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CASE REPORT

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A very rare vascular complication of the Edwards expandable eSheath during transcatheter aortic valve replacement

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Abstract

Transcatheter aortic valve replacement (TAVR) has revolutionized the management of severe symptomatic aortic valve stenosis. TAVR is now indicated as an alternative to surgical replacement in a wide risk profile ranging from high to low surgical risk. Although vascular complications have decreased in frequency over time, with the introduction of lower profile delivery systems and sheaths, they remain one of the most frequently encountered and serious complications of TAVR. Patient-specific predisposing factors have been well characterized. However, much less is known about device-specific complications. Awareness of the possible device-related complications may lead to earlier identification, prompt management, and better outcomes. We report a previously unreported complication of the Edwards expandable eSheath that lead to avulsion of the external iliac artery following successful TAVR with a 29-mm Edwards Sapien 3 transcatheter heart valve. Bleeding was promptly controlled with an occlusion balloon and emergency surgical repair was required with a favorable outcome.

KEYWORDS

avulsion, self-expanding sheaths, transcatheter aortic valve implantation, vascular complication

1 | INTRODUCTION

Transcatheter aortic valve replacement (TAVR) has revolutionized the management of severe symptomatic aortic stenosis. There has been a continuous refinement of TAVR devices and delivery systems and the favorable results of randomized studies with good short- and medium-term results have led to guideline support for TAVR across the entire risk spectrum.[1,2] Vascular complications and bleeding have been shown to increase 30-day and 1-year mortality in patients undergoing TAVR.[3] Although the risk of vascular complications has significantly fallen, with recent trials in low-risk patients reporting a 2% risk of major vascular complications at 30 days,[4] there are very rare but potentially catastrophic access sheath-related complications, the early detection of which may be lifesaving.

We report a previously undescribed complication of an Edwards expandable femoral sheath (eSheath; Edwards Lifesciences) used for delivery of a 29-mm Edwards Sapien 3 transcatheter heart valve (THV) that lead to complete avulsion of the external iliac artery necessitating emergency deployment of an occlusion balloon and emergency surgical repair. We discuss the possible mechanisms of this complication and the steps that may be taken to mitigate vascular injury. To our knowledge, this life-threatening complication has not been previously described.

2 | CASE REPORT

An 81-year-old male patient with symptomatic severe aortic valve stenosis was referred to our institution electively for TAVR. He presented with progressively worsening exertional dyspnea (New York Heart Association [NYHA] class III). Past medical history included nonobstructive coronary artery disease, chronic kidney disease (CKD) stage III, mild chronic obstructive pulmonary disease, atrial fibrillation, dyslipidemia, and prostate hypertrophy. Echocardiogram parameters were in keeping with severe aortic stenosis with a maximum transvalvular velocity of 4.1 m/s, mean pressure gradient of 45 mmHg, dimensionless index of 0.21, and aortic valve area of 0.55 cm^2 (Figure 1A). Left ventricular ejection fraction was reduced at 45% and there were no other significant valvular abnormalities. Blood tests showed a normal hemoglobin of 131 g/l, reduced estimated glomerular filtration rate of 53 ml/min/1.73 m^2 (CKD stage III), and elevated N-terminal-prohormone B-type natriuretic peptide of 1423 ng/l.

The patient was discussed by the Heart Team and deemed high risk for surgical intervention but appropriate for TAVR. An electrocardiography-gated TAVR protocol computed tomography (CT) angiogram for preprocedural planning was undertaken. The aortic valve was bicuspid (Sievers type 1) with severe calcification and a calcified raphe between the right and left cusps (Figure 1B). The annular area was measured at 709 mm^2 and there was no calcification in the annulus or the left ventricular outflow tract. The mean diameter of the sinuses was 38 mm and the height of the left and right coronary arteries was 16 mm.

The right common femoral, external iliac, and common iliac arteries had no significant tortuosity or atherosclerotic disease and were free of calcification with a minimum diameter of 9.4 mm (Figure 2A–D). Based on these measurements, TAVR with a 29-mm Sapien 3 THV (Edwards Lifesciences) via percutaneous right femoral access was planned.

The patient was admitted electively and the procedure was performed under conscious sedation in a catheter laboratory with transthoracic echocardiographic monitoring. A 16-Fr eSheath was inserted in the right common femoral artery using ultrasound guidance and micropuncture technique. Two suture-mediated closure devices (Proglides; Abbott Vascular) were deployed in a standard preclose fashion. The aortic valve was crossed and an Amplatz Extra Stiff guidewire (Cook Medical) was positioned in the left ventricle. In light of severe aortic valve calcification and horizontal angulation of the ascending aorta predilatation with a 25-mm balloon was undertaken before THV placement. In view of the large size of the annulus, the 29-mm S3 THV deployment balloon was overfilled by 4 cc.[5] The THV was inserted into the 16F eSheath, using the loader, and advanced into the descending aorta without difficulty. Here, the THV was loaded onto the deployment balloon and advanced into the native aortic valve. The THV was deployed with rapid ventricular pacing via the left ventricular guidewire (Figure 3A).[6] Postdeployment transthoracic echocardiogram showed minor paravalvular regurgitation and no pericardial effusion (Figure 3B).

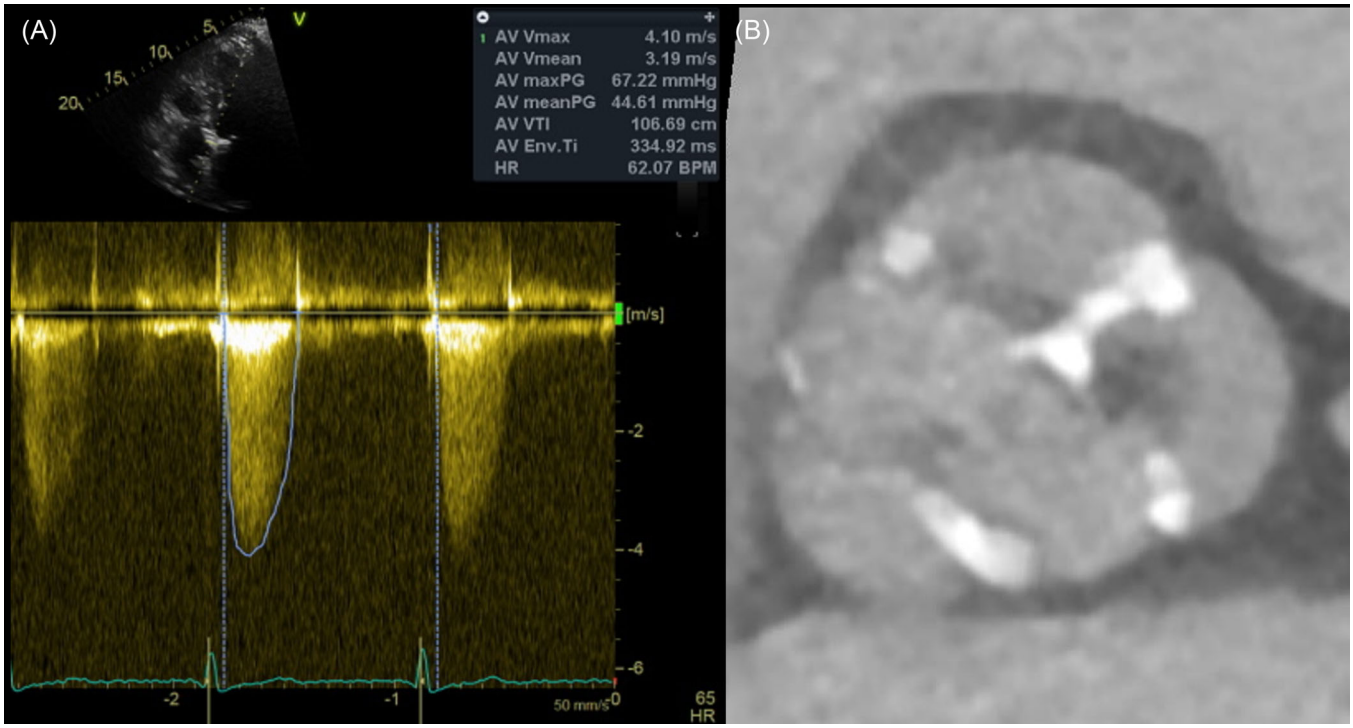

FIGURE 1 (A) Continuous Doppler across the aortic valve. (B) Computed tomography short axis at the level of the aortic valve showing a severely calcified bicuspid aortic valve with a fusion of left and right leaflets. AV, aortic valve; HR, heart rate; VTI, velocity time integral. [Color figure can be viewed at wileyonlinelibrary.com]

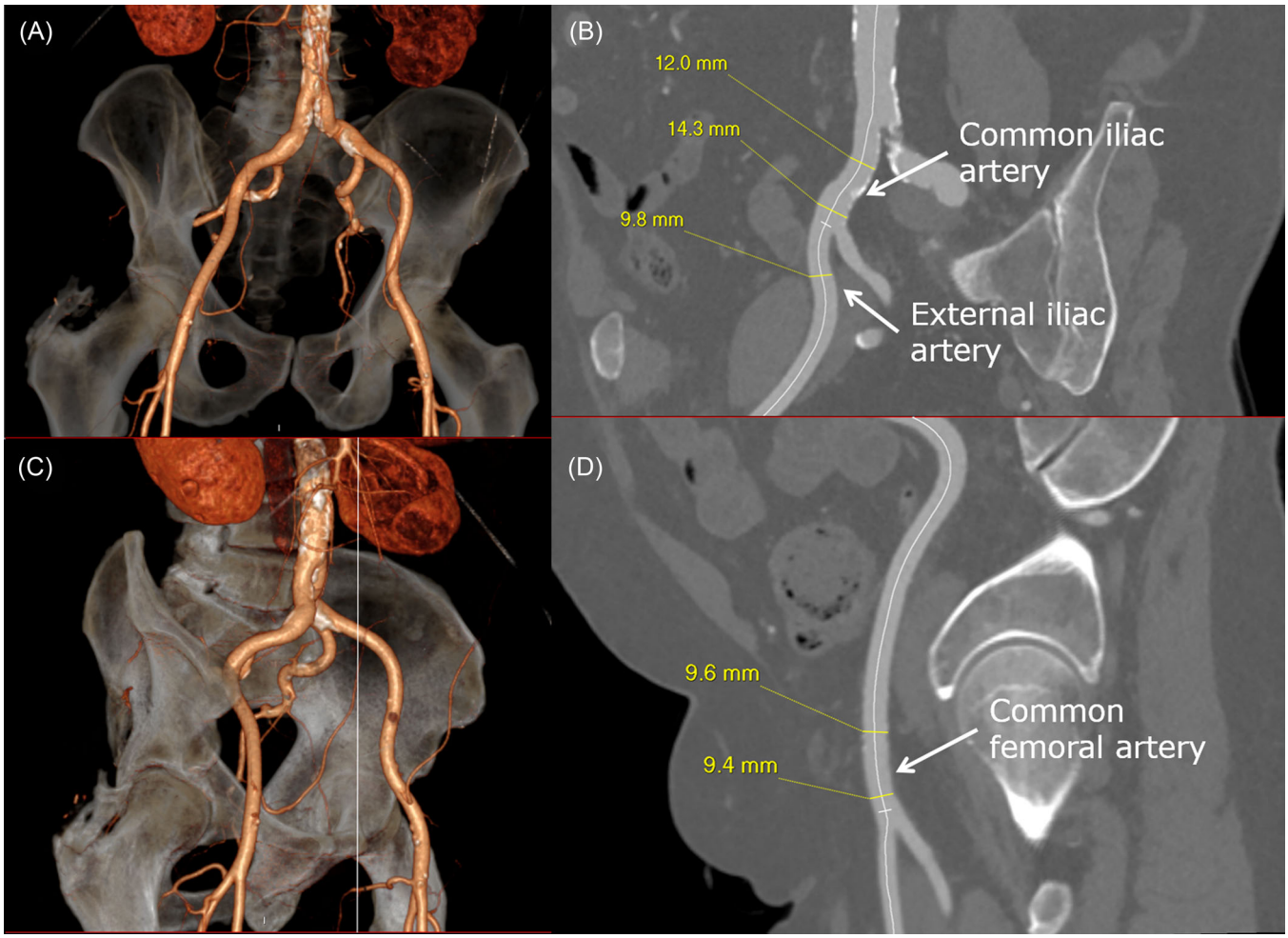

FIGURE 2 (A) Anteroposterior projection at the level of the iliofemoral arteries showing minimal calcification and tortuosity. (B) Longitudinal reconstruction at the level of the bifurcation of the right common iliac and external iliac artery showing minimal calcification and diameter >9 mm throughout. (C) Right anterior oblique 30° projection at the level of the iliofemoral arteries showing minimal calcification and tortuosity. (D) Longitudinal reconstruction at the level of the bifurcation of the right common femoral artery showing minimal calcification and a diameter of >9 mm throughout. [Color figure can be viewed at wileyonlinelibrary.com]

The Commander delivery catheter (Edwards Lifesciences) was withdrawn over the aortic arch on the Amplatz delivery wire while simultaneously removing flex from the catheter. As the Commander catheter was withdrawn into the distal tip of the eSheath, some modest resistance was encountered. To ensure that the deployment balloon had been fully deflated, the indeflator was substituted with a 50 cc luer lock syringe with which suction was applied to the deployment balloon. The withdrawal was continued, although moderate resistance persisted. Fluoroscopy of the eSheath at this time did not reveal any obvious abnormality. As the deployment balloon of the Commander catheter entered the right common iliac artery the patient complained of pain.

Fluoroscopy revealed a modestly increased profile of the section of the eSheath containing the deployment balloon (Figure 4A). It was not noticed at this time but a later review of the fluoroscopic image also showed a smaller-than-normal profile of the eSheath distal to the catheter nosecone (Figure 4A).

On seeing the widened profile of the delivery balloon in the eSheath, the Commander catheter was readvanced until the tip of the nosecone emerged from the tip of the eSheath. Negative suction to ensure full deflation was reapplied with the 50 cc luer lock syringe. On this occasion, there was some aspiration of blood-stained fluid, suggesting loss of integrity of the hypotube.

The mechanism of the resistance in retrieving the THV balloon through the eSheath was unclear. However, given the discomfort experienced by the patient upon retrieval efforts, we hypothesized that there may have been some injury to the iliac artery. Rather than continuing attempts to withdraw the Commander catheter through the eSheath, it was now decided to remove the catheter and eSheath en bloc and to replace this with a fresh 16F eSheath and to explore for evidence of vascular injury.

We anticipated that there may have been damage to the iliofemoral vasculature, potentially with extravasation, and simultaneously readied a 32-mm Coda balloon (Cook Medical) for inflation in the abdominal aorta. The volume to inflate the Coda balloon was

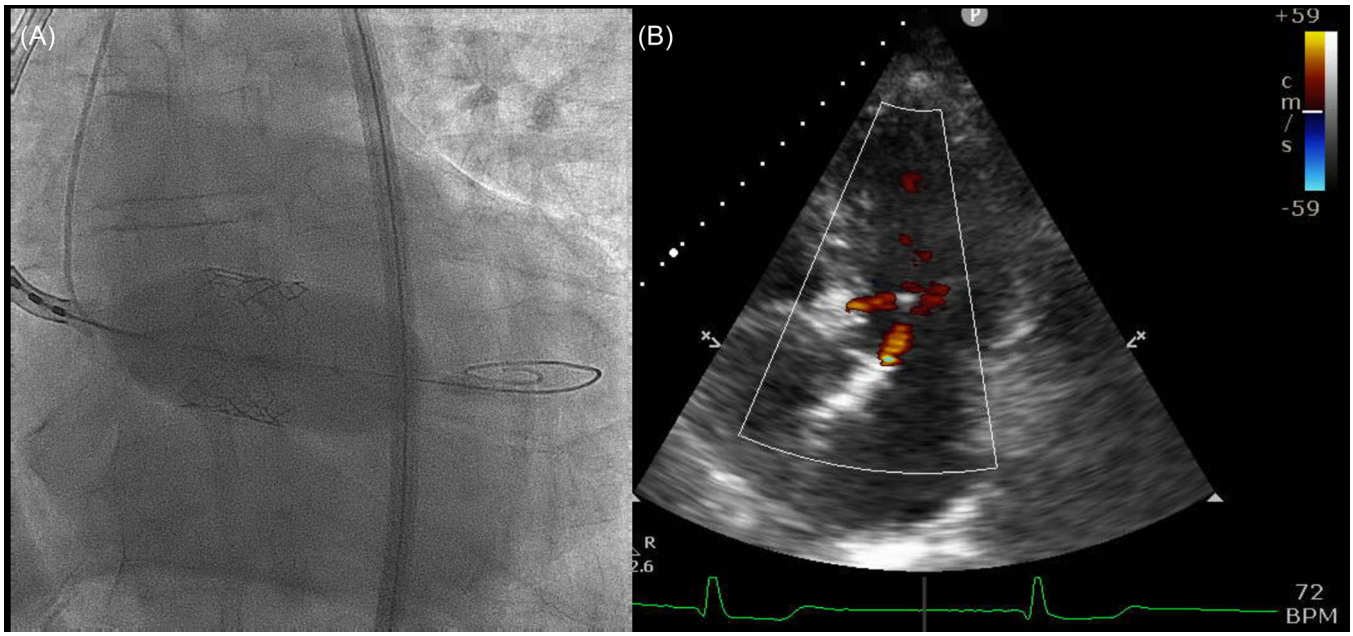

FIGURE 3 (A) Deployment of a 29-mm Sapien 3 transcatheter heart valve. (B) Postdeployment echocardiogram showing mild paravalvular leak. [Color figure can be viewed at wileyonlinelibrary.com]

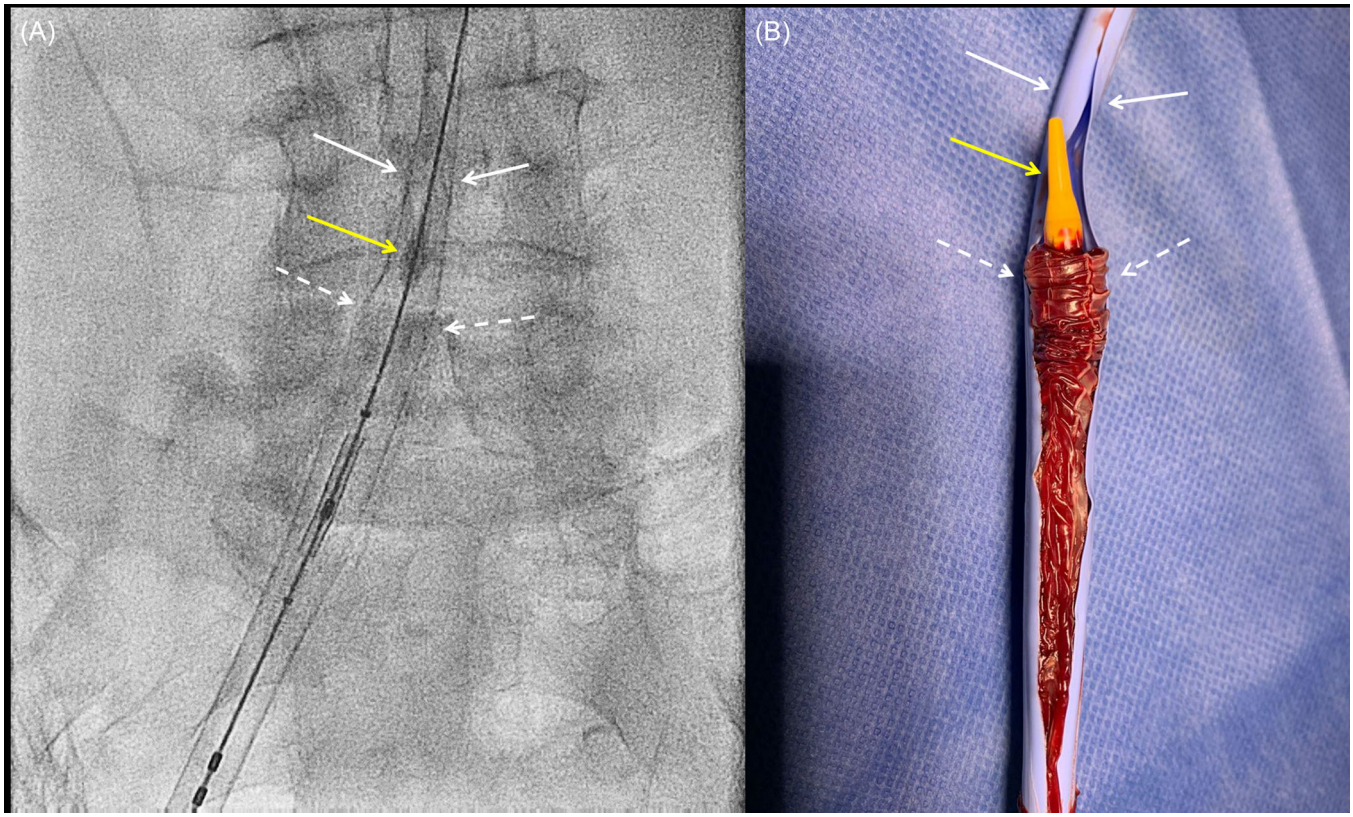

FIGURE 4 (A) Anteroposterior fluoroscopic image showing the deformed eSheath with deflated THV balloon retracted into the eSheath. Continuous white arrows point to the relatively collapsed distal segment of the eSheath due to the stripping of the inner lining. Yellow arrow points to the nosecone. White dashed arrows point to the swelling of the eSheath due to the concertinaed inner lining. (B) Ex vivo findings of the same eSheath. Continuous white arrows point to the collapsed distal segment of the eSheath stripped of the inner lining. Yellow arrow points to the nosecone. White dashed arrows point to the swelling of the eSheath caused by the retracted, concertinaed inner lining. [Color figure can be viewed at wileyonlinelibrary.com]

determined from the infrarenal diameter of the abdominal aorta from the preprocedure planning CT and the size chart of the Coda balloon. Upon en block retrieval of the Commander catheter and the eSheath from the right femoral artery, some modest, but not excessive, resistance was encountered. Upon removal, it became evident that a segment of the external iliac and common femoral artery had been avulsed with the eSheath (Figure 5). There was a precipitous drop in blood pressure due to presumed blood loss from the external iliac artery. Immediately, the new 16F eSheath was advanced over the guidewire, which was still in place, followed by the Coda balloon, which was advanced and inflated in the abdominal aorta. Hemostasis was confirmed with the Coda balloon positioned below the renal arteries (Figure 6A and Supporting Information: Video 1). An angiogram through the eSheath showed escape of contrast through the external iliac vessel (Figure 6B and Supporting Information: Video 2). Blood pressure recovered quickly with fluid resuscitation. The on-call vascular team was called and an on-table emergency pelvic exploration was undertaken under general anesthesia.

At surgery, avulsion of the right external iliac and common femoral arteries was confirmed but with no further identification of damage proximally. Following cross-clamp of the proximal common iliac artery a Dacron graft was placed connecting healthy parts of the external iliac artery proximally and common femoral artery distally. Good distal perfusion in the right leg was confirmed at the conclusion of the procedure.

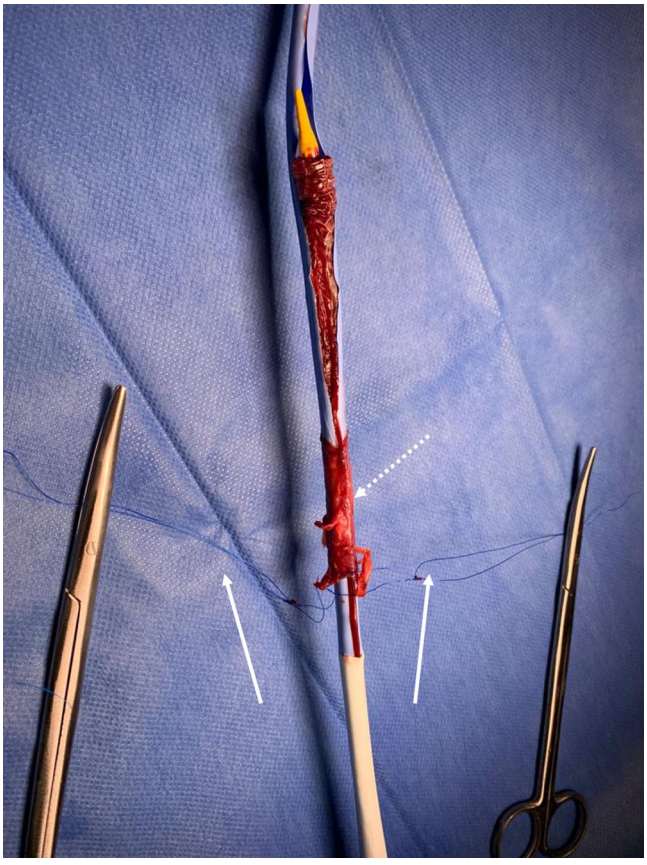

FIGURE 5 Segment of avulsed iliofemoral artery wrapped around the eSheath (white dashed arrow). White continuous arrows point to the Proglides sutures still attached to the arterial access point. These were removed intact with the avulsed vessel and eSheath. [Color figure can be viewed at wileyonlinelibrary.com]

Upon ex vivo inspection of the retrieved eSheath, it was apparent that it had lost its integrity with the separation of the inner lining from the outer plastic component. We hypothesize that retrieving the THV deployment balloon through the eSheath resulted in the stripping of the inner lining of the eSheath, resulting in a concertina effect and formation of a large diameter noncompressible swelling around the balloon (Figure 4B). This swelling led to the splitting of the eSheath seam bringing the concertinaed inner lining into direct contact with the vessel wall, causing abrasion and avulsion of the vessel. The ex vivo observations were consistent with the fluoroscopic findings. Although the diameter of the iliofemoral vessels was well above the minimum recommended diameter by the valve manufacturer (6 mm), the increased diameter of the clustered inner lining likely exceeded the inner diameter of the vessel, resulting in vessel avulsion and consequent hemorrhage.

Following emergency surgery, the patient was extubated and transferred to the intensive care unit. He developed acute kidney injury that responded to medical management and supportive measures without the need for hemofiltration. Recovery was slow but otherwise uneventful and the patient was discharged home on Day 20 post-TAVR. A predischarge echocardiogram showed good THV parameters with a maximum transvalvular velocity of 1.6 m/s, peak pressure gradient of 9.7 mmHg, mean pressure gradient of 5 mmHg, aortic valve area of 3.1 cm^2, and no detectable paravalvular leak and normalization of systolic function with an ejection fraction of 60%. Upon review at 6 months, the patient was well with no ischemic symptoms in the right leg and NYHA class I symptoms.

3 | DISCUSSION

The risk of vascular complications during TAVR has significantly fallen over time as a result of refinements in the procedural technique, operator experience, smaller caliber and more flexible sheaths, and comprehensive preprocedural planning with CT angiography. Nonetheless, the rate of major vascular complications remains significant at 2%–8% at 30 days post-TAVR in low- and intermediate-risk cohorts.[4,7–9] More precisely, iliofemoral rupture has been reported at 3%–5%.[10] Vascular complications overall portend a guarded prognosis with longer length of hospital stay, higher cost, and increased mortality at 1 year.[11–14]

Factors that increase the risk of vascular complications have been well described and include vascular calcification, particularly circumferential, peripheral vascular disease, female gender, and larger caliber sheaths.[15]

Iatrogenic vascular access-related vessel avulsion is a very rare complication of TAVR with conventional equipment and has been mainly described for the radial artery during left heart catheterization

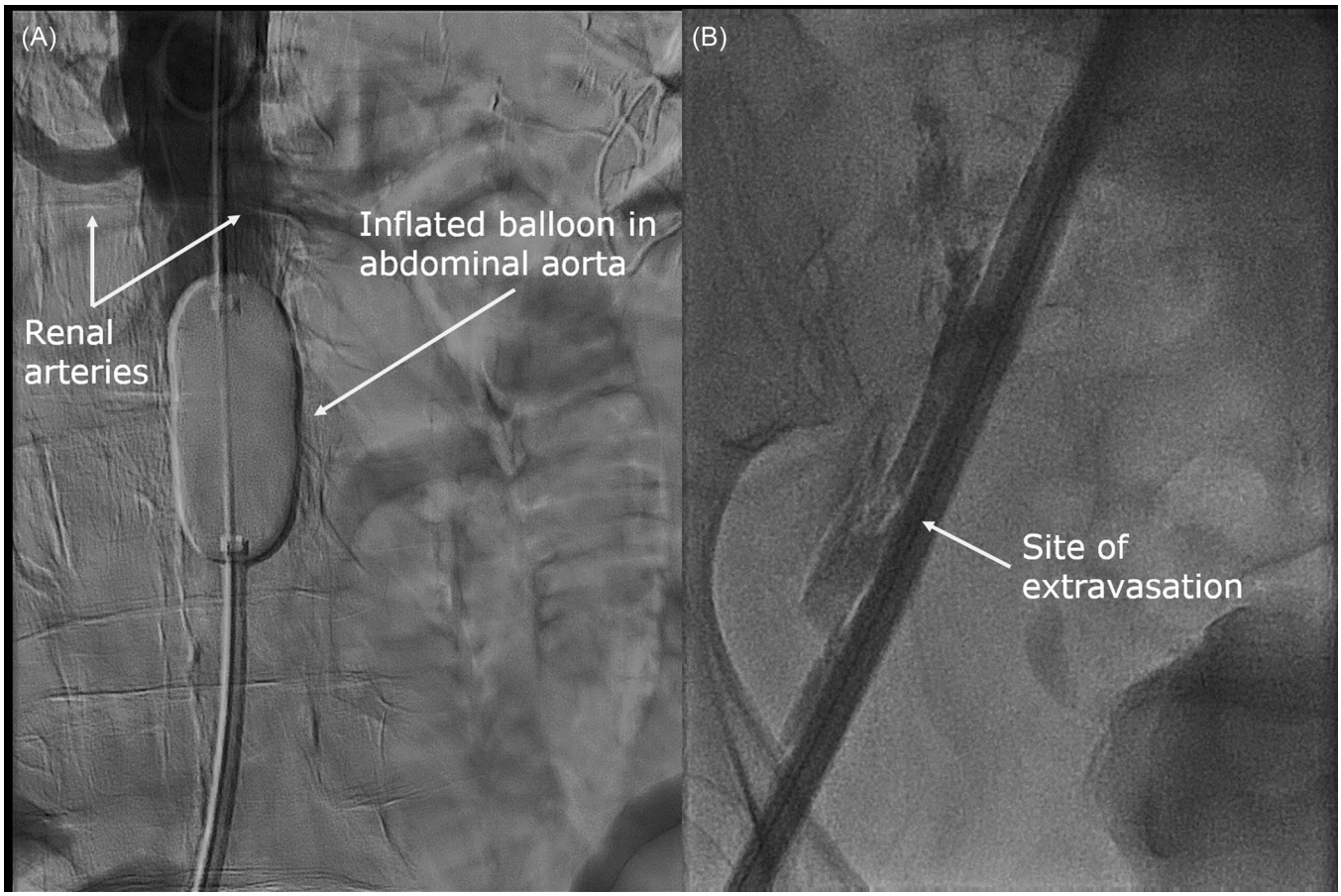

FIGURE 6 (A) Digital subtraction angiography. Inflated Coda balloon in the abdominal aorta. Renal arteries opacified with contrast above the Coda balloon. No contrast opacification past the Coda balloon confirming hemostasis. (B) Site of extravasation from external iliac artery.

in previous case reports.[16–18] Femoral artery avulsion is exceedingly rare in nontraumatic situations.

CT angiography is an indispensable tool used for a comprehensive assessment of vascular access and procedural planning. Nongated CT angiography of the thorax, abdomen, and pelvis is used with axial profiles and multiplanar reformats for assessment of the aorta and iliofemoral vasculature and reviewed for tortuosity, calcification, presence of aneurysms and/or dissection, and measurement of vessel diameter. All the above are crucially important and inform the operators on the suitability of femoral access or, in the case of unsuitability, of alternative vascular access options.[15]

Specific complications with the Edwards eSheath have only rarely been reported. A previous report has described the exiting of an Edwards Sapien 3 THV through an eSheath upon advancement through a calcified abdominal aorta in an elderly patient.[19] In that case, it was postulated that the interaction of the eSheath with spicules of calcium resulted in the premature splitting of the seam and exiting of the THV in the aorta. The complication was detected on fluoroscopy and the THV was successfully retrieved into the eSheath.

In our case, there were no unfavorable characteristics on CT angiography, and more precisely, no significant calcification, tortuosity, or atherosclerotic disease in the iliofemoral vasculature.

We hypothesize that this unusual complication was related to an interaction between the stiff, deflated deployment balloon of the Commander catheter, and the tip of the eSheath, which resulted in the separation of the lining from the outer wall. The free edge of the separated inner lining was then dragged down with the balloon increasing its profile and resulting in its exposure to the vessel wall through the open seam of the eSheath. The rigid concertinaed lining around the balloon then came into direct contact with the vessel wall through the open seam in the outer coat, causing abrasion and eventual avulsion of the vessel. The balloon did not rupture and the damage to the balloon hypotube occurred secondary to retrieval efforts.

In a bench model with a used 14F eSheath from an uncomplicated case with a 23-mm Sapien 3 Ultra, we observed a small gap between the inner lining and the outer coat (Figure 7). The inner lining can be stripped from the more rigid outer coat with relative ease (Supporting Information: Video 3).

The inner lining of the eSheath is made of polytetrafluoroethylene, otherwise known by its trade name Teflon®. This polymer provides the elongation/expansion and lubricity properties to the eSheath. The inner lining is attached to the outer plastic cover, which is made of high-density polyethylene and polyurethane, which provide tensile strength and low friction properties.

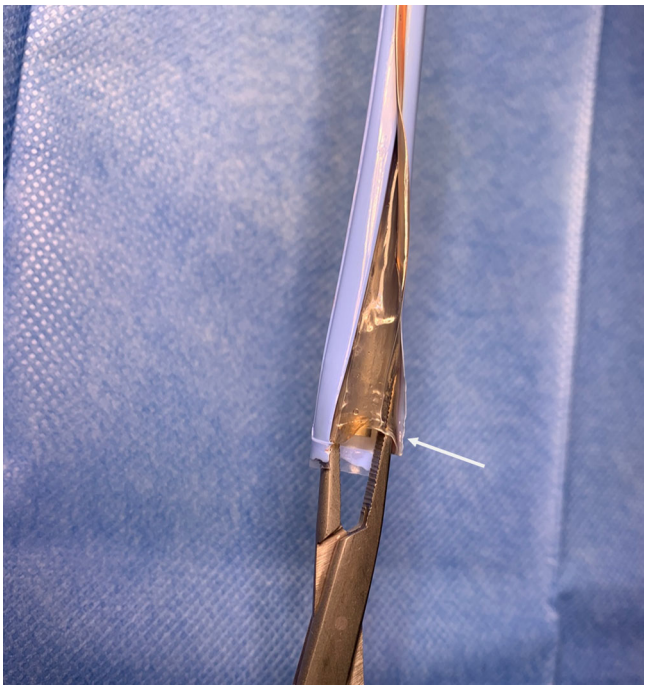

FIGURE 7 Used 14F eSheath after an uncomplicated case with a 23-mm Sapien 3 Ultra. A gap is evident between the inner and outer coats (arrow). [Color figure can be viewed at wileyonlinelibrary.com]

Our case also highlights the importance of maintaining guide wire access, occlusion balloons, and prompt availability of emergency vascular surgery in mitigating the injury from vascular complications. In our case, pre-emptive preparation of an appropriately sized occlusion balloon for inflation in the abdominal aorta was lifesaving and provided us with the necessary time to undertake fluid resuscitation and arrange vascular surgery.

The Coda balloon is a dedicated compliant over-the-wire balloon for large vessel temporary occlusion. It comes in two sizes, 9 Fr, which dilates up to 32 mm, and 14 Fr, which dilates up to 46 mm. The final diameter of the balloon is dictated by the inflation volume as per the manufacturer's volume/balloon diameter nomogram. The 9-Fr balloon is compatible with a minimum 12-Fr sheath. Alternative large-vessel occlusive balloons are available in the market including but not limited to the REBOA balloon (BVM Medical), Standard Occlusion Balloon Catheter (Boston Scientific), and QXMEdical Occlusion Balloon Catheter (QXMedical).

This is the first instance of femoral artery avulsion at our institution in over 1500 procedures and occurred in the hands of a highly experienced operator. The injury was surprising as the vessels were large caliber, free of disease, and in the absence of excessive force. We believe that knowledge of this rare complication may lead to actions that may mitigate or even prevent vascular injury. We propose that if resistance is encountered on withdrawing the Commander balloon into the E sheath tip and an appearance of the eSheath similar to that observed in this case (Figure 4A) is witnessed, then stripping of the lining may have occurred. In this circumstance, we would recommend *advancing* the balloon until the nose cone just exits the eSheath. This maneuver should straighten the concertinaed lining. The eSheath and Commander should then be removed en bloc while maintaining the guide wire position with no further attempts to retrieve the Commander catheter through the eSheath. A fresh eSheath may then be inserted and an inspection made for vascular injury. We believe these actions may avoid the injury caused by the concertinaed lining.

4 | CONCLUSIONS

Iliofemoral artery avulsion is a very rare but potentially life-threatening vascular access-related complication during large-bore arterial access procedures. This condition needs immediate identification and management.

In the case described, avulsion injury occurred due to a rare complication of the eSheath. It is hypothesized that vessel injury occurred as a result of the inner lining of the eSheath becoming detached from the outer jacket, due to interaction with the deflated deployment balloon, and becoming concertinaed as it was dragged by the balloon and forming a dense hard swelling. The rough surface of the concertinaed lining around the balloon may then cause abrasion and vessel avulsion due to its large profile.

Knowledge of the mechanism of this injury may allow operators to take actions that may mitigate or even prevent vascular injury.

CONFLICT OF INTEREST

Sagar N. Doshi is a proctor for Edwards Lifesciences and Boston Scientific and has received speaker fees from Boston Scientific, Medtronic, and Abiomed. The remaining authors declare no conflict of interest.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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