

## MAJOR AMPUTATION INCIDENCE DECREASES BOTH IN NON-DIABETIC AND IN DIABETIC PATIENTS IN HELSINKI

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### ABSTRACT

**Background and Aims:** The aim of the study was to assess the changes in diabetes-related lower extremity amputations and to compare it with the development of amputations for critical leg ischaemia in patients without diabetes.

**Material and Methods:** Clinical records of 1094 patients undergoing major lower limb amputations for vascular disease in the town of Helsinki during 13 years from 1990 to 2002 were analyzed retrospectively. Data concerning patient factors, diagnosis, existence of diabetes and amputation level were recorded. The study period was divided into three parts (1990–1994, 1995–1998 and 1999–2002) and results were compared between diabetic and nondiabetic vascular amputees during these time periods.

**Results:** From 1990 through 2002, 561 of patients undergoing major lower limb amputation had diabetes mellitus. The overall incidence of major amputations of diabetics reduced from the first time period to the last period by 23%. At the same time, the incidence of amputations in non-diabetic patient group decreased 40%. If the incidence rate for amputations is expressed per million individuals with diabetes, 33% decrease was observed during the study period.

**Conclusions:** The decrease in major amputation rates among diabetic as well as non-diabetic patients can be attributed to the increased interest in amputation prevention, with a contribution by vascular surgeons being made in both groups.

Key words: Amputation; diabetes mellitus; vascular surgery

### INTRODUCTION

Annually, 2% of all diabetic patients will develop a foot ulcer, while 15% will ulcerate over a lifetime (1). The link between diabetic foot ulcers and lower extremity amputations is indisputable: foot ulcers precede 85% of diabetic amputations (2). Diabetic patients account for 40–70% of all lower extremity amputations (3–5). Majority of all diabetes-related major

lower limb amputations occur in patients with type II diabetes (6).

Diabetic foot ulcers are usually caused by multiple factors, with the combination of peripheral arterial disease (PAD) and neuropathy playing a causal role in approximately 30–40% of these ulcers (7). The most important factors related to the development of foot ulcers are peripheral neuropathy and foot trauma. The third major component is impaired wound healing, related to reduced blood supply at the wound area (8).

The incidence of diabetes mellitus is increasing in Finland (9). The incidence of type I diabetes in Finland was 36.5/100 000 in year 2000 being one of the highest incidences in the western world (8) and is predicted to be 50/100 000 by the year 2010 (9, 10). Rising trends in the prevalence of type II diabetes has

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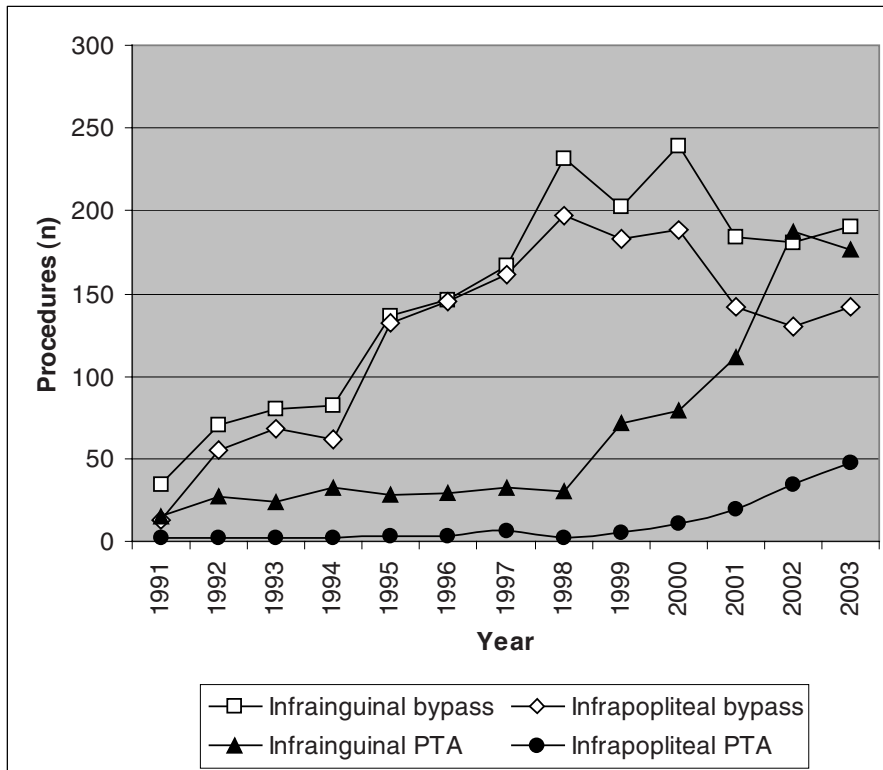


Fig. 1. Infrainguinal vascular procedures for critical leg ischaemia in HUCH in 1991–2003 according to Eskelinen et al. 2005 (40).

also been reported in Finland (11). Diabetes prevalence in Finland was calculated to be 130 000 and 200 000 in 1990 and 2000, respectively with an increase of 54% in 11 years (12, 13). Both increased incidence and decreased mortality among diabetic subjects have contributed to the increased trend in the prevalence of diabetes (11).

Prevention, assessment, and treatment of diabetic foot ulcer and critical leg ischaemia (CLI) has, however, improved in recent years. The operative management of CLI has undergone an evolution over the last three decades. Several studies have shown an inverse correlation between the incidence of infrainguinal bypass reconstruction and that of amputation (5, 14–18). Equal patency and limb salvage rates after infrainguinal revascularization for diabetic and non-diabetic patients have been reported (19–24). Furthermore, implementation of a multidisciplinary team approach for prevention and treatment of diabetic foot ulcers has reported to be effective means of preventing amputations (25–31).

A diabetic foot center run by diabetologists was established in Meilahti hospital 1988 and a multidisciplinary diabetic foot team in Meilahti hospital was established in 1993. High overall increase in vascular procedures for CLI has also taken place at the study area during last 13 years (Fig. 1).

This study was undertaken to assess the changes in diabetes-related lower extremity amputations in the town of Helsinki and to compare it with the development of amputations for CLI in patients without diabetes.

## MATERIAL AND METHODS

The study population comprised the town of Helsinki with some 520 000 inhabitants (492 400 in 1990 and 559 330 in 2002). Data for the population in Helsinki were obtained from the Statistics Finland.

We examined retrospectively the clinical records of patients who underwent major lower limb amputations for vascular disease including diabetes in the town of Helsinki during 13 years from 1990 to 2002. A major amputation was defined as an amputation requiring a prosthesis (above-knee (AK), below-knee (BK)). Knee- and hip disarticulations were included in BK- and AK-amputations, respectively. Amputations of Lisfranc, Chopart or Syme type were excluded. A total of 1094 lower limb major amputations were analyzed. If re-amputations were done for the same patient during the same calendar year, only the final level of amputation was recorded. In the beginning of the study period, major lower limb amputations were performed in seven different hospitals in Helsinki. These seven hospitals included a university hospital (Helsinki University Central Hospital including Surgical and Meilahti hospitals both with vascular surgical activity and Töölö hospital with orthopedics, traumatology and plastic surgery and four surgical town hospitals (Maria, Koskela, Herttoniemi and Malmi hospitals). Data were collected from all of these hospitals. Vascular surgery was centralized to Meilahti hospital 1998 and since then majority of amputations are performed there. Only very few amputations for vascular disease are still done in Töölö hospital, but no operations are performed in the town hospitals since 2000.

To reassure accurate incidence figures during the study period, total major amputation numbers in Helsinki were cross-checked also from the National Research Centre for Welfare and Health (Stakes). Stakes amputation registry

does not contain information of the proportion of diabetics among amputees.

Data concerning patient factors, diagnosis, existence of diabetes and amputation level were recorded. Demographic data of vascular amputees during 1990–2002 in Helsinki is presented in Table 1. Diabetes was defined according to WHO (32). The study period was divided into three intervals (1990–1994, 1995–1998 and 1999–2002) and results were compared between these time periods.

Normality of distributions was established with the Kolmogoroff-Smirnoff goodness of fit test with the Lilliefors method of significance correction. The Independent Samples T-test was applied for comparisons between two normally distributed groups. When the distributions were skewed, the Mann-Whitney U-test was applied. Associations between categorical variables were analysed with the Chi-Square-test or the Fisher's Exact-test when appropriate. The statistical analyses were conducted with SPSS 12.0.1 statistical software (SPSS Inc, Chicago, Ill., U.S.A.).

## RESULTS

From 1990 through 2002, 561 of patients undergoing major lower limb amputation had diabetes mellitus,

533 had ischaemia only. Of the 561 diabetics, 283 (50.4%) were men. The overall mean age among diabetics was 72 (range 29–102) being significantly lower than among non-diabetics (76 years, range 32–100,  $p < 0.001$ , Table 1). Male diabetics were younger than females, the mean age being 68 years (range 31–97) and 76 (29–102) years, respectively ( $p < 0.001$ ). Among younger diabetic amputees (under 60 years) 74% were male, while 46% of diabetic amputees 60 years or over were male ( $p < 0.001$ ). At the same time among younger nondiabetic amputees (under 60 years) 67% were male, while 42% of nondiabetic amputees aged 60 years or over were male ( $p < 0.001$ ).

The BK-/AK-ratio was significantly lower among nondiabetics (table 1). The proportion of BK- and AK-amputations among diabetics and nondiabetics through the three time periods are shown in table 2. Among diabetic amputees aged under 60 years 74% had BK-amputation while 55% of diabetics 60 years or over had BK-amputation during the study period (Table 2).

The overall incidence of major amputations of diabetics (per million inhabitants) reduced from the first time period to the last period by 23% (Table 3) At the same time the incidence of major amputations for vascular disease among nondiabetics reduced from the first time period to the last one by 40%. There was

TABLE 1

Comparison of diabetic and nondiabetic vascular amputees.

	DM	non-DM	P
Age (mean, range)	72.1 (29–102)	76.3 (32–100)	< 0.001
Gender (% of females, n)	50% (278/561)	56% (297/533)	NS (0.046)
BK/AK -ratio (n)	1.4 (323/238)	0.6 (198/335)	< 0.001

TABLE 2

BK/AK amputation ratios in diabetic and nondiabetic leg ischaemia.

	BK/AK -ratio (n)			p-value
	1990–1994	1995–1998	1999–2002	
Diabetics	1.7 (129/74)	1.4 (102/73)	1.0 (92/91)	0.03
Nondiabetics	0.6 (65/114)	0.7 (75/113)	0.5 (58/108)	NS (0.6)
Diabetics < 60 years of age	5.2 (26/5)	2.7 (19/7)	1.8 (20/11)	NS (0.22)
Nondiabetics < 60 years of age	1.4 (10/7)	1.6 (13/8)	3.3 (13/4)	NS (0.51)
Diabetics > 60 years of age	1.5 (103/69)	1.3 (83/66)	0.9 (72/80)	NS (0.07)
Nondiabetics > 60 years of age	0.5 (55/107)	0.6 (62/105)	0.4 (45/104)	NS (0.43)

TABLE 3

Major amputation rates for diabetic and nondiabetic leg ischaemia.

	Time period			p-value
	1990–1994	1995–1998	1999–2002	
Amputation incidence (DM) a	94.6	84.5	73.2	NS (0.4) <sup>b</sup>
Amputation incidence (non-DM) a	89.0	70.7	53.4	
DM in patients < 60 years of age	31/48 (65%)	26/47 (55%)	31/48 (65%)	NS (0.56)
DM in patients > 60 years of age	172/334 (52%)	149/316 (47%)	152/301 (51%)	NS (0.52)

<sup>a</sup> Mean annual amputation incidence/1 000 000 inhabitants

<sup>b</sup> P-value for comparison of incidence reductions between DM and non-DM patients.

no statistically significant difference between these two reductions (23% in diabetics versus 43% in non-diabetics,  $p=0.4$ ).

When taking into consideration diabetes prevalence in year 1990 and 2000 in Finland, diabetes-specific incidence rates could be calculated. By this means a 33 % fall in major amputations per million individuals with diabetes was observed during the study period

## DISCUSSION

Foot ulceration in the diabetic patient is a source of great physical and emotional stress to the patient and represents a significant burden for the health care system and costs to the payer (25,33). Coexistent painless neuropathy seems to be the *primum movens* for foot ulceration in diabetics, but lower extremity ischaemia is the major limiting factor for wound healing (34, 35). Pure neuropathic ulcers without atherosclerosis will often heal under conservative treatment (8), but recurrences are common. Prompt diagnosis and correction of any arterial insufficiency in diabetic patients with foot wounds is of the utmost importance in order to avoid progression of the tissue lesions. Alarming, 15% of all foot ulcers will ultimately require amputation (36).

Besides higher rates of lower extremity amputation, increased incidence and severity of coronary artery disease, and higher cardiovascular mortality are well recognized in diabetic patients. Considered together, these may suggest poorer outcome in treated patients or, even worse, may completely discourage any aggressive vascular surgical treatment in these patients (22). However, despite decreased survival among diabetics (19, 23, 24) there is evidence that bypass grafting to the leg is worthwhile (19–24). In a nation-wide analysis of diabetes as a risk factor for postoperative major mortality and morbidity after surgery for CLI in Finland during 1991–1999, diabetes was found to be an independent risk factor for postoperative BK amputation (37). The acute graft occlusion rate was equal for diabetics and nondiabetics. In cases in which the graft was patent at 30 days, significantly more diabetics than nondiabetics underwent amputation. The authors concluded that this would support the suggestion that in diabetics reconstruction is often performed too late, and that diabetics more commonly must undergo amputation due to major tissue loss, despite successful revascularisation (37). Indeed, **fundamentals of diabetic foot management** are prompt control of infection and surgical drainage, evaluation for ischaemia, prompt arterial reconstruction, and subsequent secondary procedures on the fully vascularized foot (38). Another important issue is the improved prevention policy.

In a population-based study by Larsson and colleagues (30), the incidence of diabetic major amputations decreased by 78% along with the overall decrease of amputations from 160/million inhabitants in 1982 to 36/million inhabitants in 1993 in the Lund University Hospital catchment area in Sweden. In 1983 a multidisciplinary diabetic foot team was estab-

lished in the area. However, a considerable decrease was also noted in amputations for vascular disease without diabetes. There is one nationwide analysis of incidence of diabetes-related lower limb amputations (per million individuals with diabetes), and it shows a 36% decrease in amputations in men and a 38% decrease in women with diabetes on Netherlands 1991–2000 (31). Diabetes prevalence rates were estimated from a continuous morbidity registration of four family practices in Nijmegen in this particular study. The independent impact of vascular surgery without diabetic foot team on these figures was not truly analysed. In addition, in this analysis, also minor amputations were included in the study.

It was estimated in 1984 in Southern Finland that the frequency of lower limb major amputations in the study area is arising significantly in the following years with the increase of lifetime expectancy, the amount of elderly population and the number of type II diabetics (39). The incidence of major amputations in diabetic patients has, on the contrary, exhibited a 23% fall from the beginning of 1990s (1990–1994) to the beginning of this millenium (1999–2002) in Helsinki. If the incidence rate for amputees is expressed per million individuals with diabetes, as high as 33% decrease was observed. HUCH has an aggressive policy to attempt revascularization for all patients with CLI, who have possibilities to maintain independence with the preserved limb presuming that the limb is salvageable and the patient's condition allows surgical or radiological procedures. Diabetes alone never deters aggressive attempts at limb salvage.

On the basis of the results we conclude with several others that increase in vascular revascularization reduces the number of major lower limb amputations also in diabetic patients. Establishment of the diabetic foot team and better treatment of diabetic foot ulcers also have an important role in the prevention of amputations. Thus this study can not give a direct answer of the impact of vascular surgery or work of the multidisciplinary diabetic foot team in decreasing amputation figures. Both seem to improve results. In general, it is difficult or impossible to give the answer to the question of what caused the decrease in amputation rate of diabetics and to a what extent; what is the exact part of multidisciplinary team in decreasing amputation figures. As at the same time increase in vascular surgical activity commonly has happened at the areas studied.

The proportion of AK-amputations rose synchronously with the fall in amputation incidence. Our study group has found similar trend in previous analyses of all amputated patients in Southern Finland (13). It seems likely that the number of BK-amputations could be altered by infrapopliteal revascularization and the relative amount of AK-amputations inevitably rises.

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