AGGRESSIVE REVASCULARIZATION IN PATIENTS WITH CRITICAL LOWER LIMBS ISCHEMIA

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Background: This study was conducted to conduct an audit of our policy of aggressive arterial reconstruction in patients with critical lower limb ischemia, so as to determine the success in treatment of these cases in terms of limb salvage and patient survival. **Methods:** This study was carried out at department of general and vascular Surgery, Combined Military Hospital Rawalpindi from January 1995 to January 2000. A total of 114 cases were studied. All patients were admitted for assessment of an ischemic leg. Pre operative angiography was routinely performed. All patients underwent definitive treatment (bypass surgery, amputation and lumber sympathectomy) within three days of admission. Pre operative risk factors including age, sex, pre-existing diabetes mellitus, presenting symptoms, ankle systolic pressure were evaluated, with their effect on limb salvage and patient survival. **Results:** Of the 114 cases included 102 (89.5%) were males. Forty-six patients (40.3%) were diabetic. Revascularization was attempted in 76 limbs, 61 (80.3%) underwent femoropopliteal bypass and 15 (19.7%) underwent femorodistal bypass. Twenty patients (17.5%) with Berger's disease, of the 114 cases included, were treated by lumbar sympathectomy. Eighteen limbs were beyond salvage necessitating amputation. Risk factors had no effect on limb salvage or mortality. Overall mortality was 4% and over all 30-day graft patency rate was 77.7%. One-year graft patency rate was 62.5%. **Conclusion:** By pursuing an aggressive policy of revascularization, good results can be obtained in terms of limb salvage and survival rates.

Key Words: Critical ischemia, femoropopliteal bypass, amputation, saphenous vein.

INTRODUCTION

The optimal methods of diagnosis, assessment and treatment of patients with severe leg ischemia remain controversial. Established treatment options are amputation or arterial reconstruction. Advances in surgical and anesthetic techniques allow reconstruction to be offered to an increasing proportion of patients, but it is not yet universally accepted that limb salvage surgery should be attempted on all patients with critical leg ischemia.[1] The overall outcome of these patients remains poorly documented and the treatment of severe leg ischemia may be associated with high rates of perioperative mortality and limb loss[2], which suggests that patient selection for different forms of treatment is important. This study examined the treatment of patients with critical leg ischemia. The success of treatment in terms of limb salvage and patient survival is presented with an analysis of the effects of preoperative risk factors on outcome to identify subgroups of patients at high risk. We found that the outcome could not be reliably predicted by preoperative assessment. Therefore, a selective approach to reconstructions may deny limb salvage to some patients. This unit employed a policy of aggressive arterial reconstruction, attempting bypass surgery whenever feasible.

This retrospective study was carried out to determine the success of an aggressive approach in treatment of these cases, in terms of limb salvage and patients' survival; an analysis of the effects of pre-operative risk factors on the outcome of surgery, in order to identify subgroups of patients at high risk; and to compare the results of our study with those of other series.

MATERIAL AND METHODS

A consecutive series of 114 patients with critical lower limb ischemia were studied. They were referred to a single consultant vascular surgeon at CMH Rawalpindi over a five-year period, from January 1995 to January 2000.

The majority of the patients were admitted for assessment of an ischemia leg. Patients were also investigated for concomitant cardiac disease. Ankle-brachial pressure index measurements were performed using an 8-MHz Doppler velocimeter. Preoperative arteriography was routinely performed in all cases except in those whom the diagnosis was obvious, like patients with acute critical limb ischemia due to embolism or in whom further definitive treatment was not feasible due to coexisting medical ailments. All patients underwent definitive treatment within three days of admission.

The effects of the following preoperative risk factors on limb salvage and patient survival were evaluated: age (>65 years), sex, pre-existing diabetes mellitus, the presenting symptoms and the ankle systolic pressure at presentation (<50 mm of Hg).

Primary amputation was considered only if,

the weight-bearing area of the foot was necrotic, the patient was unable to walk again due to contractures across the joints and the patients were diabetic with palpable peripheral pulses and small vessel disease.

Although the conduit of first choice for most bypass procedures was the long saphenous vein, Polytetrafluoroethylene (PTFE) prosthesis was used for reconstruction procedures when the vein was not appropriate or not available. For femorodistal bypass, reversed long saphenous vein was the conduit of choice. Prosthetic graft was occasionally used for below knee reconstruction. Magnifying glasses (loupes) were used for construction of anastomoses, whereas the sutures used in these small arteries was 6/0 polypropylene. In most of the cases, general anesthesia was administered, but in some patients with severe cardiovascular or pulmonary disease, epidural or spinal anesthesia was employed.

The presentation (rest pain or tissue necrosis), treatment and outcome of all patients were documented including the effects of preoperative risk factors. The data was collected from the records of the operation theater, the ward and the out patient department. These records are routinely maintained in this hospital.

Graft patency was determined by a palpable pulse distal to the graft and by color and temperature comparison with the contra lateral limb at regular out patient follow-up visits.

Graft patency rates, the mortality rates and the effects of preoperative risk factors were analyzed by calculating percentages and ratios. Minimum and maximum follow up periods for the patients were 5 months and 26 months respectively. Mean follow up period was 12 months. .

RESULTS

Of the 114 cases included in this study, 102 were males with the median age 62 (range 34-77) years. Forty-six patients (40.3%) were diabetic. Ten patients (8.8%) presented with bilateral critical ischemia and seven (6.1%) returned with contra lateral limb ischemia after a successful reconstruction.

Ischemic rest pain alone was the presenting feature in 35 limbs (30.7%) and tissue necrosis (ulceration/gangrene) in 71 (62.3%). Eight cases (7%) presented with acute critical ischemia. The median ankle systolic pressure was 43(0-180) mm of Hg, 74 (64.9%) had an ankle systolic pressure of 50 mm of Hg or less.

Revascularization by arterial reconstructive surgery was attempted in 76 limbs (66.7%), of these 61(80.3%) were femoropopliteal and 15(19.7%) were femorodistal. Twenty patients (17.5%) with Berger's disease were treated by lumbar sympathectomy. Eighteen limbs (15.8%) were beyond salvage and were treated by amputation, out of these eight (44.4%) were above knee and ten (55.6%) below knee amputations (figure 1).

The effects of risk factors: age, sex, diabetes mellitus, presenting symptoms, and ankle systolic pressure on limb salvage were evaluated: To perform this analysis, patients and limbs were divided into two groups for each risk factor. Analysis showed that diabetes had no significant effect on limb salvage or mortality. Similarly, the other risk factors analyzed had no effect on limb salvage (Table 2 and 3).

Overall mortality rate was 4% and overall 30 days patency was 77.7%. Cumulative secondary patency rate was 62.75% (Table 4).

The level of reconstruction appeared to make some difference to graft survival, 30-days patency rates were comparable in patients undergoing femoropopliteal or femoro-crural bypass procedure, but the secondary rate was lower after femoro-crural bypass. In this group eight patients (53%) required intervention for primary graft failure. Thrombectomy alone was required to restore patency of the graft.

Of the 61 limbs that underwent femoropopliteal bypass, 4 (6.6%) required an alternative to long saphenous vein. The alternative graft used was Polytetrafluoroethylene (PTFE). Results obtained with these were poor as compared with those achieved with the long saphenous vein, with 30-day patency rate of 50% and a cumulative secondary patency rate of 40 %(Table 5).

Table 1: Fontaine Classification of Limb Ischemia

Stage 1	No clinical symptoms
Stage 2a	Intermittent claudication, well compensated
Stage 2b	Intermittent claudication, poorly compensated
Stage 3	Ischemic rest pain
Stage 4	Ischemic ulcer, gangrene

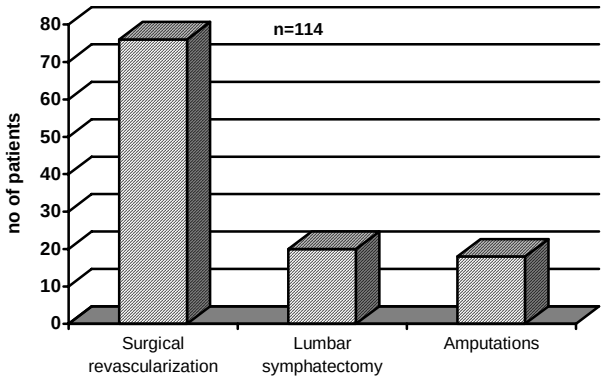

Figure 1: Method of Treatment

Table 2: Limb salvage in relation with age, sex and diabetes. Limb Salvage Rate (%)

n=114	1 Month	12 months
Age in years (no of patients)		
<65 (21)	80	76
>65 (93)	83	79
Sex (no of patients)		
Male (102)	87	78
Female(12)	62	60
Diabetes (no of patients)		
Yes (46)	79	76
No (68)	84	82

Table 3: Limb salvage in relation with ankle systolic pressure and presentation.

Limb Salvage Rate (%)

n=114	1 Month	12 months
Ankle systolic pressure (no of patients)		
<50 (74)	77	75
>50 (40)	80	78
Presentation (no of patients)		
Rest pain (35)	82	76
Tissue necrosis (71)	80	75
Trauma (8)	66	60

Table 4: Graft patency and mortality rates for patients undergoing arterial reconstruction for CLI

N=76	1 Month Patency%	12 months Patency%	Mortality %
Bypass procedure (no of patients)			
Femoropopliteal (61)	85.5	75.5	3.5
Femora-distal (15)	70	50	4.5
Total (76)	77.7	62.5	4

Table 5: Comparative patency rates of autologous vein and PTFE grafts in femoro-popliteal bypass

n=61	1 Month Patency%	12 months Patency%
Type of graft (no of patients)		
Long saphenous vein graft (61)	88	78
PTFE grafts (15)	50	40

DISCUSSION

In patients with severe leg ischemia, revascularization produces a superior quality of life than amputation.[3,4] The guidelines of the European Consensus Document were applied to all patients in this series.

Increasing number of surgical and endovascular interventions are being done,[4-6] but endovascular interventions were not employed in any of our patients. Similarly, the latest diagnostic techniques like color duplex imaging were not used in this study simply because of non-availability. Therefore, the results of this study cannot be compared fairly with those studies that utilize the above-mentioned diagnostic and treatment modalities. Patients undergoing surgical reconstructions yielded a 30-days graft patency rate of 77.7% (Table 4). Primary amputation was considered only in those patients who had extensive tissue necrosis of the weight bearing area of the foot, which included the heel, big toe, lateral aspect of the sole and the heads of the metatarsal bones; severe fixed contractures; and those with no prospect of walking again e.g. very old and debilitated patients who were already bed ridden or wheel chair dependant.

In this series, revascularization was attempted in 66.6% of patients with a primary amputation rate of 15.7%. The perioperative 30-day mortality in the present series was 4%. Previous studies have shown that age[7] and poor medical condition[8] should not be considered reasons for preferring amputation to revascularization. This policy has been adopted in this study as well. It is essential to treat preexisting risk factors such as diabetes, hypercoagulability, hyperlipidaemias and medical problems like pulmonary and cardiac disease before definitive therapy of severe limb ischemia.

Success of the bypass graft depends on the careful assessment of the inflow and distal run off vessels, meticulous surgical technique, and close monitoring of the graft in the postoperative period.

Tissue necrosis is often considered associated with a worse outcome than rest pain alone. In the joint vascular research group study conducted by Wolfe in 411 patients in 1984,[9,10] rest pain alone led to amputation in only 16% of limbs, whereas gangrene or ulceration resulted in a major amputation rate of 31%.[9] The result of the present study does not support this and similar findings in a subgroup of non-diabetic patients have been published.[11] Revascularization is therefore worthwhile despite extensive tissue necrosis provided the weight-bearing area of the foot remains unaffected. Diabetic patients are five times more likely to develop critical limb ischemia; they have a 10-15 times higher amputation rate with perioperative mortality rate of 25% and 3-year survival rate of 50%.[12] In Wolfe's series, diabetics were more likely to undergo amputation than non-diabetic patients.[9] The results of the present study suggest that with aggressive treatment, limb salvage and mortality rates are same for diabetic and non-diabetic patients. Some authors have claimed that patency in diabetics, with controlled disease are superior to those in patients without this disease[13] and have reported remarkably good patency rates in patients operated on for critical ischemia by reconstruction to the pedal arteries.

The patency rates for femorodistal bypass using long saphenous vein compare favorably with other series that have included patients operated for intermittent claudication.[14] A limb salvage program as described here is relatively economical and does not

require sophisticated radiological or technical support. In the present instance, it constitutes the special interest of a general surgeon.

The limb salvage methods may improve in the future by adopting advanced methods of assessment and treatment of ischemic limbs. These include; color duplex imaging, magnetic resonance imaging, percutaneous transluminal angioplasty, minimally invasive endovascular surgery and thrombolysis. Magnetic resonance imaging has the potential to provide anatomical as well as haemodynamic information and can thus reduce the reliance on contrast based invasive techniques. Percutaneous transluminal angioplasty can reduce the hospital stay of the patient but has specific indications and can only be used to treat a small percentage of patients. Minimally invasive endovascular surgery can reduce the trauma associated with open bypass procedures, as well as improving patency rates. As the role of thrombolysis is increasing, the role of Thrombectomy and embolectomy will diminish in acute type of limb ischemia.

CONCLUSION

By pursuing an aggressive policy of revascularization, satisfactory results can be obtained in terms of limb salvage and survival rates.

Age, sex, tissue, diabetes mellitus and ankle systolic pressure do not affect the outcome and should not be considered contraindication to revascularization. Patients with critical limb ischemia are usually old and have many concomitant ailments particularly ischemic heart disease. These patients cannot survive the trauma of amputation. Though the 12-month graft patency rate is 62.5%, arterial reconstruction still provides a good quality of life in their last days. Amputation, on the other hand, will make them an invalid at a stage in life when they cannot learn to survive with only one lower limb.

The limb salvage rates may improve in future by adopting advanced methods of assessment and treatment of ischemic limbs.

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