

Stent Grafts for Central Venous Occlusive Disease in Patients with Ipsilateral Hemodialysis Access

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ABSTRACT

Purpose: To assess long-term outcomes of stent grafts in patients with symptomatic central venous stenoses and occlusions ipsilateral to hemodialysis grafts or fistulas.

Materials and Methods: The study included 52 of 55 consecutive patients with symptomatic stenoses of the central veins draining upper limb dialysis access grafts or fistulas treated with stent grafts. Indications for stent grafts were poor angioplasty results, rapid recurrence, or total occlusion. Endpoints were lesion patency and access patency following intervention. Mean follow-up was 25 months with a median of 24 months and 1.25 additional procedures per patient year. Patency rates were calculated using Kaplan-Meier analysis.

Results: All stent grafts were successfully deployed. The lesion patency rates at 6, 12, 24, and 36 months after intervention were 60%, 40%, 28%, and 28%. The access patency rates at 6, 12, 24, and 36 months after intervention were 96%, 94%, 85%, and 72%. There was one major complication and no minor complications. In 40 patients (77%), the internal jugular vein confluence was covered by the stent graft. In five patients, the dialysis circuits became occluded, with no clinical sequelae in four; one patient was lost to follow-up. The contralateral brachiocephalic vein was covered in three patients (6%), preventing contralateral access construction in one patient.

Conclusions: Central vein stent graft placement in patients with hemodialysis access is associated with prolonged access patency. Coverage of major vein confluences, which occurred in 83% of the patients in this series, can compromise future access and should be avoided whenever possible by careful technique.

ABBREVIATION

PTA = percutaneous transluminal angioplasty

Central venous occlusive disease ipsilateral to dialysis access is a common finding with an incidence of 2%-40%(1–4). It may be asymptomatic, but it also can cause upper extremity, facial, or breast swelling and compromised dialysis and may lead to loss of dialysis access (4). In 12%-13% of patients with hemodialysis access, symptomatic central vein occlusive disease that may require some form of intervention occurs (2,5,6).

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There is no ideal treatment for this problem. Although surgery can result in prolonged patency, the associated morbidity and lack of widespread expertise have prevented it from becoming the mainstay of treatment (3). Endovascular percutaneous transluminal angioplasty (PTA) with low morbidity and good short-term patency is the accepted treatment for symptomatic central venous occlusive disease in these patients (7). However, poor primary patency rates are common after PTA secondary to elastic recoil or recurrent intimal hyperplasia requiring repeated dilations, often at short intervals, to maintain reasonable secondary patency rates. Davidson et al (8) used intravascular ultrasound to study the immediate results of PTA in 38 patients including 11 with central venous occlusive disease and found immediate elastic recoil to <75% of the balloon diameter in 50% of cases. Bare metal stents have been used to try to overcome this shortcoming but have not demonstrated a definite advantage in long-term patency over PTA (4,9-11).

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In view of the encouraging results reported for stent grafts for recurrent cephalic arch stenosis (12), we used them for cases of symptomatic central venous occlusive disease according to the Kidney Disease Outcomes Quality Initiative criteria (7) with the addition of selected cases of complete occlusion. This article summarizes our experience with stent grafts in symptomatic central venous occlusive disease.

MATERIALS AND METHODS

This single-center retrospective study was carried out at a university-affiliated hospital with a busy regional hemodialysis access center and was approved by the hospital's ethics committee. From October 2006 to September 2010, 55 patients with symptomatic central vein occlusive disease were treated with stent grafts. Two patients died within 1 week of insertion from unrelated causes, and one patient had occlusion of access at 3 weeks and refused further treatment. These three patients were excluded from the study. No other patients in whom stent grafts were placed during the study period were excluded; however, patients in whom an occlusion could not be crossed were not included in the study.

Table 1. Demographic Data and Insertion	d Indications for Stent Graft
No. Patients	52
Male/female	31/21
Mean age (y)	68.2 (range, 32–87)
Indication for stent graft*	
Elastic recoil	29
Rapid recurrence	20
Occlusion at presentation	10
Not recorded	4

*In 11 patients, there was more than one indication for stent graft placement.

Table 2. Access	Type and	Treatment Sites
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	Right	Left
Access type		
Radiocephalic fistula	8	3
Brachiocephalic fistula	10	12
Brachial transposed basilic fistula	4	0
Forearm graft	5	2
Upper arm graft	2	6
Treatment site		
Subclavian vein	9 (2)*	13 (5)
Brachiocephalic vein	15 (2)	8 (2)
Both veins	5 (2)	2

*Numbers in parentheses indicate patients with prior bare metal stents in the treated area. Two of the bare stents, one right subclavian and one left subclavian, demonstrated fractures.

Table 3. Number of Interventions before Stent Graft Insertion			
No. Interventions	No. Patients		
0	8		
1	7		
2	7		
3	11		
4	4		
5	4		
> 5	11		

Previous PTA and bare metal stent insertion procedures (median = 3 per patient).

PTA = percutaneous transluminal angioplasty.

The subclavian and brachiocephalic veins and the superior vena cava were considered central veins. Demographic data and data concerning details before stent graft insertion are listed in Tables 1-3. Central venous occlusive disease was suspected if the following findings were present: clinical signs of increased venous pressure such as arm or face swelling, abnormal dialysis monitoring and surveillance criteria (high static pressure or decreased efficiency [Kt/V, defined as (the fractional clearance of urea as a function of its distribution volume) - dialyzer clearance of urea (K, in L/min) × treatment time (t, in min) divided by the volume of distribution of urea in the body (V, in mL)], and prolonged bleeding after needle removal. A hemodynamically significant stenosis was defined as a \geq 50% reduction in normal vessel diameter on angiography accompanied by a hemodynamic, functional, or clinical abnormality (7).

If Doppler ultrasound confirmed the finding of a >50% stenosis according to our criteria of a stenotic to prestenotic peak systolic velocity ratio of > 2.5, during or before stenosis, the patient was referred for endovascular treatment. When the diagnosis of central vein stenosis with Doppler ultrasound was not clear-cut, patients were referred for angiography solely on the basis of obvious clinical signs.

Patients were identified from our customized department database of procedures, which is kept separate from hospital files. Stent grafts were placed in the central veins for one of the following indications: symptomatic recurrent central venous occlusive disease occurring within 3 months of a previous successful PTA, symptomatic total occlusion with or without previous PTA, or significant residual stenosis (> 50%) immediately after PTA. The decision to place a stent graft was at the discretion of the operator, so that not all potential patients received a stent graft. In some cases, the decision not to place a stent graft was based on the unavailability of a suitably sized stent graft, and in others it was based on technical and clinical considerations, such as the condition and tortuosity of the access veins and the estimated life expectancy of the patient. Bare metal stents were not used throughout the study period.

Endovascular Interventions

All interventions were performed as outpatient procedures with standard monitoring and intravenous sedation. Periprocedural antibiotic coverage with intravenous cefazolin 1 g was administered at the discretion of the operator.

Antegrade puncture of the access was performed in all cases, and initial angiography was performed from the puncture site to the right atrium. Stenoses were assessed by measuring their narrowest point as a percentage of the nearest normal-diameter segment of the same vein. Balloon diameter was determined by visual approximation or using integrated measuring software (Siemens AG, Forchheim, Germany), which was available from January 2010. After administration of 5,000 units of heparin, PTA was performed using a 4-cm-long, high-pressure balloon dilation catheter (Bard Peripheral Vascular, Inc, Tempe, Arizona) with 1–2 mm oversizing relative to the adjacent normal vein.

Stent grafts used in this study were the HEMOBAHN and VIABAHN (W. L. Gore & Associates, Flagstaff Arizona) and the FLUENCY PLUS (CR Bard Angiomed, Karlsruhe, Germany). In 29 patients, 30 HEMOBAHN stent grafts with diameters of 10 mm (3 stents), 11 mm (9 stents), and 13 mm (18 stents) were placed. In 23 patients, 27 FLUENCY PLUS stent grafts with diameters of 10 mm (5 stents) 12 mm (19 stents), and 13.5 mm (3 stents) were placed. The anatomic locations of the treated central vein lesions are shown in Table 2. For stent graft placement, an appropriately sized introducer sheath (9-F-12-F) was placed, and the initial guide wire was replaced by a 260-cm-long Amplatz stiff wire (Cook, Inc, Bloomington, Indiana). The stent grafts were oversized by 1 mm relative to the adjacent normal vein and deployed using bony landmarks or roadmapping.

Filling of the internal jugular vein by collateral flow or reflux was seen in 15 patients, but patency was not systematically assessed by duplex ultrasound before stent graft placement. For brachiocephalic vein lesions, the confluence with the contralateral brachiocephalic vein was localized by venography and subsequent reference to bony landmarks or roadmapping. For stenoses located in a straight segment of vein or if there was a difference in vein diameter on either side of the stenosis of ≥ 2 mm, we used the FLUENCY PLUS stent. For stenoses involving curved segments of vein, the more flexible HEMOBAHN or VIABAHN stent grafts were used. After stent deployment, balloon dilation was performed to the diameter of the initial PTA. The sheath was removed after placement of a purse-string suture for hemostasis.

Follow-up after Stent Graft Deployment

Clinical follow-up examinations and surveillance with duplex ultrasound scanning were scheduled for 1 month after the intervention and every 3 months thereafter for all patients; however, not all patients complied with this protocol. The assessments were carried out by one of the authors (D.S.) who is a registered vascular technician and a vascular surgeon. Endpoints measured were lesion patency and access patency following intervention. Complications from stent graft deployment and the number of subsequent interventions at or within 5 mm of the implant were also recorded.

Outcomes and Statistical Analysis

Lesion patency following intervention was defined as the interval between stent graft deployment and the time of the first subsequent intervention at or adjacent to the treatment site (13). Lesions ≤ 5 mm from the stent edge were considered adjacent. Target lesions were assumed to be patent if there was continued resolution of arm swelling and improvement of previously abnormal hemodynamic values.

Access patency following intervention was defined as the time from stent graft placement to any surgical intervention or access abandonment owing to surgeon's choice, loss of follow-up, or an untreatable lesion anywhere in the circuit after all percutaneous reinterventions (13). The patient charts, digital database, and digitized imaging records were reviewed. Results were plotted as Kaplan-Meier survival curves using Prism software (Graph Pad Software, San Diego, California).

RESULTS

All of the stent grafts were successfully deployed. The lesion patency rates at 6, 12, 24, and 36 months after intervention were 60%, 40%, 28%, and 28%. The access patency rates at 6, 12, 24, and 36 months after intervention were 96%, 94%, 85%, and 72%. These results are shown as a Kaplan-Meier analysis in Fig 1.

Patients in the study were followed for a mean of 25 months (median, 24 months; range, 1–58 mo). In 31 patients, 136 additional interventions were performed (mean 2.6 procedures per patient; range, 1–14 procedures) at a rate of 1.25 procedures per patient year. The indications for reintervention were recurrent symptomatic stenosis in 119 of the procedures and symptomatic occlusion in the other 17. The additional procedures included 104 PTAs, 30 additional stent graft deployments, and 2 failed attempts to cannulate occluded stent grafts.

There were no procedural complications. One patient developed symptomatic chylothorax after stent graft placement at the left subclavian-brachiocephalic vein confluence. After failure of conservative management with drainage and talc pleurodesis, the patient underwent thoracic duct ligation 3 months after stent graft insertion but died 6 weeks later of postoperative complications.

Circuit occlusion occurred in 10 patients (19%) at a mean of 20 months after the procedure (median, 20 mo; range, 3–45 mo). These cases consisted of two patients with elective access closures for severe recurrent arm





Figure 1. Kaplan-Meier survival curves for lesion and access patency following intervention. Numbers at risk and standard errors are shown in the table below the graph.

swelling; three patients with occlusions involving the entire circuit, which were electively abandoned; two patients who were treated at other institutions by dialysis catheter placement with no attempt at recanalization; one patient with removal of an infected arteriovenous graft 28 months after stent graft insertion; and two patients with failed recanalizations.

In 40 (77%) patients, the region of the confluence of the internal jugular vein was excluded by the stent graft with no consequent facial or neck swelling. In 11 patients, this area had been previously covered by a bare stent. Of the remaining 29 patients, 17 died with patent accesses at a mean of 19 months after insertion (range, 1-52 mo). Five patients had occlusion of their circuits at a mean of 20 months after insertion (range, 5-32 mo), including one patient whose jugular vein was seen to be patent before stent graft placement. Four of these patients had contralateral internal jugular vein catheters inserted, two of whom subsequently had a contralateral fistula constructed. The fifth patient was lost to follow-up. Seven patients, including one whose jugular vein was seen to be patent before stent graft placement, remain alive with patent accesses at a mean of 33 months after insertion (range, 14-46 mo).

In three patients, the confluence with the contralateral brachiocephalic vein was covered by the stent graft with no immediate adverse consequences. One of these patients died with a patent access circuit at 52 months after insertion. The second patient had a left stent graft and a right-sided intravenous pacemaker. At 27 months after stent insertion, this patient had occlusion of the fistula, but the stent graft

remained patent. A left internal jugular dialysis catheter was successfully placed. In the third patient, the stent graft became occluded 29 months after insertion, but the access (brachial artery to transposed basilic vein) remained patent. Attempted recanalization was unsuccessful, and the patient has continued to undergo dialysis using that fistula for 16 months despite recurrence of mild ipsilateral arm swelling.

DISCUSSION

Central venous occlusive disease in patients undergoing dialysis can cause arm swelling or dialysis access dysfunction. In contrast to more peripheral occlusions, central venous occlusive disease usually precludes creation of future dialysis access in the entire ipsilateral limb. These lesions are caused by intimal hyperplasia associated with dialysis catheters, increased blood flow from arteriovenous shunting, and extrinsic compression of the left brachiocephalic vein (3,4,14,15). The first-line treatment for this condition is balloon angioplasty, but the ideal treatment for recurrent symptomatic disease is currently under evaluation.

Recurrence after PTA secondary to recoil or intimal hyperplasia is common (8) with primary patency rates at 12 months ranging from 0-43% (3,15). Bare metal stents are prone to in-stent stenosis caused by intimal hyperplasia via the fenestrations. Use of bare metal stents has not improved patency rates (9–11).

Stent grafts are known to decrease the incidence of stenosis after PTA by interposing an inert layer to



Figure 2. A 67-year-old man with a right forearm graft placed 20 months before stent graft insertion. Recurrent subclavian and brachiocephalic vein stenoses required four angioplasties at 3- to 4-month intervals. (a) Severe subclavian and brachiocephalic stenoses (arrows) before the fourth PTA. The internal jugular vein is not visualized. There was 60% recoil after PTA to 12 mm (not shown). (b) Central venogram obtained 52 months after insertion of a 13×100 mm HEMOBAHN stent graft and PTA to 12 mm was filmed during PTA of a venous anastomotic stenosis (not shown). The previously seen axillary vein stenosis has received a stent (arrowhead). The stent graft is patent after requiring five PTAs for stenoses at its central end. There are mild recurrent central stent and mid-stent stenoses (arrows), which were not dilated at this procedure.

separate the thrombogenic vascular wall from the blood flow and impede the migration of smooth muscle cells (16). Their superiority over PTA in hemodialysis graft venous anastomotic strictures has been demonstrated in a randomized study (17). The Kidney Disease Outcomes Quality Initiative guidelines for stent insertion are elastic recoil and recurrence within 3 months of PTA (7). We also treated 10 patients with occlusion at presentation. Eight of these patients had another indication, and two had primary stent graft placement owing to known noncompliance with our surveillance program.

This study of stent grafts in central venous occlusive disease with long-term follow-up demonstrated access patency rates of 85% at 24 months after intervention and 72% at 36 months after intervention. Previous studies have reported primary assisted patency rates after PTA of 59%–66% at 24 months (9,15,18) and 33% at 36 months (10). Reported secondary patency rates after bare metal stent placement are 22%–100% at 24 months (3). These studies have used inconsistent indications and methods of reporting patency making it impossible to compare our results with them. The results of two randomized trials comparing PTA and the GORE VIABAHN Endoprosthesis with Heparin Bioactive Surface in the cephalic arch and central veins are awaited (NCT01271881, NCT01200914).

There have been few studies, none of them randomized, of the use of stent grafts in central vein lesions related to dialysis access, but these have shown encouraging results. Anaya-Ayala et al (19) reported 25 patients with 12-month secondary and access patency rates of 100% and 94%, respectively. Kundu et al (20) reported 14 hemodialysis patients with central vein occlusion with primary patency of 100% at 9 months, and Jones et al (21) reported a primary assisted patency rate of 75% at 24 months in 30 patients with dialysis access fistulas.

One disadvantage of stent grafts is the possible covering of major venous confluences. This problem has been

discussed previously by Turmel-Rodriguez et al (22), but there are no studies that have related to this point in detail. Excluding the internal jugular vein confluence may be unavoidable because the occurrence of stenoses in this area (Fig 2a, b). This will exclude its use for future central venous catheterization in the event of loss of circuit patency. In some cases, careful stent graft selection and placement may avoid this problem (Fig 3a-f). The true incidence of internal jugular vein loss in our series is unknown because patency of this vein before the procedure was not determined by ultrasound, and nonfilling on angiography does not indicate occlusion. It is reasonable to assume that at least some of these occlusions occurred because of previously placed internal jugular vein catheters. Even assuming prior internal jugular vein patency, the impact of covering the orifice in this group of patients was minimized because of their prolonged circuit patency and limited life expectancy. Five patients with exclusion of the internal jugular vein confluence had occlusion of their access circuit with no known detrimental sequelae. However, the seven patients who have patent accesses still may have occlusion of their circuits with possible adverse sequelae from lack of this access option. We recommend assessing the patency of both internal jugular veins by duplex ultrasound in all patients before excluding this confluence. The benefit of prolonging access patency should be weighed against the loss of this access for dialysis catheters. If the ipsilateral internal jugular vein is patent and the contralateral vein is occluded, stent graft placement across the jugular vein confluence should be reconsidered.

Coverage of the contralateral brachiocephalic confluence can be avoided by careful localization of this landmark and correct choice of stent graft. In this series, coverage of the contralateral brachiocephalic confluence was caused by inappropriate device selection (Fig 4a–d) and lack of adequate stabilization during deployment and resulted in the inability to construct a contralateral access



Figure 3. A 73-year-old man 54 months after construction of a left forearm arteriovenous graft. Recurrent subclavian vein stenosis required three PTAs over a 9-month period. (a) Subclavian vein stenosis before the third PTA (arrow). (b) Result immediately after PTA to 12 mm demonstrates no residual stenosis (arrow). (c) Total occlusion of the subclavian vein (arrow) occurred 2 months later. (d) After recanalization and PTA to 12 mm resulted in 70% recoil (not shown), a 10 \times 60 mm FLUENCY PLUS stent graft was placed across the stenotic segment extending into the brachiocephalic vein and covering the internal jugular vein confluence (arrows). (e) Arm swelling recurred 6 weeks after stent insertion. Venography demonstrated 60% stenosis of the vein at the peripheral end of the stent graft (arrow). PTA to 10 mm was performed with a 20% residual stenosis (not shown). (f) The stent graft occluded with continued arteriovenous graft patency 3 months after the PTA. After recanalization, a 10 \times 50 mm HEMOBAHN stent graft (arrows) was placed to treat the recurrent stenosis at the peripheral end of the stents. During the succeeding 18 months, three PTAs were required for recurrent stenosis at the peripheral portion of the newer stent graft. Venography performed 20 months after initial stent placement during treatment of arteriovenous graft occlusion demonstrated patent central veins (not shown).

in one patient with circuit occlusion. Although these results showed good long-term patency, there were 10 circuit occlusions, and multiple additional procedures were required to maintain patency. Thus stent grafts cannot be considered the optimal treatment for central vein disease.

This study has some limitations. Because of the method of data collection, cases in which an occlusion could not be crossed were not included, and so this study is not based on intention to treat but includes only patients with successful recanalization. The decision to place a stent graft was at the discretion of the operator, and stent graft use was mostly for salvage rather than for primary placement introducing selection bias into the study. In many cases, the evidence for continued stent patency was indirect, being based on lack of recurrence of the original symptoms or abnormal dialysis surveillance criteria. Theoretically, a stent graft could occlude with sufficient collateral flow so as to be clinically and hemodynamically undetectable, seeming to maintain lesion patency following intervention. Similarly, the use of the non-target lesion-specific endpoint of access patency following intervention allowed for the possibility of both stent graft occlusion with continued use of the access circuit (circuit patent with stent graft occluded in two patients) and peripheral access occlusion with continued central stent



Figure 4. A 75-year-old man 3 months after construction of a right brachiobasilic graft. (a) Recurrent severe arm swelling 2 months after removal of an internal jugular vein dialysis catheter and concurrent brachiocephalic vein PTA to 12 mm. Venography shows occlusion at the confluence with the left brachiocephalic vein, which fills by collateral flow (arrow); this was dilated to 12 mm with 45% recoil (not shown). In view of the rapid recurrence and recoil, a 12×40 mm FLUENCY PLUS stent graft was placed below the acutely angled subclavian brachiocephalic junction to avoid occluding this curved segment and dilated to 12 mm. (b) Venography performed 2 weeks after insertion to investigate severe arm swelling demonstrated 65% stenosis peripheral to the stent (arrow) and exclusion of the left brachiocephalic confluence (arrowhead). (c) A second 12×60 mm FLUENCY PLUS stent graft was placed to treat this stenosis (arrows). Seven PTAs to 12 mm subsequently were required for symptomatic mid-stent and distal stent graft stenoses (not shown). (d) The result after final PTA for recurrent arm swelling 43 months after initial stent insertion shows no stenosis.

graft patency (circuit occluded with stent graft patent in two patients), and so access patency does not always accurately reflect the condition of the central veins. In addition, the use of the indirect, operator-dependent assessment of the central veins by Doppler ultrasound may have led to inaccuracies; however, the reliance on symptoms in the absence of abnormal duplex findings would have prevented failure to treat significant lesions. This heterogeneous group includes two types of stent grafts and patients with prior bare metal stents, and we cannot be sure that these different subpopulations behaved in a similar way.

In conclusion, this series confirms the good long-term patency of stent grafts previously reported in smaller studies (19–21), but it also demonstrates that careful technique must be used to accurately deploy the stent grafts and to avoid if possible covering major vein confluences. Maintaining patent confluences may minimize future access loss. The status of both internal jugular veins is an important factor in deciding whether or not to insert a stent.

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INVITED COMMENTARY

New Device, Same Problem, No Definitive Answer

The recent publication by Verstandig et al (1) adds to the growing collection of publications regarding the use of stent grafts within dialysis access circuits. Initial studies have pointed in the direction of superior but varied patency compared with traditional methods of angioplasty and/or stent placement within dysfunctional dialysis accesses. However, a majority of the studies are retrospective (2,3), with only one randomized prospective study published (4). The lack of published randomized trials highlights many of the major problems with current retrospective studies. These include what constitutes proper follow-up, what is the true patency of an intervention without uniform standards of assessment and definitions, comparison versus an accepted treatment, and, most importantly, unbiased assessment of a specific outcome. For example, in two randomized studies, angioplasty patency at 6 months ranged from 23% to 40%, compared with the published National Kidney Foundation Kidney Disease Outcomes Quality Initiative standard of 50% at 6 months, which is based on retrospective data (4-6).

Central venous stenosis or occlusions in patients with upper-extremity hemodialysis accesses is a particularly troubling area. All published studies are retrospective and do not address differences in patency based

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on location of the lesions or types of accesses or compare different devices. For example, a subclavian vein stenosis at the point of crossing the first rib and clavicle is known to be functionally narrowed compared with the right innominate vein. In addition, what are appropriate or optimal sizes of devices to be used for each vein segment? What is an objective measure of efficacy?

Although stent grafts are purported to be better than angioplasty or bare metal stenting, or both, within the central venous stenosis literature, there has been no comparative prospective study to ascertain if there is actually a difference in access circuit patency. In addition, the use of stent grafts is not without concern. As pointed out in the study of Verstandig et al (1), the internal jugular vein confluence was covered in 40 of 52 patients and the contralateral innominate vein in three patients. Does the potentially-but not definitively proven-improved lesion and access circuit patency justify the loss of a venous access site in a hemodialysis recipient? Is ignoring the Kidney Disease Outcomes Quality Initiative indication for stent treatment of recurrent central venous stenosis in less than 3 months and repeat frequent angioplasty a more comprehensive solution than excluding future usable veins? Additionally, there is some concern regarding infection risk with use of these devices. The study of Verstandig et al (1) mentions one arteriovenous access becoming infected, yet, in a single study examining infection risk (7), an incidence of 6.9% was observed with stents and stent grafts placed in outflow veins.

It is also important to note that patency within the study of Verstandig et al (1) was assessed with clinical examination and duplex ultrasound. Neither measure is considered an objective assessment of treated central venous lesion patency, and such findings can be highly variable in patients. The use of such a standard does limit

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