Title

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CASE REPORT

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Retrieval of Large Balloon Fragments During Transcatheter Pulmonary Valve Implantation Using a Novel Retrieval System

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ABSTRACT

The removal of balloon fragments from the pulmonary artery without damaging the pulmonary and tricuspid valves can be difficult. Four cases during transcatheter pulmonary valve replacement are described in which a novel retrieval system was used to facilitate safe removal. (**Level of Difficulty: Advanced.**) (J Am Coll Cardiol Case Rep 2023;26:102058)

Transcatheter pulmonary valve replacement (TPVR) is a long-standing alternative to surgical valve replacement. Balloon rupture is a rare yet well-documented complication of TPVR with the Edwards Commander delivery system. We report a series of 4 patients in whom TPVR with the 26-mm Edwards SAPIEN 3 transcatheter heart valve (Edwards Lifesciences) was complicated by rupture, circumferential tearing, and detachment of balloons during attempts to remove. We describe the use of the ŌNŌ retrieval system (ŌNŌCOR Vascular) to augment snaring of the balloon fragment and to safely guide it into the retrieval sheath with no damage to the surrounding cardiac and vascular structures. The retrieval system, which can be introduced through a 12-F or larger vascular sheath, comprises an expandable nitinol basket (35-mm maximum diameter) affixed to a braided catheter shaft with a 7.5-F internal diameter lumen that can accommodate the introduction of catheters, snares, graspers, and so on. Approval for the study was obtained according to

LEARNING OBJECTIVES

- To recognize balloon fragment detachment during delivery system retrieval.
- To understand the potential role of a novel retrieval system for the retrieval of large balloon fragments.

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The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the Author Center.

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ABBREVIATIONS AND ACRONYMS

IVC = inferior vena cava

PA = pulmonary artery

RA = right atrium

RV = right ventricular

TEE = transesophageal echocardiogram

TPVR = transcatheter pulmonary valve replacement

Institutional Review Board protocols at the participating institutions.

CASES

Demographic, diagnostic, and procedural data for the 4 patients are summarized in **Table 1**.

CASE 1. After conduit preparation with high-pressure serial balloon dilation and stenting, a 26-mm SAPIEN 3 transcatheter heart valve (Edwards Lifesciences) was implanted via a Gore 24-F DrySeal Introducer Sheath (W.L. Gore and Associates) using an Edwards Commander delivery system with 2 mL additional fluid in the inflation device. The balloon ruptured with approximately 1 mL fluid left in the inflation device. The valve was deployed in the intended location and functioned well. Initially, the balloon could not be recaptured into the long sheath within the main pulmonary artery (PA). Upon bringing the entire system to the inferior vena cava (IVC), the delivery balloon was thought to be recaptured within the long sheath after considerable backward force was applied. Upon inspection, it was evident that the midportion of the balloon was no longer attached to the shaft and was not retained within the sheath. A transthoracic and transesophageal echocardiogram (TEE) demonstrated the balloon fragment in the right atrium (RA) adjacent to the tricuspid valve, moving to-and-fro in and out of the right ventricular (RV) cavity (**Figures 1A and 1B**, Video 1). A Cook 16-F 35-cm Check-Flo introducer sheath (Cook Group Inc) was advanced over the interventional wire to the RA followed by a coaxial 14-F long sheath. The 12-F retrieval system was advanced to the distal end of the long sheath. A 20-mm Amplatz Goose Neck snare (Medtronic) and 5-F catheter combination were advanced through the retrieval system. Initially, it was difficult to snare the balloon fragment because it prolapsed through the tricuspid valve into the right ventricle. The retrieval system was advanced into the RV apex, and then the basket was opened and pulled back gently to ensure that the balloon fragment was free in the RA and not entangled in the tricuspid tension apparatus. The balloon fragment was snared under TEE guidance, after which the retrieval system was further advanced out of the sheath onto the balloon fragment and the entire system was pulled to the IVC (**Figure 1C**). The retrieval system was reopened completely within the IVC to realign the balloon fragment and collapse it into the long sheath, after which it was successfully removed from the body (Video 2).

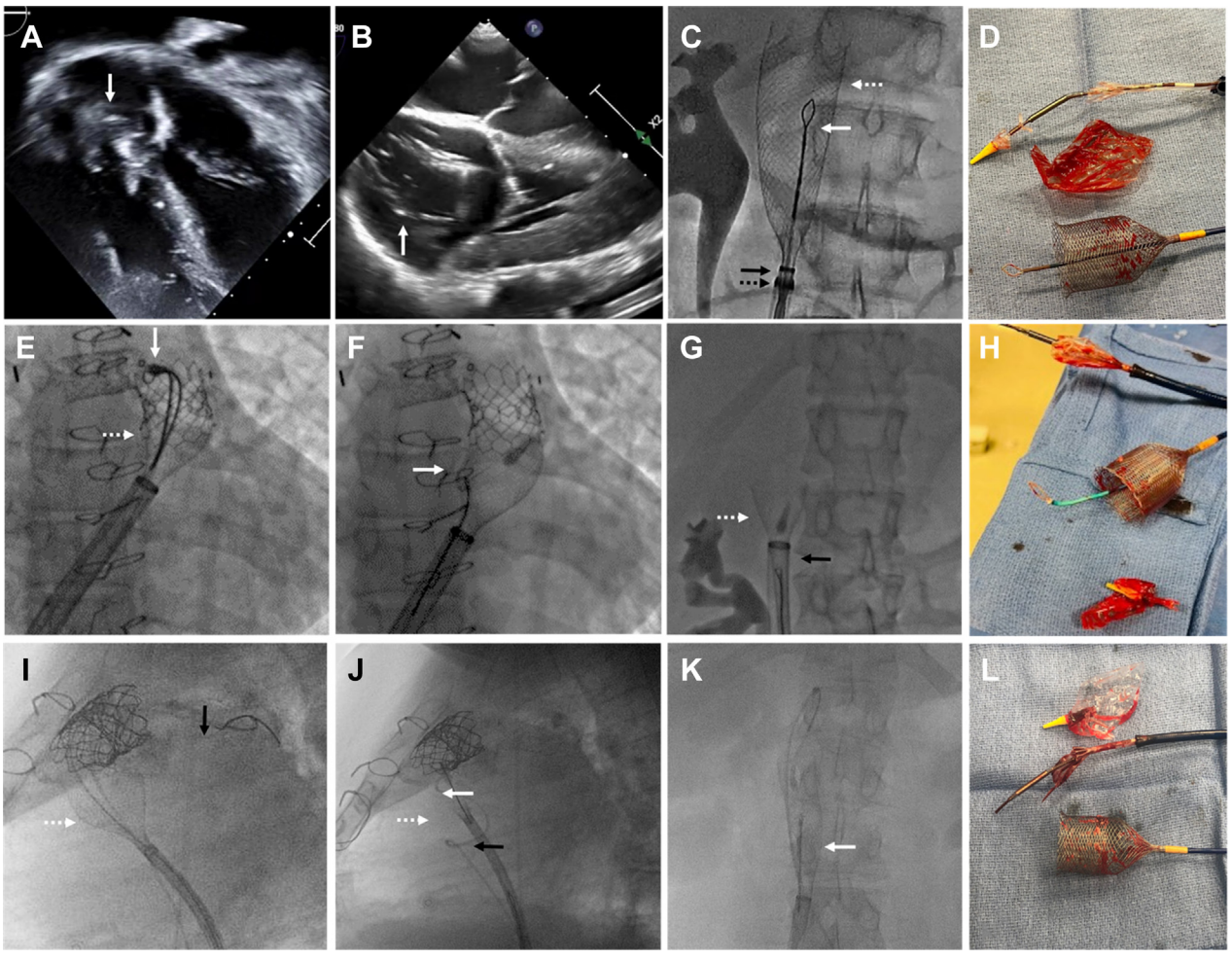
CASE 2. A Mosaic bioprosthetic pulmonary valve (Medtronic) was intentionally fractured, during which there was a pinhole rupture of the 26-mm Vida balloon (Becton, Dickinson and Company). This balloon was easily removed via a 16-F long sheath without complication. A 26-mm transcatheter heart valve was implanted within the bioprosthetic valve in

TABLE 1 Demographic, Diagnostic, and Procedural Data

Patient #	Age (y)	Sex	Weight (kg)	Diagnosis	RVOT Characteristics	RVOT Preparation Before SAPIEN Valve Placement	Balloon Volume/Pressure	Location of Balloon Retrieval
1	16	M	67.5	TOF, pulmonary atresia, MAPCAs	27-mm valved aortic homograft RV-PA conduit Extensive calcification present Peak-to-peak gradient 58 mm Hg	Balloon dilation and prestent placement	24 mL	RA, RV
2	26	F	53.4	TOF, pulmonary atresia	25-mm Mosaic bioprosthetic valve Extensive calcification Peak-to-peak gradient 25 mm Hg	Intentional valve frame fracture before SAPIEN valve placement	23 mL	Inferior aspect of SAPIEN 3 valve
3	20	M	102.0	TOF, pulmonary atresia, MAPCAs	22-mm pulmonary homograft RV-PA conduit Extensive calcification present Peak-to-peak gradient 117 mm Hg	Balloon dilation and prestent placement	23 mL	Inferior aspect of SAPIEN 3 valve within RV-PA conduit
4	15	M	62.3	TOF	25-mm Epic Supra bioprosthetic valve No calcification present Peak-to-peak gradient 38 mm Hg	Balloon dilation	20 atmospheres	Left pulmonary artery

MAPCA = major aortopulmonary collateral artery; MPA = main pulmonary artery; PA = pulmonary artery; RA = right atrium; RV = right ventricle; RVOT = right ventricular outflow tract; TOF = tetralogy of Fallot.

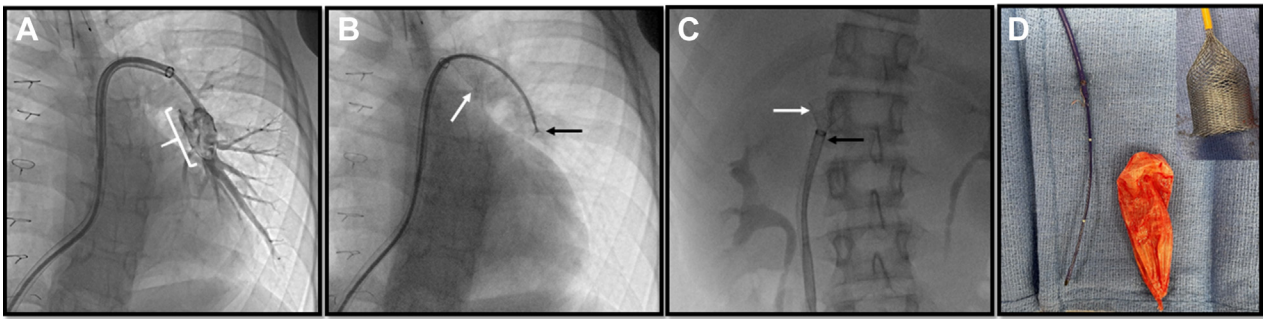
FIGURE 1 **Retrieval of Balloon Fragment in 3 Patients**



(A to D) Patient 1. (A and B) These transthoracic echocardiographic images show the balloon free-floating between the right atrium and ventricle within the tricuspid valve apparatus (solid white arrow). (C) A snare (solid white arrow) within the retrieval system (dashed white arrow) is advanced in a 14-F long sheath (solid black arrow) within a 16-F long sheath (dashed black arrow) to the right atrium where the balloon is snared (this fluoroscopic image shows removal not introduction). The entire system is pulled together to the inferior vena cava (IVC) where the balloon, snare, and retrieval system are collapsed into the sheath (also shown in Video 2). (D) This photograph shows the delivery system, balloon fragment, and snare within the retrieval system after removal from the body. (E to H) Patient 2. (E) A snare (solid white arrow) looped around the wire and advanced within the retrieval system (dashed white arrow) to the right ventricular outflow tract (RVOT) where the distal balloon fragment is snared. (F) The interventional wire is removed, a second proximal snare (solid white arrow) is positioned just inferior to the implanted transcatheter heart valve, and the initial snare is removed. (G) The balloon fragment and retrieval system do not collapse within the RVOT, so the entire system is pulled gently through the tricuspid valve and repositioned in the IVC, where it is collapsed into the long sheath (solid black arrow) (also shown in Video 2). (H) This photograph shows the delivery system, balloon fragment, and snare within the retrieval system after removal from the body. (I to L) Patient 3. (I) The tip of the interventional wire tip (solid black arrow) is snared via contralateral femoral venous access, and the retrieval system with a coaxial snare (dashed white arrow) is placed inferior to the implanted transcatheter heart valve. (J) The ruptured balloon (solid white arrow) is snared within the retrieval system (dashed white arrow) and partially collapsed into the 13.8-F deflectable sheath (solid black arrow). (K) The entire unit is withdrawn across the tricuspid valve and into the IVC, where the retrieval system is re-expanded and the system is fully collapsed into the 24-F long sheath (also shown in Video 3). (L) This photograph shows the delivery system, balloon fragment, and retrieval system after removal from the body.

standard fashion. During the attempted withdrawal of the delivery system into the long sheath in the RV outflow tract, there was a circumferential tear and avulsion of the distal balloon fragment, which remained on the interventional wire in the main PA. After removal of the disarticulated proximal portion of the balloon catheter, a 12-F retrieval system was advanced over the interventional wire with a coaxial

FIGURE 2 Retrieval of Angioplasty Balloon Fragment



(A to D) Patient 4. (A) A filling defect (between white brace) in the left pulmonary artery is seen, representing the ruptured balloon. (B) A 6-F bioptome is advanced through a 7-F JR 4 guide catheter through the retrieval system (white arrow) and opened (black arrow) to grasp the ruptured balloon. (C) The entire system (closed bioptome through guide catheter, partially collapsed retrieval system [white arrow] and 16-F long sheath [black arrow]) was then pulled out of the femoral venous access site. (D) This photograph shows the catheter shaft, balloon fragment, and retrieval system after removal from the body.

guide catheter and a 25-mm snare looped around the interventional wire. The balloon fragment was snared with the wire still in place, and then the wire was removed, after which the retrieval system was opened below the transcatheter heart valve and the snared balloon was retracted into the retrieval device. The entire system was gently pulled to the IVC, taking care to avoid injury to the tricuspid valve. The snared balloon and retrieval basket were repositioned in the IVC to ensure coaxial alignment and then pulled into the long sheath. Intracardiac echocardiography confirmed mild tricuspid regurgitation, improved from moderate before the catheterization.

CASE 3. The conduit was prepared via high-pressure balloon dilation and stenting, after which a 26-mm transcatheter heart valve was implanted similar to case 1. During removal of the delivery system, it was apparent that almost all of the balloon was retained inside the right ventricle-to-PA conduit, still on the guidewire, resulting in obstruction and hemodynamic instability. A 13.8-F Destino Twist deflectable sheath (Oscor) was advanced over the wire to the right ventricle-to-PA conduit. Via contralateral femoral venous access, the tip of the interventional guidewire was snared in the PA, creating a loop to avoid distal embolization of the fragment (**Figure 1G**). A 12-F retrieval system and 25-mm snare catheter were advanced over the interventional wire, and the balloon was snared in the RV outflow tract and then collapsed into the 13.8-F deflectable sheath (**Figure 1H**, Video 3). The entire closed-loop system was then withdrawn to the IVC where the snare on the guidewire was released, and the retrieval system was reopened and used to realign and guide the balloon fragment into a 24-F long sheath and out of the body (**Figure 1I**).

CASE 4. During serial dilation of a 25-mm Epic Supra bioprosthetic valve (Abbott) in the pulmonary valve position, multiple high-pressure balloons ruptured, including a 26 × 4 Vida balloon (BD Interventional). Upon withdrawal of the 26 × 4 balloon, it was noted that the balloon had completely separated from the catheter shaft. Initial angiography showed that the balloon was at the main pulmonary artery-right pulmonary artery junction. During manipulation, the balloon was later found to have embolized to the left pulmonary artery (**Figure 2A**). A 16-F long sheath was advanced to the proximal left pulmonary artery, and a 12-F retrieval system was advanced through the long sheath. Using a 7-F JR 4 guide catheter (Medtronic Inc) within the retrieval system, snares were attempted to help retrieve the embolized balloon fragment within the retrieval system. Snare retrieval was not successful, and, ultimately, the balloon fragment was carefully grasped (using biplane fluoroscopy) with a 6-F bioptome (**Figure 2B**) through the 7-F JR 4 guide catheter. The balloon was then pulled into the retrieval system and collapsed within the long sheath, which was confirmed by tactile traction. The entire system (closed bioptome through the guide catheter, retrieval system, and 16-F long sheath) was then withdrawn as a unit, allowing the balloon fragment to be pulled out of the body via the femoral venous access (**Figures 2C and 2D**). The

patient underwent successful implantation of a 26-mm transcatheter heart valve within the bioprosthetic pulmonary valve at the same procedure.

DISCUSSION

Balloon rupture is a known and well-documented complication during transcatheter heart valve deployment, particularly within a calcified structure.[1-4] However, circumferential tears at the time of balloon rupture and detachment of fragments are less common. Heavy calcification was the likely mechanism of initial circumferential balloon rupture in the first 3 patients and the use of high-pressure angioplasty within a stenotic bioprosthesis in the fourth patient. In cases 1 and 2, the subsequent complete detachment of the balloon fragment from the delivery system likely occurred during the initial attempts to collapse the balloon into the long sheath in which considerable backward force was applied. This series reiterates the need for cautious balloon retrieval as well as careful inspection of the balloon following valve deployment to ensure the complete intact balloon is removed from the body.

Detached free-floating balloon fragments are not only difficult to snare but also can be entirely radiolucent, making visualization and retrieval even more challenging. When the balloon fragment is retained on the interventional wire and can be withdrawn to the iliofemoral venous level, traditional techniques including contralateral venous access and snaring of the distal tip of the interventional wire may be used before fragment retrieval.[3] However, large balloon fragments may not readily withdraw into even the largest of retrieval sheaths, in part because of difficulty aligning the irregular and bulky fragment with the sheath, and in doing so present significant risk for vascular injury, need for surgical intervention, bleeding, and death.[5] Moreover, removing fragments from the PA or within the heart may be challenging because of difficulty aligning the fragment with the sheath as well as the added risk of disrupting the surrounding cardiac structures.

The retrieval system used in these cases is a recently Food and Drug Administration-approved braided nitinol basket used to facilitate retrieval of large embolized objects; since it became available, it has been used to successfully retrieve atrial thrombus, atrial tumors, atrial septal defect devices, and other intracardiac foreign bodies.[6-9] The retrieval basket is flared distally such that backward tension on the shaft outside of the body is converted to radial compression force within the basket. The inward radial force aligns the object coaxially with the sheath, allowing safe compression of the snared object into the retrieval sheath. The retrieval system may initially be used to cover and shield a snared object as it is carefully withdrawn from a location with vital surrounding structures. After withdrawal to a safer location, such as the IVC, the basket can be re-expanded to better align and collapse the snared object within the retrieval sheath. In the cases described, the retrieval system was able to facilitate safe percutaneous retrieval of embolized balloon fragments while avoiding harm to the pulmonary and tricuspid valves.

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Drs Aboulhosn and Levi are consultants for Medtronic Inc and Edwards Lifesciences. Dr McElhinney is a consultant for Medtronic Inc. Dr Qureshi is a consultant for Medtronic Inc and W. L. Gore and Associates.

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KEY WORDS congenital heart defect, pulmonic valve, valve replacement

APPENDIX For supplemental videos, please see the online version of this paper.