# Acute single leaflet detachment following implantation of a PASCAL PRECISION P-10 device and its management

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Early publication date: September 15, 2023 Single leaflet detachment (SLD) is a wellknown complication of transcatheter edgeto-edge repair (TEER) and occurs in up to 5% of procedures [1, 2]. Usually SLD results in mitral regurgitation (MR) recurrence and clinical symptoms worsening. Percutaneous SLD management might be difficult or even impossible, and surgical treatment may be required. We present a patient with acute SLD of PASCAL PRECISION P-10 (Edwards LifeSciences, Irvine, CA, US) that was successfully managed with implantation of two adjacent PASCAL PRECISION ACE devices.

A 73-year-old male with heart failure (New York Heart Association [NYHA] class III) and severe functional MR (effective regurgitant orifice [ERO], 0.5 cm<sup>2</sup>) (Figure 1A, B) due to ischemic etiology was scheduled for a TEER procedure with the PASCAL system. Direct measurement of left atrial pressure (LAP) confirmed significant MR (Figure 1C). A PASCAL P-10 device was implanted in the A2/P2 region. The leaflet optimization technique was used both for the posterior and anterior leaflets to ensure the optimal length of insertion. Nevertheless, despite careful echocardiographic guidance before device release, acute SLD had occurred and led to an immediate recurrence of severe MR. The Pascal P-10 device remained attached to the anterior leaflet only (Figure 1G). Two Pascal ACE devices were then implanted medially and laterally to stabilize the position of the P-10 device (Figure 1H). To avoid a significant mitral gradient, the ACE devices were positioned as close as possible to the initially implanted P-10. The final echocardiographic result was acceptable (Figure 1F) with less than moderate MR, mean mitral gradient (MGM) of 4.2 mm Hg, and full stabilization of



**Figure 1.** Echocardiographic and hemodynamic evaluation before, during, and after the transcatheter edge-to-edge repair (TEER) procedure. **A.** Transthoracic echocardiography with significant functional mitral regurgitation (MR). **B.** Transesophageal echocardiography with significant functional mitral regurgitation (MR). **B.** Transesophageal echocardiography with significant functional MR. **C.** Left atrial pressure before the TEER procedure. **D.** Left atrial pressure after the TEER procedure. **E.** Transthoracic echocardiography at 30-day follow-up. **F.** Immediate intraprocedural echocardiographic result after implantation of two Pascal ACE devices medially and laterally to P-10 with single leaflet detachment. **G.** Single leaflet detachment of the Pascal P-10 device (red arrow points at the gap between P-10 and the posterior leaflet). **H.** Transesophageal appearance of Pascal P-10 stabilized by two Pascal ACE devices (white arrow points at the P-10 device)

the P-10 implant. The hemodynamic response reflected by changes in LAP additionally confirmed the good result of the TEER procedure (Figure 1D). The post-procedural period was uneventful. Follow-up transthoracic echocardiography revealed good and stable results with less than moderate MR and an MGM of 5 mm Hg. The patient was discharged home two days after TEER. At 30-day follow-up, the patient's condition improved to NYHA class I. Echocardiography confirmed the good and stable TEER results. (Figure 1E). The clinical and echocardiographic improvement was also reflected by a decrease in NT-proBNP level from 8874 before TEER to 2111 at 30-day follow-up.

The current report is the first description of SLD in a patient treated with a new-generation device – the PASCAL PRECISION system. The upgraded instrument is considered to provide more precise, predictable, and stable device positioning, which is believed to result in the reduction of the potential risk of clip detachment in comparison with previously implanted systems. In the described case, SLD occurred despite accurate "clocking" and optimal deployment, and its mechanism remains unclear. Nevertheless, we documented that full stabilization of the largest available TEER device (P-10) in the case of SLD occurrence is possible with the use of two additional smaller devices and may result in a satisfactory MR reduction (without creating a significant MGM) and satisfactory clinical outcomes.

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