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

Authors: Aleksandra Mioduszewska, Zbigniew Chmielak, Bohdan Firek, Jerzy Pręgowski
Article type: Clinical vignette
Received: July 27, 2023
Accepted: August 28, 2023
Early publication date: September 15, 2023
Acute single leaflet detachment following implantation of PASCAL PRECISION P-10 device and its management

Aleksandra Mioduszewska, Zbigniew Chmielak, Bohdan Firek, Jerzy Pręgowski

Department of Interventional Cardiology and Angiology, National Institute of Cardiology, Warszawa, Poland

Correspondence to:
Aleksandra Mioduszewska, MD,
Department of Interventional Cardiology and Angiology,
National Institute of Cardiology,
Alpejska 42, 04–628 Warszawa, Poland,
phone: +48 22 34 34 272,
e-mail: amioduszewska@ikard.pl

Single leaflet detachment (SLD) is a well-known complication of transcatheter edge to 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. The percutaneous SLD management might be difficult or even impossible, and surgical treatment may be required. We present the 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.

73-year-old male with heart failure (New York Heart Association [NYHA] class III) and severe functional MR (effective regurgitant orifice [ERO], 0.5 cm²) (Figure 1A, B) due to ischemic etiology was scheduled for TEER procedure with PASCAL system. Direct measurement of left atrial pressure (LAP) confirmed significant MR (Figure 1C). The Pascal P-10 device was implanted in A2/P2 region. The leaflet optimization technique was used both for posterior and anterior leaflet to ensure optimal length of insertion. Nevertheless, despite careful echocardiographic guidance prior to the device release, acute SLD had occurred and led to 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 P-10 device (Figure 1H). To avoid significant mitral gradient, the ACE devices were positioned as close as possible to the initially implanted P-10. The final
echocardiographic result was approvable (Figure 1F) with less than moderate MR, mean mitral gradient (MGM) of 4.2 mm Hg and full stabilization of P-10 implant. The hemodynamic response reflected by changes in LAP additionally confirmed the good result of TEER procedure (Figure 1D). The post-procedural period was uneventful. Follow-up transthoracic echo revealed good and stable result with less than moderate MR and MGM of 5 mm Hg. Patient was discharged home two days after TEER. At 30-day follow-up the patient’s condition improved to NYHA class I. The echocardiography confirmed good and stable result of TEER. (Figure 1E). The clinical and echocardiographic improvement was also reflected by the decrease in NT-proBNP level: from 8874 prior TEER to 2111 at 30-day follow-up.

The current report is the first description of SLD in patient treated with the new device generation, 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 potential risk of clip detachment in comparison with previously implanted systems. In the described case, SLD occurred despite accurate “clocking” and optimal deployment and it’s mechanism remains unclear. Nevertheless, we have documented that full stabilization of the largest available TEER device (P-10) in case of SLD occurrence is possible with the use of two additional smaller devices and may result in satisfactory MR reduction — without creating significant MGM and followed with satisfactory clinical outcome.

**Article information**

**Conflict of interest:** None declared.

**Funding:** None.

**Open access:** This article is available in open access under Creative Common Attribution-Non-Commercial-No Derivatives 4.0 International (CC BY-NC-ND 4.0) license, which allows downloading and sharing articles with others as long as they credit the authors and the publisher, but without permission to change them in any way or use them commercially. For commercial use, please contact the journal office at kardiologiapolska@ptkardio.pl.

**REFERENCES**


Figure 1. Echocardiographic and hemodynamic evaluation before, during and after transcatheter edge to edge repair (TEER) procedure. A. Transthoracic 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. The single leaflet detachment of Pascal P-10 device (red arrow points at the gap between P-10 and posterior leaflet). H. Transesophageal appearance of Pascal P-10 stabilized by two Pascal ACE devices (white arrow points at the P-10 device)