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BRIEF COMMUNICATION

Transthoracic echocardiography monitoring during atrial septal defect and ventricular septal defect device closures using a three-dimensional printed transducer holder

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Abstract: Transthoracic echocardiography (TTE) is noninvasive but can only be performed intermittently during fluoroscopy. In a prior study, we created a transducer holder device to allow for hemodynamic monitoring in the intensive care unit. The current study is the first instance of the use of a three-dimensional (3D)-printed TTE transducer holder, which is easily customized and personalized to a previous transducer holder at relatively low cost and short production time, to enable continuous TTE monitoring during device closure of an atrial septal defect (ASD) and ventricular septal defect (VSD). There were 14 ASD patients and 9 VSD patients scheduled to undergo device closure. The study's real-time TTE monitoring was performed by using a 3D-printed transducer holder over the course of the entire implantation procedure. There were 23 patients who successfully underwent septal closures using the 3D-printed holder that enabled real-time images over the entire procedure. The median duration for real-time TTE guidance was 15 minutes for the ASD and 36 minutes for the VSD and the median fluoroscopy time was 11 minutes for the ASD and 30 minutes for the VSD. One migrating VSD occluder and one case of aortic regurgitation after occluder deployment were noted by real-time TTE monitoring during the procedure. Our novel 3D-printed transducer holder can provide transesophageal echocardiography-like real-time imaging during device closure of an ASD and a VSD and may become a new alternative method in ASD and VSD closures. It can also prevent radiation exposure for the intervention team who would otherwise need to perform TTE during live fluoroscopy.

Keywords: 3D printed transducer holder device; Real-time transthoracic echocardiography monitoring; Transcatheter closure of ASD or VSD.

1. INTRODUCTION

Device closure of septal defects in congenital heart disease has been rapidly increasing worldwide. Transesophageal echocardiography (TEE) has become the main imaging technique for guiding device closure of a ventricular septal defect (VSD) or an atrial septal defect (ASD).[1–13] Since it is noninvasive, transthoracic echocardiography (TTE) has the advantage of avoiding general anesthesia but can only be performed intermittently under fluoroscopy. In a prior study, we created a transducer holder to allow for hemodynamic monitoring in the intensive care unit (ICU).[14] The novelty of the current study is the implementation of a novel 3D-printed TTE transducer holder, which is more easily customized and personalized compared to previous transducer holders at relatively low cost and short production time that can continuously offer important guidance during ASD and VSD device closures in real time.

This study was designed to evaluate the feasibility and safety of this novel 3D-printed transducer holder to provide real-time imaging during device closure of ASD and VSD.

2. METHODS

2.1. The 3D-printed transducer holder

A 3D-printed transthoracic transducer holder was made by scanning an existing transducer into digital 3D print files. The transducer was scanned by an Ertec EVA scanner. A Stratasys J750 (Ever Young BioDimension Corp, Taichung, Taiwan) was used for printing the transducer holder (Fig. 1). The 3D-printed transducer holder was molded with resin using 30° hardness. The device has a broad-brimmed part for skin attachment (44 mm) and a high-tubed portion that spans two-thirds the length of the transducer for transducer grabbing. The ductility of the resin material allows the transducer to be rotated freely to acquire a long- or short-axis parasternal view. A disposable gel-skin patch using Adapt barrier rings (Hollister 7806, Hollister Incorporated, Stuarts Draft, VA, USA) secures the holder to the patient's chest (Fig. 2).

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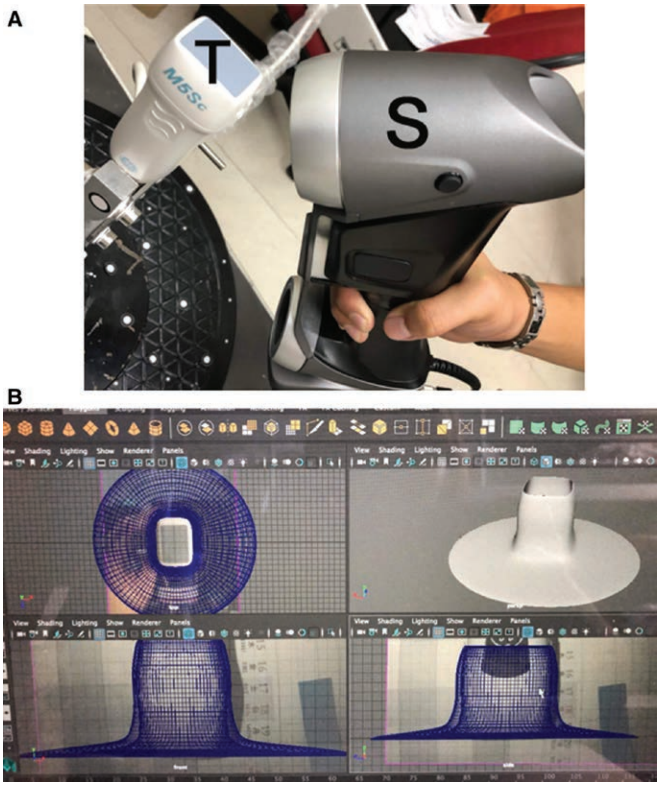

Fig. 1 Three-dimensional printed transducer holder device. A, The transducer (T) was scanned by Ertec EVA scanner (S). B, Printed by Stratasys J750 printer.

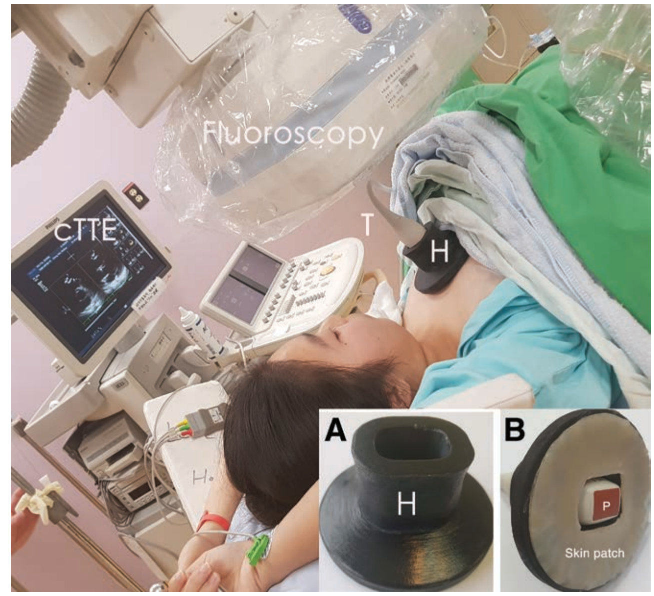

Fig. 2 A 6-year-girl with atrial septal defect underwent device closure using 3D printed transducer holder- transthoracic echocardiography (TTE) monitoring system. Three-dimensional (3D) printed holder (H) (red dotted circle line) gripped the Philip X5-1 transducer (long arrow) (connected with Philip iE33 Philips Healthcare, Andover, MA) placed at left 2nd-4th intercostal space to perform real-time TTE monitoring (parasternal view) during the device closure procedure under live fluoroscopy. (A) Close-up view depicting the 3D printed transducer holder (H). (B) The bottom view of the transducer holder with a disposable gel skin patch. T= transducer.

2.2. Echocardiography protocol

Our 3D-printed transducer holder is specifically designed for the Philip X5-1 transducer, which connects to Philips iE33 (Philips Healthcare, Andover, MA). TTE was performed before catheterization to obtain the desired images for real-time TTE monitoring during the procedure. The left parasternal view is the preferred image for delineating the atrial and ventricular septum.

2.3. Patients

This study's protocol was approved by the Institutional Review Board (Cheng Hsin General Hospital (CHGH-IRB 655107-27). All patients (or their parents or guardians) gave written informed consent before participation in the study. From June 1, 2019, a total of 23 consecutive patients with a secundum ASD or a perimembranous VSD who had undergone device closure were enrolled. All study participants underwent standard monitoring of blood pressure, heart rate, and oxygen saturation. The device implantation was performed as previously described.[1,9] In our study, the implantation procedure was performed under deep sedation (midazolam and ketamine) in spontaneously breathing pediatric patients aged <15 years.[15] Conscious sedation was used with local lidocaine anesthesia in the groin for the patients >15 years. The transthoracic transducer using a 3D-printed transducer holder was placed in the left chest wall at the 2nd-4th intercostal space to obtain the modified four-chamber view (Fig. 3). Real-time TTE images were used to guide the procedure and monitor for any complications. The same 3D-printed transducer holder was used in all patients.

3. RESULTS

Our study included 14 patients with an ASD (median age, 13 years [range: 3-70]; median weight, 45 kg [range: 3-59]; median ASD size, 8 mm [range: 4-24]) and 9 patients with a VSD (median age, 11 years [range: 1-37]; median weight, 40 kg [range: 10-57]; median VSD size, 3.5 mm [range: 3-4.5]). All devices were implanted in 23 patients with an ASD or a VSD under the guidance of fluoroscopy and real-time 3D-printed transducer holder-TTE monitoring. Real-time TTE images provided guidance during the procedure on the size of the defect, crossing of the guided wire, balloon sizing, the delivery of the catheter, deployment of the device, as well as assessments on its position for closure of the ASD (Fig. 3) or the VSD (Fig. 4). The septal occluder was released only after confirming from real-time TTE monitoring that the device was correctly positioned without residual shunting. No complications related to the 3D-printed transducer holder occurred during the procedure. The median size of the implanted Amplatzer (AGA Medical Corporation, MN, USA) Septal Occluder for the ASD was 10.5 mm (range: 6-28). Two 16-mm "Cribriform" septal occluders were used for patients with a fenestrated atrial septum. The median duration for real-time TTE guidance was 15 minutes (range: 12-50) and the median fluoroscopy time was 11 minutes (range: 8-25). Meanwhile, the median size of the implanted ADOII occluder for the VSD was 4 mm (range: 3-5) × 6 mm (range: 4-6). The median duration for real-time TTE guidance for the VSD closure was 36 min (range: 20-60) and the median fluoroscopy time was 30 min (range: 15-45). One ADOII occluder (4 × 3 mm) migrated into the right ventricle after the occluder was deployed. This was promptly noted by real-time TTE monitoring (Fig. 5A) and the occluder was retrieved and a larger (6 × 4 mm) occluder was successfully reimplanted. One case was converted to surgical intervention due to the presence of aortic regurgitation after ADOS II deployment (Fig. 5B).

4. DISCUSSION

TTE can only be performed intermittently, precluding continuous imaging monitoring. Our previous report showed that a tailored

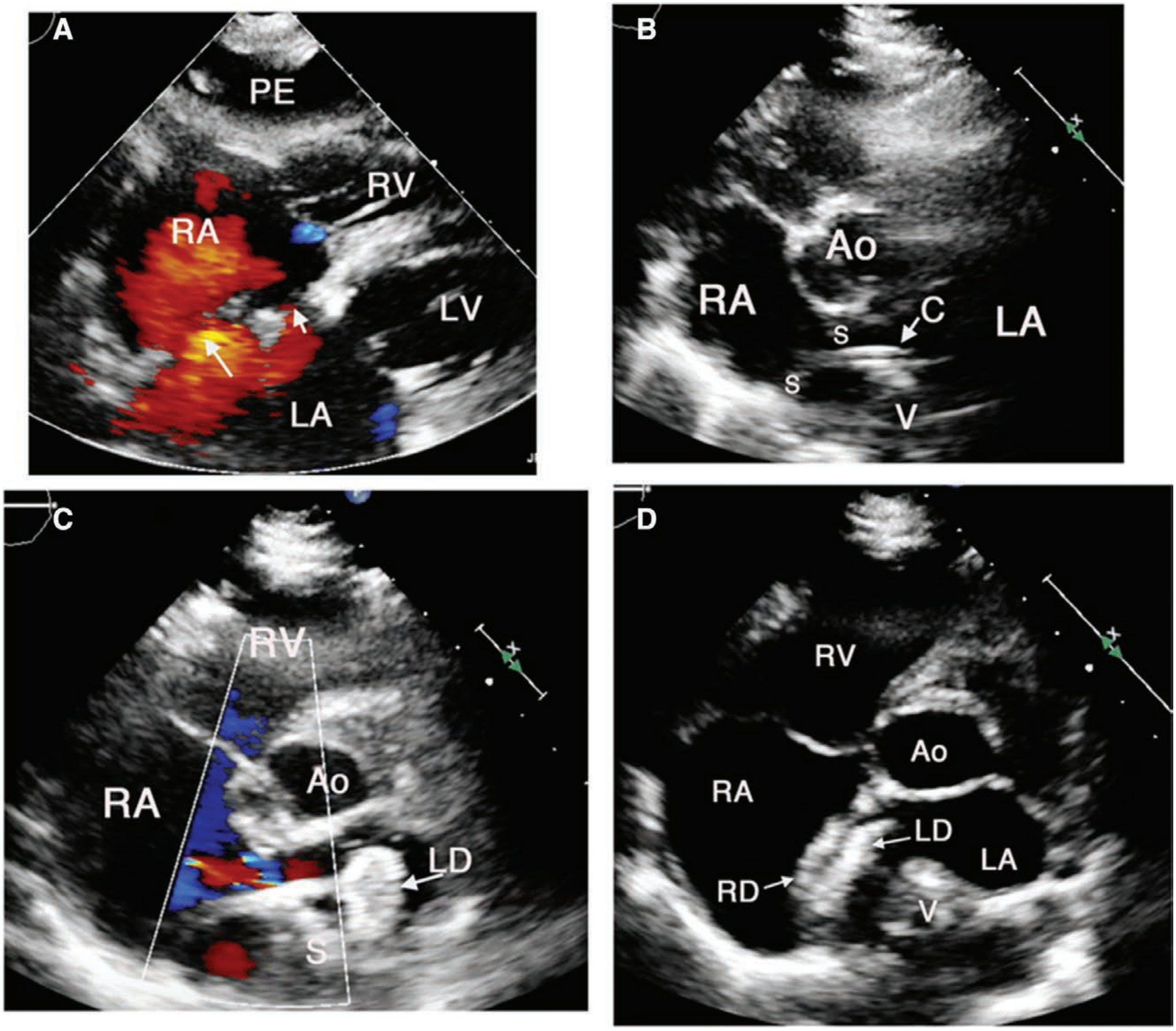

Fig. 3 The corresponding real-time TEE monitoring system in Fig. 2. (A) The modified parasternal four- or five-chamber view of three-dimensional printing holder-transthoracic echocardiography (TTE) monitoring demonstrates mild pericardial effusion (PE) and two ASDs (3 mm denoted by the short arrow and 8 mm denoted by the long arrow). (B) The delivery cable (C) was advanced through the atrial septal defect into the left atrium (LA). (C). The LD of the Amplatzer (AGA Medical Corporation, MN, USA) Multifenestrated Septal Occluder ("Cribriform") was deployed in the LA. (D). The occluder was correctly positioned and successfully released. Ao = aorta; LD = left disc; LV = left ventricle; RA = right atrium; RD = right disc; RV = right ventricle; S = septum; V = vertebrate body.

transducer holder can be successfully used in ICU patients undergoing open heart surgeries for continuous echocardiography monitoring postoperatively for 24 hours.[14] It is also noninvasive and more feasible in ICU patients without intubation. This study showed that additionally, real-time 3D-printed transducer holder-TTE monitoring can provide guidance during ASD and VSD device closure under live fluoroscopy. In this study, one case of occluder migration and one case of aortic regurgitation after deployment were noted by real-time TTE monitoring. The complications during the procedure were detected promptly and treated without delay.

3D printing has already been used successfully in several medical applications, including the manufacture of eyeglasses, custom prosthetic devices, surgical implants, and hearing aids.[16,17] The advantage of 3D printing in medicine is being able to easily produce customization and personalization according to different transducer models. It is also fast to design and to manufacture at a relatively low cost. The manufacturing of a 3D-printed holder takes 4 hours to make and costs USD 100 for each.

TEE is the main imaging technique during device closure procedures. While effective, TEE is semi-invasive and requires general anesthesia and endotracheal intubation, which can prolong the procedural time, resulting in increased patient risk and overall cost. In contrast, real-time TTE monitoring is noninvasive and easily tolerated, making it suitable for a minimalist approach to device closure procedures.

In conclusion, this novel, customized 3D-printed holder has the potential to revolutionize patient monitoring by providing real-time monitoring during device closure of an ASD and a VSD. The nature of this 3D-printed transducer holder allows the use of any commercial transducer. This real-time TTE monitoring system not only provides real-time cardiac imaging guidance during ASD and VSD closures and early detection of any complications but also prevents radiation exposure to the intervention team (mainly through ultrasonography) who would otherwise need to perform the TTE during live fluoroscopy. The main drawback of this tool is that it is not suitable for subcostal projection.

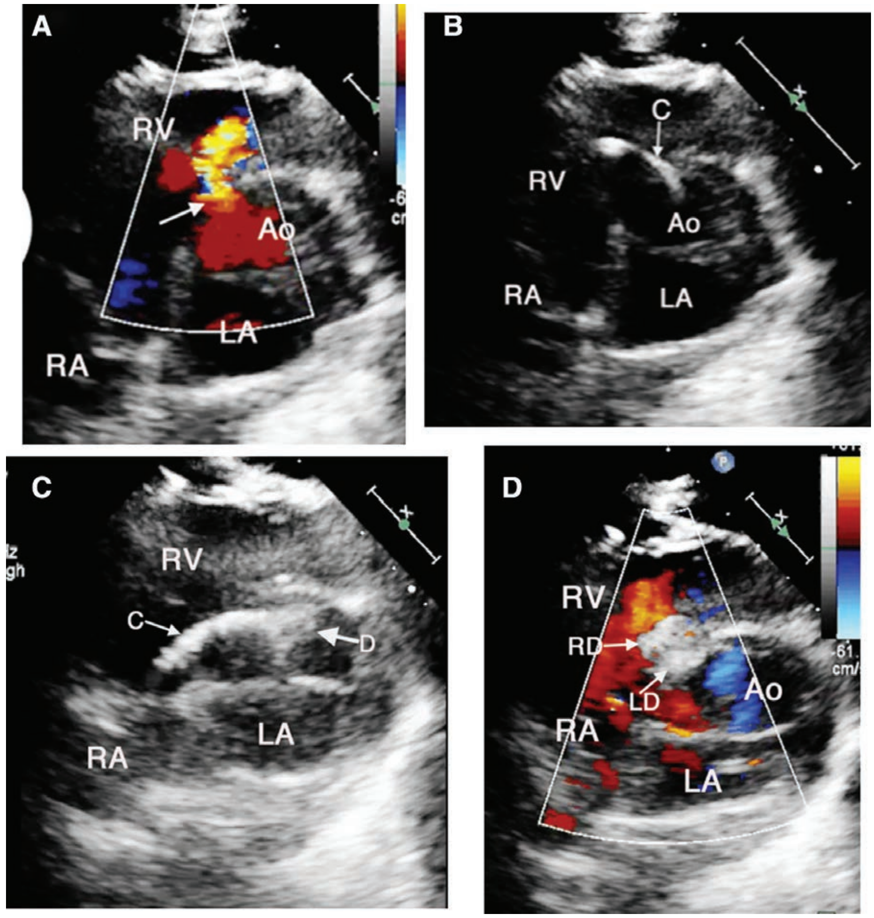

Fig. 4 Three-dimensional printed holder-transthoracic echocardiography (TTE) monitoring in an 8-year boy with ventricular septal defect (VSD) underwent device closure with 3 × 6 mm Amplatzer (AGA Medical Corporation, MN, USA) ductal occluder. The modified parasternal short-axis view showing (A) preoperative echocardiographic determination of the VSD size (3 mm in diameter) and location (arrow); (B) the guide wire was steered to enter the right ventricle (RV) through the VSD; (C) release of the left ventricular side of the occluder (D) both the disks of the occluder were released and the Doppler displayed no residual shunt and no aortic regurgitation. AO = ascending aorta; C = Cable; D = occluder disc; LA = left atrium; LD = left disc; LV = left ventricle; RA = right atrium; RD = right disc; RV = right ventricle.

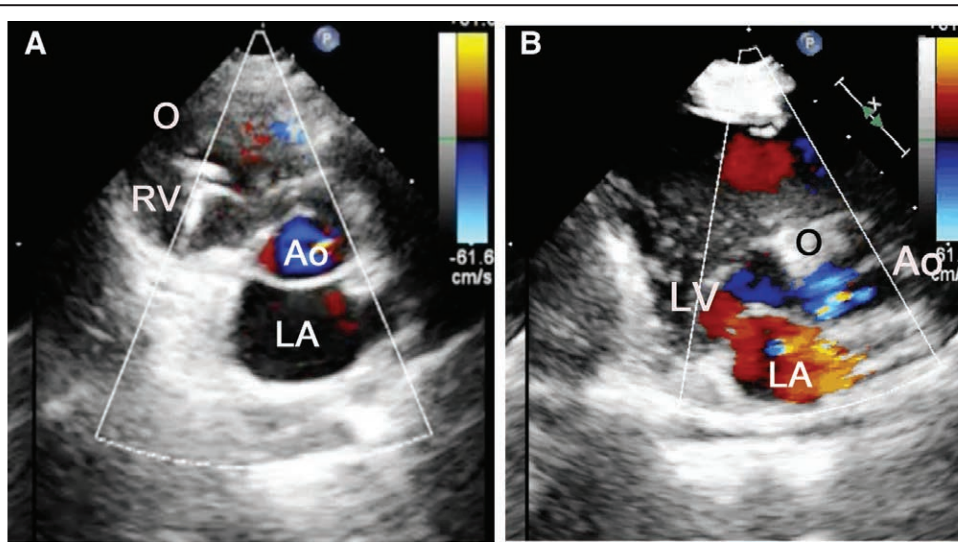

Fig. 5 The complications during ventricular septal defect closure were (arrow) noted by three-dimensional printed transducer holder-transthoracic echocardiography (TTE) monitoring. (A) One Amplatzer (AGA Medical Corporation, MN, USA) ductal occluder (ADO) II (4 × 3 mm) migrated into right ventricle (RV;) after occluder deployed was noted, which was retrieved and (arrow) successfully reimplanted with a larger occluder (6 × 4 mm). (B) One procedure was converted to surgical intervention due to the presence of aortic regurgitation after ADOS II deployed (arrow). LA = left atrium; LV= left ventricle; O = occluder; RA = right atrium.

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