Feasibility, safety, and efficacy of real-time three-dimensional transoesophageal echocardiography for guiding device closure of interatrial communications: initial clinical experience and impact on radiation exposure

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Aims

Our aim was to assess the feasibility and safety of real-time (RT) three-dimensional (3D) transoesophageal echocardiography (TEE) for guiding transcatheter closure of interatrial communications and to evaluate its additional benefit over conventional 2D TEE in reducing radiation exposure for the patient.

Methods and results

Twenty-five patients undergoing device closure of their interatrial defect had the procedure guided by fluoroscopy, 2D TEE, and RT 3D TEE. We retrospectively compared this group with a historical control group in which interventional guidance was performed using fluoroscopy and 2D TEE alone. The application of RT 3D TEE allowed safe device deployment in all patients without any complications, resulting in a reduction of mean fluoroscopy time (10 ± 6 to 6 ± 4 min, P < 0.01), mean dose area product (DAP) (964 ± 628 to 535 ± 464 cGy cm², P < 0.01), and mean DAP per individual body surface area (494 ± 317 to 273 ± 221 cGy cm²/m², P < 0.01).

Conclusion

RT 3D TEE as an adjunct to 2D TEE is a feasible and safe tool to guide transcatheter device closure of interatrial communications, resulting in a reduction of radiation exposure. These data indicate that RT 3D TEE can be used to safely monitor interatrial defect closure in clinical routine.

Keywords

RT 3D TEE • Transcatheter device closure • Interatrial communications

Introduction

Transcatheter device closure of interatrial communications has become an established technique for the prevention of paradoxical embolism in patients with patent foramen ovale (PFO) and an effective alternative treatment to surgery for selected patients with atrial septal defects (ASD) associated with significant left-to-right-shunting.1–3 The device closure procedure has traditionally been guided using a combination of fluoroscopic and two-dimensional (2D) transoesophageal echocardiography (TEE) imaging.4 Because of only two spatial dimensions, 2D TEE is limited to detect the position of a catheter or a device relative to its surrounding structures, requiring the acquisition of multiple-image planes in order to mentally reconstruct the anatomical setting. Recently, transthoracic real-time (RT) 3D echocardiography was used to navigate ASD closures in infants from a subcostal window,5 resulting in a decrease in fluoroscopy time.6 In adults, the image quality of transthoracic imaging is often not sufficient to

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adequately guide closing procedures of interatrial communication. The recently developed RT 3D TEE has been shown to provide guidance of ASD and PFO closures, providing fast and complete information regarding the appropriate deployment and position of the device with regard to the surrounding structures. The aim of this study was to evaluate the feasibility and safety of RT 3D TEE in guiding transcatheter device closure of interatrial communications and its additional benefit over conventional 2D TEE in reducing radiation exposure for the patient.

Methods

Study design and patients
Between March 2007 and March 2008, we performed an observational non-randomized study including 25 consecutive patients with ostium secundum ASD and haemodynamically relevant left-to-right shunting (n = 6) or with PFO associated with an episode of transient ischaemic attack or stroke (n = 19). In this cohort of patients, the intervention was guided using fluoroscopy, 2D TEE, and additionally RT 3D TEE with the intention to minimize the use of 2D TEE and to guide the procedure exclusively by RT 3D TEE. Primarily, we performed a feasibility study including five patients to assess practicability and safety of RT 3D TEE for guidance of transcatheter ASD and PFO closure. Because of successful device implantation in these initial patients, we proceeded with the efficacy study including 20 additional patients. Upon completion of our initial experience using RT 3D TEE in this set of 25 patients, we sought to evaluate a complementary benefit of RT 3D TEE images over conventional 2D TEE and fluoroscopic images concerning procedure time and radiation exposure. We therefore retrospectively compared this group with a historical control cohort of 25 patients, matched for the type of interatrial defect, age, gender, and body mass index, in which interventional guidance was performed using fluoroscopy and conventional 2D TEE alone between July 2003 and October 2007. Quantitative measures of radiation exposure, interventional procedure time, and duration of TEE intubation were compared. All patients had a pre-procedural 2D TEE to document their type of interatrial communication and to determine the position and the size of the defect. The study was approved by the local Ethics Committee and all patients provided written informed consent.

Device closure under fluoroscopic guidance
All interventional procedures were performed by two interventional cardiologists with a minimum of 10 years experience in device closure interventions. Defects were closed percutaneously using either an Amplatzer septal occluder (n = 47, AGA Medical Corporation, Golden Valley, MN, USA) or a Cardia Intrasept device (n = 3, Cardia Medical Device, Cheshire, UK). Device implantation procedures were identical in both groups. Patients were anticoagulated using intravenous heparin to achieve a target-activated clotting time of 250–300 s. After local anaesthesia of the right femoral groin, a 12-F valved sheath (Cordis, Miami, FL, USA) was inserted into the right common femoral vein, and a guide wire (Cook, Bjaeverskov, Denmark) was advanced along the inferior vena cava across the interatrial septum defect into the left upper pulmonary vein under fluoroscopic guidance. The correct passage of the wire across the interatrial defect was confirmed (Figure 1A). After the advancement of the guide wire into the left upper pulmonary vein under fluoroscopic guidance, the correct passage of the wire across the interatrial defect was confirmed (Figure 1B). During the placement of the device, several rotated 2D image planes were used to assess the on-line visualization of the defect and its margins. (Figure 1C and D). Once the operators were satisfied with the device position, a further confirmatory 2D TEE was performed prior to release to confirm that both discs were properly positioned along the sides of the interatrial septum (Figure 1E and F). After final implantation of the device, a contrast suspension of agitated saline was injected intravenously to exclude the presence of residual leaks.

Device closure under transoesophageal echocardiography guidance
Both the 2D TEE and the RT 3D TEE examinations were performed by the same experienced echocardiographer. Probe intubation was performed with local anaesthesia using lidocaine spray and conscious sedation as needed (midazolam 2.5–10 mg i.v.). The lubricated probe was inserted orally at the beginning of the intervention with the patient lying in the supine position after the insertion of the sheath into the right common femoral vein. In order to achieve the best view of the interatrial septum, the position of the transducer was switched to the bicaval (90°) or the basal short-axis view (30–60°) and was adjusted during the intervention as mandatory. Gain settings were accomplished within the 2D mode until the right atrium, the interatrial septum, and the left atrium could be clearly visualized and were used as a prerequisite for optimal 3D images, respectively.

Two-dimensional transoesophageal echocardiography
The interventional procedure in the 2D TEE control cohort was monitored using a multiplanar 5–7 MHz TEE probe connected to a Philips Sonos 5500 ultrasound system (Philips Medical Systems, Andover, MA, USA). This TEE system allows acquisition of all conventional modalities (M-mode, 2D multiplanar imaging, pulsed- and continuous wave Doppler, colour Doppler). The atrial septum was scanned until the transducer was in a position to allow optimal visualization of the interatrial defect (Figure 1A). After the advancement of the guide wire into the left upper pulmonary vein under fluoroscopic guidance, the correct passage of the wire across the interatrial defect was confirmed (Figure 1B). During the placement of the device, several rotated 2D image planes were used to assess the on-line visualization of the defect and its margins. (Figure 1C and D). Once the operators were satisfied with the device position, a further confirmatory 2D TEE was performed prior to release to confirm that both discs were properly positioned along the sides of the interatrial septum (Figure 1E and F). After final implantation of the device, a contrast suspension of agitated saline was injected intravenously to exclude the presence of residual leaks.

Real-time three-dimensional transoesophageal echocardiography
The device closure in the RT 3D TEE group was performed using a commercial 3D-capable echocardiographic system (Philips IE 33, Philips Healthcare, Andover, MA, USA), equipped with a new matrix array TEE transducer technology that contains a large number of transducer elements (more than 2500 active elements), enabling the acquisition of both 2D and RT 3D TEE images. The RT 3D TEE probe (X7-2t, 7 MHz, Philips Healthcare) is of similar size to a conventional multiplanar 2D TEE probe, measuring 1.5 cm in width, 1.0 cm in height, and 4.5 cm in length, with a cross-sectional area of ~10 x 14 mm². In addition to all conventional 2D TEE modalities, this new system offers three 3D acquisition modes:

(i) Live 3D displays a pyramidal data set of ~50° × 30°.
(ii) 3D zoom displays a truncated pyramidal data set of ~85° × 85°.
Full-volume 3D provides a pyramidal data set of 100° × 100°.

This wide-angle mode requires ECG gating and breath-holding, because the wide-angle data set is compiled by merging four to seven narrower RT 3D pyramidal scans.

The 3D zoom mode was subsequently used to image the interatrial defect using an en face view (Figure 2A and B). In order to gain the best spatial perspective, the 3D data set was rotated to allow simultaneous views from the right and left atrium. Deployment of the left atrial disc was monitored on-line using the 3D zoom mode (Figure 2C and D). Further withdrawal of the sheath with the deployment of the right atrial disc and the final release of the device was monitored using the live 3D mode (Figure 2E). To ensure appropriate position of both discs along the interatrial septum, the 3D zoom mode was utilized (Figure 2F). In order to acquire delineation of the interatrial septum including both atria, the full-volume 3D mode was used because it provides the largest 3D pyramidal data set. In this mode, the 3D data set was rotated to visualize the device from both the left (Figure 3A) and right atrial perspective (Figure 3B) to ensure the correct positioning of the device. Finally, the imaging mode was switched back to live 3D during injection of a contrast suspension of agitated saline to detect the presence of residual leaks (Figure 3C and D).

Figure 1 Guidance of device closure using two-dimensional transoesophageal echocardiography. Imaging of the interatrial septum providing visualization of the defect and its margins (A) and confirming the correct position of the guide wire through the defect (B). After deployment of the left atrial disc (C) and withdrawal of the sheath towards the interatrial septum (D), implantation of the right atrial disc and confirmation of appropriate device position can be monitored with two-dimensional transoesophageal echocardiography (E–F). IAS, interatrial septum; LA, left atrium; RA, right atrium.
Continuous variables are presented as mean ± standard deviation. Categorical data are presented by frequencies and percentages. Clinical and procedural data were compared with unpaired t-test in case of continuous data; in the case of categorical data, Fisher’s exact test was performed. Applied tests were two-sided and resulting P-values less than an alpha level of 0.05 were considered to indicate statistical significance.

**Results**

The clinical patient characteristics are summarized in Table 1. There were no significant intergroup differences. All patients tolerated the oesophageal intubation of the lubricated probe under conscious sedation without the need for general anaesthesia or orotracheal intubation. The results from our feasibility study, including five patients, demonstrated that the combination of 2D

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**Figure 2** Guidance of device closure using real-time three-dimensional transoesophageal echocardiography. Real-time three-dimensional transoesophageal echocardiography allows the assessment of defect size and shape, including the residual rim of the interatrial septum and the complete circumference in its surrounding anatomical structures in real-time (A). After passage of the guide wire through the defect, the patent foramen ovale (PFO) can be clearly visualized (B). Spatial orientation of the device and the relation of the left atrial disc to atrial septal defect (ASD) size can be assessed (C). Withdrawal of the sheath towards the interatrial septum can be monitored on-line, providing accurate information regarding the spatial position of the left atrial disc and its distance to the interatrial septum (D). After final device deployment, the three-dimensional image enables visualization of the correct position of the occluder and its relation to the interatrial septum (E–F). IAS, interatrial septum; LA, left atrium; RA, right atrium.
Feasibility, safety, and efficacy of RT 3D TEE

TEE and RT 3D TEE was feasible to navigate the device closure procedure. The novel RT guidance technique allowed adequate visualization of the size and shape of the interatrial defect, catheters, and devices together with the adjacent anatomy. These results led us to perform a subsequent efficacy study in 20 consecutive patients with device closure under 2D TEE and RT 3D TEE guidance. The devices were successfully deployed in all patients without complications, such as aspiration, oesophageal injury, bleeding, or cerebrovascular accidents. There were no documented leakages after final implantation requiring repositioning of the device. All procedural variables are listed in Table 2. With increasing experience using the new technique for guiding device closure of interatrial defects, the RT 3D TEE proportion of the total TEE exposure time relative to 2D TEE increased from 61 to 85% in ASD closure ($P < 0.001$), and from 73 to 98% in PFO closure, respectively ($P < 0.001$). Device deployment in PFO closures was exclusively guided by RT 3D TEE at the end of this study, whereas in ASD closures a combination of both 2D TEE and RT 3D TEE was still necessary. When comparing the combination of 2D TEE and RT 3D TEE guidance with 2D TEE guidance alone, there were no significant differences in mean catheterization procedure time ($43 \pm 15$ vs. $42 \pm 14$ min, $P = 0.81$). The TEE intubation time was minimally longer in the RT 3D TEE group ($33 \pm 13$ vs. $36 \pm 13$ min, $P = 0.41$). However, the additional use of RT 3D TEE significantly decreased mean fluoroscopy time ($10 \pm 6$ to $6 \pm 4$ min, $P < 0.01$, Figure 4A) and also significantly reduced mean dose area product (DAP) ($964 \pm 628$ to $535 \pm 464$ cGy cm$^2$, $P < 0.01$, Figure 4B), as well as mean DAP/body surface area ($494 \pm 317$ to $273 \pm 221$ cGy cm$^2$/m$^2$, $P < 0.01$, Figure 4C) when compared with conventional 2D TEE.

**Table 1** Clinical characteristics of the study population

<table>
<thead>
<tr>
<th></th>
<th>2D TEE (n = 25)</th>
<th>2D TEE + RT 3D TEE (n = 25)</th>
<th>$P$-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>42 ± 10</td>
<td>40 ± 11</td>
<td>0.72</td>
</tr>
<tr>
<td>Men/women</td>
<td>15/10</td>
<td>14/11</td>
<td>1.00</td>
</tr>
<tr>
<td>ASD</td>
<td>6</td>
<td>6</td>
<td>1.00</td>
</tr>
<tr>
<td>PFO</td>
<td>19</td>
<td>19</td>
<td>1.00</td>
</tr>
<tr>
<td>Body mass index (kg/m$^2$)</td>
<td>25 ± 3.2</td>
<td>24.6 ± 3.1</td>
<td>0.67</td>
</tr>
</tbody>
</table>

2D TEE, two-dimensional transoesophageal echocardiography; RT 3D TEE, real-time three-dimensional transoesophageal echocardiography; ASD, atrial septal defect; PFO, patent foramen ovale.
of the interventional device closure, but it is limited in its ability to delineate the position of both discs relative to the interatrial septum between both discs. During device closure of interatrial communications in children, more extensive guidance of device closure and reduction of radiation exposure. Our findings demonstrate that RT 3D TEE constitutes a novel and safe imaging technique, supplementary to 2D TEE for guidance of percutaneous closures of interatrial defects.

The most important goal of any imaging modality suitable for guidance of cardiac interventions is accuracy in performing the procedure and prevention of complications. As identified in this study, RT 3D TEE is feasible and safe for guiding device closure of interatrial communications in humans. In this study, no complications were reported and device deployment was successful in all patients. Real-time three-dimensional transoesophageal echocardiography allows us to visualize the exact cardiac pathomorphology and enables accurate imaging of catheters and devices, together with their surrounding anatomy which enhances monitoring of the procedure while providing excellent spatial orientation, which might even be useful in less echogenic devices. Fluoroscopy fails to delineate the position of both discs relative to the interatrial septum, and 2D TEE lacks adequate visualization of the interatrial septum between both discs. During device closure of interatrial communications, the most significant imaging issue is malpositioning of the device, which may result in device embolization.

Two-dimensional TEE has become an essential and integral tool of the interventional device closure, but it is limited in its ability to detect the position of a catheter or a device relative to its surrounding environment because of the ability to provide only two spatial dimensions. Even in the hands of experienced operators, numerous rotational cut planes are necessary in order to mentally reconstruct the anatomical shape of an inter-ASD. Although several approaches for off-line 3D reconstruction have been successfully accomplished, these images are not available during the intervention and therefore are useless for on-line monitoring of the procedure. The results of our study demonstrate that the use of RT 3D TEE overcomes these limitations, presenting high-quality 3D images of the heart for on-line monitoring of the interventional procedure. The additional benefit of combining RT 3D TEE and 2D TEE is reflected by a significant reduction of radiation exposure for the patient owing to the supplementary information provided by the 3D images. This could be especially useful for cardiac interventions performed during pregnancy in mothers with strokes due to PFO, or in young individuals with congenital heart disease, in whom a reduction of radiation is beneficial. The mean estimated risk for fatal cancer or hereditary effects is 1 case per 1000 diagnostic procedures, 2 cases per 1000 ASD procedures, and 4 cases per 1000 VSD procedures.

With the advantages of improved cardiac imaging using RT 3D TEE, the risk for radiation-induced malignancies may be further diminished, because of less intensive radiation exposure. Improved image quality during guidance of transcatheter device closure of interatrial communications has already been demonstrated to reduce radiation exposure using intracardiac echocardiography (ICE). However, ICE technology has its own limitations, including its invasive nature requiring a second large venous access and high costs. Recently, transthoracic RT 3D echocardiography has been shown to reduce fluoroscopy time during device closure of interatrial communications in children. Moreover, in adults, transcatheter closure of ASD and PFO has been performed without the use of any fluoroscopy. However, it may be difficult to generalize these results, because they represent a single-centre experience. In our study, we were able to monitor the withdrawal of the sheath and the release of both discs under RT 3D TEE guidance without the use of fluoroscopy only in patients with PFO. To our present knowledge, fluoroscopy is still required to some extent, especially in patients with ASD and during placement of the guide wire through the interatrial defect into the left upper pulmonary vein. Furthermore, in patients with ASD, RT 3D TEE alone is currently not sufficient for adequate guidance of device closure and reduction of radiation exposure. Our

### Table 2 Procedural data

<table>
<thead>
<tr>
<th></th>
<th>2D TEE (n = 25)</th>
<th>2D TEE + RT 3D TEE (n = 25)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CardioStar devices</td>
<td>3 (12%)</td>
<td>0 (0%)</td>
<td>0.24</td>
</tr>
<tr>
<td>Amplatzer devices</td>
<td>22 (88%)</td>
<td>25 (100%)</td>
<td>0.24</td>
</tr>
<tr>
<td>Diameter of balloon sizing, ASDs (mm, n = 6)</td>
<td>16.7 ± 4</td>
<td>18.2 ± 5.4</td>
<td>0.60</td>
</tr>
<tr>
<td>Diameter of balloon sizing, PFOs (mm, n = 19)</td>
<td>10.4 ± 3.9</td>
<td>10.5 ± 2.4</td>
<td>0.92</td>
</tr>
<tr>
<td>Successful device deployment</td>
<td>25 (100%)</td>
<td>25 (100%)</td>
<td>1.00</td>
</tr>
<tr>
<td>Procedural complications</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aspiration</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>1.00</td>
</tr>
<tr>
<td>Oesophageal injury</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>1.00</td>
</tr>
<tr>
<td>Bleeding</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>1.00</td>
</tr>
<tr>
<td>Cerebrovascular accident</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>1.00</td>
</tr>
</tbody>
</table>

2D TEE: two-dimensional transoesophageal echocardiography; RT 3D TEE, real-time three-dimensional transoesophageal echocardiography; ASD, atrial septal defect; PFO, patent foramen ovale.

**Discussion**

The major findings of this purely observational and non-randomized study are as follows. (i) Guidance of device closure of interatrial communications is feasible and safe using RT 3D TEE. (ii) With growing experience, the proportion of applying RT 3D TEE increases significantly on a steep learning curve to an extent that allows for device deployment in PFO closures exclusively guided by RT 3D TEE. (iii) The additional application of 2D and RT 3D TEE during these procedures significantly reduces radiation exposure. Our findings demonstrate that RT 3D TEE constitutes a novel and safe imaging technique, supplementary to 2D TEE for guidance of percutaneous closures of interatrial defects.

The most important goal of any imaging modality suitable for guidance of cardiac interventions is accuracy in performing the procedure and prevention of complications. As identified in this study, RT 3D TEE is feasible and safe for guiding device closure of interatrial communications in humans. In this study, no complications were reported and device deployment was successful in all patients. Real-time three-dimensional transoesophageal echocardiography allows us to visualize the exact cardiac pathomorphology and enables accurate imaging of catheters and devices, together with their surrounding anatomy which enhances monitoring of the procedure while providing excellent spatial orientation, which might even be useful in less echogenic devices. Fluoroscopy fails to delineate the position of both discs relative to the interatrial septum, and 2D TEE lacks adequate visualization of the interatrial septum between both discs. During device closure of interatrial communications, the most significant imaging issue is malpositioning of the device, which may result in device embolization.

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results demonstrate, though, that with increasing experience and after some time of adopting to the 3D images, the proportion of using RT 3D TEE accumulates during the learning process to a conceivable extent that this new technique might be used solely for guidance of PFO closure more likely than for ASD closure. This corroborates with our results demonstrating that device deployment in PFO closures is possible using RT 3D TEE alone.

In conclusion, the combination of 2D TEE and RT 3D TEE could become an important imaging modality, enabling improved spatial resolution of the anatomy of the heart with reduced use of radiation. These advantages over 2D TEE, ICE, and fluoroscopy may accelerate decision process during interventions and increase procedural safety and efficacy both in a short- and long-term perspective.

**Study limitations**

The major limitation of this study is the fact that it was performed purely observational, non-randomized, and not in a prospective fashion. Both cohorts were evaluated and compared retrospectively. The selection of retrospective cohorts is problematic. Even with years of experience, the technology and the techniques improve over time. Thus, it may not be accurate to compare radiation exposure in a present cohort with that in a historical cohort that was investigated earlier. A prospective study design randomizing patients to either 2D TEE or RT 3D TEE would be preferable. Another limitation of this study might be the fact that the reduction in radiation can also in parts be explained by the overall learning curve of device closure of interatrial defects.

RT 3D TEE represents a technological solution for many of the drawbacks of conventional 2D TEE and 3D off-line reconstruction techniques. Despite its clinical value, this methodology is not devoid of limitations. It is currently restricted by a relatively low temporal resolution (38–50 ms) compared with conventional 2D TEE with a temporal resolution of <10 ms, which in certain clinical situations might be a limitation. Similarly, spatial resolution is also lower to that provided by high-end 2D systems. In addition, on-line measurement of 3D distances and volumes has not yet been implemented. Current measurements have to be made off-line using dedicated software. Another limitation is the fact that in its current phase of development, it slightly prolongs the length of the TEE. This was also corroborated by a recent study performed by Sugeng et al.19 and is likely due to the learning time required with the new probe.

**Conflict of interest:** none declared.

**References**


