ORIGINAL ARTICLE

CLINICAL EXAMINATION AND FOOT PRESSURE ANALYSIS OF DIABETIC FOOT: PROSPECTIVE ANALYTICAL STUDY IN INDIAN DIABETIC PATIENTS

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ABSTRACT

Aim: Clinical examination of diabetic foot to find out its pathological Complications and analysis of plantar foot pressure of diabetic foot patients in Indian population.
Method: This was prospective analytical study in Indian diabetic patients. 102 patients were evaluated through clinical, vascular, neurological and plantar foot pressure assessment.
Results: 35% patients developed diabetic neuropathy. ABI- 62% patients had vascular complication. On foot examination 51% patients had nail changes, 32% had foot lesion and 52% had foot deformity. 7.8% had Charcot joint arthropathy, 5.8% had interdigital infection, 38.2 % had restricted joint mobility of first MTP joint. 20% had past history of foot ulceration; out of which 71% had high peak pressure point areas at healed ulcer area. High pressure values were seen in healed ulcer group patients. Average value of peak foot pressure in dynamic mode is- left foot 156.41Kpa (min 105 Kpa- max 346 Kpa) and right foot is 153.05 Kpa (min 100Kpa-max 245Kpa). Maximum values of peak pressure were seen at abnormal pressure point areas such as 4-5th metatarsal heads, lateral aspect of foot and middle of arch.
Conclusion: Meticulous clinical examination can easily identify diabetic neuropathy and related pathological complications of diabetic foot. This shall help for early diagnosis and prevention of diabetic foot complications. Foot pressure analysis can be useful tool to screen patients of diabetic foot for abnormal high pressure point areas and can predict future risk of ulceration due to high foot pressure. This study states findings in Indian diabetic patients.

Key words: clinical examination of foot, diabetic neuropathy, foot pressure analysis.

INTRODUCTION

Diabetes Mellitus (DM) is one of the most common chronic diseases in nearly all countries and is fast becoming the epidemic of 21st century.[1] People with DM in developing countries are of working age, between 40 and 60 years, and over 60 years in developed countries. This could have a long-lasting adverse effect on a nation's health and economy, especially for developing countries.[2] India leads the world with largest number of diabetic subjects earning the dubious distinction of being termed as the "Diabetes capital of the world". It is estimated that the total number of people with diabetes in 2010 to be around 50.8 million in India, rising to 87.0 million by 2030.[3] The long-term sequel of the diabetic foot includes motor neuropathy that leads to the clawing of toes and prominent metatarsal heads. Motor neuropathy is perhaps the most important etiopathogenic factor in the production of high foot pressure. Motor neuropathy causes intrinsic muscle atrophy that promotes foot deformity and decreased joint mobility. The final result of these changes is the development of high foot pressures under the metatarsal heads and loss of toe function, especially of the great toe.[4-6]

Furthermore, autonomic neuropathy accompanies the development of chronic sensorimotor neuropathy and at the foot level is responsible for denervation and subsequent anhydrosis of the foot. This leads to atrophic skin, fissures, and callous formation. Additionally, increased blood stagnation and swelling in the foot predisposes the foot to ulceration.[7-9] Because of sensory neuropathy, high foot pressures may lead to tissue breakdown and the development of ulceration. The combination of peripheral vascular disease and neuropathy makes the diabetic patient particularly susceptible to foot ulceration and infection.[10] Diabetic foot amputations are one of the most frequent of diabetic complications. Patients with foot complications spend higher percentage of their income (32.3%) for treatment when compared with those without foot infections.[11]

Eighty five percent (85%) of diabetes related lower extremity amputations are preceded by ulceration. Increased dynamic foot pressures are among the identified risk factors in the formation of diabetic foot ulcer.[12] Jeremy Rich [13] tried to find out correlation of Forefoot and Rear foot Plantar Pressures in Diabetic Patients to Foot Ulceration. He conclude that the peak foot pressures of the forefoot, but not the rear foot, correlate with neuropathy measurements and can also predict foot ulceration over a 36month period. Measurements of the forefoot peak pressures, rather than the whole foot, may therefore be more useful in identifying the at risk patient for developing foot ulceration.

Limited literature is available to predict data on complications of diabetic foot and foot pressure analysis in Indian population. This study aims to find out prevalence of pathological complications of diabetic foot and analysis of plantar foot pressure in Indian population.

Objective

The objective of this study were to find out prevalence of pathological complications and risk factors of diabetic foot in a study population and correlate between different clinical parameters; and to find out peak high foot pressure areas for early identification and prevention of risk of future foot ulceration due to high foot pressure.

METHODOLOGY

After confirming suitability for the study, the patients and care takers were explained the nature and duration of examination involved in the study. A written informed consent was obtained from participating subjects prior to participation in the study. Institutional ethics committee approved the study.

This was a prospective analytical study conducted in diabetic foot care clinic at All India Institute of Physical Medicine and Rehabilitation, Mumbai, India. All patients coimg to the clinic between May 2011 to Dec 2013 were included in the study after assessing for inclusion and exlusion criterias New as well as referred patients for diabetic foot care clinic were included in the study.

Sample size (n): One hundred and two (102) diabetic patients.

Inclusion Criteria: Patients with age between 35 to 85 years of both sexes; who are able to walk independently and having old healed foot ulcers were included in the study.

Exclusion criteria: Patinet having non healing chronic ulcers; acute ulcers; amputation on one or both limb; systemic complications of diabetes mellitus; spine deformity; and abnormal gait were excluded from the study..

After assessment of inclusion and exclusion criteria, patients were first assessed for clinical examination.The parameters assessed include:

1. **Demographic parameters** including age, sex, and total duration of diabetes mellitus from date of diagnosis.
2. **Neuropathy diagnosis** has been done by use of neuropathy symptoms score and neuropathy disability score. **Young et al**[14] criteria for clinical diagnosis of DPN (NSS + NDS Score > 10) used as bed side tool. NSS (Neuropathy Symptoms Score) is burning, numbness or tingling, fatigue, cramping, aching, or nocturnal exacerbation. Score of 1 is given for each symptom and 2 are given for night exacerbation. Neuropathy Disability Score (NDS): This was used to quantify the severity of diabetic neuropathy obtained from physical examination and was based on the examination of tendon reflexes and sensory modalities as previously described. The patellar and Achilles tendon reflexes were examined. NSS and NDS score used as bedside tool for diagnosis of diabetic neuropathy.[15]
3. **Vascular examination** of lower limb has been done by ankle brachial index. Ankle brachial index has been done by measuring blood pressure at brachial and ankle region using hand held Doppler ultrasound machine. Ankle brachial index calculated by using formula ankle blood pressure/brachial blood pressure
4. **Integumentary examination** includes autonomic changes of peripheral neuropathy. This includes skin examination, loss of hair over dorsum of foot, tibia and nail changes, and interdigital infection.
5. **Musculoskeletal examination** for deformity of toes. Examination includes: hammer toe, clawing of toes, bunion, hallux rigidus, high arch, flat foot, amputation of toes, dislocation,hallux valgus,rocker bottom deformity, etc. Other findings include corn, callosity and fissure. Patient examined for past healed ulcer site.
6. The total **range of motion at the first metatarsophalangeal joint (MTPJ)** was measured by Goniometer. For the first MTPJ, the range of motion from the maximal passive plantar flexion to maximal passive dorsiflexion was measured. Normal passive range of motion of the first metatarsal joint is 70° of extension and 45° of flexion.
7. **Radiological examination** done to find out prevalence of Charcot joint neuro-arthroparthy in study population.

8. **Foot Pressure Mapping**: Multiple foot pressure mapping systems are available for measurement of plantar foot pressure. In shoe and platform methods are used widely for measuring plantar foot pressure. In this study, the machine used is a mat platform with basic EDMD system. It captures 100 images per second. The mat was calibrated for each patient by using the patient's weight and foot size before each testing session. The mat system was employed to measure the static and dynamic plantar foot pressures. Subjects were instructed to stand bare foot on the mat. Static analysis of the subject's foot pressure was done and area of contact and peak pressure was recorded.

Dynamic analysis was done by asking patient to walk without footwear over the mat. Value of maximum peak plantar pressures for the entire foot was obtained. Several practice runs were made to familiarize the patient with the system and to ensure the recording of natural gait. The environmental conditions of temperature were maintained. The mean reading of three mid-gait footsteps was entered for final data analysis. Machine software is calibrated with color codes. A peak pressure area with red color shows maximum pressure and blue color shows least pressure.

Calibration: the pressure is force per unit area. P=F/A. The pressure color codes calibration is automatic through software and is standardized to patient's value according to his foot contact area and body weight. (Red = maximum pressure area, Blue= minimum)

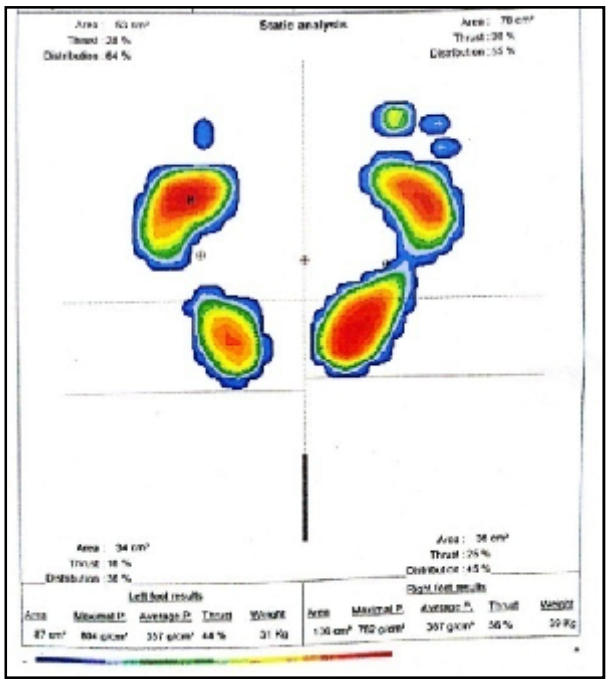

Figure 1: Foot Pressure analysis Report. (Static phase) Red color showing maximum peak pressure point area

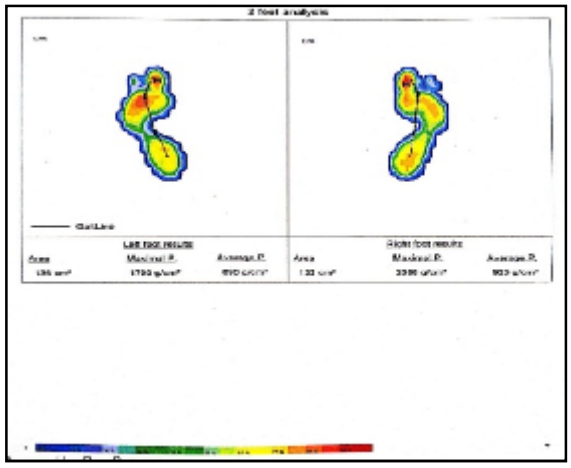

Figure 2: Foot Pressure analysis Report. (Dynamic phase) Red color showing maximum peak pressure point area

Statistical analysis: Microsoft excel 2007 and IBM SPSS statistics 20.

RESULTS

Total number of patients included in study n= 102. Average age of all patients was 61.52 years. (Minimum age: 39, Maximum age: 83 years SD 10.05) Sex distribution- 88 were male and 34 were females. Average duration of diabetes mellitus was 11.49 years. (Minimum 1 to maximum 35 years SD 7.53)

Table 1: Ankle Brachial Index Values

Ankle brachial index Range	Cases	Severity Of Ankle brachial index
Above 1.2	0	Normal Or Acceptable
1.0 To 1.99	2	
0.9 To 0.99	37	
0.8 To 0.89	34	Mild Arterial Disease
0.5 To 0.79	29	Moderate Arterial Disease
Less Than 0.5	0	Severe Arterial Disease

Table 1 show that 62% have impaired ABI. Out of that, 33% have mild arterial disease and 29 % moderate arterial disease.

Diabetic neuropathy: Total number of patients who developed diabetic neuropathy was 36. In diagnosed diabetic neuropathy patients, average duration of years to develop diabetic neuropathy was 12.9 years. In non neuropathy diabetic patients, average duration of diabetes is 10.6 years. Statistically no significant correlation has been found between duration of diabetes mellitus and diabetic neuropathy.(p=0.18)

Statistical correlation applied between various clinical parameters. No association found between duration of diabetes mellitus versus diabetic neuropathy and its complications. Positive association has been seen between neuropathy and joint mobility, neuropathy and history of past ulcer group patients.

Table: 2 various complications of diabetic foot

Diabetic foot complication	No.(%)
Nail changes	
Normal	50 (49.0)
Atrophy of Nail Of Great Toe	19 (18.5)
Atrophy of Nail Of All Toes	24 (23.5)
Onychodystrophy	5 (4.9)
Lesions of foot	
Normal	70 (68.0)
Callosity	17 (17.0)
Fissure	12 (12.0)
Corn	3 (3.0)
Foot deformities	
Normal	60 (58.0)
Hammer Toe Deformity	10 (10.0)
Clawing Of Toes	4 (4.0)
Hallux Valgus	3 (3.0)
Plano Valgoid Foot	8 (8.0)
Rocker Bottom Foot	2 (2.0)
High Arched Foot	9 (9,0)
Amputation Of Toes	5 (5.0)
Dislocation Of Toe	1 (1.0)
Other foot examination findings	
Charcot Joint Arthropathy	8 (7.8)
Interdigital Infection	6 (5.8)
Loss Of Hair Over Tibial Shin	51 (50.0)
Skin Changes	49 (48.0)
First MTP Joint Mobility Restriction	39 (38.2)

Pressure in Past healed ulcer patients: 21 patients had past history of foot ulceration with most common on base of great toe.

Table 3: Showing peak Pressure Points areas in Patients with Old Healed Ulcer and Non Ulcer Patients

Variable	Past Healed ulcer	Dynamic peak pressure point
Base of great toe	11	8
Other toe	1	1
MT Head	4	4
Mid foot	4	1
Lateral aspect of foot	1	1
Heel	0	0
Total	**21**	**15**

Table 4: showing average peak pressure value in left and right foot (Dynamic mode) in Patients with Old Healed Ulcer and Non Ulcer Patients

	Pressure in non ulcer patients	Pressure in Healed Ulcer patients
Right Foot	153.31Kpa	155.79 Kpa
Left Foot	155.05 Kpa	161.64 Kpa

Table 5: Pressure Values In Static and Dynamic Mode (Abberivations- kpa: Kilo Pascal)

	n	Minimum	Maximum	Mean	Std. Deviation
Pressure Dynamic- Left	102	105kpa	346kpa	156.41kpa	34.731
Pressure Dynamic- Right	102	100kpa	245kpa	153.07kpa	30.801
Pressure Static- Left	102	44kpa	118kpa	68.69kpa	14.872
Pressure Static –Right	102	44kpa	118kpa	67.72kpa	13.282

Table 6: maximum peak pressure point areas of foot

Pressure point	Left foot (static)	Right foot (static)	Left foot (dynamic)	Right foot (dynamic)
no pressure point	44	45	13	19
base of great toe	1	1	28	27
first and second metatarsal	13	9	35	32
third to fifth metatarsal	4	10	15	13
lateral aspect of foot	1	0	3	4
middle of arch	3	3	6	5
heel	0	0	2	2

Patients who had past ulcer history, 71% (15) had maximum peak pressure point areas at healed ulcer area. This signifies that 71% patient had risk of recurrent ulceration due to high pressure at same old healed ulcer site.

Maximum pressure values were seen in dynamic mode as compared to static mode.

Abnormal peak pressure point areas are - 3rd,4th and 5th metatarsal heads, middle of foot, and lateral aspect of foot. In dynamic mode abnormal peak pressure point areas are high.

Table 7: Maximum Pressure point areas in different parts of foot

Overall Pressure Points (area wise): Dynamic mode	No (%)
fore foot	88 (86.0)
mid foot	11 (10.0)
hind foot	3 (3.0)

Above table shows that forefoot has more peak pressure point areas than mid foot and hind foot.

DISCUSSION

Very few Indian studies have been done on diabetic foot complication and foot pressure analysis. Vicente I et al,[16] Studied prevalence and risk factors of Ankle-brachial index in patients with diabetes mellitus. They found that Prevalence of a low ABI in subjects with or without diabetes was 11.3% and 4.3% and prevalence of a pathological ABI was 18.8% and 7%, respectively. Factor associated with a low or pathological ABI were gender, age, duration of diabetes, the type of anti-diabetic treatment and the presence of vascular disease in another vascular bed. After multivariate adjustment, only age and duration of diabetes continue being significant.

In this study no significant correlation has been found between ABI and other variates. According to Ramachandran, C. et al,[17] Indians are susceptible to the major complications related to diabetes like coronary artery disease, neuropathy, nephropathy and retinopathy. In this study overall prevalence of diabetic neuropathy was 35%. Average duration of years to develop neuropathy was 12.9 years. M J Young et al [17] done a cross-sectional multicentre study of randomly selected diabetic patients to establish the prevalence of peripheral neuropathy. The overall prevalence of neuropathy was 28.5%. The prevalence of diabetic peripheral neuropathy increased with age. Neuropathy was associated with duration of diabetes. They concluded that Diabetic neuropathy increases with both age and duration of diabetes, until it is present in more than 50% of Type 2 diabetic patients aged over 60 years.

In this study 38.2% patients had restricted joint mobility of first MTP joint. Positive correlation has been seen between neuropathy and joint mobility. C. H. M. van Schie[18] studied biomechanics of diabetic foot and shown the importance of range of motion of first MTP joint. The main motion of the first MTPJ and the lesser MTPJs is in the sagittal plane (dorsiflexion and plantar flexion). During propulsion the body weight is moving forward over the hallux creating relative dorsiflexion of the first MTPJ.

Maximum loading of the first MTH and hallux is practically at the same time during stance in normal gait, highlighting the importance of the load bearing function of both the hallux and first MTH. Michael J Mueller et al [19] studied Plantar Stresses on the Neuropathic Foot during Barefoot Walking. In their study they proposed mechanism for occurrence of high metatarsal head peak pressure. They says that, the Soft tissue clearly plays an important role in stress distribution, and the thicker tissue under the rear foot compared with the forefoot may help to distribute stresses evenly to the underlying bony structures.

People with diabetes mellitus and peripheral neuropathy have a high incidence of hammer-toe deformity (hyperextension of the metatarsophalangeal joint) that is associated with high plantar pressures and skin breakdown. Although the precise reason for the hammertoe deformity is not known, weakness and atrophy in the intrinsic muscles of the foot from peripheral neuropathy are thought to contribute for further discussion of the muscle and bone changes secondary to peripheral neuropathy. People with intrinsic muscle weakness develop hammer toe deformity. Early identification of restriction of First MTP joint mobility and hammer toe deformity can help to reduce skin break down subsequent ulcer formation.

Tatiana Almeida Bacarin, et al[20] studied Plantar pressure distribution patterns during gait in diabetic neuropathy patients with a history of foot ulcers. Results were-Neuropathic subjects from both the diabetic neuropathy and Diabetic without neuropathy groups showed higher plantar pressure than control subjects. At midfoot, the peak pressure was significantly different among all groups: control group (139.4±76.4 kPa), diabetic neuropathy (205.3±118.6 kPa) and DNU (290.7±151.5 kPa) (p=0.008). They concluded that A history of foot ulcers in the clinical history of diabetic neuropathy subjects influenced plantar pressure distribution, resulting in an increased load under the midfoot and rearfoot and an increase in the variability of plantar pressure during barefoot gait. The progression of diabetic neuropathy was not found to influence plantar pressure distribution. The findings of above study and pressure values coincide with this study.

Andrew J M Boulton, et al [21] studied Dynamic Foot Pressure and Other Studies as Diagnostic and Management Aids in Diabetic Neuropathy. They used microprocessor-controlled optical system. Fifty-one percent of neuropathic feet had abnormally high pressures underneath the metatarsal heads compared with 17% of the diabetic controls and 7% of non diabetic subjects. All those feet with previous ulceration had abnormally high pressures at the ulcer sites. They conclude that simple bedside investigations, such as measurement of the VPT alone, may be useful in identifying those patients at risk of foot ulceration. Foot pressure studies may then be used in such patients as a predictive and management aid by determining specific areas under the foot that are prone to ulceration.

Dynamic foot pressure is important for prediction of ulcer due to high foot pressure. In our study High pressure values with abnormal peak pressure point areas are seen at metatarsal heads and mid foot area. Richard M Stess et al[22] in their study "The Role of Dynamic Plantar Pressures in Diabetic Foot Ulcers" studied dynamic pressure variables, such as normalized peak pressure of maximum pressure picture

(MPP), pressure-time integral (PTI), and force-time integral (FTI), were measured Using the EMED-SF plantar pressure analyzer, in each foot. They concluded that Neuropathic patients have an increase in dynamic plantar foot pressures placing them at risk for plantar ulceration. Instruments such as the EMED-SF system can be helpful in detecting possible sites of plantar ulcerations by locating the areas of maximum pressure.

Dynamic plantar foot pressure assessment is important for Identification of high pressure areas of foot and can help to prevent future ulcer.

CONCLUSION

Meticulous clinical examination can easily identify diabetic neuropathy and related complications of diabetic foot. This will help for early diagnosis and prevention of diabetic foot complications. Foot pressure analysis can be useful tool to screen patients of diabetic foot for high pressure point areas and can predict future risk of ulceration due to high foot pressure. This study gives findings and data of complications of diabetic foot and foot pressure analysis in Indian diabetic patients as limited studies are available.

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