

Patency of infrainguinal bypass grafts after endovascular treatment of distal anastomotic steno-obstructive lesions

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Aim. Thrombosis is the most common complication of infrainguinal bypass graft procedures, the main factors being myointimal hyperplasia at the level of the distal anastomosis or the development of atherosclerosis. Owing to the complexity of redo surgery at this site, endovascular techniques are indicated for the repair of these lesions.

Methods. From January 1999 to June 2001, a total of 19 patients received 20 combined interventions of infrainguinal bypass thrombectomy and endovascular treatment of distal anastomotic single obstructive lesions (1.5-2 cm in length). Percutaneous transluminal angioplasty (PTA) was performed in 11 alloplastic femoro-popliteal bypass grafts and in 9 saphenous vein below-knee bypass grafts (6 femoro-popliteal, 2 femoro-posterior tibial, 1 femoro-peroneal bypass graft). Stenting was performed in 8 cases of femoro-popliteal bypass (72.7%) and in 6 cases of below-knee bypass (66.6%).

Results. The Kaplan-Meier test showed that the early and 36-month patency rates were 100% and 61.1%, respectively, with a 95% limb salvage rate at 36 months (only 1 thigh amputation 6 months after combined thrombectomy and stenting of a femoro-peroneal bypass). In the above-knee and below-knee districts, 36-month patency rates were 55.5% and 66.6%, respectively ($p < 0.7$ NS). Moreover, 2 cases (25%) of above-knee and 3 (50%) of below-knee bypass obstruction were observed after stenting of the distal anastomosis ($p < 0.7$ NS). The time period between the primary and secondary operations ranged from 2 to 84 months (average, 13.8 months).

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Conclusion. Primary patency and limb salvage rates showed that, because of the technical difficulties in operating on an area with a high component of scar tissue, endovascular procedures for the treatment of small, single anastomotic stenoses associated with infrainguinal bypass thrombosis may be considered an effective alternative to conventional redo surgery.

KEY WORDS: Graft occlusion, vascular - Angioplasty, balloon - Stents.

Thrombosis is the most frequent complication leading to infrainguinal bypass failure. Failure usually occurs within 2 years due to the development of myointimal hyperplasia at the distal anastomotic site, whereas the main cause of later failure (after more than 2 years) is correlated with the development of atherosclerosis.¹ Bypass-related thrombosis leads to the recurrence of severe intermittent claudication; in more severe cases, major ischemia may develop, with an increased risk of limb loss.

Conventional surgical procedures for the repair of distal anastomotic lesions include venous or alloplastic patch angioplasty or implantation of a short graft with a new anastomosis created distal to the first or complete replacement of the bypass. Revision of the distal anastomosis is, however, complex and

technically difficult in so far as it is performed on areas with a high component of scar tissue.

Mini-invasive endovascular techniques for the revision of anastomotic stenoses offer the advantage of not requiring surgical resection of the perianastomotic segment, thus reducing the complexity and duration of the intervention, and limiting perioperative complications and anesthesiologic risk as well.

In this study, we analyzed the results of endovascular treatment of distal anastomotic stenosis following infrainguinal bypass interventions performed between January 1999 and June 2001.

Materials and methods

At our institute, from January 1999 to June 2001, we performed 20 endovascular treatments of distal anastomotic stenosis following infrainguinal bypass, in 18 of which after thrombectomy, in 19 patients (15 men [79%] and 4 women [21%]; age range, 55-81 years; mean age, 66 years).

Clinically, revascularization was performed in 18 patients (90%) with acute or subacute ischemia of the lower limb (obstructed bypass) and in 2 (10%) with Fontaine stage II B arteriopathy (patent bypass). The mean time period between the first intervention and the revision was 13.8 months (range, 2-84 months).

Percutaneous transluminal angioplasty (PTA) of the distal anastomosis was carried out in 11 patients (55%) using a femoro-popliteal alloplastic bypass and in 9 (45%) a below-knee bypass with an autogenous saphenous vein (6 low femoro-popliteal, 2 posterior femoro-tibial, 1 femoro-peroneal bypass). Because residual stenosis greater than 20% was demonstrated at control angiography, a stent was placed in 8 (72.7%) cases of femoro-popliteal and in 6 (66.6%) of below-knee bypass grafts.

After administration of local anesthesia, a short segment of the bypass was isolated at its opening with a small transverse incision and the thrombus was removed by thrombectomy using a Fogarty catheter in 18 cases (90%). In 2 cases (10%), the hemodynamically significant stenosing lesion, which had been diagnosed prior to graft failure, was dilated. The stenosing lesion (1.5 cm to 2 cm in length) was dilated using a balloon catheter (2.5 mm to 6 mm in diameter). Dilatation was maintained for 45-60 seconds at a pressure between 10 atm and 15 atm, after which 14 self-expanding stents

were placed (12 Memotherm, Bard, Miami, USA; 2 Symphony, Medi-tech, Boston Scientific, Watertown, USA) to repair suboptimal results, dissection or residual stenosis in 14 patients (70%).

The patients then entered a follow-up period, during which they underwent clinical examination and echo Doppler ultrasonography at 3, 6, 12 and 24 months in order to assess maintenance of vessel patency and limb salvage.

The results were entered into a database; statistical analyses were performed with the use of SPSS version 6.1.2 for Windows. Reported data were analyzed using the χ^2 test, Student's *t*-test and actuarial curves constructed according to the Kaplan-Meier method.

Results

The cumulative patency rate in the early postoperative period following all endovascular infrainguinal bypass interventions was 100% (20 out of 20); whereas at 3 years the rates calculated by the actuarial curve method dropped to 61.6% (12 out of 20). Primary patency at 36 months was 54.5% (6 out of 11) in the above-knee and 66.6% (6 out of 9) in the below-knee segments ($p < 0.7$ NS) (Figure 1).

In the presence of a stent over the distal anastomosis, bypass occlusion recurred in 2 cases (25%) in the above-knee and in 3 (50%) in the below-knee segments ($p < 0.7$ NS).

Vessel patency after interventions with PTA alone was 50% (3 out of 6) compared with a 64% patency rate (9 out of 14) in those combined with stent placement ($p < 0.7$), whereas above-knee and below-knee stent patency was 75% (6 out of 8) and 50% (3 out of 6), respectively (Figure 2).

Stratification of patency rates of graft repair by time to secondary intervention (less than or greater than 3 months after the first operation) at 36 months was 37.5% (3 out of 8) and 75% (9 out of 12), respectively ($p < 0.05$) (Figure 3).

Analysis of the results of limb salvage showed a cumulative rate of 98.3% in the early postoperative period and 83.3% at 3 years (Figure 4). Only one thigh amputation was performed 6 months following thrombectomy and stenting of a femoro-peroneal bypass. No general complications or perioperative deaths were reported for our case series.

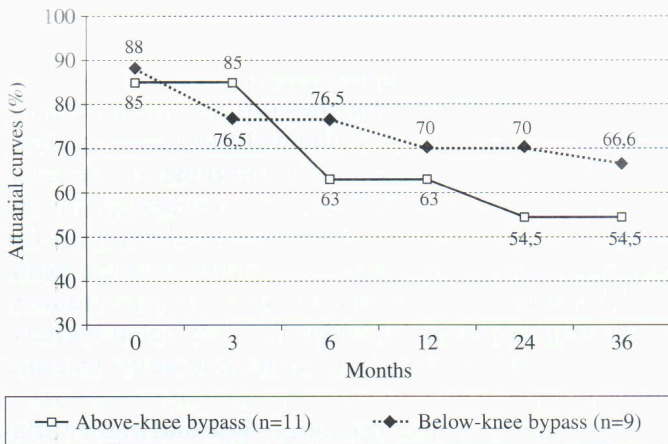


Figure 1.—Actuarial curves: cumulative patency (Kaplan-Meyer method).

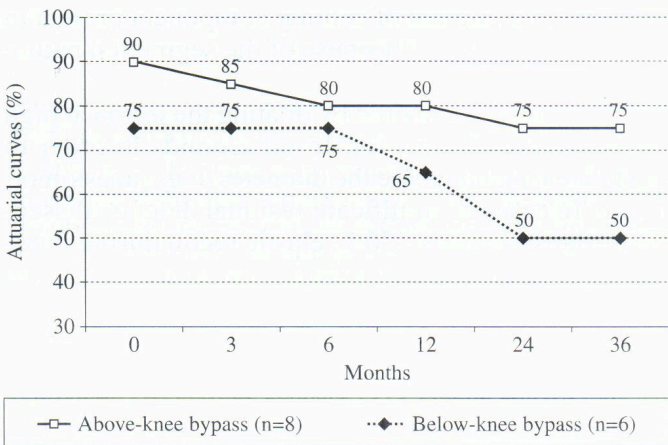


Figure 2.—Actuarial curves of patency with stents.

Discussion

The widespread use of angioplasty has led to the development of revision techniques for the repair of lesions that may jeopardize graft patency and salvage of the revascularized limb. The critical element is early diagnosis for the prophylactic treatment of stenosing lesions at the anastomotic site or along the graft.¹

The natural history of anastomotic stenosis is associated with a threefold risk of graft occlusion, and several studies have shown a significantly higher secondary patency rate in prophylactically treated cases than in those treated after stent thrombosis.^{2,3} However, indications for the use of endovascular techniques as an alternative to conventional “open” revascularization sur-

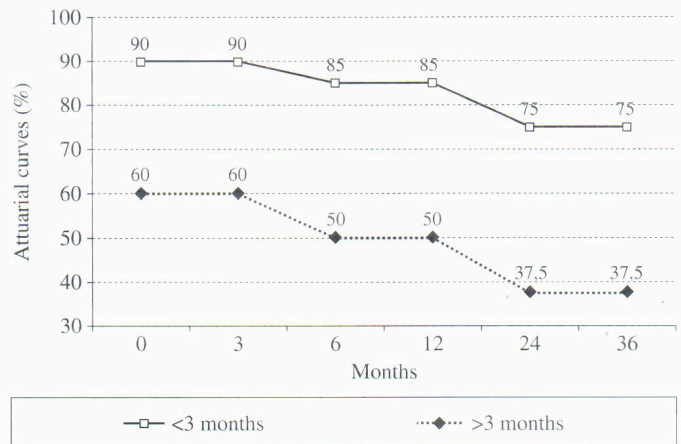


Figure 3.—Patency in relation to time since primary intervention.



Figure 4.—Limb salvage.

gery remain controversial due to the conflicting results that various studies have reported (Table I).

Advocates of surgical treatment have cited the higher incidence of restenosis after PTA compared with surgery, although endovascular procedures have been demonstrated to be more easily repeatable in general and well tolerated by the patient (Table II).

As observed in a previous study we conducted,⁹ recent clinical studies^{2,3} have shown that the determination of optimal selection criteria may contribute to a more accurate selection of patients eligible for endovascular repair and to better results compared with those of earlier studies reported in the literature. Stenotic focal lesions that develop starting 3 months after an operation, measuring 1.5-2.5 cm in length, and in saphenous vein prostheses with a diameter greater than 3.5 mm are associated with better long-

TABLE I. — Endovascular surgery of bypass-related distal anastomosis.

Author	Year	Follow up (years)	Patency (%)
Perler ⁴	1989	3	27
Whittemore ⁵	1991	3	23-28*
Berkowitz ⁶	1992	5	43**
Sanchez ⁷	1994	2	17-66*
Houghton ³	1997	1	82
Rua ⁸	1998	2	23
Avino ²	1999	2	63**

> 1.5 cm; * < 1.5 cm
** assisted patency rate

TABLE II. — Patency after endovascular versus conventional surgery.

Author	Year	PTA (%)	Surgery (%)
Perler ⁴	1989	27 (2 years)	62 (5 years)
Berkowitz ⁶	1992	43 (5 years)	62* (5 years)
Avino ²	1999	63 (2 years)	63* (2 years)

** assisted patency rate

term patency rates. Moreover, in a study conducted by Avino and co-workers,² these results were comparable with those achieved with conventional surgery.

We believe that the indication defined by these criteria justifies the cumulative patency rate of 61.1% shown in our clinical series. Moreover, this result is very similar to that reported in other case series in which single, small anastomotic stenoses were treated.^{2, 3, 7}

In addition to the focal nature of the treated lesion, the time period between the first and the secondary interventions has proved to be important, as confirmed by our observation that among the predictive factors for long-term patency considered, a period longer than 3 months was the only statistically significant element (Figure 3). In fact, early lesions are biologically more active and are more likely to recur if treated with PTA.² No significance was found for above- or below-knee location of the graft-related distal anastomosis, location of the stent or type of stent.

Stenting in this type of pathology remains disputed and has not yet been coded. Its use has been applied chiefly to the repair of residual stenosis and has yielded better long-term patency rates than PTA alone (64.2% and 50%, respectively), although this difference was not statistically significant given the small number of cases in the 2 groups considered.

The indication for stenting, like that for balloon catheter dilatation, is particularly influenced by the anatomic-pathologic characteristics of the anastomotic stenoses. Histologically, they differ from atherosclerotic lesions detectable on the walls of native arteries. They have a high fibrocellular component correlated with hyperplasia of the smooth muscle cells in the denuded intima, with progressive thickening of the intima, cellular proliferation and alteration of the extracellular matrix.^{6, 7, 10} As the lesion grows, the stenosis extends in length and the fibrotic component increases, with a minor tendency of the plaque to fracture after dilation.¹⁰

This requires longer operation time and higher dilation pressure, as elastic recoil of the stenosis may occur more easily, whereas early dilation of anastomotic stenoses (beyond the 3-month cut off) is easier because of the greater amount of cellular component present in the lesion matrix and because of the segmental nature of the lesion.^{6, 7}

The stenosis is repaired by dilating the lesion at high pressure (10-15 atm) for 45-60 seconds in order to modulate it and increase the diameter of the anastomotic site. In cases of significant residual defects (dissections, flaps, stenosis >20%, elastic recoil during intraoperative angiography), a stent is implanted in the site of the lesion.

Although no consensus exists for an optimum procedure of anastomotic stenosis repair,² in light of the results reported above, endovascular surgery may also have a place in this field. While endovascular procedures performed as redo surgery may be less effective than primary procedures in terms of patency, the results they produce can still be considered adequate, particularly if evaluated in terms of limb salvage in a population with an elevated risk of amputation.

The technical difficulties that can be encountered during conventional secondary surgical procedures seem to offer another reason arguing in favor of endovascular treatment of anastomotic stenoses, for it allows the prevention of causing iatrogenic arterial, venous and/or nerve injury during the phases of repeated isolation of an area with a high scar tissue component.

Endovascular surgery should, therefore, be considered the treatment of choice for anastomotic stenosis in cases of eligible lesions in so far as it is simple, repeatable, and less invasive than conventional vascular surgery, where failure of the attempt does not preclude an eventual conversion to surgery.

Conclusions

Infrainguinal bypass-related distal anastomotic steno-occlusive lesions should be treated prophylactically using endovascular repair even in asymptomatic patients. In cases of diagnosed graft thrombosis, the thrombus can be removed and the cause of graft failure located and the vessel dilated, with restoration of an adequate outflow, leading to satisfactory results in terms of patency and limb salvage.

The basic selection criteria comprise single, focal lesions, from 1.5 cm to 2.5 cm in length, that have developed 3 months after the first operation; if a vein graft was placed, the lesion should be at least 3.5 mm in diameter. In all other cases, surgical treatment is recommended.

Riassunto

Pervietà dei bypass sottoinguinali dopo trattamento endovascolare delle lesioni steno-ostruttive dell'anastomosi distale

Obiettivo. La complicità tardiva più frequente degli interventi di bypass sottoinguinale è rappresentata dalla trombosi, dovuta, soprattutto, all'iperplasia miointimale o all'evoluzione della malattia aterosclerotica a livello dell'anastomosi distale. Il trattamento endovascolare può costituire l'indicazione di prima scelta di queste lesioni, in considerazione soprattutto della difficoltà che presentano i reinterventi in tale sede.

Metodi. Nel periodo gennaio 1999-giugno 2001, 19 pazienti sono stati sottoposti a 20 interventi di trombectomia di bypass sottoinguinale e a trattamento endovascolare di lesioni singole steno-occlusive dell'anastomosi distale con lunghezza compresa tra 1,5-2 cm. L'angioplastica transluminale percutanea dell'anastomosi distale è stata eseguita in 11 casi di bypass alloplastico femoro-popliteo e in 9 casi di bypass sottogenicolare in vena safena autologa (6 bypass femoropoplitea bassa; 2 bypass femoro-tibiale posteriore; 1 bypass femoro-peroniero). Uno stent è stato posizionato in 8 casi di bypass femoro-popliteo (72,7%) e in 6 casi di bypass sottogenicolare (66,6%). Il tempo intercorso dall'intervento primario è stato di 13,8 mesi (2-84 mesi).

Risultati. L'analisi statistica calcolata con test di Kaplan-Meyer ha evidenziato una pervietà totale immediata del 100% e del 61,1% a 36 mesi, con salvataggio dell'arto del 95% a 36 mesi (è stata eseguita una sola amputazione di

coscia 6 mesi dopo intervento di trombectomia e stenting di bypass femoro-peroniero). In particolare la pervietà primaria a 36 mesi risulta del 55,5% nel distretto sopra-genicolare e del 66,6% nel distretto sottogenicolare ($p < 0,7\%$ NS). È stata evidenziata, inoltre, la reocclusione del bypass dopo stenting dell'anastomosi distale in 2 casi (25%) nel distretto sopra-genicolare e in 3 casi (50%) nel distretto sottogenicolare ($p < 0,7\%$ NS).

Conclusioni. Alla luce dei risultati di pervietà primaria e di salvataggio dell'arto, le procedure endovascolari eseguite come trattamento delle lesioni anastomotiche singole e di breve estensione causata da trombosi dei bypass sottoinguinali possono rappresentare una valida alternativa alle procedure chirurgiche tradizionali di *redo surgery* in considerazione delle difficoltà tecniche che queste comportano in aree a elevata componente cicatriziale.

PAROLE CHIAVE: Chirurgia endovascolare - Bypass femoro-popliteo - Bypass femoro-distali - Iperplasia anastomotica - Stenosi anastomotica - Angioplastica percutanea - Stent.

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