Angiographic Changes following the Use of a Purse-String Suture Hemostasis Device in Hemodialysis Access Interventions

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PURPOSE: To evaluate late angiographic changes at the puncture site with use of a suture lock device for hemostasis after hemodialysis access interventions.

MATERIALS AND METHODS: Thirty-five patients who underwent percutaneous intervention of a failing or thrombosed access had 76 puncture sites (58 grafts, 15 fistulas, three composite) managed with a purse-string suture lock device. All patients had follow-up fistulograms available for analysis. Fistulograms at the site of sheath insertion were retrospectively compared with those obtained during subsequent hemodialysis access procedures to assess for changes in access lumen diameter. Access type, sheath size, and heparin dose were examined as predictors of access diameter change at the puncture site.

RESULTS: The mean time to follow-up fistulography was 4.7 months; the cumulative observation time of the patient cohort was 30.5 dialysis years. The mean change in access diameter at the previous puncture site was −0.3%. No puncture sites became aneurysmal or stenotic during follow-up. Two of the 76 puncture sites (both grafts) developed mild (±28%) and moderate (±43%) bulging at the sheath site. The remaining 74 puncture sites (97%) showed no significant change in access diameter. The mean change in access diameter among fistulas was −6.2%, and that among grafts was +1.5% (P = .06). Neither sheath size (P = .26) nor heparin dose (P = .48) had an effect on access diameter.

CONCLUSIONS: No patients developed aneurysms or stenosis at the puncture site after use of a suture lock device for hemostasis. This technique is consistent, safe, and effective in obtaining hemostasis after dialysis access interventions of fistulas and grafts.

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Abbreviations: ANOVA = analysis of variance, DSA = digital subtraction angiography

MORE than 340,000 patients in the United States currently undergo hemo-

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dialysis for end-stage renal failure (1). Most patients have an autologous arteriovenous fistula or synthetic arteriovenous graft, and percutaneous angioplasty and thrombectomy are routinely used to extend the functional life span of failing or thrombosed access sites.

Purse-string suture methods for hemostasis of hemodialysis access sites after percutaneous intervention are effective in providing immediate puncture site hemostasis (2–4). Limitations to the conventional version of this technique include the inability to control the degree of tension on the purse-string suture and a simple means of suture removal. A temporary suture lock device has been used in this setting to enable ease of suture removal and to adjust suture tension, so that patients with residual heparin activity and/or larger sheath sizes will require greater tension on the suture (5). However, the long-term effects of this technique on the puncture site have not been characterized.

We used a suture lock device after access interventions to adjust purse-string suture tension and assessed late angiographic changes at the closure site in a cohort of hemodialysis patients undergoing percutaneous intervention.

MATERIALS AND METHODS

This retrospective study was approved by our institutional review board. By using an electronic quality
assurance database, we identified a cohort of hemodialysis patients. Patients were included in the study if (a) they underwent percutaneous intervention of a failing or thrombosed hemodialysis access, (b) a suture lock device was used to obtain hemostasis, (c) the patient returned to our institution for subsequent percutaneous intervention of the same hemodialysis access, and (d) digital subtraction images of the vascular access site were obtained during the initial and subsequent procedures. Patients were excluded if they had undergone (a) a subsequent vascular intervention within 1.5 cm of the prior access entry site, (b) subsequent percutaneous intervention at another medical facility, and (c) surgical revision of the hemodialysis access during the follow-up period.

Patient Population

During a 38-month period, 35 patients had 76 puncture sites managed with a purse-string suture and suture lock device after percutaneous hemodialysis interventions and had high-resolution, digitally subtracted follow-up fistulograms available for analysis. Fifty-eight punctures were in grafts, 15 were in fistulas, and three were in composite accesses. Composite access punctures were categorized according to the segment of puncture. The distribution of access types is listed in the Table. Immediate hemostasis was achieved in all patients. Puncture site hemostasis with a purse-string suture closure and follow-up fistulography were considered independent events if located at the puncture site. Patients who underwent percutaneous intervention at any outside medical facility, and (c) surgical revision of the hemodialysis access during the follow-up period.

Suture Lock Device Method

At the completion of the percutaneous intervention, a purse-string suture around the puncture site was created with the vascular sheath(s) in place by using 2.0 monofilament (nylon or polypropylene) suture. Care was taken to confine needle passage through the epidermis and into the superficial dermis and not to extend deep into the hemodialysis access. The free ends of the suture were trimmed to an even length and fed through the suture lock device. Then, the sheath was removed with simultaneous adjustment of suture tension to achieve immediate hemostasis, as previously described (5). Activated clotting time was not routinely obtained before sheath removal. The suture was locked to the appropriate tension with the device, and the patient was transferred to the interventional holding area. The purse-string suture was typically removed by the physician or nursing personnel 15–20 minutes later by loosening the suture lock to expose the suture adjacent to the skin. Occasionally, if hemostasis was not present at this point, the device was repositioned to the appropriate tension and the patient reassessed 15–20 minutes later. When hemostasis was achieved, a single suture limb was cut flush with the skin, and the remaining suture was removed with gentle traction. A standard adhesive bandage was applied. If needed, brief manual compression was performed if there was oozing from the suture needle punctures.

Follow-up

Initial digital subtraction angiography (DSA) images were compared with matching DSA images obtained during subsequent hemodialysis access procedures. Fistulograms were directly compared by using angiographic, soft tissue, and osseous landmarks to enable direct comparison of the initial site of purse-string closure with the follow-up fistulogram. For patients who returned for additional interventions beyond the second intervention, the most recent fistulogram was used to assess for late angiographic changes. Additional puncture sites from percutaneous intervention during this interval, if managed with purse-string closure, were considered as independent events if located at least 1.5 cm from the initial puncture site. Patients who underwent percutaneous intervention at any outside institution in the interval between purse-string suture closure and follow-up fistulography were excluded from the study group.

Analysis

All digital subtraction images were analyzed by two observers (T.W.I.C., S.H.M.) from angiography films by using a precision ruler to the nearest 0.5 mm, or from DSA images on the picture archiving and communication system with electronic calipers. To account for differences in magnification between DSA studies, diameter changes in the lumen of the hemodialysis access were calculated as a percentage of initial lumen diameter at the puncture site. The type of percutaneous intervention (thrombectomy vs angioplasty), access type (graft vs fistula), sheath size (in French), and heparin use were also recorded for each patient.
RESULTS

The mean change in access diameter at the previous puncture site was 

\(-0.3\%\) (Fig 1). No puncture sites became aneurysmal (defined as \(>50\%\) increase in luminal diameter compared to the reference diameter of the vessel) during the follow-up period.

Two puncture sites (both within grafts) developed mild (+28%) and moderate (+43%) bulging at the site of the prior puncture site closure (Fig 2). Sheath sizes used during these interventions were 7 and 8 F, respectively.

Neither of these changes interfered with access function or cannulation.

When fistulas and grafts were considered separately, the mean change in access diameter among 18 fistula puncture sites (three hybrid access sites were punctured within the native fistula segment) was 

\(-6.2\%\) compared to +1.5% among 58 puncture sites within grafts (\(P = .06\), unpaired t test).

To determine whether larger sheath sizes were associated with greater changes in lumen diameter after device use, we stratified puncture sites according to sheath size. The mean change in access diameter at the previous puncture site was 

\(-1.7\%\) among 54 puncture sites that were 6 F, +2.5% among 15 puncture sites that were 7 F, +9.4% among five punctures that were 8 F, and +10.5% among two punctures greater than 8 F (\(P = 0.26\), ANOVA). This included one puncture site where a 12-F sheath had been placed during retrieval of a transversely ruptured high-pressure angioplasty balloon.

We next examined whether changes in lumen diameter after suture lock device use was associated with heparin dose during intervention. When stratified according to total heparin dose during the procedure, the mean change in access diameter was 

\(-0.1\%\) among 21 puncture sites in interventions with no heparin, +1.5% among 37 puncture sites in interventions with 2,000–3,000 units of heparin, 

\(-5.3\%\) among 15 punctures with 4,000–6,000 units of heparin, and +0.7% among three puncture sites with 7,000 units of heparin (\(P = .48\), ANOVA).

DISCUSSION

Unlike most percutaneous endovascular therapies, hemodialysis access interventions involve direct puncture of the site of therapy. Manual compression of the access can produce a decrease in access flow, which, in certain situations, can result in re-thrombosis. It was this observation that led to our adoption of a technique to provide puncture site hemostasis without occlusive pressure, adaptable to a wide range of patient anatomy, sheath sizes, and residual heparin activity. We have found this technique to be consistent, well accepted by patients, simple to learn, and highly effective in achieving immediate hemostasis in both fistulas and grafts. This technique improves efficiency within the interventional suite and does not require patients to return at a later date for suture removal. Instead, the purse-string suture is adjusted to an appropriate tension to achieve hemostasis and then removed before the patient leaves the observation or holding area. This ability to control suture tension prevents excessive force, which can lead to skin necrosis (6), and also eliminates the risk of a retained suture serving as a nidus for subsequent infection. A single-use, commercial form of this device is also available (Fig 3).

Despite the efficacy of this technique, as with any hemostasis device or method, long-term effects on the puncture site are an important consideration. Aneurysms and pseudoaneurysms are common within hemodialysis fistulas and grafts, respectively, and can be associated with a range of morbidity—including poor cosmesis,

Figure 1. (a) Fistulogram shows insertion of a 7-F sheath in a right upper arm loop graft (arrow) during a thrombectomy procedure. (b) Fistulogram obtained 7 months later shows no evidence of an aneurysm at the site of the prior sheath and modified purse-string closure (arrow). (c) Fistulogram of a left upper arm loop graft shows the 6-F sheath insertion site (arrow) during an angioplasty procedure. (d) Fistulogram obtained 6 months later shows no evidence of aneurysm at the site of the prior sheath and modified purse-string closure (arrow).
difficulty in cannulation, skin erosion, and rupture (7). Surgical revision, endograft repair, or access ligation and abandonment may be necessary (8,9). During percutaneous thrombectomy, these aneurysmal segments can harbor residual thrombus, which can be challenging to remove and lead to repeat thrombosis (10,11). We were therefore interested in determining whether this purse-string suture technique and the suture lock device were associated with late changes to the puncture site (8).

We did not observe the development of any aneurysms at the puncture site during a mean period of observation of 4.7 months, with a total observation time of the cohort of 30.5 dialysis years. Two patients (two of 76 punctures, 2.6%) developed mild and moderate bulging at the punctures site where the suture lock had been used. These patients had 8- and 12-F sheaths, respectively. Because most dialysis thrombectomy and angioplasty procedures can be performed through 6-F sheaths, we were concerned that this technique might not be applicable to patients with larger puncture sites. However, when we stratified puncture sites according to sheath size, we did not observe a significant difference between sheath size and changes in access diameter. A trend toward modest (9%–10%) changes in access diameter and a sheath size of 8 F and larger was observed, although this did not reach statistical significance.

We also found no association between heparin dose and changes in access diameter at the puncture site. One of the inherent advantages of this technique for hemostasis is that it obviates the need for obtaining an activated clotting time before sheath removal. It is possible that if we routinely obtained an activated clotting time before device placement it would be possible to predict which patients would require having the device in place for a longer period of time (typically 20–30 minutes). In practical terms, we always loosen the device and test the integrity of the puncture site with gentle manual agitation before device and suture removal. If patients continue to have oozing from the puncture site, the device is retightened and the patient observed until hemostasis is complete.

This study has several limitations. This was a retrospective study, and the patient cohort was relatively small. Because this was a study assessing angiographic outcomes, we only included patients for whom follow-up fistulograms were available for re-

**Figure 2.** Angiographic changes in two patients who developed bulging at the sheath site. (a) Fistulogram of a left upper arm straight graft shows 8-F sheath insertion site (arrow) during angioplasty. (b) Fistulogram obtained 9 months later shows that the graft diameter has increased 43% at the site of the prior sheath and modified purse-string closure (arrow). (c) Fistulogram of a left upper arm straight graft shows the 7-F sheath insertion site during angioplasty (arrow). (d) Fistulogram obtained 8 months later shows that the graft diameter has increased 28% at the site of the prior sheath and modified purse-string closure (arrow).

**Figure 3.** Suture lock device. The free ends of a purse-string suture are fed through a snaring suture (arrow), which is then pulled through the device to lock the suture tension to the degree required for puncture site hemostasis (SlipNot; Merit Medical Systems, South Jordan, Utah). (Available in color online at www.jvir.org.)
view. It is possible that patients who would have developed substantial aneurysmal changes would not return for fistulography because they would have required surgical revision, thereby biasing the study by failing to detect these effects. All of the patients were identified within our electronic database of hemodialysis patients which, among other data, records whether a patient undergoes surgical revision. None of the patients were identified as having undergone surgical revision and/or access abandonment during the period of the study. We typically obtained fistulograms in a posteroanterior direction; it is possible that additional oblique views would have detected additional changes at the puncture site. The period of observation of the patient cohort was variable (mean, 4.7 months; maximum, 33 months); it is possible that we may have failed to detect changes that may have occurred over a longer period of observation. Conversely, it is also possible that the two patients in whom we did identify changes at the site of the previous puncture site closure might have developed these secondary to dialysis needle placement. Although we are not aware of any patients having delayed bleeding from the puncture site, because of the retrospective nature of the study this could also have occurred.

In conclusion, we found that no patients developed aneurysms or pseudoaneurysms at the puncture site after the use of a purse-string suture and suture lock device for hemostasis following dialysis interventions. Most of the puncture sites (74 of 76, 97%) had no significant changes in access diameter. This technique is consistent, safe, and effective in obtaining hemostasis after dialysis access interventions.

References