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Long-term mortality rates after lower extremity amputation in individuals with and without diabetes mellitus (DUDE-10): A retrospective matched cohort study

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ABSTRACT

Background/objectives: To determine mortality rates after lower extremity amputation (LEA) in individuals with and without diabetes mellitus (DM).
Methods: Retrospective, observational study using data from a database covering >99 % of the Dutch population. LEAs in 2016 were identified, and mortality data from 2016 to 2021 were analyzed. Study group 1 (SG1) included individuals with DM and LEA (DM+/LEA+) with two control groups (CG), DM+/LEA− (matched by age, sex, without (1a) and with (1b) socioeconomic status matching). Study group 2 (SG2) (DM+/LEA+) was composed after matching with non-DM individuals with LEA (DM−/LEA+ (2a)).
Results: Among 5145 individuals with LEA in 2016, 56 % had DM. Five-year mortality was 61.2 % in SG1 (DM+/LEA+) and 27.9 % in CG1a (DM+, LEA−) and 1b. Study group 2 (DM+/LEA+) had a 62.6 % five-year mortality rate, compared to 56.4 % in CG2a (DM−/LEA+).
Conclusions: Mortality after LEA is high, especially in DM; socioeconomic status (SES) does not significantly impact mortality.
Level of evidence: Level III retrospective cohort study.

1. Introduction

Many individuals living with diabetes mellitus (DM) fear the long-term complications of the disease. Besides cardiovascular, renal, and eye complications, DM-related foot complications are a significant concern. All these complications can seriously affect the quality of life and life expectancy.[1] People with a longer duration of DM can develop complications like peripheral neuropathy (PN), peripheral arterial disease (PAD), and limited joint mobility (LJM), increasing the risk of DM-related foot ulcers (DFU). Lifetime risk in DM for developing a DFU is 19–34 %, and 20 % of DFUs result in lower extremity amputation (LEA).[2] A strong relationship is observed between DFU and LEAs and long-term poor metabolic control, underweight, smoking, coexisting cardiovascular disease, chronic kidney disease, and retinopathy.[3] Without timely diagnosis and treatment, DFUs progress, leading to functional decline, increased hospitalization risk, LEA, and death.[3] Amputation risk rises with infections, PAD and ulcers penetrating bone and joints.[4] LEAs in individuals with and without DM are associated with a poor prognosis and represent a pivotal life event.[5] After an LEA, people become more dependent on healthcare, requiring rehabilitation, physiotherapy, and devices, leading to higher healthcare costs.[2]

About one-third of individuals undergoing a major LEA become non-ambulatory without properly fitting prostheses[6] and are also prone to weight gain.[7] DM and ill-fitting prostheses are independent predictors of mortality.[8]

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Abbreviations

DM	Diabetes Mellitus
DFU	Diabetic Foot Ulcer
LEA	Lower Extremity Amputation
SES	Socioeconomic status
PN	Peripheral Neuropathy
LJM	Limited Joint Mobility
PAD	Peripheral Arterial Disease
APCD	All-payer Claims Database
NZa	Nederlandse Zorg Authoriteit (Dutch healthcare authority)
T2DM	Diabetes Mellitus Type 2
T1DM	Diabetes Mellitus Type 1
SG1	Study group 1(DM+, LEA+)
SG2	Study group 2 (DM+, LEA+)
CG1a	Control group 1a (DM+, LEA−)
CG1b	Control group 1b (DM+, LEA−)
CG2a	Control group 2a (DM−, LEA+)
CKD	Chronic Kidney Disease
AKA	Above Knee Amputation
BKA	Below Knee Amputation

Clinical risk factors associated with higher mortality rates after an LEA include DM, PAD, coronary artery disease, cerebrovascular disease, end-stage renal disease, and dialysis dependence.[9] A systematic review recently found 1, 5, and 10-year overall mortality rates after non-traumatic major LEA to be 33.7 %, 64.4 %, and 80 %, respectively.[7] For individuals with DM, a relative mortality risk ratio of 1.35 was reported after 5 years of follow-up compared to those without DM, with overall mortality rates of 27.3 % after 1 year and 63.2 % after 5 years.[7]

National data on LEAs in the Netherlands have been reported in recent years.[10–12] In a recent study describing data from the Netherlands from 2016 to 2020, individuals with DM had a 17-fold higher risk of amputation compared to those without DM.[13]

National data from the Netherlands on mortality after LEA in individuals with or without DM were unavailable. Therefore, the aim of this study is to determine mortality rates after lower extremity amputation in individuals with and without diabetes mellitus for the entire Dutch population.

2. Methods

2.1. Design

This matched observational cohort study used data from an all-payer claims database (APCD), managed by the Vektis Health Care Information Center, covering >99 % of the Dutch population.[13] Vektis receives data from all Dutch health care insurers and combines and interprets reimbursement data, enabling informed decision-making and policy development in the Dutch healthcare market.

2.2. Identification, selection and matching of data

We analyzed APCD data from 2016, identifying individuals with and without DM who underwent LEA(s). Amputations performed in Dutch hospitals, are recorded using specific codes from the Dutch healthcare authority (Nederlandse Zorg Authoriteit = NZa), differentiating between care products and activities. Matching individuals were selected based on details outlined in Table 1, with a schematic representation shown in Fig. 1.

In 2016, we previously had identified 5145 individuals who underwent LEAs, 2238 without DM and 2907 with DM.[13] This cohort formed the basis for the mortality analysis. For a detailed description of the design of this larger study we refer to DUDE-8.[14] We obtained longitudinal mortality data for 2808 (96.6 %) individuals with DM and 1919 (85,74 %) without DM who had LEAs in 2016.

Table 1
Selection criteria for the LEA and non-LEA groups in 2016:

SG1; Study Group 1	Individuals with DM and LEA (DM+, LEA+) as identified by the NZa-codes
CG1a; Control Group 1a	Individuals with DM without LEA (DM+, LEA−), matched 1:2 on age, sex assigned at birth, and type of DM
CG1b; Control Group 1b	Individuals with DM without LEA (DM+, LEA−), matched 1:2 on age, sex assigned at birth, type of DM and SES
SG2; Study Group 2	Individuals with DM and LEA (DM+, LEA+) (subgroup of SG1 DM+, LEA+) as identified through the NZa-codes, who ultimately could be matched to individuals as defined in CG2a (DM−, LEA+)
CG2a; Control Group 2a	Individuals without DM and with LEA (DM−, LEA+), who could be matched for age and sex assigned at birth 1:2

Two matching groups of individuals with DM but without LEAs were included as controls (CG1a (DM+, LEA−), CG1b (DM+, LEA−)) in a 1:2 fashion. Following the former research work with Vektis data of Geurten,[17] it was decided to continue with a 1: 2 matching. Control group 1a was matched on age, sex assigned at birth, and type of DM, while the second group (CG1b DM+, LEA−) was additionally matched on socio-economic status (SES). SES classification was based on 4-digit zip codes and divided into three classes (low, mid, and high) using the 25th and 75th percentiles. The score is based on prosperity, education level and labor market participation. People living in the same zip code area received the same SES classification, consistent with the methodology used in earlier studies.[15,16] For matching on age, the age of all individuals as of December 31, 2016, was used.

Matching individuals with LEA without DM (SG2 (DM+, LEA+)/CG2a) was challenging due to the limited number of non-diabetic individuals undergoing LEAs in 2016. Consequently, 1:2 matching was only possible for some individuals, and 1:1 matching was used for the majority.

2.3. Definitions

The NZa-codes used to acquire the data for the present study for major amputations are: 038590 (amputation upper leg), 038690 (amputation lower leg), 03869 (exarticulation of the lower leg). And for minor amputations: 038790 (amputation of the tarsus), 038791 (amputation or exarticulation of a toe), 038793 (exarticulation of the foot), 038794 (Chopart exarticulation, Lisfranc, respectively trans metatarsal amputation). As the APCD lacks clinical diagnoses, we identified DM and its type (T1DM vs T2DM) using the methodology described by Geurten et al.,[17] reiterated in DUDE-8.[14] Since the APCD contains nationwide information on health care insurance, information on individuals who pass away are shared by the insurance companies with Vektis within a month after death. This information will then be available within the database. No cause of death is registered.

2.4. Data availability

Formal consent from the Dutch health insurers was needed for this study. The consent of the Dutch health insurers was registered in a mandate with numbers 6-449-1, 6-449-2 and 6-449-3. The datasets containing data on an individual level as generated and analyzed for this study are not publicly available due to privacy regulations and are contained within the Vektis Health Care Information Center environment. Therefore, our research group did not receive individual data, but aggregated data in response to a written request for each specific question.

Data are contained within the Vektis Health Care Information Center environment. Re use of our data by other interested parties will again

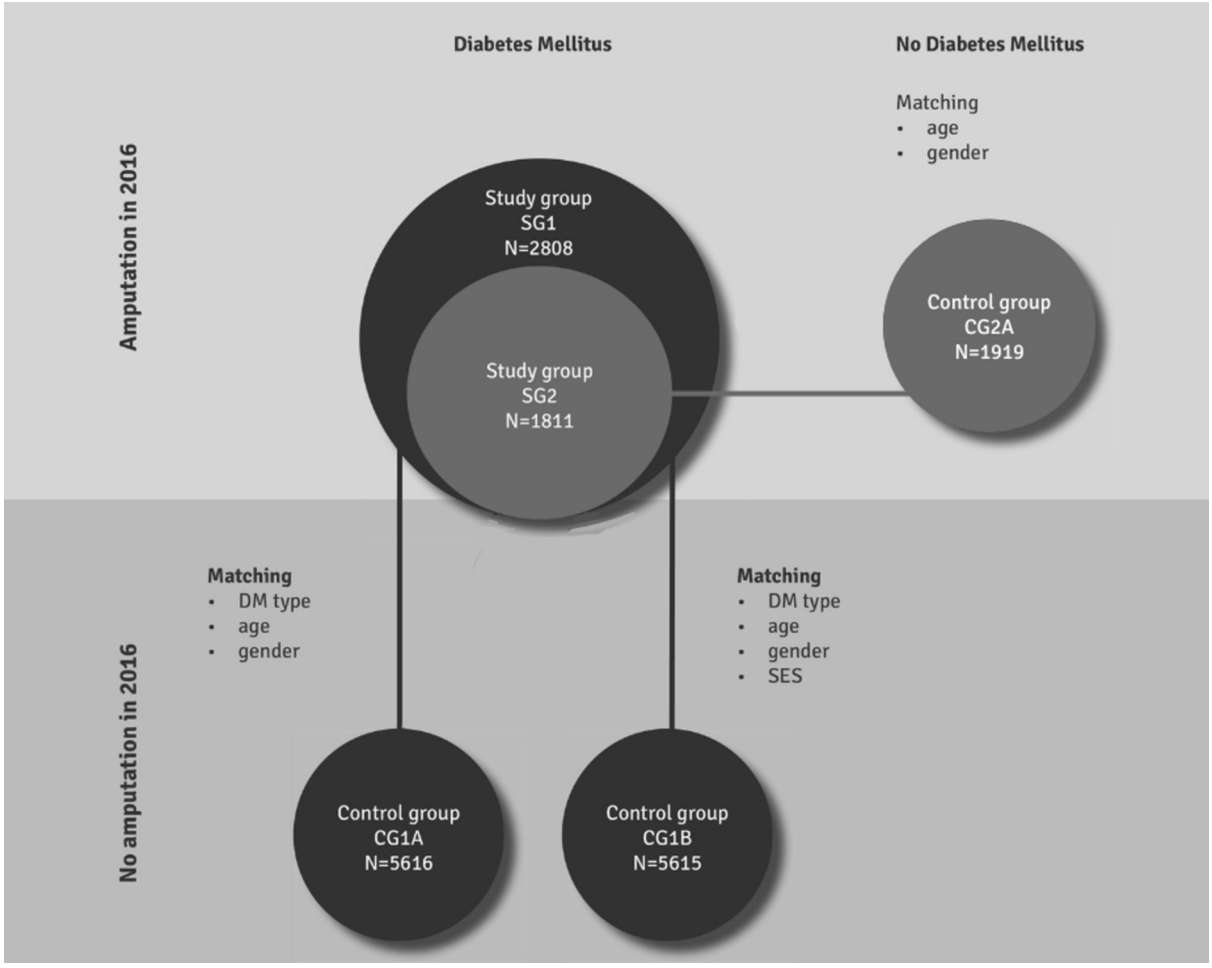

Fig. 1. Schematic representation of the study and control groups.

need formal consent of the Dutch health insurers.

2.5. Statistical analyses

As stated, Vektis provided data at an aggregated level, meaning that only summary descriptive statistics were available for this study. Concerning mortality, numbers of individuals deceased per year were provided. Due to potential privacy risks, data were provided only for those groups with ten patients or more.

3. Results

For the present study, we obtained information from the APCD on 2808 individuals with DM (SG1, DM+/LEA+) and were able to match them with 5616 and 5615 individuals with DM without an LEA in the groups CG1a (DM+/LEA−) and CG1b (DM+/LEA−), respectively. In the second matching procedure, 1811 individuals with DM (SG2, DM+/LEA+) were matched with 1919 individuals without DM (CG2a, DM−/LEA+), all of whom underwent a lower extremity amputation (LEA). Table 2 shows the characteristics of the different groups.

The average age of individuals with DM having a LEA was over 70 years with a clear majority of individuals with male sex assigned at birth. The matching procedure on SES had no influence on the mortality as CG1a (DM+/LEA−) and CG1b (DM+/LEA−) showed comparable mortality rates (see Table 3 and supplemental Table S1).

Mortality rates of the different groups are shown in Table 3 and Fig. 2. By 2022, approximately 60 % of individuals with LEA in 2016, both with and without DM, had died. The five-year mortality rate was SG1 (DM+, LEA+) 61.2 %, CG1a (DM+, LEA−) 27.9 %, CG1b (DM+, LEA−) 27.9 %, SG2 (DM+, LEA+) 62.6 %, CG2a (DM−, LEA+) 56.4 %. For separated years see Fig. 2.

4. Discussion

The present study is the first to provide national mortality rates in matched individuals with and without DM following LEAs in the

Table 2
2016 group characteristics; combined T1DM/T2DM.

	N=	Age (years)	M/F (%)	A10A (insulin) only	A10B (non-insulin glucose lowering agents) only	A10A + A10B	No A10A or A10B
SG1. DM+/LEA+	2808	70.6 ± 12.1	70/30	26.4 %	30.9 %	34.7 %	8.0 %
CG1a. DM+/LEA−	5616	70.6 ± 12.1	70/30	22.3 %	48.8 %	12.5 %	16.4 %
CG1b. DM+/LEA−	5615	70.5 ± 12.1	70/30	22.6 %	48.8 %	12.8 %	15.7 %
SG2. DM+/LEA+	1811	71.3 ± 12.6	65/35	27.8 %	29.9 %	34.3 %	8.0 %
CG2a. DM−/LEA+	1919	71.3 ± 13.2	62/38	–	–	–	100.0 %

Data are presented as numbers or percentages (%).

Table 3
Mortality 2016–2021.

Group	Total group of individuals with an LEA in 2016	Cumulative deceased n = and cumulative %	2016	2017	2018	2019	2020	2021	2022
SG1									
DM+	2808	n=	418	790	1078	1314	1529	1719	1812
LEA+		%	14.9 %	28.1 %	38.4 %	46.8 %	54.5 %	61.2 %	64.5 %
CG1a									
DM+	5616	n=	239	497	753	991	1272	1564	1707
LEA−		%	4.3 %	8.9 %	13.4 %	17.7 %	22.7 %	27.9 %	30.4 %
CG1b									
DM+	5615	n=	238	502	755	1000	1286	1567	1712
LEA−		%	4.2 %	8.9 %	13.5 %	17.8 %	22.9 %	27.9 %	30.5 %
SG2									
DM+	1811	n=	276	529	717	806	1011	1133	1196
LEA+		%	15.2 %	29.2 %	39.6 %	44.5 %	55.8 %	62.6 %	66,0 %
CG2a									
DM−	1919	n=	282	526	714	856	972	1082	1144
LEA+		%	14.7 %	27.4 %	37.2 %	44.6 %	50.7 %	56.4 %	59,6 %

Netherlands.

To be able to compare the Dutch mortality rates with those in other countries are regions, part of the data is standardized to 5 years mortality rates. The 5-year mortality rates observed in our study were 54.5 % for individuals with DM and 50.7 % for those without DM after LEA, somewhat lower than the 64.4 % pooled rate reported in a recent systematic review by Meshkin et al.[7] In another meta-analysis including 21 studies on LEAs in various patient groups (PAD, DM, dialysis) 1-year and 5-year mortality rates after LEAs were 47.9 % and 62.2 %, respectively.[9] It is important to note that Meshkin's review focused on major amputations, whereas our study, using the APCD, could not differentiate for mortality outcomes, between major and minor amputations. Additionally, our dataset includes traumatic amputations, which may slightly favor survival rates as these individuals generally have fewer comorbidities.

Previously, we have demonstrated that individuals with DM in the Netherlands have a 17-fold higher risk of amputation compared to those without DM.[13] However, when we assessed the mortality rates after LEAs in individuals with and without DM, we found only a small difference in mortality rates between individuals with (SG1, DM+, LEA+) and without DM (CG2a DM−, LEA+) following LEAs. This might be due to the presence of (probably) extensive vascular damage and thus vulnerability present in individuals undergoing an LEA, irrespective of the presence or absence of DM. High mortality rates in the first year post-LEA (15 % in both groups) underscore this vulnerability. However, based on the available data, we are unable to identify specific underlying reasons.

Despite matching with another group of persons, the mortality rates of SG1 (DM+, LEA+) and SG2 (DM+, LEA+) show similar results. Matching on SES (CG1b, DM+/LEA−) had no significant influence on the mortality rate in our study. This is in contrast with the literature, where clear differences are found to the detriment of a lower SES.[18] This different finding might be explained by the healthcare system in the Netherlands: all individuals are obliged to have health insurance and thus have equal access to primary and secondary care. Preventive and curative foot care is part of the universal and reimbursed healthcare in the Netherlands. Therefore, even people with the lowest SES have access to reimbursed foot care; this in turn suggests that availability and use of foot care facilities are not dependent on income differences in the Netherlands.

4.1. Limitations

Of course, our study has also limitations. This study was based on an all-payer claims administrative database. Data were collected based on reimbursement data from hospital claims and thus van be considered comprehensive. Still, the obtained information does not allow differentiation between, for example, traumatic and non-traumatic amputations. Neither is information available on clinical data, such as smoking habits, BMI, lifestyle factors, degree of glucose regulation, and laboratory results. We have some information about diagnoses of peripheral arterial disease, renal disease, and cardiovascular disease, but we could not obtain sufficiently reliable information about the severity of concomitant diseases. It would be of great interest if the cause of death of the individuals in the database was known. It would be highly beneficial to be able to properly determine whether individuals who passed away had undergone a major or minor amputation and whether they had critical PAD, kidney failure, or cardiovascular disease. Based on clinical reasoning, one would expect that those with a major LEA, kidney failure, and PAD, would experience the worst outcomes. However, further research is essential to validate or refute whether this assumption holds true Since we did not have information regarding the mortality rates after subdivision into major and minor LEAs, there is a lack of information to draw more firm and detailed conclusions on possible differences in mortality rates after either minor or major LEAs. We hope to be able to repeat this study in the future with the possibility of further differentiation between the groups.

4.2. Strengths

One of the key contributions of this study is the use of a comprehensive dataset from the Vektis Health Care Information Center, covering the vast majority of the Dutch population. This robust dataset allows for a thorough analysis of mortality trends following LEAs and provides valuable insights into real-world outcomes. Moreover, using matching procedures to compare mortality rates between individuals with and without DM, enhances the validity of the findings.

5. Conclusions

Mortality rates are high and comparable in both individuals with and without DM who underwent a LEA in the Netherlands. Individuals with DM face an over 100 % higher mortality risk over the studied period of six years compared to the matched group of individuals with DM

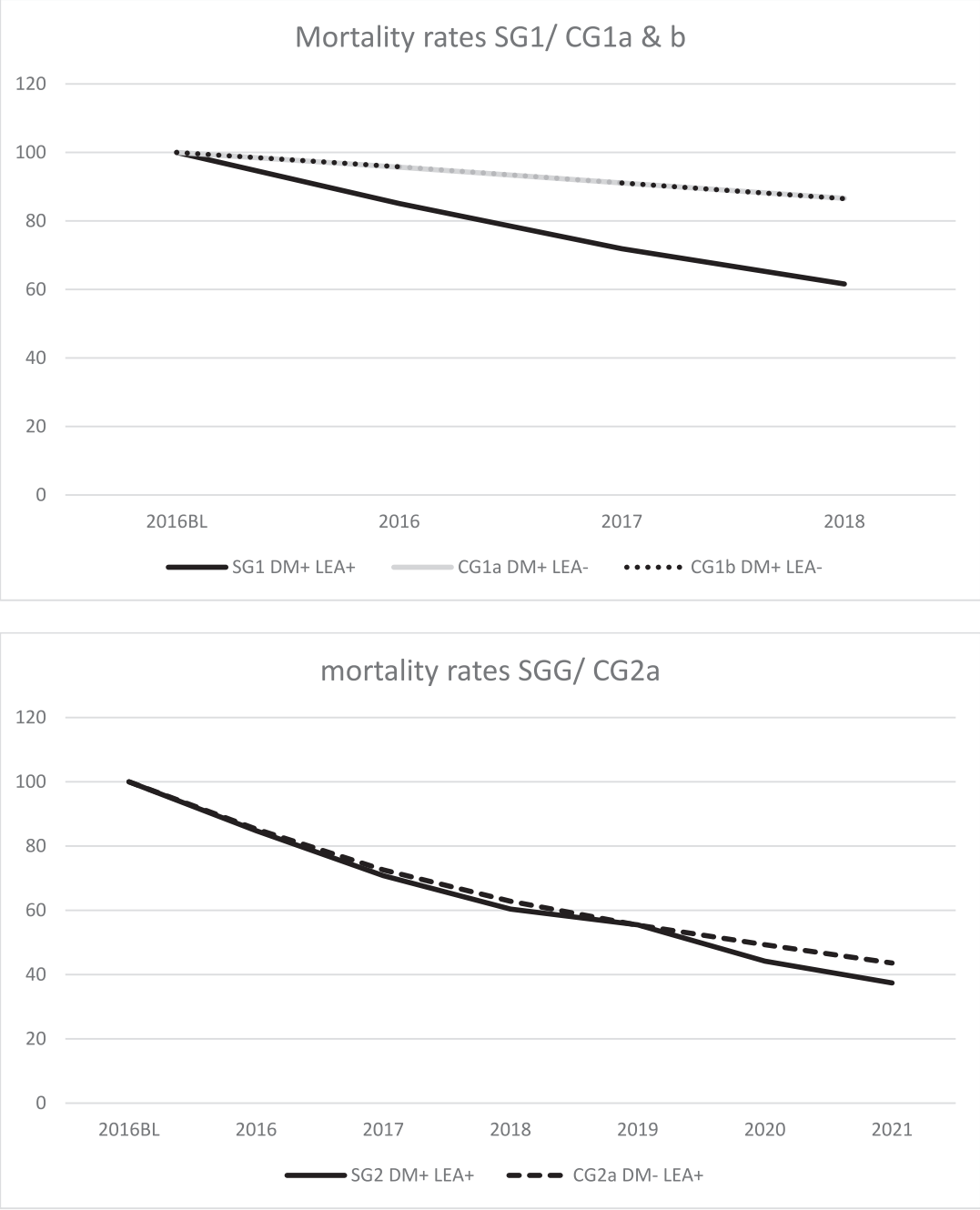

Fig. 2. Mortality rates in various subgroup.

without an LEA in both of the matched control groups. Differences in mortality rates between DM and non-DM groups are present but small. In the Dutch situation SES seems not to have an impact on LEA. There is a need for further research on risk factors for amputation and the mechanisms rising the mortality to optimize both the preventive care and the actual post-LEA care, possibly also improving the quality of life for individuals affected by LEAs.

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jdiacomp.2025.108956.

Ethics and registration

This study is part of the DUtch Diabetes Estimates (DUDE) initiative and has been approved by the Medical Ethical Committee of Isala Zwolle (METC230603). The study was registered on Clinical Trials https://clinicaltrials.gov/study/NCT05939271 with trial number NCT0593927.

CRediT authorship contribution statement

L. Rosien: Writing – original draft, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **H.J.G. Bilo:** Writing – review & editing, Supervision, Investigation, Data curation, Conceptualization. **J. Oskam:** Writing – review & editing, Conceptualization. **D. Ruwaard:** Writing – review & editing. **R.O.B. Gans:** Writing – review & editing, Supervision. **M.A. Edens:** Writing – review & editing. **M.J. Molegraaf:** Writing – review & editing. **P.R. van Dijk:** Writing – review & editing, Supervision, Investigation,

		2016BL	2016	2017	2018	2019	2020	2021	2022
SG1	N total	2808	2390	2018	1730	1494	1279	1089	996
DM+ LEA+	N deceased		418	372	288	236	215	190	93
▬▬	% alive	100	85,1	71,9	61,6	53,2	45,5	38,8	35,5
CG1a	N total	5616	5377	5119	4863	4625	4344	4052	3909
DM+ LEA-	N deceased		239	258	256	238	281	292	143
▬	% alive	100	95,7	91,1	86,6	82,3	77,3	72,1	69,6
CG1b DM+ LEA-	N total	5615	5377	5113	4860	4615	4329	4048	3903
▪▪▪▪▪▪	N deceased		238	264	253	245	286	281	145
	% alive	100	95,8	91,1	86,6	82,2	77,1	72,1	69,5
SG2	N total	1811	1535	1282	1094	945	800	678	615
DM+ LEA+	N deceased		276	253	188	149	145	122	63
▬▬	% alive	100	84,8	70,8	60,4	55,5	44,2	37,4	34,0
CG2a	N total	1919	1637	1393	1205	1063	947	837	775
DM- LEA+	N deceased		282	244	188	142	116	110	62
▬ ▬ ▬	% alive	100	85,2	72,6	62,8	55,4	49,3	43,6	40,4

Fig. 2. (*continued*).

Conceptualization.

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Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Leonie Rosien reports financial support was provided by NVvP. Leonie Rosien reports financial support was provided by Isala W&I foundation. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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