

Chronic Critical Leg Ischaemia Must Include Leg Ulcers

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Objectives: In a previous series on conservative treatment in patients with leg ulcers and severe arterial occlusive disease (systolic digital blood pressure (SDBP) < 30 mmHg) a 70% risk of leg amputation and a negligible potential for ulcerhealing was found. This series assess the efficacy of arterial reconstruction in such patients.

Design: Retrospective study of consecutive patients in a department of vascular surgery and of dermatology in cooperation with the wound healing center.

Material and Methods: Thirty-nine patients with 42 ulcerated legs underwent arterial revascularisation. 88% of the procedures were distal to the inguinal ligament.

Main results: One patient died postoperatively (3%). Seven (18%) had wound complications, but none had graft infections. After 1 year the cumulative secondary patency was 90%, ulcer healing 70% and the limb salvage 90%. Thus only four legs (10%) had been amputated.

Conclusions: Arterial revascularisation for leg ulcers is indicated when conservative treatment fails. Legs with ulceration and SDBP < 30 mmHg should be included in the concept of chronic critical ischaemia.

Key Words: Arterial reconstruction; Critical ischaemia; Leg ulcer.

Introduction

In Danish departments of Dermatology about 25% of the in patient capacity is occupied by patients with chronic leg ulcers.¹ About 20% of leg ulcer patients suffer occlusive arterial disease and arterial insufficiency is probably the dominant factor in at least half of these cases.^{2,3} In a recent report from this hospital⁴ it was documented that in severe ischaemia (systolic digital blood pressure (SDBP) < 30 mm Hg), the risk of amputation within one year was almost 70% and the rate of ulcerhealing or improvement only 27%. On the basis of these results arterial reconstruction is now considered in such cases and the present report documents the results.

Material and Methods

In a 1.5 year period (1st January 1991 to 30th June

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1992) 39 consecutive patients with 42 ulcerated legs were treated with arterial reconstruction or angioplasty. There were 24 women and 15 men; the median age was 74 years (range 70–81 years). Fifteen patients were diabetics. The patients were referred from the department of Dermatology or from general practitioners. The median diameter of the ulcers was 6 cm (1–15 cm). The median duration of ulceration was 5.6 months (4–12 months) for 35 of the patients. In four cases recurrent ulcers had been present for many years. Conservative treatment including control of oedema with diuretics, bandages and regular wound dressing had been given in all cases for 2 to 6 months (median 3.5 months) prior to arterial revascularisation. The indication for surgical intervention was either deterioration of the ulcer or no response to conservative treatment and in most patients opiates for severe pain were required.

The systolic ankle, blood pressure (SABP) and the systolic digital blood pressure (SDBP) of the hallux were measured by strain gauge technique.⁵ SABP could be measured in only 32 patients due to the painful ulcers, whereas the SDBP could be measured in all patients (Table 1).

Table 1. Preoperative and one month postoperative distal systolic blood pressure values in 35 limbs with ischaemic leg ulcers and patent grafts (median and range)

	Systolic blood pressure		
	Digital (mmHg)	Ankle (mmHg)	Ankle/arm index (%)
Preoperative	20 (10-30)	50 (20-77)	33 (13-59)
Postoperative	50 (30-80)	100 (60-115)	77 (43-100)

Statistics

The cumulative patency of arterial reconstructions (secondary patency) and limb salvage is presented using Kaplan Meyer analysis.

Results

It is noteworthy that nearly 88% of the revascularisation procedures were distal to the inguinal ligament (Table 2). In addition to these primary procedures 5 redo procedures were required. Four patients died during the follow-up period. One patient died from pulmonary embolism 3 days after a PTA, while the others died after 1, 4, and 7 months. One of these died after an amputation for graft occlusion. The other died from causes not associated with the arterial reconstructions.

Besides one death from pulmonary embolism, a non-lethal myocardial infarction was encountered in another patient. Two seromas in the groin and two deep wound infections were treated surgically. Three cases of superficial skin infection were treated with antibiotics.

The primary patency was 81% after 12 months and 71% after 18 months. In three patients occluded reconstructions were treated with a redo procedure. One patient had two redo procedures to secure

Table 2. Forty-seven vascular procedures performed on 39 patients with ischaemic leg ulcers

Above inguinal ligament:			
Angioplasty			1
Bypass			4
Below inguinal ligament:			
Angioplasty			8
Femoropopliteal bypass:	Supragenicular	PTFE	10
		Dacron	1
	Infragenicular	<i>in situ</i>	3
		PTFE	2
		<i>in situ</i>	5
Infra-popliteal bypass		<i>in situ</i>	7
Combined:			1
Re-do:			5

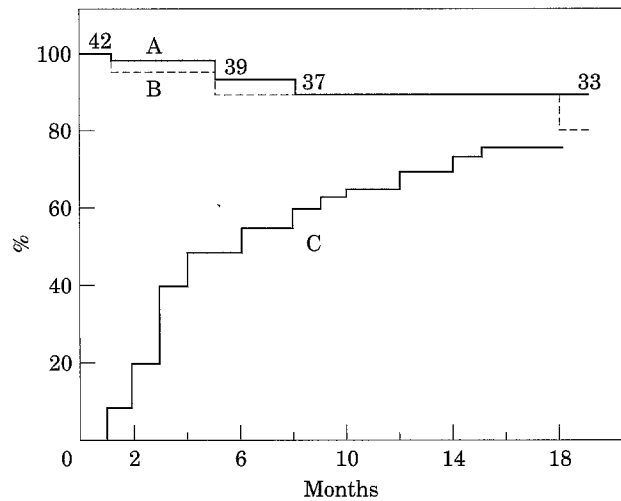


Fig. 1. (A) Cumulative limb salvage with numbers of limbs at risk; (B) secondary graft patency of arterial reconstructive procedures and (C) rate of ulcer healing.

patency. Thus the secondary patency rates were 90% and 81% after 12 and 18 months respectively (Fig. 1). One leg was amputated within 1 week due to progressive gangrene caused by graft occlusion. Two legs were amputated after 4 months and one leg after 7 months. Limb salvage was thus 90% at 18 months (Fig. 1).

Fifty-five percent of the ulcers had healed 6 months after the operation. The healing rate increased to 70% after 12 months and 75% after 18 months (Fig. 1). In three cases the ulcerations did not respond to revascularisation. In three other cases ulceration recurred within 1 year due to graft occlusion. In two of these cases healing was again achieved by new arterial reconstructions. Thus 10% had non healing ulcers at the time of evaluation.

Thirty-six percent of the vascular procedures were made in diabetic patients. The pre- and postoperative SABP and the SDBP corresponded to those of the non-diabetics. The healing rate of the ulcers after 12 month was 80% in the non-diabetic and 64% in the diabetic group (Fig. 2). One leg amputation occurred in the non-diabetic group and three in the diabetic group corresponding with limb salvage rates of 96% and 79% after 18 months. Although the results were better in the non-diabetic group the differences were not statistically significant (log rank test). Three out of the five wound infections were in diabetic patients.

Discussion

Although it is generally accepted that arterial reconstruction is required in leg ulcer patients with severe

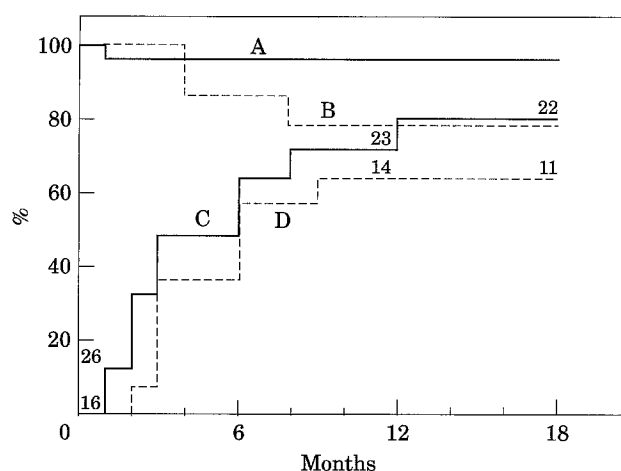


Fig. 2. (A) Cumulative limb salvage in non diabetic ulcerated legs; and (B) in diabetic ulcerated legs. (C) Cumulative ulcerhealing rate in non diabetic and (D) in diabetic ulcerated legs.

occlusive arterial disease, information on specific indications and results is not available. Our previous finding of a 67% risk of amputation⁴ with SDBP < 30 mmHg has recently been confirmed by Nielsen *et al.*^{6,7}, who found a 67% risk of amputation in leg ulcers at SDBP < 20 mmHg. Moreover, SDBP values above which there was no risk of amputation were 30 and 35 mmHg respectively in these two studies. The main result of the present study is the low rate of amputation after arterial revascularisation, i.e. only 10%. This comparison with historical data should, however, be discussed in detail.

A high rate of amputation associated with low digital pressures were found in two consecutive series on conservative ulcer therapy.^{4,6} The present series is consecutive regarding patients suitable for arterial intervention. Although not directly comparable the age distribution was about equal in the three series in question, i.e. the median age varied between 74 and 77 years. More important is that revascularisation was performed only after a trial of conservative ulcer treatment of at least 2 months. Only patients with deterioration of the ulcer or patients with severe pain in an ulcer that did not respond to the non-invasive treatment had revascularisations. Thus only limbs threatened by amputation were treated invasively.

Arterial reconstruction was postponed not only to exclude patients with ulcers that healed by conservative means but also due to the increased perioperative risk of infection. Taking into consideration the close proximity between the leg ulcers and the surgical incisions, wound complications were, however, few and there were no graft infections. The mortality during the first year was 10% after surgery as compared to 48%⁴ and 11%⁶ in the series on

conservative treatment. The last argument speaking in favour of arterial revascularisation is that 26% of the ulcers healed on conservative treatment⁴ but 70% healed after revascularisation. This last figure compares with healing in non-ischaemic leg ulcers.⁸

There are a number of reasons for including the low pressure leg ulcer in the concept of critical ischaemia, which at present relates to the foot with rest pain and/or gangrene with SDBP \leq 30 mmHg or SABP \leq 50 mmHg.⁹ The risk of a lower limb amputation due to these leg ulcers compares with the risk in foot lesions in the same low pressure zone.¹⁰⁻¹⁴ As in patients with critical ischaemia of the foot,¹⁵ the low pressure leg ulcer patients require infrainguinal revascularisation in about 85% of the cases suggesting that the occlusive pattern of the arteries is much the same. Finally limb salvage after arterial reconstruction in both groups increases to about 90%.

In two cases, where the ulcers treated with successful revascularisation did not heal the clinical findings suggested that chronic venous disease was the major pathogenetic factor and that the arterial occlusive disease had developed later. The elimination of arterial insufficiency prevented amputation but did not influence the healing of the chronic venous ulcers.

In conclusion leg ulcer patients should be examined for arterial occlusive disease. SDBP \leq 30 mmHg indicates "critical ischaemia" and arterial revascularisation should be performed when conventional ulcer treatment is not efficient. We feel that the time for randomisation into conservative treatment versus arterial intervention has passed for this low pressure group. However, controlled series are still required for establishing guidelines for treatment of leg ulcers with less severe arterial insufficiency.

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