Case Reports

Percutaneous Management of Retro-Flex 3 Balloon Rupture

and Separation of the Edwards SAPIEN Delivery System

Kelly D. Green, MD
Alain Waked, MD
Usman Majeed, MD
Marat Fudim, MD
Mark A. Robbins, MD
Marshall Crenshaw, MD
David Zhao, MD

We report the case of an 85-year-old woman with severe aortic stenosis who underwent transcatheter aortic valve replacement with use of the Edwards SAPIEN® valve system. The procedure was complicated by rupture of the valve-deployment balloon, with separation and retention of the nose cone of the RetroFlex 3® delivery system in the iliac artery. Our endovascular retrieval of the equipment was successful, and we achieved access-site hemostasis by deploying a covered stent. To our knowledge, this is the first report of the endovascular retrieval of a malfunctioning delivery system during transcatheter aortic valve replacement. ***(Tex Heart Inst J 2014;41(6):641-4)***

Key words: *Aged, 80 and over; cardiac catheterization/adverse effects; endovascular procedures/adverse effects/instrumentation; equipment failure; heart valve prosthesis implantation/adverse effects; iliac artery/injuries; treatment outcome*

From: *Department of Medicine, Division of Cardiology (Drs. Crenshaw, Green, Robbins, Waked, and Zhao), and Department of Medicine (Dr. Fudim), Vanderbilt University Medical Center, Nashville, Tennessee 37232; and Department of Medicine (Dr. Majeed), Meharry Medical College, Nashville, Tennessee 37208*

Dr. Zhao is now at Wake Forest Baptist Medical Center, Winston-Salem, North Carolina.

Address for reprints: *Kelly D. Green, MD, 1215 – 21st Ave. S., #5209, Nashville, TN 37232*

E-mail: *Kelly.D.Green@Vanderbilt.edu*

As the relatively new field of transcatheter aortic valve replacement (TAVR) develops, new techniques are emerging for managing procedural sequelae. Rupture of the valve-deployment balloon with retention of the nose cone of the Edwards SAPIEN® RetroFlex 3® delivery system (Edwards Lifesciences Corporation; Irvine, Calif) is a rare occurrence; the 2 previously reported cases were managed surgically. We describe our endovascular retrieval of the failed equipment.

Case Report

In February 2013, an 85-year-old woman with New York Heart Association functional class III symptoms was evaluated for severe aortic stenosis. Her calculated aortic valve area was 0.4 cm^2. A transthoracic echocardiogram showed normal left ventricular systolic function. The patient's comorbidities included severe pulmonary hypertension, oxygen-dependent chronic obstructive pulmonary disease, and prior radiation therapy for breast cancer. Her calculated logistic EuroSCORE was 43.02%. As a high-risk operative candidate, she was referred for TAVR.

Arterial access was obtained through a 6F, 11-cm sheath (Cook Medical, Inc.; Bloomington, Ind) in the left common femoral artery (LCFA) and a 22F (25F external diameter) Edwards SAPIEN sheath in the right common femoral artery (RCFA). The RCFA was preclosed with use of 2 Perclose ProGlide® 6F Suture-Mediated Closure Systems (Abbott Vascular, part of Abbott Laboratories; Abbott Park, Ill) before sheath insertion. During the deployment of a 23-mm Edwards SAPIEN valve, fluoroscopy revealed the rupture of the RetroFlex 3® valve balloon (Fig. 1). Initially, we were concerned about incomplete valve expansion; however, fluoroscopic and transesophageal echocardiographic images confirmed that the valve was well seated with only trace perivalvular aortic insufficiency. As the delivery system was retracted, the ruptured balloon would not enter the distal end of the 22F sheath. An attempt was made to withdraw the balloon and sheath as a unit, but the nose cone became lodged in the common iliac artery. With further traction, the nose cone and the distal portion of the balloon separated from the shaft (Fig. 2) and were retained in the common iliac artery (Fig. 3). The LCFA sheath was emergently exchanged for a larger 14F sheath (Cordis, a Johnson & Johnson company; Miami Lakes, Fla) to accommodate a Coda® Balloon Catheter (Cook Medical), which was inflated in the distal aorta for hemostasis. The 22F sheath and remaining delivery system were removed, leaving only the modified Amplatz Super Stiff™ Guidewire (Boston Scientific Corporation; Natick, Mass) in the RCFA, along with the retained nose cone. A 26F GORE® DrySeal Sheath (W.L. Gore & Associates, Inc.; Flagstaff, Ariz) was inserted into the RCFA and advanced

into the right external iliac artery. A 45-cm TERUMO® sheath (Terumo Medical Corporation; Somerset, NJ) was advanced over the Super Stiff wire through the 26F DrySeal sheath up to the retained nose cone. An 18- to 30-mm ENSnare® device (ev3 Endovascular, Inc., part of Covidien; Plymouth, Minn) was used to capture the retained nose cone (Fig. 4). The nose cone, snare, and DrySeal sheath were removed as a unit over the Super Stiff wire (Figs. 2 and 5). A new 22F Edwards sheath was placed in the RCFA, and the Coda balloon was deflated. Through a 45-cm Destination® sheath (Terumo Medical) from the contralateral LCFA, an angiogram revealed contrast extravasation from the right external iliac artery (Fig. 6). Possible causes of the lack of hemostasis were simple failure of the Perclose system, external iliac disruption from removal of the unsheathed nose cone, or both. An 8 × 38-mm iCAST™ covered stent (Atrium Medical Corporation; Hudson, NH) was delivered through the LCFA access, extending from the distal external iliac artery into the proximal common femoral artery. Completion angiograms

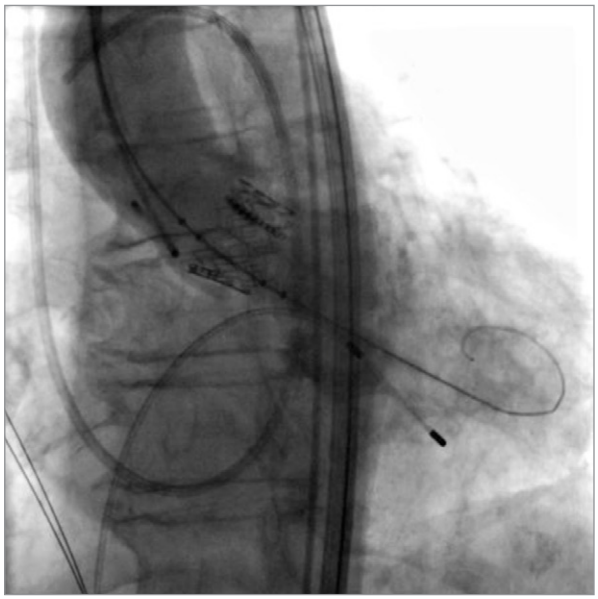

Fig. 1 *Fluoroscopic image shows the deployed Edwards SAPIEN® valve and contrast medium from the rupturing balloon.*

Supplemental motion image is available for Figure 1.

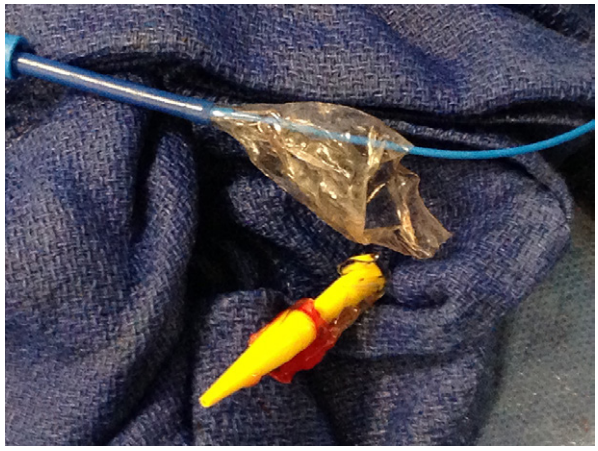

Fig. 2 *Photograph shows the delivery system with the proximal portion of the balloon attached. The nose cone (yellow) is attached to the distal portion of the balloon.*

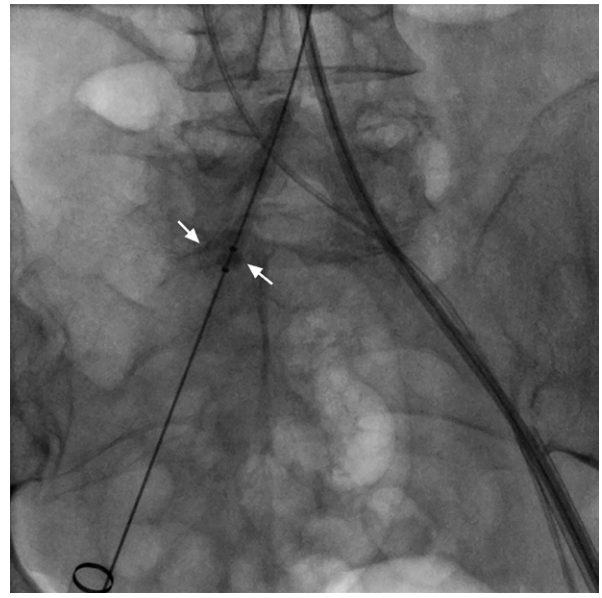

Fig. 3 *Fluoroscopic image shows the nose cone, lodged within the common iliac artery. The two dots mark the proximal end of the nose cone.*

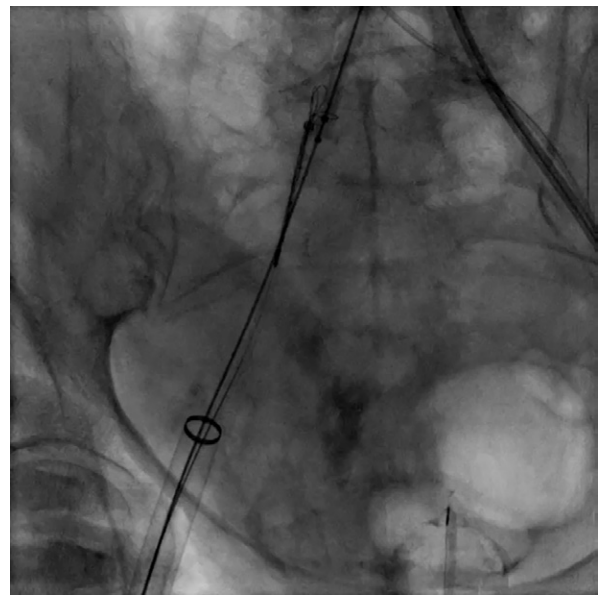

Fig. 4 *Fluoroscopic image shows the ENSnare® device, advanced through the TERUMO® sheath, securing the nose cone.*

Supplemental motion image is available for Figure 4.

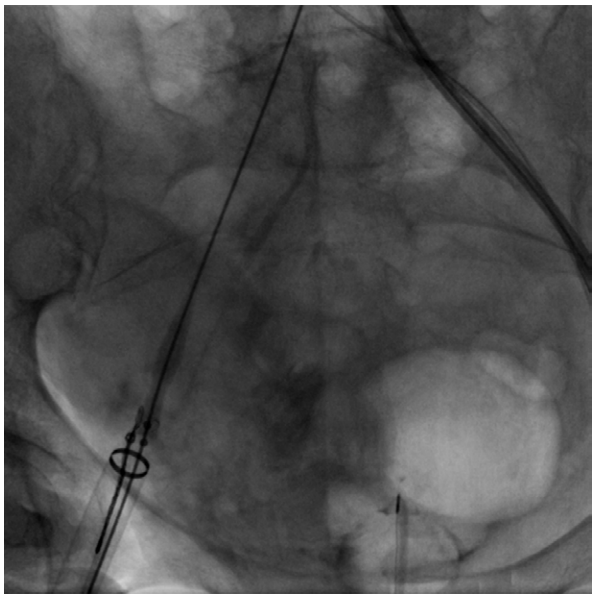

Fig. 5 *Fluoroscopic image shows extraction of the nose cone.*

Supplemental motion image is available for Figure 5.

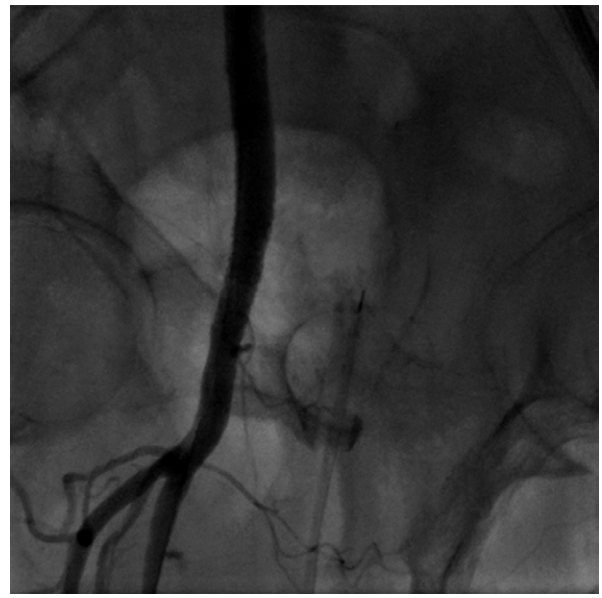

Fig. 7 *Completion angiogram shows patent external iliac and femoral arteries after stent deployment.*

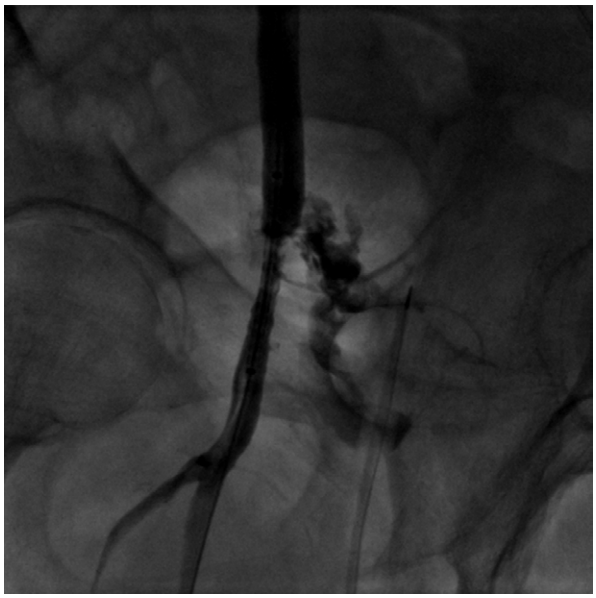

Fig. 6 *Angiogram shows extravasation of contrast medium from the external iliac artery after removal of the instruments.*

revealed complete hemostasis with patent right iliac and femoral arteries (Fig. 7). The patient was extubated the next day and was discharged to an inpatient rehabilitation unit on postoperative day 6. Upon 6-month follow-up, the patient was doing well.

Discussion

Balloon rupture during transcatheter valve replacement has rarely been reported. Gul and colleagues[1] reported a similar case of balloon rupture during valve deployment. As did we, they experienced circumferential balloon rupture, but without separation of the nose cone from the proximal portion of the delivery system. They similarly felt tension in the iliac artery during extraction, at which point they converted to surgical removal. The U.S. Food and Drug Administration's Adverse Event Reporting website[2] describes another instance of valve-balloon rupture during deployment. The nose cone and distal balloon separated from the delivery system in the iliac artery during removal, as in our case. Surgical cutdown enabled removal of the retained segments. In both cited reports, as in our patient, severe aortic annular calcification was present and is postulated to have caused the balloon rupture.

In its product information, Edwards Lifesciences Corporation includes both balloon rupture and separation as potential adverse events; however, our review of the medical literature revealed no discussion regarding the prevention or management of nose cone separation after balloon rupture. We now think that, although the ruptured balloon would not enter the sheath, the resistance that led to the separation of the nose cone might have occurred because the nose cone lodged within the iliac artery itself. If we are faced with rupture again, a reasonable approach would be to withdraw the balloon gently to the end of the sheath and—if there is no resistance—remove the delivery system in the usual fashion. On the other hand, if resistance is encountered, we might instead pull the entire system into the iliac artery and inflate an aortic occlusion balloon through the contralateral side. The 22F sheath and the delivery system would then be withdrawn, over the wire, as a

single unit, with immediate reinsertion of a new 22F sheath. If the nose cone were to lodge within the artery itself, we might again attempt its retrieval with the EN-Snare device, as we successfully did in this case.

The other 2 cases mentioned herein were managed surgically. To our knowledge, ours is the first report of the endovascular management of this sequela. No long-term outcomes of TAVR-associated vascular sequelae managed by means of endovascular techniques are known; however, published reports have described favorable short-term outcomes.[3]

References

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