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Increased mortality among patients with diabetes following first-ever transfemoral amputation



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ABSTRACT

Aims: Transfemoral amputation (TFA) is associated with a high postoperative mortality though it is unclear whether diabetes is associated with an increased mortality or not. The aim was to examine mortality at 1 week and 1 year after first-ever TFA with special reference to diabetes.

Methods: We included 162 first-ever TFAs from 1996 to 2012. Mortality data were collected with the use of the Swedish personal identification number.

Results: The median age was 85 years. Diabetes mellitus were present in 19% (n = 30) of the patients and 67% (n = 109) had cardiovascular disease. Mortality was significantly higher for patients with diabetes compared to patients without diabetes at 1 week (30% vs. 8%, p = 0.001) and at 1 year (80% vs. 57%, p = 0.02). This difference was significant in multivariable analysis.

Conclusions: We conclude that postoperative mortality was high. The high mortality rate emphasizes the need for early and adequate evaluation of every patient's overall condition and whether amputation is beneficial or not. Although further studies are needed to analyze the specific causes of early death in amputees and we suggest close monitoring of blood-sugar in patients with diabetes and early treatment of infections and cardiac events in all patients.

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1. Introduction

Transfemoral amputation (TFA) is used as a procedure in peripheral arterial disease (PAD) including critical limb ischemia, gangrene and embolus; infection and after severe traumatic injuries. It can also be used as a secondary salvage procedure after a failed more distal amputation in the same limb. Most patients considered for a major non-traumatic lower extremity amputation (LEA) have multiple

co-morbidities contributing to a high mortality [1–3]. Factors such as high ASA-class [3–5], renal failure [1,6], more proximal amputation [1,7–10] and higher age [7,11] are correlated to an increased postoperative mortality.

Whether diabetes affects the mortality or not after LEA is unclear. Some studies have reported increased mortality for patients with diabetes compared to patients without [1,3,12,13] while others have failed to demonstrate any correlation [2,14–16], or even reported decreased mortality for the

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groups with diabetes [8,10]. In other papers the increased mortality for patients with diabetes is shown first after several years, initially reducing [17] or not affecting [18] the mortality rate. A recent systematic review has evaluated the 30-day mortality [11] and another has evaluated the 5-year mortality [19] but to our knowledge no studies have assessed the immediate postoperative mortality. During the first week after the amputation, the patient is most of the time still in the emergency hospital and therefore accessible to early interventions if complications do occur. There is a lack of knowledge in the literature of the early postoperative mortality.

Previous studies have shown a decrease of the amputation rate in patients with diabetes [20,21] but still the morbidity and mortality after the procedure is significant. The importance of previous amputations has been neglected which makes comparison of studies more difficult. Only a few larger series have been published on first-ever major amputations with patients with diabetes included [2,22] and very few papers include exclusively transfemoral or above-knee amputations [14]. More often the material includes both below- and above-knee amputations or both minor (amputation through or below the ankle) and major amputations (amputation above the ankle). Knowledge of factors affecting the mortality is of great importance in decision making before surgery, not only for treating physicians and patients but also for relatives.

2. Materials and methods

2.1. Data collection

The study was conducted at Stockholm South Hospital. The inclusion criteria for this study were first-ever TFAs performed during March 1996 through December 2012. We defined first-ever TFA as the first procedure in the patient, not only in the index limb. Patients were identified through a prospective clinical audit and through our operating theater information management system. Individual patients' records were retrospectively searched for medical and demographic data including indication, age, gender, ASA-classification and the presence of diabetes mellitus (Type 1 and Type 2) or cardiovascular disease (atrial fibrillation, coronary artery disease or congestive heart failure) as well as previous lower extremity amputations. All reoperations such as wound debridement, more proximal re-amputation and contralateral major LEA were identified in patients' records up until deceased or until 31 December 2014. The decision of the amputation-level was up to the surgeon and the reason for the amputation was classified by the surgeon preoperatively. PAD was defined as embolus, critical limb ischemia with resting pain, non-salvable foot ulcers or gangrene. Other indications included infections, such as infected joint prosthesis or necrotizing fasciitis, and failed fracture fixations or fractures in elderly patients not eligible for primary fracture fixation. Patients were regarded to have diabetes if they had a diagnosis of any type of diabetes in medical records or were treated with oral hypoglycemic agents or insulin at the time of amputation. The exclusion criteria were previous contralateral major LEA, simultaneous bilateral TFA and

contralateral TFA during the first year after index procedure. Previous minor amputations were not an exclusion criteria.

Mortality data were collected with the use of the unique Swedish personal identification number. The average age-specific 1 year mortality rate for a population corresponding to the median age in our material were calculated for 1996–2012 from the national database Statistics Sweden.

The primary aim of this study was to examine all-cause mortality at 1 week and 1 year after first-ever TFA with special reference to diabetes mellitus, and to compare the mortality rate with an aged matched Swedish population. The secondary aim was to analyze the reoperation rate following TFA. The results may influence pre- and postoperative care of these patients.

2.2. Statistical analysis

The statistical software used was IBM SPSS Statistics, Version 23 for Windows (SPSS Inc., Chicago, Illinois). Nominal variables were tested by the Chi-square test or Fisher's exact test. All tests were two-sided. Logistic regression analyses were performed to evaluate factors associated with postoperative mortality. Age, gender, indication for surgery, cardiovascular disease and diabetes were tested as independent variables in the model. First, crude associations for each variable were studied in a univariable model. Secondly, a multivariable model was used to study the adjusted associations. The associations are presented as odds ratios (ORs) with 95% confidence intervals (CIs). The results were considered significant at $p < 0.05$.

This study was approved by the Regional Ethics Committee (D.nr 2017/2129–32).

3. Results

3.1. Patient characteristics

We found 184 patients, of which 162 patients with first-ever transfemoral amputation were included in the cohort and 22 patients were excluded (see Fig. 1). Exclusion from the study was done due to previous contralateral major LEA ($n = 13$), simultaneous bilateral TFA ($n = 4$) and contralateral TFA the first year after index procedure ($n = 5$).

Patient demographics and clinical variables are summarized in Table 1. There were no significant differences between the groups regarding age, gender or ASA-classification. The median age was 85 years (range 54–100). A majority (67%) of the patients were female ($n = 109$). The majority (85%) of the patients were categorized as ASA 3 or 4 ($n = 138$). Diabetes mellitus were present in 19% ($n = 30$) of the patients and 67% ($n = 109$) had a cardiovascular disease. Patients with cardiovascular disease were overrepresented in the group with diabetes compared to those without (83% vs. 64% $p = 0.04$). The indication for surgery was PAD with or without diabetes in 78% ($n = 126$) and other causes (trauma or infection) in 22% ($n = 36$) of the patients. In the group of PAD 27% ($n = 34$) were amputated due to an embolus, 12% ($n = 15$) due to critical limb ischemia and 61% ($n = 77$) due to PAD and ulcers. There were no traumatic amputations in

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