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Fogarty balloon application technique in dislodging residual thrombus on the single sheath entry point at the apex of thrombosed loop grafts

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PURPOSE
We aimed to evaluate the effectiveness of the Fogarty balloon application in dislodging residual thrombus at the sheath entry point in a graft by using single apex puncture to declot thrombosed hemodialysis loop grafts.

MATERIALS AND METHODS
The apex puncture technique was used in 520 cases to declot 376 hemodialysis loop grafts (male/female, 150/226; mean age, 58 years). The Fogarty balloon application technique, which uses the Fogarty balloon to fill the apex, was used to compress or displace the sheath entry point residual thrombus that did not wash away spontaneously by arterial flow. The frequency of the use of the technique, technical success, complications, and primary patency were evaluated.

RESULTS
Sheath entry point thrombi were washed away spontaneously in 281 of 520 procedures (54%), and 184 procedures (35.4%) underwent a Fogarty balloon application. For a variety of reasons, the Fogarty balloon application technique was not performed in the remaining 55 procedures (10.6%). The technique was successful in 171 of 184 procedures (92.9%), and failed in 13 procedures, which required additional sheath insertion for the removal of sheath entry point thrombus. Complications included sheath dislodgment from the apex during Fogarty ballooning in one procedure and puncture site bleeding in one procedure. Primary patency was 60%, 35.2%, and 15.3% at 3, 6, and 12 months postprocedure, respectively.

CONCLUSION
The Fogarty balloon application technique is safe and useful for the removal of residual thrombus at the apical, peri-sheath zone when declotting occluded hemodialysis loop grafts.

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Percutaneous declotting is the preferred method for the treatment of thrombosed hemodialysis arteriovenous fistulae and grafts (1–3). A variety of different declotting methods have been developed for clinical use, including pulse-spray pharmacomechanical thrombolysis (3, 4), mechanical thrombectomy (using Amplatz Clot Buster, AngioJet, or Arrow percutaneous thrombolytic device) (4–7), and aspiration thrombectomy (8). In general, two separate puncture sites are required to enter the arterial and venous limbs of the graft for declotting. An alternative approach for declotting is to perform percutaneous catheterization of a thrombosed loop hemodialysis graft using the apex-puncture technique (9). This involves gaining single access at the loop graft apex to access both the venous and arterial limbs for clot removal, angioplasty of the anastomotic stenosis, and finally removal of the arterial plug. However, its advantages are limited in controlling intimal hyperplasia and residual thrombi at the peri-sheath/graft apex. Apical residual thrombi in the peri-sheath zone can be washed away spontaneously; however, in some cases, removal requires a second sheath insertion. In this study, we used the Fogarty balloon application technique, whereby the Fogarty balloon is used to compress or displace the peri-sheath, apical residual thrombi.

Here, we describe a simple technique for the removal of residual thrombus at the graft apex during the apex puncture procedure to declot occluded loop hemodialysis grafts. We believe that this technique may help to resolve the problems of apex puncture technique.

Materials and methods

During a seven-year period from November 2002 to December 2009, the apex-puncture technique with thromboaspiration was used in 520 sessions for declotting hemodialysis loop grafts in 376 patients (male/female, 150/226; mean age, 58±13.0 years). Graft locations were as follows: forearm (242 patients), upper arm (118 patients), and groin (16 patients).

Informed consent for invasive intervention was obtained from all patients. Each patient was placed in the supine position on the fluoroscopy table, and the limb with the graft was placed on a board. Intravenous midazolam hydrochloride and fentanyl citrate was administered as needed. The graft region was prepared and draped in standard sterile fashion. The graft apex was located by palpation. After applying local anesthesia with 1% lidocaine, a 21-gauge needle was advanced 1–2 cm horizontally in the subcutaneous tissue to puncture the graft. After confirming the position of the needle in the graft by injecting small amounts of contrast media, a 0.018 inch wire was advanced into the venous limb of the graft. The wire was then substituted with a 0.035 inch J wire and a 7 F Desilet-Hoffman sheath (Cook Medical, Bloomington, Indiana, USA) was inserted. A 10 mL syringe was connected to the sheath, and aspiration

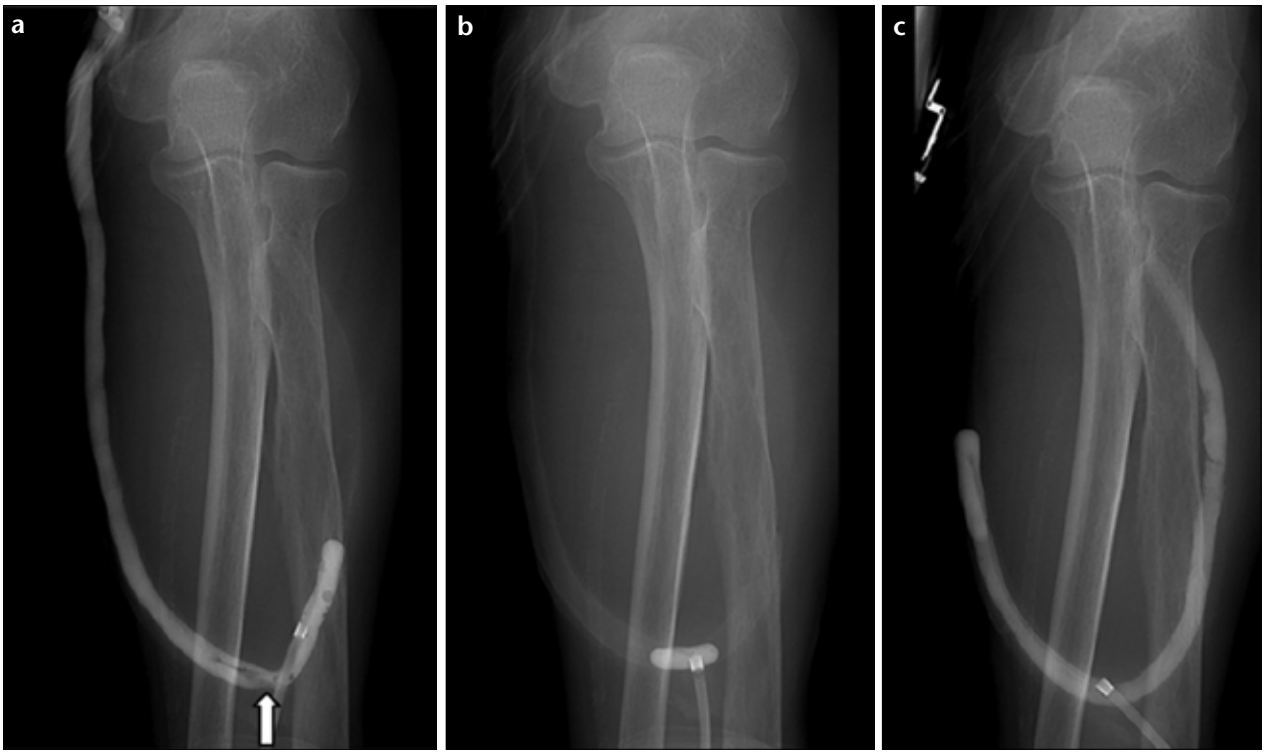

Figure 1. a–c. Images of a 63-year-old man with loop graft obstruction in the left forearm. Thrombi caught at the graft apex are noted **(a,** *arrow***)**. However, there is no evidence of intimal hyperplasia at the apex. As the Fogarty balloon is slowly inflated, the ballooning portion of the Fogarty catheter is slid from the tip of the sheath and fills the graft apex **(b)**. Residual thrombi are compressed by the Fogarty balloon. A follow-up fistulography **(c)** shows no residual thrombi at the apex of the graft.

thrombectomy was performed. An angioplasty balloon catheter with a 6 or 7 mm diameter was inserted into the central vein, and 5000 IU of heparin was injected. The balloon catheter was used to dilate stenosis in the venous outflow tract. Once the venous limb was free of thrombi, the sheath was redirected into the arterial limb, and an aspiration thrombectomy was performed. A 5 F Fogarty arterial embolectomy catheter (Edwards Lifesciences, Irvine, California, USA) was advanced into the artery, and the arterial plug was removed by pulling the inflated Fogarty balloon back from the artery into the arterial limb. Residual thrombi at the graft apex were spontaneously washed away by the arterial flow. In some cases, the thrombi at the apex were not washed away spontaneously, which necessitated the application of the Fogarty balloon.

When a residual thrombus was present at the graft apex, the Fogarty balloon application technique was used to displace or compress the thrombus and facilitate its removal (Fig. 1). The technique involves maximal withdrawal of the sheath to the puncture site. The ballooning portion of the Fogarty catheter is advanced to the tip of the sheath, which is positioned at the apex of the graft. As the Fogarty balloon is slowly inflated using a 2 mL syringe filled with contrast material, the ballooning portion is moved from the tip of the sheath and fills the graft apex in a T shape. Firm pressure is then applied for several seconds, which compresses or displaces the thrombi. Holding the sheath manually during Fogarty inflation helps prevent the dislodgment of the sheath from the graft. All Fogarty catheter manipulations were controlled under fluoroscopic visualization. The thrombus will often be washed away by arterial flow when the balloon is deflated. A purse-string stitch using a No. 3 polypropylene suture (Ailee Company, Busan, Republic of Korea) was placed around the entrance site of the vascular sheath after the final post-treatment angiogram. Hemostasis was achieved by tightening the stitch after removal of the vascular sheath.

Technical success was defined as the complete or near complete removal of residual thrombi. The frequency of Fogarty balloon application technique use, technical success, complications, and primary patency were evaluated.

Results

Technical success for percutaneous aspiration thrombectomy was achieved in 507 of 520 procedures (97.5%). Residual thrombi at the apex were spontaneously washed away in 281 of 520 procedures (54%) when the arterial plug was removed. In these cases, there was no intimal hyperplasia at the apex. In 55 procedures (10.6%), we did not attempt the Fogarty balloon application technique and instead inserted a second sheath for the following reasons: intimal hyperplasia with or without residual thrombus at the graft apex (n=20), acutely angled graft apex (n=8), intimal dissection at the graft apex (n=4), failed apex puncture (n=4), massive residual thrombus without intimal hyperplasia at the graft apex (n=2), sheath removal during redirection (n=1), and other (n=16). In 184 procedures that received the Fogarty balloon application technique, it was deemed successful in 171 procedures (92.9%). The Fogarty balloon application technique was unsuccessful in 13 procedures, which required additional sheath insertion at another site to facilitate thrombus removal for the following reasons: 1) hidden intimal hyperplasia with

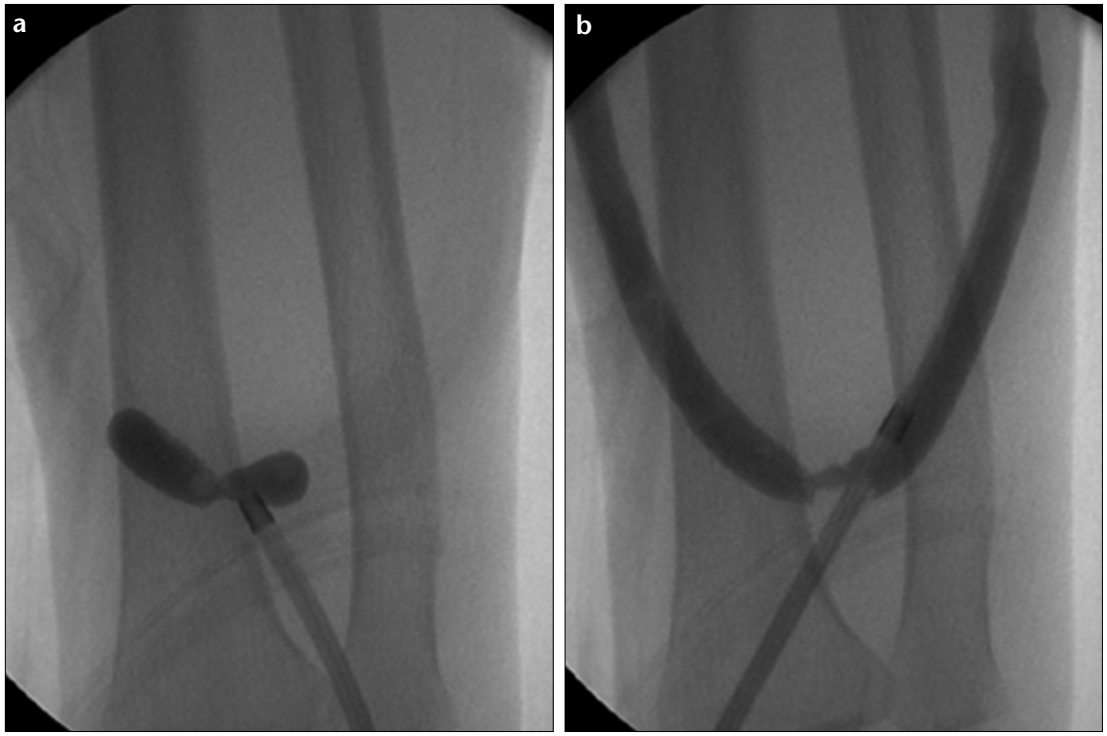

Figure 2. a, b. Images of a 53-year-old woman with loop graft obstruction in the right forearm. Fogarty balloon is not fully dilated due to the intimal hyperplasia at the apex of the graft **(a)**. Repeat fistulography shows distinct intimal hyperplasia at the apex **(b)**.

residual thrombus at the graft in four procedures (Fig. 2); 2) dislodged sheath from the apex during Fogarty ballooning in two procedures; 3) incomplete removal of residual thrombi at the apex after application of the Fogarty balloon in six procedures; and 4) puncture site bleeding in one procedure.

The incidence of intimal hyperplasia at the graft apex was 24/520 (4.6%), which was proportionate to the frequency of the apex puncture procedure. The mean graft age of patients in the apex stenosis group and no apex stenosis group was 42.5±36.5 and 34.6±27.3 months, respectively, which did not show statistically significant difference. The 3, 6, and 12 months postintervention primary patency were 60%, 35.2%, and 15.3%, respectively (Fig. 3). Complications included dislodgment of the sheath from the apex in one procedure, and puncture site bleeding in one procedure.

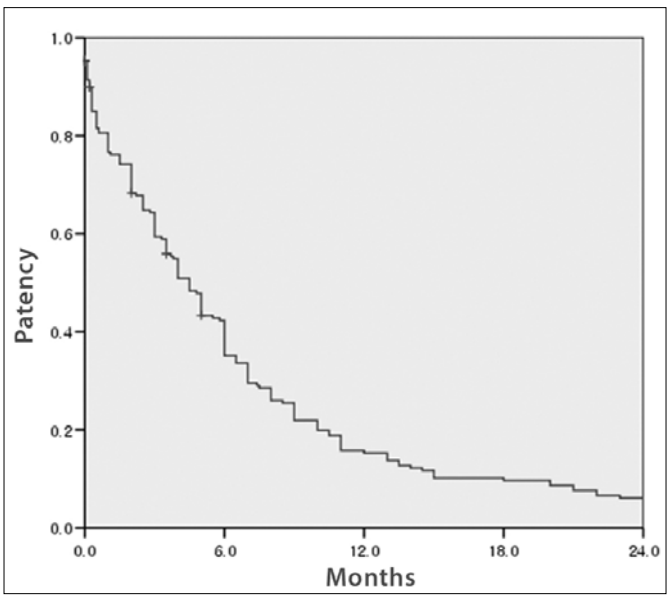

Figure 3. Post-treatment primary patency.

Discussion

A variety of methods, including pulse-spray pharmacomechanical thrombolysis, balloon-assisted thrombectomy, and several mechanical thrombectomy devices have been developed for the treatment of thrombosed hemodialysis grafts (3–8). The dual access approach has been the most adopted method for performing percutaneous thrombectomy in loop-configured grafts. Hathaway and Vesely (9) introduced the apex puncture technique for mechanical thrombolysis of loop hemodialysis grafts. The apex puncture technique has several advantages compared to the dual access technique. However, its use is limited to controlling intimal hyperplasia and remains ineffective in the removal of residual thrombi at the graft apex. However, it must be emphasized that intimal hyperplasia does not occur as frequently at the apex as it does at the venous or arterial limb of the graft. In these cases, it is essential to insert another sheath to approach the graft apex. Residual thrombus caught by the sheath is often washed away by

arterial flow, but it requires additional manipulation for removal if it is not washed away spontaneously. The residual thrombi were spontaneously washed away in many cases of our procedures. It has been well established that percutaneous thrombectomy procedures can generate pulmonary emboli, but one study reported that no patients had scintigraphic evidence of pulmonary embolization and all patients remained asymptomatic (10). Therefore, a symptomatic pulmonary embolism is a rare event, and percutaneous thrombectomy of a hemodialysis graft is considered to be a safe procedure.

In this study, we found that the incidence of intimal hyperplasia at the graft apex was 4.6% (24/520), but markedly increased with increased frequency of graft apex puncture history. Peri-sheath thrombi were not washed away spontaneously in 46% of patients (239/520), and required additional manipulation. Hathaway and Vesely (9) suggested removing the sheath momentarily over a guide-wire and allowing the thrombi to be washed away. We also attempted this approach by removing the sheath, which was successful in three patients, but in many cases the procedure was unsuccessful.

The arterial plug was pulled back with a Fogarty catheter during aspiration thrombectomy. The Fogarty balloon catheter is a widely accepted tool used for surgical thrombectomy of hemodialysis access grafts (11). In addition, interventional radiologists use a Fogarty balloon catheter or an occlusion balloon catheter for displacement of the arterial plug at the arterial anastomosis (12, 13). Since November 2002, we have attempted the Fogarty balloon application technique when residual thrombi were noted at the graft apex, instead of removing the sheath over a guide-wire. The technique of removing apical residual thrombi caught by the sheath is very simple. In many cases, residual thrombi caught by the sheath were small in quantity, and intimal hyperplasia did not frequently coexist at the graft apex. Thrombi compressed by the Fogarty catheter were easily displaced from the apex by arterial flow. Unlike conventional angioplasty balloon catheters, the compliant nature of the Fogarty balloon allows relatively atraumatic manipulation within the inflow artery and hemodialysis graft. Silberzweig et al. (11) reported two cases of arterial pseudoaneurysm after graft recanalization with use of the Fogarty catheter. However, ingraft pseudoaneurysm related with the Fogarty balloon manipulation has not been reported.

In this study we experienced two cases of sheath dislodgment from the graft, which required a second puncture. One case occurred during Fogarty inflation and another occurred during sheath redirection. Holding the sheath manually and inserting a safe guide-wire during Fogarty inflation helps prevent sheath dislodgment from the graft. However, the incidence of this occurrence was very low, and we did not use a safe wire during Fogarty inflation.

We believe that a second sheath insertion would be essential when residual thrombi at the apex are associated with intimal hyperplasia. Occasionally, short segmental intimal hyperplasia at the graft apex was not detected due to the thrombi and was only detected during Fogarty balloon compression. Intimal hyperplasia at the graft apex detected during the Fogarty balloon application procedure was seen in four patients of our study. Even after removing the thrombi, a second sheath insertion would be needed, because it is almost impossible to dilate intimal hyperplasia at the apex using a Fogarty balloon alone.

In several cases, residual thrombi not associated with intimal hyperplasia were not removed after performing the Fogarty balloon compression technique, and required a second sheath insertion for conventional ballooning. This may have been due to incomplete compression of the thrombus for various reasons, such as incomplete withdrawal of the sheath or an acutely angled graft apex.

Although the number of cases in this study was large, there were some limitations. For example, this was a retrospective study, and many patients were outpatients, which made it difficult for follow-up. In addition, we did not compare the other techniques for removal of the residual thrombus at the graft apex.

In conclusion, the Fogarty balloon application technique is an effective and safe method for the removal of residual thrombus caught by the sheath during the apex puncture procedure in occluded loop hemodialysis grafts.

Conflict of interest disclosure

The authors declared no conflicts of interest.

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