Angioscopic Observations after Percutaneous Thrombectomy of Thrombosed Hemodialysis Grafts

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Index terms: Angioscopy • Dialysis • Grafts, stenosis or thrombosis • Thrombectomy

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Abbreviations: PTD = percutaneous thrombectomy device, PTFE = polytetrafluoroethylene

PURPOSE: To use angioscopy to evaluate and compare the amount of residual thrombus and endoluminal wall damage in hemodialysis grafts after percutaneous thrombectomy procedures.

MATERIALS AND METHODS: Thirty-nine thrombectomy and angioscopy procedures were performed in 35 patients. Percutaneous thrombectomy methods included eight different mechanical thrombectomy devices and the “lyse and wait” technique. Videotaped images of 33 angioscopic examinations were independently reviewed by three radiologists. Two parameters—the amount of residual thrombus and degree of endoluminal wall damage—were scored on a scale of 1 to 5. Data were initially analyzed to validate the grading system and then further studied to compare the different thrombectomy techniques.

RESULTS: The Spearman rank order analysis validated the data pertaining to the amount of residual thrombus (r = 0.71, P < .0001), but there was poor correlation between reviewers regarding the degree of endoluminal wall damage. Combined scores from three reviewers revealed that the Cragg brush and Percutaneous Thrombectomy Device (PTD) left the smallest amounts of residual thrombus. The other methods tested, listed by increasing amount of residual thrombus, were the Endovac, Hydrolyser, Amplatz Thrombectomy Device, AngioJet, Oasis, and the lyse and wait technique. There were two complications related to angioscopy procedures.

CONCLUSION: Subjective observations reveal that wall-contact thrombectomy devices leave less residual thrombus than hydrodynamic devices, aspiration devices, or the lyse and wait technique.

THE United States Food and Drug Administration has approved eight mechanical thrombectomy devices for use in hemodialysis grafts. A comparison of the published results from the clinical studies of these various devices reveals similar technical success rates of 89%–95% and similar primary patency rates of 35%–50% at 3 months (1–6). Although these reported success rates are similar, there may be differences in the effectiveness of these devices for macerating or removing thrombus. In a recent study, Müller-Hülsbeck and colleagues (7) used three different mechanical thrombectomy devices in an in vitro model and found significant differences between their efficacy in thrombus removal. However, to our knowledge, the clinical effectiveness of these devices—the ability to remove thrombus from a thrombosed hemodialysis graft—has not been previously evaluated and compared. This study was intended to assess and compare the clinical performance of different mechanical thrombectomy devices. Angioscopy
was performed to evaluate the amount of residual thrombus and the endoluminal appearance of hemodialysis grafts after mechanical thrombectomy. In addition, angioscopy was also performed after three lyse and wait procedures.

**MATERIALS AND METHODS**

Between April 1998 and June 1999, 196 patients were referred to the interventional radiology department for treatment of a thrombosed polytetrafluoroethylene (PTFE) hemodialysis graft. Patients were prospectively enrolled in this study if the principal investigator was available to perform the procedure and the patient consented to angiographic examination. Patients were excluded if they had clinical evidence of respiratory problems or fluid overload. This entailed exclusion of patients with symptomatic dyspnea or orthopnea and patients who were receiving continuous supplemental oxygen. In addition, patients were excluded if initial diagnostic venography demonstrated occlusion of the native venous outflow or a long segment stenosis (>6 cm) in the native veins.

Thirty-nine angioscopy procedures were performed immediately after percutaneous thrombectomy in 35 patients (25 women, 10 men). All thrombectomy and angioscopy procedures were performed by one interventional radiologist experienced in performing each of the thrombectomy methods used in this study. All procedures were performed on an outpatient basis.

Table 1

<table>
<thead>
<tr>
<th>Graft Location/Configuration</th>
<th>Right</th>
<th>Left</th>
</tr>
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<tbody>
<tr>
<td>Forearm Loop</td>
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</tr>
<tr>
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<tr>
<td>Upper Arm Loop</td>
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<tr>
<td>Thigh Loop</td>
<td>3</td>
<td>2</td>
</tr>
</tbody>
</table>

The location and configuration of the hemodialysis grafts are listed in Table 1. The mean graft age at the time of the angioscopy procedure was 14.3 months (range, 5–82 months). Four patients underwent two separate thrombectomy and angioscopy procedures. These second procedures were performed 20, 36, 201, and 213 days after the respective first procedures.

- **Angioscopy System**

  All angioscopy procedures were performed with use of a 2.3-mm-diameter, disposable (single-use) angioscope (Intramed model 700047; Baxter, Irvine, CA), which is 80 cm in length and contains a 1-mm-diameter irrigation channel. A focusing coupler (Intramed model 700018; Baxter) was used to connect the light source and camera (LCI-200 Illumination and Imaging System; Welch-Allyn, Skaneateles Falls, NY) to the angioscope.

  An endoscopic irrigation pump (Intramed model 700043; Baxter) was connected to the irrigation channel of the angioscope with use of standard irrigation tubing and controlled with use of a foot pedal. The irrigation pump supplied a continuous flow of saline at a rate of 60 mL/min or a bolus rate of 120 mL/min. The average amount of saline infused during the angioscopy procedures was 371 mL (range, 190–626 mL).

  Before moving the angioscope into the operative field, a sterile ultrasound transducer sleeve (Civco Medical Instruments, Kalona, IA) was used to cover the camera head, light source cable, and irrigation tubing. Real-time images were observed on a color video monitor and recorded with use of a 3/4-inch videocassette recorder.

- **Mechanical Thrombectomy and Angioscopy Procedure**

  Before the thrombectomy procedure, each hemodialysis graft was examined to determine its location and configuration and to exclude graft infection. Conscious sedation was achieved with use of intravenous anxiolytic and analgesic medications.

  Vascular access was obtained with use of the apex puncture technique in the majority (94%) of patients (8). An 18-gauge needle was used for initial access and a 0.035-inch guide wire was advanced into the venous limb under fluoroscopic observation. With use of a multipurpose angiographic catheter (Cook, Bloomington, IN), the guide wire was advanced through the venous anastomosis into the native veins. Venography was performed to evaluate the central and peripheral native veins before initiating the thrombectomy procedure. The angiographic catheter was removed and replaced with an 8-F vascular sheath (DialEase; Mallinckrodt Medical, St. Louis, MO), which was advanced into the venous limb. Through the side arm of the sheath, 3,000 U of heparin was slowly injected into the graft. During the thrombectomy procedure, a 50/50 mixture of contrast material and saline was intermittently injected through the side arm of the sheath to opacify the lumen of the graft.

  All mechanical thrombectomy devices were used in accordance with the manufacturer’s instructions. The device was activated and advanced back and forth under fluoroscopic observation to macerate or remove thrombus from the venous limb. The speed at which the device was moved within the graft was based on the manufacturer’s recommendations. None of the thrombectomy devices were used over a guide wire.

  After use of the Trerotola Percutaneous Thrombolytic Device (PTD) (Arrow International, Reading, PA), the manufacturer recommends aspirating residual thrombus fragments. A 20-mL syringe was attached to the side arm of the vascular sheath and aspiration was applied in an attempt to remove residual thrombus from the graft. Angioscopy of the venous limb was performed after this recommended maneuver.

  A Cragg brush (Micro Therapeutics, San Clemente, CA) and Castaneda brush (Micro Therapeutics, San Clemente, CA) were used to perform the thrombectomy procedure. A 1-mm-diameter irrigation channel was used to opacify the lumen of the graft. Before moving the angioscope into the operative field, a sterile ultrasound transducer sleeve (Civco Medical Instruments, Kalona, IA) was used to cover the camera head, light source cable, and irrigation tubing. Real-time images were observed on a color video monitor and recorded with use of a 3/4-inch videocassette recorder.

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were used in conjunction with urokinase (Abbott Laboratories, Abbott Park, IL). A mixture of urokinase (250,000 U/5 mL) and heparin (5000 U/1 mL) was slowly infused into the graft via the side arm of the sheath. The brush catheter was then advanced into the venous limb to perform the thrombectomy procedure.

The lyse and wait procedures were performed as described by Cynamond et al (9) with one minor variation. The initial vascular entry into the graft (with use of a 21-gauge angiocath) was confirmed by the injection of a small amount of contrast material under fluoroscopic observation. This was done to certify that the thrombolytic agent was appropriately delivered into the graft, thereby validating the post-thrombectomy angiographic evaluation. After insertion of the angiocath, a mixture of urokinase (250,000 U/5 mL) and heparin (5000 U/1 mL) was slowly injected into the graft while the arterial limb was compressed near the arterial anastomosis. The patient was then placed in an observation area and assessed intermittently for at least 1 hour before the thrombectomy procedure was continued.

After thrombectomy of the venous limb, the mechanical device was removed. In the majority of patients, the angioscope was inserted into the graft immediately after the mechanical thrombectomy procedure, before angioplasty of the venous anastomotic stenosis was performed. The angioscope was directed down the central lumen of the venous limb by maneuvering the vascular sheath or by manually compressing the graft to manipulate the distal tip of the angioscope (Fig 1). Seven patients with very high-grade stenosis at the venous anastomosis underwent angioplasty before insertion of the angioscope. This allowed decompression of the saline infusion during angioscopy, decreasing the potential for embolization of debris across the arterial anastomosis.

After the angioscopy procedure, the vascular sheath was redirected into the arterial limb. The thrombectomy device was used to remove the thrombus from the arterial limb. The arterial plug was dislodged with use of a 6-F Thru-Lumen Fogarty catheter (Baxter) over a 0.035-inch guide wire. A final completion fistulogram was obtained. A purse-string suture was used to close the vascular access site.

The devices used to perform the mechanical thrombectomy procedures are listed in Table 2. Three patients underwent lyse and wait procedures.

- **Data Analysis**

Demographic information was compiled from the medical records at the patient’s hemodialysis treatment center. Procedural information, such as the type of mechanical thrombectomy device and amount of saline infused, was prospectively recorded at the time of the angioscopy procedure.

The results of this study, consisting of 5.5 hours of video images, are observational and therefore subject to interpretation. A grading system was developed and then used by three reviewers to create a qualitative data set. These data were first analyzed to determine their validity. After established as valid, these quantitative data were further studied and used for statistical analysis.

The videotapes of 33 angioscopy procedures were graded independently by three experienced interventional radiologists, none of whom had performed the angioscopy procedures. The videotapes of six angioscopy procedures were not graded. The excluded studies included two procedures in which the Amplatz thrombectomy device (Microvena, White Bear Lake, MN) was used, one in which the AngioJet (Possis, Minneapolis, MN) was used, one in which the PTD was used, one in which the Hydrolyser (Cordis, Warren, NJ) was used, and one in which the lyse and wait procedure was used.

The angioscopic records of three procedures were rejected because of poor image quality. Two patients had substantial blood flow within their grafts that interfered with angioscopic imaging. In the third patient, the poor quality of the imaging was caused by graft tortuosity; the angioscope could not be manipulated to visualize the central lumen of the graft. The videotaped one angioscopy procedure was inadvertently erased and unavailable for review. Two patients had complica-

<table>
<thead>
<tr>
<th>Thrombectomy Device</th>
<th>No. of Angioscopic Procedures</th>
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<tr>
<td>Amplatz Thrombectomy Device</td>
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</tr>
<tr>
<td>Cragg brush</td>
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</tr>
<tr>
<td>Percutaneous Thrombolytic</td>
<td>5</td>
</tr>
<tr>
<td>Device</td>
<td></td>
</tr>
<tr>
<td>Oasis catheter</td>
<td>4</td>
</tr>
<tr>
<td>Hydrolyser catheter</td>
<td>3</td>
</tr>
<tr>
<td>Endovac</td>
<td>3</td>
</tr>
<tr>
<td>“Lyse and wait”</td>
<td>3</td>
</tr>
<tr>
<td>Castaneda brush</td>
<td>1</td>
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</table>
The residual thrombus data were converted to quantitative data. The grading system provided a reasonable and valid method to translate a visual image (ie, the amount of residual thrombus) into quantitative data.

The combined grades reveal that the Cragg brush and PTD had similar results and left the smallest amounts of residual thrombus after thrombectomy (Table 5, Fig 2). The other devices, listed in increasing scores, or amounts of residual thrombus, are the Endovac, Hydrolaser, Amplatz Thrombectomy Device, AngioJet, and Oasis. The three lyse and wait procedures and the one procedure involving the Castaneda brush left the largest amounts of residual thrombus.

When the three categories of devices were compared, the results demonstrated that the wall-contact devices generally leave smaller amounts of residual thrombus than the hydrodynamic or aspirating devices do (Table 6, Fig 3). Subjectively, the lyse and wait technique left the largest amount of residual thrombus. However, only three lyse and wait procedures were performed, so these results should be interpreted cautiously.

There was poor correlation between the three reviewers regarding the grading of endoluminal wall damage and wait procedures and the one procedure involving the Castaneda brush left the largest amounts of residual thrombus.

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damage. According to the Spearman rank order test, the highest correlation ($r = 0.41$, $P = .019$) was not sufficient to warrant further analysis.

There was a weak inverse correlation ($r = -0.28$) between the amount of residual thrombus and wall damage; this relationship was not statistically significant ($P = .12$).

Older grafts often have roughened and irregular endoluminal surfaces which may allow the thrombus to become more firmly attached. However, we found no relationship between graft age and the amount of residual thrombus ($P = .78$).

Table 5
Combined Raw Scores from the Three Reviewers of the Amount of Residual Thrombus by Device Type

<table>
<thead>
<tr>
<th>Grade</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
<th>G</th>
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<tr>
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<td>4</td>
<td>3</td>
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</tr>
<tr>
<td>Grade 2</td>
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<td>8</td>
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<td>0</td>
<td>1</td>
<td>1</td>
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</tr>
</tbody>
</table>

No. of Procedures Graded† 4 7 6 1 4 2 3 2 4

Note.—A = PTD; E = Oasis catheter; I = AngioJet; B = ATD; F = Hydrolyser catheter; C = Cragg brush; G = Endovac; D = Castaneda brush; H = Lyse and wait.

* The grade, or amount, of residual thrombus increases from minimal (grade 1) to a large amount (grade 5).
† There are three scores for each procedure, one score for each reviewer. For example, four PTD procedures (column A) generated 12 scores.

Table 6
Combined Raw Scores from the Three Reviewers of the Amount of Residual Thrombus by Device Category

<table>
<thead>
<tr>
<th>Grade</th>
<th>Device Category</th>
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<tr>
<td>1</td>
<td>12</td>
</tr>
<tr>
<td>Total†</td>
<td>11</td>
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</table>

Note.—A = PTD, Cragg brush, Castaneda brush; B = ATD, Oasis, Hydrolyser, Endovac, AngioJet; C = Lyse and wait.

* The grade, or amount, of residual thrombus increases from minimal (grade 1) to a large amount (grade 5).
† There are three scores for each procedure, one score for each reviewer. For example, 11 PTD procedures (A) generated 33 scores.

Figure 2. Bubble-plot of residual thrombus scores by device type. Area of bubble is proportional to the percentage of total scores assigned by the three reviewers. Compare with Table 4. A = PTD, E = Oasis catheter, B = ATD, F = Hydrolyser catheter, C = Cragg brush, G = Endovac, D = Castaneda brush, H = Lyse and wait, I = AngioJet.

Figure 3. Bubble-plot of residual thrombus scores by device category. Area of bubble is proportional to the percentage of total scores assigned by the three reviewers. Compare with Table 5.

Another interesting observation was that catheter-type devices, such as the Amplatz Thrombectomy Device, AngioJet, Oasis, and Hydrolyser, would routinely track along the outer curvature of loop configuration grafts (Fig 4). These devices were effective in removing thrombus along the periphery of the lumen and occasionally failed to remove thrombus from the medial (inner) aspect of the graft lumen. This
of the graft injury, the surgeon could not identify the damaged area. The perforation was not repaired. A diagnostic fistulogram obtained 3 months later revealed only minimal endoluminal irregularity at the perforation site.

A second patient experienced the acute onset of dyspnea during the angioscopy procedure. It had been 4 days since the patient’s most recent hemodialysis treatment. The patient’s symptoms were attributed to pulmonary congestion—caused by fluid overload—as opposed to an acute pulmonary embolus. Before terminating the procedure, the patient received 285 mL of saline during angioscopy. Oxygen (6 L/min) was administered via a nasal cannula and the patient was transferred to an observation area, where she was allowed to sit upright. Her symptoms gradually resolved during a 2-hour observation period. She was discharged to an outpatient hemodialysis center, where she underwent a hemodialysis treatment without complication.

## DISCUSSION

Several important and interesting observations were made during the course of this study. Angioscopy clearly showed that fistulography underestimates the amount of debris and residual thrombus within a hemodialysis graft. During this study, thrombectomy procedures were typically continued until fistulography demonstrated minimal, if any, residual thrombus within the graft. However, angioscopy commonly revealed more residual intraluminal thrombus than was appreciated by angiography. White et al (11) reported a similar observation: angiography had a sensitivity of 19% for the detection of thrombus in coronary artery bypass grafts; angioscopy had a sensitivity of 71% (11).

One reason for this discrepancy may be the incorporation, or layering, of thrombus onto the endoluminal surface of the graft. When imaged during fistulography, this thickened, irregular endoluminal surface could be attributable to pseudointimal hyperplasia, a common finding in older grafts. Angioscopy revealed that this material was often not pseudointimal hyperplasia but, instead, chronic wall-adherent thrombus.

Teirstein et al (12) also noted this observation in their comparison of angiography to angioscopy for the detection of thrombus during interventional cardiology procedures in 75 patients. They reported that the sensitivity of angiography for detecting intraluminal thrombus was 100%, whereas the sensitivity for detecting mural thrombus was only 10%. They found the overall thrombus detection rate of angiography was 12%, compared to a rate of 41% with use of angioscopy.

Angioscopic observations also revealed that the endoluminal surface of a PTFE hemodialysis graft is covered uniformly by a thin layer of delicate grayish-white material. This endoluminal layer covers the exposed surface of the PTFE and functions as a boundary layer between the graft and flowing blood stream. This thin layer is fragile and can be easily disrupted by the manipulation of devices within the graft. Wall-contact devices commonly sheared off this thin layer, occasionally denuding the entire endoluminal surface. We attempted to quantify these findings but, unfortunately, there was poor correlation between the three reviewers with regard to their grading of the degree of endoluminal wall damage.

This study demonstrated that a variable amount of residual thrombus is present in hemodialysis grafts after a percutaneous thrombectomy procedure. Angioscopy has been similarly used to evaluate thrombus after surgical thrombectomy procedures. Holzenbein and colleagues (13) reported on their use of angioscopy during a broad range of surgical procedures related to vascular access for hemodialysis. They described their angioscopic observations after surgical thrombectomy of 34 hemodialysis grafts. Fifty-two abnormal findings were noted, including residual thrombus in 56% of the grafts. Although the
amount of thrombus was not quantified, 21% of patients required a second procedure to remove residual thrombus. Similarly, Segalowitz et al (14) reported their angioscopic observations after surgical thrombectomy of 25 arterial bypass grafts and seven hemodialysis grafts. Angioscopy revealed significant amounts of residual thrombus or neointimal debris in all 32 patients.

The ultimate fate of postthrombectomy residual thrombus within a hemodialysis graft is unknown. Much of it may be washed away to the pulmonary arterial bed when blood flow is restored within the graft. Adherent thrombus that is not washed away may become incorporated onto the endoluminal surface of the graft or may be gradually degraded by the patient’s fibrinolytic system. Although residual thrombus was readily visualized with angiography, the total volume of thrombus was quite small and may not be clinically significant in most patients.

During our study, all mechanical thrombectomy devices were kept within the hemodialysis grafts and were not advanced into the native veins or arteries. One previously published report described the acute effects of the use of a wall-contact device, the PTD, within the inferior vena cava of rabbits (15). These histologic studies by Lajvardi et al (15) demonstrated acute endothelial denudation of nearly the entire inferior vena cava after use of the PTD. These findings are consistent with our angioscopic observations in PTFE grafts. To our knowledge, the long-term effect of this type of vascular wall injury in human veins and arteries is unknown.

In this observational study, the wall-contact devices were more effective in removing thrombus than hydrodynamic or aspiration devices or the lyse and wait technique. There was minimal, if any, residual thrombus remaining within the graft after thrombectomy with the Cragg brush or PTD. It is important to note that both these devices also commonly disrupted the delicate endoluminal lining of the graft. They produced a denuded, raw-appearing surface, the clinical significance of which is unknown. One may speculate that the surface will be readily re-covered with a new fibrinous layer, but the graft may be at increased risk for graft re-thrombosis during this time period. Hydrodynamic or aspiration devices do not disrupt the endoluminal surface, but commonly leave residual thrombus that may also predispose the graft to early rethrombosis.

There are several limitations to this investigation. The patients were not randomized to the different thrombectomy devices, which resulted in marked differences in the number of procedures performed with use of each device. Second, this investigation was strictly observational and the results are subjective.

Our study provided several interesting and thought-provoking observations. Future studies of this type in larger numbers of patients may provide us with additional information and insight to determine which type of thrombectomy technique is best suited for the treatment of thrombosed hemodialysis grafts.

References