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Functional Ability in Patients with Critical Limb Ischaemia is Unaffected by Successful Revascularisation☆

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Abstract *Objective:* Patient- and society-oriented measures of outcome have a critical role in determining the effectiveness of any treatment in patients with critical limb ischaemia (CLI). In particular, the impact of an intervention on patient's dependency and functional performance is relevant but is largely unknown.

The aim of the study was to investigate whether the limitations encountered in the activities of daily living (ADLs) measured with the Katz Index (KI) in patients with CLI were changed by the treatment.

Methods: During the period 2006–2008, 248 consecutive patients undergoing repair for CLI were investigated with an ADL questionnaire for assessing KI before and after a mean of 16.19 months from treatment. Changes in KI were stratified by type of treatment and outcome.

Results: There were 165 males and 83 females, mean age 73.3 ± 8.3 years; 125 patients showed tissue loss and 123 rest pain alone, 98 received surgical bypass and 150 endovascular repair. Pre-operative KI mean was 10.42. At the post-operative assessment, there was significant worsening in patients' functional outcome (mean KI decreased to 9.78) despite relief of pain (81.5%), tissue healing (72%), good vessel patency (83.8%) and low amputation rate (9.7%). Deterioration of KI was not significantly higher in patients undergoing endovascular repair. Patients receiving major amputation started with worse pre-operative functional score (KI mean 9.42) and did further deteriorate (KI mean 7.71) after demolition surgery. However, patients who received successful revascularisation showed deterioration in the dependence index.

Conclusions: Successful vascular treatment is not associated with improved functional ability in patients with CLI, especially when already highly dependent in their activities. Large

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nationwide preventive and educational programmes should be implemented to prevent irreversible and severe health deterioration in populations with CLI.

Critical limb ischaemia (CLI) is a disease process with tremendous cardiovascular burden. The care of patients with CLI is not straightforward because many of them have significant co-morbidities including diabetes, renal disease and advanced age that further contribute to the overall morbidity, mortality, dependency and poor life satisfaction. Furthermore, CLI is associated with significant reduction in health-related quality of life and, of more relevance, in functional independency with reported patients' perception status comparable to or worse than patients with recent myocardial infarction or cancer. The decision to perform a revascularisation procedure (whether by surgical bypass or endovascular treatment) versus amputation or treat with medical therapy alone remains a challenge.

To be effective, any intervention for CLI needs to be measured within the global functional perception of health and dependency.

Many standardised health measurement scales failed to reliably consider the functional ability in patients with CLI. Furthermore, the results of different studies using either general health-quality instruments (e.g., Short Form 36 Health Survey (SF-36)) or more specific questionnaires (e.g., Vascular Quality of Life Questionnaire, VascuQol) did not provide reliable information and comparable data and did not assess impact of revascularisation on functional dependency.[1,2] Currently, there are no quality of life instruments that have been standardised in a large patient population requiring treatment for CLI and the Trans-Atlantic Inter-Society Consensus Document on Management of Peripheral Arterial Disease (TASC) claimed that specific instruments capable of detecting improvement in functional outcome in this patient population must be developed.[3]

The Katz Index of Independence in Activities of Daily Living (ADL), commonly referred to as the Katz ADL, is one of the most employed general instruments to assess functional status as a measurement of the patients' ability to perform activities of daily living independently.[4,5] This instrument, largely validated in the elderly/geriatric population is simple, quick, easy to understand and complete also for elderly patients, stroke populations and patients with disabilities. Furthermore, it can be useful for recording data retrospectively.

The purpose of this study was to document outcome of functional status using a general ADL instrument after revascularisation for CLI.

Methods

For the purpose of this study, all patients who provided informed consent and underwent planned elective infrainguinal lower-extremity revascularisation between January 2006 and December 2008 for an indication of CLI were investigated. Consecutive patients without a history of primary amputation and who survived after the revascularisation procedure were included. Criteria for inclusion were CLI defined as ischaemic rest pain and/or gangrene or non-healing ischaemic ulceration corresponding to categories 4, 5 and 6 of the Society of Vascular Surgery/International Society for Cardiovascular Surgery (SVS/ISCVS) standards[6] and according to the TASC guidelines.[3] In the presence of diabetic patients, CLI was diagnosed by clinical findings in combination with signs of diminished perfusion, transcutaneous oxygenation ($tcPO_2$) findings and radiologic/ultrasound diagnostics.

All revascularisation procedures, either by endovascular or open surgery, were included for the analysis, regardless of the specific inflow site, outflow site and conduit or stent material/configuration. The included lesions were according to the TASC classification type B, C or D for vascular anatomy.[3]

Risk factors and co-morbidities

Risk factors and co-morbidities were registered prospectively during the admission intake. Co-morbidities examined included coronary artery disease (history of myocardial infarction or angina), chronic obstructive pulmonary disease (COPD), hypertension (history of hypertension or blood pressure $>$140/90 mmHg on the pre-operative evaluation), history of tobacco use (never; $<$1 year or current), hyperlipidaemia (total cholesterol level higher than 200 mg/dl or when the patient took lipid-lowering drugs for history of high cholesterol levels), diabetes mellitus (insulin dependent or controlled by oral medications or diet) and renal disease (normal, creatinine $\leq$1.5 mg/dl renal insufficiency, serum creatinine $>$1.5 mg/dl or dialysis dependent). Procedure details were also evaluated.

All patients received planned revascularisation and unplanned re-interventions. Revascularisation procedures were divided into percutaneous endovascular and bypass graft (BG) repairs. Endovascular procedures were carried out by conventional balloon dilatation of the target lesion with or without stent placement, and were performed under local anaesthesia with or without sedation. BG procedures were performed according to standard vascular techniques using preferably an autologous vein for crural BG. The choice of revascularisation was left to the surgeon's discretion, according to extension and type of lesions.

Follow-up data

Vital status and patency was confirmed during follow-up visits scheduled at 1 month and every 6 months after the revascularisation. Follow-up data included vital status, patency of the graft or target artery, amputation status and symptoms (asymptomatic, claudication, rest pain or tissue loss). The BG or endovascular target vessel patency was determined by duplex ultrasound examination. 'Patency' was defined as patency across the same limb segment by one or more additional procedures (preserving or not the original graft). The decision to re-intervene and the type of re-intervention were driven by the SVS/ISCVS and TASC reporting standards.[3,6]