ICE-ASSISTED TRANSCATHETER CLOSURE OF INTERATRIAL SHUNTS: TEN-YEAR FOLLOW-UP

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ABSTRACT

Background. Intracardiac echocardiography (ICE) is rapidly becoming a necessary tool in the catheterisation laboratory. We sought to prospectively evaluate the effectiveness of ICE-aided transcatheter closure of interatrial shunts.
Methods. In a prospective 10-year registry, we enrolled 378 patients (mean age 48±13.7 years, 214 females) who had been referred to three different centres for catheter-based closure of interatrial shunts. All patients were screened with transoesophageal echocardiography (TOE) before the operation. Eligible patients underwent ICE study with mechanical Ultra-ICE probe (Boston Scientific Corp, USA) and closure attempt.
Results. After the ICE study and measurements, 23 patients did not proceed to transcatheter closure due to: unsuitable rims, atrial myxoma not diagnosed by pre-operative TOE, or inaccurate TOE measurement of defects more than 40 mm. The remaining 355 patients underwent transcatheter closure: TOE-planned device type and size were modified in 175 patients (49.3%). There were no cases of aortic or atrial erosion, device thrombosis, or atrioventricular valve inferences. Globally the rates of procedural success, pre-discharge occlusion, and major complications rate were: 99.1%, 93.3%, and 0%, respectively. On mean follow-up of 9.1±2.3 years, the follow-up occlusion rate was 98.7% with no long-term complications.
Conclusions. ICE-aided transcatheter closure of interatrial shunts appears to be safe and effective in adult patients thus, eventually minimising device size over and underestimation, and potential complications of balloon sizing and general anaesthesia.

Keywords: Atrial septal defect, percutaneous, catheter-based closure, intravascular, interventional, device, echocardiography, congenital, patent foramen ovale.

INTRODUCTION

Due to favourable results achieved by percutaneous closure as compared to medical therapy and surgical closure,[1-2] transcatheter closure has emerged as the first-line therapy for the management of secundum atrial septal defect (ASD), and thanks to the positive results of the last recent trials,[3-4] also for patent foramen ovale (PFO). It has been suggested that intracardiac echocardiography (ICE) improves safety and effectiveness of transcatheter device -based closure of interatrial shunts,[5-6] but the impact of this imaging tool on long-term follow-up has not yet been evaluated. We sought to prospectively evaluate 10-year outcomes of ICE-aided transcatheter closure of interatrial shunts in adults.

METHODS

In a prospective 10-year registry, we enrolled 378 patients (mean age 48±13.7 years, 214 females) who have been referred to three different centres for catheter-based closure of interatrial shunts. In line with our institutional protocol, all patients were screened with transoesophageal echocardiography (TOE) prior to the intervention. Inclusion criteria

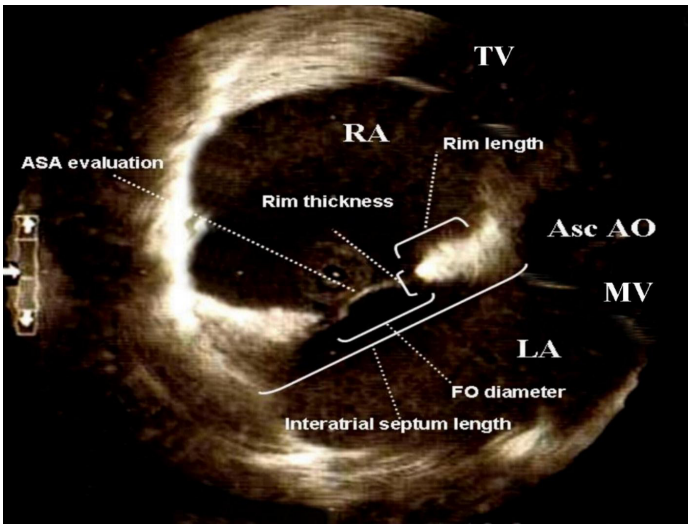

Figure 1: Typical measurements of right atrial components during ICE examination.
(Asc AO: ascending aorta; LA: left atrium; MV: mitral valve; RA: right atrium; TV: tricuspid valve).

for percutaneous closure of atrial septal defects included: Qp/Qs more than 1.5, enlargement of right atrium (more than 16.84 mm area) and ventricle (inflow tract of right ventricle more than 35 mm),[7] and atrial septal defect less than 40 mm. Indications for percutaneous closure of patent foramen ovale (PFO) defects included all of the following: a concurrent shower or curtain shunt pattern on transcranial Doppler [8] with or without Valsalva manoeuvre, positive (single or multiple ischemic foci) cerebral magnetic resonance imaging or previous clinical stroke or transient ischemic attack, and medium or large patent foramen ovale on TOE.[9] All patients with secundum atrial septal defect and/or patent foramen ovale were investigated by transthoracic echocardiography and transcranial Doppler, respectively, before TOE. The Hospital Ethical Board approved the study and written informed consent was obtained from all patients enrolled in the study.

Echocardiography Protocols

TOE was conducted using a GE Vivid 7 (General Electric Corp., Norfolk, VA, USA) with bubble test and Valsalva manoeuvre under local anaesthesia. Patients who met the criteria for secundum atrial septal defect or PFO closure were offered an ICE study using the mechanical 9F 9MHz Ultra-ICE catheter (EP Technologies, Boston Scientific Corporation, San Jose, CA, USA). The ICE study was conducted as previously described,[10] by performing a manual pull-back from the superior vena cava to the inferior vena cava through five sectional planes; measurement of diameters of the oval fossa, the entire atrial septum length and rims were obtained with electronic calliper edge-to-edge on the aortic valve plane and the four-chamber plane. PFO tunnel length was also measured. Intracardiac echocardiographic monitoring of the implantation procedure was conducted on the four-chamber plane. Normal diameter of fossa ovalis was defined as fossa ovalis <15 mm in the four-chamber view. Atrial septal aneurysms were classified according to Olivares et al.[11] Hypertrophic rims were defined as having a thickness ≥8 mm, whereas lipomatosis was defined as thickness of ≥15 mm, on ICE study. Long tunnel-type PFO was defined as length ≥10 mm by intracardiac echocardiogram.

Radiological Equipment

We used the GE Medical System Innova 2100 20-20 cm Flat Panel radiological equipment in all cases. Field size used was 20-20 cm. An estimation of the effective dose was obtained from the measurements of the total dose-area product that is automatically recorded by the radiological equipment during the procedures. Fluoroscopy and procedural times were also calculated.

Closure Protocol

Combined antibiotic therapy (Gentamicin 80 mg plus Ampicillin 1 gm, or Vancomicin 1 gm if there was a documented allergy to penicillin) was administered intravenously one hour before the procedure. The right femoral vein was catheterised through a six French sheath which was used for preoperative right cardiac catheterisation, and replaced with larger long sheath for device implantation, whereas the left femoral vein was catheterized through a eight French sheath which was replaced with a pre-curved nine French long sheath for the ICE study.

Intraoperative Closure Criteria and Device Selection

On the basis of ICE findings and measurements, the operators selected the Amplatzer Occluder family (PFO Occluder, Cribriform Occluder, ASD Occluder, AGA Medical Corporation, Golden Valley, MN) or the Premere™ PFO Closure System (St. Jude Medical Inc. GLMT), the Biostar Occluder (NMT) or the GORE GSO device (WL Gore & Associates, Inc, Flagstaff, Arizona, USA). The operators selected the Amplatzer PFO occluder when atrial septal aneurysm was unidirectional and mild (2RL or 2LR), and the Biostar or the Gore Septal Occluder when the aneurysm

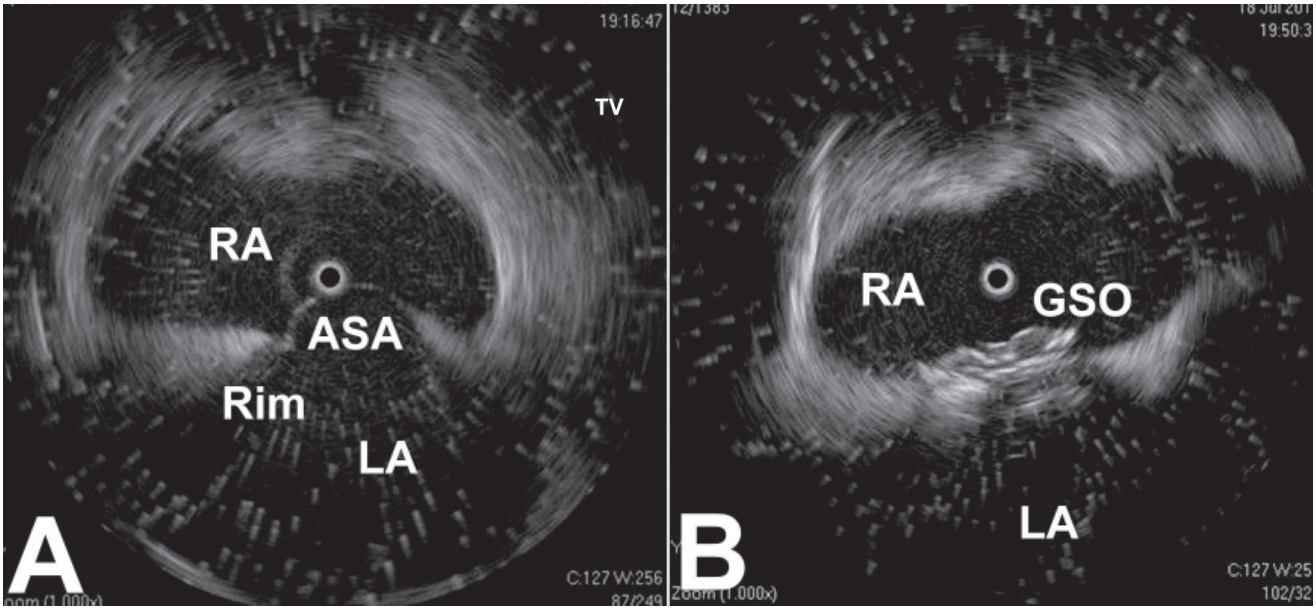

Figure 2: Patient with moderate atrial septal defect and hyperthrophic rims before (A) and after (B) closure with a Gore Septal Occluder (GSO).
(LA: left atrium; RA: right atrium; TV: tricuspid valve).

was unidirectional and moderate (3RL or 3LR atrial septal aneurysm). The Premere occlusion system was chosen when atrial septal aneurysm was absent or in the case of motionless or unidirectional atrial septal aneurysm (1R, 2L atrial septal aneurysm), when PFO tunnel length was more or equal to 10 mm, and in all case of hypertrophy of the interatrial septum rims (thickness more than 10 mm). The Amplatzer Cribriform Occluder was selected in the case of bidirectional moderate aneurysm (3 RL or 3LR), in all cases of large aneurysm (4 and 5RL or 4 and 5LR) and in all cases of multi-perforated atrial septal aneurysm, being careful to cross the most central hole in the oval fossa with the guide-wire during ICE guidance.

The Amplatzer ASD Occluder was selected in the case of secundum atrial septal defect, when anomalous venous return was angiographically excluded. Device sizing was obtained as described by Rigatelli et al.[12] by the measurement of the diameter on the aortic valve plane (short axis of an ideally elliptical defect) and the four-chamber plane (long axis of an ideally elliptical defect), which are perfectly orthogonal views. In all cases, care was taken to choose a device with an entire left disk diameter which did not exceed the ratio device size or entire atrial septum length of 0.8mm on ICE.

Medications

Aspirin 100 mg for 6 months has been prescribed to all patients with no coagulation abnormalities who received a Premere, Gore or Amplatzer devices. Aspirin 100 mg and Clopidogrel 75 mg for 6 months have been prescribed to patients who received the Biostar device. Warfarin for 6 months was prescribed to patients with coagulation abnormalities such as abnormal factor V of Leiden and anticardiolipin, antiphospholipid antibodies.

Follow-up Protocol

In patients who underwent closure, TOE was scheduled at 1 month and repeated at 6 months post-closure if there was more than a trivial shunt, to assess for potential erosions or thrombosis and residual shunts. Patients with PFO-related syndromes also underwent transcranial Doppler ultrasound and magnetic resonance imaging of the brain prior to and 1 month after the procedure. Transthoracic echocardiography was scheduled at 6 and 12 months after the transcatheter closure to assess mid-term residual shunt, and the effect of the device on atrial and heart valve function.

Any residual shunt was graded as trivial, small, moderate, or severe as previously described.[13] Clinical examination was scheduled at 1, 6, and 12 months.

Definition

Success was defined as the ability to release the device in a stable position under fluoroscopy and ICE guidance with no more than a trivial shunt on immediate angiography and on transthoracic echocardiography at 24 hours after closure. Immediate complications included various degrees of groin haematoma, atrial wall perforation, and pericardial effusion, entrapment of device, sheath or ICE equipment through venous valves or embryonic remnants, and air embolism. Pre-discharge occlusion rate was defined as a percentage of complete occlusion (presence of no more than a trivial shunt). Aortic erosion and device removal were included in the mid-term complication rate.

Statistical Analysis

Chi-square, corrected Chi-square, and T-student tests were used to compare frequencies and continuous variables, with a significance level $p<0.05$. Kaplan–Meier curve was employed to evaluate actuarial occlusion rates.

	Mean or No. (%)
Age	48±19.1
Male/Female	83/157
Secumdum atrial septal defect:	98/355 (27.6)
-Cribrosus atrial septal defect	38/355 (10.7)
-Mean right ventricle diameter (millimeters)	49±21.8
-Mean Qp/Qs	2.4±0.8
-Mean pulmonary artery pressure (mmHg)	39±11.3
-Residual shunt after surgery	1/355 (0.3)
Patent foramen ovale:	257/355 (72.3)
-Previous stroke	189/257 (73.5)
-Migraine with aura	41/257 (15.9)
-Migraine with no aura	54/257 (21.0)
-Positive cerebral magnetic resonance imaging	257/257 (100)
- Transcranial Doppler curtain pattern	98/257 (38.3)
- Transcranial Doppler shower pattern	159/257 (61.8)
-Platypnea orthodeoxya	3/257 (0.9)
-Contraindication to scheduled neurosurgery	3/257 (0.9)

Table 1. Demographic and clinical data of the 355 patients who underwent transcatheter closure.

RESULTS

After ICE study and measurements, 23 patients did not proceed to transcatheter closure due to: unsuitable rims in 13 patients after ICE recalculated rim length and thickness, atrial myxoma not diagnosed by preoperative TOE in 2 patients, and inaccurate TOE measurement of defects >40 mm (9 patients). The remaining 355 patients underwent attempted transcatheter closure (Table 1).

Device Selection and Measurement Results

After ICE study and measurements (Table 2), the TOE-planned device type and size was changed in 175 patients (49.3%): 97 patients with PFO (Amplatzer PFO Occluder rather than Premere for 10, Amplatzer Cribrosus rather than Amplatzer PFO for 35, Premere rather than Amplatzer PFO for 52 patients), and 78 patients with secundum atrial septal defect patients. Despite the fact that TOE may underestimate the size of the defect, it was used to obtain an estimate of the defect size range and interatrial anatomy so as to provide the proper range of device sizes and

Anatomical characteristics (mm)	TOE	ICE	p
Diameter of the interatrial septum	28±9.8	37±10.6	<0.01
Secundum atrial septal defect diameter	16.9±6.9	22±10.1	<0.01
Length of anterosuperior rim (aortic rim)	4.2±1.3	5.8±1.1	<0.03
Oval fossa diameter	20.1±4.5	23±7.9	<0.03
Patent oval foramen tunnel length	11±3.1	13±4.9	<0.04
Patent oval foramen size	5.4±0.6	6.3±0.5	<0.01
Rim thickness	9.2±9.6	12.2±7.6	<0.01

Table 2. Comparison between preoperative TOE and intraoperative ICE measurements of anatomical features of the interatrial septum.
(Measurements refer to the four-chamber view).

types in the cardiac catheterisation lab. In cases of floppy rims detected by TOE, ICE was able to precisely measure the thickness of the rims. Accurate measurement of rim thickness is essential since rim thickness less than 1.2 mm is unlikely to support the device disks: this resulted in larger ASD and fossa ovalis diameters as measured by ICE compared to TOE.

The Amplatzer ASD Occluder mean waist diameter was 27.7 mm in the 60 ASD patients, whereas the Amplatzer ASD Cribriform Occluder was 25/25 mm in 126 patients and 30/30 mm in 38 patients. The Amplatzer patent foramen ovale Occluder disk mean diameter was 25 mm in 32 patients, and 35 mm in 2 patients. The Premere device size was 25 mm in 30 cases, and 20 mm in 45 cases, The Biostar was 28 mm in 4 patients, whereas the Gore GSO size was 25mm in 6 patients and 30mm in 12 patients.

Procedural and Early Results

Transcatheter closure was successful in 352/355 (99.1%) of the patients. In one case of ASD the device was removed intraoperatively because of an incorrigible misalignment, in two cases of PFO, the implanted device was withdrawn as it was positioned too close to the aortic root on ICE.

In three cases of PFO, the release of the Amplatzer Occluder was difficult and complicated by thoracic pain because it became snared in a venous valve remnant during sheath advancement. Forced and prolonged sheath manipulation during the procedure was judged to be the cause of pericardial effusion in 3 patients, and groin haematoma not requiring blood transfusion occurred in 7 patients. 7 patients suffered either from arrhythmias: supraventricular tachycardia (2 patients) and atrial fibrillation (2 patients) within 24 hours of the procedure; sinus rhythm was restored in 5 patients with antiarrhythmic drugs, and in 2 patients with electrical cardioversion. In 2 patients (1 with a PFO and 1 with an secundum atrial septal defect), TOE at 1 month revealed moderate shunts, indicating that the initial successful closure had subsequently failed probably due to the worsening of device misalignment not fully evaluated on transthoracic echocardiography. It was therefore agreed, with the patients' consent, to surgically remove the devices.

10-Year Follow-Up

Over a 9.1±2.3 follow-up (range 2-10), only 1 patient (with a secundum atrial septal defect) had documented permanent atrial fibrillation. No aortic erosions or device thrombosis, or recurrent ischemic cerebral events were observed. Pre-discharge and follow-up occlusion rates are reported in Table 4.

	Pt (%)
Procedure success rate	352/355 (99.1)
Complications rate:	12 (3.3)
-sheath or device entrapment	2 (0.5)
-groin haematomas	7(1.9) †
-pericardial effusion°	2(0.5) ‡
-air embolism	1(0.2)
Fluoroscopy time (minutes)	7±4.2
Procedural time (minutes)	35.5±5.8
Total Dose Area Product (Gycm2)	26.7±1.88

Table 3. Procedure results.
°≤200 cc; † not requiring blood transfusion; ‡ conservatively managed.

DISCUSSION

Although our experience included patients with different clinical entities (ASD and PFO) our study suggests that ICE -guided device-based closure of interatrial shunts is safe, effective and allows for good long-term outcomes with a low complication rate and a low radiation exposure rate for the patients. In our experience, all were minor complications, such as groin haematomas and supraventricular arrhythmias, not ICE-related. These data compared very well with past literature of surgical repair and TOE-guided catheter-based repair. Previous studies on secundum atrial septal defect closure reported excellent immediate success and occlusion rates ranging 93 to 99%, with a complication rate ranging 6.9 to 14%.[14-16] In particular the most clinically dangerous long-term complications, such as erosion and device thrombosis have been reported to be 0.1 and 2.5%.[17-19] Transcatheter closure of ostium secundum atrial septal defect has been performed for years using deep sedation or orotracheal intubation, TOE, and the sizing balloon technique for size measuring the 'stop-flow' diameter of the defects. In most laboratories, ICE is replacing TOE, because it avoids general anaesthesia and related morbidity, as well as increasing patient comfort. A few cost assessment

	Rate	Notes
Pre-discharge occlusion: - Secundum atrial septal defect (98) - Patent foramen ovale (257) -Total	 94.9 % 82.5% 85.9%	 3 small shunts, 2 moderate shunts 25 trivial shunts, 10 small shunts, 10 moderate shunts
Follow up occlusion: - Secundum atrial septal defect - Patent foramen ovale -Total	 97.9 % 93.3% 94.6%	 1 moderate shunts: device removal (Amplatzer) 8 trivial shunts, 7 small shunts, 2 moderate shunts

Table 4. Pre-discharge and long-term occlusion rates.

studies, mainly conducted outside Italy, also suggest a beneficial economic impact of this technique on global costs.[20-21]

ICE has been demonstrated to provide a higher accuracy than TOE in anatomical measurements and implantation guidance,[22-23] shortening catheterisation and interventional procedure time with no difference in rate of closure. Moreover, ICE has been suggested as the optimal imaging technique for anatomical morphological measurements and sizing the defect, decreasing the radiation exposure dose[24-25] findings, which were all confirmed in our study.

As already demonstrated in our previous studies,[26-27] ICE is particularly accurate for measuring the length and thickness of the rims as it is possible to calculate the precise diameter of the secundum atrial septal defect, as suggested in data of patients who had floppy rims on TOE and were successfully closed with a larger device than the one predicted on the basis of TOE alone. Regarding PFO, we identified some 'sensible' characteristics that may affect the complications and closure rates including: the PFO tunnel length, thickness of the rims, oval fossa diameter, and atrial septal aneurysm severity. We believe that all these factors deserve careful attention because of their potential to result in device misalignment, improper device configuration, and uncovering of misdiagnosed fenestration, as previously demonstrated.[28] For both secundum atrial septal defect and PFO, selecting a device with a disk diameter that does not exceed the entire interatrial septum length on ICE can be a simple rule that prevents complications such as atrial and aortic erosion, or atrioventricular valve dysfunction.[29]

In conclusion, despite a number of limitations, including the different anatomic substrate between PFO and secundum atrial septal defect, and the different failure rates associated with different devices, our study confirmed our previous mid-term results suggesting that ICE evaluation may offer optimal guidance during catheter-based closure of interatrial shunts, thereby optimising long-term effectiveness and potentially lowering long-term complications.

REFERENCES

1. Karamlou T, Diggs BS, Ungerleiser RM, McCrindle BW, Welke KF. The rush to atrial septal defect closure: Is the introduction of percutaneous closure driving utilization? Ann Thorac Surg. 2009;88:1386.

2. Vida VL, Berggren H, Brawn WJ et al. Risk of surgery for congenital heart disease in the adult: a multicentered European study. Ann Thorac Surg. 2007;83:161-8.

3. RESPECT trial. Carroll JD. TCT 2012 Miami, personal communication

4. PC trial. TCT 2012 Miami, personal communication12.SPREAD – Stroke Prevention and Educational Awareness Diffusion: Stroke Italian Guidelines. IV Edition. 2005. www.spread.it.

5. Hijazi Z, Wang Z, Cao Q, Koenig P, Waight D, Lang R. Transcatheter closure of atrial septal defects and patent foramen ovale under intracardiac echocardiographic guidance: feasibility and comparison with TOE. Catheter Cardiovasc Interv. 2001;52:194-9.

6. Zanchetta M, Onorato E, Rigatelli G et al. ICE-guided transcatheter closure of secundum atrial septal defect: a new efficient device selection method. J Am Coll Cardiol. 2003;42:1677-82.

7. Lang RM, Bierig M, Devereux RB et al. Recommendations for chamber quantification. Eur J Echocardiogr. 2006;7:79-108.

8. Sloan MA, Alexandrov AV, Tegeler CH. Assessment: Transcranial Doppler ultrasonography: report of the Therapeutics and Technology Assessment Subcommitee of the American Academy of Neurology. Neurology. 2004;62:1468-81.

9. SPREAD – Stroke Prevention and Educational Awareness Diffusion: Stroke Italian Guidelines. IV Edition. 2005. www.spread.it.

10. Rigatelli G, Hijazi ZM. ICE in cardiovascular catheter-based interventions: different devices for different purposes. J Invasive Cardiol. 2006;18:225-33.

11. Olivares-Reyes A, Chan S, Lazar EJ, Bandlamudi K, Narla V, Ong K. Atrial septal aneurysm: a new classification in two hundred five adults. J Am Soc Echocardiogr. 1997;10:644-56.

12. Rigatelli G, Dell'avvocata F, Cardaioli P, Giordan M, Dung HT, Nghia NT et al. Safety and long-term outcome of modified ICE-assisted "no-balloon" sizing technique for transcatheter closure of ostium secundum atrial septal defect. J Interv Cardiol. 2012;25:628-34.

13. Boutin C, Musewe NN, Smallhorn JF, et al. Echocardiographic follow-up of atrial septal defect after catheter closure by double-umbrella device. Circulation. 1993;88:621-7.

14. Luermans JG, Post MC, Ten Berg JM, Plokker HW, Suttorp MJ. Long-term outcome of percutaneous closure of secundum-type atrial septal defects in adults. Eurointervention 2010;6:604-10.

15. Suchon E, Pieculewicz M, Tracz W, Przewlocki T, Seadowski J, Podolec P. Transcatheter closure as an alternative and equivalent method to the surgical treatment of atrial septal defect in adults: comparison of early and late results. Med Sci Monit (2009) 15: pp.CR612-7.

16. Knepp MD, Rocchini AP, Lloyd TR, Aiyagari RM. Long-term follow-up of secundum atrial septal defect closure with the Amplatzer septal occluder. Congenit Heart Dis. 2010;5:32-7.

17. Hein R, Buscheck F, Fischer E et al. Atrial and ventricular septal defects can safely be closed by percutaneous intervention. J Interv Cardiol. 2005;18:515-22.

18. Krumsdorf U, Ostermayer S, Billinger K et al. Incidence and clinical course of thrombus formation on atrial septal defect and patient foramen ovale closure device s in 1,000 consecutive patients. J Am Coll Cardiol. 2004;43:302-9.

19. Amin Z, Hijazi ZM, Bass JL, Cheatham JP, Hellenbrand WE, Kleinman CS. Erosion of Amplatzer septal occluder device after closure of secundum atrial septal defects: review of registry of complications and recommendations to minimize future risk. Catheter Cardiovasc Interv. 2004;63:496-502.

20. Kim JJ, Hijazi ZM. Clinical outcomes and costs of Amplatzer transcatheter closure as compared with surgical closure of ostium secundum atrial septal defects. Med Sci Monit. 2002;8:CR787-91.

21. Alboliras ET, Hijazi ZM. Comparison of costs of ICE and TOE in monitoring percutaneous device closure of atrial septal defect in children and adults. Am J Cardiol. 2004;94:690-2.

22. Bartel T, Konorza T, Arjumand J, Ebradlidze T, Eggebrecht H, Caspari G et al. ICE is superior to conventional monitoring for guiding device closure of interatrial communications. Circulation. 2003;107:795-7.

23. Boccalandro F, Baptista E, Muench A, Carter C, Smalling RW. Comparison of ICE versus TOE guidance for percutaneous transcatheter closure of atrial septal defect. Am J Cardiol. 2004;93:437-40.

24. Boccalandro F, Muench A, Salloum J, Awadalla H, Carter C, Barasch E et al. Interatrial defect sizing by intracardiac and TOE compared with fluoroscopic measurements in patients undergoing percutaneous transcatheter closure. Catheter Cardiovasc Interv. 2004;62:415-20.

25. Rigatelli G, Cardaioli P, Roncon L, Giordan M, Bedendo E, Oliva L et al. Impact of ICE on radiation exposure during adult congenital heart disease catheter-based interventions. Int J Cardiovasc Imaging. 2007;23:139-42.

26. Zanchetta M, Rigatelli G, Pedon L, Zennaro M, Maiolino P, Onorato E. Role of ICE in atrial septal abnormalities. J Interv Cardiol. 2003;16:63-77.

27. Rigatelli G, Cardaioli P, Dell'Avvocata F, Giordan M, Braggion G, Aggio S et al. The association of different right atrium anatomical-functional characteristics correlates with the risk of paradoxical stroke: an intracardiac echocardiographic study. J Interv Cardiol. 2008;21:357-62.

28. Amin Z, Hijazi ZM, Bass JL, Cheatham JP, Hellenbrand WE, Kleinman CS. Erosion of Amplatzer septal occluder device after closure of secundum atrial septal defects: review of registry of complications and recommendations to minimize future risk. Catheter Cardiovasc Interv. 2004;63:496-502.

29. Li W, Han Yu C, Zhang C, Wu S, Huber CH, Ma L. Severe mitral valve insufficiency after transcatheter atrial septal defect closure with the Amplatzer septal Occluder: a device-elated complication. J Card Surg. 2009;24:672-4.