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Access-Related Venous Stenoses and Occlusions: Treatment with Percutaneous Transluminal Angioplasty and Dacron-Covered Stents

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Abstract

Purpose: To determine the effectiveness of using Dacron-covered stents to treat access-related venous stenoses and occlusions.

Methods: Twenty-two Dacron-covered stents were placed in 20 patients: in the basilic or axillary vein ($n = 2$), cephalic vein ($n = 3$), subclavian vein ($n = 5$), and at the venous anastomosis of the polytetrafluoroethylene (PTFE) implant graft ($n = 10$).

Results: Initial technical success was 100%. The cumulative primary and secondary patency rates were 57% and 83% at 6 months, 29% and 64% at 12 months, and 29% and 53% at 18 months. A statistically significant difference in the stent patency was revealed by comparing the patients with stents in the subclavian vein and patients with upper arm stents. The secondary patency rates of the upper arm stents were 73% after 6, 12, and 18 months.

Conclusions: Percutaneous placement of Dacron-covered stents is a safe and effective procedure for salvage of a dialysis fistula. First results are promising, with a tendency to prolongation of the time interval between reinterventions.

Key words: Dialysis shunt—Venous grafts and prostheses—Transluminal angioplasty—Stent placement

During the past 10 years percutaneous transluminal balloon angioplasty (PTA) has become an accepted alternative treatment to surgical revision for hemodialysis access-related venous stenoses and occlusions [1, 2]. However, the patency rates in the follow-up period are low because of the high frequency of restenosis due to intimal hyperplasia [3, 4]. Since 1988, noncovered endoprostheses (commonly the Wallstent) have been used to improve shunt patency [5, 6]. In the central veins, bare stents demonstrate better patency rates than PTA alone [7]. However, there is controversy regarding the role of stent placement in upper arm veins. Vorwerk et al. [7] reported that placement of a metal stent in the upper arm veins and at the venous anastomosis of grafts did not improve the long-term patency rate. This statement contradicts the results of Turmel-Rodrigues et al. [8], who showed that stent placement prolongs the time between reinterventions.

Neointimal hyperplasia is the major reason for restenosis following stent placement. To overcome the problem of restenosis due to intimal hyperplasia we used the insertion of a covered endoprosthesis as an alternative approach. In this study we investigated the use of Dacron-covered nitinol stents in 20 patients.

Materials and Methods

Between December 1993 and April 1997, 22 Dacron-covered stents (EndoPro System 1, MinTec, Freeport, Bahamas; or Passager, Boston Scientific, Watertown, MA, USA) were placed in 20 patients (4 men, 16 women; average age 63.7 ± 9.2 years). The hemodialysis shunt was a native fistula in 10 patients (4 Cimino-Brescia fistulas and 6 upper arm shunts) and a polytetrafluoroethylene (PTFE) implant in 10 patients. The lesions were located on the right side in 14 patients and on the left side in six. Fifteen stenoses, two occlusions, and three aneurysms were treated. The stents were implanted in the basilic or axillary vein in two patients, in the cephalic vein in three patients, in the subclavian vein in five patients, and at the venous anastomosis of the PTFE implant graft in 10 patients. The stent diameters varied from 7 to 12 mm, and were slightly larger (1–2 mm) than the diameter of the balloon catheter to prevent migration. The choice of stent length was based on observations of the entire lesion with an overlap of approximately 1–1.5 cm at each end of the lesion.

The clinical symptoms included extremity swelling and pain, and increased subcutaneous venous collaterals. Shunt dysfunction was revealed by increased venous dialysis pressure, recirculation, and prolonged bleeding at the puncture site following dialysis in 17 patients, with additional shunt thrombosis in three patients.

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The Cragg EndoPro System and Passager are self-expanding stents made of nitinol wire and covered with a woven fabric graft. The stent is formed from a monofilament (0.28 mm thick) of nitinol shaped into a tube with a series of longitudinal zigzags. The zigzags are stabilized by a ligature of 7-0 polypropylene.

Indications for covered stent placement were residual stenosis after initial angioplasty (greater than 50%) with persistent filling of venous collaterals in six patients, frequently recurring obstructions after balloon angioplasty or after placement of bare stents (less than 3 months) due to neointimal hyperplasia in eight patients, vascular leakage following angioplasty in three patients, and the treatment of false aneurysms in three patients.

The percutaneous interventions included antegrade venous puncture of the shunt vein in patients with a native fistula or of the venous side of the PTFE grafts. In three patients with PTFE-shunt thrombosis, the technique of recanalization and thrombolysis included the placement of two catheters in a crossed configuration: one directed to the arterial anastomosis and the other to the venous anastomosis. Ten milligrams of human tissue plasminogen activator (rt-PA) were required for local catheter lysis, generally achieved in about 30–40 min. Following a safe passage of the stenosed segment, balloon angioplasty (diameter 6–8 mm) was performed. Stent placement was always performed via the hemodialysis access antegrade approach or via the cephalic vein, with a 8–10 Fr delivery sheath being used. A 3000–5000 IU bolus of heparin was injected. To achieve exact stent positioning, we prefer to place the stent with a road-mapping technique. Following stent placement angioplasty was repeated. After completion of the procedure the puncture site was manually compressed. All patients were anticoagulated according to the manufacturer's recommendation. Beginning the evening of the procedure, the patients were given low-molecular-weight heparin (i.e., enoxaparin) 40 mg twice a day for 15 days, ticlopidine (250 mg per day) for 1 month, and aspirin (100 mg per day) for 1 month. Clinical follow-up examinations (auscultation, Doppler ultrasound, measurement of recirculation rate, and venous pressure during the dialysis) were performed for all patients. The interventions were performed on an outpatient basis.

For clinical observations the following parameters were used: prolonged bleeding time at the puncture site, increase in venous counterpressure during dialysis, and the recirculation rate. If a reobstruction was suspected, angiography and eventually the intervention was repeated.

Patency rates were calculated by means of Kaplan–Meier analysis. Primary stent patency was defined as the interval between insertion of the stent and the time of shunt failure related to restenosis or reocclusion within the stent. Secondary patency was defined as the termination of stent patency after all percutaneous reinterventions. Follow-up ended with loss of the shunt, renal transplantation, or the death of the patient.

Results

Immediate procedural success was achieved in all patients. Eighteen patients had a single Cragg Endopro stent or Passager stent inserted, and two patients received two stents. In one patient the lesion in the subclavian vein was treated with two stents to achieve complete coverage of the lesion by the stents. In another patient a severe stenosis developed due to intimal hyperplasia at the proximal end and in the uncovered segment at 9 and 15 months following the placement of a Cragg stent in the axillary vein. These constrictions were successfully dilated. A restenosis at the same site occurred 18 months after primary stent placement. Due to frequent restenoses, this patient underwent additional stenting and PTA (Fig. 1A, B). Migration of the proximal stent and restenosis at the proximal end occurred within 3 months after secondary stent placement. The patient underwent PTA with good results (Fig. 1C, D).

The primary stent patency was 67% at 3 months, 57% at 6 months, and 29% at 12 months and 18 months. With repeat treatment the stent secondary patency rate was 89% after 3 months, 83% after 6 months, and 64% and 53% after 12 and 18 months respectively (Fig. 2).

Statistical comparison of two subgroups (subclavian vein stent placement with upper arm stent placement) of this population was performed. The 3-month (and 6-month) secondary patency was 86% (70%) for upper arm stents and 60% (60%) for subclavian vein stents (log-rank test $p < 0.03$) (Fig. 3).

As mentioned above, implantation of Dacron-covered stents was performed in eight patients due to frequent restenosis following the PTA or implantation of bare metal stents. Comparison of the frequency of reinterventions in this group of patients showed reintervention intervals of 2 months and 4 months before and after the implantation of the covered stents respectively. These results show a promising tendency toward prolongation of the reintervention interval, but due to the small number of patients do not reach statistical significance.

In one patient the extremity swelling did not improve despite the fact that the covered stent in the subclavian vein and cephalic vein remained open. Old thrombosis of the axillary and brachial vein was presumed to be the underlying cause of the upper arm edema in that patient. The shunt was abandoned, and surgical shunt placement performed at the other side. In another patient stent obstruction occurred in association with thrombosis of the access site 7 days following stent placement in the venous anastomosis of the PTFE graft. Surgery was performed with excision of the stent.

Within the follow-up period, six episodes of reocclusion and five episodes of restenosis occurred. Four reocclusions and all the cases of restenosis were related to intimal hyperplasia. Local thrombolysis and angioplasty were successfully performed in five cases of reobstruction. In all episodes of restenosis a PTA was successfully performed and additional stent placement required in one patient. Within the observation period four patients died and one underwent renal transplantation.

Complications

Early rethrombosis of the stent was found in two patients with a PTFE graft within 6 hr of stent placement. Both patients underwent successful local thrombolysis. No inflammatory reactions, stent infection or migration, pulmonary embolism, or bleeding complications were observed following placement of the Dacron-covered stents.

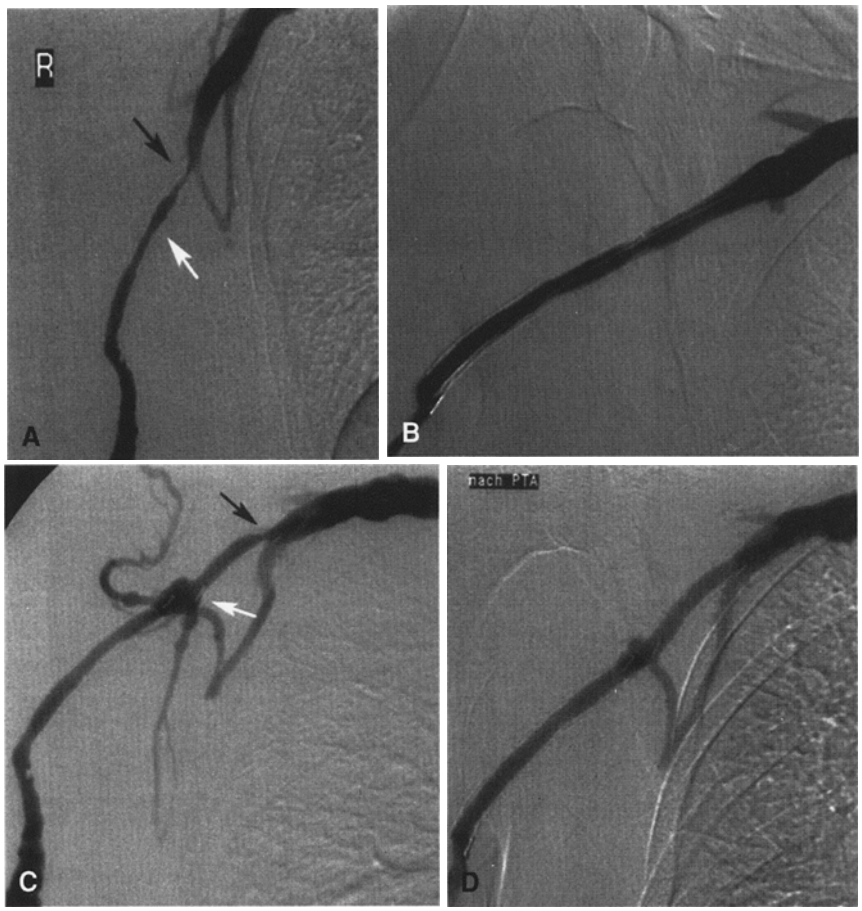

Fig. 1. **A** Restenosis at the end of the stents (white arrow) and in the uncovered segment of the axillary vein (black arrow) 18 months after primary placement of a covered stent. **B** Secondary stent placement. **C** Migration of the proximal stent (black arrow) and restenosis at the proximal end of the central stent (white arrow). **D** Good result after PTA.

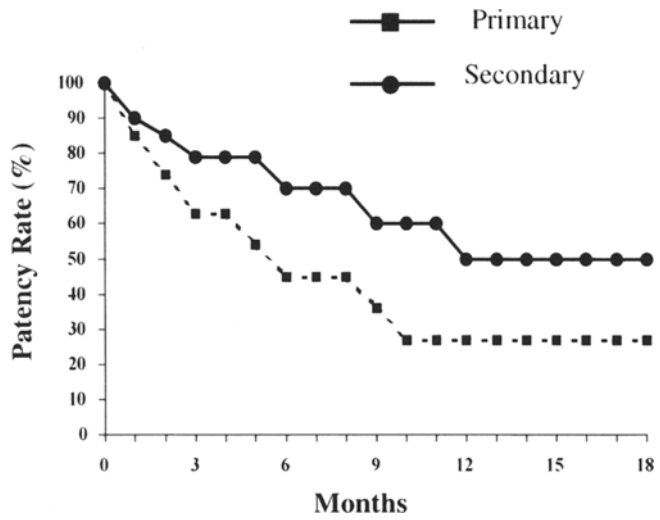

Fig. 2. Primary and secondary patency rates for all stents.

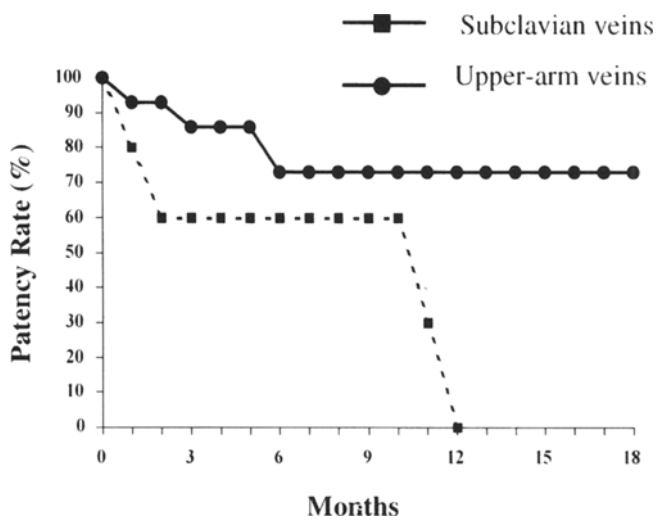

Fig. 3. Cumulative secondary patency rates for upper arm and subclavian stents.

Discussion

One of the major reasons for subclavian vein stenosis in patients with hemodialysis shunts is the long-term use of a central venous catheter [9]. Stenosis of upper arm veins is related to intimal hyperplasia, stimulated by increased turbulent flow and shear stress, particularly in the region of valves [5, 10].

Venous stenosis in the outflow tract is a main reason for inadequate shunt function. It shows as an increase in the venous pressure, prolonged bleeding following the hemodi-

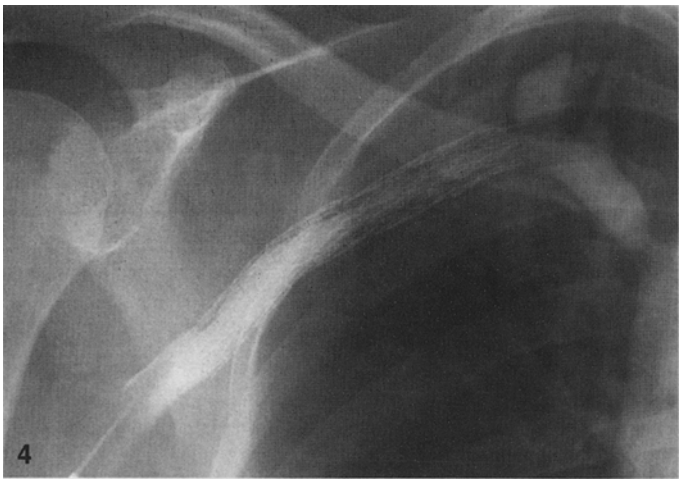

Fig. 4. Severe intimal hyperplasia in the central "bare" stent while the distal Dacron-covered stent is widely open.

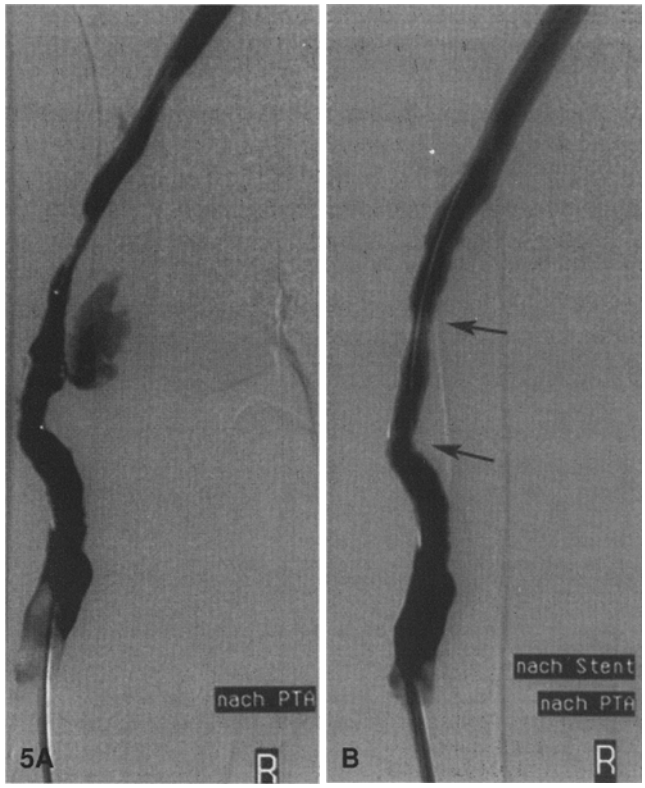

Fig. 5. **A** Rupture of the cephalic vein following PTA. **B** After Cragg stent placement (arrows).

alysis, and a high level of recirculation. Moreover, stenosis of upper arm veins can also lead to thrombosis of the hemodialysis shunt itself. It should be mentioned that the degree of narrowing in the vein is less significant in comparison with the arterial stenosis, and is determined by the localization of lesions and by the development of collateral vessels. Even 50% narrowing of a vein in the outflow tract can be a reason for inadequate functioning of the hemodialysis shunt [7, 11].

It is well known that neointima is homogeneously distributed along the length of the stent following the implantation of "bare" metallic stents. In one patient of our group two stents were placed simultaneously. The proximal stent in the subclavian vein was a "bare" nitinol stent, since implantation of a coated stent in this location could result in occlusion of the jugular vein. The distal stent between the axillary and subclavian veins was a Dacron-covered Cragg stent. The indication for its placement was a false aneurysm of the axillary vein. Angiograms obtained after 6 months demonstrated severe intimal hyperplasia in the central stent while the stent-graft was widely open (Fig. 4). However, this example is the only one in our group of patients where a metal stent and a stent-graft were implanted simultaneously side by side in different venous segments. For this reason we can not confirm with any reasonable certainty the retardation of intimal growth following insertion of a Dacron-covered stent. On the other hand, restenosis related to intimal hyperplasia primarily developed at the stent ends following the implantation of Dacron-covered stents. Similar observations were reported following the implantation of Dacron-covered stents in the femoral artery [12].

Vessel rupture following PTA is a serious complication that may result in the development of a significant hematoma and even compartment syndrome. Implantation of a Dacron-covered stent allows bleeding to be stopped fast and reliably (Fig. 5).

Recently, several publications have appeared regarding the placement of metallic endoprostheses for access-related venous stenoses and occlusions [7, 10, 13, 14]. The main indication for stent implantation was insufficient primary angioplasty results. Gianturco stents were used in 19 patients by Quinn et al. [10], who found a secondary cumulative patency rate of 42% after 2 years. Wallstents were deployed more frequently. Gray et al. [13] reported a cumulative assisted patency rate of 76% after 6 months, and 33% after 12 months. Slightly better results were reported by Vesely et al. [14]: 64% after 6 months, 56% after 12 months, and 22% after 24 months. Vorwerk et al. [7] have estimated the overall cumulative shunt patency in 65 patients as 86% after 1 year, 77% after 2 years, and 70% after 3 years. In the only study we were able to find in the literature regarding the implantation of Dacron-covered stents [15], the cumulative patency rate was reported as 67.7% after 6 months, and 55.4% after 12 months. Our results are slightly better than those reported by Quinn et al. and Gray et al., and are comparable with the results reported by Vesely et al. One possible reason for our results being slightly worse than those reported by Vorwerk et al. may be related to the inhomogeneity of our patient group. It is primarily related to the lesions in the subclavian vein. In three patients out of five in our group, the Cragg stent in the subclavian vein was installed by using the so-called "stent-in-stent" technique,

for example following frequently recurring stenosis and reocclusion of previously implanted metallic endoprostheses. In all these patients the stents were deployed around the subclavian–brachiocephalic vein corner. Increased turbulence of the blood flow in this area and possibly mechanical irritation due to contact between the clavicle and the first rib lead, in our opinion, to especially aggressive intimal hyperplasia. Analysis of the long-term results in our group of patients without taking into account the cases related to the subclavian veins revealed significantly better cumulative secondary patency rates following the installation of covered stents in the upper arm vein (73.3% after 6, 12, and 18 months). These results are slightly better than those reported by Vorwerk et al. [7] after placement of metallic endoprostheses in the upper arm veins (50%). The small number of patients with Dacron-covered stents in the subclavian vein in our group is related to the strict indications required for the implantation of this type of endoprosthesis in this area, as well as to an increased risk of occlusion of the jugular vein. In two patients in our group, thrombosis of this vein was confirmed prior to placement of the Cragg stent. In three other patients the coated stents were installed in the proximal subclavian vein; thus the jugular vein remained patent.

Given the small number of patients in our group, we did not compare the immediate and long-term results following the implantation of Dacron-covered stents or traditional metal endoprostheses. It is possible that future improvements in the design of the metal frame and the covering materials (for example nitinol and Gore-Tex in the new Hemobahn) for covered stents could lead to significant improvements in the long-term results. The first reported results regarding the implantation of these new stents in the arteries of the lower limbs are encouraging: 83% primary and 87% secondary patency rates at 6 months of follow-up [16].

In conclusion, our preliminary experience shows that percutaneous placement of Dacron-covered stents is a safe and effective procedure for salvage of a dialysis fistula. The indications for stent-graft placement should be assessed on an individual basis, but a stent-graft seems mandatory for a vessel rupture after PTA. With a close shunt surveillance program to detect venous outflow tract obstruction, and with secondary interventions, we have achieved cumulative secondary patency rates in the upper arm veins of 86% after 3 months and 73% after 6, 12, and 18 months. These results show a promising tendency, although so far there has been no statistically significant prolongation of the reintervention interval after implantation of Dacron-covered stents.

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