Case Report

JHSMR Journal of Health Science and Medical Research

Case Series Utilizing a Novel Rotational Mechanical Thrombectomy Device for the Treatment of Thrombosed Arteriovenous Grafts in Thailand

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Received 25 July 2025 ● Accepted 30 September 2025 ● Published online 20 March 2026

Abstract:

Endovascular treatment of thrombosed hemodialysis access is a standard option for restoring flow. Standard treatments, including pharmacomechanical thrombolysis, mechanical thrombectomy, or a combination of therapies, have been commonly used. Mechanical thrombectomy is widely accepted for the treatment of thrombosed arteriovenous fistulas or grafts because the devices have been proven effective and easy to use. Hence, we present a case series of thrombosed hemodialysis grafts successfully salvaged with endovascular mechanical thrombectomy utilizing a rotational thrombectomy system.

Keywords: arteriovenous grafts, mechanical thrombectomy device, salvage, thrombosis

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J Health Sci Med Res 2026;44(5):e20261340
doi: 10.31584/jhsmr.20261340
www.jhsmr.org

Introduction

Thrombosed hemodialysis access is an urgent condition encountered in end-stage kidney disease patients who undergo regular hemodialysis. Early treatment of the thrombosed hemodialysis access has been shown to maintain the quality of life for these patients[1,2]. Surgical thrombectomy is still a traditional treatment option in many countries because of what is often considered lower procedural costs. However, previous publications have reported low procedural success rates ranging from 28% to 73%[3,4]. Percutaneous endovascular treatments have become a standard method for access salvage due to their minimally invasive nature, high technical success, and low complication rates[5-7]. Endovascular salvage includes thrombo-aspiration, thrombolysis, pharmacomechanical thrombolysis, mechanical thrombectomy, or a combination of the therapies[5-7].

Currently, mechanical thrombectomy is an alternative for treating thrombosed arteriovenous grafts (AVGs) at many institutions because it is highly effective with rapid morcellation facilitating thrombus removal[7-9]. This study reports a case series of thrombosed AVG with successful salvage utilizing the Cleaner XT™ rotational thrombectomy device.

Case Report

Patients

This study included five end-stage renal disease patients undergoing serial hemodialysis, who had experienced thrombosed AVG and underwent mechanical thrombectomy utilizing a Cleaner thrombectomy device at a university hospital in Southern Thailand. There were three females and two males. Their ages ranged from 67 to 80 years. There were three left brachio-axillary AVGs, one right brachio-brachial AVG, and one left brachio-anticubital AVG. Three patients had the co-existence of central left brachiocephalic vein occlusion. All patients underwent percutaneous mechanical salvage of their thrombosed AVG using the Cleaner XT™ rotational thrombectomy device, employed within 48 hours after the onset of graft thrombosis.

Procedure

Informed consent was obtained from all the patients before the procedure. Ultrasound was used to evaluate the entire graft, both arterial and venous anastomosis, and for draining veins. The procedure was performed under local sedation and sterile technique. An 8 French (Fr) vascular sheath was inserted into the arterial limb of the U-shaped graft. Cannulation was performed near the arterial-graft anastomosis of the straight graft in antegrade fashion; whereas, another 8 Fr sheath was advanced into venous limb of the U-shape graft or near the venous-graft anastomosis of the straight graft retrograde, then a 5 Fr diagnostic catheter was advanced via the antegrade sheath into patent draining vein, then angiogram was performed to evaluate the patency of the central vein: 70 IU/kg of unfractionated heparin was intravenously administered.

Adjunctive thrombolysis was performed utilizing tissue plasminogen activator (t-PA) in two patients due to extensive thrombus burden in the entire graft with extension of the thrombus into the draining central vein. A 4-Fr, 20-cm infusion length, multiple side-hole infusion catheter (Cragg-McNamara, EV3, CA, USA) was advanced via the retrograde sheath, with its tip placed at the arterial-graft anastomosis, then 2.5 mg of tPA was used, with 1 mg loaded bolus via infusion catheter, and then serial infusion of 0.25 mg via the infusion catheter every 30 sec with a 1-mL syringe. Similarly, adjunctive thrombolysis was then performed via the antegrade sheath for the thrombus in the draining vein and venous limb of the graft.

A Cleaner XT™ rotational thrombectomy device (Argon Medical Devices, Plano, TX, USA) was advanced via the retrograde sheath to macerate the thrombus in the arterial limb of the graft, followed by thrombo-aspiration

with a 6-Fr, 45-cm guiding sheath (DuraSheath, Medical International GmbH, Dresden, Germany) to remove the thrombus. Next, a similar step was performed via the antegrade sheath, removing the thrombus from the draining vein and venous limb of the graft. Subsequently, an angiogram was performed to survey for residual thrombus and underlying stenotic sections. Additional rotational thrombectomy with the Cleaner XT™ thrombectomy device was performed, followed by thrombo-aspiration to address any residual thrombus noted during the angiogram. Then, balloon angioplasty was performed with the noncompliant balloon (Mustang, Boston Scientific, MA, USA) using a diameter of 7 mm until full expansion to treat the underlying significant stenosis. The final angiogram was performed to evaluate circuit patency. All vascular sheaths were extracted, followed by the application of manual compression to ensure hemostasis.

Results

Procedural success, defined as complete restoration of patency of the fistula circuit, was demonstrated in four out of five cases (Figure 1). Initial hemodialysis was performed without issue on all patients who experienced procedural success. Early procedural termination in a patient who experienced intraoperative cardiac arrest during the procedure was counted as a procedural failure, as thrombectomy and access flow restoration were incomplete prior to cardiopulmonary resuscitation and normalization of vital signs within 1 min. Due to the incident, the procedure was terminated, and the patient was investigated for the cause of cardiac arrest. Electrocardiography showed no myocardial ischemia or infarction. Computed tomography (CT) of the brain revealed no findings of intracranial hemorrhage or acute large territory infarction. Blood electrolytes were normal. CT pulmonary angiography revealed a small, discrete embolus in a segmental branch artery of the right middle lobe, with no pulmonary hypertension noted in the RV/LV ratio comparison. (Figure 2). This patient was immediately hemodialyzed with a tunneled hemodialysis catheter and an appointment for new fistula creation at the right upper extremity. Although the cause of cardiac arrest was considered indeterminant in this patient, the patient was still placed on anticoagulation due to the small pulmonary embolus.

Discussion

Endovascular salvage of arteriovenous (AV) access has now become the preferred option over surgery in most patients due to its demonstrated benefits, including being minimally invasive, replicable, providing for minimal delay in dialysis, and enabling thrombus removal, along with the treatment of culprit stenosis in the same session[5,10]. Despite the increasing use of endovascular approaches in the modern era, surgical thrombectomy may still have some clinical advantages, such as a lower risk of thrombus dislocation, minimal use of thrombolytic drugs, and the ability to surgically repair ruptured access sites or pseudoaneurysms during the same operation. Additionally, for large aneurysmal fistulas, the surgical approach is still preferred for removing chronic wall-adherent thrombus and revising aneurysms[10]. Endovascular techniques, by definition, include thrombolysis, mechanical thrombectomy, or a combination of these techniques. Thrombolysis involves the percutaneous infusion of de-clotting or lysing agents directly into the thrombus, and it is primarily effective for acutely formed fresh thrombi. A few of the thrombolysis techniques described in the literature, such as the lyse-and-wait and pulsed-spray techniques, aim to shorten lysis time and enhance the thrombolytic effect[2,6,10]. Yeo et al. reported outcomes of catheter-directed thrombolysis in AVF thrombosis, showing a 92% technical success rate. Primary patency at 12, 24, and 36 months was 87%, 62%, and 36%, respectively[5]. However, thrombolysis alone has limited efficacy due to its inability to remove arterial

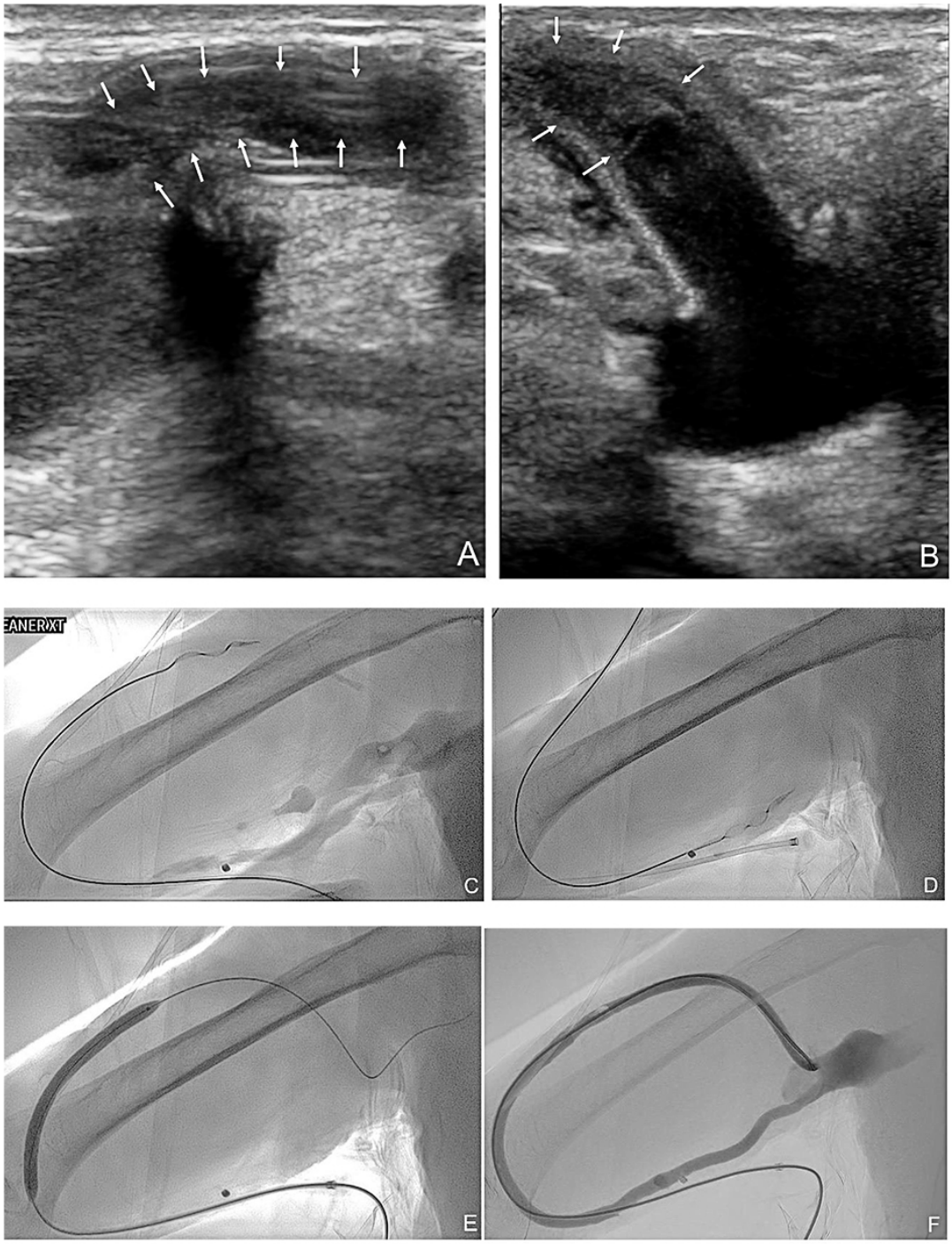

Figure 1 Ultrasound of the arteriovenous graft showing intraluminal thrombus (arrows) at (A) the venous limb and (B) the arterial limb; (C) and (D) mechanical thrombectomy for maceration and fragmentation of the thrombus along the graft; (E) balloon angioplasty to macerate the residual thrombus and treat the underlying stenosis; (F) final angiography showing patent the arteriovenous graft.

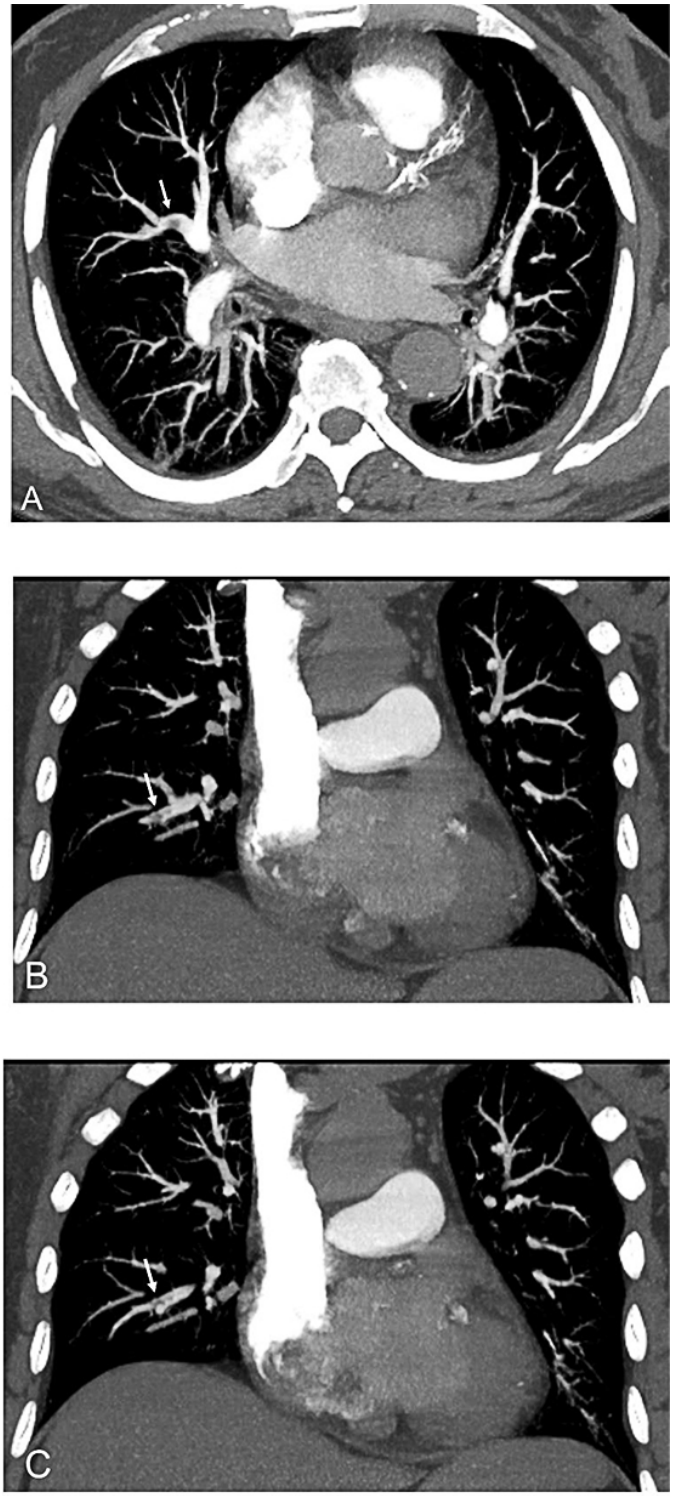

Figure 2 The axial (A) and coronal (B) & (C) views of computed tomography angiography of the pulmonary arteries showing a small thrombus (arrow) in the middle lobe segmental branch of the right pulmonary artery

fibrin plugs that are resistant to thrombolytic agents, and its ineffectiveness in directly macerating and removing clots in patients with a high clot burden, often leading to longer procedural duration times and the need for intensive care monitoring[2,5,6,9]. Mechanical thrombectomy has demonstrated advantages over infusion lysing, such as shorter procedure times and decreased use of thrombolytic agents, which are clinically associated with bleeding risks and no need for intensive care monitoring[2,7]. Conventional thrombectomy techniques, which use a balloon to macerate clots and remove arterial plugs, have traditionally been used in some centers in combination with a de-clotting agent, a method called pharmaco-mechanical thrombolysis. Several endovascular thrombectomy devices have been reported in the literature for use in AVF thrombectomy. The AngioJet device (Boston Scientific, Marlborough, Massachusetts) uses the Venturi effect, which generates a high-pressure saline jet to fragment the clot and creates negative pressure aspiration to remove the clot[8]. Several studies have reported the use of the AngioJet in AVG and AVF thrombectomy, showing a 91% technical success rate, with primary patency at 1, 3, and 6 months being 71%, 60%, and 37%, respectively. However, it is not a mechanical wall-contact device and may not be effective for organized, wall-adherent clots, especially in aneurysmal and dilated fistulas. Notably, the use of the AngioJet has been reported to be associated with transient bradyarrhythmia caused by its hemolytic effect[10-11]. The Indigo aspiration thrombectomy system (Penumbra, Alameda, CA, USA) is a vacuum-assisted device that enables the continuous aspiration of clots, benefiting patients with contraindications to thrombolysis, low pulmonary reserve (unable to tolerate pulmonary embolism), or right-to-left shunting. Moreover, some literature favors the use of aspiration thrombectomy in thrombosed hemodialysis reliable outflow (HeRO) grafts, which typically contain a large clot burden when they occlude [10]. A prior study showed that the use of the Indigo system for AVG and AVF thrombectomy resulted in a 97% technical success rate, with a six-month primary patency rate of 71%. No hemolytic complications were reported[10]. Complications of endovascular thrombectomy include peri-access hematomas, vessel rupture, pseudoaneurysms, arterial embolization, and pulmonary embolism[8,10]. The risk of serious complications may be minimized with proper patient selection, gentle device manipulation, and meticulous procedural techniques [6]. Subclinical pulmonary embolism is common but rarely clinically symptomatic[8]. However, in patients with low pulmonary reserve, the risks and benefits of the procedure should be carefully discussed. The use of periprocedural systemic anticoagulation and thrombectomy devices with aspiration functions may be helpful[6,9-10].

The Cleaner Rotational Thrombectomy System (Argon Medical, Plano, TX, USA) is a rotating sinusoidal wire with a simple handheld controller, designed for clot maceration. The wire conforms to the vessel wall diameter, maximizing wall contact to effectively remove wall-adherent thrombus. The system also features a side port that can be used to infuse thrombolytic agents. When thrombolytics are combined with wire rotation, a fluid vortex is created, which helps macerate thrombi, strip clots from the vessel wall, and enhance the thrombolytic effect[6,10-11]. Bong et al. reported a 12-month efficacy outcome using the Cleaner XT™ rotational thrombectomy system for salvaging thrombosed AV access[11]. The study included 34 patients with AV access thrombosis and found technical and clinical success rates of 100%. The primary patency rates at 1, 3, 6, and 12 months were 89%, 80%, 68%, and 56%, respectively. As a wall-contact device, the Cleaner system is capable of removing older, more organized, wall-adherent clots, potentially leaving behind less thrombogenic material and allowing for treatment in aneurysmal vessel segments where traditional balloon maceration or other thrombectomy methodologies may show limited efficacy. This could lower the risk of re-thrombosis[11]. Complications occurred in 5.9%

of cases, including hematoma and venous rupture. No clinically significant pulmonary embolism was detected[11].

This case study represents the first case use of mechanical rotational thrombectomy in Thailand to treat AVG thrombosis documented in the clinical literature. Based on our case series, the technical success rate was 4 out of 5 patients (80%). This case series shows results consistent with previous studies, where the use of the Cleaner XT™ rotational thrombectomy system for endovascular salvage of AV access thrombosis resulted in high technical success rates [11]. One technical failure occurred due to an intra-procedural cardiac arrest, which prevented the completion of the procedure. The only detected evidence was a small segmental pulmonary embolism. We hypothesize that the patient may have had a poor cardiopulmonary reserve, rendering them unable to tolerate even a small pulmonary embolism, which may have precipitated the cardiac arrest. Cardiac dysfunction is prevalent in the ESRD population, particularly right ventricular dysfunction[6]. We strongly recommend that, before attempting endovascular salvage of acutely thrombosed AV access, a thorough assessment of the patient's cardiopulmonary reserve should be conducted. Identifying the signs of poor reserve is crucial to guide thrombectomy device selection, procedural strategy, and ensure gentle intra-procedural device manipulation[6,9].

Conclusion

Endovascular treatment of thrombosed AVG using rotational mechanical thrombectomy is effective and safe. This technique and device can be used as an alternative for the treatment of thrombosed dialysis access in the current practice.

Acknowledgement

The authors would like to thank all the patients.

Conflict of interest

The authors report that there are no competing interests to declare.

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