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INTERVENTIONAL RADIOLOGY
TECHNICAL NOTE

Endovascular treatment of surgically implanted arterial graft thrombosis by using manual aspiration thrombectomy

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ABSTRACT
The purpose of this study was to present our experience with guiding catheters in manual aspiration thrombectomy of occluded infra-aortic bypass grafts. This material was designed as a guiding catheter but was also used for thrombus aspiration. Six consecutive patients (all male; mean age, 61.0±5.7 years; range, 54–68 years) who underwent manual aspiration thrombectomy at the discretion of the operator for infra-aortic bypass graft thrombosis between 2002 and 2010 were retrospectively reviewed. The angiographic success described as either stenosis or residual thrombus less than 30% was 67%. Primary patency was 50%, and secondary patency was 66.7%. Additional stents were needed in four lesions of three patients. Manual aspiration thrombectomy is intended to remove both soft acute blood clots and hard organized embolic and thrombotic obstructions. Manual aspiration thrombectomy appears to be a safe and effective method for treating delayed graft thrombosis. This method provides an alternative to surgical thrombectomy, especially for patients who are not good candidates for the surgery.

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Occlusion of bypass grafts placed in the supra-inguinal position may occur as a result of *in situ* thrombosis of a ruptured plaque or cardioembolism (1). Early aortofemoral graft occlusions occur in 1% to 2% of patients in the postoperative period. Late prosthetic graft thrombosis occurs in 10% to 15% of aortofemoral and femoropopliteal bypass operations within five years of surgery (2, 3). Early graft occlusions (within 30 days of surgery) are usually due to technical difficulties with the bypass procedure. These problems are best treated by surgery with graft thrombectomy and correction of the underlying technical problem. Delayed thrombosis is most commonly attributed to anastomotic intimal hyperplasia and/or progression of atherosclerotic disease in the outflow vessels. Surgical therapy of the underlying cause of thrombosis is associated with significant perioperative morbidity and limited patency (4).

Catheter-directed thrombolysis (CDT) allows local high dose delivery of pharmacologic thrombolytic agents directly into the thrombus. It is usually effective in dissolving the thrombus and unmasking the underlying lesion, but has limitations, such as failure to reestablish flow in 20% to 40% of cases, which then mandates surgical thrombectomy, a complication rate of 15%–25%, distal embolization, and required infusions for 12–48 hours (5, 6). Percutaneous mechanic thrombectomy is used as an alternative or adjunct to pharmacologic thrombolysis and/or surgical thrombectomy for management of acute thrombotic and thromboembolic arterial and venous occlusions. The use of adjunctive mechanical thrombectomy to augment pharmacological CDT provides comparable procedural success and may reduce the required thrombolytic dose and infusion duration (7). A mechanical thrombectomy device that is easy to use and can safely and efficiently remove acute, subacute, and chronic thrombi from any vascular bed could become the first line of treatment (8). Manual aspiration thrombectomy (MAT) may be the simplest percutaneous mechanical thrombectomy method, but it is not in the same category as the mechanical devices. MAT may have several practical, cost, and conceptual advantages over current mechanical thrombectomy devices.

Over the last decade, MAT has been our primary treatment modality for acute, subacute, and, rarely, early chronic thrombosis of the arterial and venous systems, including thrombosis arising from dialysis grafts and fistulas. CDT has been used as an adjunctive therapy rather than as the primary thrombus removal method in selected patients. The purpose of our study was to determine the efficacy of clot removal, the procedure-related embolization rate, and the midterm rates of primary patency, secondary patency, death, and amputation-free survival for

MAT-based treatment of acutely occluded infra-aortic bypass grafts.

Materials and methods

Patients

Six consecutive patients (all men; mean age, 61.0±5.7 years; range, 54–68 years) with angiographically-proven thrombosis of an aortobifemoral or aortounifemoral arterial bypass graft who were treated with MAT between 2002 and 2010 were retrospectively evaluated. All patients were symptomatic with acute or chronic limb ischemia. All patients presented with clinical features of graft thrombosis and were diagnosed using color Doppler ultrasonography. Angiography performed during the endovascular procedure confirmed the diagnosis.

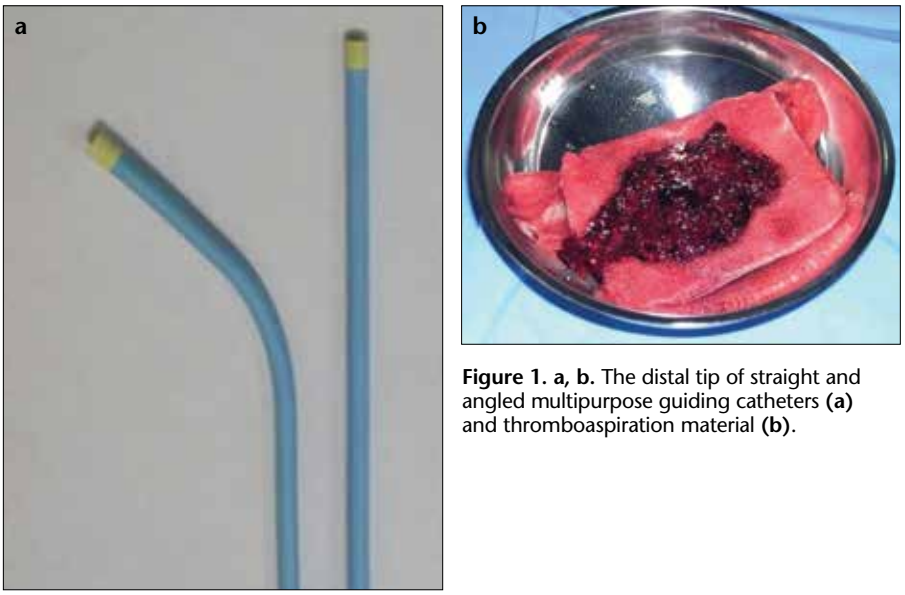

Figure 1. a, b. The distal tip of straight and angled multipurpose guiding catheters **(a)** and thromboaspiration material **(b)**.

Procedure

The method of aspiration has been described elsewhere (9). Access to the artery or the graft itself was obtained under ultrasonography guidance via a single wall puncture made using an 18 G needle, allowing for the possibility of thrombolytic therapy after MAT. A 5 F to 7 F vascular sheath (Cordis Corporation, Miami, Florida, USA) was placed and a heparin dose of 5000 IU was administered intra-arterially or intravenously. Diagnostic angiograms were obtained. A 5 F to 7 F straight-tip or curved-tip guiding catheter (Cordis Corporation; Fig. 1a) attached to a 20 mL luer lock syringe was inserted through the vascular sheath. Suction was performed manually from the point nearest to the sheath to the point furthest from the sheath. Care was taken not to push the thrombus away from the graft and into the native artery. Once the thrombus was engaged, the catheter was withdrawn while maintaining suction to hold the thrombus (Fig. 1b). If the entrained thrombus squeezed within the introducer sheath, the cover of the sheath was removed and aspiration was applied to the sheath lumen. Guidewires were not used to advance the guiding catheter in the thrombosed grafts, because approximately 10 to 20 passes of the guiding catheter were needed in each case. If the thrombus was adherent to the graft wall, a multipurpose type curved guiding catheter was used to clean the thrombus (Fig. 1a). Removing the most proximal and most distal parts of the thrombus was left to the end of the procedure to prevent embolization of the thrombus proximally to the renal arteries and distally to the limb arteries.

After MAT with or without CDT, angiograms were obtained to reveal any underlying obstructive lesion in the graft anastomosis or the native artery. Any significant obstructive disease (>50% luminal diameter narrowing) was treated with percutaneous transluminal angioplasty (PTA). If there was residual diameter stenosis of >30%, a nitinol self-expanding stent was deployed and dilated with the same size balloon catheter.

Results

Two patients had acute symptoms before the intervention (less than 15 days), and four patients had chronic symptoms (30 days to three months). Symptoms included severe pain at rest (two patients) and newly occurring or exacerbated claudication symptoms (four patients). Digital subtraction angiography depicted the following thrombotic occlusion sites: both limbs of an aortobifemoral graft (n=1), one limb of an aortobifemoral graft (n=2), and the full length of an aortounifemoral graft (n=3). Five grafts had complete graft thrombosis; two had underlying anastomotic stenosis. One patient had partial thrombosis with anastomotic stenosis at the first administration and complete thrombosis at the second and third admission. Among the five patients, only one intervention was necessary; one patient required repeated interventions performed at three different dates.

The methods used for patient management are summarized in the Table. MAT was possible for five of six graft occlusions. MAT was applied as a first option treatment for graft thrombosis in four patients, and after the previous CDT for removal of residual thrombus in one patient. In one patient, strict stenosis of the distal graft anastomosis was not being passed from retrograde fashion and the patient underwent surgery without MAT (technical failure). Lesion lengths ranged from 5 to 29 cm for complete thrombosis and from 3 to 15 cm for partial thrombosis. MAT was also used for aspiration of native artery thrombosis accompanied proximally to the graft in one patient and distally to the graft in a second patient.

All thrombus removal from grafts was performed with retrograde access. After MAT, one patient underwent PTA to treat residual chronic thrombosis located within the graft. Two other patients were also treated with PTA for residual chronic thrombosis within a previously placed stent at the anastomotic site and for underlying stenosis of anastomosis. One of these patients required a second PTA of a previously placed stent at the proximal anasto-

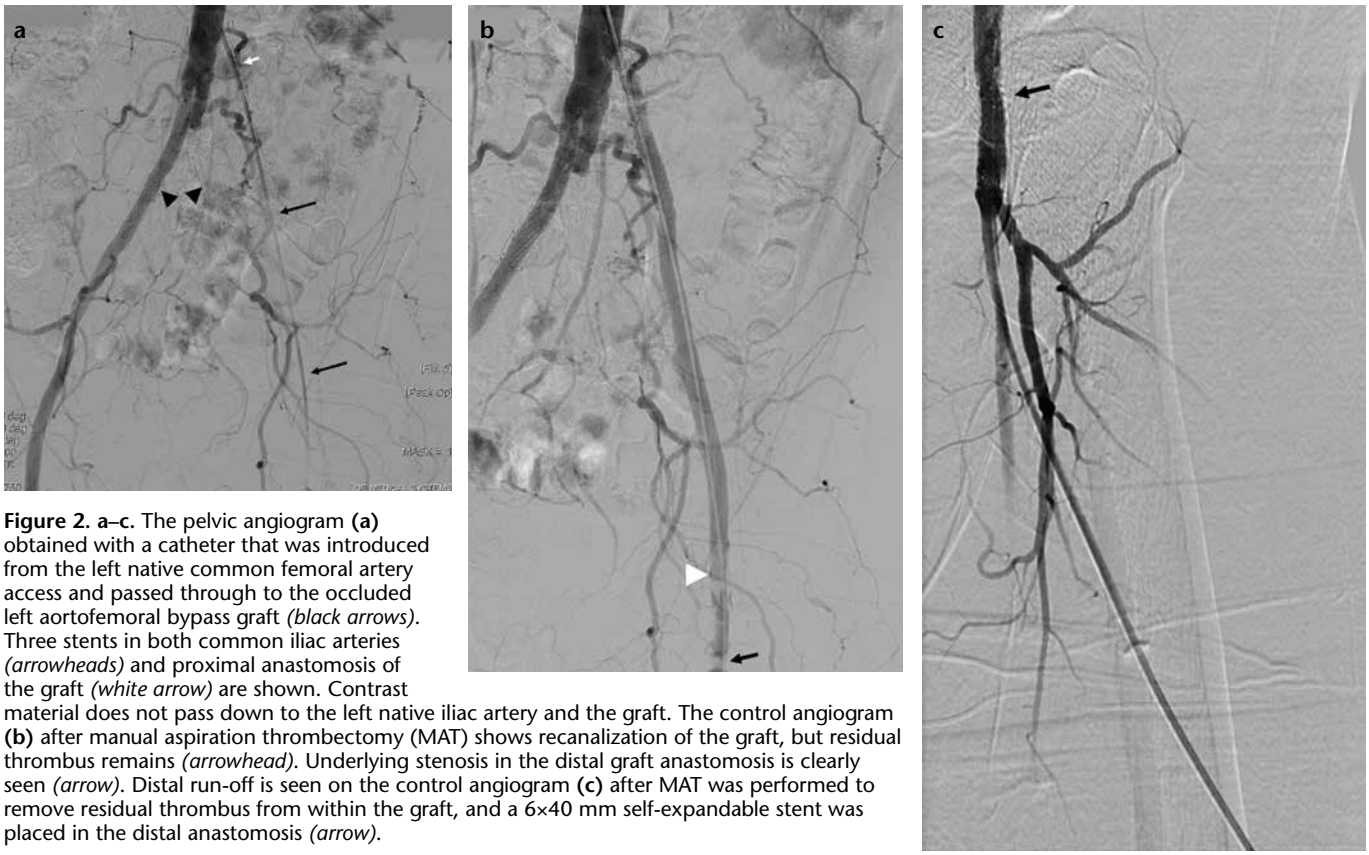

Figure 2. a–c. The pelvic angiogram **(a)** obtained with a catheter that was introduced from the left native common femoral artery access and passed through to the occluded left aortofemoral bypass graft *(black arrows)*. Three stents in both common iliac arteries *(arrowheads)* and proximal anastomosis of the graft *(white arrow)* are shown. Contrast material does not pass down to the left native iliac artery and the graft. The control angiogram **(b)** after manual aspiration thrombectomy (MAT) shows recanalization of the graft, but residual thrombus remains *(arrowhead)*. Underlying stenosis in the distal graft anastomosis is clearly seen *(arrow)*. Distal run-off is seen on the control angiogram **(c)** after MAT was performed to remove residual thrombus from within the graft, and a 6×40 mm self-expandable stent was placed in the distal anastomosis *(arrow)*.

motic site and for distal anastomotic site stenosis. Four lesions, among three patients, required stent placement: one for residual thrombus and three for stenosis of anastomosis.

Repeated interventions were necessary in one patient, a 57-year-old male with a left aortofemoral bypass graft. Initially, the patient underwent MAT and PTA to treat proximal anastomotic stenosis and accompanied partial thrombosis. Three months later, the patient again underwent MAT to treat complete graft thrombosis; the procedure failed due to residual thrombi of more than 50%, and the patient immediately underwent surgery due to loss of distal pulses. On follow-up six months after the surgery, the patient underwent reintervention for repeated graft occlusion. After the MAT, the patient underwent PTA of a previously placed stent at the proximal anastomotic site, and a new stent was inserted to treat distal anastomotic stenosis (Fig. 2).

One patient underwent CDT after incomplete thrombus removal with MAT. MAT successfully resolved residual graft thrombosis, and an additional six hours of PTA was administered to the popliteal thrombus from a new antegrade access. One patient (n=1, 20%) had distal thromboembolism to the popliteal artery and crural arteries during MAT. The arteries were successfully recanalized with MAT.

A mean of 85% (range, 70%–100%) of the thrombus was removed with MAT and CDT to restore blood flow. Two patients required surgery for reocclusion and one for technical failure. Three grafts (50% of patients) were patent without reintervention at the end of 24 months. After 36 months, four of the grafts (66.7% of patients), including one reintervention, were patent.

Discussion

This study shows the results of MAT in patients who received prosthetic vascular bypass grafts for occlusive aortoiliac or femoral artery disease and presented with acute and chronic limb ischemia. MAT was successful in removing most or all of the thrombus in four out of six patients with or without adjunctive CDT. Reintervention was required in one patient who underwent a technically successful procedure. One patient had distal thromboembolism, which was successfully managed with MAT during the same session. No other complications were encountered.

Vascular recanalization should be rapid, safe, and efficacious. Current strategies often use thrombolysis initially with subsequent use of mechanical thrombectomy devices if thrombolysis is inadequate to recanalize the vessel. Thrombolysis can be a lengthy and costly procedure with inherent risk. Thrombectomy devices have been developed in an attempt to prolong the therapeutic time window for stroke and to treat patients with contraindications to thrombolysis (8). The percutaneous declotting techniques published to date can be divided into pharmacomechanical and purely mechanical methods. Various motorized pharmacomechanical thrombectomy devices with different mechanisms for clot removal are commercially available and fall into one of two broad categories depending on their mechanism of action for clot extraction: microfragmentation (rotational) or hydro-

Table. Method of the management for graft occlusion in each patient

Patient number	Graft location	Graft age (years)	Gender	Number of interventions	Stenosis	MAT	tPA	PTA	Stent	Success
1	Aortobifemoral	66	Male	1	-	+	-	+	+	+
2	Aortobifemoral	57	Male	1	-	+	-	-	-	-
3	Aortobifemoral	68	Male	1	-	-	-	-	-	-
4	Right aortofemoral	64	Male	1	+	+	-	-	+	+
5	Left aortofemoral	57	Male	1	+	+	-	+	+	+
				2	+	+	-	-	-	-
				3	+	+	-	+	+	+
6	Right femorofemoral	54	Male	1	-	+	+	+	-	+

MAT, manual aspiration thrombectomy; tpA, tissue plasminogen activator; +, present or applied; -, absent or not applied.

dynamic (rheolytic). Several pharmacomechanical thrombectomy devices are designed to use both mechanical fragmentation and pharmacological thrombolytic agents for more complete and rapid thrombus removal. Rotational thrombectomy devices employ a high-speed rotating basket or impeller to fracture the thrombus into small particles (10). For these reasons, these devices are not available for intra-arterial use. Hydrodynamic, or rheolytic, recirculation devices rely on the Venturi effect to fragment the thrombus via retrogradely directed high-speed saline jets (350–450 km/hour). The disintegrated thrombus is then aspirated into the device. Currently, three hydrodynamic thrombectomy devices are available: 1) the Hydrolyser catheter (Cordis Corporation); 2) the shredding embolectomy thrombectomy catheter SET (HP-Medica, Augsburg, Germany; currently distributed under the name Oasis catheter, Boston Scientific, Natick, Massachusetts, USA); and 3) the Angiojet rheolytic thrombectomy system (Possis Medical Inc., Minneapolis, Minnesota, USA). The initial results from clinical studies evaluating hydrodynamic thrombectomy devices suggest that this is a low-risk procedure. However, the devices are more expensive than those for percutaneous aspiration thrombectomy, fibrinolysis, or even a Fogarty balloon (11). Additionally, they are less effective when treating older adherent thrombi and have high rates of recurrent thrombosis and distal embolization, thus explaining the adjunctive thrombolysis that is often required with these devices.

Thrombus aspiration also can be achieved with an aspiration catheter. Syringe suction is applied manually to a catheter, with thrombus entrained in the catheter by this extraction force. Although the efficiency and volume of thrombus extracted with these catheters are not equivalent to those of rheolytic catheters, the advantages of these catheters include ease of use and deliverability to small-caliber distal vasculature. The most common application in the lower extremity would therefore be the management of distal embolization during peripheral intervention. Several aspiration catheters are currently available for use in the peripheral vasculature. The Pronto V3 extraction catheter (Vascular Solutions, Minneapolis, Minnesota, USA) has a dual lumen, monorail design that is compatible with a 6 F guiding catheter and a 0.014-inch wire. Thrombus is extracted by bringing the catheter to the desired site over a wire, and aspiration is performed using two 30 mL locking vacuum syringes. Other aspiration catheters include the Rio Catheter (Boston Scientific) and the Diver CE (ev3 Inc., Plymouth, Minnesota, USA), which has multiple side holes designed to improve flow and minimize clogging. The effectiveness of a hydrodynamic thrombectomy device decreases with increasing distance to thrombus material in the cross section of the vessel lumen. Better results were achieved when narrower vessel calibers were chosen (1).

Thrombus aspiration also can be achieved using guiding catheters. Straight or angled tip multipurpose guiding catheters are inserted through the vascular sheath to the most distal part of the thrombus and suction is performed manually with a 20 mL syringe. Syringe suction is applied manually to a catheter, with thrombus entrained in the catheter by this extraction force. Once the thrombus is engaged, the catheter is withdrawn while maintaining suction to hold the thrombus. *In vitro* studies have demonstrated that the efficacy of using a rheolytic thrombectomy catheter for thrombus removal could be improved from 49% to 89% by using a guiding catheter; the rheolytic thrombectomy catheter could be better guided for treatment of wall-adherent thrombus (12). We used curved tip catheters in addition to straight tip catheters for the same reason. Our rate of distal embolization due to MAT (16.7%) was not more than the reported rate of 2%–18% for current peripheral arterial thrombectomy devices and 15%–25% for surgery (5, 6, 8).

MAT is a simple, cheap method that could safely and efficiently remove intact complex acute, subacute, and chronic thrombus from any vascular bed. The technique is limited because of the risk of dissection in native arteries, especially in the hands of inexperienced physicians (9), though this risk of dissection could possibly be ignored for grafts. The present data suggest that the MAT method may have several practical, cost, and conceptual advantages over current commercially available mechanical retrieval systems.

The small number of patients and the retrospective nature of the case infor-

mation are the main limitations of this study. However, this study presents the largest series of patients to date who underwent endovascular treatment for acute and subacute limb ischemia with percutaneous manual aspiration.

In conclusion, MAT is intended to remove both soft acute blood clots and hard organized embolic and thrombotic obstructions. MAT seems to be a safe and effective method for treating delayed graft thrombosis. This method provides an alternative to surgical thrombectomy, especially for patients who are not good candidates for the surgery.

Conflict of interest disclosure

The authors declared no conflicts of interest.

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