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Very long-term outcomes of transcatheter secundum atrial septal defect closure using intracardiac echocardiography without balloon sizing

G. Rigatelli [a,*], N.T. Nghia [b], M. Zuin [c], L. Conte [d], K. D'Elia [d], A. Nanjundappa [e]

[a] *Section of Adult Congenital and Adult Heart Disease, Cardiovascular Diagnosis and Endoluminal Interventions, Rovigo General Hospital, Rovigo, Italy*
[b] *Interventional Cardiology Department, Cho Ray Hospital, Ho Chi Minh City, Viet Nam*
[c] *Section of Internal and Cardiopulmonary Medicine, University of Ferrara, Ferrara, Italy*
[d] *Department of Cardiology, Rovigo General Hospital, Rovigo, Italy*
[e] *CAMC Vascular Center of Excellence, West Virginia University, Charleston, WV, USA*

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AIM: To assess the long-term outcomes of device-based closure of atrial septal defects (ASDs) with no sizing balloon.

MATERIAL AND METHODS: Two hundred and eighty-one consecutive patients (mean age 34±13 years, 178 women) underwent intracardiac echocardiography (ICE)-aided transcatheter closure of secundum ASDs over a 15-year period (September 2002 to March 2017). Sizing of the ASDs was calculated under ICE guidance (UltraICE, EP Technologies, Boston Scientific Corporation, San Jose, CA, USA) using the concept of "supportive rim" for ASDs without the aid of a sizing balloon. Follow-up was conducted by transoesophageal and transthoracic echocardiography.

RESULTS: The procedure was carried out successfully in all patients with 0% related mortality and 5.7% procedural complications. The Amplatzer ASD Occluder was implanted in 251 patients (89.3%, mean size 26.4±10.2 mm) whereas the Gore Cardioform was used in 30 patients (10.6%). Over 10.3±3 years of follow-up (range 1–15) 100% of patients were alive. The complete occlusion rate was 97.8%. No aortic or atrial free wall erosions, device thrombosis, or device frame fractures were detected during the follow-up period.

CONCLUSION: The present study suggested that ICE-guided closure of ASDs with current devices without sizing balloons is safe and effective with very low procedural and late complications even in the very long-term follow-up.

* Guarantor and correspondent: G. Rigatelli, Viale Tre Martiri, 45100 Rovigo, Italy. Tel.: +3903471912016; fax: +39044220164.
E-mail address: jackyheart@libero.it (G. Rigatelli).

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Introduction

Transcatheter-based closure of secundum atrial septal defects (ASDs) is nowadays well accepted as the first-line therapy for simple isolated ASDs in both children and young adults, providing effective closure with a low rate of complications.[1,2] Standard techniques include the use of transoesophageal echocardiography (TEE) guidance and balloon-sizing technique.[3] Intracardiac echocardiography (ICE) is an accepted alternative to TEE guidance providing excellent anatomical detail at the same cost.[4]

The balloon-sizing technique, although quite simple to perform, has been proved to overestimate the defects and may carry some risks, such as iatrogenic enlargement of the ASD, thoracic pain, and rupture of interatrial septum.[5] Although the standard technique still includes balloon sizing of the defect, its value when using three-dimensional echocardiography or ICE has changed[6] with a downgrade of its importance. Conversely, data regarding long-term outcomes of ICE-assisted ASD closure without the sizing-balloon technique are very limited in current medical literature. Therefore the aim of the present study was to assess the long-term impact of ICE-guided device-based closure of ASDs without the balloon-sizing technique in young adults.

Materials and methods

Two hundred and eighty-one consecutive patients (mean age 34±13 years, 178 women) were treated with ICE-aided transcatheter closure of secundum ASD over a period of >15 years (September 2002 to March 2017). No patent foramen ovale (PFO) or other anatomical entities related to stroke prevention were included in the analysis.

Inclusion criteria for percutaneous closure of ASD included: (1) Qp/Qs >1.5, (2) enlargement of the right atrium (RA; area >16.84 mm^2) and (3) ventricle (area of inflow tract of right ventricle >35 mm)[7] and (4) ASD <40 mm. The hospital ethics board approved the study and written informed consent was obtained from all patients.

Echocardiography protocols

All patients with secundum ASD were investigated using transthoracic echocardiography (TTE) before TEE. TTE and TEE was conducted using a GE Vivid 7 (General Electric, Norfolk, VI, USA). ASD was measured using Doppler ultrasound at the end-diastolic frames, noting the type of defect and anomalous pulmonary venous returns, if present. Qp/Qs and pulmonary arterial pressure were also measured and recorded.[8] The presence of other abnormalities, such as the association of ASD with aneurysm of incomplete fossa ovalis floor, were recorded and graded.

ICE study and sizing protocol

All patients underwent intracardiac echo-guided procedure by means of mechanical 9 F 9 MHz 360° scan probe (UltraICE, EP Technologies, Boston Scientific Corporation, San Jose, CA, USA).[9] The ICE protocol has been already described elsewhere.[6] Briefly, the Ultra ICE catheter was inserted via a 55° pre-curved 8.5 F long venous sheath (Convoy, EP Technologies, Boston Scientific Corporation) from the left femoral vein and advanced through the inferior vena cava (IVC) into the RA to obtain two orthogonal planes. The following specific anatomical landmarks may be used to facilitate the uninitiated beginner to orientate the image: the ascending aorta at 2 o'clock, the crista terminalis at 10 o'clock, and the right atrial auricle at 12 o'clock on the screen. Thus, the left-sided structures were displayed on the viewer's right and the right-sided structures on the viewer's left, whereas the anterior-sided structures appear at the top of the screen and the posterior-sided structures appear at the bottom of the screen. With the probe in this neutral position and the transducer positioned between the sixth and seventh intervertebral disks of the thoracic spine, the aortic valve plane view was obtained at the level of the fossa ovalis (Fig 1a). The four-chamber view was obtained with a 55° pre-curved introducer sheath advanced up to the end of the catheter and turned posterior and leftward, with the transducer orientation perpendicular relative to the long-axis of the heart in order to longitudinally scan the atrial septum (Fig 1b). The ICE study allowed the measurements of the oval fossa diameter, both rims, and atrial septum lengths, as well as their thickness using an electronic calliper edge-to-edge. The presence and severity of the ASD,[10] as well as hypertrophic rims (defined as having a thickness ≥8 mm, whereas lipomatosis was defined as thickness of ≥15 mm[11]), or a prominent Eustachian valve (EV; defined as a valve with thickness >1 mm that protrudes for at least 10 mm within the RA from the border of the IVC), or a large Chiari network (CN; defined as EV with thickness <1 mm and filamentous appearance[12]) were noted. Embryonic septal remnants, the presence of floppy rims, and filaments throughout the RA were also recorded for the potential to identify challenges or contraindications to the interventional procedure. ASD sizing was performed accordingly the concept of "supportive rim"[5] without the aid of a sizing balloon. The device was selected carefully so that the entire left disk diameter did not exceed the entire atrial septum length obtained on ICE measurement (a ratio of device left disk diameter/interatrial septal diameter of ≤0.8 was felt to be safe).

Catheterisation procedure and parameters and closure protocol

The GE Medical System Innova 3100 30″-30″ flat panel was used in all cases. Field sizes used were 20″-20″. An estimation of the effective dose was obtained from the measurements of the dose–area product (DAP). DAP, fluoroscopy DAP (FDAP), and total DAP (TDAP) were recorded automatically by the radiological equipment during the procedures. Fluoroscopy and procedural time were also noted. Combined antibiotic therapy (80 mg gentamicin/1 g ampicillin or 1 g vancomycin 1 g if there was a documented allergy to penicillin) was administered intravenously 1 hour prior to procedure. The right femoral vein was catheterised

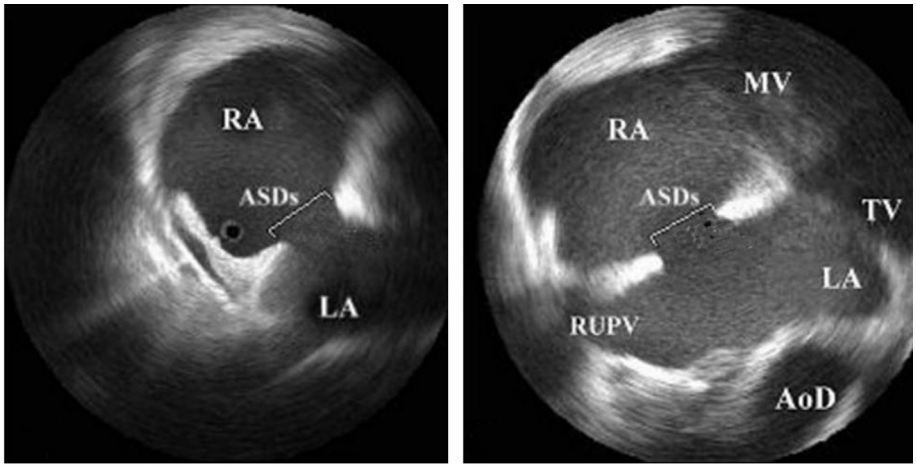

Figure 1 Aortic valve plane (a) and four-chamber plane (b) as seen on ICE studies. The left-sided structures will be displayed on the viewer's right and the right-sided structures on the viewer's left, whereas the anterior-sided structures at the top of the screen and the posterior-sided structures at the bottom of the screen. LA: Left atrium; MV: mitral valve; AO: ascending aorta; FO: oval fossa; RA: right atrium; RUPV: right upper pulmonary vein; SVC: superior vena cava; TV: tricuspid valve.

with an 8 F sheath, which was used for preoperative right cardiac catheterisation and pulmonary pressure measurement, and replaced with a 10 or 12 F long sheath for device implantation. The left femoral vein was catheterised with an 8 F sheath, which was replaced with a pre-curved 9 F or steerable 8 F sheath for the ICE study (Fig 2). Aspirin at a daily dose of 100 mg for 6 months was administered to all patients. In case of allergy, 75 mg clopidogrel was given daily.

Intraoperative closure criteria and device selection

Based on ICE findings and measurements, the Amplatzer ASD Occluder (AGA Medical Corporation, Golden Valley, MN, USA) device was selected in the case of secundum ASD >20 mm. The semi-rigid mixed tissue/nitinol frame device Cardioform Occluder (WL Gore, Flagstaff, AZ, USA) was selected for small (<20 mm) or "flat" type ASDs: in such cases, the ASD was measured using ICE as previously mentioned, but the device selected was 5 mm larger than the mean ICE diameter.

Definitions

Procedural success was defined as an implanted device of good position on the ICE monitoring images. Complications were divided into acute (within 30 days) and long-term complications. Acute complications included device embolisation, sheath or device entrapment in intracardiac structures, groin haematomas, pericardial effusion, air embolism, intra-procedural arrhythmias such permanent atrial fibrillation (AF), permanent atrio-ventricular block (AVB). Intra-procedural AF or AVB resolved spontaneously within the end of the procedure were reported but not counted into the complications rate. Long-term complications included aortic or atrial free wall erosions, device thrombosis, device removal or late (>30 days) embolisation, device frame fractures, permanent or parossysmal atrial fibrillation (AF; revealed at cardiologic examination or on 24 hours Holter electrocardiogram), new-onset or increased mitral valve regurgitation (as assessed on TTE), and device-related death (any death possibly related to the implanted device).

Follow-up

In patients who underwent closure, TEE 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. TTE was scheduled at 6 and 12 months and then every 2 years after the transcatheter closure to assess 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]

Statistical methods

Values were expressed in frequencies and mean ± SD. Statistical analysis was performed using a statistical software package (SAS for Windows, version 8.2; SAS Institute, Cary, NC, USA).

Results

Population enrolled

Over the study period, 281 consecutive patients (103 male and 178 female patients, mean age 34±13 years) received ASD catheter-based closure. The baseline characteristics of the patients enrolled are shown in Table 1. Single and multiple ASD closures were performed in 95.2% and 7.1% of patients, respectively. Only two patients (0.7) had a residual shunt after surgery. TEE revealed a mean right ventricular diameter of 49±21.8 mm while the mean ratio between Qp and Qs was 2.4±0.8. Direct mean pulmonary artery pressure before closure was 28.4±9.3 in patients ≤20 years old (n=98) versus 34.6±8.5 in patients >20 years old (183 patients, p<0.01).

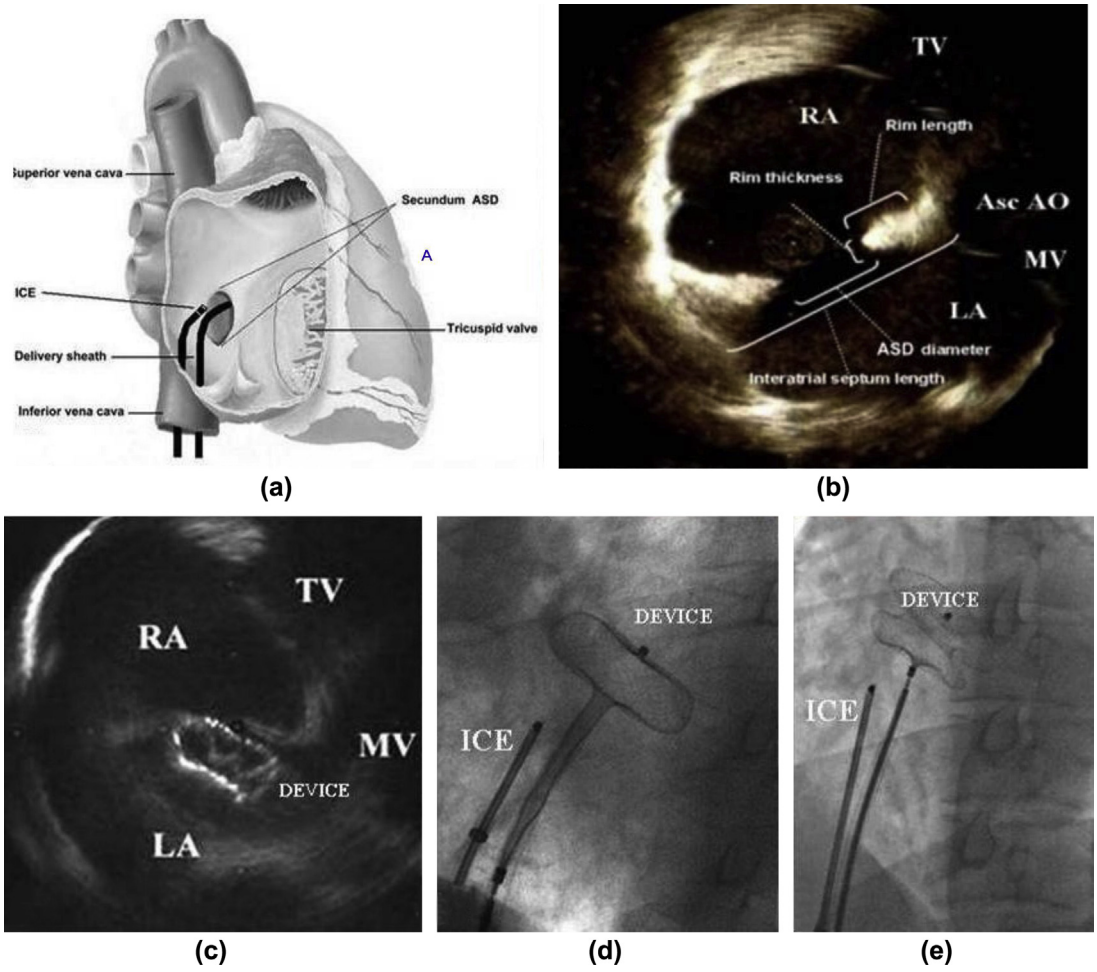

Figure 2 Complete intraoperative assessment and closure procedure. (a) Position of the ICE catheter and device long sheath in the right atrium during the procedure. (B) Measurements of the defect and interatrial septum components in the four-chamber view. Opening of the left disk on ICE monitoring (c) and fluoroscopy (d); complete deployment of the device (e). ASO: atrial septal occluder; LA: left atrium; MV: mitral valve; RA: right atrium; TV: tricuspid valve.

Procedural characteristics

The procedure was carried out successfully in all patients with effective device implantation in all cases. Intraoperative ICE findings and measurements are shown in Table 2. Specifically, mean ASD diameter was 24±10.1 mm while the mean length of the aortic rim was 5.8±1.1 mm. Atrial septal aneurysm, graded as 1–3 or 4–5, as proposed by Olivares-Reyes *et al.*[10] was observed in 17.4% and 29.5% of patients, respectively. Of the patients, four had deficient rims. EV and CN were detected in 46.9% of patients.

Table 1
Demographic and clinical data of patients with atrial septal defect (ASD) closure.

	Mean or *n* (%)
Age (years)	34±13
Male/female	103/178
Single ASD	268/281 (95.2)
Multiple ASD (≥2 ASDs)	20/281 (7.1)
Residual shunt after surgery	2/281 (0.7)
Mean right ventricle diameter (millimetres)[a]	49±21.8
Right atrial area (cm^2)	25.1.±6.3
Right ventricle area (cm^2)	20±8.4
Right ventricle ejection fraction	49.5±11.2
Mean Qp/Qs [a]	2.4±0.8
Mean pulmonary artery pressure (mmHg) [a]	39±11.3

[a] Measures obtained by transoesophageal echocardiography (TEE).

Table 2
Intraoperative ICE and transoesophageal echocardiography findings and measurements.

Anatomical structures (%)	ICE
ASD floppy rims (1 or >1)	39/281 (13.8)
Embryonic remnant	21/281 (7.4)
Deficient rims (one or two rims)	68/281 (24.2)
Atrial septal aneurysm 1–3	49/281 (17.4)
Atrial septal aneurysm 4–5	83/281 (29.5)
Eustachian valve/Chiari network	132/281 (46.9)
Other pathological findings[a]	13/281 (4.6)
Mean interatrial septum diameter (mm)	37±10.6
Mean ASD diameter (mm)	24±10.1
Length of anterosuperior rim (aortic rim)	5.8±1.1

ICE, intracardiac echocardiography; ASD, atrial septal defect.
[a] Atrial mixoma, pulmonary venous return, cor tratriatum

Devices and acute outcome

The Amplatzer ASD Occluder was implanted in 251 patients (89.3%, mean size 26.4±10.2 mm) whereas the Gore Cardioform was used in 30 patients (10.6%, 25 mm device in 21 patients and 30 mm device in nine patients). In two patients, double Amplatzer ASD Occluders devices were used to repair a complex multiple ASD. The mortality rate was 0%, while postoperative complications were observed in 16 patients (5.7%). Among these, groin haematomas not requiring surgery or blood transfusion and non-haemodynamically relevant pericardial effusion were the most frequent detected (2.8% and 1.8%, respectively). Mean procedural time was 35.5±5.8 minutes while mean fluoroscopy time was 10±1.2 minutes (Table 3).

Long-term outcomes

Over 10.3±3 years of follow-up (range 1–15) 100% of patients were alive. Compared to pre-procedural values, at the 12 month TTE, the mean pulmonary arterial pressure reduced from 39±11.3 to 19.9±8.1 mmHg ($p<0.01$), whereas the mean Qp/Qs decreased from 2.4±0.8 to 1.1±0.2 ($p<0.01$). Only one patient (0.3%) underwent surgical removal of an Amplatzer ASD Occluder at 6 months due to misalignment: the patient had a remnant of a duplicated primordial septa rim correctly seen on ICE and the device was anchored to this false rim rather to the true one, which resulted in misalignment with a moderate shunt on follow-up. The device was explanted and the ASD repaired with a patch based on the patient's preference. No aortic or atrial free wall erosions, device thrombosis, or device frame fractures were detected during the follow-up period (Table 4).

Discussion

The present study demonstrated that ICE-assisted transcatheter closure of secundum ASDs without balloon sizing is an effective and safe approach in the long-term. Specifically, it provided a satisfactory occlusion rate, a low number of complications and avoided an unnecessary high radiation dose for both patient and staff.[14] The most dreaded long-term complications, including erosion and device thrombosis, which have been reported in the past to range between 0.1 and 2.5%,[15] were absent in the present series. The 5.7% complication rate counted only minor, not clinically significant complications, such as groin haematomas and pericardial effusion. Moreover, the use of the <0.8 ratio between the ASD and major device disk diameter resulted in a very highly safe and effective strategy also in patients in whom a slightly smaller device was selected: in all these patients a small initial shunt disappeared at the follow-up.

Table 3
Procedure results.

	Pt (%)
Procedure success rate	281/281 (100)
Complications rate:	16/281 (5.7)
temporary AVB	2/281 (0.6)
groin haematomas	8/281 (2.8)[a]
pericardial effusion	5/281 (1.8)[b]
coronary air embolism	1/281 (0.3)[c]
Fluoroscopy time (minutes)	10±1.2
Procedural time (minutes)	35.5±5.8
Total dose–area product (Gy·cm^2)	26.7±1.88

[a] Not requiring blood transfusion or surgery.
[b] Conservatively managed excepted one requiring drainage.
[c] Transient ST elevation on electrocardiogram without further sequelae.

The need for balloon sizing has been questioned over the last 10 years: as clearly demonstrated, stretched-balloon sizing usually tends to overestimate the defect,[16] and although rarely, it may result in a variety of complications including arrhythmias, thoracic pain, and laceration of the interatrial septum.[17]

Alternative sizing method such as TEE-guided measurement of ASD plus 4–6 mm to obtain the device waist to be implanted, maximum colour flow diameter, and single-plane balloon-sizing with ICE, which measures a diameter coincident with that seen at fluoroscopy,[18] have been proposed but no long-term outcomes for these techniques regarding closure rates, atrial or aortic erosion, and device thrombosis has been provided.

Some previous investigations have already suggested the equivalence or even the superiority of ICE over TEE in guiding ASD closure. As suggested by Alqahtahni *et al.*,[4] ICE closure of ASD is associated with less complications, shorter length of stay, and very similar costs compared to TEE closure. Furthermore, as demonstrated by Kavvouras *et al.*[19] ICE guidance was superior in identifying structural defects that were not detectable by TEE, especially in cases with deficient rims.[20]

Moreover, ICE guidance can overcome some artefacts, as the air in the oesophagus, trachea and stomach, that are generally observed during TEE, and obviously, it does not require sedation and anaesthesiology support, which makes ASD closure easier and faster compared to TEE-guided procedures. Finally, three-dimensional echocardiography has been proposed to guide ASD closure, but at the moment, it appears much more useful in patient follow-up rather than in device implantation.[21] Certainly, it can provide improved anatomical definition in challenging cases such as those with multiple ASDs.

The study suffers from several limitations including the retrospective fashion and the use of the mechanical ICE probe which is unusual in USA or in Northern Europe, which has lower imaging resolution, a different code of imaging interpretation, the need for a pre-curved sheath to obtain the two main projections, and a lack of Doppler capability.

Despite these technical limitations, mechanical ICE is highly reproducible by different operators and can depict the entire interatrial septum in two almost perfect orthogonal planes with minimal manipulation of the catheter and two only views, all features that have an excellent impact on simple congenital heart disease interventions such as interatrial shunt closure. Moreover, differently from the electronic probes existing in the market,[22] the mechanical system allows for complete visualisation of the entire RA and atrial septum, which is useful for cases with

Table 4
Pre-discharge and long-term outcomes in details.

	Rate	Remarks
Pre-discharge occlusion	93.9%	10 small shunts, 7 moderate shunts
Follow-up occlusion:	97.8%	5 moderate shunts, 1 large shunt with subsequent 1 device removal (Amplatzer)
Long-term complications:	5/281 (1.7)	
Atrial fibrillation	2 (0.7%)	Mean time from intervention of 6.4±2.1 years: one with Amplatzer, one with Cardioform.
Device thrombosis	0 (0%)	-
Erosion	0 (0%)	-
Mitral valve regurgitation	2 (0.7%)	2 patients with 30 mm Amplatzer ASD: MV 1+ to 2+/4.
Device embolisation/removal	1 (0.3%)	A patient with a 26 mm Amplatzer ASD Occluder because of misalignment felt dangerous
Device fracture	0 (0%)	-

associated atrial abnormalities, such as embryonic remnant of septa, permanence of an incomplete aneurysmal floor of the fossa ovalis, or presence of prominent venous valves. Mechanical ICE can give additional important information about device placement technique, avoiding device entrapment or misalignment, or unnecessary additional device implantation as suggested by the number of complex ASD treated, the absence of embolisation, even late, and erosion in these patients.

In conclusion, the present study suggested that ICE-guided closure of ASDs without balloon sizing is safe, effective, and is associated with a low incidence of peri-operative and long-term complications. Further and longer studies are needed to assess the outcomes of device closure of ASDs using alternative imaging tools such as three-dimensional echocardiography or TTE.

Conflict of interest

The authors declare no conflict of interest.

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