Experience with the largest custom-made 48 mm fenestrated atrial septal occluder device and its 4-year follow-up

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ABSTRACT

Atrial septal defects (ASDs) measuring <38 mm are referred for transcatheter closure. Availability of larger devices up to 46 mm extended the inclusion criteria. An elderly hypertensive male with a 44 mm secundum ASD and coexistent sick sinus syndrome and atrioventricular (AV) nodal block presented with syncope. Balloon interrogation unmasked restrictive left ventricular (LV) physiology. After AV synchronous pacing, balloon-assisted deployment of a custom fenestrated 48 mm Figulla septal occluder (Occlutech Inc., Schaffhausen, Switzerland) prevented a rise of LV end-diastolic pressures beyond 12 mmHg. Echocardiogram and computed tomography after 4 years confirmed a patent fenestration and favorable remodeling. This report of the clinical use of the largest ASD device demonstrated the feasibility of closure of extremely large defects despite a restrictive LV.

Keywords: Fenestrated device, largest atrial septal occluder device, nitinol septal occluder, restrictive left ventricular physiology

INTRODUCTION

Transcatheter closure of secundum atrial septal defect (ASD) measuring <38 mm is a preferred treatment strategy if the margins are adequate.[1] Availability of 42–46 mm occluders allowed the inclusion of defects up to 42 mm.[2] A custom fenestrated 48 mm septal occluder was used to successfully treat an elderly hypertensive male with a large 44 mm secundum ASD and restrictive left ventricular (LV) physiology. This report presents the 4-year follow-up imaging of the largest device used in clinical practice in the literature.

CASE REPORT

Echocardiogram in a 69-year-old hypertensive male presenting with an episode of syncope showed 44 mm × 36 mm transversely oval secundum ASD and moderate pulmonary hypertension. The retroaortic rim was absent and the posteroinferior margin measured 5–6 mm. Even though neurological evaluation and neuroimaging were normal, he was initiated on levetiracetam for abnormal electroencephalogram. There was sinus bradycardia with varying atrioventricular (AV) nodal blocks on electrocardiogram. Holter monitoring showed sinus pauses longer than 2 s with high-grade AV block. Hemodynamic assessment showed 4.3:1 left-to-right shunt, mild hyperkinetic pulmonary hypertension, atrial "a" and "v" waves of 10 mmHg, and mean atrial pressure of 7 mmHg. When the stop-flow size of ASD measured 43 mm on balloon interrogation, the left atrial pressure measured with a catheter across the defect into the left upper pulmonary vein increased to 30 mmHg with "v" waves of 55 mmHg indicating a

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restrictive LV physiology [Figure 1]. This pressure rise was additionally contributed by junctional bradycardia. Dual-chamber permanent pacing was done to correct the bradyarrhythmia. A coronary angiogram showed insignificant atherosclerosis. He was treated with diuretics, ramipril, aspirin, and statins. Antiepileptics were discontinued.

After 3 months, ASD device closure was planned with a 48mm Figulla septal occluder (Occlutech Inc., Schaffhausen, Switzerland) with a left atrial disc measuring 64 mm and right atrial disc measuring 58 mm and a custom-made 8 mm fenestration. The institutional review board permitted the use of the large device. A long 16F braided Mullins sheath (Cook Medical, Bloomington, IN, USA) positioned in the left pulmonary vein across the ASD entangled the leads. After identifying the sheath to be anterior to the leads on a lateral view, the sheath was withdrawn and positioned posterior to the leads, preventing an interaction between the sheath and the lead [Figure 2]. The LV end-diastolic pressures increased to 12 mmHg after the fenestrated device release, deployed using balloon-assisted technique [Figure 3]. The interatrial gradient across the fenestration was 6 mmHg. He was continued on aspirin, atorvastatin, and ramipril for hypertension. He was asymptomatic at 4 years of follow-up. A recent echocardiogram showed stable device position, normal pulmonary artery pressures, and a patent fenestration with left-to-right flows [Figure 4]. Computed tomography after 4 years showed good cardiac remodeling with normal right-sided chambers. The device waist measured 46 mm and the left atrial disc measured 62 mm [Figure 5]. There were no postprocedural complications. Electrocardiogram demonstrated a synchronous atrioventricular paced rhythm.

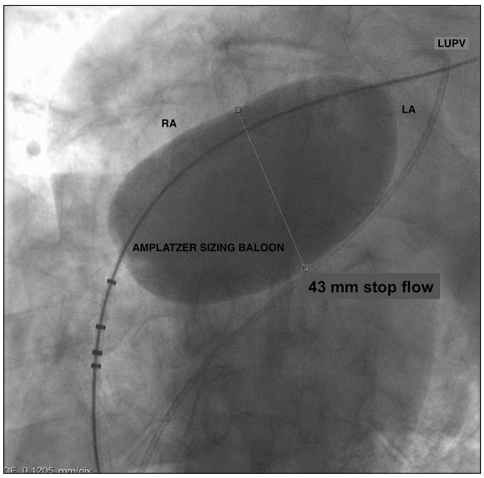

Figure 1: The large atrial septal defect measured 43 mm using the stop-flow technique on a sizing balloon interrogation even though no waist was noted. Creation of waist between LA and RA was avoided to prevent a tear of the small posteroinferior margin. A parallel catheter placed in the LUPV showed elevation of LA pressure from 7 mmHg to 30 mmHg. LA: Left atrium, RA: Right atrium, LUPV: Left upper pulmonary vein

DISCUSSION

Device closure of ASD is preferred to surgery for appropriate defects <38 mm.[1] Defects beyond this size are referred as extremely large ASD.[2,3] Such defects are often associated with rim deficiencies. Devices larger than 40 mm but up to 46 mm have been shown to be safe and effective, without any significant increase in the incidence of erosions, atrial arrhythmias and AV nodal conduction blocks, thromboembolism, and postprocedural headaches.[2]

Our patient had an extremely large ASD with an absent retroaortic margin as well as a small 5–6 mm posteroinferior margin. The stop-flow diameter on balloon interrogation was 43 mm and the transverse diameter of the oval defect on transesophageal echo was 44 mm. Considering the small posteroinferior margin, the defect needed at least a large 48 mm device.[4] Device closure was planned due to high surgical risks in the elderly patient with restrictive left ventricle and permanent pacing leads.

Unlike devices up to 46 mm that require up to 14F delivery sheaths, a 48 mm device needed a relatively rigid large braided 16F sheath. As the right ventricular lead through the tricuspid valve was anatomically anterior to the oval fossa, the sheath should be positioned

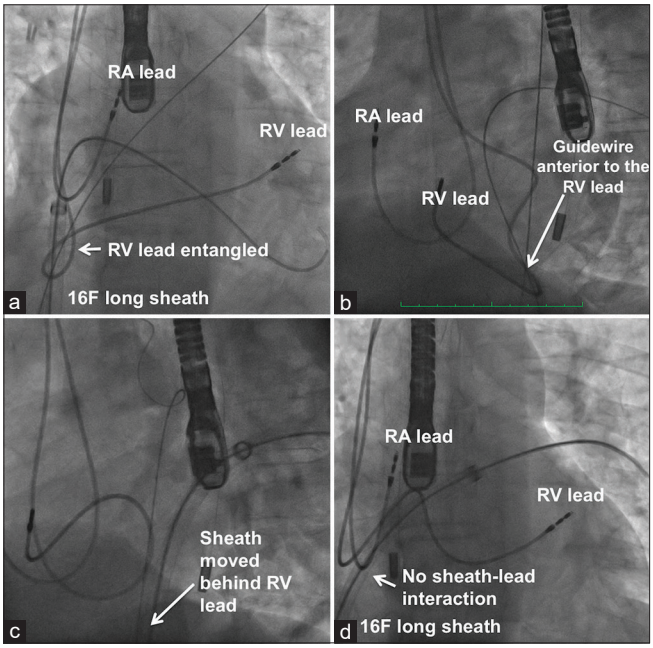

Figure 2: The large 16F delivery sheath entangled with the RV lead (a). Its anterior relation was recognized on a lateral view (b) and the sheath was repositioned posteriorly (c). This maneuver prevented an interaction between the sheath and the lead (d). The more superiorly located RA lead did not cause any interference. RV: Right ventricular, RA: Right atrial

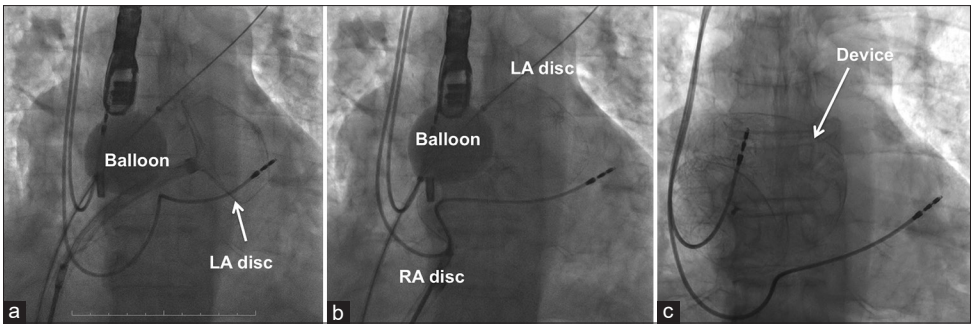

Figure 3: Balloon-assisted technique (a) was utilized for deploying the LA disc followed by the RA disc (b). Final position of the device after withdrawal of the balloon was shown in (c). LA: Left atrium, RA: Right atrium

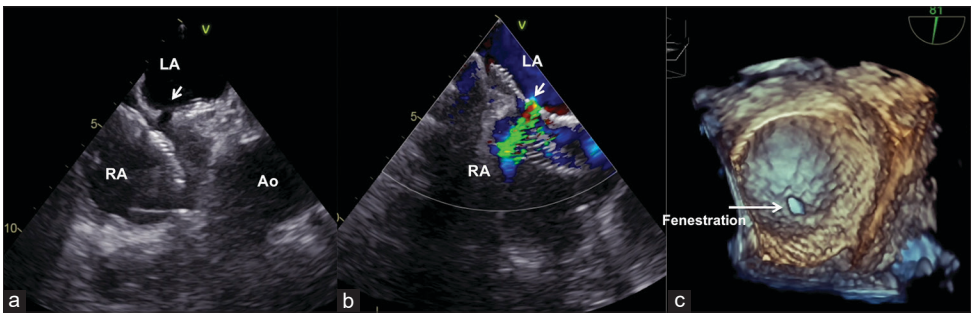

Figure 4: Transesophageal echocardiogram after 4 years (a) showed the fenestration (arrow), with color flows (b) from the LA to the RA. Three-dimensional echocardiogram (c) showed the fenestration in the left atrial enface view. LA: Left atrium, RA: Right atrium

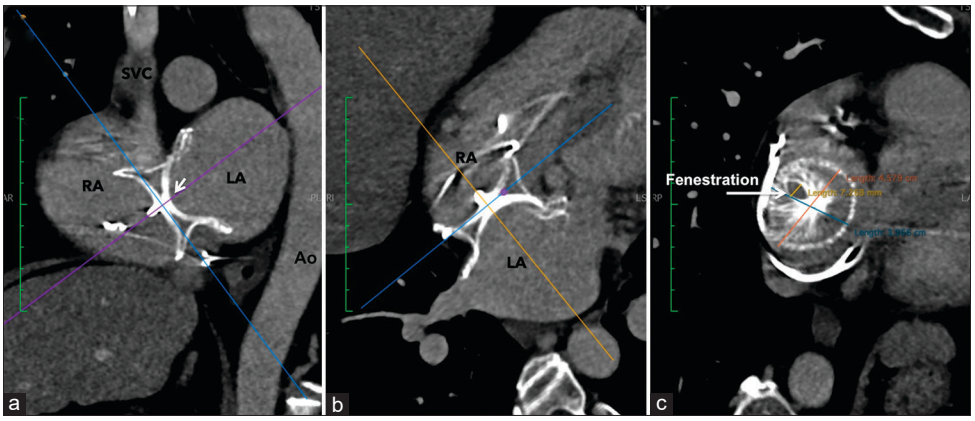

Figure 5: Multiplanar reformatted computed tomographic images in modified sagittal (a), axial (b), and coronal (c) views demonstrated good remodeling of the RA. The device waist measured 46 mm in the coronal plane and fenestration measured 7 mm. RA: Right atrium

posterior to the lead. This was not recognized initially on fluoroscopy in anteroposterior projection, leading to a brief lead entanglement. Balloon-assisted technique was followed to prevent the prolapse of the large device into the right atrium.[5] Oval fossa defects might coexist with electrical disorders causing malfunction of the sinus node and AV node.[6]

Follow-up after transcatheter device closure using a custom-made 48 mm device has not been published so far, to the best of our literature search. A poster presentation from Cairo University Hospital reported an acute procedural result of the same fenestrated 48 mm Occlutech occluder in a patient with a 39 mm defect associated with severe pulmonary hypertension.[7] A different form of a 48 mm nitinol septal occluder was used for hybrid peratrial device closure, where the technique used a large sheath through an atrial purse string using ministernotomy.[8] The right atrial hub of this device was attached to a suture to enable surgical retrieval, indicating a different design altogether from the routine transcatheter devices.

Elevated LV end-diastolic pressures might be seen as a part of normal aging in elderly patients due to negative LV remodeling, and additionally provoked by mild coronary atherosclerosis, hypertension, and AV dyssynchrony in our patient.[9] Custom fenestrations

prevented an abrupt hemodynamic change after ASD closure.[10] Clinicians should have a cautious lookout for diastolic dysfunction and elevation of left heart pressures in elderly patients even years after the device closure.

CONCLUSION

This first report of intermediate-term follow-up after device closure of an extremely large secundum ASD with a custom fenestrated 48 mm occluder in a patient with severely restrictive LV physiology demonstrates the safety and feasibility of very large occluders in clinical practice.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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