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A UK Perspective on Independence and Mobility following Infra-inguinal Lower Limb Bypass Surgery for Critical Limb Ischaemia.

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Abstract

Background: Critical limb ischaemia (CLI) is a common condition associated with high levels of morbidity and mortality. To date, most work has focussed on surgeon-oriented outcomes such as patency, but there is increasing interest in patient-oriented outcomes such as mobility and independence.

Objective: To determine the effect of infra-inguinal lower-limb bypass surgery (LLBS) on post-operative mobility in a UK tertiary vascular surgery unit, and investigate causes and consequences of poor post-operative mobility.

Methods: We collected data on all patients undergoing LLBS for CLI at our institution over a three-year period and analysed potential factors that correlated with poor post-operative mobility.

Results: Ninety-three index LLBS procedures were performed for patients with CLI during the study period. Median length of stay was 11 days (IQR 11 days). Twelve month rates of graft patency, major amputation and mortality were 75%, 9% and 6% respectively. Rates of dependence increased four-fold over the first post-operative year, from 5% pre-operatively to 21% at twelve months. Female sex and poor pre-operative mobility were predictive for poor post-operative mobility ($P=.04$ and $P<.001$ respectively), both initially and at twelve-month follow-up. Patients with poor post-operative mobility had significantly prolonged length of hospital stay (15 versus 8 days; $P<.001$).

Conclusions: Patients undergoing LLBS for CLI suffer significantly impaired post-operative mobility, and this is associated with prolonged hospital stay, irrespective of successful revascularisation. Further work is needed to better predict which patients will benefit from revascularisation and in whom a non-operative strategy is optimal.

Introduction

Critical limb ischaemia (CLI) is defined as the presence of chronic ischaemic rest pain, ulcers or gangrene attributable to objectively proven arterial disease [1]. Recent estimates suggest that up to 1000 new cases of CLI per million population are diagnosed every year in Europe and North America and CLI is associated with high short and longer term mortality rates [1,2]. Revascularization is required to prevent ultimate limb loss and, although there is an increasing vogue towards endovascular intervention, there is strong support for the role of infrainguinal lower limb bypass surgery (LLBS) [3,4].

Traditional measures of the success of LLBS have focused on measures of technical success such as graft patency, limb salvage or ankle-brachial pressure index, as these are easily measured, objective measures. There has been a shift towards more patient-centred outcome measures to determine the "success" of intervention [5]. This is particularly important in conditions such as CLI, where rates of co-morbid disease are high [6]. Such measures include quality of life analysis with well-validated disease specific QOL tools available for lower limb ischaemia [7]. Chetter et al.[8] were one of the first groups to highlight that graft patency equates to an immediate and lasting improvement in health related QOL, but such infrainguinal arterial reconstruction is itself a potentially morbid procedure and graft patency itself does nor guarantee clinical improvement[9]. Other important patient specific outcomes include residential status and mobility reflecting functional outcome. Reflecting this change of focus, the recently published Comprehensive Risk After Bypass (CRAB)[10] score is the first risk-scoring tool for LLBS to include functional status within its scoring algorithm. No study has yet presented data related to contemporary practice within the UK health care system. Thus, this study aimed to determine the effect of infra-inguinal LLBS on post-operative mobility and to investigate both causes and consequences of poor post-operative mobility. We also provide the first external validation of the CRAB score as a predictor of outcomes in LLBS.

Methods

Patients

Data was collected retrospectively on all patients undergoing infra-inguinal LLBS for CLI at a tertiary vascular surgical unit from 1st January 2009-31st January 2012. Both paper and electronic notes were interrogated in all cases where these were available. A single set of paper notes could not be retrieved so this patient was excluded from the analysis for all quantities that could not be reliably extracted from the electronic records. The hospital electronic medical records system is linked to the Office for National Statistics for recording mortality. Information was collected on basic demographics, basic haematological and biochemical measurements, co-morbidities, presence or absence of tissue loss, bypass origin and target vessels, graft type, length of hospital stay and ambulatory status on admission to and discharge from hospital. Pre-surgical data was then used to calculate FINNVASC, PREVENT III, Revised Cardiac Risk Index (RCRI) and Comprehensive Risk Assessment for Bypass (CRAB) scores to allow risk prediction of post-operative outcomes [10-13]. Details of these scores are given in Supplementary Table 1.

There was a cohort of patients who had multiple bypass procedures performed. It was felt that if subsequent procedures were within 12 months of the previous bypass, the patient may not have recovered from the previous operation and thus determining the baseline for comparisons with would be difficult. As such a “repeat” operation on either the ipsilateral limb or on the contralateral limb was deemed to be a new ‘episode’ only if their previous lower limb bypass operation was performed at least one year previously. Repeat operations less than one year after the previous bypass were excluded. Graft patency was determined using arterial duplex scanning.

Definitions of Mobility

For the purposes of analysis, mobility was stratified into three groups – “dependent” patients, who were either bed or wheelchair bound; “aided” patients, who were ambulant but with significant dependence on mobility aids (including those who mobilised with a prosthesis); and “independent” patients, i.e. those without significant dependence on mobility aids. The “aided” category was defined as mobilizing with prosthesis, walking frame or one or more elbow crutches. The “independent” category was defined as either being fully independent from walking aids, or requiring no more than a walking stick for assistance. Physiotherapists determined mobility on admission and discharge. Vascular specialist nurses, physiotherapists or surgeons determined mobility at routine 12-month follow-up. No home visits were made.

Statistical analysis

The primary outcome was independent mobility one year after surgical revascularisation. Secondary outcomes were graft failure and mortality, both in-hospital and twelve months after LLBS; and length of hospital stay during the index admission. Graft failure was defined as occlusion of the graft on duplex ultrasound or contrast CT. Non-parametric analysis was performed in the R statistical package [14] version 2.15.2 to assess for univariate predictors of poor post-operative mobility using Fisher’s exact test for categorical variables and Mann-Whitney U test for continuous variables. Multivariate analysis was not performed.

Results

100 procedures were performed on 90 different patients with CLI, with a total of 93 bypasses being considered as distinct index 'episodes'. Sixty-four were performed in men, and the overall mean (standard deviation) age was 70±11 years. Of the 93 bypasses performed, 51 were performed electively, 53 were for tissue loss (31 with gangrene and 22 with ulceration only) and in 20 the distal bypass target vessel was the above knee popliteal artery. Further graft-specific details are given in Supplementary Tables 2 and 3. Six patients underwent repeated LLBS during the one-year follow up period. Further details of the lesions treated and the reasons for choosing LLBS over endovascular intervention are given in Supplementary Tables 4 and 5.

The median length of hospital stay was 11 days (IQR 11 days). No patients died either prior to hospital discharge or within 30 days of surgery. Three patients were lost to follow-up within 12 months equating to three bypass procedures in total. The 1-year mortality rate was 6% (5 patients). Two patients progressed to major amputation during their index admission and at 12 months, 25% of grafts had occluded with 9% of patients having progressed to major amputation. Nineteen patients required minor amputations (seventeen digital amputations and two forefoot amputations). Twenty-six patients had endovascular intervention within the first year of follow-up aimed at maintaining graft patency. Five of these grafts subsequently failed despite these interventions. Further details of re-interventions are given in Table 1. Three patients required contralateral LLBS during the first year of follow-up.

Mobility

On admission, 68/93 patients were classified as independent, 21 as aided and 4 were dependent. At discharge, 51 patients were independent, 35 were aided and 7 were dependent. Data was available for 82 patients at 12 months, at which point 52 patients were independent, 13 were aided and 17 were dependent. Further breakdown of changes in mobility over the first year of follow-up are given in Table 2 and Figure 1. Of the six patients who underwent redo LLBS, all were independently mobile prior to their initial operation. Three of these patients remained independent at one year follow-up, one required the aid of a frame, one had amputation below the knee after repeated graft failure so was dependent upon a wheelchair, and one died of other causes. There were eight patients who were dependent at 12 month follow-up despite patent grafts. Of these, three had contralateral amputations on admission and failed to resume using their prostheses following surgery and one went on to have a below the knee amputation despite a patent graft for chronic pain at 11 months so was dependent at 12 month follow-up, but subsequently went on to mobilise with a prosthesis. The remaining four patients became dependent as a result of co-morbidities.

Factors Predictive of Post Operative Mobility

Poor mobility on discharge was strongly associated with prolonged length of stay, and predicted by poor pre-operative mobility ($P<.001$). Men and current smokers were significantly more likely to leave hospital independently mobile ($P=.04$ and $P=.05$ respectively), but the male cohort was also significantly younger (median age of men 69 years versus 78 years for women, $P=.002$). Patients presenting as an emergency were less likely to be independently mobile on discharge, though this failed to reach statistical significance ($P=.10$). Further details are presented in Table 3.

At 12-month follow-up, poor mobility was again associated with pre-morbid mobility and prolonged length of hospital stay during the index admission ($P<.001$) as well as being associated with graft failure. Men were still more likely to be mobile, but the associations with smoking and urgency of operation had disappeared. Assessment using the PREVENT III, FINVASC and RCRI risk scoring models was not associated with poor mobility at any time point. In contrast, the CRAB score was associated with poor post-operative mobility both at discharge and 12-month follow-up ($P<.001$ and $P=.01$ respectively). Further details are presented in Table 4.

Discussion

Traditional markers of outcome for patients undergoing lower limb bypass procedures have tended to be concerned with mortality, morbidity and graft patency [15]. These are obviously important, but over recent years there has been increasing weight placed upon more patient related / reported outcomes [5]. These include pain, ulcer healing, residential status and post-operative mobility. The cohort of patients with CLI are often elderly, have underlying mobility issues and the nature of the surgery can be extensive with associated limb related complications that can hinder post-operative mobility. This study emphasises the significance of LLBS with regards to post-operative mobility, with a large number of patients failing to achieve independent mobility in the immediate post-operative period. Indeed, the requirement of walking aids significantly increases hospital stay. Although there is some improvement over the post-operative period with regard to independent mobility at one year, the rate of wheelchair dependence in the first post-operative year increased four-fold. This clearly implies a significant additional burden on healthcare resources.

Women undergoing LLBS for CLI were significantly more likely to have poorer mobility both at discharge and at 12-month follow-up. This may in part be related to the women being significantly older than their male counterparts. Not surprisingly, graft failure at one year was associated with poor mobility at follow-up, although graft failure didn't automatically lead to amputation.

One surprising finding was that patients who were still smoking on admission were more likely to be independently mobile on discharge, with this association not evident at one year. It is possible that the initial good mobility was driven by the desire to leave the ward for regular cigarette breaks, although we are not advocating continued smoking in this patient cohort.

These results are broadly in keeping with the findings of a recent large systematic review that identified ten studies analysing over 3000 patients with CLI [16]. The authors found pre-operative mobility predicted post-operative mobility and that wheelchair dependence increased from 9% in the pre-operative population to 22% at follow-up. In addition, absence / limited tissue loss, younger age and long-term graft patency predicted good mobility, while diabetes and female sex predicted poor mobility.

Infrainguinal LLBS is still a commonly performed procedure within the UK [17].

The results presented in our study represent “real-world” experience outside the context of clinical trials and are likely to reflect practice within other UK centres. The retrospective nature of the study is associated with obvious limitations but we feel our data capture is sufficient to reach robust conclusions. The relatively small sample size of the study means that negative results should be interpreted with caution.

It is becoming increasingly evident that patient related outcomes are becoming more relevant in daily practice. Chisci et al have developed a patient orientated scoring system for revascularisation in critical limb ischaemia [18]. Using this they suggested that up to 60% of patients would benefit from revascularisation, suggesting that a non-operative approach including palliation could be indicated in patients with poor pre-operative living status. This is in part borne out within our study, where no patient with dependency maintained long term mobility. Indeed, eight patients were dependent at 12 month follow-up despite patent grafts, highlighting the inadequacy of graft patency as a measure of outcome. Before confining such patients to primary amputation or palliation, however, in-depth studies are required to specifically identify patients who will not benefit from surgical revascularisation, particularly in light of the technological advances in endovascular treatments. The correlation of the CRAB score with post-operative mobility is promising in this regard, as it represents a step towards improving our ability to predict which patients are likely to have poor functional

outcomes, with reasonable predictive power at discharge. Predictive power in the longer term was still not optimal, so although this may represent a useful tool to direct resources during the inpatient stay, it cannot be relied upon as a guide for longer-term prognosis.
The strong association of poor mobility with prolonged length of stay and the implications of this in terms of both patient experience and healthcare burden, make this is an important area for further work in a patient population that is only going to increase in size.

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