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Influence of Patient Setting and Dedicated Limb Salvage Efforts on Outcomes in Charcot-Related Foot Ulcer

Brian M. Schmidt, DPM¹, Crystal M. Holmes, DPM, CWS¹

¹University of Michigan, Ann Arbor, MI, USA

Abstract

Charcot neuroarthropathy is a devastating consequence of diabetes mellitus and peripheral neuropathy. Because of its rarity, the condition is often misdiagnosed or poorly managed. When misadventure occurs, patients with Charcot neuroarthropathy can suffer ulceration, infection, amputation, and death. When patients have Charcot-related foot ulcers, the risks are amplified. Utilizing advanced electronic medical record analysis, a 30-month investigation was undertaken to determine if patients with diabetes mellitus and a concomitant diagnosis of Charcot-related foot ulcer were at greater risk of complications because of location setting of initial treatment for their condition. Charcot foot-related ulcers that are diagnosed in the outpatient setting had established foot specialist care. The outpatient management of the condition lead to a significant reduction in the amount of admissions to a higher acuity setting. However, patient outcomes did not vary once established and dedicated limb salvage efforts were employed. In this large contemporary population managed in a tertiary health system, patients with Charcot-related foot ulcer had negative outcomes when they were initially treated in an inpatient setting and had a significantly greater likelihood of readmission as compared with individuals who had established focused limb salvage care.

Keywords

Charcot foot; diabetic foot; limb salvage; ulcer

Charcot neuroarthropathy (CN) is a destructive process in the foot and ankle that can lead to deformity, ulceration, infection, amputation, and death.^{1,2} It also leads to significant immobility, which has further unintended consequence. Therefore, the impact and diagnosis of CN can create life-altering devastation. The condition itself is often misdiagnosed³ and relatively unknown among primary care providers.⁴ As a result, patients often suffer delayed diagnosis.^{3,5} When diagnosed early and correctly, the rate of complications is reduced 5-fold.³

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Corresponding Author: Brian M. Schmidt, Department of Internal Medicine, Division of Metabolism, Endocrinology, and Diabetes, University of Michigan Medical School, 24 Frank Lloyd Wright Drive, Lobby C, Ann Arbor, MI 48106, USA. bmcs@med.umich.edu.
Author Contributions

Brian M. Schmidt researched the data, organized and wrote the manuscript, and compiled all of the references. Crystal M. Holmes assisted with writing of the manuscript and reviewed/edited the manuscript.

Declaration of Conflicting Interests

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The risk factors associated with development of CN are well understood and include the following: age, increased body mass index,⁶ duration with diabetes,⁷ presence of peripheral neuropathy and loss of protective sensation,⁸ and decreased bone mineral density.⁹ However, once the diagnosis of CN is established, treatment options are created to maintain or create a plantargrade foot type. Maintaining or creating a plantargrade foot may be achieved through nonsurgical or surgical intervention. When a Charcot-related foot ulcer is present, patient outcomes suffer.¹⁰

It is well established when patients are enrolled in focused limb salvage clinics, patient outcomes are improved with regard to diabetic foot ulcers (DFUs).^{11–13} In particular, a significant reduction in major nontraumatic lower extremity amputations (LEA) and an overall increase in debridement/wound care services provided is seen.¹⁴

However, the impact of these limb salvage efforts on CN with Charcot-related foot ulcer is not well established. In fact, the importance of diagnosis setting and enrollment in a focused limb salvage clinic may impact patients with CN and DFU.

We present a subset of patients at our institution with both CN and DFU who were treated nonsurgically and enrolled into a focused limb salvage clinic as soon as a diagnosis of CN was made. We sought to investigate the influence of initial patient setting on patient outcomes. Patients were placed into cohorts depending on initial location setting of the above-queried diagnoses. All patients were managed with a fully integrated and specialized podiatry service within a large tertiary academic health system overseeing the care of more than 40 000 patients with diabetes mellitus annually. A comprehensive approach was used including close follow-up and standard treatment protocols once care was established. Patients were followed until a primary outcome occurred and for at least 1 year after receiving intensive specialized limb salvage efforts.

Research Design and Methods

We conducted an observational electronic medical record database study of patients with either type 1 or type 2 diabetes mellitus and a concomitant diagnosis of CN with DFU at our institution over 1.5 years to evaluate the influence of patient setting on patient outcomes. Our institution is a tertiary level 1 academic hospital with over 3500 faculty members. Our dedicated diabetic limb salvage team consists primarily of podiatry and vascular surgery with additional support from plastic surgery, orthopedic surgery, infectious disease, wound care nurses, endocrinologists, and a comprehensive wound care center. Care is organized based on acuity including a comprehensive podiatry consultation service for all diabetic foot inpatient care and robust outpatient clinics dedicated to limb salvage for close follow-up and chronic needs. The study period was from October 2015 through April 2018 (30 months). Consecutive patients were evaluated. The patients were followed for at least 1 year after initial treatment for CN with DFU by the faculty podiatrist until a primary outcome was reached.

Primary outcomes were then analyzed once realized. Outcome assessment is based on the EURODIALE (European Study Group on Diabetes and the Lower Extremity) study.¹⁵

Primary outcome measured is complete wound healing. Wound healing is defined as complete reepithelialization with no drainage during 2 consecutive follow-up visits. Secondary outcomes measures include minor (partial foot) amputation and major (above or below knee) amputation, nonhealing (>1 year), lost to follow-up, (re) admissions, and death.

Patients were identified and included in the study if they were diagnosed with CN with DFU on treatment by a faculty podiatrist at our institution. A separate group with only CN (no Charcot-related foot ulcer) was obtained from a combination of inpatient and outpatient resources for comparison of patient characteristics.

A diagnosis of CN was deduced from a thorough history and physical examination, dermal thermography,¹⁶ radiographs,¹⁷ and magnetic resonance imaging when available. Radiograph definition of CN was made based on location of CN event.¹⁷ When available, and particularly in the outpatient setting, pedal dermal temperatures greater than 4°F as compared with contralateral limb temperature at similar location correlated strongly to area of CN event.¹⁶ Using these tools, diagnosis of CN was confirmed and then presence of DFU was noted. Patients with CN and multiple DFUs were excluded from this study.

Patients meeting the above-mentioned criteria were then segregated into cohorts by initial treatment setting of the aforementioned diagnosis. An inpatient was an individual who was admitted to the hospital for a direct complication (cellulitis, infection, etc) with regard to their CN and DFU that required inpatient podiatric service consultation. The hospital algorithm for diabetic foot-related complications triages these concerns to podiatry for further consideration and management. By contrast, an outpatient was an individual diagnosed with CN and DFU by podiatry in the outpatient setting initially.

Following identification of CN and DFU, patients were followed longitudinally in the diabetic foot clinic at our institution. Inpatients were appointed to the outpatient clinical setting immediately following hospital discharge while outpatients were regularly appointed for close follow-up. Standard of care for CN with DFU at our institution is designed after standard of care for annual diabetic foot examinations that include history, assessment of pedal skin, vasculature, neurological testing, and musculoskeletal examination.¹⁸ All patients receiving care in this study were managed nonsurgically. Surgical treatment, such as amputation, occurred when prompted by uncontrolled infection or unstable foot. Because these patients have a concomitant DFU, regular wound debridement, and wound care, ulcer offloading with most applicable device was attempted, eradication of infection (as needed), calcium and vitamin D supplementation (as needed), and formal education regarding disease through patient handouts and direct physician contact were implemented.

Statistical analysis was performed. A univariate analysis was performed using Microsoft Excel (2016). Paired Student's *t* tests were used with equal sample sizes. When unequal variances and unequal sample sizes presented, Welch's *t* test was employed. Fischer's exact tests were performed with contingency tables. For type I errors, statistical significance difference of <5% (*P* .05) was assumed to be significant.

Results

Descriptive Statistics

A total of 1162 inpatient consults were made to the podiatry service at our institution during the study period. Thirty inpatients met inclusion criteria of having diabetes mellitus, CN, and a concomitant diagnosis of DFU (2.58%). A total of 3807 patients were seen in the outpatient setting during the same period and 76 patients were found to meet the above-mentioned inclusion criteria (1.99%). A control group of 20 patients with CN without Charcot-related foot ulcer was also evaluated. The average age of the inpatient cohort was 60.6 ± 15.1 while the outpatient cohort was 58.5 ± 13.9 . Gender, as defined by the percentage of men, was 66.7% in the inpatient cohort and 67.1% in the outpatient setting. The average body mass index (kg/m^2) in the inpatient group was 30.8 ± 7.7 and in the outpatient group 30.0 ± 7.5 . Significance was not reached with each of the defined descriptors listed above ($P > .05$), as shown in Table 1. Also, no significant difference was seen between patients with CN and no Charcot-related foot ulcer versus the Charcot-related foot ulcer group.

Comorbid conditions included coronary artery disease, chronic kidney disease, hypertension, hyperlipidemia, peripheral neuropathy, depression, diagnosis of osteomyelitis, and previous amputation (Table 1). The prevalence of the conditions listed above was not significantly different among groups except that depression and osteomyelitis was more prevalent in patients with DFU ($P < .05$).

Additionally, patients diagnosed with CN and DFU in the outpatient setting were found to have established care with a podiatrist versus the inpatient setting ($P = .0001$), as shown in Table 1.

Outcomes

Eleven inpatients healed their DFU (36.7%), 7 patients had minor or major LEA (23.3%), 5 patients did not heal within 1 year of initial inpatient consultation (16.7%), and an additional 5 patients were lost to follow-up (16.7%). Of the 5 patients lost to follow-up, surgical reconstruction of the Charcot foot was attempted in 3 cases (10%). Two patients were truly lost to follow-up (6.7%), and 2 patients perished during the study timeline (6.7%). Admissions for CN with DFU-related complications occurred in 11 patients (36.7%). Thirteen of these individuals could ambulate without assistance at the end of the study period (52%).

Thirty-six outpatients healed their DFUs (47.4%), 14 patients had minor or major LEA (18.4%), 10 patients did not heal within 1 year of initial outpatient presentation (13.2%), and an additional 15 patients were lost to follow-up (19.7%). Of the 15 patients lost to follow-up, surgical reconstruction of the Charcot foot was attempted in 3 patients (3.9%). Twelve patients were truly lost to follow-up (15.8%), and one patient perished during the study timeframe (1.3%). Admissions for CN with DFU-related complications occurred in 12 patients (15.8%).

Surgical interventions were recorded and outcomes followed. Three patients underwent surgery in each cohort as aforementioned. The inpatient Charcot patients who underwent surgery demonstrated either Lisfranc CN ($n = 2$) or Chopart joint CN ($n = 1$). In contrast, the outpatient cohort patients had a more heterogeneous CN joint distribution, including ankle, calcaneus, and Lisfranc joint involvement ($n = 1$ each). Those who underwent an attempt at Charcot foot reconstruction following inpatient hospitalization experienced zero limb loss events. Each of the outpatients who underwent surgery also did not experience limb loss at 1-year follow-up. Hundred percent ($n = 3$) of patients in the inpatient surgical group experienced wound healing complications but only one individual did not heal their initial wound following surgical intervention at 1-year follow-up. Likewise, in the outpatient surgical group, all patients experienced either wound healing complications or surgical site dehiscence. Ultimately outpatients undergoing surgery healed their wounds by 1-year follow-up.

For all cohorts evaluated, there was an increased readmission rate in the inpatient cohort with CN and DFU, which was approximately $2.3\times$ more frequent and significantly different from ($P < .05$) the outpatient cohort. All other outcome measurements did not reach significance ($P > .10$) between the cohorts (Table 2).

Discussion

Charcot neuroarthropathy is a devastating condition. Its treatment is complicated by its rarity,¹⁹ misdiagnosis, delayed diagnosis,^{3,5} and lack of established foot care.^{19,20} Further compounding care for these patients is the presence of a Charcot-related foot ulcer. Overall osteomyelitis prevalence is high in both cohorts, with an average of 38.7% ($n = 41$), but the difference between inpatient and outpatient cohorts was not significant ($P > .05$).

In this orphaned subset of patients, even with a Charcot-related foot ulcer present on admission, only 10% of inpatients admitted with CN + DFU had established care with a foot specialist. This was approximately 8-fold less ($P = .0001$) than those who were initially diagnosed in the outpatient setting. We believe that this delay in diagnosis or recognition is likely the result of an absence of a focused (diabetic) foot perspective.

However, regardless of patient demographics and medical comorbidities, we found patients with both CN and DFU did not have significantly varied primary outcomes once specialist foot care was established ($P = .39$). In addition, when an inpatient diagnosis of CN + DFU was made, we demonstrate the rate of readmission for these patients is greater than double than those diagnosed as outpatients.

Our brief observations demonstrate early success with focused nonoperative approach to management of CN with Charcot-related foot wounds. The presence of a Charcot-related foot wound has been shown to increase the likelihood of a major LEA by a factor of 6.¹⁰ In our patient population of 106 feet, the major LEA rate was 8.5%, considerably less than previous reports in the literature of above 20%,¹⁰ but consistent with reports of managing around 60% of patients non-surgically.²¹ The rates of major and minor LEA did not vary among our cohorts and the authors attribute this to the increased prevalence of osteomyelitis

in each cohort. Importantly, limb salvage was occurring in the vast majority of patients (n = 97) even in patients with more profound disease status.

We attribute our success to increased focus on patient education and patient compliance, both of which have been shown to reduce the risk of infection, (re-)admission, and amputation.^{22,23} We demonstrate that acuity of diagnosis is not necessarily a risk factor for poor outcome, so long as access to focused limb salvage is available.

This study is not without limitations. First, this study is a retrospective review and follow-up was only for 1 year after initial presentation. The sample size of 106 Charcot feet is small and not powered fully for multivariate analysis given our event rate ratio. Patients with Charcot-related foot ulcers can experience complications and it is well established that DFUs reoccur at a rate of approximately 40% within 1 year after closure.²⁴ Secondly, our study only accounts for individuals who were managed by the podiatry team at our institution. It would be incomplete to state that all patients with CN are managed by our team alone, as this condition often involves a larger multidisciplinary network. In addition, the patients in our study with CN + DFU were statistically more depressed, but because it accounted for only 4 patients, a definitive link cannot be drawn.

In conclusion, the focus of our work demonstrates the importance of enrolling patients with diabetic foot complications into a limb salvage program and improving preventative care measures. This represents a paradigmatic shift toward outpatient care, management, and earlier identification of disease state. In the highest risk patients, those patients with both CN and DFU, establishing regular care is essential. Our study is, to our knowledge, the first of its kind to evaluate the influence of patient setting on patient outcomes in this cohort.

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Table 1.

Descriptive Characteristics of Study Patients^a.

	CN + No Charcot-Related Foot Ulcer (N = 20)	Inpatient CN +DFU (N = 30)	Outpatient CN + DFU (N = 76)
Age	55.7 ± 11.3	60.6 ± 15.1	58.5 ± 13.9
Gender (% men)	60	66.7	67.1
BMI (kg/m ²)	33.3 ± 6.94	30.8 ± 7.7	30.0 ± 7.5
Race (% African American)	10	15.8	10.0
Coronary artery disease (%)	20	26.7	11.8
Chronic kidney disease (%)	35	13.3	18.4
Hypertension (%)	45	40	25
Hyperlipidemia (%)	25	33.3	17.1
Depression (%)	0	3.3 ^b	3.9 ^b
Previous amputation (%)	5	20	10.5
Osteomyelitis diagnosis (%)	0	53.3 ^b	32.9 ^b
Established podiatry care with us (%)	50	10	78.9 ^c

Abbreviations: CN, Charcot neuroarthropathy; DFU, diabetic foot ulcer; BMI, body mass index.

^aData are mean ± standard deviation, or % of population.^bDenotes significant difference ($P < .05$) between CN without foot ulcer and CN with foot ulcer.^cDenotes significant difference ($P < .05$) between CN with foot ulcer inpatient and CN with foot ulcer outpatient.

Table 2.

Primary and Secondary Patient Outcomes by Cohort.

	Overall	Inpatient CN + DFU (N = 30)	Outpatient CN + DFU (N = 76)
Healed (%)	44.3	36.7	47.3
Minor amputation (%)	11.3	13.3	10.5
Major amputation (%)	8.5	10.0	7.9
Surgical reconstruction (%)	5.6	10	3.9
Lost to follow-up (%)	13.2	6.7	15.8
Not healed > 1 year (%)	14.2	16.7	13.2
Death (%)	3.9	6.7	1.3
Additional admissions	21.7	36.7	15.7^a

Abbreviations: CN, Charcot neuroarthropathy; DFU, diabetic foot ulcer.

^aDenotes significant difference ($P < .05$) between CN with foot ulcer inpatient and CN with foot ulcer outpatient.