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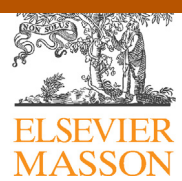

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CLINICAL RESEARCH

Transcatheter closure of complex atrial septal defects is efficient under intracardiac echocardiographic guidance

La fermeture par cathétérisme interventionnel des communications interauriculaires complexes est efficacement réalisée par monitorage échographique intracardiaque

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KEYWORDS
ASD/PDA/PFO closure;
Adult congenital heart disease;
Intracardiac echocardiography imaging

Summary

Background. — Studies on intracardiac echocardiography for transcatheter closure of secundum atrial septal defect (ASD) only include ASDs ≤ 38 mm diameter without rim deficiency.

Aims. — To assess transcatheter closure of complex ASDs under intracardiac echocardiography guidance.

Methods. — Retrospective study from January 2006 to January 2012 in all consecutive adult patients referred to our centre for percutaneous device closure of ASD. Complex cases were defined as defect > 38 mm and/or defect with rim deficiency other than the anterior-superior rim.

Results. — Transcatheter closure was performed in 93 consecutive adult patients (59 women) with a median age of 48 (18—88) years. Complex cases comprised 17 patients (18%) with a

Abbreviations: ACSO, Amplatzer Cribriform Multi-Fenestrated Septal Occluder; ASD, atrial septal defect; ASO, Amplatzer Septal Occluder; ECG, standard 12-lead electrocardiography; ICE, intracardiac echocardiography; PFO, patent foramen ovale; TEE, transoesophageal echocardiography; TTE, transthoracic echocardiography.

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median age of 54 (20—81) years and a median weight of 58 (45—99) kg. Thirteen cases had one or more deficient rims other than the anterior-superior rim, whereas nine had an ASD size > 38 mm. Transcatheter closure was successful in 14 cases, whereas three cases failed (18%). Minor complications occurred in three patients (18%). All the other non-complex ASDs were successfully closed percutaneously. Among the 93 patients, rim deficiency other than the anterior-superior rim tended to be associated with failure of transcatheter closure ($P = 0.058$).
Conclusion. — Transcatheter closure of complex ASDs is safe and effective under intracardiac echocardiographic guidance.

MOTS CLÉS
CIA/canal artériel/FOP fermeture ;
Cardiopathie congénitale de l'adulte ;
Imagerie par échocardiographie intracardiaque

Résumé
Contexte. — Les études sur l'échographie intracardiaque dans la fermeture par cathétérisme interventionnel des communications interauriculaires ostium secundum incluent seulement les défauts septaux de diamètre ≤ 38 mm sans berges déficientes.
Objectif. — Évaluer la fermeture par cathetérisme et sous par échographie intracardiaque des communications interauriculaires complexes.
Méthodes. — Il s'agit d'une étude rétrospective entre janvier 2006 et 2012 incluant tous les patients adultes référés dans notre centre pour la fermeture par cathétérisme interventionnel d'une communication interauriculaire. Les défauts septaux complexes étaient définis par un diamètre > 38 mm et/ou une ou plusieurs berges déficientes autre que l'antéro-supérieure.
Résultats. — La fermeture percutanée a été effectuée consécutivement chez 93 patients adultes (59 femmes) à l'âge médian de 48 (18—88) ans. Dix-sept patients (18 %) étaient des cas complexes avec un âge et un poids médian de 54 (20—81) ans et 58 (45—99) kg respectivement. Treize cas avaient une ou plusieurs berges déficientes autres que l'antéro-supérieure alors que 9 patients avaient un défaut septal > 38 mm de diamètre. La fermeture par cathétérisme a été efficace dans 14 cas et un échec dans 3 cas (18 %). Des complications mineures sont survenues chez 3 patients (18 %). Toutes les communications interauriculaires non complexes ont été fermées avec succès. Parmi les 93 patients, la déficience d'une berge autre que l'antéro-supérieure tendait à être associée à un échec de fermeture ($p = 0{,}058$).
Conclusion. — La fermeture par cathetérisme des communications interauriculaires complexes est efficace et non risquée avec l'échographie intracardiaque.

Background

Transcatheter closure under transoesophageal echocardiography (TEE) and intracardiac echocardiography (ICE) guidance has become an accepted alternative to surgical repair for most types of ostium secundum atrial septal defect (ASD) [1,2]. The technique is commonly used in patients with a defect < 38 mm in diameter without deficient rims, and allows safe and effective ASD closure in 80—88% of unselected cases [3,4]. However, TEE is associated with the need for general anaesthesia in the majority of the cases and may provide suboptimal imaging and measurement of the defect [5—7].

Despite the risk inherent to its invasive nature, with the need for an 8-French sheath venous access, ICE provides excellent real-time detailed images that can be invaluable in guiding certain cardiac interventions [8]. For transcatheter ASD closure, this obviates the need for general anaesthesia and has become a safe monitoring technique, with decreased procedural time and radiation exposure compared with TEE [6,9]. Moreover, ICE has been demonstrated to be more accurate than TEE for taking anatomical measurements and guiding implantation [6,9,10]. However, most studies on ICE monitoring for transcatheter ASD closure also included cases of patent foramen ovale (PFO) [6,8—13], with the exception of one cost-effectiveness study [14], two studies comparing TEE and ICE [5,15] and one report on children weighing < 15 kg [16]. Moreover, in all the previously published studies on ICE monitoring, large ASDs (> 38 mm) and defects with deficient rims were excluded, whereas the feasibility of transcatheter closure under TEE monitoring has been reported in such cases [4,17—20]. Consequently, the feasibility of ASD closure under ICE guidance in complex cases (> 38 mm and/or deficient rims) has not been demonstrated.

The aim of the present study was to assess the safety and effectiveness of ICE monitoring for transcatheter closure of secundum ASDs in an unselected patient population including complex cases with large (> 38 mm) ASDs and/or deficient rims.

Methods

Study population

Since 2006 in our institution, ICE has fully replaced TEE as a guiding imaging tool for transcatheter ASD closure in the

adult population. Children still undergo ASD closure under general anaesthesia and TEE guidance because of their lack of cooperation, the need for an additional 8-French venous access and the extra cost of ICE that does not offset the cost of anaesthesia care in France. Hence, we retrospectively studied all consecutive adult patients referred to our centre for percutaneous device closure of ostium secundum ASD from January 2006 to January 2012. This retrospective study was approved by the local ethics committee.

Patients aged ≥ 18 years with a haemodynamically significant ostium secundum ASD were eligible for the ICE-guided procedure, including those with clinical signs of heart failure, significant arrhythmia or a Qp/Qs ratio > 1.5. In addition, transcatheter closure was proposed for patients with secundum ASDs presenting with a stroke or showing any evidence of paradoxical embolization, regardless of the haemodynamic significance. All patients with a PFO were excluded from the study. Three patients with Down's syndrome had transcatheter closure under general anaesthesia and were also excluded.

Preintervention protocol and definition of complex cases

All patients had a physical examination, standard 12-lead electrocardiography (ECG), transthoracic echocardiography (TTE) and TEE. TTE and TEE included multiple views to assess the ASD number, position, diameter, rim adequacy and relationship with adjacent cardiac structures. The rim around the ASD was classified as adequate (≥ 5 mm) or deficient (< 5 mm) for the coronary sinus rim, the inferior-posterior rim (towards the inferior vena cava), the inferior rim (towards the atrioventricular valves), the posterior rim (towards the pulmonary veins) and the superior-posterior rim (towards the superior vena cava) [17]. Although patients with rim deficiencies and those with large defects are generally contraindicated [3,5,11—13], we consider them for transcatheter closure in our institution, based on previous studies [17—20] and our experience of successful closure in such complex cases with a modified implantation method [4].

Consequently, we defined a case as 'complex' when transcatheter closure was attempted in a patient usually referred for surgery [3,5,11—13]: diameter of the defect > 38 mm (on precatheterization TEE and/or per-catheterization ICE and/or after calibration with the sizing balloon) and/or any rim deficiency other than the anterior-superior rim, as it is well established that deficiency in the anterior-superior rim towards the aorta does not influence the success rate of transcatheter ASD closure [3,4].

Echocardiographical guidance

The ICE catheter was introduced via the femoral vein using an 8-French sheath (11-French up to March 2009). An Acuson AcuNav TM ultrasound catheter (Siemens Ultrasound, Mountain View, CA, USA) was used for imaging and echocardiography was performed with an Acuson Sequoia C512 (Siemens Ultrasound, Mountain View, CA, USA) by the same experienced echocardiographer (G.H.). The imaging technique for ICE in ASD closure has already been reported in detail [6—10]. Briefly, the probe is advanced to the interatrial septum level and the catheter is manoeuvred to provide four standardized views: the 'home view', with the transducer towards the tricuspid valve; the septal view, with the transducer towards the interatrial septum to image the defect and the interatrial septum; a horizontal long-axis view or four-chamber view, with the transducer towards the superior vena cava (and the inferior vena cava by withdrawing the probe); and a perpendicular short-axis view, displaying the aortic valve in cross section (and the anterior-superior rim).

Device closure protocol

Interventional procedure

The protocol of device closure has been reported previously [21]. Briefly, transcatheter closure was performed using venous access through the femoral vein under local anaesthesia. Patients received 100 IU/kg of heparin (maximum 5000 IU) and antibiotic prophylaxis (cefamandole: 50 mg/kg). All patients underwent right heart catheterization as a first step in the interventional procedure.

Atrial septal defect sizing method

Two perpendicular unstretched ASD diameters were measured by ICE. Balloon sizing of the defect was only performed for large (> 20 mm) or complex defects, with the Meditech balloon (Boston Scientific, Watertown, MA, USA). The sizing balloon was introduced over the guidewire, passed into the left atrium and inflated; it was gradually deflated until it passed across the ASD then it was passed through a sizing plate to determine the stretched diameter of the defect, which corresponded with the waist diameter of the balloon.

Device selection and implantation

The closure device was selected based on the type and size of the ASD. A size 2 mm greater than the stretched diameter device was generally chosen, except in cases with important discrepancies between the size of the defect on different views, where a device smaller than the largest measured diameter was implanted.

Three types of device were used: the Amplatzer Septal Occluder (ASO) (AGA Medical Corporation, Plymouth, MN, USA); the Amplatzer Cribriform Multi-Fenestrated Septal Occluder (ACSO) (AGA Medical Corporation, Plymouth, MN, USA); or the Cardia Intrasept ASD Occluder (Cardia Inc., Eagan, MN, USA).

The ASO was used for single or adjacent multiple defects, whereas the ACSO was used for distant multiple defects. The Cardia Intrasept ASD Occluder was only used in one single small ASD case. The adequate positioning of the device was assessed under simultaneous fluoroscopic guidance and ICE. Before and after release of the device, positioning and relationships with cardiac structures were studied on ICE. In cases with a large defect, additional transthoracic views were often obtained. The presence of a residual shunt was documented by Doppler flow imaging showing a left-to-right shunt across the interatrial septum; it was defined as trivial (< 1 mm jet width), small (1—2 mm), moderate (2—4 mm) or large (> 4 mm) [3].

When the conventional implantation technique failed, a modified implantation technique involving the sizing

balloon was employed, based on our previously published work [4]. Briefly, the sizing balloon (Meditech; Boston Scientific, Watertown, MA, USA) was advanced over a wire placed in the left or right superior pulmonary vein, and was inflated within the interatrial septum or sometimes even in the left atrium in order to use it as a rim to anchor the device. Thereafter, the Amplatzer device was fully deployed while the balloon was still inflated. Once the Amplatzer device was fully delivered with the inflated balloon between the left and right atrial disc, the balloon was slowly deflated. If this approach failed, we tried this modified implantation technique again, with delivery of the left atrial disc just outside the opening of the right superior pulmonary vein.

Follow-up and medical treatment

Patients were evaluated by clinical examination, ECG and TTE on the day after implantation. After discharge, follow-up ECG and TTE were performed 1 week, 1 month and 6 months after ASD closure. Further life-long follow-up was recommended, with ECG and TTE 1 year after ASD closure and every other year.

Acetylsalicylic acid (160 mg/day) was started after the procedure and maintained for 6 months after transcatheter closure. Patients with pre-existing anticoagulation therapy were maintained with the same treatment without additional antiplatelet therapy.

Statistical analyses

Data are expressed as mean ± standard deviation if normally distributed or as the median (range). Analyses were performed to compare complex and non-complex cases (Table 1) and to identify the factors that could be associated with the occurrence of failure. Non-parametric two-sided tests were used to compare continuous data (Mann-Whitney test) and categorical data (Fisher's exact test). For all two-tailed tests, a value of $P < 0.05$ was regarded as statistically significant. All analyses were performed using SPSS software, version 17.0 for Windows (SPSS Inc., Chicago, IL, USA).

Results

Patient population

Ninety-three patients (59 women; 63%) underwent transcatheter closure of an ostium secundum ASD during the study period, at a median age of 48 (18—88) years. Twenty-seven patients (29%) had pulmonary arterial hypertension with a mean pulmonary artery pressure ≥ 25 mmHg, which was considered to be reversible in all cases because of significant left-to-right shunt (Qp/Qs ratio > 1.5/1) on room air and/or vasodilatation testing with inhaled nitric oxide plus oxygen. Complex cases comprised 17 patients (18%), including 11 women, with a median age of 54 (20—81) years and a median weight of 58 (45—99) kg. Thirteen patients presented with one or more deficient rims other than the anterior-superior rim, whereas nine had an ASD diameter > 38 mm (Table 1). The median ASD diameter in complex cases was 39 (18—43.5) mm.

Demographic and clinical data for complex and non-complex cases are compared in Table 2. There were no statistical differences between the two groups, except that only non-complex cases presented with a paradoxical embolism ($P = 0.037$).

Transcatheter closure

Transcatheter closure was attempted in the 17 complex cases under ICE guidance (Table 1; Fig. 1). The median size of the 17 ASO devices used was 40 (20—40) mm, including a 40 mm ASO in 10 patients. The modified-sizing balloon-assisted technique was used to adequately position the device in 10 complex cases.

Failure to close the ASD percutaneously occurred in only three complex cases: one patient with complete inferior-posterior rim deficiency; one patient with an ASD of diameter > 40 mm (42 mm by ICE with unrestrictive passage of the 40 mm sizing balloon through the defect); one patient with a very large defect and inferior rim deficiency.

In another complex case with a moderately sized ASD and inferior-posterior deficiency, the defect was measured as being 20 mm by ICE. We decided to implant a 22 mm device without confirmation of the ASD size by balloon sizing. However, although the device was correctly positioned, it looked oversized under ICE imaging with 'mushrooming' misconfiguration. The device was removed because of the potential risk of erosion, and balloon sizing of the defect was performed. The diameter was found to be 18 mm and a 20 mm ASO was subsequently implanted with an excellent result. No other complex patient required more than one device.

The remaining 76 non-complex cases were successfully closed with the device initially selected after ASD sizing. Amplatzer devices were used in all cases, except in one patient with a small ASD in whom one 25 mm Cardia Intrasept ASD Occluder was implanted. Eight patients with multiple ASDs received an ACSO (25/25 mm in three patients, 35/35 mm in one patient and 40/40 mm in four patients).

Minor complications included: eight cases of haematoma at the femoral puncture site that healed spontaneously; one migraine headache (probably related to nickel allergy and successfully treated with prednisone); and two mild pericardial effusions that healed spontaneously. Major complications only occurred in three non-complex patients: one important groin haematoma requiring blood transfusion; one retroperitoneal haematoma that was hyperalgic for 10 days; and one arterial tear (laceration of a perivesical branch of hypogastric artery) successfully treated by percutaneous embolization. There were no significant differences between complex and non-complex patients.

The only borderline statistically relevant risk factor for failure to close the ASD was the presence of deficient rims other than the anterior-superior rim ($P = 0.058$).

Follow-up

The mean hospital stay was 3 ± 2 days, without any difference between complex and non-complex cases. After a mean follow-up of 3.3 ± 0.8 years, all patients are doing well. Three non-complex patients have a mild residual shunt by TTE.

Table 1 Characteristics and transcatheter closure in complex cases.

Patient	Rim deficiency	ASD size, by ICE (mm)	Device size (mm)	MSBAT	Success	Minor complications
1	SP	37	40	+	+	
2	SP	41	40	+	+	GH + PE
3	IP	43.5	40	+	+	
4	IP	39	40		+	
5		40	40		+	
6	P	34	36	+	+	
7	P	26	28	+	+	
8		42	40	+		
9	IP	18	20		+	
10		39	40		+	
11	IP	34	36	+		
12	IP	24	28		+	
13	SP	34	36		+	
14	P	36	36	+	+	PE
15	P	40	40	+	+	
16		39	40	+	+	GH
17	I	41	40			

ASD: atrial septal defect; GH: groin haematoma; I: inferior rim; ICE: intracardiac echocardiography; IP: inferior-posterior rim; MSBAT: modified-sizing balloon-assisted technique; P: posterior rim; PE: pericardial effusion; SP: superior-posterior rim.

Table 2 Comparison of complex and non-complex cases treated with transcatheter closure.

	Non-complex cases ($n = 76$)	Complex cases ($n = 17$)	P
Age (years)	47 ± 18	49 ± 19	0.65
Men	28 (37)	6 (35)	0.91
Body surface area (m^2)	1.76 ± 0.22	1.72 ± 0.23	0.44
Clinical characteristics			
Dyspnoea	28 (37)	7 (41)	0.79
Arrhythmias	12 (16)	4 (24)	0.48
Paradoxical embolism	16 (21)	0 (0)	0.037
Ischaemic stroke	15 (20)	0 (0)	0.06
Acute myocardial infarction	1 (1)	0 (0)	0.999
Chest pain	7 (9)	0 (0)	0.34
mPAP (mmHg)	21.6 ± 9	24.3 ± 11	0.23
Qp/Qs ratio	2.1 ± 0.8	2.2 ± 0.5	0.49
Procedural time (minutes)	92 ± 38	101 ± 39	0.43
Complications (per patient)	9 (12)	3 (18)	0.46
Minor	6 (8)	3 (18)	0.36
Major	3 (4)	0 (0)	0.999

Data are mean $\pm$ standard deviation or number (%). mPAP: mean pulmonary artery pressure.

Discussion

Several previous studies have demonstrated the feasibility of transcatheter ASD closure under ICE guidance in non-complex cases [5—16]. With 18% of cases being complex, our study is the first to assess ICE-guided closure in an unselected adult population.

In the present study, rim deficiency other than the anterior-superior rim was considered as the only borderline risk factor for failure to close the ASD ($P = 0.058$). Among 13 cases with deficient rim other than the anterior-superior rim, 11 were successfully closed, whereas two cases failed; both combined inferior rim deficiency, inferior-posterior rim deficiency and very large defects (diameter 36 to > 40 mm). Only a few previous reports have validated transcatheter closure in cases with deficient rims, under TEE or ICE guidance [17,19,20]. However, the vast majority of the patients had deficiency of the anterior-superior rim [17,20], with the exception of one recent study that specifically addressed cases with inferior-posterior rim deficiency [19]. Due to

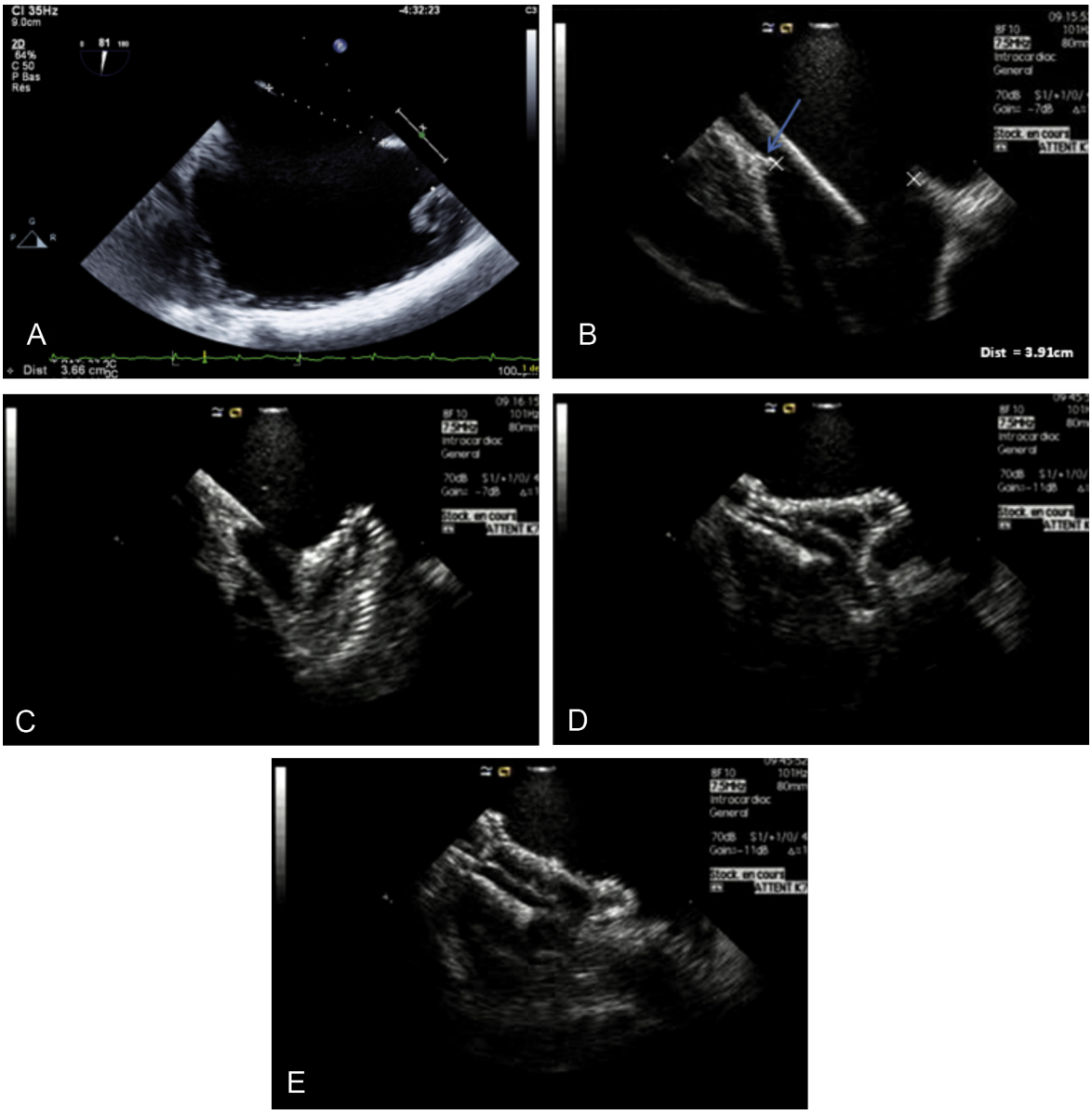

Figure 1. A large ostium secundum defect measuring 37 mm, with potential deficiency of the inferior-posterior rim, which cannot be clearly seen by transoesophageal echocardiography (A). The deficiency of the inferior-posterior rim (arrow) can be seen more distinctly with intracardiac echocardiography (septal view; B); the defect measures 39 mm. An attempt to close with a 40 mm Amplatzer Septal Occluder device failed initially, with immediate prolapse of the left atrial disc through the defect, which is evident on the intracardiac echocardiogram (C). With the use of the modified-sizing balloon technique, the device can be successfully positioned (D) and released (E).

several modified implantation methods developed to optimize device closure in challenging cases [4], deficiency of the anterior-superior rim does not represent a contraindication in the current era [3,4,17—20]. Such patients were not included in our complex cases group.

Also, transcatheter closure of very large defects (> 38 mm) was likewise accomplished in eight out of our nine cases with a 40 mm ASO device. No major complication occurred in this challenging subgroup of patients. In a previous international registry reporting transcatheter closure under TEE or ICE in 33 patients with the 40 mm ASO, three of the patients required emergency surgery for device embolization ($n = 2$) or atrial wall perforation ($n = 1$). Interestingly, the two device embolizations reported in this previous study occurred under TEE guidance, whereas no device embolized under ICE guidance [18].

In agreement with other reports, we found that ICE provides a better view of the posterior-inferior portion of the interatrial septum than TEE [6,7,9,11]. Moreover, ICE seems to result in less underestimation of the defect than TEE, allowing more accurate selection of the closure device [5,12]. In the present study, only one complex patient needed an additional device because the device chosen initially, based on ICE assessment alone, was too large. All this suggests that ICE offers the most effective approach for closure of cases with large defects and deficient rims.

Regardless of ICE accuracy, it is essential and mandatory to perform precatheterization TEE in every patient, to rule out any cardiac features that may contraindicate transcatheter closure, such as abnormal pulmonary venous return or complete inferior-posterior rim deficiency. Additionally, although this was not performed systematically in our patient population, three-dimensional TEE, which provides more precise imaging and measurements, such as the circular index of the ASD (defined as the ratio of the maximal diameter to the minimal diameter on a three-dimensional image), should better clarify the indications for transcatheter closure in the near future [22].

Study limitations

Beyond its retrospective nature, our study limitations lie in the exclusive adult population that was involved. For several well-recognized reasons (cost of the ICE, systematic general anaesthesia in paediatric population, increased morbidity of an additional venous access in children compared with adults), transcatheter ASD closure in children is performed under general anaesthesia and TEE guidance in our institution. Finally, there was no control group with TEE guidance. Comparison between the two imaging techniques in terms of cost and feasibility of transcatheter closure in complex cases would have been particularly interesting with such a control group.

Conclusion

Transcatheter closure of ASD under ICE monitoring is safe and efficient in an unselected patient population including complex cases. More studies are needed, as well as long-term follow-up, to confirm the safety and efficacy of ICE in this patient population.

Disclosure of interest

Alain Fraisse is a consultant and proctor for St. Jude Medical, France.

The other authors declare that they have no conflicts of interest concerning this article.

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