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Transcatheter Closure of an Atrial Septal Defect by Using a Self-Fabricated Fenestrated Ceraflex Occluder in an Elderly Patient with Concomitant Mitral Regurgitation

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Abstract

In recent years an increasing number of elderly patients resort to transcatheter treatment of their congenital heart lesions. Atrial Septal Defect (ASD) closure in cases of coexisting left ventricular dysfunction and/or left valvular disease carries the risk of pulmonary congestion, hence implantation of a fenestrated device is a therapeutic option in these cases. We present a symptomatic 74-year-old patient with a large secundum ASD and concomitant moderate to severe mitral regurgitation, pulmonary hypertension, as well as severe tricuspid regurgitation. After thorough analysis of possible treatment options by the Heart Team, a transcatheter ASD closure by using a self-fabricated fenestrated CeraFlex ASD occluder (LifeTech Scientific Co., Shenzhen, China) was performed. This led to a significant reduction of the tricuspid regurgitation and amelioration of patient symptoms. This unique case underlines the feasibility, safety and efficacy of a hand-made fenestrated device for ASD closure in patients with moderate to severe mitral regurgitation.

Keywords: Atrial septal defect; Mitral regurgitation; Tricuspid regurgitation; Pulmonary hypertension; Fenestrated occluder device

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Introduction

Atrial Septal Defect (ASD) constitutes a congenital heart lesion commonly found not only in the pediatric population but also in adults, mainly because they may remain asymptomatic until adulthood [1]. When symptoms develop, they usually present as exertional dyspnea, fatigue or palpitations indicative of cardiac arrhythmia [1]. If left untreated the ASD may lead to right heart failure. Recent guidelines recommend ASD closure in cases of enlargement of the Right Ventricle (RV), provided there is no irreversible Pulmonary Hypertension (PHTN) or Left Ventricular (LV) disease [2]. Elderly people with ASD frequently have concomitant LV disease and PHTN due to comorbidities such as left chamber valvular disease or arterial hypertension leading to LV diastolic dysfunction. This carries the risk of acutely developing congestive heart failure after ASD closure and renders the benefit of the procedure in this population uncertain [3-6]. Most recent data suggest that ASD closure, even at an advanced age, can lead to favorable cardiac remodeling as well as to functional class improvement, mentioning however that partial occlusion with a fenestrated device could be better tolerated in selected patients with significant LV disease/PHTN [7-11].

We report the management of an elderly patient, inoperable by conventional surgical techniques, with a large secundum ASD and elevated LV filling pressures due to moderate to severe Mitral Regurgitation (MR).

Case Presentation

A 75-year-old woman was admitted to our Center complaining of severe dyspnea on exertion and swelling of lower extremities. Her past medical history included permanent atrial fibrillation, a known large secundum ASD, chronic kidney disease and a recent hospitalization for dyspnea which responded to intravenous diuretics. On admission, physical examination revealed a 3/6 systolic murmur at the lower sternal border, bilaterally decreased breath sounds, a palpable liver and severe lower limb edema. An electrocardiogram showed atrial fibrillation with right axis deviation and a narrow QRS. NT-proBNP levels were remarkably elevated (3.236 pg/ml- upper limits 125 pg/ml). Transthoracic (TTE) and Transesophageal Echocardiogram (TEE) confirmed the presence of a secundum ASD with a significant left to right shunt and prolapse of the anterior mitral valve leaflet

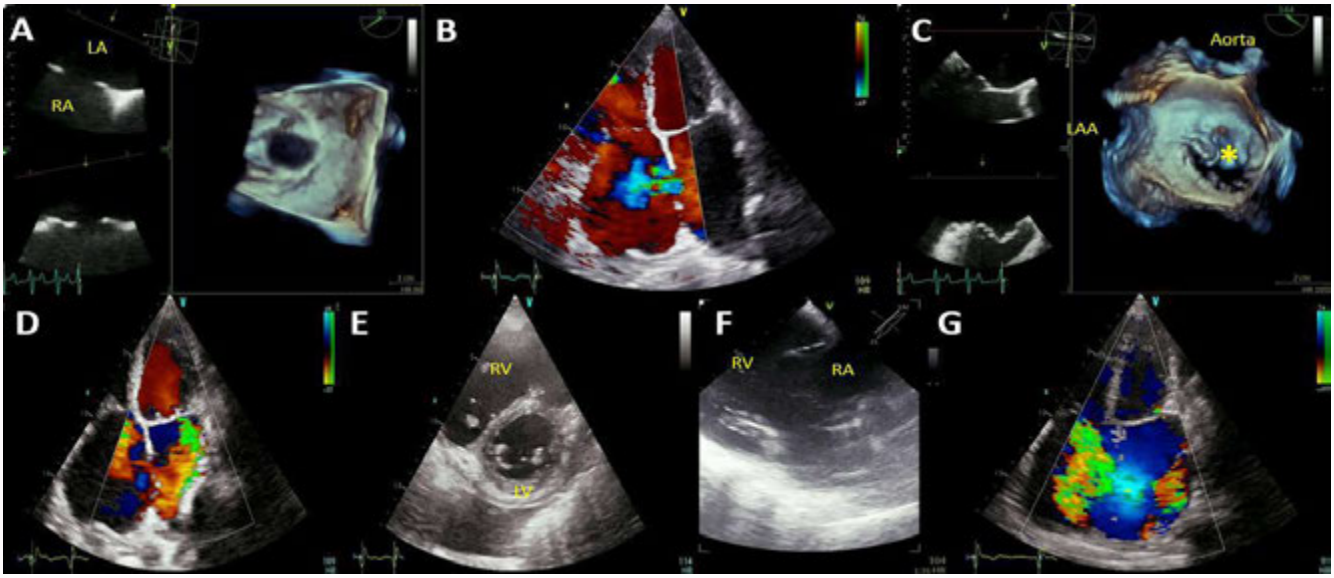

Figure 1: Transthoracic and transesophageal echocardiogram views showing a large secundum atrial septal defect (A), with left to right shunt (B), prolapse of A2 scallop of the anterior mitral valve leaflet (C) leading to a moderate to severe mitral regurgitation (D), D-shape of the left ventricle as well as right ventricular enlargement (E) and dilatation of the tricuspid valve annulus (F) causing severe tricuspid regurgitation (G).
LA: Left Atrium; RA: Right Atrium; LAA: Left Atrial Appendage; *: Prolapsing A2 Scallop

Figure 2: Cardiac CT showing atrial septal defect and small remaining posterior wall dimensions (arrow).
*: Atrial Septal Defect; LA: Left Atrium; RA: Right Atrium

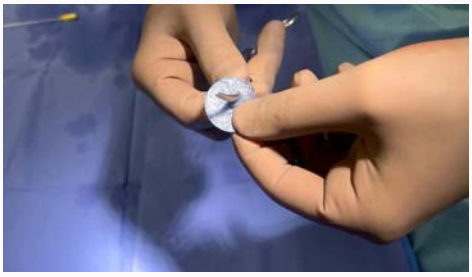

Figure 3: Ceraflex occluder device fenestration.

(A2 scallop) leading to a moderate to severe MR (EROA 0.34 cm^2, Regurgitant Volume 51 ml) (Figure 1A-1D). The RV was dilated with moderately reduced systolic function [RV systolic excursion velocity (RVS') 8 cm/sec], while the Left Ventricle showed preserved Ejection Fraction (LVEF 55%) and D-shape morphology due to volume overload (Figure 1E). Furthermore, severe TR was documented (EROA 0.4 cm^2), caused by dilation of the tricuspid valve annulus and volume overload due to the presence of the ASD (Figure 1F, 1G). Right-heart catheterization showed mainly post-capillary PHTN (mean pulmonary artery pressure 38 mmHg, wedge pressure: 25 mmHg, pulmonary vascular resistance 3.17 and 2 WU pre and post oxygen administration respectively) and a hemodynamically significant ASD with a calculated Qp/Qs of 2.1. Coronary angiography revealed minimal non-obstructive CAD. Being a high surgical risk patient for combined intervention on mitral, tricuspid valve and ASD (Euroscore II 8.54), the Heart Team suggested the transcatheter management. An initial intervention for tricuspid regurgitation was considered redundant due to its secondary nature. Transcatheter mitral Edge-to-Edge Repair (TEER) was also rejected as a first-line therapeutic option because of the expected instability of the clip delivery system through the large interatrial defect. Transeptal puncture of the septum posteriorly to the ASD was considered unfeasible, based on the patient's anatomy after cardiac CT (Figure 2).

Consequently, ASD closure was decided as a first-line of intervention, with possible transcatheter mitral/tricuspid repair later, if needed. Following latest guidelines, a balloon occlusion testing with simultaneous right atrial, pulmonary arterial, Pulmonary Capillary Wedge (PCWP) and left ventricular measurements was conducted before ASD closure revealing a 7 mmHg (from 23 to 30 mmHg) increase in PCWP without signs or symptoms of pulmonary oedema (Table 1). However, due to the elevated wedge pressure, it was decided to use a fenestrated device. The fenestration was self-fabricated by creating a 4 mm-diameter hole in the 22 mm CeraFlex occluder device that was chosen (Figure 3). The device was placed uneventfully.

Results

After the procedure, the patient remained in good clinical condition without signs or symptoms of LV decompensation. TTE performed on the first postoperative day revealed a whiff of left to right flow through the created hole. Two months later the patient reported remission of the peripheral oedema and significant clinical improvement (now being in functional NYHA I class). This was

Table 1: Balloon occlusion testing: simultaneous right atrial, pulmonary arterial, pulmonary capillary wedge and ascending aorta pressure measurement in different conditions.

	Condition I (baseline)		Condition II (ASD occlusion)		Condition III (17 min after occlusion)	
PVR	3.17 wood units					
Qp/Qs	2.1		1.0		1.0	
	Oximetry (%)	**Pressures** (mmHg)	**Oximetry** (%)	**Pressures** (mmHg)	**Oximetry** (%)	**Pressures** (mmHg)
SVC	73	18	68	18	71	17
IVC	64					
Mid RA	85	18	68	18	71	17
RV	85	58/16	68	60/13	71	55/15
PA	85	58/22/34	68	60/21/34	71	55/23/33
PCW	98	23	97	29	98	30
Ao	98	124/75/91	97	131/76/94	98	129/73/92

PVR: Pulmonary Vascular Resistance; Qp/Qs: Pulmonary Flow/Systemic Flow; SVC: Superior Vena Cava; IVC: Inferior Vena Cava; mid RA: mid Right Atrium; RV: Right Ventricle; PA: Pulmonary Artery; PCW: Pulmonary Capillary Wedge; Ao: Aorta

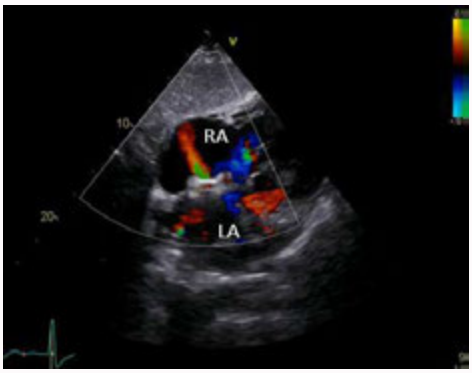

Figure 4: Left to right flow through the created fenestration of the device, 2 months after the procedure.
LA: Left Atrium; RA: Right Atrium

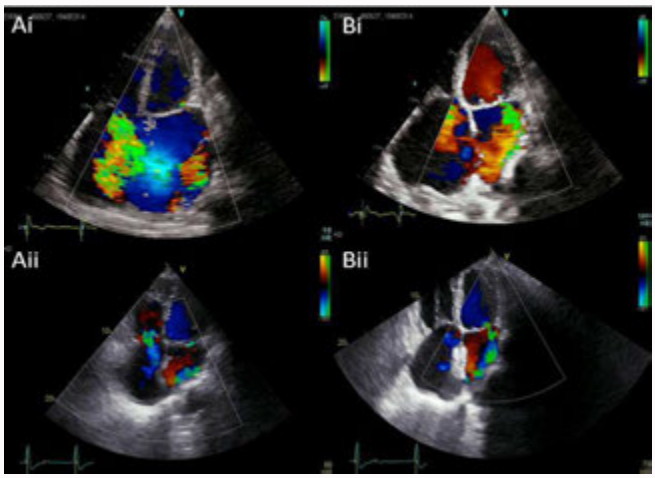

Figure 5: Transthoracic echocardiogram evaluation of Tricuspid (A) and Mitral (B) regurgitation before (Ai, Bi) and 2 months after fenestrated occlusion (Aii, Bii).

accompanied by markedly reduced daily diuretic requirements. TTE showed the still patent fenestration in the occluder (Figure 4) and a significant reduction of TR (now being mild to moderate) and of RV dimensions as well as a decrease of the RV systolic pulmonary pressure by 20 mmHg. The MR severity remained the same (Figure 5A, 5B). NT-proBNP levels were also decreased (800 pg/ml).

Discussion

ASD with significant left to right shunt has been related to an increased risk of morbidity and mortality and current evidence suggests that all ASDs associated with RV dilatation should be considered for closure irrespective of age [1]. The recent guidelines state that closure can improve patient's clinical and functional status at any age, particularly when it is performed by catheter intervention [2]. Moreover, recent developments in closure devices have rendered the transcatheter approach as the treatment of choice in these cases [12-14].

In patients with LV dysfunction, ASD closure can lead to acute hemodynamic changes, increased LV filling pressures and pulmonary congestion [10]. In these cases, a balloon occlusion test before the actual closure for pressure reassessment is recommended, in order to decide among complete, fenestrated or no closure [2]. There are no clear recommendations on how to interpret the balloon occlusion test results. Most authors agree that an increase in PCWP of more than 10 mmHg from baseline or a PCWP above 20 mmHg, as in this case, portends an increased risk for pulmonary edema. They stress however that creating a fenestration in the occlusion device may prevent such abrupt hemodynamic changes [15].

Patients with ASD and PHTN must be carefully evaluated by right heart catheterization and Pulmonary Vascular Resistance (PVR) must be calculated [2]. Generally, in patients with PVR <5 Wood Units (WU), ASD closure is considered safe and associated with a favorable prognosis and a gradual decrease in PHTN. However, even when PVR is <5 WU, patients with PHTN undergoing ASD closure have worse outcome compared to patients without [3]. Partial occlusion with fenestrated devices has also been suggested as an option in these patients with promising results [9,16]. In a recent review the efficacy of fabricated devices was reported in more than 40 patients with LV dysfunction and/or PHTN [9]. However, none of these published cases had concomitant severe MR and in none of them a CeraFlex occluder device was used, as in our case.

TEER is a procedure of evident safety and efficacy for symptomatic patients with severe MR, who are judged inoperable or of high surgical risk [17]. Although performed through a transeptal

approach, the coexistence of a large ASD, as in our patient, creates special technical problems leading to instability of the clip delivery system. In a published case report of a patient with concomitant mitral regurgitation and ASD, the access to the left atrium for clip delivery was achieved not through the defect but *via* a separate transseptal puncture posteriorly [18]. A similar approach was entertained in our patient but was considered as non-attainable due to the small dimensions of the posterior septal wall.

Overall, the optimal treatment for our, inoperable by conventional means, elderly patient with large ASD, coexisting moderate to severe MR and severe TR as well as a dilated RV, was debatable. After rejecting transcatheter intervention for mitral regurgitation and based on the above-mentioned evidence, ASD closure was decided as the first-line of treatment, with the possibility of a later TEER through the occlusion device. Considering the results of the balloon occlusion test, we opted for a self-fabricated fenestrated device in order to unload the left chamber pressures. The best way of creating a fenestration in the occlusion device as well as its optimal size have not yet been clarified. In previous reported cases fenestrations were made with a fixed surgical opening in the device's nitinol mesh or with the placement of a stent to ensure long term patency [19]. In our patient, following the example of other operators, we decided to manually fenestrate the CeraFlex device, accepting the possibility of gradual endothelization with eventual closure, which is not necessarily unfavorable. On the one hand its closure may lead to further decrease of PHTN, while on the other hand it may decrease the possibility of a paradoxical embolism [9,16]. Judging by the significant clinical improvement, at least in the short term, our therapeutic approach is justified.

Conclusion

This case report suggests that transcatheter use of a self-fabricated fenestrated CeraFlex occluder in an inoperable elderly patient with combined secundum ASD, moderate to severe MR and severe TR seems to be feasible, safe and offers clinical improvement.

Disclosures

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