PLANTAR PRESSURE DISTRIBUTION PROFILE OF TYPE 2 DIABETES MELLITUS WITH DIABETIC FOOT SYNDROME: A HOSPITAL-BASED OBSERVATIONAL STUDY

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INTRODUCTION: The prevalence of diabetic foot syndrome is increasing in the Indian population. It is a triad of neurological, vascular, and biomechanical changes due to long term diabetes mellitus (DM). Altered plantar pressure distribution is a risk factor for developing diabetic foot ulcers. The purpose of this study is to evaluate the altered plantar pressure distribution in diabetic peripheral neuropathy individuals with peripheral vascular disease in comparison with diabetic peripheral neuropathy and non-diabetic neuropathy. Therefore, the objective of the study is to evaluate the plantar pressure distribution and parameters in type 2 DM (T2DM) with diabetic foot syndrome.

METHODS: In this study, 60 participants with T2DM were recruited in either one of the three groups: 20 Diabetic non-neuropathy (DNN), 20 Diabetic peripheral neuropathy (DPN), and 20 Diabetic peripheral neuropathy with the peripheral arterial disease (DNPAD). Then we compared the plantar pressure parameters like maximum plantar pressure, pressure-time integral, fore foot-hind foot ratio, and total contact area were measured using a WinTrack plantar pressure system.

RESULTS: The diabetic peripheral neuropathy with peripheral vascular disease group shown a significant difference in all the plantar pressure parameters measured in comparison with the diabetic peripheral neuropathy group. There was increased Maximum plantar pressure, pressure-time integral and forefoot hindfoot ratio, and reduced total contact area of the foot ($p < 0.05$).

CONCLUSION: For patients, with combined peripheral neuropathy and peripheral vascular disease have increased plantar pressure distribution, are at higher risks of developing neuro-ischemic foot, which further leads to diabetic foot ulcers.

КЛЮЧЕВЫЕ СЛОВА: plantar pressures; dynamic gait analysis; type 2 diabetes mellitus; diabetic foot

РАСПРЕДЕЛЕНИЕ ПОДОШВЕННОГО ДАВЛЕНИЯ ПРИ САХАРНОМ ДИАБЕТЕ 2 ТИПА С СИНДРОМОМ ДИАБЕТИЧЕСКОЙ СТОПЫ: КЛИНИЧЕСКОЕ ОБСЕРВАЦИОННОЕ ИССЛЕДОВАНИЕ

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ВВЕДЕНИЕ. Распространенность синдрома диабетической стопы среди населения Индии увеличивается. Синдром диабетической стопы — это триада неврологических, сосудистых и биомеханических изменений, вызванных длительным сахарным диабетом (СД). Изменение распределения давления подошвы является фактором риска развития язв диабетической стопы.

ЦЕЛЬ. Оценить распределение и параметры подошвенного давления при СД 2 типа (СД2) с синдромом диабетической стопы.

МЕТОДЫ. В этом исследовании приняли участие 60 пациентов с СД2. Всего было выделено 3 группы пациентов: 20 пациентов без диабетической нейропатии, 20 с диабетической дистальной нейропатией без поражения сосудов и 20 с диабетической дистальной нейропатией с поражением периферических артерий. Затем мы сравнили параметры подошвенного давления, такие как максимальное подошвенное давление, интеграл давления и времени и общую площадь контакта, которые были измерены с использованием системы подошвенного давления WinTrack.

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РЕЗУЛЬТАТЫ. Группа диабетической дистальной нейропатии с поражением периферических сосудов показала значительную разницу во всех измеренных параметрах подошвенного давления по сравнению с группой диабетической дистальной нейропатии без поражения сосудов. Было увеличено максимальное подошвенное давление, интегральное давление-время, а также уменьшена общая площадь контакта стопы (p<0,05).

ЗАКЛЮЧЕНИЕ. Пациенты с дистальной нейропатией и поражением периферических сосудов имеют повышенное распределение подошвенного давления, подвержены более высокому риску развития нейроишемического поражения, что в дальнейшем приводит к язвам стопы.

KEYWORDS: подошвенное давление; динамический анализ походки; сахарный диабет 2 типа; синдром диабетической стопы

INTRODUCTION

Diabetic foot syndrome (DFS) is defined as a group of syndromes, including neuropathy, ischemia, and infection leading to tissue breakdown and subsequent amputation. This is responsible for the significant number of hospital admissions for diabetic individuals resulting in increased health care costs and poor quality of life status[1]. It is a triad of vascular, neurological, and musculoskeletal impairments of the foot. DFS is one of the most common complications of diabetes and is associated with a higher degree of morbidity and mortality[2]. The international working group for the diabetic foot (IWGDF) risk stratification category system categorized the DFS into four categories based on the characteristics of risk of developing foot ulcers [3,4,5,] as shown below. (Table 1)

Among the various pathophysiological causes, the most frequent complication consists of diabetic peripheral neuropathy (DPN), vascular insufficiencies like peripheral arterial disease (PAD), foot deformity, and abnormal joint mobility[6]. These factors can affect plantar pressure distribution in the feet of individuals with diabetes. It has been predicted that approximately 15% of individuals with DFS develop a lower limb complication in their lifetime[7,8]. DPN is the most severe and intractable microvascular complication of diabetes mellitus. It involves the somatic sensory and motor nerves, as well as the autonomic nerves, especially of the lower limb[9]. In India, the prevalence of diabetic foot syndrome in type 2 diabetes mellitus (T2DM) ranges from 30.2% to 52.8%[10,11]. Peripheral arterial disease is likewise accountable for the development of diabetic foot syndrome. It is also a macrovascular complication in which an insufficient supply of blood to the lower extremity is seen, which leads to poor quality of life in individuals with T2DM. The symptom of PAD includes cramping pain or discomfort at the calf region while walking, which in other terms, is defined as intermittent claudication, which restricts mobility. Globally, the prevalence of PAD in T2DM was found to be 12%, and in India, it is around 8.52%[12].

Several studies have reported improvements in peak pressure and pressure-time integrals in diabetic subjects, but none have explored these variations between diabetics without neuropathy and neuropathic and peripheral artery disease participants[13,14,15]. As the prevalence is increasing, most of the clinical practice is restricted to either neurological or vascular parameters. In diabetic foot syndrome, early changes in musculoskeletal, neurological, and vascular leads to altered biomechanics, which is a strong predictor of diabetic foot ulcers. Hence, there is a need for detailed biomechanical evaluation focusing on kinetics and kinematics like plantar pressure parameters in T2DM with DFS.

AIM

Aim of the present study is to evaluate the plantar pressure distribution and parameters in type 2 diabetes mellitus with diabetic foot syndrome.

METHODS

Research Design and Setting

This cross-sectional observational study design was conducted, and participants were recruited from a tertiary health care center in Karnataka, India. A total of 60 participants were recruited for the study utilizing a comprehensive diabetic foot evaluation sheet which includes neurological, vascular, and musculoskeletal components. It was three groups in our study: Diabetic non-neuropathy (DNN) (n=20); Diabetic neuropathy without the peripheral arterial disease (DPN) (n=20), and Diabetic neuropathy with the peripheral arterial disease (DNPAD) (n=20).

Ethics Approval

After the approval from the institutional ethics committee (IEC 169/2019), the study was initiated. Detailed information about the study was given in the patient information sheet and informed consent was obtained from all the participants.

Table 1. The Working Group for the Diabetic Foot (WGDF) 2019 Risk Stratification System

Category	Ulcer risk	Characteristics
0	Very low	No LOPS and No PAD
1	Low	LOPS or PAD
2	Moderate	LOPS + PAD, or LOPS + foot deformity or PAD + foot deformity
3	High	LOPS or PAD, and one or more of the following: - History of a foot ulcer (or) Lower-extremity amputation (or) End-stage renal disease

Notes: LOPS — loss of protective sensation, PAD — peripheral artery disease

Conformity Criteria

Diabetic peripheral neuropathy was identified in the presence of 1) monofilament 10g, absent in one or more sites, 2) vibration perception threshold (VPT) more than 20V, and 3) Absence of Ankle reflexes. The peripheral arterial disease was identified by 1) presence of claudication pain in lower limb while walking in less than 5 min, 2) Ankle-brachial index (ABI) less than 0.90. Exclusion criteria include any orthopedic, visual, neurological, or other disability that could affect gait and stance, including current pain, fracture, active or history of ulceration or amputation of the toes.

Procedure

Peripheral arterial pressure measurement: The participants were made to rest for 15 min on a couch and the procedure was explained to them. The dominant side of the participant was taken for the examination. A blood pressure cuff was tied to the participant's lower limb and the pressures were recorded from the posterior tibialis artery with the help of a Doppler (Hadeco smartdop 30EX, 2017). After this, the cuff was tied to the upper limb and systolic pressure was recorded from the brachial artery and ABI was obtained[12].

Plantar pressure parameters were measured on the WinTrack pressure plate (Medicapteurs France SAS, Balma, France). Maximum plantar pressure (MPP), Pressure-Time integral (PTI), Forefoot-Hind foot ratio (FHR), and Total contact area (TCA) were measured, and data were analyzed using WinTrack software (Medicapteurs France SAS, Balma, France). Initially, three trials were conducted for participants to walk at an average pace on the pressure plate platform[11].

Statistical Analysis

EZR was used for descriptive statistics. The demographics and the plantar pressure parameters are reported as mean ± SD. The mean difference between the groups was shown in percentage change. One-way ANOVA was conducted to measure the level of significance.

RESULTS

The demographic characteristics of the three study groups are shown in Table 2. We have observed statistically significant differences in MPP, PTI, and FHR, and TCA between the three groups of subjects matched with age. DNPAD group showed significantly higher MPP, PTI, and FHR and lowered TCA in comparison to DPN and DNN groups with $p < 0.05$. Table 3, Table 4.

Table 2. Demographics characteristics of study groups

	DNN	DPN	DNPAD
N	20	20	20
Age (Years)	58.1±8.9	61.3±8.5	64.2±8.2
Gender (Male/Female)	9/6	8/7	10/5
Body weight (kg)	64.1±11.6	71.8±12.1	67.8±9.5
Height (cm)	159.7±12.06	165.7±8.7	161.9±12.6
BMI (kg/m^2)	25.4±3.4	26.7±3.9	26.1±2.67
Diabetes mellitus (years)	7.4±2.7	12.4±5.6	13.6±4.3
HbA_{1c} (%)	6.7±1.4	7.2±1.5	7.6±1.8
VPT, V	6.3±2.92	28.3±5.4	31.6±6.7
Brachial artery (mmHg)	121.06±14.07	128.4±21.1	131.6±19.9
ABI	1.06±0.12	1.08±0.10	0.74±0.09

Notes: VPT — vibration perception threshold, ABI — ankle-brachial index

Table 3. Plantar pressure parameters of all study groups

	DNN	DPN	DNPAD	p-value
Maximum plantar pressure (KPa)	333.1±56.6	410.2±52.5	476.3±76.6	<0.05*
Pressure-Time integral (KPa*s)	107.7±15.8	126.1±19.1	150.1±27	<0.05*
Forefoot-Hind foot ratio	0.94±0.24	1.26±0.23	2.02±0.18	<0.05*
Total contact area (cm^2)	133.2±11.7	106.3±8.5	86.5±6.8	<0.05*

Table 4. Mean difference change between the groups

	DNN - DPN	DPN - DNPAD	DNN - DNPAD	p-value
Maximum plantar pressure (kPa)	20.74%	14.91%	35.38%	<0.05*
Pressure-Time integral (kPa*s)	15.71%	17.37%	32.89%	<0.004*
Forefoot-Hind foot ratio	29.1%	46.3%	72.9%	<0.03*
Total contact area (cm^2)	22.4%	20.5%	42.5%	<0.001*

DISCUSSION

Limited research focused on altered plantar pressure distribution has been conducted on diabetic foot in individuals with diabetic neuropathy and peripheral arterial disease separately. This study aimed to document the comprehensive profile of plantar pressure parameters, focusing on individuals with a history of DPN and PAD. The significant finding from this study is a profile of altered plantar pressure distribution in participants with DPN and PAD. A range of alterations was evident, including significantly increased MPP, PTI, and FHR and reduced TCA significantly.

The results of this study support earlier studies and are consistent with the well-described plantar pressure pattern typically described in DPN[7,13,15]. In this study, all the individuals underwent comprehensive diabetic foot evaluation which constitutes musculoskeletal components like MMT, Muscle length, Foot posture index, vascular components like pedal pulse palpation, foot thermography, pedal pressures like ABI, TBI, neurological components like reflexes, vibration perception threshold, monofilament, hot and cold perception. Our findings describe broad-spectrum alterations in plantar pressure profiles which form a coherent image of altered distal function during normal gait. Of note in this analysis is that they compared the significant differences across DNPAD, DPN, and DNN. This represents the progressive nature of chronic diabetes complications and may indicate a higher risk of biomechanically induced higher plantar pressure, leading to ulceration as the severity progresses[5,16]. Importantly, the results of this study support emerging research identifying risk factors in DFU, indicating that diabetic foot syndrome may play an essential role in changing plantar pressure patterns

The possible reason may be due to altered biomechanics of the lower limb in diabetes because of chronic hyperglycemia in progressive chronic T2DM. There was a moderate to the strong correlation between glycated hemoglobin and loss of protective sensation[17]. In sensory and motor neuropathies, somatosensory inputs are declined, leading to the inability to feel the elevated plant pressure or discomfort during gait or functional tasks at specific foot regions[18]. Another explanation could be that in T2DM , altered glucose metabolism reduces muscular forces in hip and knee flexors and extensors, dorsal and plantar flexors, which may increase joint reaction forces, and lead to altered joint kinetics and kinematics reducing shock absorption of the foot all of which could contribute to altered plantar pressure distribution[19,20]. In a study by Naomi, it was observed that the thickness of plantar soft tissue under metatarsal heads is reduced in the neuro-ischemic foot in comparison to neuropathic foot[16]. This may highlight the role of PAD and its impact on plantar soft tissue thickness in diabetic patients in increasing plantar pressure. Our study is in parallel with another study conducted by Pataky et al., Which concluded that among diabetic neuro-ischemic patients with PAD, a significant relationship was found between peripheral vascular disease and elevated plantar pressures[21].

Research limitations

The strength of the study is that this is the first study in south India to compare the plantar pressure distribution among different components of diabetic foot syndrome with the age-matched population. The sample size of 20 participants per group is comparable with most diabetes gait studies using dynamic plantar pressure measurement. Several limitations should be considered when interpreting findings from this study. Study groups were reasonably well-matched, although the DNPAD group had a higher ratio of men compared to other groups. The effect of these differences is not known. Nevertheless, the literature suggests that diabetic foot was more common in men than women due to their increased physical activity, linked to the resulting neuropathy, making them more vulnerable to injury [22].

Other factors like the presence of callus, foot deformities, limited joint mobility, and walking speed, which may also contribute to altering plantar pressure distribution, were not evaluated. The standard limitations associated with dynamic gait occur when a sense of awareness about the style of walking can be affected. It is accepted that the design of this study can identify observations among groups but cannot investigate the causal relationship.

CONCLUSION

It has been found that individuals with a moderate risk of diabetic foot syndrome have increased plantar pressure parameters in comparison with mild risk individuals. Our results highlight the importance of early evaluation and diagnosis of plantar pressure distribution in diabetic foot syndrome. In the future, additional research is required looking at strategies for reducing and redistribution of PP and preventing the risk of DFU and for predicting ulcer risk

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