Interventional Cardiology

AngioJet Thrombectomy to Salvage Thrombosed Native Dialysis Fistulas

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Purpose: To investigate outcomes following treatment of thrombosed native dialysis fistulas with AngioJet thrombectomy.

Materials and Methods: We retrospectively reviewed an existing database and included patients according to the following criteria: thrombosed fistula, native fistula, and use of the AngioJet system for mechanical thrombectomy. Outcomes included clinical success, complications, and patency rates.

Results: One hundred and nine patients with 135 episodes of native fistula thrombosis were included in the study. Clinical success was achieved in 76% (103 of 135) of the procedures. Fistulas salvaged within three days of thrombosis had higher clinical success rates than those salvaged after three days (80% vs. 63%). The average procedure time was 82 ± 37 minutes. Complications occurred in 15% (20 of 135) of the procedures, but all were not device-related. The primary patency rates were 67%, 57%, and 39% and the secondary patency rates were 74%, 72%, and 70% at 30, 90, and 180 days, respectively. In the Cox regression analysis, only diabetes mellitus, current smoker, right-sided fistula and small vessel size were independent predictors of primary patency.

Conclusion: Percutaneous thrombectomy using the AngioJet system is effective for the salvage of thrombosed native dialysis fistulas. It has an acceptable complication rate, primary patency rate, and secondary patency rate.

Key Words: AngioJet • Dialysis fistula • Thrombectomy • Thrombosis

INTRODUCTION

Durable vascular access is a major determinant of long-term survival for patients undergoing hemodialysis. Native arteriovenous (AV) fistulas are considered the vascular access of choice according to the National Kidney Foundation's Dialysis Outcomes Quality Initiative (NKF/DOQI) guidelines.[1] Although native fistulas are associated with better longevity than prosthetic grafts, thrombosis does eventually occur. Because of the limited number of arterial and venous sites for fistula creation, the importance of salvage of thrombosed fistulas cannot be overemphasized. However, endovascular declotting of a thrombosed native fistula is a more challenging procedure than that for prosthetic grafts for several reasons: first, when declotting wall-adherent clots, thin-walled native veins are more prone to injury or rupture; second, the anatomy of native veins is more complex than grafts with multiple stenoses; third, aneurysmal dilatation of native veins makes the clearance of thrombi more difficult.[2]

Mechanical thrombectomy is a well-established endovascular procedure for prosthetic grafts and has demonstrated equivalent results to surgical revision or pharmacological thrombolysis.[3-8] Theoretically, percutaneous mechanical thrombectomy offers an alternative to surgical revision or pharmacological thrombolysis, with a lower risk from anesthesia or hemorrhagic complications.[9] Although there have been many

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studies on the declotting of prosthetic grafts, studies focused on the declotting of native fistulas are relatively uncommon.[10-14]

A variety of mechanical devices have been investigated and shown to be effective for clot-removal in prosthetic grafts. However, published data about their effects specific to native fistulas is relatively limited. The AngioJet device is designed to remove thrombus from native vessels such as the coronary and peripheral arteries.[15-17] To our knowledge, only a very limited number of studies have investigated the use of AngioJet on native dialysis fistulas.[13,18] The aim of this study was to report our single-center experience of (1) the immediate success and complications; and (2) the six-month primary and secondary patency rates for AngioJet thrombectomy of thrombosed native dialysis fistulas.

MATERIALS AND METHODS

Study design

We retrospectively reviewed an existing database at our institution from September, 1999 to September, 2005. Procedures fulfilling all of the following criteria were included: (1) native fistula, (2) thrombosed fistula, and (3) thrombectomy using AngioJet only. Thrombosis was suspected by the loss of a thrill or bruit over the vascular access and was confirmed by a fistulogram demonstrating complete occlusion of vascular access. All procedures fulfilling the above criteria within the study period were included in an intention-to-treat basis. In the hemodialysis centers of our institution and nearby hospitals, patients with suspected thrombosed native fistulas were referred to our angiographic unit for endovascular salvage. Treatment was organized immediately, usually within 24-48 hours of the seek for help. A conventional percutaneous salvage technique using balloon maceration was attempted first.[19] The AngioJet method was used only in patients with a large clot burden (with a risk of significant pulmonary embolism as judged by the operator) or wall-adherent thrombus (resistant to balloon maceration and causing inadequate thrill). If endovascular attempts failed, the patients were referred for surgical management.

Demographic data and procedural information were extracted from the angiographic images, detailed procedural reports, dialysis records and hospital records. Follow-up and patency data were obtained by review of hospital and dialysis records, angiographic follow-up in cases requiring further intervention, and direct communication with the referring nephrologists if necessary. Data collected included demographics (age, sex, age of fistula, location of fistula), procedural details (heparin use, device type, balloon sizes, physical examination post-procedure, complications, and residual findings) and outcome of procedure. Institutional review board approval was not required at our hospital for this type of retrospective analysis.

Endovascular techniques

Before thrombectomy

Retrograde puncture in a patent segment of the vein downstream from the thrombosed segment, or an antegrade puncture via the radial artery, was performed using a 30 mm 20-gauge sheathed needle (Terumo, Tokyo, Japan). After the needle was removed, a 45-cm, 0,025-in hydrophilic guide wire was inserted to pass through the thrombosed segment or upstream radial artery. The 20-G sheath was removed and a 6 to 7-Fr sheath (Terumo, Tokyo, Japan) was inserted through the guide wire. One or two sheaths were placed depending on the location of the thrombosed segment. Occluded fistulas were crossed directly by a 0.032-in hydrophilic guide wire (Terumo, Tokyo, Japan) coupled with a 4 to 6 × 20 to 40 mm over-the-wire compliant balloon catheter (Wanda, Boston Scientific, Natick, MA). The balloon size was determined by the patient's previous fistulography or angioplasty report if available, or the diameter of the adjacent normal vein or artery. If it was difficult to traverse the occluded segment, a 6-Fr JR4 catheter (Cook, Bloomington, IN) coupled with a 0.032-in hydrophilic guide wire was used. The guide wire was then removed, leaving the JR4 catheter or balloon catheter in the venous lumen. A puff of contrast medium was injected gently through the catheter to confirm the true lumen and to visualize the downstream fistula. Anticoagulation with 5,000 U of heparin and moderate sedation with midazolam and fentanyl were given via the JR4 catheter or balloon catheter according to the individual operator's discretion. One or two sheaths were placed depending on the anatomy of the fistula and the location of the

thrombosed segment. In cases with a short plug-like thrombus obstructing the radial-cephalic anastomosis or nearby downstream vein ("short-segment thrombus"), maceration of the thrombus was attempted first with an angioplasty balloon inflated at low pressure. In our institution, treatment with mechanical thrombectomy was attempted only in cases with a large thrombus burden or a wall-adherent thrombus that was resistant to balloon crushing or maceration ("long-segment thrombus").[14]

Thrombectomy with AngioJet

The AngioJet catheter was introduced via a percutaneous approach through a 6-Fr sheath and passed over a 0.018-inch or smaller guide wire. After priming the AngioJet system, the AngioJet catheter was passed over the guide wire through the thrombus segment repeatedly at 2-4 mm/second. The AngioJet device works through a high-pressure saline jet passing from the tip of the catheter, up the catheter shaft to an exhaust pump external to the patient. A low-pressure zone at the tip of the catheter draws thrombus into the jet stream, resulting in fragmentation and extraction of the thrombus. The catheter was passed through the venous outflow first, and then moved in a retrograde fashion toward the arterial anastomosis. Several passes were usually required to clear as much thrombus as possible.

After thrombectomy

After as much thrombus was cleared as possible, the underlying stenosis was treated with balloon angioplasty. Using an inflation device with a pressure gauge, the angioplasty balloon was inflated gradually until the stenosis was eliminated, and then kept at the same pressure for 60 seconds. If the waist of the stenosis was not eliminated after a maximal inflation pressure for 60 seconds, either cutting balloon (Peripheral Cutting Balloon, Boston Scientific, Natick, MA) or non-compliant high-pressure balloon (Conquest, Bard, Covington, GA) angioplasty was used to eliminate the stenosis.[20,21] After completion of the procedure, diagnostic fistulography was performed from the arteriovenous anastomosis to the central vein. The short sheath was then removed and the puncture site was manually compressed until hemostasis was obtained. An antiplatelet agent such as aspirin or clopidogrel was given routinely for three days post-procedure, but heparinization was not routinely continued.

Follow-up

All patients were followed at their respective hemodialysis unit. Patients were referred to our angiographic unit based on the following criteria: decreased or absent thrill, increased pulsatility, development of collateral veins, limb swelling, difficulty in canalization, prolonged bleeding after hemodialysis, high venous pressure during hemodialysis (dynamic venous pressure exceeded threshold levels three consecutive times), decreased hemodialysis flow rate (total fistula blood flow less than 500 mL/min measured by ultrasound dilution [Transonic Flow-QC; Transonic Systems, Ithaca, New York] or a 25% reduction in blood flow from that at baseline), and an abnormal recirculation measurement (> 10% using the urea-based method). When abnormal clinical or hemodynamic parameters suggested fistula dysfunction, patients were referred for repeat fistulography and intervention as appropriate.

Study outcomes and definitions

According to the reporting standards of the Society of Interventional Radiology (SIR),[22] anatomic success was defined as the restoration of blood flow combined with less than 30% maximal residual diameter stenosis at the conclusion of the procedure. Clinical success was defined as the resumption of normal dialysis for at least one session. The procedure time was defined as the time interval from the start of percutaneous puncture to the final post-treatment angiogram. Complications were categorized in accordance with SIR published guidelines. Post-interventional primary patency was defined as the interval after the intervention until the next access thrombosis or repeated intervention. Post-interventional secondary patency was the interval after the intervention until the access was surgically declotted, revised, or abandoned.

Statistical analysis

In this analysis, each fistula thrombosis was treated as a separate event for patients with more than one episode of fistula thrombosis. Patency during follow-up was determined by review of angiographic data, radiology reports, medical records, and direct communication with hemodialysis centers. Kaplan-Meier survival curves were used to estimate primary and secondary patency rates. Procedures that failed to achieve clinical success

were included in patency estimations. Cox proportional hazards regression analysis was used to evaluate predictors of primary patency. All variables with $p < 0.2$ in univariate analysis were included in multivariate models. Hazard ratios and 95% confidence intervals were calculated. A p value of less than 0.05 indicated statistical significance. Statistical analyses were performed using STATISTICA 7.0 software for Windows (StatSoft Inc., Tulsa, OK).

RESULTS

From September, 1999 through September, 2005, 135 AngioJet thrombectomy procedures were performed on 109 patients (47 women and 62 men) with thrombosed native fistulas. Patient ages ranged from 26 to 91 years (mean = 61 years). Fistula ages ranged from one to 276 months (mean = 43 months). The fistula types included: 90 forearm fistulas and 45 upper-arm fistulas; 100 left-sided fistulas and 35 right-sided fistulas. (Table 1) Twenty-six patients underwent more than one thrombectomy procedure due to recurrent fistula thrombosis. In all the procedures, angioplasty was required to dilate stenoses. In four procedures, a cutting balloon was required for stenoses resistant to conventional balloon angioplasty. Adjuvant pharmacological thrombolysis or endovascular stenting was not used in any of the procedures. Intra-procedural heparin was administrated in 90 procedures (67%).

Immediate outcome (Table 2)

Technical success was achieved in 105 of 135 thrombectomy procedures (78%), and clinical success was achieved in 103 of 135 procedures (76%). Technical failure was attributed to failure of clot removal in 27 procedures; the other three failures were due to vessel rupture during wire insertion or balloon dilatation. Technical and clinical success for patients presenting within three days of the access thrombosis was 81% and 80%, compared to 67% and 63% for presentations after three days, respectively. The average procedure time was 82 ± 37 minutes.

Twenty (15%) complications occurred during the 135 procedures: one arterial embolization, six venous ruptures, and 13 puncture site hematomas. All venous ruptures were due to balloon angioplasty or wire perforation, as opposed to the thrombectomy procedure. Three of the ruptures were successfully rescued by balloon tamponade. In the other ruptures, balloon tamponade failed to seal the rupture with a resulting hematoma. The procedure was abandoned with recurrence of thrombosis. No episodes of symptomatic pulmonary

Table 1. Characteristics of patients and fistulas

	N = 109
Characteristics of patients	
Age (yrs)	61 ± 14
Male sex	57% (62/109)
Diabetes mellitus	28% (31/109)
Hypertension	38% (42/109)
Current smoker	20% (22/109)
Dyslipidemia	7% (8/109)
Characteristics of fistulas	
Shunt age (months)	43 ± 49
Side of fistula	
Left-sided fistula	73% (80/109)
Right-sided fistula	27% (29/109)
Type of fistula	
Radiocephalic fistula	28% (30/109)
Brachiocephalic fistula	67% (73/109)
Other	5% (6/109)

Values are percentages or mean ± SD.

Table 2. Success, patency and complication rates of thrombectomy procedures

	N = 135
Procedure time (min)	82 ± 37
Success rates	
Technical success	78% (105/135)
Clinical success	76% (103/135)
Primary patency rates	
1 month	67%
3 month	57%
6 month	39%
Secondary patency rates	
1 month	74%
3 month	72%
6 month	70%
Complication rates	
Major	14% (19/135)
Minor	0.7% (1/135)

Values are percentages or mean ± SD.

embolism were observed following thrombectomy.

Patency outcomes

Primary patency rates at 30, 90, and 180 days were 67%, 57%, and 39%, and secondary patency rates at 30, 90, and 180 days were 74%, 72%, and 70%, respectively. (Table 2 and Figure 1) Univariate analysis demonstrated that diabetes mellitus, an upper-arm fistula, and small vessel size were determinants of poor primary patency. In the multivariate analysis, diabetes mellitus, current smoker, a right-sided fistula and small vessel size were independent predictors of poor primary patency. The type of AngioJet catheter was not associated with primary or secondary patency rates. (Table 3)

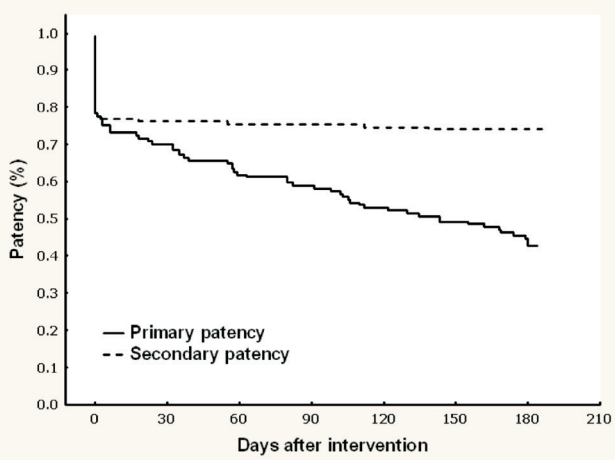

Figure 1. *Kaplan-Meier curves of primary and secondary patency rates.*

DISCUSSION

Main findings

Our study demonstrates that mechanical thrombectomy using AngioJet accompanied by treatment of the underlying stenosis is a safe and effective method for use in native dialysis fistulas. This technique achieved high secondary patency rates and acceptable primary patency rates compared to surgical revision or pharmacological thrombectomy.[23-25]

Comparison to previous studies using AngioJet

Littler et al. reported a better immediate primary patency rate (89%) in their study of 44 AngioJet procedures in native fistulas. However, the reported primary patency rates at 1, 3 and 6 months were 71%, 60%, and 42%, respectively, which are similar to our results. In Littler et al.'s study, a new version of the AngioJet catheter, DVX, was used, which is more powerful than previous versions of AngioJet catheters. In our study, 103 of the 135 procedures (76%) were conducted using the older AngioJet F105 catheter and 32 of the 135 procedures (24%) were conducted with the newer AngioJet AVX catheter. This could explain why our immediate success rate was similar to that of Vesely et al. for grafts

Table 3. Univariate and multivariate Cox regression analysis for predictors of six-month primary patency

	Univariate analysis		Multivariate analysis	
	HR (95% CI)	p	HR (95% CI)	p
Age (year)	1.00 (0.99-1.02)	0.86		
Male gender	0.95 (0.60-1.49)	0.84		
Hypertension	1.20 (0.76-1.88)	0.44		
Diabetes mellitus	1.65 (1.03-2.63)	0.03	2.06 (1.26-3.49)	< 0.01
Dyslipidemia	1.30 (0.63-2.68)	0.51		
Current Smoker	1.67 (0.99-2.83)	0.06	2.14 (1.24-3.70)	< 0.01
Shunt age (month)	1.00 (0.99-1.01)	0.33		
Right-sided fistula	1.51 (0.83-2.71)	0.17	2.23 (1.14-4.33)	0.02
Upper-arm fistula	1.95 (1.04-3.66)	0.04	1.75 (0.92-3.34)	0.09
Vessel size (mm)	0.63 (0.46-0.86)	< 0.01	0.70 (0.50-0.97)	0.02
Use of heparin	1.16 (0.77-1.72)	0.54		
AngioJet F-105 catheter	1.21 (0.71-2.05)	0.48		
Presence of complication	1.63 (0.98-2.72)	0.06	1.72 (0.99-2.97)	0.06

CI, confidence interval; HR, hazard ratio.

(73%) but inferior to that of Little et al. In addition, Littler et al. used a graft stent in nearly half of their patients, which could have resulted in better immediate patency results than our study.

Comparisons to studies using other thrombectomy devices

Shatsky et al. reported a 79% technique success rate in their study of 44 thrombectomy procedures in native fistulas using PTD.[11] Rajan et al. reported a 73% clinical success rate in their study of 30 thrombectomy procedures in native fistulas using balloon thrombectomy, an aspiration catheter, a Hydrolyser device, or pharmacological thrombolysis.[10] The success rates of the above studies were similar to that of our current study using the AngioJet system (76%). Despite taking an average of 10 minutes to set up the AngioJet system, our total procedural time was still less than that of previous studies.[10,12] The total procedural time included the time required for obtaining vascular access, wire insertion, thrombus removal and stenosis dilatation. Although specific clot-removal time was not available in our study, total procedural time is a more appropriate parameter for comparison between different studies. The complication rate in our study was 15%, and the majority were minor complications. Our complication rate is similar to that of Shatsky et al. (13%), but higher than that of Rajan et al. (7%).[11,13] The selection bias of only including fistulas with large or wall-adherent thrombus is the most likely reason for our higher complication rate. Our six-month primary patency rate (42%) was similar to those of Rajan (36%) and Shatsky (38%).[11,13]

Although the patency rates were poor compared to previous studies using different thrombectomy modalities (Turmel-Rodriques 70%, Liang 81%, Rajan 28%), a direct comparison between these series is not valid.[10,26,27] The lack of a uniform study method, reporting standards, and disparity between thrombus burdens limits the validity of such a comparison. In particular, percutaneous thrombectomy devices were used only for fistulas with large or wall-adherent thrombus in our study and that of Shatsky et al. In consequence, the patency results may be negatively biased by the inclusion of only severely diseased fistulas with large clot burden, as shown in our previous study.[14] In addition, patency after salvage of thrombosed fistulas is likely to depend on other variables, including the characteristics of the underlying stenosis, effect of stenosis dilatation, and underlying pathology of the thrombosed fistula. Clot removal is only one of the contributors.

Surgical thrombectomy is performed by using a Fogarty thrombectomy catheter, supported by correction of the stenosis. However, there are only scattered reports of surgical thrombectomy available, with a wide variation in initial success rates.[24,28,29] In addition, for more proximally or centrally located stenoses, preference should be given to endovascular techniques rather than surgical revision. The effect of surgical thrombectomy depends greatly on the expertise of vascular surgeons. Furthermore, the availability and accessibility of vascular surgeons varies widely between different institutions. According to the NKF/DOQI guidelines, the preference for surgical or percutaneous procedures should be based on expediency and physician expertise at respective centers.[1]

Advantages and drawbacks

Compared to surgical thrombectomy, percutaneous procedures are usually conducted under local anesthesia and can be performed as outpatient procedures. In addition, the underlying stenosis can be treated concomitantly during the endovascular procedure. Compared to pharmacological thrombolysis, mechanical thrombectomy is faster, as reflected by the mean procedure time (82 ± 37 minutes) in our current study. In addition, a higher rate of systemic or local bleeding complications can be expected from the use of thrombolytic agents, and this complication was uncommon in our study. Compared to mechanical thrombectomy devices that operate through a wall-contact mechanism, the AngioJet catheter works through a recirculation mechanism without wall-contact. The difference in mechanism of action theoretically protects the vascular intima from the mechanical injury of wall-contact devices.[9,30]

The main action of the AngioJet catheter is exerted through the side hole of the catheter, often resulting in removal of only those clots facing the side hole. As a result, thrombus removal by AngioJet may be incomplete, with some residual thrombus adherent to the vessel wall. Safety issues are another concern in mechanical thrombectomy. In our study, no episodes of symptomatic pulmonary embolism were observed. The risk of pulmonary

embolism is minimal because the clot is homogenized into slurry and aspirated out of the vascular access by the AngioJet catheter.[31] The risk is further minimized by performing balloon dilatation of underlying stenoses only after clot removal. We cannot exclude the presence of small pulmonary emboli in our study as scintigraphy was not performed routinely on asymptomatic patients. Blood loss secondary to the suction and hemolytic effect of the AngioJet method is another concern, especially in hemodialysis patients who usually have chronic anemia. In our study, change in blood volume was not assessed. However, in a previous study of thrombosed hemodialysis grafts, the effect of AngioJet and surgical thrombectomy on hematocrit was similar.[5] Transient cardiovascular symptoms, such as chest tightness, bradycardia or dyspnea, have been observed when patients undergo AngioJet thrombectomy. These symptoms have been proposed to be a by-product of the hemolytic effect. In our experience, these symptoms are usually self-limiting and last only for a few seconds. They may also be masked by the sedatives used during the procedure.[13] The majority of complications experienced were venous rupture or hematoma, unrelated to the AngioJet device, and resulting from wire insertion or balloon dilatation. Only one arterial embolus developed during the thrombectomy procedure, and this was successfully managed by balloon embolectomy. The local cost in New Taiwan dollars (NTD), was 40,000 NTD for the disposable AngioJet thrombectomy catheter with pump set. (the external drive device was not included). In contrast, surgical thrombectomy with revision costs 20,000 NTD only. In light of the current financial crisis in our health insurance system, the high cost of the AngioJet method seems to be a significant barrier to its application in Taiwan.

Clinical implications

Despite growing evidence that endovascular procedures can salvage thrombosed native fistulas, temporary catheters are still frequently placed pending surgical revision, rather than early referral for endovascular thrombectomy. Our findings demonstrate that percutaneous thrombectomy achieves comparable immediate success and complication rates to surgical revision or pharmacological thrombectomy. More importantly, the native fistulas maintained good functionality as reflected by the high six-month secondary patency rate. Accordingly, early referral for percutaneous thrombectomy should be encouraged to minimize the use of temporary catheters, even for native fistulas.

Study limitations

The primary limitation of our study is its retrospective nature. Secondly, we did not use stents because they were not included under the health insurance system. Thirdly, the newer AngioJet catheter was used only in a minor proportion of procedures.

CONCLUSION

In summary, percutaneous thrombectomy of native fistulas using AngioJet is an effective procedure with acceptable complication and primary patency rates and a high secondary patency rate. To achieve optimal results, early referral of patients for percutaneous thrombectomy should be encouraged.

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