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Original Article

Diabetes and vulnerabilities in people undergoing lower-extremity amputation

Martin Gillies Banke Rasmussen[1, 2*], Sara Fokdal Lehn[3, 4, 5*], Lise Tarnow[3], Lau Caspar Thygesen[4] & Jan Erik Henriksen[1]

1) Steno Diabetes Center Odense, Odense University Hospital, 2) Research Unit for Exercise Epidemiology, Department of Sports Science and Clinical Biomechanics, Centre of Research in Childhood Health, University of Southern Denmark, 3) Steno Diabetes Center Sjaelland, 4) National Institute of Public Health, University of Southern Denmark, Copenhagen, 5) The Research Unit PROgrez, Copenhagen University Hospital – Slagelse Hospital, Denmark

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ABSTRACT

INTRODUCTION. Knowledge of the characteristics of those who undergo major lower-extremity amputation (LEA) in Denmark is lacking. In this study, we described socioeconomic and demographic factors, comorbidity, healthcare contacts and mortality in people who underwent major LEA.

METHODS. This was a descriptive observational study. We identified first non-traumatic major LEAs (2019-2021) in the National Patient Registry and classified people by diabetes status. We matched the LEA population to people from the general population based on age, sex, calendar quarter and diabetes status and linked data on socioeconomic and demographic factors, comorbidity, healthcare contacts and mortality from national administrative registries

RESULTS. The LEA population constituted 3,088 people (no diabetes: N = 1,722, 55.8%; type 1 diabetes: 153, 5.0%; type 2 diabetes: N = 1,213, 39.3%). Compared to the reference group, a higher proportion of the LEA population were single, had basic education, were in a low-income group and resided in a non-urban municipality. The LEA population had many healthcare contacts leading up to their major LEA, and a very high proportion had comorbidities, most notably cardiovascular disease (85.1%). Lastly, 30-day and one-year mortality were 15.8% and 29.3%, respectively.

CONCLUSIONS. About two in five who underwent major LEA had diabetes. We found marked social inequality, higher comorbidity, higher mortality and more healthcare contacts in the LEA population than in the reference group.

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In Denmark, nearly 370,000 people are living with diabetes [1], and this figure continues to rise [2]. Moreover, 7.1% of adult Danes have prediabetes [3]. Lower-extremity amputation (LEA) is typically a consequence of peripheral arterial disease, peripheral neuropathy and diabetic foot ulcers, i.e. potential complications of diabetes [4-6]. LEA is among the most feared complications among people with diabetes [7]. LEA affects mobility, social activities and mental well-being [8]. Furthermore, LEA is associated with a high mortality, e.g., an approximately 50% one-year mortality in people with type 1 diabetes (T1D) who have undergone transfemoral amputation [9].

Prevention of LEA depends heavily on early monitoring and timely specialised care, including surgical revascularisation [10]. Knowledge of personal characteristics and healthcare contacts in the period leading up to an LEA is essential for targeted prevention. Few studies have studied these characteristics in a Danish context

and in people with diabetes. One study focusing on people who underwent LEA in 2010-2011 found that almost half had diabetes. The majority were men, unmarried and with low educational attainment. Moreover, the prevalence of comorbidity was high [11]. Another study found that compared to an LEA population without diabetes, those with diabetes underwent LEA at a younger age [9]. Regarding healthcare contacts, a study found that 64% had attended a hospital or outpatient clinic within three years prior, and 97% had visited their general practitioner (GP) in the year leading up to their LEA. However, 2% neither had a hospital nor a GP contact in the year preceding LEA [11]. However, we need up-to-date data on the characteristics of people who undergo LEA to develop strategies that may prevent disease progression leading to LEA.

We describe socioeconomic and demographic factors, comorbidity, healthcare contacts and mortality in people who underwent non-traumatic major LEA in 2019-2021. Figures are provided by diabetes status and in a matched study group from the general population.

Methods

Study design

This was a descriptive, observational study using Danish administrative registries.

Data access

The Danish Data Protection Agency approved this project. Data were made available via Statistics Denmark's online access and were linked via the civil registration number (CPR) provided to all citizens with permanent residence in Denmark.

Major lower-extremity amputation

We identified first-incident major LEA in the National Patient Registry (NPR) from 2014-2021 using NOMESCO procedure codes for trans-tibial (KNGQ09, KNGQ19 and KNGQ99) and trans-femoral (KNFQ09, KNFQ19, and KNFQ99) amputations [12], not excluding people who had undergone minor LEA. We limited our study population to those who underwent their first major LEA in 2019-2021 (the LEA population). We excluded traumatic major LEAs via either concomitant diagnoses indicative of trauma, hospital contacts due to accidents, acts of violence, suicide attempts and other types of self-harm (Supplementary 1). Additionally, we excluded all people ≤ 30 years of age (likely trauma).

Diabetes

We identified people with diabetes using a previously described algorithm [13]. Briefly, it identifies diabetes indicators in the NPR, the National Health Services Register, the National Prescription Registry, the Danish Adult Diabetes Database and the Danish Registry of Diabetic Retinopathy (DiaBase, available until 2018). The Diabase is a Danish clinical quality database that contains data from screenings for diabetic eye disease at private ophthalmologists or hospital eye departments in adults with diabetes [14]. Based on diagnoses and reimbursed medication, we classified people as either T1D or type 2 diabetes (T2D).

Socioeconomic and demographic factors

We gathered data on age, sex, municipality and relationship status from Statistic Denmark's Population Register. Statistics Denmark defines a relationship from records of either marriage or registered partnership, but their figures are also based on whether people live together and have children. Based on the Population Education Register and the Labour Market Module at Statistics Denmark, we identified educational attainment and occupational status, respectively. Educational attainment was categorised as 1) low (only elementary school), 2) middle level (high school or vocational training) or 3) high (bachelor's degree and above). We categorised

occupational status as 1) employed or student, 2) outside the workforce (unemployed or someone who receives social benefits), 3) early retirement disability pension or 4) age-related retirement. Lastly, we computed income quartiles from the weighted family income registry for the entire Danish adult population separately for those aged 30-64 years and those 65 years and above and categorised our sample accordingly.

HbA_{1c}, morbidity and all-cause mortality

We identified latest HbA_{1c} assessment (NPU27300) within one year from the index date from the National Laboratory Database. We retrieved data on comorbidity from the NPR ten years before the LEA index date based on medical diagnoses (primary and secondary). To identify cardiovascular disease and kidney disease, we also retrieved data on treatment procedures. For osteoporosis, chronic obstructive pulmonary disease/asthma and mental illness, two purchases of disease-specific medications two years before the date of LEA, according to the National Prescription Registry, was also suggestive of comorbidity (Supplementary 1). We computed the 30-day, six-month and one-year mortality using Danish Cause of Death Register data.

Healthcare contacts

We summarised the number of GP contacts (including e-contacts) based on the National Health Services Register and the number of hospital inpatient and outpatient contacts from the NPR in the year leading up to the major LEA index date. Ambulatory hospital contact and a hospitalisation were defined as a hospital stay of ≤ 12 hours and > 12 hours, respectively. If any part of a hospital stay was acute, we categorised the entire hospital contact as acute. We also identified those referred to home care in the Eldercare Database at Statistics Denmark.

Statistical analyses

The LEA population was matched (exact matching) 1:4 to people in the Danish Population Register according to age (years), sex (male/female), diabetes status (none/T1D/T2D) and calendar quarter. We computed frequencies, percentages, medians and lower and upper quantiles for descriptive variables stratified by diabetes status. We tested group differences using a t-test (paired or unpaired) or Kruskal-Wallis test (non-normal distributions) for continuous variables. For categorical variables, we conducted either χ^2 tests (for unpaired data), McNemar's test or Bowker's test of symmetry (for paired data). We computed incident major LEA per 10,000 citizens by diabetes status, which we modelled using Poisson regression with diabetes status as an independent variable. We deemed $\alpha = 0.05$ statistically significant.

All statistical procedures were conducted in SAS 9.4.

Trial registration: not relevant.

Results

Sample flow

We identified 3,156 people who underwent a first major LEA in 2019-2021. After exclusion of putative trauma-related major LEA (n = 48), 3,088 people remained in the sample, of whom 1,366 (44.2%) had diabetes (T1D: 5.0% and T2D: 39.3%) at their major LEA index date (Supplementary 2).

The incidence rates of major LEA remained stable during 2019-2021. Compared to those without diabetes, the incidence rates were 14.9 (95% confidence interval (CI): 5.7-34.8; $p < 0.001$) and 9.0 (95% CI: 3.6-22.6; $p < 0.001$) times higher for those with T1D and T2D, respectively. Moreover, the incidence rate was 1.6 (95% CI: 1.1-2.3; $p = 0.019$) higher for those with T1D than for those with T2D (Supplementary 2). There were some numerical differences in rates between Danish regions (Supplementary 2).

Socioeconomic and demographic factors

Compared to the reference, a statistically significantly larger percentage of the LEA population was single, had retired early, had elementary school education, was in the lowest income group and resided in a non-urban municipality (**Table 1**).

TABLE 1 Socioeconomic and demographic factors of people undergoing their first non-traumatic major lower leg amputation and for a matched reference group (2019-2021). Q1, Q2, Q3 and proportions were computed.

	LEA population					Matched reference				p-value: total LEA population vs total matched reference
	no diabetes	T1D	T2D	total LEA population	p value: T1D vs T2D	no diabetes	T1D	T2D	total matched reference	
n	1,722	153	1,213	3,088	-	6,888	612	4,852	12,352	-
Age, Q2 (Q1-Q3), yrs	75.0 (67.0-83.0)	63.0 (55.0-72.0)	73.0 (66.0-79.0)	74.0 (66.0-81.0)	< 0.001	75.0 (67.0-83.0)	63.0 (55.0-72.0)	73.0 (66.0-79.0)	74.0 (66.0-81.0)	-[d]
Sex, % male	56.9	71.2	71.0	63.1	0.947	56.9	71.2	71.0	63.1	-[d]
Relationship status[a], % single	62.0	57.5	55.5	59.2	0.633	43.1	36.9	42.8	42.0	< 0.001
Education, %				0.030						< 0.001
Elementary school	46.9	39.2	48.5	47.1		35.3	25.2	40.6	37.1	
Short and vocational	42.6	45.1	41.5	42.3		42.3	50.8	45.6	44.1	
Medium to long education	10.5	15.7	10.0	10.6		22.0	24.0	13.5	18.8	
Occupational status, %					< 0.001					< 0.001
Employed or student	6.7	12.4	7.7	7.4		21.0	42.5	18.2	21.0	
Outside the workforce[b]	4.8	11.8	5.4	5.4		2.6	9.3	5.3	4.0	
Retired early	10.6	33.3	12.4	12.4		2.1	7.7	5.7	3.8	
Age-related retirement	77.9	42.5	74.6	74.8		74.3	40.5	70.9	71.3	
Weighted family income					0.112					< 0.001
Low: < Q1	41.5	43.1	42.2	41.9		25.3	24.0	31.2	27.6	
Low-middle: ≥ Q1-< Q2	31.4	23.5	31.4	31.0		23.8	23.4	28.4	25.6	
Middle-high: ≥ Q2-< Q3	18.7	20.9	18.1	18.6		24.4	24.0	22.4	23.6	
High: ≥ Q3	8.4	12.4	8.3	8.5		26.5	28.6	18.0	23.3	
Non-urban municipality[c] of residence, %	72.6	69.9	72.1	72.2	0.583	66.6	64.7	64.0	65.5	< 0.001

LEA = lower-extremity amputation; Q1 = lower quantile; Q2 = median; Q3 = upper quantile; T1D = type 1 diabetes; T2D = type 2 diabetes.
a) Statistics Denmark defines a relationship from records of either marriage or a registered partnership, but also based on whether people live together and share children; moreover, two unrelated people of the opposite sex who live together and whose age difference is < 15 yrs are in a relationship. Conversely, people who do not live together and are not in a registered partnership are defined as single.
b) Those who were unemployed or who received social benefits
c) Those who were not capital or metropolitian municipalities.
d) We did not conduct statistical tests between the total LEA population and the total matched reference for the variables age and sex given that we matched the groups by these variables.

Among the LEA population, those with T1D underwent major LEA approximately ten years earlier than the other groups (Table 1). The LEA population with T1D had the lowest proportion of people with elementary school education and the highest proportion of people who had retired early (one third). The LEA population without diabetes and those with T2D differed in age, sex and relationship status, although they were otherwise not different ($p \geq 0.233$ for the remaining sociodemographic variables).

Morbidity

HbA_{1c} and the proportion with morbidity was higher in the LEA population than in the reference group ($p < 0.001$ for all variables) (**Table 2**). The relative differences in percentages were largest for CVD and kidney disease. Notably, around half of the LEA population had a mental illness, whereas this was the case for less than a third in the reference group. The LEA population with T1D had a higher HbA_{1c} and a longer diabetes duration than the LEA population with T2D ($p < 0.001$ for both variables) (Table 2).

TABLE 2 Morbidity in people undergoing their first non-traumatic major lower leg amputation and in a matched reference group (2019-2021). Q1, Q2, Q3 and proportions were computed.

	LEA population					Matched reference				p-value: total LEA population vs total matched reference
	no diabetes	T1D	T2D	total LEA population	p value: T1D vs T2D	no diabetes	T1D	T2D	total matched reference	
Diabetes duration, Q2 (Q1-Q3), yrs	N/A	41.3 (27.3-47.6)	16.5 (9.7-23.7)	18.0 (10.5-25.5)[b]	< 0.001	N/A	29.7 (18.0-40.7)	10.3 (5.4-16.0)	11.1 (5.9-18.3)[c]	< 0.001[d]
HbA_{1c}, Q2 (Q1-Q3), mmol/mol [HbA_{1c} within 1 yr of index date: n; %]	38.0 (35.0-41.0) [1,260; 73.2]	68.0 (60.0-83.0) [147; 96.1]	56.0 (46.0-70.0) [1,145; 94.4]	43.0 (37.0-58.0) [2,552; 82.6]	< 0.001	37.0 (35.0-40.0) [3,804; 55.2]	60.0 (52.0-70.0) [573; 93.6]	50.0 (44.0-58.0) [4,329; 89.2]	43.0 (38.0-52.0) [8,706; 70.5]	< 0.001
Morbidities, %[a]										
Cardiovascular disease	83.5	82.4	87.7	85.1	0.062	28.6	26.5	40.3	33.1	< 0.001
COPD or asthma	36.6	35.3	43.0	39.1	0.071	16.4	16.8	21.5	18.5	< 0.001
Musculoskeletal disease	37.8	29.4	35.7	36.5	0.125	27.3	23.2	31.8	28.9	< 0.001
Kidney disease	11.3	24.8	23.3	16.7	0.662	2.2	5.7	5.8	3.8	< 0.001
Mental illness	47.0	47.7	43.5	45.7	0.326	23.2	24.4	26.3	25.5	< 0.001
Prior non-traumatic minor amputation, 2014-2021	10.3	39.9	32.7	20.5	0.074	0.1	1.5	0.6	0.4	< 0.001

LEA = lower-extremity amputation; Q1 = lower quantile; Q2 = median; Q3 = upper quantile; T1D = type 1 diabetes; T2D = type 2 diabetes.
a) We identified comorbidities within 10 yrs prior to the exact index date; for cardiovascular disease, osteoporosis, COPD or asthma and mental illness select medications purchased within 2 yrs prior to index date were also diagnostic of the mentioned morbidities.
b) Among the 1,366 people with diabetes in the LEA population.
c) Among the 5,464 people with diabetes in the matched reference group.
d) Comparing the 1,366 people with diabetes in the LEA population with the 5,464 people with diabetes in the matched reference group.

Healthcare contacts

The LEA population had more contacts with primary and secondary Danish healthcare in the year leading up to their major LEA than the reference group ($p < 0.001$ for all variables).

Among the LEA population, those with T1D had more elective ambulatory hospital contacts than those with T2D but had fewer GP contacts (**Table 3**).

TABLE 3 Number of healthcare contacts[a] in the year before first non-traumatic major lower leg amputation in people who underwent major lower leg amputation and in a matched reference group (2019-2021). Q1, Q2, Q3 and proportions were computed.

	LEA population					Matched reference				p-value: total LEA population vs total matched reference
	no diabetes	T1D	T2D	total LEA population	p value: T1D vs T2D	no diabetes	T1D	T2D	total matched reference	
Hospital contacts, Q2 (Q1-Q3), n										
Acute hospitalisation	2.0 (1.0-3.0)	2.0 (1.0-3.0)	2.0 (1.0-3.0)	2.0 (1.0-3.0)	0.471	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.0 (0.0-0.0)	< 0.001
Elective hospitalisation	0.0 (0.0-1.0)	0.0 (0.0-1.0)	0.0 (0.0-1.0)	0.0 (0.0-1.0)	0.687	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.0 (0.0-0.0)	< 0.001
Acute ambulatory contact	1.0 (0.0-1.0)	1.0 (0.0-2.0)	1.0 (0.0-2.0)	1.0 (0.0-2.0)	0.391	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.0 (0.0-0.0)	< 0.001
Elective ambulatory contact	7.0 (3.0-15.0)	19.0 (11.0-34.0)	13.0 (6.0-23.0)	10.0 (4.0-20.0)	< 0.001	1.0 (0.0-4.0)	6.0 (3.0-10.0)	2.0 (0.0-6.0)	1.0 (0.0-5.0)	< 0.001
Contacts with GP, Q2 (Q1-Q3), n	27.0 (15.0-43.0)	27.0 (16.0-41.0)	32.0 (19.0-50.0)	29.0 (16.0-45.0)	0.016	12.0 (6-0-21.0)	13.0 (7.0-24.0)	19.0 (12.0-29.0)	15.0 (8.0-25.0)	< 0.001
Home care referral, %	38.8	39.9	37.7	38.4	0.598	13.5	8.2	14.4	13.6	< 0.001

GP = general practitioner; LEA = lower-extremity amputation; Q1 = lower quantile; Q2 = median; Q3 = upper quantile; T1D = type 1 diabetes; T2D = type 2 diabetes.
a) We identified healthcare contacts 1 yr prior to index date. However, for referral to home care we looked at referrals during the calendar year preceding the index year, e.g., if the index date of the major LEA was December 1st 2021, we identified those who had been referred to home care in 2020.

A total of 24 people (median age 66.0 years (lower quantile (Q1)-median (Q2): 61.5-78.0 years), 75% male) in the LEA population had no hospital contacts in the year leading up to their LEA (data not shown). Among these, 37.5% had T2D, and the remainder did not have diabetes.

Mortality

The LEA population had a much higher proportion of mortality than the reference group ($p < 0.001$ for all variables) (**Table 4**). Approximately one in six patients in the LEA population had died one month after their index date, whereas one in three had died one year after their index date. There were no statistically significant

between-group differences in mortality within the LEA population ($p \geq 0.100$ for all variables).

TABLE 4 30-day, six-month and one-year all-cause mortality in people who underwent first major lower leg amputation (2019-2021). Proportions were computed.

	LEA population					Matched reference					p-value[c]: total LEA population vs. total matched reference
							diabetes				
Follow-up[a]	no diabetes	T1D	T2D	total LEA population	p value[c]: T1D vs.T2D	no diabetes	T1D	T2D	T1D and T2D combined	total matched reference	
30-day					0.282						< 0.001
Mortality, %	16.1	12.3	15.7	15.8		0.5	-	-	0.2	0.4	
n[b]	272	18	187	477		12	-	-	32	44	
6-mo.					0.094						< 0.001
Mortality, %	30.4	21.7	28.7	29.3		2.3	1.6	2.5	-	2.3	
n[b]	448	28	303	779		145	9	116	-	270	
1-yr					0.067						< 0.001
Mortality, %	36.6	26.5	35.6	35.7		4.8	2.2	5.2	-	4.8	
n[b]	426	27	298	751		253	10	194	-	457	

LEA = lower-extremity amputation; T1D = type 1 diabetes; T2D = type 2 diabetes.
a) Because follow-up data on mortality were limited to deaths until 1 January 2022, the % are calculated only for major amputations that take place with sufficient follow-up time between amputation index date and 1 January 2022; therefore, most can be included in the calculation of 30-day mortality and a limited number in the calculation of 1-yr mortality.
b) Number of deaths and thus the numerator of the respective fractions.
c) From tests where both the LEA population and the matched reference group have sufficient follow-up time (as described above).

Discussion

This national registry-based study identified 3,088 people who underwent their first non-traumatic major LEA in 2019-2021 in Denmark. Among these people, 5.0% had T1D and 39.3% had T2D. The majority were elderly men who were single, had elementary school education, were in age-related retirement and had a low income. We identified marked social inequality in the LEA population compared to a matched reference group, also matched on diabetes status. Moreover, the LEA population had markedly more chronic disease, hospital-, GP- and home care contacts and much higher mortality than the reference group.

As in our study, another Danish study found that among people with major LEA caused by peripheral arterial disease, 51.4% had basic educational attainment and 62.7% were unmarried [6]. In a Canadian study of people with LEA, among those with diabetes and those without diabetes, 75.4% and 64.5% had CVD, respectively [15]. These percentages are lower than those reported in our study. Kidney disease was more prevalent in those who underwent major LEA than in the reference group. Likewise, other studies have reported that among individuals who underwent major LEA, 34.8% of those with diabetes and 13.8% of those without diabetes had renal failure. [15]. Moreover, more than a third of the LEA population died within one year of major LEA and 12.3-15.7% died within 30 days. These figures are slightly lower than the numbers reported elsewhere [16, 17]. We also found that half of the LEA population had mental illness before LEA. Danish national guidelines recommend screening for the psychosocial needs of the major LEA population due to the life-changing circumstances of LEA [18]. Our findings underpin such recommendations. The dual burden of somatic and mental disease adds to the complexity of this group and underscores the need for a targeted, interdisciplinary treatment and care approach. Danish national guidelines further underpin the need for interprofessional treatment and care for people with major LEA [18], where personal characteristics (old age, sex, low educational attainment, and low income) must be considered.

Within the LEA population, we found that a considerable percentage of individuals with T1D had retired early and belonged to the highest education and income groups, unlike those with T2D. Moreover, people with T1D had a higher HbA_{1c} and a larger proportion of kidney disease. Also, those with T1D had more outpatient contacts, while the LEA population with T2D had more GP contacts. In Denmark, T1D is treated chiefly at hospitals, whereas most people with T2D are treated at their GP. Few people in the LEA population had very few or no healthcare contacts. Similarly, a Danish study found that 18% of people who underwent LEA had only GP

contacts in the year prior to their amputation, and 2% had neither a hospital nor a GP contact [11].

Regular foot and footwear inspections, preventive foot and shoe care, multidisciplinary management of foot ulcers and early diagnosis of vascular disease are recommended to prevent LEA among people with diabetes [4]. However, more than half of the LEA population did not have diabetes, while both groups were highly vulnerable. LEA prevention and rehabilitation should target high-risk populations both with and without diabetes.

The strengths of this study include our use of nationwide registries and an algorithm to categorise people by diabetes status. Even so, the algorithm may be subject to under- or misclassification. Despite matching key variables, we acknowledge that many other factors determine the distributions of social and healthcare factors. Moreover, comparisons within the LEA population must be made with extra caution. Lastly, multiple testing increases the risk of type 1 error.

Conclusions

We identified a highly vulnerable LEA population with pronounced social inequality compared to a matched reference group. Two of every five in the LEA population had diabetes. The LEA population had markedly more somatic and mental disease, more healthcare contacts and higher mortality than the reference group. We recommend interdisciplinary preventive initiatives to target this vulnerable population and research investigating predictors of major LEA.

Correspondence *Martin Gillies Banke Rasmussen*. E-mail: martin.gillies.banke.rasmussen@rsyd.dk

*) Shared first authorship

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