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ORIGINAL RESEARCH

Morbidity and Mortality Rates in People with Diabetes Mellitus With an Active Charcot's Neuro-Osteoarthropathy: A 15-Year Single-Center Retrospective Analysis

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ABSTRACT

***Introduction*:** Diabetes related Charcot neuro-osteoarthropathy (CN) of the foot is associated with increased risks of amputation and premature mortality. We aimed to report the amputation and mortality rates of people with active CN and identify participant and CN characteristics associated with these adverse outcomes.
***Methods*:** A single-center retrospective study. Participants were included if they were diagnosed with an active CN with type 1 or type 2 diabetes mellitus presenting to a specialist foot clinic between January 2007 and September 2022. Participant and CN characteristics were analyzed to determine relationships with amputation or mortality.
***Results*:** 186 participants were included with 195 CN feet. Median follow-up was 8.2 years (IQR 5.3, 12.2). Male sex ($p=0.026$) and previous amputation ($p=0.003$) were associated with a significantly increased risk of amputation. The 1-year, 5-year, and 10-year mortality rates were 2.7% (5/186), 18.9% (23/122), and 40% (24/60), respectively. Previous amputation and worsening chronic kidney disease stage were associated with a significantly increased mortality risk ($p=0.005$ and $p=0.027$, respectively).
***Conclusions*:** Participants with CN had high amputation and mortality rates. The causes of death were multifactorial, suggesting clinicians should focus on early aggressive multiple risk factor intervention to reduce these adverse outcomes.

PLAIN LANGUAGE SUMMARY

Diabetes related nerve disease can lead to foot problems. One of these is where the joints of the foot become disrupted and the bones no longer align correctly – this is called a Charcot foot. It occurs in about 1 in 200 people with diabetes. Having a Charcot foot is recognized as a predictor of ulceration and amputation and also premature death. In this study, we looked at the data from 186 people with a new onset Charcot followed up at 1 hospital specialist diabetes foot clinic over 15 years, and looked at what factors determined the increased risk of having an amputation or early death. We found that being male and having a previous amputation were

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the strongest predictors of having an amputation, and having a previous amputation and long-term kidney disease were the factors most predictive of an early death. We recommend that people with a Charcot have their cardiovascular risk factors optimized as soon as possible to help prevent amputations and early death.

Keywords: Charcot neuro-osteoarthropathy; Amputation; Mortality

Key Summary Points
Why carry out this study?
Charcot foot is a rare but potentially devastating complication of diabetes and is recognized to be associated with increased risk of amputation and premature mortality.
We wanted to find out what the risk factors were for amputation and mortality in our specialist foot clinic population.
What was learned from this study?
The main risk factors for amputation for someone with a Charcot is a history of previous amputation and being male.
The main risk factors for premature mortality were a history of a prior amputation and chronic kidney disease stages 3 and 4.

INTRODUCTION

Charcot neuro-osteoarthropathy (CN) is a disease that affects the bones and joints of the foot and is a complication of neuropathy, which can affect those with diabetes. CN is thought to affect 0.2% of people living with diabetes [1]. It occurs due to peripheral neuropathy, leading to repeated trauma, resulting in fractures, dislocation and deformities of the foot and ankle [2]. Ulceration can then occur over the site of deformity. If an ulcer becomes infected, then this can lead to amputation.

Previous studies have associated CN with an increased risk of major amputation and premature mortality [3–5]. The main aim of treatment is to immobilize and offload the affected foot to allow recovery and prevent further damage and deformity. Primarily, this is achieved using below-knee casts or boots. Early treatment is associated with a reduction in the progressive deformity [6, 7]. Treatment for CN can extend to early intervention for those at a higher risk of adverse outcomes.

Rationale

A better understanding of the incidence of amputation and premature mortality in people with CN will allow people with CN to make informed treatment choices based on the available evidence, and the individuals' own needs and priorities, and improve outcomes. If healthcare teams were more accurately able to predict those who are likely to experience poorer outcomes, they would be able to work with people with diabetes to support them in managing the CN and diabetes.

Aims

We aimed to report the amputation and mortality rates of people with diabetes mellitus and active CN and identify participant and CN characteristics associated with these outcomes.

METHODS

Study Design, Setting, and Patients

This was a single-center retrospective analysis of people presenting with a new case of active CN between 2007 and 2022. The study followed up people diagnosed with active CN presenting to a single-center tertiary multidisciplinary foot clinic for 1–15 years to identify who underwent an amputation or died. Participants were included if they had a diagnosis of type 1 or type 2 diabetes mellitus and their CN developed and presented between January 2007 to September 2022.

People were identified through searching the hospital's electronic database for clinic letters with the keyword "Charcot". The diagnosis of CN was confirmed by the multidisciplinary team based within our large specialist diabetic foot clinic. The diagnosis of CN was based on clinical signs and symptoms (red, hot, swollen, with or without pain) and must have been managed as an active CN. Participants were excluded if they had a chronic CN, or if an active CN was unlikely from history and examination or imaging. A strong clinical suspicion of CN with negative imaging studies would not exclude a participant, thus participants with both stage 0 and stage 1 CN based on the Eichenholtz classification of CN were included in this study [8].

The hospital clinic and general practitioner letters to primary care of potential participants were screened to identify people who fulfilled the inclusion and exclusion criteria. If participants had multiple episodes of active CN during the inclusion period, the first episode was included in the study. In the case of simultaneous bilateral CN, both feet were included.

Data Collection

Anonymized participant, CN, and outcome data were obtained by searching people's foot clinic records, general hospital notes, radiological images, and any discharge summaries for inpatient admissions. The participant characteristics collected were age, sex, type of diabetes, duration of diabetes, glycated hemoglobin (HbA1c) at diagnosis of CN, albumin–creatinine ratio (ACR) and estimated glomerular filtration rate (eGFR). The CN characteristics were site and stage of CN – categorized using relevant imaging, according to the Sanders and Frykberg, and Eichenholtz classification systems, and history of previous CN [8, 9]. If both feet were affected by an acute CN, then analyses were done per patient in a similar fashion to that done for those where a single foot was involved.

Study Outcomes

The primary outcomes of this study were amputation (major or minor) and death, which were collected from hospital records.

The project was registered with the audit department at our institution. Formal ethical approval was not required as this was an anonymized retrospective case note analysis. Trust approval for the project was granted using the Health Research Authority tool by the audit department and the service director for diabetes and endocrinology.

Statistical Analysis

We calculated the 1-year, 5-year, and 10-year amputation and mortality rates across the cohort. Baseline characteristics were reported as mean and standard deviations or median and interquartile ranges. Data analysis was conducted in SAS 9.4 (SAS Institute Inc., Cary, NC, USA). People were grouped for analysis according to different characteristics; type of diabetes, sex, site of CN, HbA1c, eGFR, previous history of ulcer or amputation and CKD stage. Participant characteristics and CN characteristics were assessed for any associations to the outcomes, amputation and mortality. If a participant had missing data, they were excluded from analysis for the data that was not available. They would still be included for analysis of other characteristics that were available. People with an acute on chronic Charcot were included in the analysis.

Numbers were censored for mortality and morbidity and then used to plot Kaplan–Meier curves (for both amputation and mortality). The log-rank test was used to test for any differences within each characteristic, independent of any other characteristic, and the chi-squared test was calculated to determine whether the results were significant.

RESULTS

Screening

From the clinic letter search, 3,107 letters from 1087 individuals were identified containing the word 'Charcot'. The screening stage is summarized in Fig. 1.

Participant Characteristics

The majority of participants included in this study were male patients, 71.0% (132/186). The mean age of the group was 60.4 (±13.2) years.

Charcot Neuro-Osteoarthropathy Characteristics

The majority of participants did not have a previous CN, 89.8% (167/186). For 3.8% (7/186) participants, it was unknown whether there was a previous episode of CN. Of those that did, 21% (4/19) had a previous CN on the same foot and 42% (8/19) had a previous CN on the contralateral foot. Table 1 summarizes the participant and CN characteristics.

Outcomes

Morbidity

A total of 13.4% (25/186) people included in the study underwent an amputation (minor or major) during the follow-up period. A minor amputation was defined as the removal of toes or part of the foot whereas a major amputation was defined as a below or above-knee amputation. The data were pooled if data on type of amputation was not available. Five people underwent two amputations. The 1-year amputation rate was 2.2% (4/186). The 5-year amputation rate was 9.8% (12/122). The 10-year amputation rate was 13.3% (8/60). Re-amputations were not included with only the time to the first amputation being reported.

Logistic regression analysis suggested that sex (Fig. 2) and previous amputation (Fig. 3) were associated with statistically significantly increased risks of amputation. Male patients had an OR 5.7 (95% CI: 1.2 to 26.2), $p=0.026$ and previous amputation an OR 3.9 (95% CI: 1.5 to 10.2), $p=0.003$. The results suggest that HbA1c at presentation of CN ($p=0.167$) is not associated with increased amputation rates. We

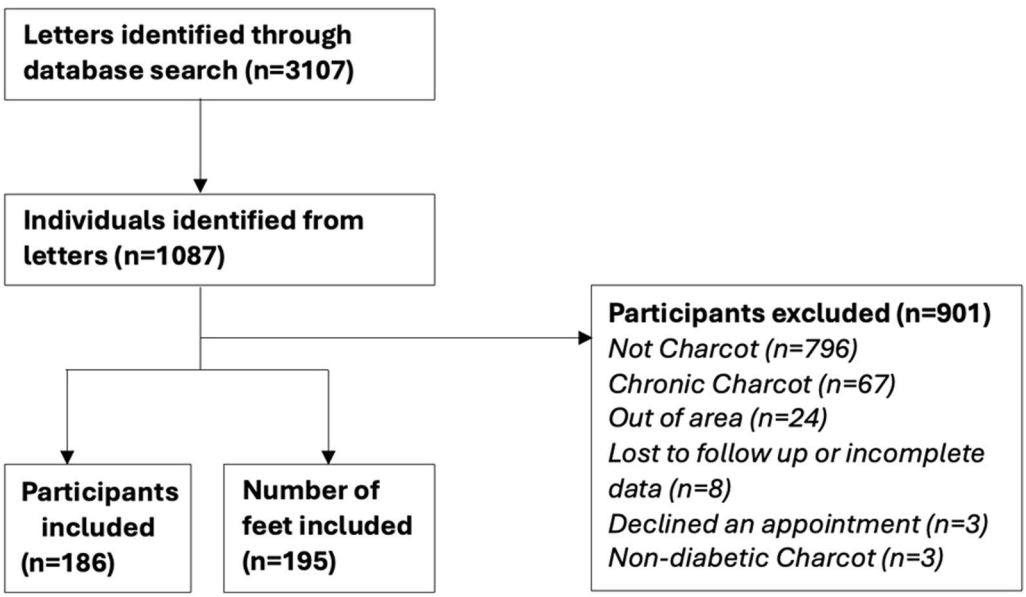

Fig. 1 Consort flow diagram showing screening process

Table 1 Participant characteristics

Baseline characteristics	**All participants [*n* = 186]**
Sociodemographic	
Male/Female [%]	132/54 [71%/29%]
Mean age (years) (SD)	60.4 (± 13.2)
Diabetes	
Type 2 diabetes mellitus	123 [66.1%]
Mean duration of diabetes (years)	31.5 (± 15.9)
Laboratory results at presentation with an active CN	
Median HbA1c (mmol/mol) (IQR) [*n* = 179]	62.9 (27.8, 51.2)
Median ACR (IQR) [*n* = 150]	3.6 (1.2, 18.2)
eGFR [%] [*n* = 180]	
< 15	2 [1.1%]
15–29	14 [7.7%]
30–44	17 [9.4%]
45–59	24 [13.3%]
60–89	70 [38.9%]
≥ 90	53 [29.4%]
Charcot characteristics	All participants [*n* = 186]
Previous Charcot [%]	
Same foot	4 [2.2%]
Other foot	8 [4.3%]
No previous Charcot	167 [89.8%]
Not known	7 [3.8%]
Charcot characteristics	All feet [*n* = 195]
Sanders and Frykberg classification [%] [9] *(Participants could have multiple sites in the foot)*	
I	48 [24.6%]
II	121 [62.1%]
III	99 [50.8%]
IV	43 [22.1%]
V	10 [5.1%]
Unknown	8 [4.1%]

Table 1 continued

Baseline characteristics	All participants [*n* = 186]
Eichenholtz classification on X-ray [%]	
Stage 0	35 [17.9%]
Stage I	159 [81.5%]
Stage II	0 [0%]
Stage III	0 [0%]
No X-ray	1 [0.5%]
Eichenholtz classification on MRI [%]	
Stage 0	13 [6.7%]
Stage I	104 [53.3%]
Stage II	0 [0%]
Stage III	0 [0%]
No MRI	78 [40.0%]

SD standard deviation, *HbA1c* glycated hemoglobin, *ACR* albumin/creatinine ratio, *IQR* interquartile ratio, *MRI* magnetic resonance imaging

found no relationship between amputation with type of diabetes ($p=0.831$), Sanders and Frykberg sites ($p=0.126$), eGFR ($p=0.369$), ulcer history ($p=0.207$) and CKD stage ($p=0.430$).

Mortality

A total of 79/186 participants had died by the end of the study. The 1-year mortality rate was 2.7% (5/186). The 5-year mortality rate was 18.9% (23/122). The 10-year mortality rate was 40% (24/60).

Previous amputation (Fig. 4) and CKD stage (Fig. 5) were associated with increased risk of premature mortality ($p=0.005$ and $p=0.027$, respectively). The results suggest that a high HbA1c of over 63 mmol/mol [8.0%] ($p=0.088$) was not associated with an increased mortality rate. We found no relationship between mortality rates with type of diabetes ($p=0.354$), sex ($p=0.7808$) Sanders and Frykberg sites ($p=0.860$), eGFR ($p=0.425$) and previous ulcers ($p=0.095$).

Logistic regression analysis was again applied adjusting for CKD and sex. The HR for mortality is 2.95 for previous amputations compared to no previous amputations (95% CI; 1.3 to 6.6; $p=0.008$). CKD is also a significant predictor with stages 3 and 4 CKD compared to stage 1 having a HR of 2.3 (95% CI; 1.01 to 5.28; $p=0.046$) and 4.9 (95% CI; 1.5 to 16.3; $p=0.01$), respectively. Sex was not a predictor of mortality HR of 1.3 (95% CI 0.58 to 3.0; $p=0.51$).

DISCUSSION

Our study has shown that in people with diabetes and an active CN, male sex and previous amputation were associated with an increased risk of amputation (major and minor). In addition, we reported 1-year (2.2%), 5-year (9.8%), and 10-year (13.3%) amputation rates, and 1-year (2.7%), 5-year (18.9%), and 10-year (40.0%) mortality rates. Our data suggests that

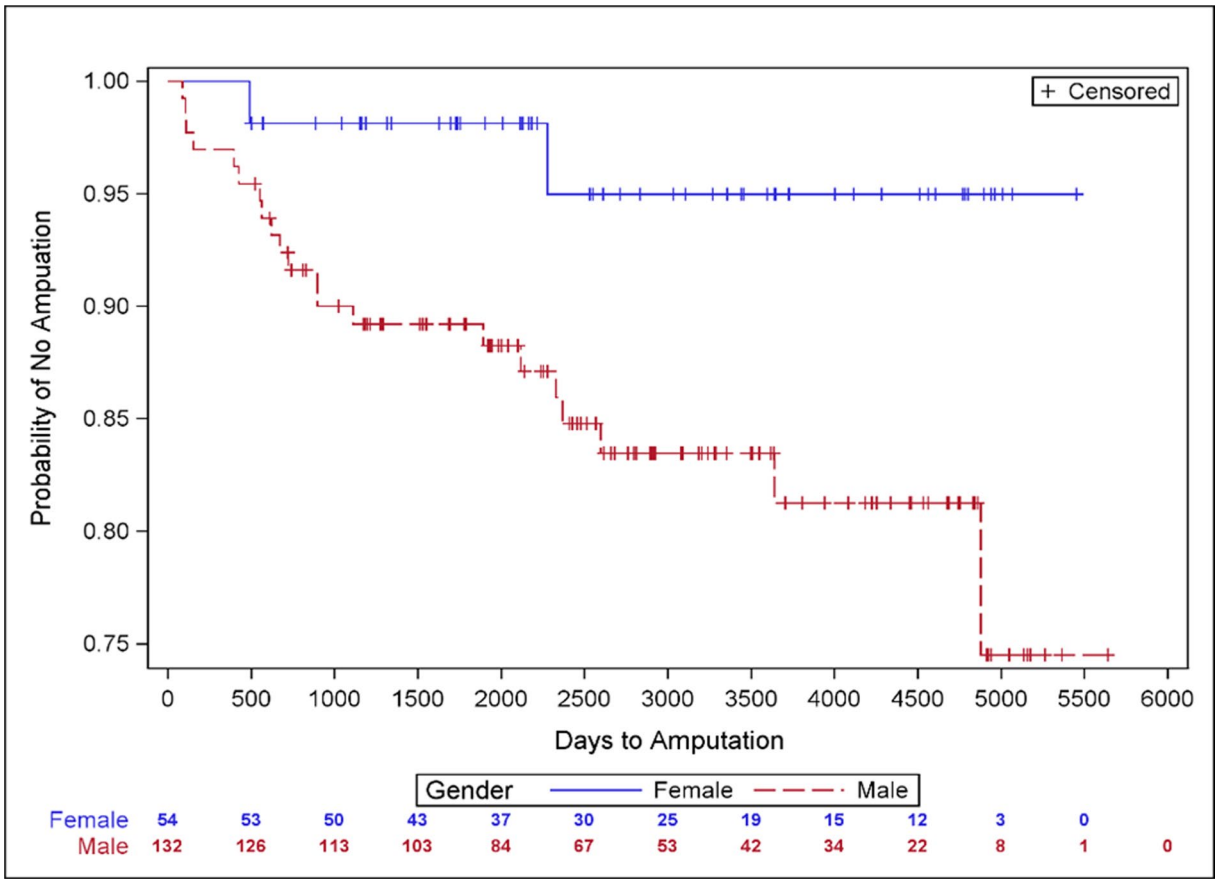

Fig. 2 Kaplan–Meier plot comparing sex and amputation

having a previous amputation and a more severe CKD stage were associated with an increased risk of premature death.

This retrospective study included 186 people with a new diagnosis of active CN between 2007 and 2022. The people included in this study are representative of those with CN as reported in other studies and case series. In agreement with previous data, our population was predominately male patients with a mean age of 60.4 (± 13.2) years [10, 11]. The most common Sanders and Frykberg stage was stage 2 (Lisfranc, tarsometatarsal joints).

There has been one recent systematic review and meta-analysis [4] and a number of studies [12–15] that have reported CN related morbidity and mortality and the associated risk factors. Sohn et al. showed that people with CN had an increased mortality compared to those with diabetes, without CN [5]. Previous work suggested no significant difference in mortality in individuals with CN compared to those with neuropathic ulcers, there was still an overall higher mortality rate in those with CN compared to controls who were matched for sex, age (± 2 years), disease type, disease duration (± 2 years) and year of referral (± 3 years) [3]. Yammine et al. supported this as they showed in their meta-analysis looking at 16 studies with a combined population of 2250 patients that 16% of people with CN went on to have an amputation, and there was a significantly higher mortality in those with CN feet and diabetic foot ulcers compared to those without any foot complications [4].

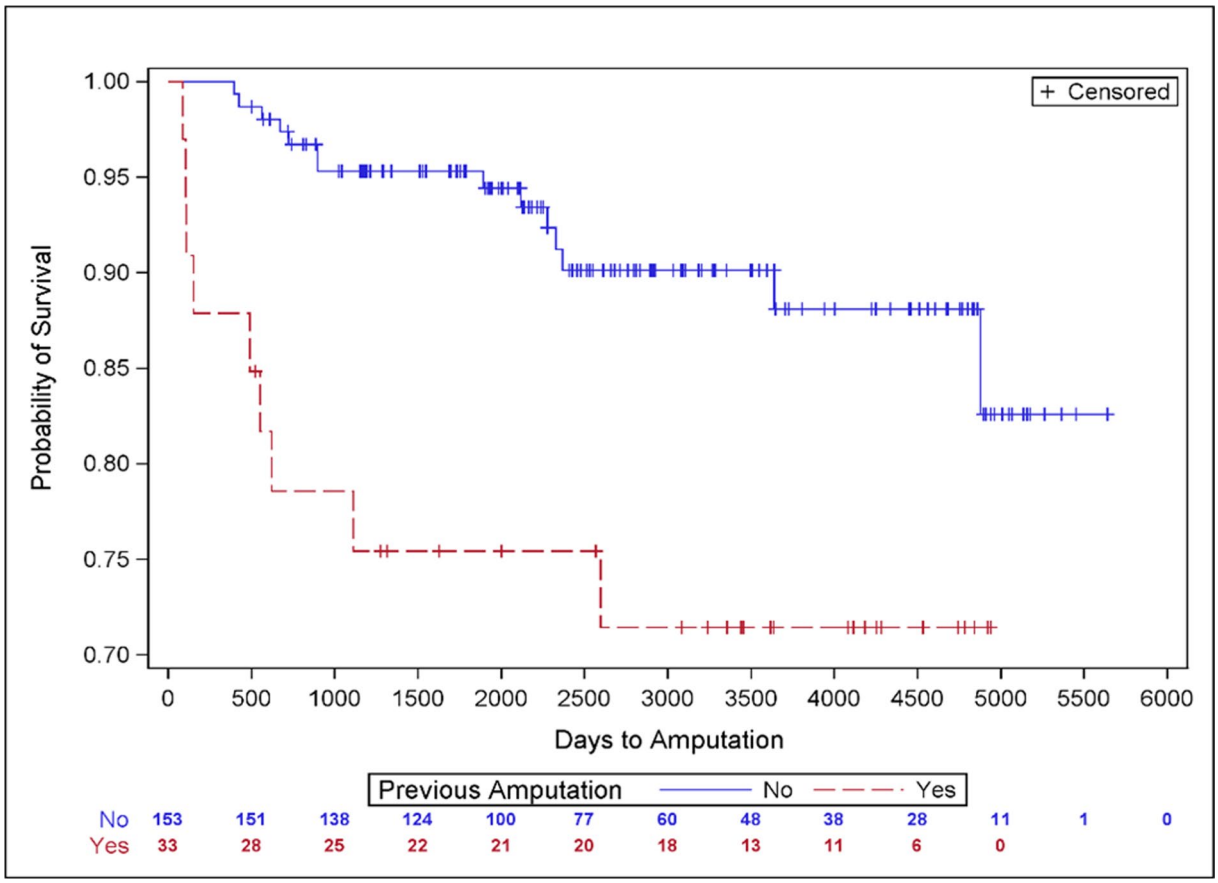

Fig. 3 Kaplan–Meier plot comparing previous amputations

Crude Rate Comparison

The meta-analysis conducted by Yammine et al. looked at the amputation and mortality frequencies associated with diabetes related CN. The authors included similar inclusion and exclusion criteria used in the present study. They reported an overall amputation rate of 15.0% from ten studies including 871 feet, comparable to the amputation rate of our study, 15.3% from 195 feet [4].

The meta-analysis also reported an overall 1-year mortality of 4.0% (from two studies including 255 participants), a 5-year mortality of 24.5% (from seven studies including 1706 participants), and a 7 + year mortality of 16.0% (from four studies including 277 participants). In comparison, the 1-year (2.7%) and 5-year (18.9%) mortality rates of our study while numerically lower were too small to be able to suggest any statistical differences. Similarly, whereas the 10-year mortality rate (40.0%) of our study was numerically higher than the 7 + year mortality rate of the meta-analysis, possibly due to the longer follow-up period, no statistical inferences can be made [4].

A previous study from our center by Stark et al. reported the 5-year outcomes for 50 people with active CN [12]. That study reported 5-year outcomes for the whole cohort, which were an 8.0% (4/50) amputation rate and 4.0% (2/50) mortality rate. Our 5-year amputation rate 9.8% (12/122) and mortality rate 18.9% (23/122) were higher than this.

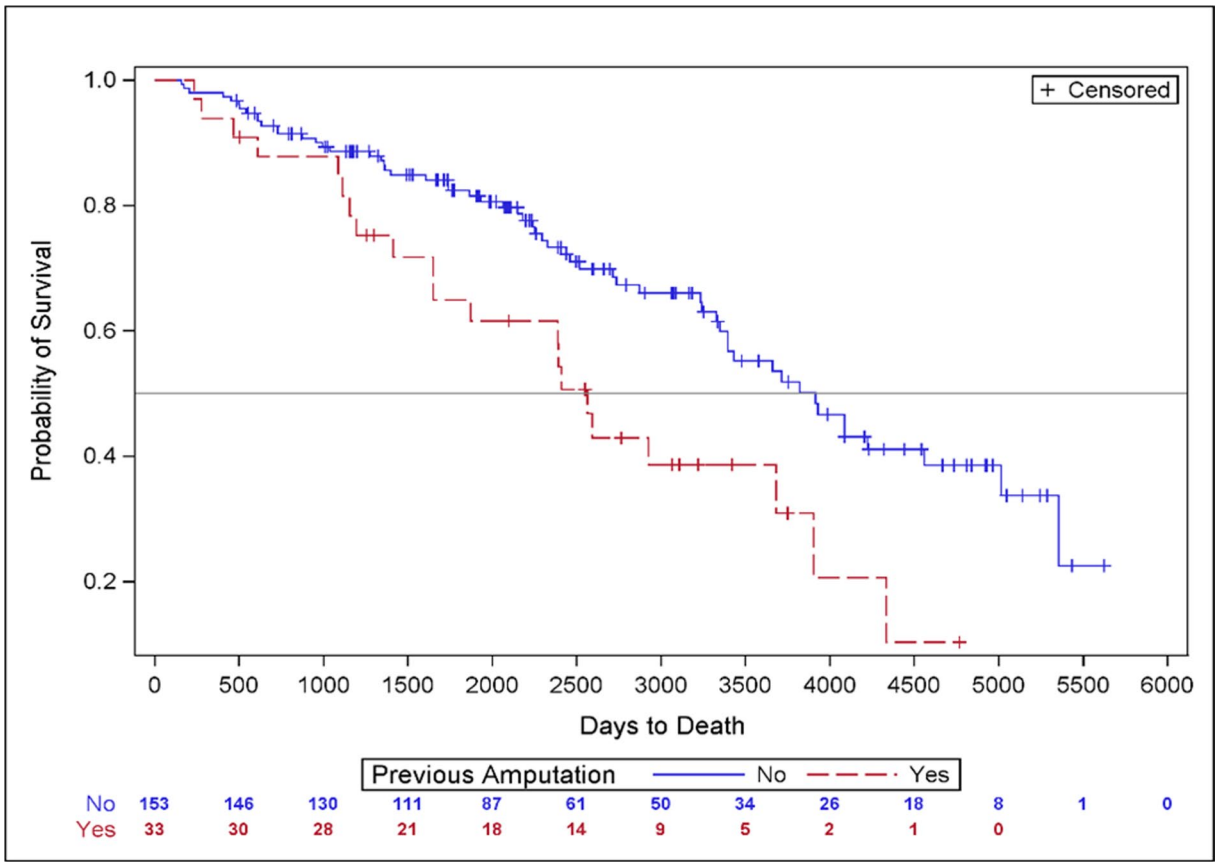

Fig. 4 Kaplan–Meier plot comparing previous amputation

Factors Affecting Amputation

Our results showed that male sex was associated with an increased risk of amputations. This aligns with data from the USA by Ramanujam et al. who reported a higher proportion of their lower extremity amputations in male patients compared to female patients [14]. It is important to highlight that their study focused only on those who required surgery, which may mean that the CN episodes are more likely to be severe as they may have been unsuccessful with conservative treatment. Male patients have previously been shown to have a higher incidence of CN which could mean that CN episodes in male patients are more likely to progress and be more severe requiring amputation as a treatment [16].

In line with another study, our study found previous amputations were associated with an increased risk of further amputation [13]. This could be explained by non-healing, or changes to lower limb biomechanics leading to transfer ulcers which go onto require amputation [17].

Factors Affecting Mortality

Van Baal et al. previously demonstrated that the mortality of a person with a CN was the same as someone with a noninfected foot ulcer, with a median survival of 7.88 (4.0–15.4) and 8.43 (3.4–15.8) years, respectively [3]. However, previous amputations were also shown to be associated with a higher mortality rate. There are many reasons why this may be. Mortality rates are higher in those who do not regain the ability to walk after an amputation compared to those

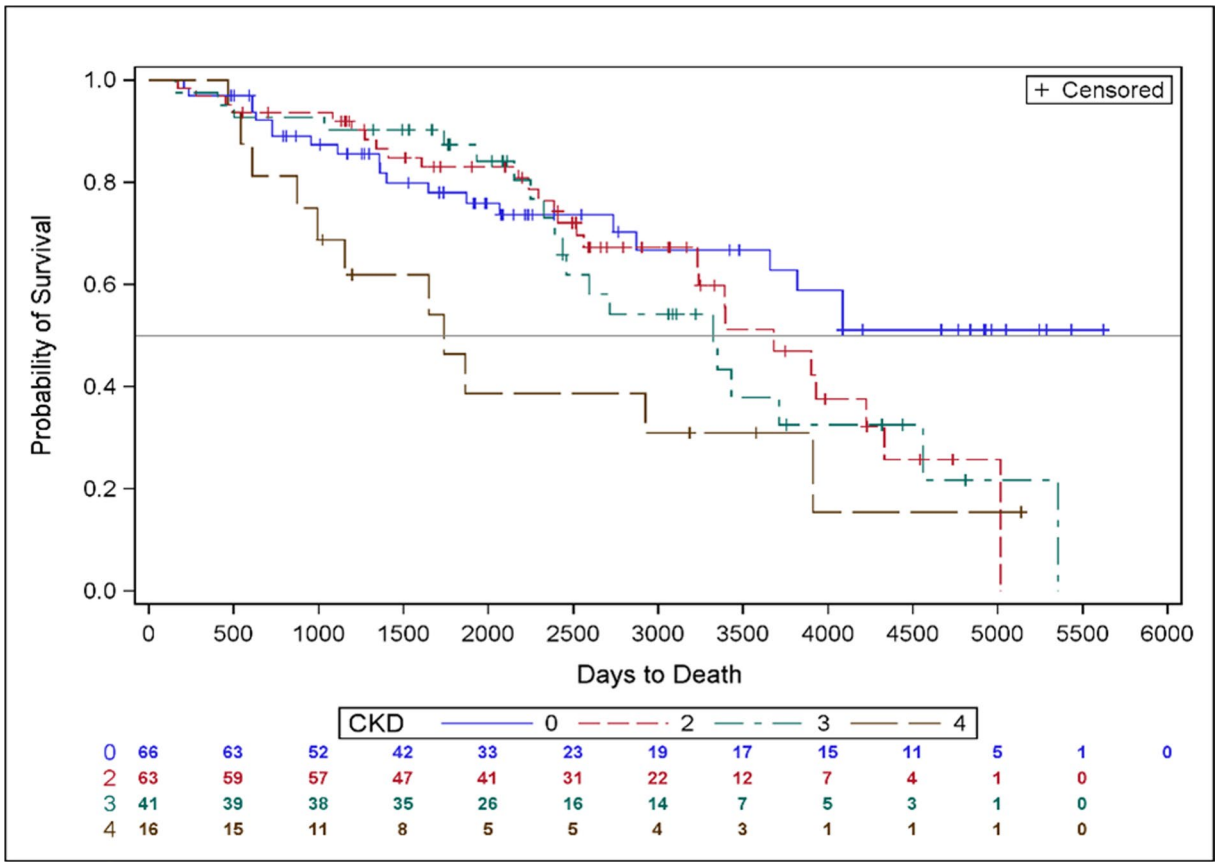

Fig. 5 Kaplan–Meier plot comparing chronic kidney disease stages

who do remobilize [18]. A person's health status prior to amputation including age, presence or absence of renal disease, peripheral arterial disease and cardiovascular disease will all impact on mortality rates [17, 19]. Worsening CKD stage was also associated with a higher mortality rate. Studies from the USA and India have reported similar findings to our work with higher mortality rates in those with renal disease and diabetic foot complications including CN, ulcers, and infections [20, 21]. The presence of CKD is associated with increased cardiovascular risk [22].

Some of our outcomes differ to the published literature. This may be because our sample size is not large enough to observe the true effect. The participant characteristics and treatment strategies may also be different compared to other published studies. Earlier offloading or the use of non-removable versus removable offloading devices in addition to a more intense approach to the prevention and management of other risk factors, such as diabetes control, CKD or cardiovascular factors, may all improve the reported outcomes. More work is needed to further understand how these participant and CN characteristics and different treatment strategies affect the outcomes of CN.

The strengths of this study are that due to it being single centerd with a consistent approach to the treatment of CN over the 15 years of this study. As per international guidelines all cases of active CN were treated with non-removable or removable knee-high offloading devices based on clinician's recommendations and individuals' preference [23].

The limitations of the study are that the center was a tertiary center so there was an increased number of participants for whom long-term follow-up data was not available. This is because once the CN had gone into remission, people were discharged back to their local care provider. Another limitation of this study is that no multivariant factors have been accounted for with regards to amputations due to a low sample size. Whilse it is appreciated that risk factors are different for different types of amputation, (major or minor) data on these were not collected. Data for confounding factors such as further foot ulcer formation, cardiovascular disease, peripheral arterial disease and stroke were not collected so the results were not corrected for. There was also no control group to compare the amputation and mortality rates to. Another limitation of this study is that it was retrospective which makes the study more susceptible to incomplete data.

CONCLUSIONS

Our data have shown that the presence of diabetes related CN is associated with an increased risk of amputation and premature mortality. Thus, when treating CN, cardiovascular factors associated with increased amputation and mortality rates should be more rigorously treated to reduce the risk of theses poorer outcomes.

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Data Availability. The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Conflict of Interest. Ketan Dhatariya is an Editorial Board member of Diabetes Therapy. Ketan Dhatariya was not involved in the selection of peer reviewers for the manuscript nor any of the subsequent editorial decisions. Ketan Dhatariya has nothing else to disclose. Dipen Patel has nothing to disclose. Catherine Gooday has nothing to disclose. Ian Nunney has nothing to disclose.

Ethical Approval. The project was registered with the audit department at our institution. Formal ethical approval was not required as this was an anonymised retrospective case note analysis. Trust approval for the project was granted using the Health Research Authority tool by the audit department and the service director for diabetes and endocrinology.

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