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Transcatheter closure of multiple atrial septal defects

Initial results and value of two- and three-dimensional transoesophageal echocardiography

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Aims To examine the feasibility of transcatheter closure of multiple atrial septal defects using two Amplatzer devices simultaneously and to describe the importance and the role of two- and three-dimensional transoesophageal echocardiography in the selection and closure of such defects.

Methods Twenty-two patients with more than one atrial septal defect underwent an attempt at transcatheter closure of their atrial septal defects at a mean ± SD age of 30·8 ± 18·6 years (range 3·7–65·9 years) and mean weight of 56·6 ± 25·5 kg (range 12·9–99 kg) using two Amplatzer devices implanted simultaneously via two separate delivery systems. During catheterization, two dimensional transoesophageal echocardiography was performed in all but one patient, during and after transcatheter closure, while three dimensional transoesophageal echocardiography was performed in six patients before and after transcatheter closure.

Results Forty-four devices were deployed in all patients to close 45 defects (one patient with three defects closed by two devices). Two dimensional transoesophageal echocardiography was helpful in selection and in guiding correct deployment of the devices. The mean size of the larger defect, as measured by transoesophageal echocardiography was 12·8 ± 5·9 mm and the mean size of the smaller defect was 6·6 ± 3·0 mm. The mean size of the larger devices was 15 ± 7·5 mm, and 8·4 ± 3·7 mm for the smaller. Three-dimensional transoesophageal echocardiography provided superior imaging and demonstrated the number, shape and the surrounding structures of the atrial septal defects in one single view. The median fluoroscopy time was 28·7 min. Device embolization with successful catheter retrieval occurred in one patient. Forty-four devices were evaluated by colour Doppler transoesophageal echocardiography immediately after the catheterization with a successful closure rate of 97·7%. On follow-up colour Doppler transthoracic echocardiography demonstrated successful closure in 97·5% at 3 months.

Conclusions The use of more than one Amplatzer septal occluder to close multiple atrial septal defects is safe and effective. The use of two- and three-dimensional transoesophageal echocardiography provided useful information for transcatheter closure of multiple atrial septal defects using two devices. Three-dimensional transoesophageal echocardiography enhanced our ability to image and understand the spatial relationship of the atrial septal defect anatomy.

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Key Words: Multiple atrial septal defects, Amplatzer septal occulder, echocardiography.

Introduction

Transcatheter closure of a single secundum atrial septal defect is an accepted alternative to surgical repair. However, the fossa ovalis may contain more than one fenestration of different sizes. The use of the Amplatzer septal occluder for transcatheter closure of a single secundum atrial septal defect is associated with a high and complete closure rate[1,2]. Furthermore, the operator has the ability to retrieve and reposition the device prior to its release. It is this character that encouraged us to use this device for patients with more than one defect. Information obtained by two-dimensional transoesophageal echocardiography plays an important role

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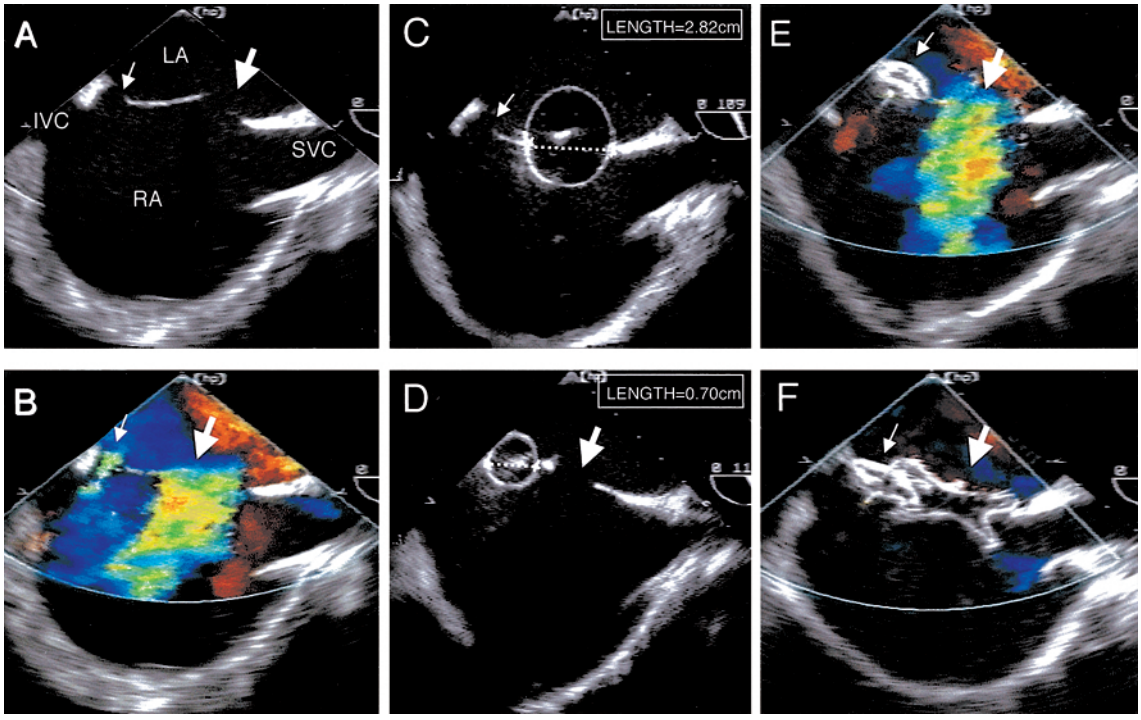

Figure 1 **Two-dimensional transoesophageal echocardiography (TEE) imaging in the long axis (bi-caval) view (A–F). A, two-dimensional image shows a larger defect (thick arrow) and a smaller defect (thin arrow). There is enough rim between the two defects. B, colour Doppler imaging validates the existence of the two defects (thick arrow denotes the larger defect and thin arrow denotes the smaller defect). C, the stretched balloon diameter is measured for the larger defect (arrow denotes the smaller defect). D, the stretched balloon diameter is measured for the smaller defect (arrow denotes the larger defect). E, the smaller device has been deployed, but not released (small arrow), while the larger defect has not yet closed (arrow); the delivery system in the larger defect cannot be seen in this frame. F, after deployment of both devices demonstrating overlapping of both devices. Colour flow Doppler interrogation demonstrated no residual shunting. IVC = inferior vena cava; LA = left atrium; RA = right atrium; SVC = superior vena cava.**

in the process of selection and closure[3]; however, we still need spatial imagination to understand the relationship between the defects and the adjacent structures. On the other hand, only one view is needed using three-dimensional transoesophageal echocardiography to show the structure of the atrial septum and its neighbouring anatomy.

Little is known about the effectiveness of transcatheter closure of multiple atrial septal defects using more than one device delivered simultaneously during one procedure. Therefore, in this study we report the results of transcatheter closure of multiple defects and evaluate the value of two- and three-dimensional transoesophageal echocardiography in the selection and closure of such defects.

Methods

Patients

Twenty-two patients (eight male/14 female) from multiple cardiac centres (see Appendix) underwent an attempt at transcatheter closure of their atrial septal defects. These patients were found to have more than one atrial septal defect during a transoesophageal echocardiography evaluation performed as part of the closure protocol. The patients ranged in age from 3·7–65·9 years (mean 30·8 ± 18·6 years) and their weight ranged from 12·9–99 kg (mean 56·6 ± 25·5 kg). Informed consent was obtained from all patients or their guardians.

Device

Details of the Amplatzer septal occluder have been published previously[1]. However, since that publication, the device now has become available in sizes up to 38 mm, requiring 12 Fr sheath for delivery.

Closure protocol

All procedures were done under general endotracheal anaesthesia with continuous transoesophageal echocardiography monitoring. Two-dimensional transoesophageal echocardiography studies were performed

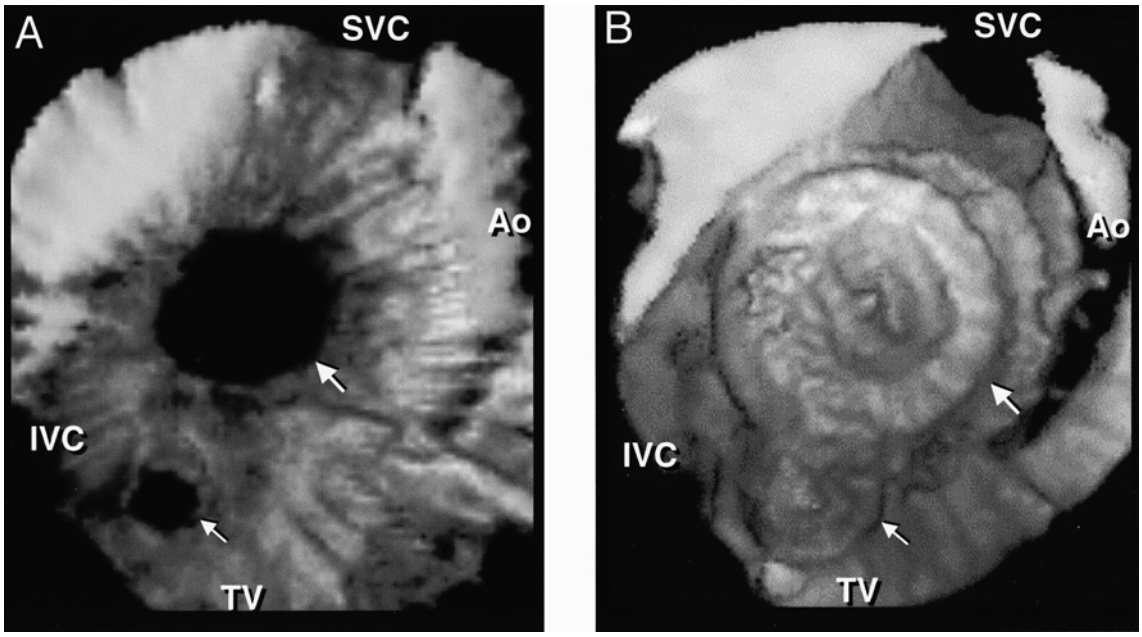

Figure 2 **Three-dimensional transoesphageal echocardiography en face view for atrial septum from right atrial side (A and B). A, before devices were deployed demonstrating two defects with sufficient rim between (thick arrow denotes the larger defect, thin arrow denotes the smaller defect) with their surrounding structures. B, after devices were deployed demonstrating overlap between the devices (thick arrow denotes the larger device and thin arrow denotes the smaller device). Ao = aorta; IVC = inferior vena cava; SVC = superior vena cava; TV = tricuspid valve.**

immediately before (to evaluate the number, position and size of atrial septal defects and also the surrounding rims, especially the distance between the two defects [Fig. 1A and B]) during and after deployment of the devices. Three-dimensional transoesophageal echocardiography was performed in six patients in one medical centre. For three-dimensional reconstruction, HP Sonos 2500 or 5500 system equipped with a three-dimensional data acquisition software package was used for the three-dimensional data acquisition. The imaging was acquired and stored every 2° using a rotational scanning method. The reference position selected was based on the whole structure of the atrial septal defect being in the region of interest. The digital data were stored in a conical volume. Three-dimensional transoesophageal echocardiography reconstruction was performed with a TomTec (Echo Scan 3.2) three-dimensional reconstruction computer system. A specific cut plane was used for reconstruction to image en face the anatomy of the atrial septal defect from the right atrium[4] (Fig. 2A). The average time required for acquisition and reconstruction of the images varied between 10–15 min (the acquisition is heart-rate dependent and the reconstruction is operator dependent). Deployment of the device was similar to the deployment of a single device[1] with slight modification[5]. Figures 1 and 3 demonstrate the echocardiographic and fluoroscopic steps of the protocol. Two separate catheters crossed the defects. The stretched balloon diameter measurements for the defect was determined using Medi-Tech sizing balloon catheters (Medi-Tech, Boston Scientific Corporation, Natick, MA, U.S.A. [Fig. 1C and D]. Two separate simultaneous delivery systems were introduced via the femoral veins. The device size (waist diameter) chosen to be deployed was equal ± 2 mm to the stretched balloon diameter. The smaller device was usually deployed first (Fig. 3B) but not released until the larger device was positioned across the defect. If stability of both devices was confirmed by two-dimensional transoesophageal echocardiography and by fluoroscopy, the devices were released sequentially (Fig. 3E–G), starting with the smaller device. Once both devices were released, repeat two-dimensional transoesophageal echocardiography was performed to assess device position and the presence of residual shunting (Fig. 1E and F). Angiography was performed in the right atrium with pulmonary levophase to assess the position of the device (Fig. 3H). Patients were awakened and allowed to recover overnight. Two-dimensional transthoracic echocardiography was performed at 24 h, and at follow-up intervals of 1 month, 3 months and 1 year in all patients to assess residual shunt, thrombus formation, or other complications, as per a previously reported protocol[6] Residual shunts were classified as: trivial — colour jet ≤ 1 mm; small — colour jet ≤ 2 mm: moderate — colour jet 2–4 mm and large — colour jet ≥ 4 mm. The current definition of successful closure, as accepted by the Federal Drugs Agency, would include complete closure and/or less than 2-mm residual shunt by colour flow transthoracic echocardiography on follow-up studies and no major complications. In six patients, three-dimensional transoesophageal echocardiography was

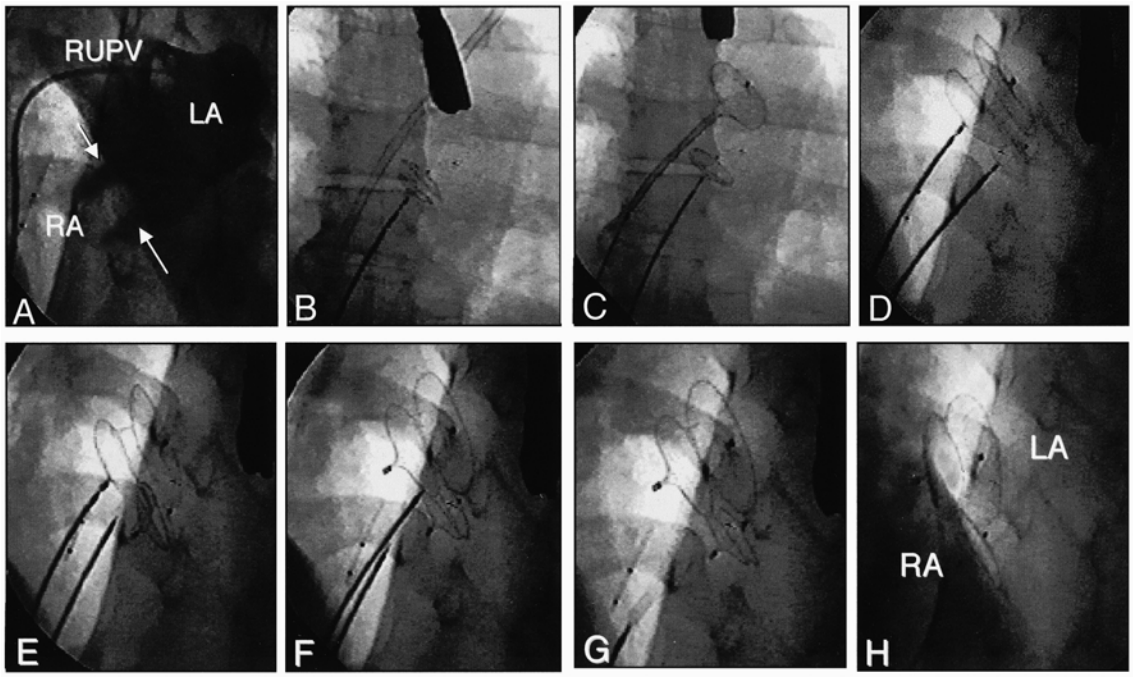

Figure 3 **Cine frames in the hepatoclavicular view demonstrating the steps of the closure protocol. A, angiogram in the left atrium reveals left-to-right shunt via two defects (arrows). B, two delivery catheters crossing the two defects. The small device was already deployed, there was a delivery sheath crossing the larger defect. C–G, positioning and releasing the two devices starting with the smaller device, then the larger one. H: angiogram in the right atrium revealing good devices position. LA: left atrium; RA: right atrium; RUPV: right upper pulmonary vein.**

also performed immediately after transcatheter closure of multiple atrial septal defects, using the same view to validate the position of each device and its relationship with the surrounding structures (Fig. 2B).

On two-dimensional transoesophageal echocardiography examination, all patients had two atrial septal defects (one patient had three defects). The mean size of the larger defect, as measured by transoesophageal echocardiography, was 12·8 ± 5·9 mm (range 5–28 mm) and the mean size of the smaller defect was 6·6 ± 3·0 mm (range, 2 ± 12 mm). The mean Qp/Qs ratio was 2·3 ± 1·3 (range 0·7–5·7).

Statistical analysis

Data are expressed as median or mean ± SD and range.

Results

Clinical data of all patients are listed in Table 1. Forty-four devices were deployed in 22 patients (45 defects); one patient had three defects closed by two devices. The mean size of the device used to close the larger defects was 15 ± 7·5 mm (range, 5–34 mm) and 8·4 ± 3·7 mm (range, 4–18 mm) for the smaller defects. For the larger defects, the mean ratio of device size to atrial septal defect size, as measured by transoesophageal echocardiography was 1·35 ± 0·5 (range, 0·63–3) and the mean ratio of device size to stretched balloon diameter was 1·0 ± 0·1 (range 0·6–1·1). The mean fluoroscopy time was 28·7 ± 21·8 min (range, 8·0–107 min) and the mean total procedure time was 148 ± 57·3 min (range 67–330 min). There was immediate complete closure documented by colour Doppler transoesophageal echocardiography in 30 devices, eight with a trivial shunt, five with a small shunt and one with a large shunt; therefore the immediate success rate, as evaluated by transoesophageal echocardiography, was 97·7%.

Complications were encountered in two patients. In one patient (#3), a 26 mm device was implanted in a large defect with stretched diameter of 29 mm (the largest device available at the time) and a 9 mm device in the small defect. The following day on routine transthoracic echocardiography, the larger device was found embolized to the main pulmonary artery. The device was retrieved in the catheterization laboratory. Five months later, a 34 mm device was successfully deployed in the large defect (this patient had no anterior rim, therefore it was the decision of the operator to choose an oversized device to close the defect). This patient had complete closure immediately and at 6 month follow-up transoesophageal echocardiography. In another patient, a brief episode of non-sustained supraventricular tachycardia was experienced upon deployment of the large device. This episode resolved spontaneously and the patient did not experience further episodes.

Table 1 Clinical data for patients who underwent TCC with multiple Amplatzer™ devices

Pts. no.	Age (years)	Wt. (kg)	L-ASD size (mm)		L-Dev. size (mm)	S-ASD size (mm)		S-Dev. size (mm)	Qp/Qs	FT (min)	PT (min)
			TEE	SBD		TEE	SBD				
1	37·2	62·1	14	20	20	12	18	18	2·3	15·5	88
2	20·5	96·6	16	22	22	4·3*	9	9	3·8	32·0	121
3	49·0	88·0	28	33	34	7	9	9	2·4	16·9	120
4	8·9	26·0	N/A	N/A	5	N/A	N/A	N/A	2·3	13·9	114
5	65·9	72·0	10	16	16	5	12	12	1·5	8·0	67
6	29·0	65·0	19	N/A	24	10	N/A	14	N/A	30·0	180
7	6·3	21·2	7	14	14	2	6	6	2·0	21·3	103
8	43·0	53·9	21	28	26	10	11	11	4·8	37·5	180
9	17·5	42·2	9	16	16	5	8	8	2·1	33·9	140
10	3·7	12·9	7	11	11	3	5·5	6	2·1	17·0	133
11	19·5	50·6	5	6	5	4	4	4	0·7	41·2	186
12	5·9	20·3	15	17	18	6	11	12	1·8	13·6	88
13	43·2	77·0	18	18	18	9	9	9	3·1	20·0	105
14	15·8	41·0	8	N/A	8	4	N/A	4	N/A	107·0	330
15	31·0	90·0	N/A	10	10	N/A	9	9	N/A	35·0	180
16	60·5	53·0	12	N/A	12	10	N/A	10	1·6	21·0	120
17	48·2	59·0	18	13	13	N/A	5	5	2·7	17·1	135
18	29·9	67·0	6	6	6	3	5	5	1·0	22·4	215
19	51·0	99·0	8	9	9	8	5	5	1·0	17·2	150
20	43·5	67·0	9	8	8	7	6	5	1·4	20·2	180
21	9·3	21·0	13	21	22	5	9	8	5·7	63·0	180
22	38·9	61·0	13	N/A	14	11	20	12	1·5	N/A	N/A
Av	30·8	56·6	12·8	15·8	15	6·6	9·0	8·4	2·3	28·7	148

Pts=patients; Wt=weight; L-ASD=large atrial septal defect; TEE=transoesophageal echocardiography; SBD=stretched balloon diameter; L-Dev=larger device; S-ASD=smaller atrial septal defect; S-Dev=smaller device; FT=fluoroscopic time; PT=procedure time; *two separate small defects; N/A: not available; Av: average.

Twenty-four hours after closure, the successful closure rate was 97·5% (35 had complete closure, one had a trivial shunt, three a small shunt and one a large shunt); at the 1 month follow-up, 40 devices were available for evaluation; the successful closure rate was 97·5% (34 had complete closure, two had a trivial shunt, three had a small shunt and 1 had a large shunt); at 3-month follow-up, 38 devices were eligible for evaluation; the successful closure rate was 97·4% (32 had complete closure, 2 had a trivial shunt, 3 had a small shunt and one had a large shunt) and at 1 year follow-up, 10 devices were eligible for evaluation, the successful closure rate was 90% (nine had complete closure and one patient had a moderate shunt); the patient with the large shunt at 3 months improved to moderate shunt.

Discussion

Transcatheter closure of a single secundum atrial septal defect has become an accepted modality of treatment in many cardiac centres. The newer generation of devices achieves higher closure rates and fewer complication rates. The Amplatzer septal occluder device has all the characteristics required for wide use: user- and patient-friendly, the operator is given the ability to retrieve and reposition the device prior to release and the success rate achieved is high. Little is known about the use of devices to close multiple atrial septal defects[5]. In this paper, we report on the initial results from multiple cardiac centres of transcatheter closure of multiple atrial septal defects using the Amplatzer septal occluder. From a technical point of view, the deployment of both devices was no different from a single device and the results are comparable to those for a single atrial septal defect.

It is important to have an accurate evaluation of the atrial septum to rule in or out the possibility of multiple defects. This is done by careful interrogation of the atrial septum by colour Doppler echocardiography, preferably by transoesophageal echocardiography at the time of catherization. During measurement of the stretched balloon diameter of any defect, colour flow mapping should be applied to the septum to rule this possibility in or out. Therefore, the selection of patients is probably the most important step in the whole process. For two devices to be implanted simultaneously inside the heart, the size of the left and right atrium should be sufficient to handle two devices. This usually requires that the patient be large enough (ideally >20 kg, unless the devices used are smaller than 10 mm) and the distance between the two defects should be at least 7 mm (in the larger size devices [more than 11 mm], a 7 mm rim is present on the left atrial disk and, therefore, a distance of at least 7 mm between the two defects needs to be present for the devices to be seated together). The immediate success rate of closure in our patients was very high due to the mechanism of closure achieved with this device (stenting the defect by the connecting waist) and also due to the operator experience with this device.

During implantation of both devices, it is recommended to deploy the left and right atrial disks of the smaller device first, but not release it, then the larger device should be deployed. In one patient, the larger disk was deployed first resulting in the inability of the small device to be opened fully, therefore, the larger device was recaptured and the smaller device was deployed first; this resulted in successful closure. The two devices may overlap, resulting in a slightly bigger profile, however, on follow-up; we have not experienced any complication from this overlap. There are no experimental or clinical data available on the endothelialization of the Amplatzer when the devices 'overlap', creating a point of no contact with the atrial septum. We empirically recommend these patients receive antiplatelet agents (aspirin) for a period of at least 6 months to prevent any potential thromboembolic episodes.

Role of two- and three-dimensional transoesophageal echocardiography

Transoesophageal echocardiography provided useful information for transcatheter closure. First, two-dimensional transoesophageal echocardiography was helpful in the selection of eligible atrial septal defect cases for transcatheter closure. Two-dimensional transoesophageal echocardiography evaluated the exact number and size of defects and the relationship of these defects to each other (rim between the two defects) and to the surrounding structures. The presence of sufficient rim between the two defects (>7 mm) permitted the deployment of two separate devices in the same patient. In one patient with three defects, there were not enough rim between the two small defects; therefore, one device was chosen to cover both small defects and another large device to cover the larger defect. Second, during device placement, two-dimensional transoesophageal echocardiography was invaluable in guiding the measurement of the balloon stretched diameter and it was especially useful in validating the position of the delivery sheath in the left atrium. Lastly, after deployment of both devices, two-dimensional transoesophageal echocardiography demonstrated the spatial relationship of the two devices (Fig. 1F). Three-dimensional transoesophageal echocardiography provided superior imaging, demonstrating the number and the shape of the atrial septal defects and the surrounding structures in one single view (Fig. 2A). Thus, the size of the atrial septal defect and the rim could be measured more easily and accurately, especially as regards the distance between multiple atrial septal defects. Three-dimensional transoesophageal echocardiography clearly demonstrated the three defects and the surrounding structures, in the patient with three fenestrations. After deployment of both devices, three-dimensional transoesophageal echocardiography could demonstrate that the larger device closed the largest defect, while the smaller device closed the two smaller defects. The drawback of this technology is that it is not readily available in all cardiac centres and also it is operator-dependent.

Conclusion

Transcatheter closure of multiple atrial septal defects using two Amplatzer devices is feasible, safe and effective. Two-dimensional transoesophageal echocardiography can provide useful information by monitoring transcatheter closure, while three-dimensional transoesophageal echocardiography enhanced our ability to better comprehend the atrial septum anatomy, rendering catheter closure easier.

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Appendix

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