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Use of the Wallstent in the Venous System Including Hemodialysis-Related Stenoses

Christoph L. Zollikofer,[1] Francesco Antonucci,[1] Gerd Stuckmann,[1] Paul Mattias,[1] Werner F. Brühlmann,[2] and Erich K. Salomonowitz[1]

[1] Department of Radiology, Kantonsspital Winterthur, Winterthur, Switzerland, and [2] Department of Radiology, Stadtspital Triemli, Zürich, Switzerland

Abstract. Eighteen patients with a total of 23 venous stenoses or occlusions were treated with the Wallstent. In 5 patients treated for malignant stenosis there was one primary failure due to insufficient stent expansion. The other 4 patients showed rapid relief of their inflow obstruction, all remaining asymptomatic despite later stent occlusion in 1 patient. Four patients were treated for benign postoperative stenoses of the iliac or femoral vein. All stents remained patent for a period of 6 weeks–58 months. Nine patients were treated for one or multiple stenoses along the venous outflow tract of hemodialysis fistulas. Of 14 lesions that were eventually stented, 12 are still patent after 3–27 months (mean 19). However, 10 secondary interventions (eight percutaneous transluminal angioplasty (PTA), two stents) and three additional stent procedures for new lesions were necessary. Although our experience is limited, we believe that patients with tumor compression or postoperative strictures of large veins benefit from treatment with stents. Stenting of venous outflow stenoses in hemodialysis fistulas can significantly prolong stent function, however, PTA should always be the first treatment of choice.

Key words: Dialysis shunts—Veins, transluminal angioplasty, grafts and prostheses

Treatment of venous stenoses with percutaneous transluminal angioplasty (PTA) has a high rate of recurrence [1, 2]. Moreover, the fibrotic nature of many benign venous stenoses or external malignant compression often preclude a primary effective dilatation. Endovascular stents have been successfully used in the arterial system mainly for atherosclerotic disease. It therefore seems logical that the technique of an inner mechanical support to prevent collapse or compression of a lumen as well as recurrencies should also be applied in the venous system [3–9]. Of special interest are obstructions of the vena cava, large caliber central veins, and the venous outflow tract of dialysis shunts. Herein we report our experience in 18 patients using self-expanding endovascular stents of the Wallstent type.

Address reprint requests to: Christoph L. Zollikofer, M.D., Department of Radiology, Kantonsspital Winterthur, Brauerstrasse 15, CH-8401 Winterthur, Switzerland

Material and Methods

Eighteen patients with a total of 23 venous stenoses or occlusions were treated with the Wallstent. There were 12 women and 6 men, aged 26–78 years (mean 47 years). According to localization and etiology of the lesions the patients were divided in three groups: 1) Palliative treatment of tumor compression in 5 patients: superior vena cava (2); inferior vena cava (1); iliac vein (1); confluence of basilic and axillary veins in 1 patient with breast carcinoma. 2) Postoperative recurrent stenoses in 4 patients: 1 had recurrent stenosis of the common iliac vein after operation of a venous spur, 2 had stenoses of the common femoral vein after crossectomy of the greater saphenous vein, and 1 had a long segment stenosis after surgical reconstruction for traumatic severance of the superficial femoral vein. 3) Stenoses of the venous outflow tract were treated in 9 patients on chronic hemodialysis (Table 1): Five patients had peripheral lesions stented (cephalic vein, basilic vein) for recurrent stenoses (4) or primarily insufficient result after PTA (1); 2 of these patients developed additional proximal stenoses 6 and 16–24 months later. Four patients had isolated central lesions of the innominate vein.

The characteristics and releasing mechanism of the Wallstent have been described previously in this issue. Most stents were implanted inguinally with the exception of the peripheral stents in patients on hemodialysis where the draining vein was directly punctured. For the superior vena cava (SVC), stents of 14-mm diameter were used in 2 patients. Two overlapping 25-mm prototype stents were used in 1 patient with metastatic obstruction of the inferior vena cava (IVC). For stents in the femoral vein and

Table 1. Hemodialysis-related stenoses

Location	No. of patients	No. of lesions	Stent diameter (mm)
(a) Isolated proximal lesion (brachioceph. vein)	4	4	10–12
(b) Isolated peripheral lesions	3	3	6–8
(c) Peripheral lesion with consecutive proximal lesion	2	2/4	8–10

(a) Stenosis in the brachiocephalic vein; (b) lesions with a few cm of the AF fistula or at or near a bracheal anastomosis of an autologous or xenograft, (c) 2 patients from (b) who later developed additional lesions

iliac vein, stent sizes were 10–14 mm. For the brachiocephalic vein we used diameters of 10 or 12 mm and for peripheral veins, such as the basilic or cephalic veins, 6 or 8 mm. Stents up to a diameter of 10 mm can be introduced through a 7 French introducing sheath, stents from 12–16 mm through a 9 French sheath, and for the prototype of 25 mm diameter stents, a 20 French introducer sheath was used. Most obstructing lesions were dilated with a balloon catheter before stent application. In cases where the endoprosthesis would not spontaneously open to a sufficient degree, balloon dilatation was performed within the implanted stent. In such cases the dimensions of the balloons were selected 1 mm smaller than the diameter of the completely expanded stent. If needed, two stents were placed in tandem overlapping each other to cover the entire length of the stenosis.

Analogous to conventional PTA, 5,000 U of heparin were given intravenously during the procedure. The patients were then treated with intravenous heparin of 800–1,000 U/h for 2–4 days, starting peroral anticoagulation with coumadin the same day. Unless contraindicated, peroral anticoagulation was continued for at least 6 months. The patients were followed clinically at regular intervals at 1, 3, 6, and 12 months and yearly thereafter. If feasible, color duplex flow studies were done at these follow-ups and phlebography, if possible, at 6 and/or 12 months

Results

Tumor Stenosis

The results are summarized in Table 2. Three of the 5 patients treated for malignant obstruction died after 6 weeks–9 months. None of these patients showed recurrent inflow obstruction at the time of death. One patient, however, with SVC syndrome showed reocclusion of the stented segment on phlebography 4 weeks after stent placement. In this patient, recanalization with thrombolysis and thrombus aspiration had to be performed 3 days after implantation of the stent. Of the 2 surviving patients, 1 with two stents in the IVC has been asymptomatic for 1 year (Fig. 1). In the other patient with a very tight stenosis at the inflow of a double basilic vein into the axillary vein, the two implanted stents did not open sufficiently in spite of vigorous additional balloon dilatation, and stent occlusion occurred 2 days after placement. The patient was taken to surgery where a hard tumor stenosis was found and the entire vein segment was bridged with a graft.

Benign Stenosis after Previous Operation

All patients currently have patent stents and are asymptomatic after a follow-up time of 6 weeks–58 months (Table 3). One patient, who was stented for a recurrent stenosis after surgery of a traumatically severed superficial femoral vein, showed moderate intimal hyperplasia of about 25% of the luminal diameter after 6 weeks. The intimal thickening, however, remained stable and the patient has been asymptomatic for more than 4 years (Fig. 2). The patient who was stented for a recurrent venous iliac spur has been free of symptoms for almost 5 years. The 2 other patients with stents in the common femoral vein are also asymptomatic but have only a limited follow-up of 6 weeks and 4 months (Fig. 3).

Hemodialysis Shunts

Nine patients were treated for one or multiple stenoses developing in the course of chronic hemodialysis along the venous outflow tract of the AV-fistula. These patients can be classified into two groups according to the localization of the stenotic lesion (Table 4). The first group (a) comprises patients with stenoses centrally in the region of the brachiocephalic vein, and the second group (b) are patients who had lesions either within a few centimeters of the AV-fistula or at or close to a brachial anastomosis of an autologous or xenograft. A subgroup (c) consists of 2 patients from group (b) who later developed additional proximal lesions (Table 1).

Proximal Lesions. These were found in 6 patients. In 2 of these, proximal lesions in the region of the subclavian and axillary vein developed between 7 and 24 months after previous stenting of peripheral lesions (Tables 1 and 4, group (c)). In the other 4 patients, the innominate vein was stented for recurrent stenoses after PTA in 3 and as primary treatment in 1 patient. One patient died 5 months after stenting, dialysis was possible until death. However, the patient suffered from arm swelling and phlebography 1 month prior to death, when a new stenosis 3 cm proximal to the stented lesion was found. The stent itself was completely patent without any signs of recurrent stenosis (Fig. 4). The follow-up of the other 3 patients ranges from 3½ to

Table 2. Tumor stenoses and results

Location	No. of patients	No. of stents	Living (mos)	Deceased (mos)	Free of symptoms	Stent patency	Stent diameter (mm)
V. cava	3	4	1 (12)	2 (1½)	3/3	2/3	14 + 25
Iliac V.	1	1	—	1 (9)	1/1	1/1	14
Basilic/axill. V.	1	2	1	—	0/1[a]	0/1[a]	8
Total	5	7	2/5	3/5	4/5	3/5	

[a] Patient free of symptoms after surgical bypass

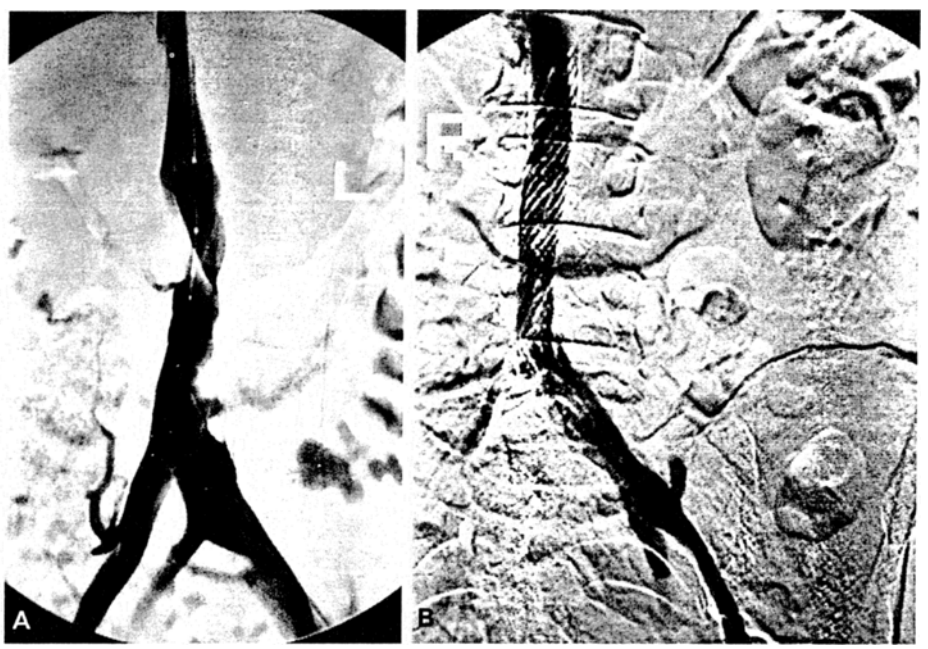


Fig. 1. A 47-year-old female with metastatic ovarian carcinoma postsurgery and irradiation. **A** Inferior vena cavography shows severe infrarenal stenosis and excentric tumor compression of the left common iliac vein. **B** Cavography 6 months after placement of two overlapping Wallstents 25 mm in diameter shows complete patency The patient has been asymptomatic for 1 year

39 months. The patient with the longest follow-up received a kidney transplant 8 months after stenting, with resection of the AV-fistula at the time of operation. A control phlebogram 18 months after stent implantation showed a widely patent stented innominate vein. However, a new high-grade stenosis had developed at the orifice of the subclavian vein. As the patient has remained asymptomatic with good collateral drainage via the internal jugular vein, no further treatment has become necessary.

Peripheral Lesions. Follow-up of the various stented lesions in the 5 patients vary from 7 to 34 months (Tables 1 and 4). There was one acute occlusion one day after stenting of a long segment stenosis of the basilic vein after undue sportive activity the day following stent placement. Percutanous recanalization was successful, however, 4½ months later the patient had severe intimal hyperplasia of the stented segment as well as of the native vein proximal to the stent. A secondary intervention was denied and the graft occluded.

A second patient received a kidney transplant 5 months after stenting of a graft anastomosis and phlebography 1 month later showed a distinct intimal hyperplasia. The patient was last seen 11 months after stenting with a clinically open stent. An additional patient had to be redilated 7 and 13 months after stenting with a functioning stent after a total of 17 months (Fig. 5). Two other patients (subgroup c) received kidney transplants 22 and 27 months after the first stenting. Recurrent intimal hyperplasia in these 2 patients, however, required 10 secondary interventions, the first starting between 3 and 9 months after stenting. Seven of these secondary interventions were necessary in 1 patient, re-

Table 3. Benign postoperative stenoses and results

Location	No. of patients	No. of stents	Follow-up (mos)	Free of symptoms	Stent patency	Stent diameter (mm)
Iliac vein	1	1	58	Yes	Yes	14
Common femoral vein	2	3	1½ – 4	Yes	Yes	10 – 12
Superficial femoral vein	1	2	52	Yes	Yes	12 + 14
Total	4	6	$\bar{m}$ 29	All	All	

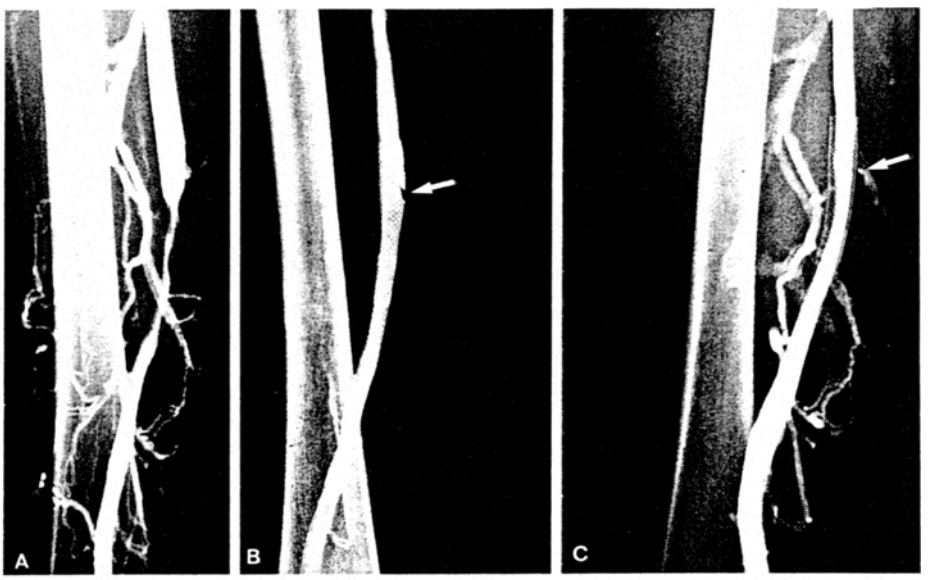
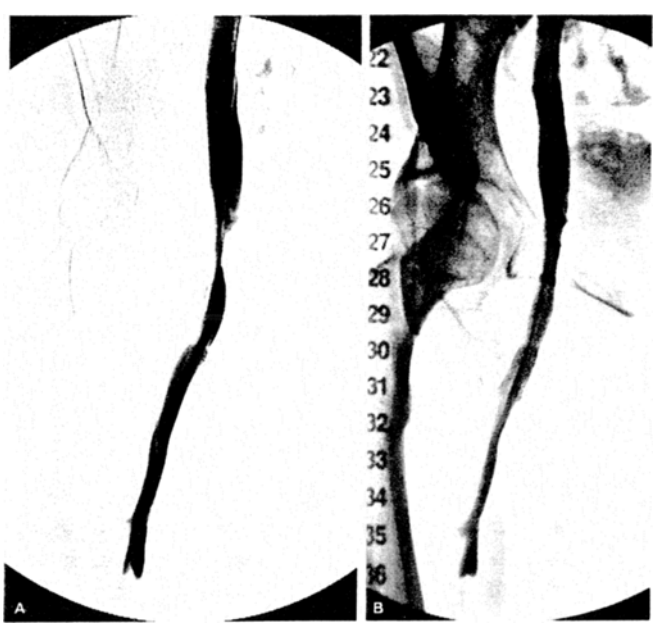


Fig. 2. A 33-year-old female with surgical reconstruction of the superficial femoral vein after traumatic severence. **A** Antegrade phlebography shows severe stenosis of the superficial femoral vein 4 weeks after surgery. **B** Immediately after placement of a 10 mm and a 12 mm Wallstent in overlapping fashion from a retrograde femoral approach there is a well-established lumen of the superficial femoral vein. Note inflow from sidebranch (arrow) **C** Follow-up venogram after 2½ years shows adequate patency in spite of moderate intimal reaction. Note patency of venous side-branch (arrow). Patient has been asymptomatic for 4½ years.



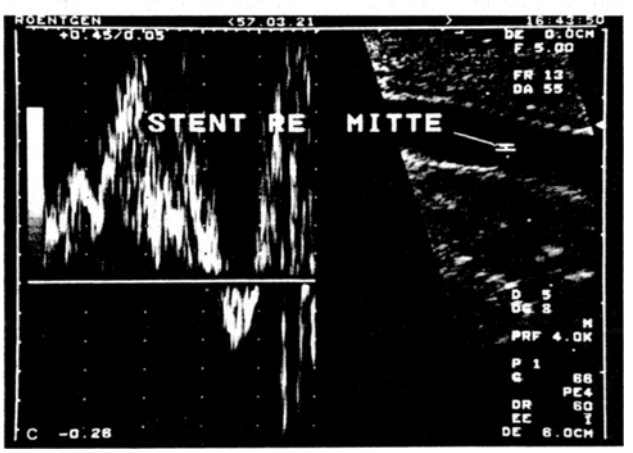


Fig. 3. A 34-year-old female with leg swelling from common femoral vein stenosis after crossectomy. **A** Phlebography shows severe stenosis of common femoral vein. **B** Normal venous lumen after placement of two overlapping 12 mm Wallstents. **C** Patient has widely patent common femoral vein on color Doppler at 4 months follow-up.

Table 4. Hemodialysis shunt-related stenoses and results

Location and no. of patients	No. of original lesions	Follow-up months (mean)	Patency[a]	Recurrence (mos)	2° Interventions	Occlusion[a]	No. of new lesions
(a) 4	4	3–39 (18)	4/4	0/4	—	—	1
(b) 2	3	7–17 (12)	2/3	3/3 (4–7)	1	1	—
(c) 2	1	24–34 (27)	6/6	2/2 (7–24)	2 PTA		
					3[b]	—	1[b]
					1 Stent		
					6 PTA		
	1				7[c]	—	3[c]
					5 Stents		
Total	9		12/13	5/9	10	1/13	5

[a] Number of stented lesions
[b] Pt 1: PTA of new lesion in subclavian vein, stented for recurrence. PTA of stented cephalic vein after 9 months
[c] Pt 2: 6 × PTA of stented graft-basilic vein anastomosis and second stent. Segmental stenting of three additional proximal lesions

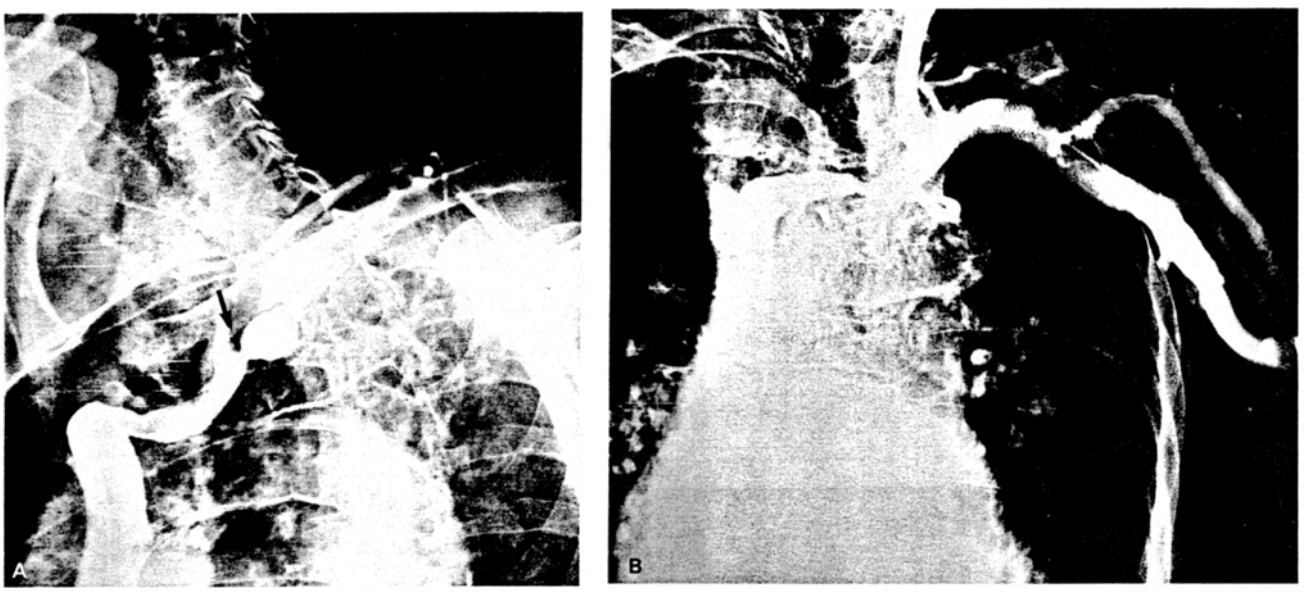


Fig. 4. A 78-year-old female on hemodialysis with left-sided arm swelling. **A** Retrograde phlebography shows severe stenosis at the confluence of the subclavian and internal jugular veins (arrow). **B** Four months after placement of a 12 mm Wallstent, the previous stenotic area is widely patent. No intimal reaction. However, a new stenosis has developed in the innominate vein. Dialysis was still possible, therefore no treatment was performed. The patient died 1 month later of underlying disease.

quiring six repeat PTAs at decreasing intervals of 5–2½ months, finally requiring a second stenting of the same lesion (Fig. 6).

In addition, both patients developed central lesions as mentioned above. In one of these a tight stenosis at the origin of the cephalic vein developed after 6 months. After successful PTA of the stenosis, a recurrence developed 10 months later which could not be sufficiently dilated and was therefore stented. Because of significant intimal hyperplasia, redilatation of the stented segment was necessary another 10 months later. The second patient needed stenting of two short segments in the subclavian and axillary vein 14 months after stenting a proximal graft stenosis in the basilic vein (Fig. 6). Nine months later, the nonstented intermediate segment of the axillary vein also had to be stented because of a new highgrade, nondilatable stenosis. The patient now has a continuous set of stents from the graft anastomosis in the basilic vein to the junction of the

Fig. 5. A 74-year-old female patient with Cimino shunt for hemodialysis. PTA had been performed twice previously for stenosis of the venous outflow tract. **A** Highgrade stenosis at the venous outflow in the forearm. **B** After placement of an 8 mm wallstent, there is only a slight residual stenosis. **C** There is a second recurrence 13 months after stenting. **D** Widely patent lumen after repeat PTA with 8 mm balloon catheter. Patient has been free of symptoms for 5 months.

subclavian and internal jugular vein. The stented venous outflow has thereby been kept functioning for a total of 3 years so far.

In summary, all patients with peripheral stents in the region of the basilic or cephalic vein developed recurrent stenoses by intimal hyperplasia at various intervals from 4 to 9 months after stenting.

Complications

In the whole group of 18 patients there were three acute occlusions, two of which were successfully treated percutaneously by fibrinolysis and thrombus aspiration. Otherwise we did not experience any serious complications, particularly no signs of stent migration or infection.

Discussion

Most frequently, percutaneous angioplasty in the venous system is applied for hemodialysis-related stenoses. These are found in the venous outflow tract of AV-dialysis fistulas or in the region of the brachiocephalic veins [2, 10, 11]. So far, there are only a few reports on percutaneous treatment of other benign or tumor-induced venous stenoses [12, 13]. The use of flexible endovascular prostheses opens up a new alternative to surgical treatment of venous obstructions.

Persisting tumor obstructions in spite of chemotherapy or radiation therapy may now be palliated successfully with endoluminal stents. The symptoms of SVC obstruction that occur in about 3–4% of patients treated for bronchial carcinoma can be rapidly palliated [9]. Our own experience shows that in obstructions of the SVC, even in the event of a later occlusion by tumor or thrombosis, bridging of the acute obstruction gains time for the development of collaterals. Endoluminal vascular prostheses are also suitable for treating tumor compression or fibrotic stenoses after radiation therapy in the region of the pelvic veins and the IVC. If an occluded segment can be recanalized with the guidewire, there is a good chance that the occlusion may be kept open with a stent. If necessary, fibrinolytic agents can be used to reopen an occluded caval segment as suggested by Rösch's article in this is-

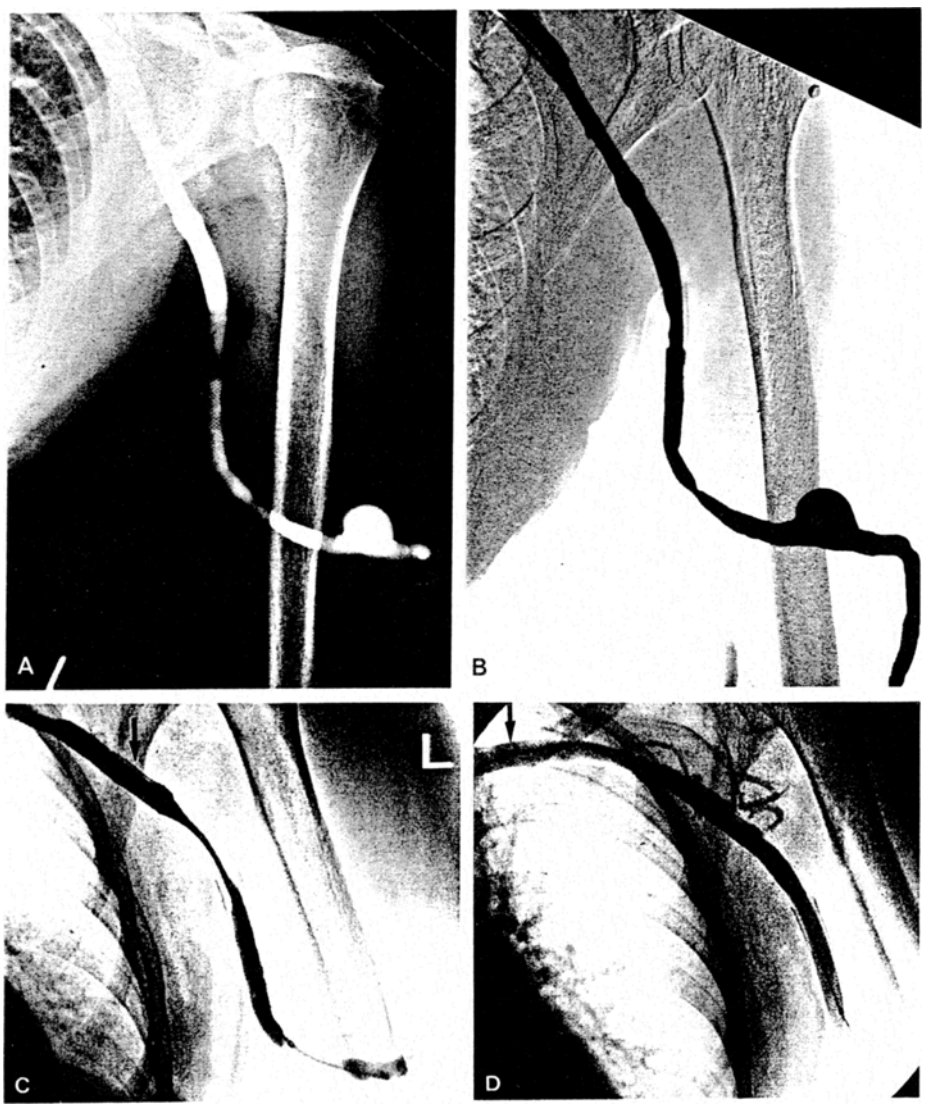


Fig. 6. A 34-year-old female on hemodialysis with stenosis at the proximal anastomosis of a xenograft to the basilic vein. This stenosis had been dilated four times prior to stenting. **A** Recurrent stenosis 4 months after first Wallstent at the site of the previous anastomotic stricture between the graft and the basilic vein. There is an incidental graft aneurysm. **B** After dilatation with an 8 mm Gruntzig balloon catheter, the lumen is well restored. **C** The sixth recurrence 18 months after stenting. Note that the stenosis is now mainly at the distal end of the stent. An additional stent in the axillary vein (arrow) had to be placed 2 months earlier for a new proximal lesion. **D** After a second stent in the basilic vein there is now good patency. Also note a third stent placed in the subclavian vein 2 months earlier for a second new proximal lesion (arrow).

sue. However, the limitations of the technique were shown in one of our patients where a tight tumor stenosis of the cephalic-axillary region could not be sufficiently improved with stenting. Stent placement should never preclude a potentially necessary surgical procedure.

Stenoses after surgical venous reconstructions, surgical venous anastomoses, or treatment of a venous spur are other important indications for stent implantation in the venous system. Our 2 cases with long-term follow-up of now approximately 4 and 5 years show that late complications (i.e., symptomatic recurrent stenoses or occlusions of large caliber veins) are extremely unlikely. Therefore, we believe that patients with May-Thurner syndrome should primarily be treated by balloon dilatation combined with stent implantation instead of surgery. Our preliminary results are also encouraging in the region of the common femoral vein, a critical region for surgical reconstruction. So far, bending of the hip joint seems not to have any adverse effects when using a flexible stent.

Apart from strictures of the AV-anastomosis itself, stenoses along the venous outflow tract are the most common cause for dialysis shunt dysfunction [2, 14]. As for Cimino shunts, the stenoses are commonly found in the draining vein; in the case of shunt grafts, in the region of the proximal anastomosis. Furthermore, stenoses of the brachiocephalic veins are bothersome complications in hemodialysis shunts [10, 15–17]. Various possible causes for these lesions are discussed, such as damage of the vascular wall by catherization or central venous lines, turbulence from increased flow particularly in

the region of valves, and finally, abnormal function of platelets damaged by hemodialysis [17, 18]. Conventional balloon dilatation, even with high-pressure balloons, of all such venous lesions yields unsatisfactory long-term patency rates of 35–50% after 1 year and only 10–32% after 2 years [19]. Intimal hyperplasia and perivenous fibrosis are the main causes for these recurrent stenoses after angioplasty [3], and endoluminal prostheses have been used to improve the long-term results. However, our experience shows that in spite of mechanical support by the endoprosthesis, restenosis secondary to intimal hyperplasia remains a continuing problem. The need for repeated PTA or percutaneous artherectomy [20] as secondary interventions to preserve shunt function are almost the rule in case of peripheral venous lesions. However, the intervals between repeated PTA can usually be doubled or tripled after stent implantation as compared with PTA alone. The time span until intimal hyperplasia became manifest in the stented region varied from 4 to 10 months in our patients. It is noteworthy that these recurrent stenoses could usually be dilated easily and a better lumen was achieved when compared with the immediate poststenting result. Careful evaluation of the whole venous outflow tract is always necessary if clinical signs of reduced fistula function occur, as 2 of our patients illustrate. Proximal lesions at a great distance from the primary stent placement may develop. The central lesions in the region of the brachiocephalic vein seem less prone to restenosis than peripheral stenoses. However, new lesions adjacent to the stented segments may develop as well.

Though repeated interventions may be necessary, we believe that stenting of complicated shunt-related lesions in dialysis patients provides a significant therapeutic improvement as it prolongs shunt function without surgical intervention. Furthermore, the secondary interventions are usually successful and technically simple. Such stent procedures are indicated both for patients in a transplant program as well as for patients on lifelong hemodialysis. However, we use stents only for patients in whom angioplasty is primarily unsuccessful or for those requiring repeat angioplasty in decreasing intervals (less than 2 months). Endoprostheses should not be used in patients whose AV-shunts have never functioned properly or whose available shunt segment for venous puncture after stent placement would be too short, as the stented segment can no longer be used for venous puncture.

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