Managing Arrow-Trerotola Percutaneous Thrombolytic Device Complications

Russell O. Simpson, BS¹ Ron C. Gaba, MD^{1,2} Andrew J. Lipnik, MD^{1,2}

¹Department of Radiology, University of Illinois Hospital and Health Sciences System, Chicago, Illinois

²Division of Interventional Radiology, University of Illinois Hospital and Health Sciences System, Chicago, Illinois

Address for correspondence Andrew J. Lipnik, MD, Division of Interventional Radiology, Department of Radiology, University of Illinois Hospital and Health Sciences System, 1740 West Taylor Street, MC 931, Chicago, IL 60612 (e-mail: alipnik@uic.edu).

Semin Intervent Radiol 2019;36:91–96

Abstract

Keywords

- ▶ dialysis interventions
- ▶ venous rupture
- ▶ foreign body retrieval
- ▶ interventional radiology

Dialysis access interventions are frequently performed by interventional radiologists. Several commercially available percutaneous thrombolytic devices can help restore patency to thrombosed arteriovenous access circuits. The Arrow-Trerotola Percutaneous Thrombolytic Device is one such device, and has a long track record of safe and effective use. However, like any medical device, complications can occur during its use. This article describes three complications and associated management strategies utilizing fundamental interventional radiology techniques of balloon tamponade, stent placement, and snare mediated foreign body retrieval.

Case 1

A 62-year-old man with end-stage renal disease secondary to hypertension was referred to interventional radiology (IR) for evaluation of a thrombosed left upper arm brachial artery-cephalic vein fistula. Physical exam confirmed lack of a thrill in the fistula. Relevant laboratory tests, including serum potassium, were within normal limits, informed written consent was obtained, and a thrombectomy procedure was planned.

Preprocedural ultrasound confirmed thrombosis of the brachiocephalic fistula. Initial vascular access was obtained in an antegrade fashion using ultrasound guidance and modified Seldinger technique. After placement of a short vascular sheath, a catheter and Glidewire (Terumo Corporation, Somerset, NJ) were used to negotiate the thrombosed cephalic venous outflow and gain access to the patent left subclavian vein. Central venography was performed, which confirmed patency of the central veins (–Fig. 1a), and 3,000 units of heparin were administered intravenously. Pullback venography was performed to establish the level of thrombosis (–Fig. 1b). Next, the thrombosed portion of the fistula was laced with 4 mg tissue plasminogen activator (tPA; Genentech, South San Francisco, CA) using pulse-spray technique via an infusion catheter. Balloon angioplasty in the

proximal cephalic venous outflow was performed with resolution of a stenosis. After using ultrasound to establish a second retrograde access, the arterial plug was dislodged using a Fogarty embolectomy balloon (Edwards Lifesciences, Irvine, CA). At this point, a faint pulse was palpable. A venogram demonstrated slow flow in the fistula, with significant residual thrombus in the cephalic outflow. A 5-Fr Arrow-Trerotola Percutaneous Thrombolytic Device (PTD; Teleflex, Morrisville, NC) was activated throughout the length of the cephalic outflow vein, including the cephalic arch, via the venous sheath in an attempt to remove the remaining thrombus and improve flow (–Fig. 1c). However, the device was noted to abruptly stop in the cephalic arch, and was subsequently removed. Follow-up venogram demonstrated extravasation from the cephalic arch (–Fig. 1d). An expanding hematoma was noted in the left shoulder, which was controlled with manual compression. As the 5-Fr PTD is not an over-the-wire device, wire access across the site of injury was not maintained, and could not be reestablished in an antegrade fashion from the existing left arm access. Thus, a third vascular access was obtained via a vein in the right upper arm. Working in a retrograde fashion from the right arm, the site of injury in the left cephalic arch was successfully crossed, and wire access was reestablished. Overlapping metal stents were placed across the venous

Fig. 1 (a) Digital subtraction venogram with a catheter positioned in the left subclavian vein demonstrates a patent central venous system. (b) Fluoroscopic image during pullback venography demonstrates minimal clot in the cephalic arch, which is under-filling secondary to fistula thrombosis. (c) Fluoroscopic image demonstrating the percutaneous thrombolytic device in the cephalic outflow (white oval). (d) Venogram from a sheath positioned in the cephalic vein outflow (black asterisk) demonstrating frank extravasation of contrast from the cephalic arch (black oval). Note the marker wire extending into the area of extravasation rather than across the injury into the subclavian vein. (e) Spot radiograph after reestablishment of wire access across the injury and following placement of the first uncovered metal stent. (f) Postdilation of the stents with a balloon, also used for tamponade of the injury. (g) Final venogram demonstrates patency of the overlapping stents (extending between white arrows), and no further extravasation. Note the new stenosis of the left subclavian vein due to mass effect of the hematoma (black arrowhead). Case courtesy of Dr. Robert K. Ryu.

injury (►Fig. 1e), and along with balloon tamponade (►Fig. 1f) successfully controlled the hemorrhage. Final fistulogram demonstrated patency of the stents and no further extravasation of contrast (►Fig. 1g).

The patient was admitted for observation and pain management for the large left shoulder and chest wall hematoma. His hemoglobin remained stable, and there were no clinical signs of bleeding. He received a full session of dialysis via the left arm fistula, with a thrill in the fistula at the time of hospital discharge.

Case 2

A 48-year-old man with renal failure secondary to chronic hypertension was referred to IR for evaluation of a thrombotic left arm brachiocephalic fistula. The fistula had been

created 6 years previously, requiring repeated angioplasty of a cephalic vein outflow stenosis in the intervening years (►Fig. 2a). The patient noted prolonged bleeding times following decannulation over the past few dialysis sessions leading up to the thrombosis. On physical exam, the left arm fistula was mildly aneurysmal, with a faint pulse near the arterial anastomosis. The patient's serum potassium level and other relevant laboratory tests were normal, informed written consent was obtained, and a thrombectomy procedure was planned.

Preprocedural ultrasound confirmed thrombosis of the brachiocephalic fistula, and standard access was obtained in both antegrade and retrograde directions. Following confirmation of central venous patency, 3,000 units of heparin were given intravenously, and 4 mg tPA was instilled throughout the thrombotic portions of the cephalic vein

Fig. 2 (a) Digital subtraction venogram of a left arm brachiocephalic fistula demonstrates a patent brachiocephalic fistula with stenosis in the outflow cephalic vein (black arrow). The patient returned 7 months later with thrombosis. (b) Fluoroscopic image during attempted declot of the thrombosed brachiocephalic fistula, showing angioplasty of the cephalic outflow stenosis with an elastic waist (white arrow). Persistent narrowing secondary to elastic recoil was noted on follow-up venography (not pictured). (c) A 10-mm bare metal stent was placed across the stenosis and postdilated to 8 mm. During percutaneous thrombolytic device (PTD) activation in the newly placed stent to remove recurrent thrombus, the stent became enmeshed in the rotational basket (not pictured). (d) The PTD was successfully removed, but the stent (black oval) was markedly deformed and peripherally migrated as a result.

fistula. Mechanical thrombectomy was then performed uneventfully through the venous sheath with a PTD. After dislodging the arterial plug with a Fogarty embolectomy balloon, a faint thrill could be felt. A venogram confirmed patency, but there was residual mural thrombus, and flow remained poor. Review of the patient's last fistulogram, performed several months previously, demonstrated a stenosis in the cephalic vein outflow that was felt to be the culprit lesion (►Fig. 2a). Prolonged angioplasty was performed (►Fig. 2b), with reduction of the stenosis; however, repeat venogram confirmed elastic recoil. The cephalic vein stenosis was several centimeters central to the cannulation zone, and a S.M.A.R.T. metal stent (Cordis, Milpitas, CA) was deployed across the stenosis and post-dilated (►Fig. 2c). Follow-up venogram demonstrated persistent flow-limiting thrombus in the fistula, and repeat thrombectomy with the PTD was performed via the venous-directed sheath. However, the rotational basket became ensnared in the newly placed stent, and could not be disentangled. With some effort, the PTD was ultimately removed in its entirety, although the stent was significantly deformed and dislodged

peripherally in the process (►Fig. 2d). The fistula rethrombosed during this time, and the stent was left in place. The declot attempt was abandoned, and a dialysis catheter was placed. The patient later underwent uneventful creation of a left arm transposed brachiocephalic fistula, which remains patent several years later.

Case 3

A 49-year-old woman with end-stage renal disease secondary to hypertension and diabetes mellitus was referred to interventional radiology for evaluation of a thrombosed left arm axillary artery–axillary vein loop graft. The graft had been implanted 2 years previously and had required multiple previous declotting procedures resulting in placement of stent grafts bridging the venous anastomosis. The patient's serum potassium and other relevant laboratory tests were normal, informed written consent was obtained, and a thrombectomy procedure was planned.

Preprocedural ultrasound confirmed thrombosis of the graft, and standard vascular access was obtained in antegrade

direction toward the venous outflow. After confirming central venous patency, tPA was administered, and the patient systemically anticoagulated with heparin. Mechanical thrombectomy of the venous limb of the graft was performed uneventfully with a 5-Fr PTD, excluding the indwelling stent grafts at the venous anastomosis (►Fig. 3a). Following removal of the PTD, a new linear radiopaque object was noted in the venous outflow limb of the graft, which remained thrombosed. Examination of the Arrow-Trerotola on the back table was notable for absence of the soft rubber tip. Using standard snare retrieval technique, the linear object was successfully removed (►Fig. 3b) and confirmed to be the disconnected soft rubber tip of the Arrow-Trerotola PTD (►Fig. 3c). Fluoroscopy was used to check the AVG to make sure it was completely clear of additional foreign bodies, and the thrombectomy procedure was successfully completed.

Discussion

Dialysis is a life-saving therapy for patients with renal failure. As of 2015, there were 468,000 patients on dialysis in the United States, the vast majority of who are on hemodialysis.¹ For these patients, maintenance of vascular access is of paramount importance. Arteriovenous (AV) fistulae and synthetic AV grafts are superior to central venous catheters with respect to infection rates and mortality, and mature fistulae are superior to grafts with respect to infection and patency rates.² Regardless of AV access type, restoration of patency in the setting of AV circuit thrombosis is critical.

Percutaneous thrombectomy is a well-established treatment for thrombosed AV fistulae and grafts. Numerous treatment strategies have been developed to safely, effectively, and quickly restore patency to thrombosed AV circuits, and multiple devices have been approved to aid thrombectomy of AV circuits, including the Argon Cleaner XT Rotational Thrombectomy System (Argon Medical, Frisco, TX), AngioJet Peripheral Thrombectomy Catheter (Boston Scientific, Marlborough, MA), and the Arrow-Trerotola PTD.

Since the FDA approval in 1997, the PTD device has gained widespread use for the restoration of flow in fistula and grafts. Two versions of the device are available: a 5-Fr version indicated for use in synthetic AV grafts and a 7-Fr over-the-wire version additionally indicated for use in AV fistulae. The entire device is disposable and consists of two components: a catheter with an expandable wire fragmentation basket and a battery-operated base-unit motor capable of spinning the basket at 3,000 rpm (►Fig. 4). The fragmentation basket is collapsed into the device catheter prior to insertion through the procedural sheath. It is then reexpanded in the clotted AV access, and gently retracted while activating the rotational fragment basket, which is again collapsed prior to removal. It is designed to fragment thrombus into small (<3 mm) pieces, which can be aspirated from the circuit prior to reestablishing flow.³

Like all percutaneous devices, understanding the indicated uses, limitations, and points of failure is critical to the safe application of the device. The Instructions for Use (IFU)—provided as an insert in every device package—details indications, contraindications, and specific use parameters for

Fig. 3 (a) Fluoroscopic image during mechanical thrombectomy with a percutaneous thrombolytic device (PTD) in a left arm axillo-axillary AV loop graft. Note the indwelling stent grafts bridging the venous anastomosis (white arrowheads). (b) Following thrombectomy, a linear radiopaque foreign body was noted in the graft (black arrow) and retrieved with a snare device. (c) Photo of the PTD with the plastic tip retrieved from the graft (black arrow).

Fig. 4 Photo of an assembled percutaneous thrombolytic device. The black oval encircles the expanded fragmentation basket, and the white arrow points to the activation trigger on the external rotator unit.

that particular device. In the first case, a 5-Fr device was used, despite its indication for grafts rather than fistulae. A 7-Fr device may have been a better choice, as it is indicated for use in both fistulae and grafts, and is an over-the-wire device. The exact etiology of the cephalic venous injury is unclear, but certainly maintaining wire access across the treated (and injured) segment would have made management of the complication significantly easier and safer. In the second case, the fragmentation basket became entangled in a freshly placed bare metal stent; in retrospect, this was an avoidable complication if the warning against use of the device in stents in the IFU had been heeded.

Device-specific complications related to use of the PTD are uncommon. The initial report demonstrating equivalent efficacy of the device compared with pulse-spray thrombolysis (the gold standard at the time) also described an equivalent major complication rate (8% with the device and 9% without), with none attributed to the device itself.³ However, the report did separately describe two devices' malfunctions including wire breakage of the fragmentation basket (2.5% incidence). The authors remarked on this as an improvement following device redesign during preclinical testing, which had previously resulted in device breakage in 21% of procedures.⁴ Per the authors, subsequent advancements have reduced breakages to "nearly zero,"³ and a review of the literature could find only one additional case.⁵

Vascular ruptures related to the Arrow-Trerotola PTD, as in our first case, are also rarely reported. In 2018, Hong et al reported a case of axillary vein rupture and entrapment of the fragmentation basket requiring surgical removal. The authors hypothesized that a valve or dissection flap from prior angioplasty may have precipitated the PTD entrapment.⁶ In our case, the exact mechanism is unclear, with possibilities including entanglement in a venous valve, activation in a small tributary of the main cephalic vein, or inadvertent direct perforation of the cephalic arch by the device. The latter two possibilities may theoretically be avoided with the 7-Fr over-the-wire version. Regardless of

cause, maintenance of wire access would have simplified management by removing the need for time consuming retrograde crossing of the injured segment. Furthermore, recrossing a vascular injury is not always possible, and would have led to a significantly less favorable outcome. Finally, control of iatrogenic endovascular injury via manual compression in superficial structures, internal balloon tamponade, or stent and stent graft placement is requisite skill necessary when performing endovascular procedures. In our case, manual compression was used for temporary hemostasis while the definitive treatment of balloon tamponade and bare metal stent placement were performed. Currently, the authors would likely use a self-expanding stent graft, such as a Viabahn (W. L. Gore, Flagstaff, AZ), which has the additional advantage of improved patency rates in the cephalic arch compared with angioplasty or bare metal stents.⁷⁻¹¹

Given the IFU warning against using the PTD in stents, case reports of stent-related complications are predictably difficult to find in the literature. Recent stent placement, poor wall apposition (more likely in fistulae than in grafts), and bare metal construction could all plausibly contribute to increased likelihood of stent entanglement with the fragmentation basket. Certainly, the authors would currently recommend against the use of the Arrow-Trerotola PTD in recently placed stents. Extreme caution should be exercised during device use even in the setting of well-endothelialized stents, while understanding that this represents off-label use not supported by the current evidence, and explicitly warned against in the IFU.

Dislodgement of the soft rubber tip of the PTD may be more common. A case series from Kim et al in 2014 reported five instances of disconnection in 453 uses of the device.¹² The disconnections occurred both in fistulae and grafts, and the apparent commonality of each case was activation of the device across a segment of the fistula or graft with an acute angulation. The likely mechanism is fixation of the soft rubber tip during rapid (3,000 rpm) rotation of the fragmentation basket, which then becomes disconnected secondary to material fatigue. The IFU does recommend a rapid pullback rate of 1 to 2 cm/second in areas of acute angulation (i.e., radius of loop graft or fistula < 3 cm). However, this is presented more as a way to reduce the likelihood of "fatigue failure of the torque cable and fragmentation basket" and does not explicitly warn of the prospect of tip disconnection. In our case, the tip may have been wedged between the AV graft material and an indwelling stent graft at the venous anastomosis, resulting in tip disconnection after the fragmentation device was activated. Fortunately, the disconnected tip was recognized before flow was restored to the graft, making snare retrieval simple.

Although the complications reported herein are grouped thematically as related to the PTD, it is important to note that any medical device can cause injury, particularly when it is not used in accordance with the manufacturer's instructions. Even under the best of circumstances, complications can and will happen. It is critical to remember basic IR techniques such as maintenance of wire access, balloon tamponade,

manual compression, and the use of snare catheters to help ameliorate the consequences of therapeutic misadventures. Anticipating likely complications of the intended procedure allows formulation of a contingency plan, and ensures the necessary equipment is readily available to treat unintended event. This preprocedural “game planning” helps one to act with speed and clarity when treating complications and can mean the difference between a hiccup in an otherwise successful procedure, or a truly disastrous outcome.

Disclosure

R.O.S. and A.J.L. have nothing to disclose. R.C.G. received research funding from the Guerbet USA, the U.S. Department of Defense, and from the NIH.

Conflict of Interest

None.

References

- 1 Saran R, Li Y, Robinson B, et al. US Renal Data System 2015 Annual Data Report: epidemiology of kidney disease in the United States. *Am J Kidney Dis* 2016;67(03, Suppl 1):S1–S305
- 2 Lok CE, Foley R. Vascular access morbidity and mortality: trends of the last decade. *Clin J Am Soc Nephrol* 2013;8(07):1213–1219
- 3 Trerotola SO, Vesely TM, Lund GB, Soulen MC, Ehrman KO, Cardella JF; Arrow-Trerotola Percutaneous Thrombolytic Device Clinical Trial. Treatment of thrombosed hemodialysis access grafts: Arrow-Trerotola percutaneous thrombolytic device versus pulse-spray thrombolysis. *Radiology* 1998;206(02):403–414
- 4 Trerotola SO, Davidson DD, Filo RS, Dreesen RG, Forney M. Preclinical in vivo testing of a rotational mechanical thrombolytic device. *J Vasc Interv Radiol* 1996;7(05):717–723
- 5 Dupaix R, Mohan PP. Trerotola device fragmentation. *Cardiovasc Interv Radiol* 2017;40(04):636–638
- 6 Hong YK, Kang KH, Kim TH, Yang HC. Vein rupture by Arrow-Trerotola percutaneous thrombolytic device in a treatment of thrombosed arteriovenous graft. *J Vasc Access* 2018;19(04):396–397
- 7 D’cruz RT, Leong SW, Syn N, et al. Endovascular treatment of cephalic arch stenosis in brachiocephalic arteriovenous fistulas: a systematic review and meta-analysis. *J Vasc Access* 2018; doi: 10.1177/1129729818814466 [Epub ahead of print]
- 8 Jones RG, Willis AP, Tullett K, Riley PL. Results of stent graft placement to treat cephalic arch stenosis in hemodialysis patients with dysfunctional brachiocephalic arteriovenous fistulas. *J Vasc Interv Radiol* 2017;28(10):1417–1421
- 9 Miller GA, Preddie DC, Savransky Y, Spergel LM. Use of the Viabahn stent graft for the treatment of recurrent cephalic arch stenosis in hemodialysis accesses. *J Vasc Surg* 2018;67(02):522–528
- 10 Rajan DK, Falk A. A randomized prospective study comparing outcomes of angioplasty versus VIABAHN stent-graft placement for cephalic arch stenosis in dysfunctional hemodialysis accesses. *J Vasc Interv Radiol* 2015;26(09):1355–1361
- 11 Shawyer A, Fotiadis NI, Namagondlu G, et al. Cephalic arch stenosis in autogenous haemodialysis fistulas: treatment with the Viabahn stent-graft. *Cardiovasc Interv Radiol* 2013;36(01):133–139
- 12 Kim HM, Kim HC, Woo S, Son KR, Jae HJ. Disconnection of the rubber tip of Arrow-Trerotola percutaneous thrombolytic device. *Korean J Radiol* 2014;15(02):254–257