Journal of Diabetes and Its Complications xxx (2013) xxx–xxx

Contents lists available at ScienceDirect

Journal of Diabetes and Its Complications

journal homepage: WWW.JDCJOURNAL.COM

Diabetic foot ulcer incidence in relation to plantar pressure magnitude and measurement location☆,☆☆,★

William R. Ledoux [a,b,c,*], Jane B. Shofer [a], Matthew S. Cowley [a], Jessie H. Ahroni [d,e], Victoria Cohen [f], Edward J. Boyko [f,g]

[a] RR&D Center of Excellence for Limb Loss Prevention and Prosthetic Engineering, VA Puget Sound Health Care System, Seattle, WA, USA
[b] Department of Mechanical Engineering, University of Washington, Seattle, WA, USA
[c] Department of Orthopaedics and Sports Medicine, University of Washington, Seattle, WA, USA
[d] Department of Surgery, VA Puget Sound Health Care System, Seattle, WA, USA
[e] Department of Biobehavioral Nursing and Health Systems, University of Washington, Seattle, WA, USA
[f] Epidemiologic Research and Information Center, VA Puget Sound Health Care System, Seattle, WA, USA
[g] Department of Medicine, University of Washington, Seattle, WA, USA

ARTICLE INFO

Article history:
Received 10 March 2013
Received in revised form 11 July 2013
Accepted 26 July 2013
Available online xxxx

Keywords:
Plantar pressure
Diabetic foot ulcer
Hallux
Heel
Metatarsal
Epidemiology

ABSTRACT

Aims: We prospectively examined the relationship between site-specific peak plantar pressure (PPP) and ulcer risk. Researchers have previously reported associations between diabetic foot ulcer and elevated plantar foot pressure, but the effect of location-specific pressures has not been studied.
Methods: Diabetic subjects (n = 591) were enrolled from a single VA hospital. Five measurements of in-shoe plantar pressure were collected using F-Scan. Pressures were measured at 8 areas: heel, lateral midfoot, medial midfoot, first metatarsal, second through fourth metatarsal, fifth metatarsal, hallux, and other toes. The relationship between incident plantar foot ulcer and PPP or pressure–time integral (PTI) was assessed using Cox regression.
Results: During follow-up (2.4 years), 47 subjects developed plantar ulcers (10 heel, 12 metatarsal, 19 hallux, 6 other). Overall mean PPP was higher for ulcer subjects (219 vs. 194 kPa), but the relationship differed by site (the metatarsals with ulcers had higher pressure, while the opposite was true for the hallux and heel). A statistical analysis was not performed on the means, but hazard ratios from a Cox survival analysis were nonsignificant for PPP across all sites and when adjusted for location. However, when the metatarsals were considered separately, higher baseline PPP was significantly associated with greater ulcer risk; at other sites, this relationship was nonsignificant. Hazard ratios for all PTI data were nonsignificant.
Conclusions: Location must be considered when assessing the relationship between PPP and plantar ulceration.
Published by Elsevier Inc.

1. Introduction

Diabetes mellitus, while affecting more than 8% of the U.S. population, has been implicated in over 60% of all non-traumatic lower extremity amputations (CDCP, 2011). The development of diabetic foot ulcers is a multi-factorial process that has been associated with, among other factors, diabetic neuropathy, minor foot trauma and foot deformities (Reiber et al., 1999). Elevated plantar pressure has also been associated with ulceration, but the relationship between pressure at a specific location and ulceration at that location remains unclear.

In a retrospective study of barefoot subjects, Boulton et al. quantified the peak pressure of four groups of feet: non-diabetic control feet (n = 82), diabetic feet without neuropathy (n = 81), diabetic feet with neuropathy but no history of ulcers (n = 59), and diabetic feet with neuropathy and a history of ulcers (n = 22) (Boulton et al., 1983). Using a threshold of 11 kg/cm^2 (1080 kPa), these authors found that feet with aberrant plantar pressure ranged from 7% for the controls, to 17% for the diabetic feet, to 31% for the diabetic feet with neuropathy, to 100% for the diabetic feet with a history of ulcers. However, this study was retrospective and did not examine the effect of location.

A cross-sectional analysis on 251 diabetic patients by Frykberg et al. examined the relationship between high foot pressures (>6 kg/cm^2 or 588 kPa) and ulceration in patients walking in stockings (Frykberg et al., 1998). Of the patients enrolled, 99 had a current

☆ Funding: This work was supported in part by the Department of Veterans Affairs, RR&D service grant numbers A2661C, A4843C and A99-1499A.
☆☆ A preliminary version of this analysis was presented in the proceedings of the 65th Annual Scientific Sessions of the American Diabetes Association, San Diego, CA: 2005.
★ The authors have no conflict of interest.
* Corresponding author. VA Puget Sound, MS 151, 1660 S. Columbian Way, Seattle WA 98108, USA. Tel.: +1 206 768 5347; fax: +1 206 764 2127.
E-mail address: wrledoux@u.washington.edu (W.R. Ledoux).

1056-8727/$ – see front matter. Published by Elsevier Inc.
http://dx.doi.org/10.1016/j.jdiacomp.2013.07.004

(n = 33) or past (n = 66) ulcer. After accounting for age, sex, diabetes duration and race, patients with higher plantar pressure were more than twice as likely to have an ulcer. However, as with Boulton et al.'s work, this study was retrospective and did not examine the effect of location.

Veves et al. prospectively followed 86 diabetic non-neuropathic (n = 28) and neuropathic (n = 58) patients for an average period of 30 months (Veves, Murray, Young, & Boulton, 1992). At follow-up, 35% (n = 15) of the patients had developed a plantar ulcer. All 15 ulcer patients had an elevated baseline barefoot peak pressure (>12.3 kg/cm^2 or 1206 kPa) and 14 of the 15 patients were neuropathic. However, this study did not examine the effect of high baseline pressure and subsequent ulceration at a specific location.

Pham et al. conducted a prospective foot screening study and collected unshod plantar pressure data at baseline (Pham et al., 2000). They followed 248 patients over a mean period of 30 months and ulcers developed in 95 feet (19%) or 73 subjects (29%); of those ulcers, 76 (80%) were in the plantar forefoot. In a multi-regression analysis, high plantar pressure (>6 kg/cm^2 or 588 kPa) and several measures of neuropathy were found to be statistically significant predictors of foot ulcer. However, as with Veves et al., this study did not examine the effect of high baseline pressure and subsequent ulceration at a specific location.

Thus, while peak pressure has been associated both retrospectively and prospectively with increased risk of ulceration, we are unaware of a study that has examined baseline plantar pressure at a specific location with a subsequent ulcer at that location. The primary purpose of this study was to address that specific issue, with an emphasis on the metatarsals. The work presented hereafter represents a subset of patients from the Seattle Diabetic Foot Study, which has been discussed elsewhere (Adler, Boyko, Ahroni, & Smith, 1999; Ahroni, Boyko, & Forsberg, 1998; Ahroni, Boyko, & Forsberg, 1999; Boyko et al., 1999; Boyko, Ahroni, Cohen, Nelson, & Heagerty, 2006; Cowley, Boyko, Shofer, Ahroni, & Ledoux, 2008), who had baseline plantar pressure measured when they were enrolled. The subjects were followed over time to see who developed an ulcer.

2. Subjects, materials, and methods

2.1. Study setting and subjects

All ambulatory General Internal Medicine Clinic patients at the Veterans Affairs Puget Sound Health Care System with diabetes between 1996 and 2002 were eligible for enrollment. The study received prior approval from the University of Washington Human Subjects Office, and informed consent was obtained from all subjects for their participation in this research. Exclusion criteria were current foot ulcer, bilateral foot amputations, wheelchair-bound or unable to walk, too sick to participate, or psychiatric illness that prevented informed consent. Subjects with clinically apparent diabetes were identified by review of hospital computerized pharmacy data for receipt of insulin, oral hypoglycemic medication or blood or urine glucose test strips, review of laboratory data, and review of medical record problem lists for the diagnosis of diabetes mellitus. The diagnosis was then confirmed by communication with clinical providers or medical record review. The vast majority of the patients in this study (perhaps 99%) lived within 50 miles of the VA Medical Center and received all their care there.

2.2. Baseline data collection

Subjects were interviewed to collect data on demographics and diabetes characteristics, and each received a physical exam. Sensory testing was performed at 9 locations on each foot using the Semmes–Weinstein monofilament. Inability to perceive the 5.07 monofilament at one or more sites was considered to represent peripheral sensory neuropathy.

2.3. Foot pressure measurements

We performed in-shoe foot-pressure measurements with F-scan insoles (Tekscan, Boston, MA) on subjects wearing their "usual" footwear walking a specified length (20 m, i.e., back and forth over a 10 m walkway) at their self-selected velocity. Sensors were placed between the patient's sock and shoe. The F-scan insole is a pressure sensor, 0.18 mm thick, with an embedded grid of 960 contact cells. Before use, the disposable sensors were trimmed to fit into shoes, with the resultant loss of ~5%–20% of the contact cells. We have previously reported the F-scan methodology and reliability data in our study subjects (Ahroni et al., 1998).

The first five midgait footsteps for each foot were considered as separate trials for this analysis; the first few steps (gait initiation), the steps involved in turning around, and the last few steps (gait termination) were ignored. Pressure was determined by F-scan software v3.821 running on a dedicated personal computer. For each step, we recorded the plantar pressure at 8 pre-specified locations: the heel, medial midfoot, lateral midfoot, first metatarsal head, second to fourth metatarsal heads, fifth metatarsal head, hallux and lesser toes by utilizing the ability of the software to create masks over specified locations; we were especially interested in this relationship at the metatarsals which biomechanically were hypothesized to have the strongest relationship between pressure and ulceration. Peak pressure and the pressure–time integral were calculated. Peak pressure is the highest pressure sensed within the mask. The pressure–time integral was calculated as the summation of the total peak pressure experienced in a given location per each time unit; it is a measure of pressure dosage.

2.4. Follow-up data collection

Foot ulcer was defined as a full-thickness skin defect that required more than 14 days to heal. Subjects were re-examined at 12–18 month intervals (mean interval = 13 months) to assess whether the outcome had occurred. Also, subjects were contacted quarterly by mail, and were encouraged to call study staff or drop by the research clinic if they suspected that they had a foot ulcer. Subjects who did not return mailed questionnaires were contacted whenever possible in person at their next scheduled clinic visit. In order to assure capture of incident foot ulcers that were not detected by the above means, study staff publicized the project throughout the VA Medical Center and emphasized the need for clinical providers to notify them of all incident ulcers seen in ambulatory, urgent care, surgical specialty clinics, and other clinical settings. Fluorescent orange labels were affixed to the hard copy medical record problem list reminding providers to check their patients' feet. As an incentive for this reporting, study staff offered to expedite triage of patients with foot lesions, thereby reducing provider workload.

2.5. Statistical methods

Differences in study participant demographic measures by ulcer outcome were assessed using t-tests (continuous measures) and Fisher's exact test (categorical measures). As a descriptive analysis, estimates of peak pressure and pressure–time integral means and standard errors by ulcer outcome were obtained from linear mixed effects regression models. Data were analyzed across 4 levels: between subject (n = 591), within subject across foot (n = 1110, 72 pressure data were collected on only one foot), within foot across site (n = 8880, each foot had 8 sites) and within site (n = 43,912, an average of 4.95 trials per subject). To account for non-independence of observations, we utilized robust variance estimates. However, these