Stenting of proximal venous obstructions to maintain hemodialysis access

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Purpose: **The purpose of the study was to evaluate the efficacy of stenting central venous obstructions in patients dependent on hemodialysis to preserve or restore central venous patency and allow for continued hemodialysis from the affected side.**
Methods: **Twenty-five self-expanding (17) and balloon-expandable (8) stainless steel stents were deployed in 19 patients with end-stage renal disease and central venous stenosis or occlusion. Nineteen lesions were treated: 11 subclavian and eight innominate. Twenty-two stents were initially implanted.**
Results: **Stent deployment was successful in all cases and immediately remedied the underlying cause of venous hypertension. Follow-up at up to 17 months revealed three deaths from unrelated causes, one occlusion at 3.25 months, and three restenoses at 16 days, 2.5 and 5 months, respectively, with successful implantation of three additional stents for a primary central patency rate of 68% (±14%) and secondary central patency rate of 93% (±7%).**
Conclusions: **Stenting of subclavian and innominate venous stenoses and occlusions effectively corrected the underlying lesions responsible for disturbed hemodynamics and, in most cases, prolonged available hemodialysis access from the affected side. Stents seem to be valuable adjuncts in the management of failing hemodialysis access due to central venous stenosis or occlusion. (J VASC SURG 1994;19:532-9.)**

Percutaneous hemodialysis catheter placement for temporary vascular access is used with an apparent low complication rate in most patients. However, stenotic or occlusive lesions in the central veins develop in 11% to 40% of patients.[1,2] These obstructions may remain asymptomatic until a vascular access graft or fistula is placed distal to them, resulting in venous hypertension, arm edema, low access flow, or thrombosis. On workup, 25% of such patients with symptoms were found to have underlying subclavian vein stenosis caused by previous central venous catheter insertion.[1]

Surgical repair of central venous obstructions is a major undertaking and is usually reserved for extreme cases. Percutaneous transluminal venous angioplasty (PTVA) is an attractive alternative for treating lesions of the subclavian and innominate veins[1]; however, the long-term patency rate has been poor.[1,3] Endovascular stenting of central venous obstructions has been reported, with favorable results in benign and malignant lesions.[4-6]

We report our 17-month experience with 25 stents in 19 patients dependent on dialysis diagnosed with stenosis or occlusion of the central veins associated with failing or failed vascular access.

PATIENTS AND METHODS

During the 17-month study period (October 1991 to April 1993), 19 adults (12 men and seven women) aged 27 to 78 years (mean age 57.6 years) with end-stage renal disease and symptomatic upper extremity venous hypertension were referred for evaluation. Of these, one patient was diagnosed with two separate central stenoses treated 3 weeks apart. A second patient with end-stage renal disease but no venous access as yet and severe arm swelling was referred for stenting after placement of a central venous catheter for monitoring during surgical decompression of a large pericardial effusion.

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Ten of 18 ipsilateral venous access grafts were thrombosed. Eight were patent, but elevated dialysis pressures or low flow precluded satisfactory hemodialysis. All grafts were constructed with 6 mm polytetrafluoroethylene (PTFE).

All 19 patients underwent digital subtraction angiography. The eight patent access grafts were directly cannulated with a 20-gauge needle. In the 11 remaining patients, arm veins were accessed with a 20- or 21-gauge needle. Results were reviewed, all viable therapeutic options were discussed, and informed consent was obtained.

The most common method of interventional access was via direct cannulation of the 6 mm PTFE graft. When this was unfeasible, an antecubital or brachial vein was identified on venography and cannulated with the aid of a digital subtraction road map or an ultrasound-guided needle (Peripheral Systems Group, Mountainview, Calif.). Catheterization from the femoral venous approach was required in only four of 22 procedures. Central venous obstructions were crossed with a selective polyethylene catheter and steerable guide wire with a digital subtraction road map, followed by exchange for an appropriately sized arterial introducer sheath (8F to 10F). PTVA was performed with 10 or 12 mm angioplasty balloons. High inflation pressures (up to 17 atm) and variable inflation times were often required for successful dilation. Several lesions had to be predilated with a smaller low-profile high pressure balloon before they would accommodate a larger percutaneous transluminal angioplasty balloon. Stents were placed immediately after dilation.

Flexible, self-expanding, 10 mm stainless steel Wallstents (Schneider USA, Inc., Minneapolis, Minn.) were delivered through an 8F sheath introduced over a guide wire. Rigid balloon-expandable Palmaz stainless steel stents (P308M, Johnson & Johnson Interventional Systems, Warren, N.J.) required a 9F or 10F sheath (Cook, Inc., Bloomington, Ind.) long enough to pass through the lesion and prevent premature dislodgement of the stent from the balloon catheter before deployment. Small-caliber, tortuous, or sharply angulated upper extremity veins were relative contraindications to delivery of Palmaz stents from the arm and generally mandated catheterization from a larger femoral vein. Patients were given neither heparin during the procedure nor oral warfarin or antiplatelet agents afterward.

At the conclusion of the procedure, the introducer sheath was removed. If a PTFE graft was punctured with a large-caliber sheath, a surgicel (Johnson & Johnson Medical, Inc., Arlington, Texas) pledget was placed over the puncture site and gentle local pressure was applied for as long as necessary (usually 15 minutes) to produce hemostasis. Otherwise, simple gentle pressure at the puncture site was sufficient to produce rapid hemostasis. There were no procedural complications or need for surgical closure of the puncture site.

Most procedures were performed on an outpatient basis. After stenting, patients with patent grafts were sent for hemodialysis. Those with occluded grafts subsequently underwent thrombolysis, thrombectomy, revision, or graft replacement as required. No inpatients were admitted specifically to undergo central venous stenting.

Records of hemodialysis pressures and flow rates from each session were maintained. Patients were referred for angiography if they had pain or swelling on the stented side, progressively increasing pressures greater than 160 mm Hg, decreasing flow rates below 225 ml/min on hemodialysis, or graft occlusion. Follow-up of symptom-free patients who had undergone stenting was done by telephone interviews with the referring nephrologists. In calculating the results, all symptom-free patients with acceptable hemodialysis pressures and flow rates were considered to have open venous outflow. All available patients were restudied by digital subtraction angiography before submission of the manuscript.

RESULTS

Nineteen symptomatic obstructions (11 stenoses and 8 occlusions) in 19 patients (Table I) were repaired with 22 stents (Table II). All attempts at stent placement were successful (Fig. 1). Arm swelling rapidly resolved after stenting.

Eight patients were diagnosed with failing grafts that precluded satisfactory hemodialysis. All grafts would have probably gone on to occlude without intervention. After placement of a stent in the ipsilateral central vein, all eight patients were able to immediately resume dialysis.

One patient had two separate ipsilateral subclavian and innominate stenoses stented at 3 weeks' interval. After repair of the severe subclavian stenosis and thrombectomy of his graft, the patient resumed hemodialysis but had progressively worsening venous hypertension. On restudy 3 weeks later, the subclavian vein and dialysis graft were patent. However, the other moderate innominate stenosis was found to have significantly progressed and was repaired with two Palmaz stents, which resulted in immediate resolution of the venous hypertension and appearance of a steal in the hand. Surgical correction

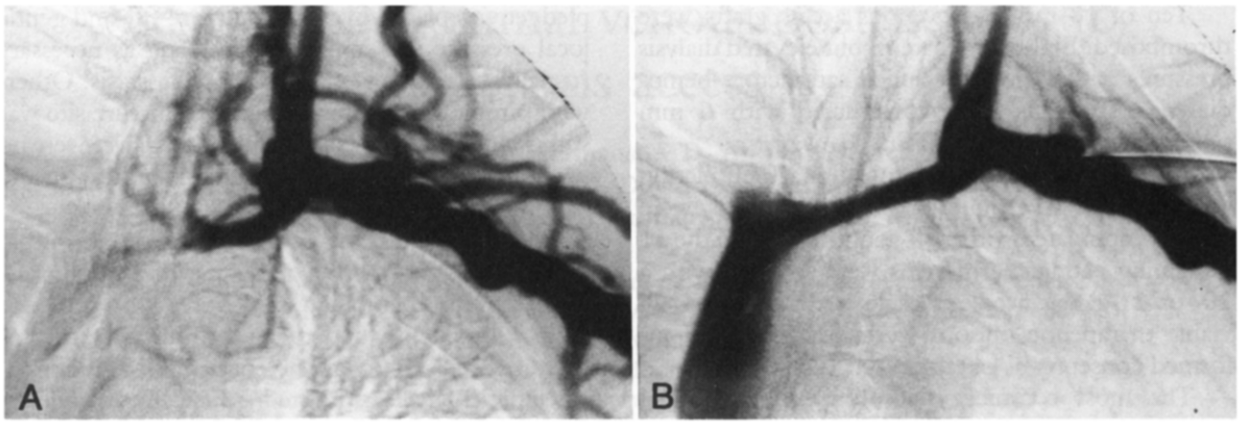

Fig. 1. Hemodynamics improved with stenting. **A,** Venous hypertension. Left innominate vein occlusion with multiple collaterals, retrograde flow in left internal jugular vein (IJV). **B,** Post implant and 5-week follow-up: normalization of pressures with prograde flow in IJV, virtually no opacification of collateral vessels.

Table I. Angiographic findings and location of central lesions in 19 patients

	Occlusion		*Stenosis*	
	Subclavian	*Innominate*	*Subclavian*	*Innominate*
Central occlusion + occluded graft	3	3	3	1
Central occlusion + patent graft		1	4	3
Central occlusion + no graft	1			
Totals	4	4	7	4

Table II. Number and type of stents placed initially

Lesion	*Wallstent*	*Palmaz stent*	*Total*
Right subclavian	5	0	5
Left subclavian	4	1	5
Right innominate	4	3	7
Left innominate	2	3	5
Total	15	7	22

of the steal was unsuccessful and the patient's graft was ligated. The stents have nevertheless remained patent for 17 months (Fig. 2).

Ten of the 19 patients in our series had angiographically proven bilateral central venous obstructions. Ten patients were admitted with recurrent graft thrombosis and central vein obstruction. After stent placement, eight of these patients underwent successful repair of their grafts and resumed hemodialysis. One patient had stent placement in anticipation of an arteriovenous graft, then opted for peritoneal dialysis. The other patient had bilateral central venous occlusions and an occluded graft. The contralateral central occlusion was successfully stented and a new graft was placed.

Primary and secondary patency rates were calculated with life-table methods (Fig. 3). The primary patency rate was 68%, and the secondary patency rate was 93% at 17 months. Three patients with three stents died of unrelated causes. All three veins were patent until the time of death.

Three patients were admitted with signs of recurrent central venous obstruction. One was reevaluated for graft occlusion 13 weeks after stent implantation. Thrombolysis and mechanical recanalisation of the stent were unsuccessful. The patient was placed on peritoneal dialysis. One patient was reevaluated at 5 months after stenting for progressively increasing dialysis pressures and mild swelling of the right arm. PTVA and insertion of a second stent

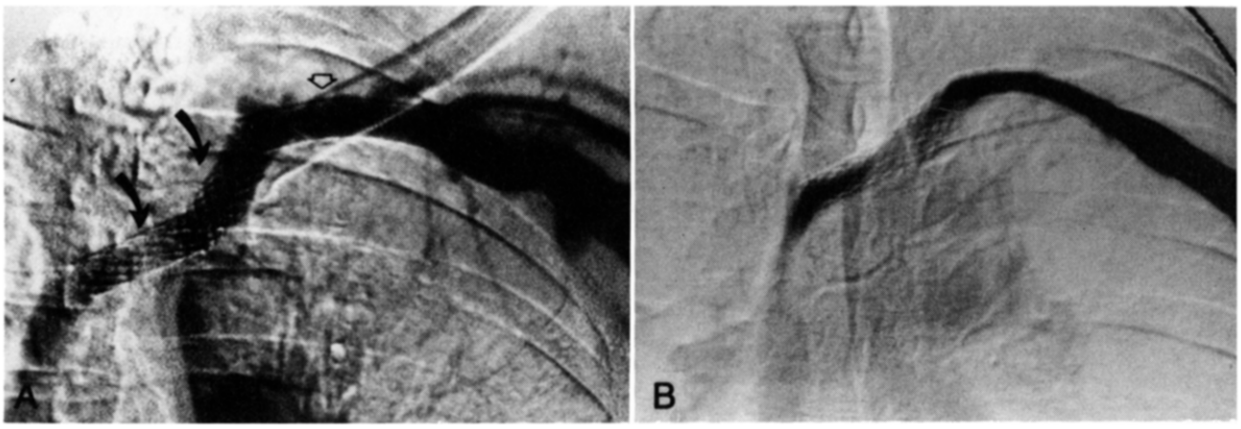

Fig. 2. A, Three-month venogram with patent left subclavian Wallstent (open arrow) and 2 left innominate Palmaz stents *(curved arrows)*. No arm swelling. Patient's graft was ligated 1 month later. **B,** Seventeen months follow-up. Stents, central veins remain patent. Arteriovenous graft was ligated 13 months ago.

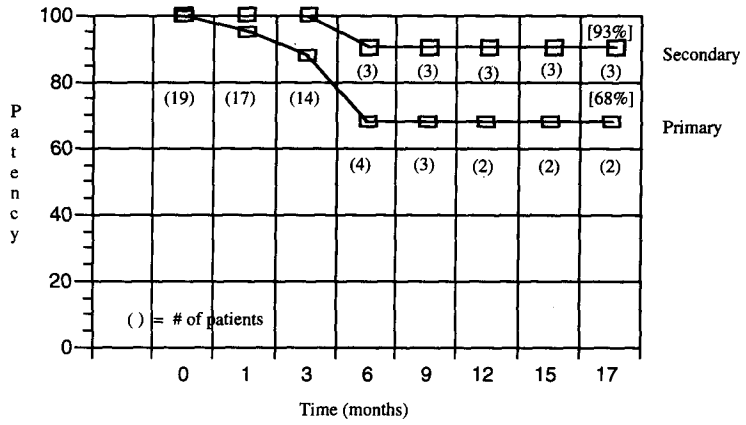

Fig. 3. Primary and secondary patency rates (percent).

resulted in relief of outflow obstruction and normalization of flow. The third patient underwent stenting in anticipation of arteriovenous graft placement. After PTVA and stenting, her arm swelling progressively worsened. A second stent was successfully placed 16 days after the initial implant to correct an inadequate anatomic result (Fig. 4).

One patient was readmitted for ipsilateral graft thrombosis after 2.5 months. Her stent was inadvertently injured during blind insertion of a temporary subclavian hemodialysis catheter by a house officer. The residual stenosis was repaired by placement of a new stent.

DISCUSSION

Central venous stenosis or occlusion has been reported in 40% of patients with prior existing subclavian catheters.[1,2,5] Perivascular fibrosis caused by trauma from repeated central venous cannulation has been implicated as a possible mechanism. Endothelial damage from cannulation and elastic recoil have also been proposed as possible causes.

PTVA of central venous obstructions is safe and effective,[1,3,5] but the long-term central patency rate has been poor because of restenosis.[3,7,8] Landwehr et al.[8] performed 12 central PTVAs in 10 patients, with excellent short-term results; however, there was a 66% recurrence rate at 1 year. Review of our own unpublished data covering the same time period as the stent study shows that from October 1991 to April 1993, we performed PTVA in 25 patients. Only seven (38%) had durable results at 17 months, whereas 18 (62%) required additional or subsequent intervention (repeat PTVA, stenting).

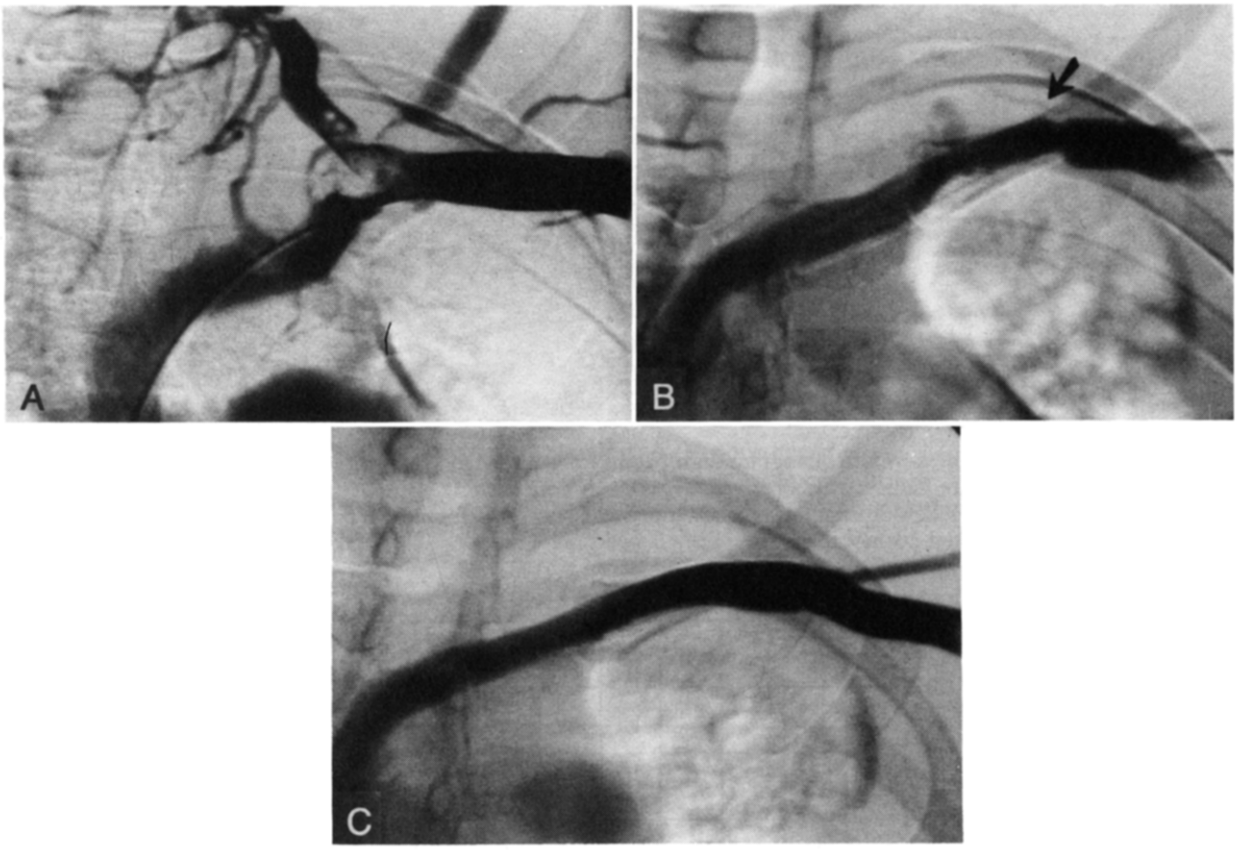

Fig. 4. A, Inadequate anatomic result after PTVA. **B,** Sixteen days after implantation; vein is deformed by sharp end of 10 mm Wallstent causing irregular narrowing. **C,** Venous repair with 12 mm Palmaz stent tapered to Wallstent. Satisfactory anatomic result.

PTVA alone or with central venous stenting may be performed immediately after diagnostic angiography on both acute and chronic stenoses and occlusions, provided that the obstruction can be crossed with a guide wire. Patients usually undergo dialysis before angiography. No patients in our series required thrombolysis before the initial dilation and stenting. Although there is a small theoretic risk of pulmonary embolism from manipulating an acutely obstructed central vein, we have never encountered such an event.

Sullivan et al.[9] studied the hemodynamics of failing dialysis grafts and found that increasing severity of central venous obstruction resulted in a progressive increase in intragraft pressures without linear correlation. Central venous stenoses seemed to produce smaller increases than venous anastomotic stenoses, presumably due to the presence of distensible collateral vessels capable of accommodating large volumes before causing marked changes in graft pressures. Although central stenoses were successfully treated with PTVA, residual stenoses were quite high, potentially predisposing to rapid occlusion. Sullivan et al.[9] concluded that techniques that maintain wide central vein patency after PTVA would be desirable.

Endovascular stenting of central venous stenoses has been used with favorable results.[4,6,7,9] Stents have several advantages over PTVA alone. They limit elastic recoil in compliant veins, exclude damaged and dissected intravascular tissue by neointimal incorporation, and most importantly, act as an intravascular support to counteract extrinsic fibrotic compression of the collapsed vessel.

Nine of the 10 subclavian obstructions in our series were situated in curved vessels, that required Wallstents. Seven Palmaz stents were deployed in straight vessels (Table II). We chose Wallstents for lesions greater than 3 cm in length and for curved vessels. Palmaz stents were reserved for short lesions in straight vessels whose diameter exceeded 10 mm.

Disadvantages of current generation stents are the result of limitations in their design. Stainless steel stents are poorly visualized on fluoroscopy. This may lead to suboptimal deployment. Rigid balloon-expandable stents are poorly suited to tortuous vessels. They require relatively straight delivery paths, do not necessarily conform to the configuration of the stented vessel and can produce intimal damage and stenosis at their extremities as a result of irritation from vessel motion (Fig. 3) or anatomic distortion. Flexible self-expanding stents are engineered to expand to a predetermined caliber. They may conform more accurately to vessel configuration; however, an undersized stent in a large caliber vessel may predispose to thrombosis. New stent designs incorporating flexibility, balloon-expandability, and improved visibility should correct these deficiencies.

Bjarnason et al.[10] reported the collapse of a Palmaz stent in the costoclavicular portion of a subclavian vein and appropriately attributed the event to powerful two-point musculoskelettal compression forces causing persistent extrinsic compression of the vein (and stent). He proposed the use of Wallstents, which theoretically should better resist compression by hoop stress. We have found that neither stent adequately resists the forces in this area where both are prone to deformity and a high failure rate (unpublished data, 1993).

We experienced no periprocedural complications. We did not prophylactically administer antibiotics and have not encountered any bacteremic episodes or infected stents. None of our patients were given anticoagulant during the procedure nor did they subsequently receive antiplatelet agents or warfarin (Coumadin). We did not experience any acute episodes of stent thrombosis. Only one stent occluded at 3 months. We believe this was due to our inability to adequately dilate and stent a very fibrotic subclavian stenosis.

Predictably, peripheral graft occlusions will result from central venous occlusion unless large collateral vessels are able to maintain adequate venous outflow. We saw only one patent graft versus six occluded grafts with central vein occlusion. On the other hand, graft occlusions may result from a variety of local technical, anatomic, mechanical, and physiologic factors unrelated to central vein patency.

Patients undergoing long-term hemodialysis are known to have abnormal platelet function. This, associated with high flow in the central veins, may to a certain degree protect them from early stent failure. Follow-up of patients to 17 months (Fig. 2) confirms these observations.

Because we have not stented patients with normal renal function, we do not know if their patency rates differ from those of patients with chronic renal failure, or whether patency is prolonged by abnormal platelet function or presence of a functioning fistula. Two of our patients have five patent stents and no functioning fistula. One of them has been monitored for 4 months, and the other has been monitored for 17 months without evidence of stent obstruction or venous hypertension.

PTVA and stent placement are relatively safe procedures and are routinely performed on an outpatient basis. Stents provide short- and mid-term relief of central venous obstructions. However, it is too early to conclusively demonstrate long-term benefit. The issue of cost must be considered, because dilation balloons and stents are expensive. But in reality, is there a safer, less expensive, and longer lasting outpatient or inpatient alternative that has yielded better results to date than this $2000 procedure?

It is essential to clearly identify all patients with stents by means of an identification bracelet or other identifier. Lists of such patients should also be made available to consulting physicians to avoid inadvertent damage of stents in the event of graft failure and the need for temporary venous access. It is hoped that surveillance of dialysis pressures and flow rates will alert physicians to impending graft failure in time to image the patient, diagnose the problem, and take appropriate corrective action. Use of the internal jugular approach for temporary hemodialysis access may reduce the risk of central venous obstruction and permanent loss of access from the affected side.

As the life expectancy of hemodialysis dependent patients increases, the limited number of access sites may dwindle to the point of becoming life-threatening. Thus, the preservation of vascular access has become an increasingly important endeavor. PTVA with stenting may prove to be an effective and durable method of preserving vascular access.

In conclusion, central venous obstructions in patients undergoing long-term hemodialysis are often due to trauma from repeated central venous cannulation and may reduce options available for permanent venous access. Stenting of central venous obstructions offers advantages over conventional PTVA and seems to be practical, effective, and durable, with excellent primary and secondary patency to 17 months, as demonstrated in our series. Although early results are encouraging, long-term follow-up with a larger series is essential to determine its true therapeutic value.

We are indebted to our nurses, Nellie Justiniani, RN, and Leticia Nesbihal, RN, for their invaluable help. We thank Debi Cook for her assistance with the statistical analysis. We are deeply grateful for all the help given us by the many nephrologists at the Newark Beth Israel Medical Center who were kind enough to supply us with patients and support our study.

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DISCUSSION

Dr. Anton N. Sidawy (Washington, D.C.). The incidence of proximal venous stenosis and obstructions is increasing because of the more frequent use of the subclavian vein to accommodate an array of therapeutic and diagnostic devices, especially temporary central hemodialysis catheters. Therefore we should consider the internal jugular vein as a site for placement of temporary dialysis catheter rather than the subclavian vein. Proximal vein occlusion usually remains asymptomatic; however, when an ipsilateral arteriovenous hemodialysis access is present, symptoms may arise or the access may fail because of an increase in venous pressure. Conservative treatment is usually unsuccessful. Ligation of the access relieves the symptoms, but ligation is a suboptimal treatment because of the loss of important site for hemodialysis.

Dr. Shoenfeld and his colleagues present a very useful study to help us deal with this problem. If successful, proximal vein dilation and stenting are excellent alternatives in these patients. However, in our practice we are not as successful, and even with stenting, proximal vein stenoses recurred if patients are monitored long enough with venography. Subclavian venography is very easily done in these patients, simply by injecting dye in the access and follow it up to the involved vein.

Your results are very good. Are there any technical aspects you can share with us that can explain your improved results?

How did you monitor these patients? Did you use venography or duplex scanning, or did you rely on clinical evaluation? I ask this question because we found that some stenoses recurred after dilation and stenting, but patients remained clinically symptom free.

How successful were you in dilating and stenting chronic, complete, long-segment occlusions? I want to remind you of a procedure we reported in 1986 (Currier CB Jr, Widder S, Ali A, Kunsisto E, Sidawy A. Surgery 1986;100:25-8) concerning placement of axillary–internal jugular vein graft with PTFE to bypass a complete chronic occlusion of the subclavian vein to maintain an ipsilateral hemodialysis access. We believe it is a useful procedure in a select group of patients in whom dilation is unsuccessful.

Dr. Richard Shoenfeld. Successful use of stents, as with any other technique, involves a learning curve. The three questions we learned to ask and answer were (1) Is the lesion sufficiently covered by the stent and is there enough stent extending beyond the lesion to prevent recurrence and occlusion? We believe that most central obstructions are caused by perivenous fibrosis rather than intrinsic vascular disease. Stenting maintains mechanical patency by overcoming the extrinsic forces, and this promotes healing. (2) Is there an adequate anatomic result? In reviewing our failures, we always found an inadequate anatomic result: there is a substantial difference between arteries and veins. In the latter, what you see is what you get, so the result must look good. (3) Does the caliber of the stent match the caliber of the vessel? In our experience, the most satisfactory results are obtained when the stent closely conforms to the size and configuration of the vessel. We try to avoid the

costoclavicular junction because stents may be easily crushed or deformed in that region.

Follow-up was done in several ways. A permanent chart is kept for every patient undergoing hemodialysis. Pressures are measured on cannulation and at frequent intervals during dialysis and recorded in the chart. If there is a progressive decrease in flow rates or increase in pressures, we are notified and the patient is studied. We do not routinely restudy patients at fixed intervals. Instead, nephrologists are contacted for follow-up information. Before writing the article, we did, however, restudy as many patients as possible.

Formation of neointimal hyperplasia in venous stents may be somewhat depressed in patients undergoing hemodialysis because their platelet function is abnormal and there is very high flow through patent stents with patent arteriovenous grafts.

It is difficult to accurately determine the length of a long-segment occlusion. Absence of opacification may be due to true vessel occlusion, simple inability to fill the patent vessel adjacent to an occlusion, or lack of opacified collateral vessels. In reality, the occlusion may be much shorter than it seems after successful probing and opacification. As in the arterial system, the shorter the occlusion, the better the chance of obtaining long-term patency.

Dr. Mark Moritz (Morristown, N.J.). I believe this study offers us an opportunity to proceed and take better care of these patients with complex conditions.

Do you typically insert your stents at the time of an operation to thrombectomize the bypass grafts in the arm by open technique, or do you do it percutaneously? If so, what is your approach to each sort of lesion?

My second question relates to some unfortunate personal experiences I've had with these patients. In patients with Paget-Schroetter syndrome where they have a costoclavicular obstruction of the subclavian vein caused by congenital deformity of the vein or trauma to the vein, have you been bold enough yet to go ahead and treat those patients, and if so, how do you do it? Do you add a fistula to keep it open, or what has been your approach to those patients?

Dr. Shoenfeld. We believe that you're better off fixing the central venous obstruction before revising or replacing the arteriovenous graft. If possible, we approach the central obstruction via percutaneous puncture of the graft. If this approach is unavailable or inconvenient, we use the femoral approach. We have not inserted a central venous stent at the time of operation by open technique.

We have not inserted stents in patients with Paget-Schroetter syndrome. We do, however, know that stents in the costoclavicular region may be easily deformed and tend to occlude.

Dr. Philip N. Sawyer (Brooklyn, N.Y.). Why are you reluctant to use anticoagulation?

Dr. Shoenfeld. I don't believe it would improve our results. We haven't had any procedural thrombosis associated with stent placement. I would like to extrapolate from the arterial side, where we give these patients anticoagulants for approximately 3 months until the stent is endothelialized. Neointimal thickness continues to increase and tends to stabilize somewhere between 6 months and 1 year. In our stented experimental dogs, neointimal thickness ranged between 215 and 480 μm. Neointimal hyperplasia in stents in large veins with high flow is generally well tolerated.

Dr. Thomas O'Donnell (Boston, Mass.). Once you have lysed the clot and taken care of the compressive syndrome with a first rib resection, the major problem has been recurrence of stenosis after balloon angioplasty of the axillary vein. As a matter of fact, Druz series showed 95% occluded by about a year and a half. So I wonder if you have extended your experience and used it in patients with primary axillary-subclavian vein thrombosis? We have anecdotal experience, hoping that it would prevent recurrence of the stenosis but maybe you with your experience in dialysis have also applied it there.

Dr. Shoenfeld. I would not categorize our experience as that of a large series. We have one case of a patient who had a left subclavian and innominate stenoses repaired with stents. After repair, a severe steal developed in the patient's hand, requiring ligation of his graft. At the 13-month follow-up, the stents and veins were widely patent. This is our only long-term follow-up of a patient with central stents and no increased flow from a graft. To reiterate, we have no experience in treating patients with Paget-Schroetter syndrome.

One of the same questions I was asked was when and where do you put in a stent? Our reply is that when we diagnose a central venous obstruction at angiography, we fix it at the same time. Most often, we access the graft, insert an introducer sheath and stent the lesion. We prefer Wallstents to Palmaz stents because the former are easier to deliver, conform to tortuous vascular anatomy and require a smaller and less complicated delivery system for development. Hemostasis at the puncture site is easily obtained with the aid of surgicel and local compression.