Long-term outcomes of primary angioplasty and primary stenting of central venous stenosis in hemodialysis patients

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Introduction: Central (superior vena cava, brachiocephalic, or subclavian) venous stenoses are a major impediment to long-term arteriovenous access in the upper extremities. The optimal management of these stenoses is still undecided. The purpose of this study was to determine the outcomes of primary angioplasty (PTA) vs primary stenting (PTS) in a dialysis access population at a tertiary referral academic medical center.

Methods: A database of consecutive hemodialysis patients undergoing endovascular treatment for central venous stenosis was developed for the period 1995 through 2003. This database was retrospectively reviewed. Vessels exposed to either primary high-pressure balloon angioplasty or primary stenting were examined. Vessels undergoing stenting after failed or suboptimal angioplasty were defined as failures at the time of stenting despite the potential continued patency upon completion of stenting. Kaplan-Meier survival analyses were performed to assess time-dependent outcomes. Cox proportional hazards analysis was performed for time-dependent variables. Data are presented as mean ± standard deviation where appropriate.

Results: PTS was used to treat 26 patients (35% male; average age, 57 ± 15 years) with 26 central venous stenoses, and 47 patients (45% male; average age, 57 ± 18 years) with 49 central venous stenoses were treated with PTA. The PTS group underwent 71 percutaneous interventions per stenosis (average, 2.7 ± 2.4 interventions), and the PTA group underwent 98 interventions per stenosis (average, 2.0 ± 1.6 interventions). The PTS group hemodialysis access site was an average of 1.0 ± 1.3 years old at the time of the initial intervention, and the hemodialysis access in the PTA group was an average of 1.1 ± 1.2 years old. Primary patency was equivalent between groups by Kaplan-Meier analysis, with 30-day rates of 76% for both groups and 12-month rates of 29% for PTA and 21% for PTS (P = .48). Assisted primary patency was also equivalent (P = .08), with a 30-day patency rate of 81% and 12-month rate of 73% for the PTA group, vs PTS assisted patency rates of 84% at 30 days, and 46% at 12 months. Ipsilateral hemodialysis access survival was equivalent between groups.

Conclusions: Endovascular therapy with PTA or PTS for central venous stenosis is safe, with low rates of technical failure. Multiple additional interventions are the rule with both treatments. Although neither offers truly durable outcomes, PTS does not improve on the patency rates more than PTA and does not add to the longevity of ipsilateral hemodialysis access sites. (J Vasc Surg 2007;45:776-83.)

The number of patients presenting for hemodialysis access and the required duration of access is growing. Management of the complications of hemodialysis access is now integral to vascular practice, and there is significant onus to maintain patency of existing grafts. Central venous stenosis potentially compromises this patency by diminishing flow or by leading to venous hypertension and incapacitating extremity edema, necessitating access ligation for symptom relief. It is consequently becoming a major impediment to dialysis access management.

Meanwhile, the management of central venous stenosis is evolving. Although open surgical treatment has diminished durability in the past, it was associated with significant morbidity. As a result, interest in percutaneous management has increased. Percutaneous treatment for central venous stenosis is feasible, efficient, and perceived as patient-friendly. The endovascular management options include high-pressure balloon angioplasty, intravascular stenting, and, more recently, cutting balloon angioplasty. The optimal management strategy is unknown, however. We retrospectively examined the outcomes of primary angioplasty vs primary stenting of central venous stenoses in patients with compromised upper extremity hemodialysis access at our institution. Patients undergoing secondary stenting for failed or suboptimal angioplasty were excluded.

METHODS

Study setting. This study was performed at a university medical center in a metropolitan area of 1 million persons and an overall catchment area of approximately 5 million in Western New York State. A database was maintained of all patients undergoing endovascular treatment of central venous stenoses in the course of managing dialysis...
access between 1995 and 2003. All central venous stenoses treated with primary angioplasty or primary stenting during this time period were followed up through 2005.

Study design. A review was undertaken of hospital and office charts of patients captured in this time period. For each patient, we identified date(s) of access creation, dates of percutaneous intervention, indications for central venous stenosis interventions, graft failure, dialysis catheter placement, as well as demographics, symptoms, existing comorbid conditions, and risk factors for atherosclerosis.

Technique. A single puncture technique was used at the hemodialysis access site to enter the venous system in patent grafts, and a double puncture technique was employed in thrombosed grafts. Contrast central venous venography is part of the diagnostic imaging performed during any intervention on a dialysis access site in the extremity. The angioplasty balloons used in this study were Bard (Murray Hill, NJ) and Boston Scientific (Natick, Mass), with burst pressures of 8 to 15 atm and operational pressures of 10 to 20 atm. Intravascular stents used in all cases except one were the Wallstent (Boston Scientific), with diameters of 8 to 12 mm and lengths of 42 to 94 mm. These are bare, self-expanding stainless steel stents. One patient received a 10-mm × 40-mm Smart (Cordis, Johnson & Johnson, Miami, Fla) stent at the time of primary stent deployment. This is a bare, self-expanding nitinol stent.

Failure was considered as either an anatomic defect requiring therapy, restenosis or occlusion noted on subsequent venography, computed tomography angiography, or magnetic resonance angiography, or recurrence of ipsilateral upper extremity swelling if present before therapy. In addition, placement of a stent at a given patient’s index lesion within the angioplasty group was also considered failure of angioplasty, and follow-up was discontinued for that patient at that time point. Likewise, patients undergoing secondary stenting for a failed or suboptimal angioplasty result at the initial angioplasty were defined as failures of primary angioplasty at time zero.

Events considered end points to functional access status were placement of new access site, resection of access site, ligation of access site, and dialysis catheter placement. Data were collected on the success rate, complication rate, long-term patency, and presence and location of stenosis. Venograms were reviewed in all cases to assess lesion characteristics and preprocedure and postprocedure results. Results were standardized to current Society of Interventional Radiology and Society for Vascular Surgery (SVS) criteria.2-3 We do not use subclavian vein catheters in any dialysis access patient as a unit policy.

Definitions. A major complication was defined as any event, regardless of how minimal, not routinely observed at the conclusion of intervention to improve patency. Loss of patency was defined according to accepted reporting standards.

Technical failure was defined as <50% gain in luminal diameter. Early failure was defined as an inability to cross the lesion at the time of the primary procedure or by the presence of an occlusion or ≥50% restenosis within the first 30 days after the initial procedure.

Residual stenosis was defined as ≥30% remaining stenosis at the conclusion of intervention in comparison to adjacent, nondiseased vein.

Statistical analysis. Measured values are reported as percentages or means ± standard deviation. Hemodialysis access patency rates are calculated using Kaplan-Meier analysis and reported using current SVS criteria.3 Standard errors are reported in Kaplan-Meier analyses. Cox proportional hazard analyses were performed to identify factors associated with outcomes. Analyses were performed using JMP 5.0.1 software (SAS Institute, Cary, NC).

RESULTS

Patient population. We identified 73 patients with 75 central venous stenoses undergoing primary percutaneous therapy during study period. Primary stenting (PTS) was done in 26 patients (35% male) in 26 central venous stenoses, and 47 patients (45% male) underwent primary angioplasty (PTA) of 49 central venous stenoses. These two groups did not differ with respect to comorbidities or other demographics identified and evaluated (Table I). Angioplasty was attempted and failed in nine PTA patients, eight of whom went on to secondary stenting at the failed intervention. We defined these eight patients as treatment failures at the time of secondary stenting, although they did achieve a period of patency after secondary stent placement.

Hemodialysis access. At the conclusion of follow-up, cumulative access survival did not differ between PTA and PTS groups (P = .13; Fig 1). Age and type of hemodialysis intervention to improve patency. Loss of patency was defined according to accepted reporting standards.

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### Table I. Patient demographics and risk factors

<table>
<thead>
<tr>
<th>Demographics</th>
<th>PTA</th>
<th>PTS</th>
<th>P</th>
</tr>
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<tbody>
<tr>
<td>Patients</td>
<td>47</td>
<td>26</td>
<td>—</td>
</tr>
<tr>
<td>Veins treated*</td>
<td>49</td>
<td>26</td>
<td>—</td>
</tr>
<tr>
<td>Male</td>
<td>45%</td>
<td>35%</td>
<td>.49</td>
</tr>
<tr>
<td>Interventions</td>
<td>98</td>
<td>71</td>
<td>—</td>
</tr>
<tr>
<td>Interventions per treated vein</td>
<td>2.0 ± 1.6</td>
<td>2.7 ± 2.4</td>
<td>.20</td>
</tr>
<tr>
<td>Patient age (years)</td>
<td>57 ± 18</td>
<td>57 ± 15</td>
<td>.98</td>
</tr>
<tr>
<td>Follow-up (years)</td>
<td>3.3 ± 0.4</td>
<td>2.7 ± 0.5</td>
<td>.64</td>
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<tr>
<td>Comorbidities</td>
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</tr>
<tr>
<td>Hypertension</td>
<td>76%</td>
<td>62%</td>
<td>.21</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>55%</td>
<td>54%</td>
<td>.92</td>
</tr>
<tr>
<td>CAD</td>
<td>20%</td>
<td>35%</td>
<td>.18</td>
</tr>
<tr>
<td>CHF</td>
<td>18%</td>
<td>19%</td>
<td>.93</td>
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<tr>
<td>History of smoking</td>
<td>20%</td>
<td>31%</td>
<td>.32</td>
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</table>

*Two patients in the PTA group underwent bilateral central vein angioplasty during the course of follow-up.
access and the patency rate are summarized in Table II. Of the 19 failed access sites within the PTS group, three were resected for graft infection, one was abandoned because of several large pseudoaneurysms impairing functional access, and one was ligated during open thrombectomy after a percutaneous access declot that had precipitated radial artery embolization. The remaining 14 failed access sites had been abandoned as a result of their inability to provide consistent functional hemodialysis.

In the PTA group, 26 of the 49 access sites failed during the study period. Two failures were the result of graft resection for infection, one resulted from upper extremity amputation for a necrotizing soft tissue infection in a patient with an autogenous fistula, and two sites were abandoned because of the poor status of the access site related to pseudoaneurysm formation and trauma from the number of times accessed over the life of the site. There were no significant differences between groups with respect to the number of access sites that failed or were censored, or the mode of access failure.

Periprocedural variables. Indications for initial intervention were not significantly different between groups and included, in descending order of incidence, ipsilateral upper extremity swelling with or without associated chest, neck, and facial swelling; increased venous pressures while on hemodialysis; and clinically diagnosed clotted access (Table III). The indication was unspecified in roughly one quarter of the primary interventions within both groups.

Considering the two groups collectively, the vessel most commonly treated was the subclavian vein in 48%, followed by the brachioccephalic vein in 48%, and the superior vena cava in 4%. An intergroup analysis demonstrated no significant differences in vessels treated (Table III). There was no significant difference in laterality of vessels treated, and none of these patients had previously undergone any form of surgical decompression.

There were no periprocedural or 30-day all-cause mortalities in either group. One 90-day, all-cause mortality occurred in the PTS group, 42 days after initial stent implantation and during the same admission. This 72-year-old patient had a history of cerebrovascular accident 12 months before the intervention and 28% cardiac ejection fraction. On completion of a 10-mm × 68-mm Wallstent placement within the left brachiocephalic vein, the patient was seen to have a small proximal filling defect, for which heparin therapy was initiated. Several days later, an episode of hypotension occurred that degenerated into ventricular fibrillation. After stabilization of the dysrhythmia and hypotension, the patient was diagnosed on computed tomography scanning with retroperitoneal bleeding. The patient never recovered neurologic function after the event and died 42 days after primary stent placement. Mortality was not significantly different between groups (P = .13).

The morbidity rates for the PTA and PTS groups were 0% and 4%, respectively (P = .17). The PTS morbidity represents one major adverse event stemming from a distal radial artery embolization that occurred after a hemodialysis access declot immediately after primary stenting. This patient was taken urgently to the operating room for open thrombectomy, after which flow was re-established, and the patient fully recovered without further negative sequelae.

Outcomes. The initial treatment of central venous stenosis was technically successful in 82% of the PTA group and 96% of the PTS group (P = .08). However, residual stenosis was significantly more common with angioplasty (53%) than with stenting (7%; P < .001; Table IV). One
A stent was sufficient to cover the entire lesion in 18 patients in the PTS group, and the remaining eight required two stents for coverage. Proper positioning was achieved in all stent deployments. Neither immediate nor delayed migration of the stent was identified.

In the PTA group, 28 of the initial 49 veins angioplastied required at least one secondary intervention after the loss of primary patency, including six that underwent immediate secondary stenting after failed initial angioplasty. Of the remaining 21 veins angioplastied, 14 remained primarily patent at the end of follow-up, and seven failed primarily between 0 and 18 months after the initial angioplasty.

Among the PTS patients, 13 of the initial 26 veins stented required at least one secondary intervention after loss of primary patency. Of the remaining 13 veins stented, five remained primarily patent at the end of follow-up, but eight failed primarily between 0 and 18 months after the initial angioplasty.

Of the 18 patients in the PTA group who had failed at the conclusion of follow-up, eight underwent stenting of the central venous lesion because of lesion recalcitrance. In addition to the six secondarily stented at the initial intervention, two were secondarily stented later, both occurring at the third percutaneous intervention. As defined in the Methods section, these stenting events were considered failures for the purpose of PTA group follow-up, which was ended at the stenting event. Otherwise, reinterventions in the PTA group did not involve placement of any stent.

Of the six patients who failed initial angioplasty and were therefore treated with secondary stenting, four failed between 42 and 421 days. One of these four was left occluded, and the remaining three underwent reintervention, including repeat stent placement in two and a failed attempt at angioplasty in one. This yielded primary and assisted primary patency rates of 40% ± 22% at both 6 months and 1 year by Kaplan-Meier analysis for these six patients.

Primary and assisted primary patency rates for the PTA and PTS groups are listed in Table IV. Neither primary patency (Fig 2) nor assisted primary patency (Fig 3) was significantly different between groups, although the assisted primary patency for the PTS group tended toward a lower rate when compared with the PTA group (P = .08; Fig 3).

Cox proportional hazards analysis was used to investigate the impact of preoperative and perioperative factors related to outcomes of primary, assisted primary, and dialysis-access patencies. When analyzing across both the PTS and PTA groups, we found that a history of congestive heart failure was positively associated with lower primary patency (risk ratio, 2.72; P = .0037) and lower assisted primary patency (risk ratio, 2.34; P = .0357).

### Table IV. Angioplasty and stenting outcomes

<table>
<thead>
<tr>
<th></th>
<th>PTA (%)</th>
<th>PTS (%)</th>
<th>P</th>
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<tbody>
<tr>
<td>Procedural success</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Technical success</td>
<td>82</td>
<td>96</td>
<td>.08</td>
</tr>
<tr>
<td>Residual stenosis</td>
<td>53</td>
<td>7</td>
<td>&lt;.001</td>
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<tr>
<td>Primary patency rates</td>
<td></td>
<td></td>
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<tr>
<td>1 month</td>
<td>76 ± 6</td>
<td>76 ± 9</td>
<td></td>
</tr>
<tr>
<td>3 months</td>
<td>58 ± 7</td>
<td>46 ± 10</td>
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<tr>
<td>6 months</td>
<td>45 ± 8</td>
<td>38 ± 10</td>
<td>.48</td>
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<tr>
<td>12 months</td>
<td>29 ± 8</td>
<td>21 ± 8</td>
<td></td>
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<tr>
<td>24 months</td>
<td>7 ± 5</td>
<td>7 ± 6</td>
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<tr>
<td>Assisted primary patency rates</td>
<td></td>
<td></td>
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<tr>
<td>1 month</td>
<td>81 ± 6</td>
<td>84 ± 7</td>
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<tr>
<td>3 months</td>
<td>77 ± 6</td>
<td>72 ± 9</td>
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<tr>
<td>6 months</td>
<td>77 ± 6</td>
<td>55 ± 10</td>
<td>.08</td>
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<tr>
<td>12 months</td>
<td>73 ± 7</td>
<td>46 ± 10</td>
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<tr>
<td>24 months</td>
<td>57 ± 9</td>
<td>29 ± 10</td>
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PTA, Primary central vein angioplasty group; PTS, primary central vein stenting group.
presence of residual stenosis after the initial intervention, which happened to be more common in the PTA group, was significantly associated with lower primary patency rates within that group (risk ratio, 2.78; \( P = .0111 \)) but was not associated with assisted primary patency rates. No preoperative or perioperative factor identified was significantly associated with the cumulative patency rate of the hemodialysis access site.

**DISCUSSION**

The clinical problem of hemodialysis access management is large and growing. The patient population in 2003 numbered 298,101, and grew at an average annual rate of 2.6% from 1999 to 2003. Contributing to this growth is the 8% drop in mortality rates for these patients since 1986.\(^4\) Attendant with this growing body of hemodialysis patients is an ever-increasing clinical volume related to hemodialysis access-related complications, including the development of central vein stenosis. Incidences of central vein stenosis of 11% to 40% have been reported for hemodialysis patients.\(^5\)\(^,\)\(^9\)

The cause of central venous stenosis in the dialysis patient has been attributed to two major factors: (1) temporary central venous catheterization for hemodialysis, particularly when the subclavian vein is accessed,\(^10\)\(^,\)\(^13\) and (2) the high-flow state induced by the creation of an arteriovenous shunt with resultant regions of increased turbulence.\(^7\)\(^,\)\(^14\) In an effort to reduce the impact of hemodialysis catheter placement, the Dialysis Outcome and Quality initiatives (DOQI) guidelines, released in 1997 and updated in 2000, advocated avoiding subclavian vein catheterization as temporary access in all patients with chronic renal failure.\(^15\) Since that time, our institution has adopted the guideline as a hospital-wide policy.

The onset of central vein stenosis can substantially complicate maintenance of hemodialysis access by increasing arteriovenous access pressure\(^1\) and generating significant local morbidity by creating extremity, chest, neck, and even facial swelling. Aside from ligation of the fistula and abandonment of the extremity for access, the only management strategy before the rapid advancements in percutaneous therapy was open surgical treatment. Although open methods have proven fairly durable, with 1-year primary patencies of 80% to 86%,\(^16\)\(^,\)\(^17\) they bear significant morbidity owing to lesion location within the chest. Therefore, beginning in the mid 1980s, evaluation of percutaneous methods began for the treatment of central venous stenosis.\(^18\)

In this article, we have retrospectively reported our experience in percutaneously treating central venous stenoses in patients with ipsilateral hemodialysis access sites during a 9-year period. It happens that during this time, interest was increasing both locally and internationally in primary stenting of central venous lesions in an effort to reduce the recurrence rates seen in these lesions when treated with angioplasty alone.

This evolution in management culminated with the publication by Haage et al\(^6\) of their experience in treating 50 dialysis-dependent patients with primary Wallstent placement. Their report in 1999 of primary Wallstent placement in patients with symptomatic arteriovenous shunt dysfunction owing to central venous obstruction represented the best patency reported to that date, with primary stent patency at 1 year of 56% and cumulative stent patency at 1 year of 97%.\(^6\) Unfortunately, no one since has reported results as successful as those of the Haage group.

These factors coincided with an increase, and then decrease, in the proportion of patients treated with primary stenting in our institution during the study period, creating a unique opportunity to compare outcomes of these two methods. Although our study groups were nonrandomized and the treatment method appeared to be operator-dependent, we were unable to identify any significant differences in lesion characteristics or group demographics that might account for any differences in outcome. We therefore postulate that our results represent the real-world experience of both primary stenting and primary angioplasty in the population of hemodialysis-dependent patients with central venous stenosis. Our results can be summarized into four basic points:

1. Both treatment methods were safely performed with high rates of initial success.
2. With respect to primary patencies, primary stenting and primary angioplasty were equivalent, although a significantly higher rate of residual stenosis was tolerated in the PTA group.
3. Assisted primary patency rates were equivalent, although a trend toward higher assisted patency rates for the PTA group was noted (\( P = .08 \)).
4. With respect to overall ipsilateral hemodialysis-access survival, primary stenting and primary angioplasty were equivalent.

Regarding the endovascular treatment of central vein stenosis, our results were consistent with essentially all reports on this subject, demonstrating safety and initial efficacy, and in contrast to the morbidity of open surgical reconstruction, reported as high as 30%.\(^19\)\(^,\)\(^20\)

Previous studies reporting outcomes of endovascular treatment for central vein stenosis fall into three broad categories: those reporting angioplasty with or without stenting after failed angioplasty or because of recurrent stenosis, those reporting only stenting but after failed angioplasty, and those reporting stenting as the initial therapy.

The aforementioned study by Haage et al,\(^6\) along with those of Shoenfeld et al,\(^21\) Quinn et al,\(^22\) Mickley et al,\(^23\) and Oderich et al,\(^24\) represent the studies to date reporting outcomes of primary stenting. The 1-year outcomes reported by these groups include primary patencies of 11% to 70% and assisted or secondary patencies of 71% to 100%.\(^6\)\(^,\)\(^22\)\(^,\)\(^25\)

Although our own 1-year primary patency of 21% falls into the lower range of primary patencies previously reported, our 1-year assisted patency rate of 46% is notably lower than those previously reported. It is unclear why this discrepancy exists. In their study of primary stent placement in 14 patients, Mickley et al\(^23\) reported patencies on the
high end for both primary and secondary patencies. They differed from the others in that they routinely administered heparin anticoagulation to an activated partial thromboplastin time of 60 to 90 seconds for 3 days after stent placement. It seems unlikely, however, that this difference, in this number of patients, would account for a higher patency 12 months out from the primary stent placement. The only universal difference between our study and the others is that whereas ours had an average follow-up of 2.7 years for those patients primarily stented, the reported average follow-up for the other primary stenting studies was 9 to 18 months. This shorter-term follow-up may in part account for the difference between our assisted patency rates and the others when evaluated 12 months beyond primary stenting.

Although not directly comparable with our report or others evaluating primary stenting, several groups have reported their studies on patients undergoing stenting after suboptimal angioplasty or early recurrence after angioplasty. They reported 1-year primary patencies of 14% to 25%, with assisted or secondary patency rates at 1 year of 33% to 67%,26,30 which is consistent with our 1-year primary and assisted primary patency rates for the PTS group. It is also consistent with the 40% primary and assisted primary patencies at 1 year for our six patients undergoing secondary stenting after failed initial angioplasty, although with the small number of patients at risk at 1 year, the standard error is admittedly high (22%).

Patencies reported for secondary stenting are much shorter than those reported for primary stenting, most likely because they represent a subset of lesions that are more recalcitrant to endovascular treatment, thereby skewing the patency rates downward. This serves to underscore the effect that patient, or rather, lesion selection has on the patency rates of these endovascular techniques when reported with the small number of patients represented in most of these studies.

The report of secondary stenting noted by Aytekin et al28 differs from other studies of central venous stenting, including our own, in that 10 of their 14 patients evaluated were stented with the Memotherm nitinol stent (Bard Angiomed), whereas other reports of stenting in the central veins used stainless steel stents almost exclusively. In these 14 patients, 1-year primary patency was 14% and secondary patency was 56%,28 results consistent with other reports of secondary stenting in this setting. Given these results in this single, small series of patients, no conclusions can yet be drawn on the impact of nitinol stenting in this patient population.

Much of the literature reporting percutaneous angioplasty as the primary management of central vein stenosis also includes patients in whom stent deployment was performed in cases of suboptimal angioplasty, usually defined as residual stenosis of 30% to 50%. This makes comparison of the results of such studies with a primary stented group, such as our PTS group, challenging because the impact of the stent when placed at the initial intervention, whether beneficial or not, could be expected to skew the results into the direction of the primarily stented group. For this reason, we elected to end follow-up of our PTA group at the time of subsequent stent placement, if it occurred, and consider that as a treatment failure. We recognize that this creates an inherent bias in favor of the PTS group because of the potential abandonment of vessels salvageable by secondary stenting. Based on that definition, we achieved 1-year primary and assisted primary patency rates of 29% and 73%, respectively in our PTS group.

These patency rates are in the range of those previously reported. Glanz et al30 reported a 30% primary patency rate at 1-year follow-up in 13 subclavian vein lesions among 19 patients with 29 axillary and subclavian vein dilations. Lumsden et al31 similarly reported a 17% 1-year primary patency rate after percutaneous treatment of 25 central venous stenoses. Quinn et al.,23 in their prospective randomized trial of PTA vs PTA with stenting, reported a 1-year primary patency of 12% and a 1-year secondary patency of 100% in patients undergoing primary angioplasty alone. As in the Quinn et al study, we showed no improvement in patency rates with stenting. This furthers the conclusion that primary stenting does not benefit long-term outcomes in these patients. Given the lackluster patencies in our six patients who underwent secondary stenting after failed angioplasty, it seems that the need to stent also carries a poor prognosis.

Our study does not address the reasons why stenting might negatively impact assisted primary patency; however, others have reviewed the reported differences in the biology of in-stent restenosis compared with that after balloon angioplasty.31 These differences include generalized injury to the vessel at the site of the stent, with more focal injury at the site of struts, followed by fibrinogen coating and the adherence of platelets and leukocytes. The vessel subsequently has a more prolonged and robust intimal hyperplastic response, with a prolonged adventitial response marked by giant cell body formation. Whether these differences have a role in divergent outcomes between central venous angioplasty and stenting has yet to be defined.

Finally, although we agree with Haage et al32 and Vorwerk et al25 that a hemodialysis-access site may fail for many other reasons while the treated central vein remains fully patent,32 we recognize that the primary reason for these patients to undergo treatment of these lesions is to manage symptoms of venous hypertension while preserving the arteriovenous access. In that sense, functional hemodialysis access patency is the bottom-line. We therefore chose to evaluate cumulative ipsilateral access utility, where we found a 1-year patency rate of 53% for the PTA group and 45% for the PTS group, a small difference that was not significant.

Based on these results, we conclude that primary stenting does not add to the management of central vein stenosis in the hemodialysis patient. Although our primary stenting assisted patency rates fell below those previously reported, our PTA group demonstrated assisted patency rates fully in the range of previous reports for primary stenting, thus calling into question any assertion about the superiority of
primary stenting. Ultimately, in our study, primary stenting was not superior to angioplasty in any of the outcomes evaluated.

Given the additional cost of stenting, one could reasonably advocate primary stenting only if it were an improvement compared with angioplasty in some meaningful outcome. The evolution of newer stent technologies, including nitinol stents, may improve the outcomes of central venous stenting, perhaps by altering the vessel’s reaction to stent placement; however, no large body of data currently exists for these stents in the central venous circulation. Taylor et al. have reported a comparison of stent designs, including steel vs nitinol, in a porcine artery model and found that nitinol stents doubled neointimal area and thickness as a result of extracellular matrix expansion but that lumen area was not different owing to expansion of the stent and, consequently, the artery. Conversely, Carter et al. reported a reduction of neointimal area and percent-stenosis in porcine coronary arteries when comparing nitinol stents with steel stents. The true impact of newer stent materials and designs in humans remains undefined.

It should be noted that we evaluated primary stenting and primary angioplasty and defined stenting after failed angioplasty as a treatment failure. There are certainly instances when immediate elastic recoil or no appreciable effect after angioplasty necessitates secondary placement of a central venous stent to establish flow and reduce venous hypertension.

In addition, this study period did not include our more recent usage of cutting balloon angioplasty within central veins that, like newer stent technology, may improve upon current endovascular outcomes.

Finally, it should be noted that the major limitation of this study is that it is nonrandomized. The choice of primary stent placement was operator-dependent, because members of our group each began adopting the technology when others in the 1990s were reporting initial success. No faculty member present during our study period was disengaged from following up patients and keeping records. Therefore, it is possible that primary stent placement was chosen for some unquantified variable that might affect stent patency, thus depressing primary stenting patency rates and hemodialysis access survival rates. Caution must therefore be advised in applying these results to the greater patient population.

CONCLUSION

Endovascular treatment with angioplasty or stenting for central venous stenosis is safe, with low rates of technical failure. Multiple additional interventions are the rule with both treatment modalities. Although neither offers truly durable outcomes, stenting does not have higher patency rates than angioplasty and does not add to the longevity of ipsilateral hemodialysis access sites. Given its greater cost and known potential consequences of bridging patent internal jugular veins or extending medially into the superior vena cava from the brachiocephalic vein, in the absence of demonstrable benefit primary, stenting of central venous stenoses should not be considered to add to the management of hemodialysis patients.

AUTHOR CONTRIBUTIONS

Conception and design: MD, DL
Analysis and interpretation: AB, CP, MD, DW, DL
Data collection: AB, CP, MD, WS
Writing the article: AB, CP, MD
Critical revision of the article: AB, CP, MD, DW, WS, DL
Final approval of the article: AB, CP, MD, DW, WS, DL
Statistical analysis: AB, MD
Obtained funding: MD
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