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Newly Designed Custom-Made Occluder For Transcatheter Closure of Post Infarction Ventricular Septal Rupture: A Cutting-Edge Technology

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Brief Summary

Newly designed custom-made occluders for treatment of post infarction ventricular septal rupture may become a cutting-edge technology to overcome the limitations of previous devices.

Abstract

Ventricular septal rupture (PIVSR) remains a lethal complication of acute myocardial infarction. Percutaneous closure is feasible and may provide an alternative treatment option to surgical repair, particularly in the non-acute phase.

Transcatheter closure of PIVSR using innovative custom-made devices may be a promising alternative to high-risk surgery.

Key words: myocardial infarction, ventricular septal rupture, transcatheter closure.
Introduction
We present the case of an 81-year-old woman who underwent percutaneous closure of PIVSR three weeks after the index event with a newly designed custom-made occluder.

Case Description
This female diabetic patient presented at emergency department 36 hours after anterior STEMI. Transthoracic echocardiography (TTE) revealed left ventricle (LV) anterior wall hypokinesia with dyskinetic apical segment, ejection fraction of 40% with angiographically normal coronary arteries. Rapid deterioration of the clinical condition occurred few days later. 2D color Doppler TTE showed normal right ventricle (RV) function and dimensions, moderate tricuspid regurgitation, systolic pulmonary pressure of 55 mmHg and a 12-mm ventricular septal rupture (VSR) located at the apical segment with significant left-to-right shunt (Figure 1. A,B,C). Magnetic resonance imaging with gadolinium contrast showed an apical myocardial dyskinesia without late enhancement excluding necrosis. On day 23, after heart team discussion, we decided to perform transcatheter closure of the rupture with a newly designed custom-made occluder (PIVSD, Occlutech Holding AG, Switzerland) (Table S1; Figures S1, S2). The waist size of the occluder was 8 mm larger than the VSR size. The device consists of two self-expanding discs (left 32 mm, right 30 mm) composed of a nitinol-wire mesh with “shape-memory” properties joined together by a flexible elliptical waist 10 mm in length and 20 mm in diameter. The procedure was performed under fluoro-angiography and TTE guidance. The PIVSR was crossed from left to right ventricle using a retrograde arterial approach (left femoral artery) with a 5F multipurpose catheter and a Terumo wire that was advanced into the superior vena cava, where it was snared via the right jugular vein establishing an arteriovenous rail. The occluder was placed at the appropriate site across the rupture and then released.
Successful implantation was confirmed by TTE and LV angiography (Figure 2). The following day, the clinical conditions improved significantly. 2D color Doppler TTE showed trace of left-to-right shunt (Figure1.D,E,F), while systolic pulmonary pressure dropped to 31 mmHg. Pulmonary/systemic shunt ratio was 1.1/1 with no RV overload. On day 36, the patient was discharged home without complications. Six months later, she remained symptom free and TTE showed correct position of the device with no residual shunt.

DISCUSSION

Transcatheter closure of PIVSR has been reported with different devices, some of them not designed for this purpose with mixed results.\textsuperscript{1-5}. The Amplatzer™ PI Muscular VSD Occluder, specifically designed for post-MI VSR repair, showed implantation success and short-term results superior to the formerly used devices.

The Occlutech PIVSD is a newly designed custom-made device with several innovative features compared to previously technologies. They include unique braiding technology, no distal hub, soft atraumatic self-expanding discs, a welded ball structure on the proximal disc which serves as an adapter for the Flex pusher allowing device self-alignment and a 10-mm compliant, elliptical connecting waist with no radial strength in order to prevent tearing of the defect borders, resulting in a smooth conformability to the septal rupture contours. The shape of the waist has been conceived with the aim of transforming the circular configuration into an elipsoidal one for safe self-expansion into the rupture and for better adaptation to the irregularly serpiginous rupture track.
**Conclusions**

The reported successful case is the result of good clinical pre-procedural management, an innovative device and excellent teamwork.

**Novel Teaching Points**

- Occlutech PIVSD occluder is a newly designed custom-made device with several innovative features compared to previous technologies.
- It may represent a cutting-edge technology to be added to the device armamentarium for PIVSR treatment when hemodynamic condition and rupture morphology are suitable to device closure.

**Funding Sources**

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**Disclosures** : Eustaquito Maria Onorato is a consultant for Occlutech, manufacturer of the device. The remaining Authors declare no conflict of interest to disclose.

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References

1. Calvert PA, Cockburn J, Wynne D et al. Percutaneous closure of postinfarction ventricular septal defect: in-hospital outcomes and long-term follow-up of UK experience. Circulation 2014;129:2395–2402.

2. Shabestari M, Ghaderi F, Hamedanchi A. Transcatheter Closure of Postinfarction Ventricular Septal Defect: A Case Report and Review of Literature. J Cardiovasc Thorac Res, 2015;7:75–77.

3. Barik R. Transcatheter closure of post-myocardial infarction ventricular defect: where are we? Indian Heart Journal 2016;68:99–101.

4. Sabiniewicz R, Huczek Z, Zbroński K et al. Percutaneous Closure of Post-Infarction Ventricular Septal Defects — An Over Decade-long Experience. J Interv Cardiol 2017;30:63–71.

5. Holzer R, Balzer D, Amin Z et al. Transcatheter closure of postinfarction ventricular septal defects using the new Amplatzer muscular VSD occluder: Results of a U.S. Registry. Catheter Cardiovasc Interv 2004;61:196–201.
Figure legends

**Figure 1.** Intraprocedural transthoracic color Doppler echocardiography (TTE). Apical four-chamber views show a 12-mm (bracket) ventricular septal defect located at the apical segment with left-to-right shunt (yellow arrow) (A, B). TTE color Doppler four-chamber views 24 hours post-procedure showing the device (arrowhead) in stable position with only trace left-to-right shunt (white arrow) (C,D).

RV: right ventricle; LV: left ventricle; LA: left atrium.

**Figure 2.** Fluoro-angiography images showing the transcatheter closure procedure “step by step”. Baseline left ventricle angiogram demonstrating a significant left-to-right shunt (white arrow) through a VSR of the apical segment (A). The delivery sheath (arrowhead) was advanced from the right jugular vein across the rupture and the distal disc (black arrow) was opened in the left ventricle (B). Left ventriculography confirming the correct distal disc position towards the septum (C). Connecting waist and proximal disc (black arrow) were opened by retrieving the delivery sheath (D). Post-procedure left ventriculography showing the PIVSD device (white arrow) still attached to the delivery cable (E) and after final release (F).
