdul-Khaliq H, et al. Transcatheter closure of atrial septal defects without fluoroscopy: feasibility of a new method. *Circulation* 2000;101:847–9.
- [14] Erdem A, Saritas T, Zeybek C, Yucel IK, Erol N, Demir H, et al. Transthoracic echocardiographic guidance during transcatheter closure of atrial septal defects in children and adults. *Int J Cardiovasc Imaging* 2013;29:53–61.
- [15] Kardon RE, Sokoloski MC, Levi DS, Perry 2nd JS, Schneider DJ, Allada V, et al. Transthoracic echocardiographic guidance of transcatheter atrial septal defect closure. *Am J Cardiol* 2004;94:256–60.
- [16] Praz F, Wahl A, Schmutz M, Pfammatter JP, Pavlovic M, Perruchoud S, et al. Safety, feasibility, and long-term results of percutaneous closure of atrial septal defects using the Amplatzer septal occluder without periprocedural echocardiography. *J Invasive Cardiol* 2015;27:157–62.