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Abstract

Background & Aim: Diabetes Mellitus can cause serious health problems including foot complications. Peripheral neuropathy affects the outer appendages, most commonly the lower limbs. Ulceration of the feet has a high possibility of advancement to amputation; thus greatly diminishing quality of life. This study investigates if patients with diabetes, who are at low-moderate risk of foot disease, have any underlying biomechanical signs which may indicate that they are at risk of future ulceration.

Methods: Twenty patients with Diabetes Mellitus at low-moderate risk of foot disease and 32 healthy individuals participated in this study. All participants completed a self-administrated questionnaire (assessing socio-demographic and lifestyle factors) and underwent a clinical foot screening examination (plantar sensation, pedal pulses and ankle range of motion), gait assessment (spatio-temporal parameters) and barefoot plantar pressure analysis. Results between the 2 groups were compared.

Results: Major differences were observed in area of plantar pressure distribution, walking speed and foot alignment between low-moderate risk participants with diabetes and healthy controls. Low-moderate risk participants with diabetes recorded elevated

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concluded that the presence of neuropathy was responsible for a major increase in plantar pressure across all findings [8, 19, 20]. Armstrong et al. [21] and Cterceko et al. [22] along with others [23-25] have concluded that the hallux, heel and mid-metatarsal regions are those most inclined to develop calluses and ulceration. Van Schie et al. [26] investigated the effect of arch index and body mass on plantar pressure for DM subjects and did not detect any difference in peak plantar pressure between the healthy and pathological groups.

We intend to eliminate the effects of body weight by comparing against case matched controls. By recruiting low- moderate risk patients, the existence of neuropathy and changes to plantar soft tissue will not be an issue. Removal of these high risk factors will allow less influential triggers of foot disease to be brought to the fore such as baseline pressure, walking biomechanics, foot characteristics and behavioral attributes. Connecting aspects of participant's daily régime, by means of questionnaire, with foot biomechanical characteristics may yield results which will indicate if certain lifestyle choices are a help or a hindrance on development of foot disease.

The primary objective of this study is to investigate if factors correlating with the determinants of ulceration are present in DM patients prior to diagnosis of diabetic foot disease. Comparing the low-moderate foot disease risk patients to non-DM controls allows for a baseline comparison in all areas examined.

Research Design and Methods

Participants

This is an exploratory case comparison study involving 20 patients with (type 1 and type 2) DM at low-moderate risk of diabetic foot disease and 32 healthy volunteers.

The DM cohort was recruited through two General Practice centers, where specific diabetes clinics take place. Volunteers with DM were invited to attend their respective health center to undergo a foot screening examination which determined their level of risk to foot disease based on The Diabetic Foot Risk Stratification and Triage Guidelines (SIGN) [27]. The SIGN system classifies foot disease risk in four categories from low to active. Classification of low-moderate diabetes foot risk implies patients present with less than one foot risk factor. Risk factors specifically pertain to loss of sensation or indications of peripheral vascular disease but without the

more susceptible to formation of calluses and pressure ulcers. Only footprints which occurred after initiation of walking (second or third step) were utilised for profiling. Also trials were eliminated if the subject did not strike the mat correctly or if the subject seemed to adapt their gait to aim for the mat.

Statistical analysis

health practitioners, with majority of participants making lifestyle modifications post diagnosis. Perhaps making changes in order to regulate DM maintained participants within the Low-moderate risk category [27].

	DM Patients (n=20)	Control Patients (n=32)	P value ***
Male	15 (75)	26 (81.3)	>0.05
Age (years) *	11 (54.5)	11 (35)	<0.05
Weight (Kg) *	78.5 (60-123)	85 (50-131)	0.6
Height (m) **	172.9 ± 8.5	168.8 ± 10.7	0.13
BMI (Kg/M ²) *	25.5 (19-37.55)	27.73 (23.78-31.13)	0.12
Education (<12 yrs)	10 (50)	14 (43.6)	>0.05
Cohabitation	15 (75)	27 (84.4)	>0.05
Employed	10 (50)	28 (87.5)	>0.05
Currently Smoke	6 (30)	6 (18.75)	0.9
Consume Alcohol	18 (90)	28 (87.5)	>0.05
Alcohol (1-4 days/week)	8 (40)	15 (46.9)	0.755
Fruit & Veg (<5 /day)	16 (82.5)	18 (57.8)	>0.05
Walk/Cycle as transport (4-7 days/week)	12 (60)	10 (30)	-0.12
Sports/Recreation (4-7 days/week)	4 (20)	9 (28.1)	>0.05
Sitting/Relaxing (>4 hours/day)	9 (45)	22 (68.8)	0.73
Hypertension (Clinically Diagnosed)	6 (30)	3 (9.4)	

pressure profile of their feet would reiterate the importance of wearing orthotics in accordance with guidelines.

Clinical assessment of foot physiognomies yielded interesting results. A significant association emerged within the DM group between pronation foot alignment and flat arch type. Table 3 highlights 52.6% of DM group have flat arches, and 42% of DM group fall into the category of pronation. A flat arch is associated with increased bodyweight [26], this could explain the prevalence of this attribute. Interestingly, these groups were matched for BMI and the control group presented with a significantly different frequency of this arch type. This may be due to fact as aforementioned many the DM group have adapted their life to manage their DM and therefore have

* Median (Range) ** Mean ± standard Deviation

*** Chi-square test -categorical variables, Mann-Whitney Test-non-normally distributed continuous variables

Table 4 Walking Characteristics.

As anticipated, plantar pressure was elevated in the DM group. The metatarsal region and the heel observed significantly increased pressure values compared to the control group. This phenomenon was previously reported in relation to determinants of DFU [7,8, 21,26]. The hallux has been determined as a chief pressure point in patients within a high risk category of ulceration [21,22]. However, this study recorded similar pressures at the hallux in both groups; this was a novel finding. Deformation and reduced ankle flexion are considered causative factors for increased pressure at the hallux [47]. Since patients involved in this study did not present with any of these triggers it is understandable why elevated pressure was not detected here. The increased pressure at the metatarsals and the heel is an important factor. Pressure is amplified at this early stage which would imply that patients are susceptible to callus formation and if not treated effectively may progress to ulceration. Results of this study indicate that foot structure and reduced walking speed greatly increase pressure. This study describes a healthy DM group. However, discrepancies still emerge compared to the control group. It is encouraged following this study, that plantar pressure analysis be included as part of all foot risk categorisation systems, as these danger area would not have been picked up on through a visual examination. The presence of abnormal pressure intensifies the future risk of foot disease to the patient [48].

	DM Patients (n=20)	Controls Subjects (n=32)	P value*
Plantar Pressure (KPa)			
Hallux	340.4 ± 148.5	336.0 ± 164.1	0.926
M2M3	620.3 ± 166.6	479.9 ± 187.0	0.012
Heel	457.5 ± 147.1	363.2 ± 104.0	0.011

Data presented as mean ± St. dev. * t-Test-normally distributed continuous variables. M2M3=Metatarsal 2, Metatarsal 3

Table 5 Plantar pressure recordings.

Limitations

This study has a number of weaknesses. Patients were compared independent of age. The control group presented a lower mean age ($p>0.05$). The variables that stood out as dissimilar concerning the temporal parameters were comparable to those previously indicated as

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