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Original Article

Continuous Aspiration Mechanical Thrombectomy for Treatment of Thrombosed Hemodialysis Reliable Outflow Grafts

Abstract

Aims: To determine the safety and feasibility of continuous aspiration mechanical thrombectomy (CAT) for restoring patency to thrombosed hemodialysis reliable outflow (HeRO) arteriovenous grafts. **Subjects and Methods:** Between December 2016 and August 2017, eleven consecutive patients (average age 63, range 39–80 years) with thrombosed HeRO grafts underwent percutaneous thrombectomy procedures (n = 21) using the Penumbra Indigo® CAT 8 or CAT D (Alameda, CA, USA) thrombectomy catheter as the primary device to clear the venous outflow tract before removing the arterial plug with a compliant balloon. A total of 21 hemodialysis declot procedures using CAT were documented and analyzed. Average procedure length and fluoroscopy time, length of thrombus cleared, blood loss, complications, and time between thrombectomy procedures were recorded and compared to the same patient's previous three thrombectomy procedures. **Results:** All procedures were technically successful (100%) at restoring graft patency; however, reocclusion within 5 days occurred in four (19.0%) cases. Three (14.3%) interventions required additional balloon maceration or sweep to clear the venous outflow following thrombectomy. Average thrombus length treated by suction thrombectomy measured 23.15 cm (range 2.2–65 cm). Average blood loss was 162.6 mL (range 50–250 mL). No procedure-related complications were recorded. The average procedure length and fluoroscopy time using suction thrombectomy was 74.7 and 14.2 min, respectively, compared with 82.0 and 14.0 min, respectively, in the previous thrombectomy procedures using standard methods ($P > 0.05$). Seventeen (81%) HeRO grafts treated by CAT presented with rethrombosis at a mean of 42.47 days (range 1–208 days, median 22 days, standard deviation [SD] 28.2 days) since CAT procedure compared to patients treated by conventional methods who presented for rethrombosis at a mean of 55.33 days (range 1–321 days, median 34 days, SD 43.1 days) since standard thrombectomy – no statically significant difference ($P > 0.05$). **Conclusion:** CAT is a safe and feasible method for removing thrombus and restoring patency to thrombosed HeRO grafts. Further studies are required to elucidate the advantages of CAT over standard thrombectomy techniques.

Keywords: *Endovascular, hemodialysis, suction, thrombectomy*

Osman Ahmed, Mohamad Omar Hadied[1], Sreekumar Madassery, Merve Ozen, Patrick Tran, Adolfo E. Lizardo[2], Jordan C. Tasse, Ulku Cenk Turba, Bulent Arslan

Department of Radiology, Section of Interventional Radiology, Rush University Medical Center, Chicago, IL, [1]Department of Radiology, Wayne State University School of Medicine, Detroit, MI, USA, [2]Department of Radiology, South Medical Clinic and Hospital, National Institute of Cancer, Mexico City, Mexico

Introduction

Hemodialysis reliable outflow (HeRO) grafts (Merit Medical; South Jordan, Utah, USA) are devices often used in patients with failed alternative methods of achieving arteriovenous (AV) access such as AV fistulas or conventional polytetrafluoroethylene (PTFE) AV grafts. HeRO grafts consist of two components;[1] expanded PTFE in the upper arm anastamosed to the brachial artery and connected to a braided nitinol outflow component with its tip in the right atrium.[2,3] This lengthy direct shunt between the artery and right atrium poses potential risk for greater thrombus burden when compared to conventional PTFE AV grafts.[4] This thrombus burden ultimately further increases the risk of subclinical pulmonary emboli during thrombectomy procedures which can result in chronic pulmonary hypertension.[5-9] This potential consequence of HeRO graft thrombectomy emphasizes the need to minimize the extent of subclinical pulmonary embolism (PE), particularly in patients with large clot volume.

Percutaneous continuous aspiration thrombectomy interventions for mechanical thrombectomy are well documented in the literature and have been shown to be safe and effective as both primary and adjunctive endovascular therapies for treating acute thromboembolic disease. In

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Address for correspondence:
*Dr. Osman Ahmed,
Rush University Medical Center,
5841 S. Maryland Ave., Chicago
60637, IL, USA.
E-mail: osman1423@gmail.com*

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the last 5 years, numerous studies have described the use of continuous aspiration mechanical thrombectomy (CAT) for both arterial and venous applications. Specifically, the role for CAT has been identified as a treatment for PE, lower extremity arterial occlusions, carotid occlusions, iliocaval thromboses, right atrial thromboses, mesenteric thromboses, as well as aspiration of vegetations on implanted cardiac leads or valves.[1,2,10-14] Given its potential to evacuate thrombus and prevent recurrent subclinical pulmonary emboli, CAT may represent a method to treat thrombosed dialysis access shunts. Currently, however, the role of CAT for restoring patency in dialysis access has not been clearly defined. The purpose of this study was therefore to investigate the safety and feasibility of using CAT to restore patency to thrombosed HeRO access grafts.

Subjects and Methods

Patients

A retrospective study, approved by the Rush University Medical Center Institutional Review Board, of all consecutive patients undergoing percutaneous thrombectomy for thrombosed HeRO grafts between December 2016 and September 2017 was conducted at a tertiary care academic hospital. Informed written consent was obtained from all patients for this study. At our institution, the standard approach to diagnose the thrombosed graft is made clinically by physical examination indicating a lack of thrill. As per institutional preference, mechanical thrombectomy devices are used routinely to treat clotted HeRO grafts. Among these cases, patients who had undergone thrombectomy using the Penumbra® (Alameda, CA, USA) Indigo CAT system were identified. Inclusion criteria included patients with HeRO grafts who had undergone at least three prior thrombectomies using standard mechanical thrombectomy techniques (to allow for comparison). Demographic and procedural variables were recorded from the patients' electronic medical charts and picture archiving and communication system database [Table 1]. Complications were documented according to Society of Interventional Radiology quality improvement guidelines for percutaneous image-guided management of the thrombosed or dysfunctional dialysis circuit.[15]

In the time period studied, a total of 183 percutaneous pharmacomechanical thrombectomies for thrombosed dialysis access shunts were performed. Among these, percutaneous thrombectomy using CAT was performed 21 times in 11 consecutive patients with HeRO grafts. Patients with HeRO grafts identified to be clotted within 1 week of presentation were treated using the CAT-D or CAT-8 Indigo® aspiration device (Penumbra®, Alameda, CA, USA). Standard institutional protocol for performing percutaneous thrombectomy on thrombosed dialysis AV shunts included correction of serum potassium to a level <6 mmol/L and an international normalized ratio <3. All CAT procedures were performed by one of three board-certified interventional radiologists with at least 3 years of experience. The follow-up duration was 6 months for all patients.

Table 1: Patient demographics

Variables	*n* (%) or (range)
Male	6 (54.54)
Female	5 (45.45)
Age, years	63 (39-80)
Mean length of ESRD	9.65
Comorbidity	
Hypertension	11 (100)
Hyperlipidemia	5 (45.45)
Diabetes mellitus	4 (36.36)
Antiplatelet therapy	
Aspirin	9 (81.81)
Clopidogrel (plavix)	6 (54.54)

ESRD: End-stage renal disease

Continuous aspiration mechanical thrombectomy devices

The CAT system consists of four components: a catheter, separator wire, reinforced tubing, and an aspiration pump. This study utilized the CAT-D (50 cm) and CAT-8 (80 cm) catheters which are both eight French in size. The reinforced tubing is a tube which connects the catheters to the portable pump to provide continuous aspiration. The separator is a wire that aids in agitation and debulking of thrombus to allow for more efficient aspiration.

Procedure technique

Thrombosed grafts were initially accessed toward the venous limb near the AV anastomosis using a micropuncture set (Cook®, Bloomington, IN, USA). An eight French sheath (Prelude®; Merit Medical®, South Jordan, UT) was subsequently placed over a stiff 0.035" guidewire. A five French angled catheter and hydrophilic guidewire were advanced into the right atrium, and pull back venography was performed to delineate the extent of thrombus and also to measure its length [Figure 1]. Next, a 65 cm total length infusion catheter (20 cm infusion length) was advanced to span across the length of thrombus. Four milligram of tissue plasminogen activator (TPA) (Activase®; Genentech, San Francisco, CA) diluted into 20 ml of heparinized saline and contrast was pulse sprayed into the infusion catheter in 1ml aliquots and allowed to dwell for 10 min.

Following TPA dwell, the CAT-D (n = 11) or CAT-8 (n = 10) device was placed and used to perform CAT throughout the graft [Figure 2]. Up to five passes of the device were performed based on operator preference and predetermined total blood loss not exceeding 250 ml during device activation. No prophylactic blood transfusions were performed.

Subsequently, a second access was obtained directed toward the arterial limb of the graft followed by placement

Figure 1: Pull-back venogram delineating central extent of thrombus burden at the level of the venous outflow connector

Figure 2: Spot radiograph taken during continuous aspiration mechanical thrombectomy using the continuous aspiration mechanical thrombectomy-D thrombectomy device – before (a) and after (b) device (arrow) was turned on and advanced. Note contrast with thrombus cleared on before and after images (dashed arrow)

of a six French sheath. An angled catheter was advanced beyond the anastomosis into the native brachial artery, and arteriography was performed from this position to assess the clot burden within the graft. Next, the arterial plug of the graft was pulled into the graft using a compliant five French Fogarty balloon over a 0.035" guidewire. Attention was paid not to displace any thrombus into the artery. Repeat arteriography was performed to confirm restored patency of the graft [Figure 3]. Any underlying stenosis treated by balloon angioplasty was recorded. Adjunctive techniques to clear thrombus such as balloon maceration or sweep were also recorded. Completion angiography was performed to confirm no residual thrombus or stenosis throughout the graft [Figure 3]. A minimum of 5000 IU intravenous heparin was administered during the procedure for systemic anticoagulation. All devices and catheters were removed at the conclusion of the procedure. Hemostasis was obtained using purse-string suture technique around the eight French access and manual compression of the six French access. Patients were discharged following routine 4 h postprocedure monitoring.

Conventional methods for HeRO graft thrombectomy involved a similar method of graft access with utilization of a thrombectomy device (Arrow-Treotola™; Teleflex Medical: Wayne, PA and Cleaner®; Argon Medical: Frisco, TX) and TPA to clear the venous outflow before pulling the arterial plug of the graft. Graft access was maintained with a 7 French and 6 French sheath for the venous and arterial limbs, respectively.

Outcome definitions

Technical success (with or without adjunctive methods) was defined as restored graft patency at the conclusion of the procedure with palpable thrill. Thrombus length cleared by CAT was also calculated using a 5 mm assumption for graft diameter of the venous outflow component and 6 mm for the arterial component.

Statistical analysis

All statistical analyses were conducted using Microsoft® Excel 2016 (Microsoft®, Redmond, WA). The formula used to determine the potential volume of clot removed was the standard volume of a right cylinder ($V = \pi r^2 h$). Paired one-tail distribution t-tests were conducted using recorded patient and procedural information from the medical record. Procedure and fluoroscopy times using conventional methods for thrombectomy were compared against the CAT method in the same patients. Time to rethrombosis between prior thrombectomy procedures using conventional techniques were also compared to CAT in the same patients. As all patients in the cohort studied underwent thrombectomy at least 3 times previously using institutional routine methods, the average of these three prior thrombectomies was chosen for the values reported in the "conventional" group. $P < 0.05$ was considered as statistically significant.

Results

All procedures were technically successful (21/21, 100%). No procedure-related complications occurred. Reocclusion within 5 days occurred in four (19.0%) cases, with two patients presenting with rethrombosis within 24 h. Three (14.3%) interventions required additional balloon maceration or sweep as an adjunctive therapy to clear the venous outflow following thrombectomy. The average thrombus length treated measured 23.15 cm. The average 23.15 cm of thrombus treated represented 6.54 mL of potential clot volume removed. The average blood loss was 162.6 mL. Seventeen (81.0%) HeRO grafts treated by CAT presented with rethrombosis of the graft at a mean of 42.47 days since CAT – procedural details are elucidated in Table 2. Average time to rethrombosis in the same patients using conventional methods was 55.33 days, not statistically significant ($P > 0.05$).

The average procedure length and fluoroscopy time using CAT was 74.7 and 14.2 min, respectively, compared with 82.0 and 14.0 min, respectively, in the previous thrombectomy procedures using standard methods ($P > 0.05$) – detailed comparison of CAT and standard thrombectomy is summarized in Table 3.

Discussion

The incidence of patients requiring thrombectomy to salvage thrombosed dialysis access shunts has been increasing over the past decade.[16] HeRO grafts are particularly prone to thrombosis since they are essentially a long segment graft extending from a target artery to the right atrium without a venous anastomosis. Wallace *et al*. reviewed HeRO grafts and showed that all successfully placed grafts in the study had thrombosed within 4 months of placement.[17] Another small study with long-term follow-up of 38 HeRO grafts showed primary patency of 38.9% and a reintervention rate of 2.5 times/year.[18] Ladenheim *et al*. retrospectively analyzed 40 HeRO grafts and showed a similar primary patency rate of 30% with an average intervention rate of 2.1 times/year.[19] A pooled review of multiple similar studies including 409 HeRO grafts confirmed similar results, demonstrating 21.9% (9.6–37.2) primary patency rate and an intervention rate of 1.5–3 times/year.[20]

Current methods for performing thrombectomy procedures include push-pull thrombectomy using an occlusion balloon, rotational thrombectomy, rheolytic thrombectomy, and balloon angioplasty for clot maceration.[21] These techniques all depend on clot maceration with the remainder of thrombus in the vessel to result in potential downstream complications. PE associated with the HeRO grafts have been reported up to 2.6%.[18,22] PE following HeRO thrombectomy procedures using current methods are rare but have been reported. Gebhard *et al*. reported a major complication of PE and death 2 days following HeRO thrombectomy using TPA and the push-pull thrombectomy technique.[3] The estimated volume of thrombus released during a typical dialysis thrombectomy was estimated in this study to be 1.6–4.7 mL.[3]

There have been multiple studies aimed at assessing the burden of released thromboemboli following repeated thrombectomy for thrombosed hemodialysis accesses.[18,23-26] In addition, the hemodynamic consequences of thrombus embolization (excluding symptomatic PE) have also been investigated. Hsieh *et al*. reported a prospective study on 52 patients assessing pulmonary arterial pressures (PAP) following repeated thrombectomy procedures and found no correlation with elevated PAP and repeated thrombectomy in the short term.[27] While similar studies have been reported supporting this finding,[9,28,29] the long-term effects of frequent thrombectomy procedures and potential embolic thrombus they produce with regard to chronic pulmonary hypertension and its related cardiovascular compromise remain largely unknown.

The poor patency rates for HeRO grafts reported in literature put affected patients at an increased risk of mechanical thrombectomy-associated complications. Given a larger thrombus burden and increased frequency of reintervention, this patient population may be at greater risk for subclinical PE and associated chronic pulmonary hypertension. The current study investigated the feasibility of continuous aspiration thrombectomy as a method for thrombectomy to salvage thrombosed HeRO grafts. Technical success was found to be 100% with no major or minor procedural complications recorded. Of

Table 2: Operative data

	Mean±SD	Median (range)
Thrombus length treated, cm	23.15±19.6	20 (2.2-65)
Thrombus volume removed, mL	6.54±5.54	5.65 (0.62-18.38)
Blood loss, mL	162.6±51.4	150 (50-250)
Fluoroscopy time, min	14.2±9.10	11.6 (3.5-29.7)
Procedure time, min	74.7±33.6	67 (21-147)

SD: Standard deviation

Figure 3: Brachial (a) and central (b) venogram demonstrating restored patency throughout the graft

Table 3: Comparing continuous aspiration approach versus conventional approach

	Mean±SD		Median (range)		P
	Non-CAT	CAT	Non-CAT	CAT	
Time to repeat thrombectomy, days	55.3±43.1	42.5±58.2	34 (1-321)	22 (1-208)	>0.05
Fluoroscopy time, min	14.0±6.6	14.2±9.1	17.4 (1.8-38)	11.6 (3.5-37)	>0.05
Procedure time, min	82.0±32.2	74.7±33.6	66 (21-238)	67 (21-147)	>0.05

SD: Standard deviation, CAT: Continuous aspiration mechanical thrombectomy

21 cases included, 17 required follow-up procedures for rethrombosis of the graft; mean patency of dialysis graft was 42.47 days compared to 55.33 days using conventional methods previously on the same patients. Patency in days across techniques was found to not be statistically different ($P > 0.05$). Given the aforementioned established high rates of rethrombosis for HeRO grafts among the end-stage renal disease (ESRD) population, percutaneous CAT for HeRO graft thrombectomy was found to be a safe and effective tool to provide durable patency and restore access for patients with challenging venous access.

Fluoroscopy and procedural times were also analyzed comparing conventional methods for thrombectomy compared to CAT. Slightly lower overall procedure times were measured (82.0 vs. 74.7 min) using CAT compared to the conventional methods utilized at the authors' institution; however, this result was not statistically significant. A theoretical advantage of the utilized CAT method includes the opportunity to reduce the risk for thrombus embolization centrally. In the current study involving 21 cases, the average length of clot treated was 23.15 cm and, when converted to a representative volume, the potential volume of clot removed averaged 6.54 mL (0.62–18.38 mL). Although not specifically investigated, CAT for percutaneous thrombectomy may theoretically reduce PE risk by allowing for physical removal of the majority of thrombus burden. Removal of thrombus burden may also have implications on the use of CAT for percutaneous thrombectomy of hemodialysis accesses when conventional percutaneous mechanical thrombectomy would otherwise be contraindicated by preexisting pulmonary hypertension or compromised cardiopulmonary function.

This study is limited by its retrospective nature, small sample size, and single institutional experience. Statistical significance of reported results is also limited by the power of a small sample size. Procedural and technical skill differences between operators may exist and could at least partially explain potential differences in fluoroscopy and procedure time. Given that patients with ESRD suffer from anemia of chronic kidney disease, the CAT method was limited by judicious application time to minimize blood loss. The average blood loss was 162.6 mL (range 50–250 mL), but no blood products were required during or after the procedure. In addition, the proposed benefits of thrombus evacuation are theoretical as the current study did not specifically investigate the benefits of CAT compared to conventional methods with respect to PE or pulmonary hypertension. Furthermore, the results for clot removal volume represented a theoretical maximum of clot volume removed as the amount of thrombus was not actually weighed or quantified during the procedure. Additional limitations of the study included a high percentage of patients with rethrombosis within 5 days of the procedure. This was partially thought to be due to the learning curve of operators using an 8 French sheath when obtaining hemostasis (not standard at the authors' institution), which required a purse string at the puncture site compared to our routine manual compression. Furthermore, the cost-effectiveness of CAT was not investigated in this study and may contribute to its overall adoption as a feasible device for this patient population. Finally, the investigated CAT technique also utilized TPA and occasional balloon maceration as an adjunctive tool for restoring graft patency. Further exploration of the CAT method without these agents may mitigate the cost associated with using the thrombectomy device.

Conclusion

In conclusion, percutaneous CAT is a safe and feasible method for salvage of thrombosed HeRO grafts. This method requires further investigation to establish its potential advantage over other conventional techniques, namely in its ability to extract thrombus en bloc and prevent downstream embolization.

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Nil.

Conflicts of interest

Osman Ahmed: Speaker, Bard/Penumbra/Argon Medical; Advisory Board Member, BTG/Abbvie. Sreekumar Madassery: Speaker, Abbott; Speaker, Cook. Bulent Arslan: Speaker and advisory board member for Penumbra®, Medtronic/Covidien®, and speaker for Cook®, W.L. Gore®, Guerbet®, and CR Bard®.

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