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Healing of Ischaemic Tissue Lesions after Infrainguinal Bypass Surgery for Critical Leg Ischaemia

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Abstract *Objective:* To evaluate healing time of ischaemic tissue lesions, limb salvage and survival in patients suffering from critical limb ischaemia (CLI) with tissue loss.
Design: Prospective single centre cohort study.
Material and methods: Consecutive patients with CLI and tissue loss (Fontaine IV) (148 patients, 150 limbs) were followed prospectively for 1 year after infrainguinal bypass. Healing time of tissue lesions, graft patency, limb salvage, survival rates and the overall need for any type of surgical and endovascular procedure were analysed. Patient comorbidities were assessed by uni- and multivariate analysis to determine risk factors for adverse outcome.
Results: Complete tissue healing, including healing of ischaemic tissue lesions and surgical wounds, at 6 and 12 months after the infrainguinal bypass were respectively 40% and 75%. The median time to complete tissue healing was 190 days. Diabetes was the only significant risk factor which delayed tissue healing. Overall patency, limb salvage, survival and amputation-free survival rates were respectively at 12 months 80%, 81%, 73% and 63%. The clinically important endpoint amputation-free survival with completely healed wounds was attained in 50% of patients at 1 year.
Conclusion: Complete healing of ischemic tissue lesions is slow even after a successful infrainguinal bypass.

Introduction

Generally it is assumed that in critical limb ischaemia (CLI) the viability of the leg is threatened, unless some improvement of the arterial supply is undertaken. The risk of major amputation is greater in legs with ischaemic lesions (CLI Fontaine IV) than in legs with rest pain only (CLI Fontaine III).[1,2] As a majority of patients with CLI have multi-segmental

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arterial disease[3,4] and an increasing proportion are diabetics whose arterial disease affects the infrapopliteal arteries,[5] an infrainguinal bypass operation is by far the most common surgical operation performed to save a leg.[4]

The results of infrainguinal bypass surgery for critical leg ischaemia have been assessed traditionally by graft patency, limb salvage and mortality rates. These measures underestimate patient morbidity and fail to consider the entire spectrum of treatments required to heal the tissue lesions and achieve limb salvage. As most of the patients suffering from CLI are elderly and have several comorbidities,[6] they often experience setbacks that can require additional treatment.[7] The aim of this study was to evaluate in how many cases complete healing of tissue lesions is achieved within 1 year after the infrainguinal bypass for CLI Fontaine IV (ulcer, gangrene) and to evaluate factors affecting the tissue healing, graft patency, limb salvage and survival. In addition we wanted to quantify the overall need for any type of surgical and endovascular procedure.

Material and Methods

The study plan was to prospectively collect 1-year follow-up data from 150 consecutive primary infrainguinal bypass procedures for critically ischaemic legs with tissue loss (CLI Fontaine IV). The bypass operations were performed between January 2005 and July 2006 in Helsinki University Central Hospital (HUCH). HUCH serves as the academic vascular centre for southern Finland with a catchment area of 1.4 million inhabitants.

An ABI $\leq$0.50 or a toe systolic pressure $\leq$30 mmHg were assumed as diagnostic criteria for critical leg ischaemia. In patients with large tissue defects, previous toe amputation or with medial sclerosis, the diagnosis of CLI was made by clinical signs, symptoms and angiographically verified arterial occlusions in the leg.

The study cohort consisted of 86 men (58%) and 62 women aged 44–95 years (median 76 years). Two patients with bilateral disease had bilateral reconstructions. The ischaemic lesion was ulcer in 81 legs (54%) and gangrene in 69 legs. Median pre-operative ankle-brachial index (ABI) was 0.43 (range 0–2.30). Comorbidities were common and half the patients had diabetes (Table 1).

Patients with previous infrainguinal bypass in the ischaemic leg were excluded. Two patients had been treated with a supra-inguinal reconstruction and one patient with an infra-inguinal percutaneous angioplasty (PTA) for claudication 3 years earlier. Unsuccessful PTA and recanalisation had been performed in 22 legs (15%) to treat CLI prior to the infrainguinal bypass. All patients underwent pre-operative angiography to evaluate the extent of arterial occlusions and to select appropriate inflow and outflow vessels. 15 legs (10%) required an inflow procedure before the infrainguinal reconstruction (Table 4). Vein grafts were used in 139 infrainguinal reconstructions (93%), 11 had prosthetic grafts. *In situ* saphenous graft vein grafts were used most frequently. The most frequent inflow site for the proximal anastomosis of the infrainguinal bypass was the common femoral artery, whereas the dorsal pedal artery was selected most commonly as the outflow artery (Table 2). Two bypasses were sequential reconstructions. The median immediate postoperative ABI was 0.98 (range 0.33–3.12). Postoperatively subcutaneous low molecular weight heparin 5000 IU twice daily was administered for 1–2 weeks and life-long aspirin (100 mg/day) was recommended, unless contraindicated. The patients were enrolled in the normal graft surveillance programme at our vascular outpatient clinic at 1 month (range 3 weeks-2 months), 6 months (range 5–7 months) and 12 months (range 11–13 months) after bypass surgery. In addition to duplex surveillance of the graft the routine follow-up included clinical assessment of the foot, ABI and toe pressure measurement. When necessary, further interventions for failing grafts or wounds were performed.

We defined tissue healing time as the time needed to achieve complete epithelialization of the ischaemic lesions and surgical wounds. Local wound care was chosen, depending on the character of each lesion. Major amputations were regarded as non-healed tissue lesions. Patients with non-healed tissue lesions 1 month before death were never considered to have tissue healing. The criterion for patency was either verification of graft flow by duplex

Table 1 Patient characteristics

Condition	Proportion	%
Male	86/148	58
Age >80 years	49/148	33
Hyperlipidemia	69/148	46
Hypertension	106/148	72
Coronary artery disease	100/148	68
Chronic pulmonary disease	24/148	16
Cerebrovascular disease	26/148	18
Diabetes mellitus	74/148	50
ESRD[a] with dialysis	11/148	7
BMI[b] > 25	63/142[c]	44[c]
Gangrene	69/150	46

[a] end stage renal disease.
[b] body mass index.
[c] the information was incomplete due to missing data.

Table 2 Details of the 150 infrainguinal bypasses

Artery	$n = 150$	%
Inflow		
Common femoral artery	104	69
Deep femoral artery	5	3
Superficial femoral artery	13	9
Proximal popliteal artery	6	4
Distal popliteal artery	22	15
Outflow		
Proximal popliteal artery	16	11
Distal popliteal artery	32	21
Tibioperoneal trunk	1	1
Anterior tibial artery	23	15
Posterior tibial artery	25	17
Peroneal artery	21	14
Dorsal pedal artery	30	20
Plantar artery	2	1