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Midterm Results Following Percutaneous Rotational Thrombectomy for Acute Thrombotic Occlusions of Prosthetic Arteriovenous Access Grafts

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Patent vascular access is critical for patients on regular hemodialysis. Prosthetic grafts are good alternatives when the superficial venous system is of poor quality. However, thrombosis is one of the main drawbacks of synthetic grafts, with reports of 59% to 90% patency rates for 1 year. In cases of thrombotic occlusion of prosthetic arteriovenous fistula grafts, percutaneous mechanical thrombectomy has recently gained clinical popularity as a potential alternative to surgical thrombectomy or pharmacologic thrombolysis. We reviewed our preliminary results from 30 percutaneous rotational thrombectomies performed in a total of 22 patients in the setting of acute dialysis–access prosthetic graft occlusion of the upper extremity. Among the 30 cases of acute occlusion of the arteriovenous graft, immediate success with angiographic flow restoration was observed in all patients except for 2 patients (both females; 6%), with *de novo* occlusion where reocclusion occurred within 12 hours despite apparent immediate angiographic patency. The mean duration between the initial presentation with acute arteriovenous

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graft occlusion and the thrombectomy procedure was 27.4 ± 12.4 hours. The mean duration of graft patency was 10.45 ± 0.6 months. A total of 75% of the arteriovenous grafts were patent at the end of 12 months of follow-up. Female gender, diabetes mellitus, and diagnosis to intervention interval were reviewed for midterm graft failure, and the presence of diabetes mellitus yielded significance ($P < 0.05$). Percutaneous techniques play important roles in the treatment of failed or failing arteriovenous fistulae and grafts. Ongoing analysis of outcomes of both percutaneous and surgical intervention is necessary to continue to identify optimum treatment algorithms.

Key words: Rotational thrombectomy – Arteriovenous access – Dialysis

Improved survival rates from nonrenal disease in the emerging population of aging patients with kidney failure and regularly scheduled hemodialysis have resulted in a more critical role for vascular access.[1] Consequently, with the improved life expectancy of these patients, successful and enduring vascular access creation has become paramount for the vascular specialist.[2] In cases of unsuitable vessels, especially in elderly or diabetic patients needing immediate cannulation, synthetic arteriovenous (AV) grafts are very helpful options because they avoid use of a central venous catheter.[3,4] But the median lifetime of prosthetic grafts has been reported as only 12 to 18 months.[5]

Percutaneous mechanical thrombectomy has recently regained clinical popularity as a potential alternative to surgical thrombectomy or pharmacologic thrombolysis in the setting of an acute thromboembolic vascular access occlusion. In this aspect, we reviewed our preliminary results with percutaneous rotational thrombectomy in the setting of acute dialysis–access graft occlusion of the upper extremity.

Patients and Methods

Between March 2011 and January 2013, 30 percutaneous rotational thrombectomies were performed in a total of 22 patients (12 men; mean age, 53.3 ± 24 years) using the Rotarex catheter (Straub Rotarex, Straub Medical, Wangs, Switzerland) following the acquisition of informed consent for the treatment and the study, in addition to Institutional Review Board approval. All procedures were in accordance with the ethics standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration.

The type of fistula was an upper-arm brachioaxillary straight and a forearm brachiocephalic loop in 9 patients with polytetrafluoroethylene graft. Location of the fistula was on the left side in 17 patients and on the right side in 5 patients. All of the patients included in the study were on anticoagulation therapy (warfarin) with a targeted international normalized ratio of 1.5 to 2.0 for the first 3 months after surgery. After 3 months, they were given only 2500 IU heparin intravenously for each dialysis procedure. Acute graft occlusions were diagnosed with clinical examination followed by color duplex ultrasonography.

The operating mechanism of the catheter is by means of over-the-wire mechanical debulking. A rotating head with 60,000 rpm creates a vortex inside the artery, thereby detaching acute to chronic thrombotic material from the vessel wall; simultaneously generated negative pressure aspirates all loose material, which is fragmented and then removed out of the patient (Fig. 1). Brachioaxillary or brachiocephalic AV polytetrafluoroethylene graft occlusions within 3 cm of the venous anastomosis site upon duplex ultrasound (mean distance, 4 ± 1 cm; range, 2–6 cm) for less than 7 days underwent thrombectomy using a mechanical rotational catheter. After the thrombectomy procedure, the residual arterial plug was removed by maceration with an

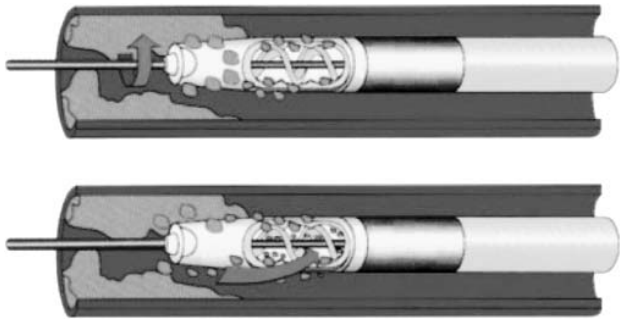

Fig. 1 The Rotarex system: working mechanism. It fractions thrombotic material by a sharp head, and it aspirates by the rotating spiral.

angioplasty balloon inflated at low pressure, so that the mechanical devices did not cross the AV anastomosis. Diagnostic fistulography was performed after restoration of flow, and the underlying stenosis was treated accordingly with balloon angioplasty (Wanda, Boston Scientific, Natick, Massachusetts, or Conquest, Bard, Covington, Georgia) in 5 interventions. For stenoses resistant to conventional angioplasty, balloon dilatation, with either a cutting balloon (Peripheral Cutting Balloon, Boston Scientific) or a noncompliant high-pressure balloon (Conquest), was used to dilate the stenosis in 3 interventions to improve recanalization. All patients received subcutaneous fractioned heparin perioperatively (subcutaneous 7500 IU 1 hour before the intervention and 2 subcutaneous 7500-IU injections for the first 24 hours after the procedure) and were discharged at the second hour. Procedures were stratified by outcome, including successful outcome, failure as determined by angiography, and dialysis-only failure. Details of the device and the technique have been discussed elsewhere.[6] A dialysis-only failure was defined as a successful procedure as determined by angiography, followed by unsuccessful dialysis. Ultimately, the outcome was considered unsuccessful if either the procedure failed or the patient was unable to be dialyzed subsequently.

All procedures were performed by operators who had been attending staff for at least 5 years. Clinical examination and monitoring the dialysis protocols were the method of follow-up. If any problem with dialysis or abnormal clinical findings were established, urgent duplex examination was performed, and then angiography was carried out if necessary. In the case of rethrombosis, reintervention was attempted. All patients also underwent routine duplex examination follow-up at the 3rd, 6th, and 12th months. Patient demographics are depicted in Table 1.

The end point was the combined outcome (success versus failure) following percutaneous mechanical thrombectomy in the angiography suite and subsequent hemodialysis. The primary covariate of interest was the time to intervention. Exploratory and descriptive analyses of age, gender, and time to intervention were recorded and reviewed. Statistical analysis was performed with continuous variables, reported as mean ± SD. Significance was accepted for a P value of less than 0.05.

Results

A total of 30 rotational thrombectomies were performed in 22 patients during the 2-year period.

Table 1 Patient demographics

Variable	Value
No. of patients	22
Age, y	53.3 ± 24
Male, %	66
No. of percutaneous thrombectomies	30
Prior history of surgical revision, n	5
Hypertension, %	73
Diabetes mellitus, %	26
Coronary artery disease, %	20
Interval between referral to procedure, h	27.4 ± 12.4
Immediate flow restoration, %	100
Dialysis-only patients, n	2
Percutaneous rethrombectomy, n	8

Among the 22 patients, 5 had a prior history of surgical thrombectomy from the AV graft. Among the 30 cases of acute occlusion of the AV graft, immediate success with angiographic flow restoration was observed in all patients except for 2 patients (both females, 6%) with *de novo* occlusion where reocclusion occurred within 12 hours, despite apparent immediate angiographic patency. These latter 2 patients were later deemed appropriate for a surgical anastomotic revision. All other patients (93%) received successful hemodialysis within 24 hours of the procedure. The mean duration between the initial presentation with acute AV graft occlusion and the percutaneous mechanical thrombectomy procedure was 27.4 ± 12.4 hours. Nineteen thrombectomy procedures (63%) were performed within 24 hours of initial admission. During a follow-up period of 1 year, 8 patients (26%) experienced rethrombosis, despite the immediate procedural success. The mean rethrombosis time for these 8 patients was 6.3 ± 1.9 months. We managed them with the same device, on the same day of dialysis failure, and all of the reinterventions were successful with respect to angiographic flow restoration and dialysis success. Neither of the 2 dialysis-only cases was treated more than 24 hours after initial referral, nor were they in the reintervention group. Complications occurred in 2 of the 30 procedures (7%). Most of them were grade 1 or grade 2 complications according to the American Society of Diagnostic and Interventional Nephrology classification,[7] due to either venous ruptures or puncture site hematomas. All of these local complications were related to wiring or angioplasty, but were not related to the thrombectomy device. No distal arterial embolization was experienced.

During the 1 year of follow-up examinations, 3 patients developed diminished flow through the

graft and unsuccessful dialysis, despite the AV graft having persistent patency at the 5th, 8th and 12th months, respectively. These patients received a surgical revision of the vascular access route. Twelve-month follow-up was complete for all patients. The mean duration of graft patency was 10.45 ± 0.6 months. Figure 2 depicts the Kaplan-Meier analysis for 12-month patency. A total of 75% of the AV grafts were patent at the end of 12 months of follow-up. Female gender, diabetes mellitus, and diagnosis-to-intervention interval were reviewed for midterm graft failure, and the presence of diabetes mellitus yielded significance ($P < 0.05$). However, regression analysis revealed no factor as a predictor of midterm graft failure. Figure 3 shows thrombotic occlusion of a U-shaped (loop) graft between the cephalic vein and brachial artery (Fig. 3a), and restoration of unrestricted flow following percutaneous thrombectomy (Fig. 3b).

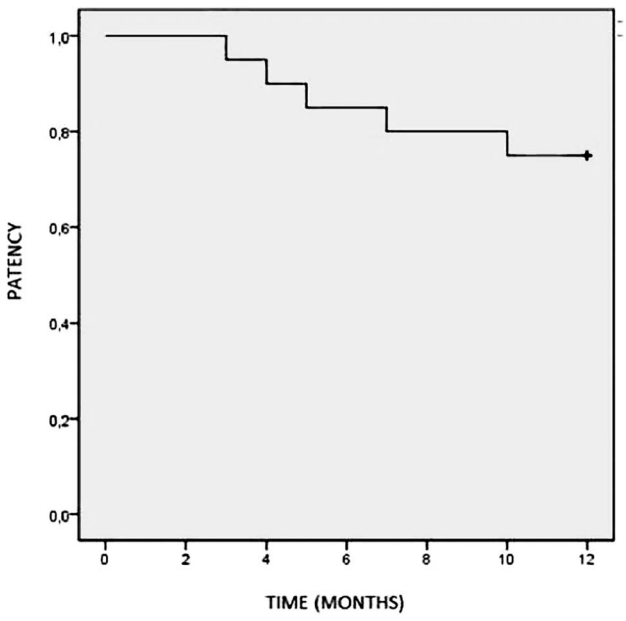

Fig. 2 Kaplan-Meier analysis for midterm patency of the AV access grafts.

Discussion

Patent hemodialysis access is critical for the survival of patients who rely on regularly scheduled hemodialysis, and a loss of patency results in higher morbidity and mortality.[8] When previous fistula fails or superficial venous system is unsuitable for the creation of fistula with autologous graft, the fistula with prosthetic grafts is a good option. Short maturation time, lower early failure rates, and easy cannulation are the major advantages of prosthetic AV grafts. But their long-term patency is lower and complication rates higher than those of autologous AV fistulas.[9,10] Acute thrombotic occlusions must be treated without delay in order to avoid the use of unnecessary central venous catheter, which is associated with high rates of early or late complications. Surgical thrombectomy with a Fogarty catheter and percutaneous thrombectomy with special devices can be performed for the treatment of graft thrombosis. Surgical thrombectomy has some disadvantages compared with percuteneous mechanical thrombectomy, requires an insicion in the graft, and failure to correct the stenosis leads to early rethrombosis. Before the development of interventional approaches, surgical thrombectomy was the way of correcting thrombosed vascular access graft. Today, this requires a multidisciplinary approach. Mechanical thrombectomy, percutaneous infusion of pharmacologic thrombolysis, and pharmacomechanical thrombolysis are available for thrombosed dialysis grafts. The experience of each center dictates which technique is preferred. Better results in the application of endovascular techniques regarding the repair of thrombosed vascular access have been reported in a comprehensive literature review.[11] When taking into account the lower invasiveness of percutaneous thrombectomies, we can assume their important role in the treatment of such patients.[12]

Percutaneous endovascular techniques have proven to be successful, with the added benefits of periprocedural morbidity when compared with surgical thrombectomy.[12,13] Studies have shown that surveillance of indwelling AV grafts can reduce the number of thromboses, and that this procedure technique can influence success.[12,14] Today, modern endovascular thrombectomy devices that use different methods of thrombus fragmentation and transportation are commercially available. Some of these devices use the vortex principle to fragment the thrombus (*e.g.*, the Amplatz and the AngioJet thrombectomy catheters), or the Venturi effect (*e.g.*, the Hydrolyser thrombectomy catheter). One of the most promising devices combining clot fragmentation and removal of the fragmented material using Archimedes' principle is the Rotarex catheter (Straub Medical). It prevents peripheral embolization of the fragmented thrombus by negative pressure. Today, the effect of the Rotarex device in lower-extremity arteries for recanalization of acute occluded arteries is accepted, but different case reports describe interventional settings in which the

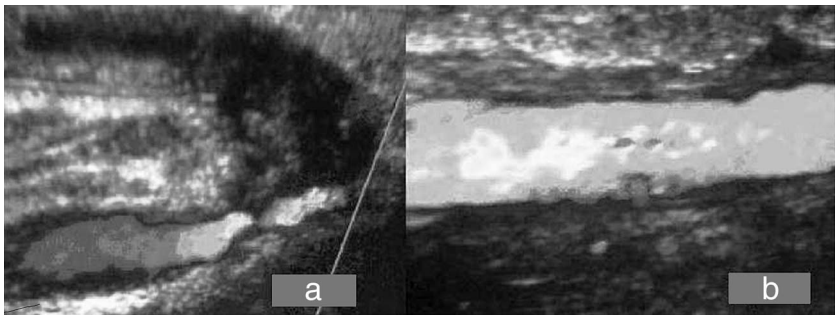

Fig. 3 (a) Color duplex view of an acutely occluded U-shaped AV access graft between the brachial artery and the cephalic vein. (b) Restoration of flow within the graft following rotational thrombectomy in the same patient.

system has also been used in other vascular regions. Such a percutaneous thrombectomy approach with local anesthesia and significantly shorter procedural time may, however, be an advantage for these dialysis-dependent patients with many coexisting risk factors, such as hypertension, diabetes mellitus, peripheral arterial disease, or coronary artery disease, leading to shorter hospital stay. However, high procedural costs and the need for interventionists accustomed to fluoroscopic imaging are the major drawbacks. Our results represent a scarce set of data yielding midterm data for outcome following percutaneous thrombectomy for AV graft occlusion. Although the immediate angiographic success rate was 100% in our relatively small cohort, early clinical success was found to be 93%. The mean diagnosis-to-procedure interval was 27.4 ± 12.4 hours, and there was no significant association between this interval and midterm reintervention-free survival. Similarly, Prologo *et al*[15] recently presented their early outcome and suggested that this interval up to 72 hours has no significant association with procedural outcome.

In addition to the small number of patients, a potential limitation of this study is the registry upon referral for graft occlusion as the starting point for the analysis. This study assumed a constant regarding the absolute time of thrombosis and the time interval from that event to clinical presentation, which might not be valid. It is noteworthy that the potential bias may therefore underestimate the clot age. Second, no control group exists for comparison or randomization.

A universal policy of endovascular therapy for occluded dialysis access results in reestablishment of function in most patients and will triple functional longevity.[16] Furthermore, although this approach remains procedure intensive, it carries low morbidity and mortality and preserves future sites of access. Overall, percutaneous techniques are assuming an increasingly important role in the treatment of failed or failing AV fistulae and grafts. Ongoing analysis of outcomes of both percutaneous and surgical interventions is necessary to continue to identify optimum treatment algorithms.

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