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To study efficacy of foot temperature monitoring and footprint study in preventing diabetic foot ulcer in type 2 diabetic patients with peripheral neuropathy

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ABSTRACT

Background: Diabetic foot ulcers (DFU) are a common complication among diabetic patients, leading to an increased risk of amputation and mortality. About 15–25% of diabetics develop DFUs, with half of these cases requiring amputation. Early identification of high-risk patients, particularly those with peripheral neuropathy, is crucial in preventing DFUs. Non-invasive methods such as foot temperature monitoring and footprint analysis have shown promise in identifying these high-risk individuals. **Aims and Objectives:** This study aimed to evaluate the efficacy of foot temperature monitoring and footprint analysis in preventing DFUs in type 2 diabetic patients with peripheral neuropathy by identifying high-risk pressure points and temperature differences. **Materials and Methods:** A prospective study was conducted on 100 patients at Maharani Laxmi Bai Medical College, Jhansi, comprising 50 patients with diabetic neuropathy and foot ulcers and 50 patients with neuropathy but without ulcers. Foot temperature was monitored using a handheld infrared thermometer, while footprint analysis was conducted using a Harris mat. Patients were followed for 5 months to monitor the development of DFUs. Statistical analysis was performed using the Chi-square test, with a significance threshold of $P<0.05$. **Results:** Out of 50 neuropathic patients without ulcers, 14 (64%) developed DFUs, primarily in those with a foot temperature difference of $>2°C$ and grade 3 or 4 pressure points. Foot temperature monitoring and footprint analysis showed a combined efficacy of 67% in predicting DFU development. The results were statistically significant ($P<0.05$). **Conclusion:** Foot temperature monitoring and footprint analysis are effective tools for predicting DFU development in diabetic neuropathy patients. Early identification of high-risk individuals allows for timely interventions, such as appropriate footwear, reducing DFU incidence and the associated risk of amputation.

Key words: Diabetic foot ulcer; Peripheral neuropathy; Foot temperature monitoring; Footprint analysis; infrared thermometer; Pressure points; Diabetic neuropathy; Ulcer prevention

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INTRODUCTION

The number of people living with both type 1 and type 2 diabetes is increasing day by day causing economic burden to the patients and the society. In India, there are about 72 million diabetic cases in 2017 expected to almost double by 2025. Diabetic foot ulcer (DFU) is seen in 15–25% of diabetic patients. Out of which 50% need amputation.[1-4] Out of which 80% of non-traumatic amputation diabetic patient with foot ulcers has a higher mortality rate and 40% higher 10-year death rate. DFU most common cause is peripheral Neuropathy followed

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by peripheral vascular disease,[5] Neuropathy in diabetic patients is manifested in the motor, autonomic, and sensory components of the nervous system. Damage to the innervations of the intrinsic foot muscles leads to an imbalance between flexion and extension of the affected foot. This produces anatomic foot deformities that create abnormal bony prominences and pressure points which gradually cause skin breakdown and ulceration. Examination of the foot is an integral part of the physical examination of every patient more so in diabetic patients. One should look for neuropathic changes, such as dry skin, fissures, deformities, calluses, and abnormal shape of the foot. Ulceration prominent vein and nail lesions. Careful attention should be given to the inter-digital spaces.[6] The aim of the study is to identify the pressure points in diabetic neuropathy patients using a Harris mat and also to record the local foot temperature over the pressure points. Thus helps in the early identification of pressure points and offloading of pressure points using suitable methods.

Aims and objectives

- To study the efficacy of foot temperature monitoring using commercially available infrared thermometer in preventing diabetic foot ulcer in type 2 diabetic patients with peripheral neuropathy.
- To study the efficacy of foot print study in preventing diabetic foot ulcer in type 2 diabetic patients with peripheral neuropathy.

MATERIALS AND METHODS

Method of collection of data

- Type 2 diabetic patients with peripheral neuropathy in the diabetic clinic, surgery outpatient department, and inpatient department of Maharani Laxmi Bai Medical College, Jhansi.

Inclusion criteria

- Age >18 years
- Type 2 diabetic patients with peripheral neuropathy.

Exclusion criteria

- Type 2 diabetic patients without peripheral neuropathy
- Diabetes mellitus with gangrene
- Malignancy
- Type 2 diabetic patients with major critical illness
- Type 2 diabetic patients with osteomyelitis.

Material used

- Commercially available infrared (IR) thermometer.
- Harris mat for footprint study
- Study design: Prospective study.

Methods

Components of the foot examination

History

While history is a pivotal component of risk assessment, a patient cannot be fully assessed for risk factors for foot ulceration based on history alone: A careful foot exam remains the key component of this process. Key components of the history include previous foot ulceration or amputation. Other important assessments in the history include neuropathic or peripheral vascular symptoms, impaired vision, or renal replacement therapy. Finally, tobacco use should be recorded, since cigarette smoking is a risk factor not only for vascular disease but also for neuropathy.

General inspection

A careful inspection of the feet in a well-lit room should always be carried out after the patient has removed shoes and socks. Because inappropriate footwear and foot deformities are common contributory factors in the development of foot ulceration, the shoes should be inspected and the question "Are these shoes appropriate for these feet?" should be asked. Examples of inappropriate shoes include those that are excessively worn or are too small for the person's feet (too narrow, too short, toe box, too low), resulting in rubbing, erythema, blister, or callus. The dermatological assessment should initially include a global inspection, including interdigital spaces, for the presence of ulceration or areas of abnormal erythema. The presence of callus (particularly with hemorrhage), nail dystrophy, or paronychia should be recorded, with any of these findings prompting referral to a specialist or specialty clinic. Focal or global skin temperature differences between one foot and the other may be predictive of either vascular disease or ulceration and could also prompt referral for specialty foot care. The musculoskeletal assessment should include evaluation for any gross deformity. Rigid deformities are defined as any contractures that cannot easily be manually reduced and are most frequently found in the digits. Common forefoot deformities that are known to increase plantar pressures and are associated with skin breakdown include metatarsal phalangeal joint hyperextension with interphalangeal flexion (claw toe) or distal phalangeal extension (hammer toe). An important and often overlooked or misdiagnosed condition is Charcot arthropathy. This occurs in the neuropathic foot and most often affects the midfoot. This may present as a unilateral red, hot, swollen, flat foot with profound deformity. A patient with suspected Charcot arthropathy should be immediately referred to a specialist for further assessment and care.

Neurological assessment

Peripheral neuropathy is the most common component cause in the pathway to DFU. The clinical exam recommended,

however, is designed to identify loss of protective sensation (LOPS) rather than early neuropathy. The diagnosis and management of the latter were covered in a 2004 ADA technical review. The clinical examination to identify LOPS is simple and requires no expensive equipment. Five simple clinical tests, each with evidence from well-conducted prospective clinical cohort studies, are considered useful in the diagnosis of LOPS in the diabetic foot. The task force agrees that any of the five tests listed could be used by clinicians to identify LOPS, although ideally two of these should be regularly performed during the screening exam – normally the 10-g monofilament and one other test. Other tests include 128 hz tuning fork test, pinprick sensation test, ankle reflexes, vibration perception threshold (VPT) using biothesiometer, vascular assessment (palpation or ankle-brachial index [ABI]), One or more abnormal tests would suggest LOPS, while at least two normal tests (and no abnormal test) would rule out LOPS. The last test listed, vibration assessment using a biothesiometer or similar instrument, is widely used in the U.S.; however, identification of the patient with LOPS can easily be carried out without this or other expensive equipment. 10-g monofilaments test: It is recommended that four sites (1st, 3rd, and 5th metatarsal heads and plantar surface of distal hallux) be tested on each foot. Areas of callus should always be avoided when testing for pressure perception. 128-Hz tuning forks test. The vibratory sensation should be tested over the tip of the great toe bilaterally. An abnormal response can be defined as when the patient loses vibratory sensation and the examiner still perceives it while holding the fork on the tip of the toe. Pinprick sensation test: A disposable pin should be applied just proximal to the toenail on the dorsal surface of the hallux, with just enough pressure to deform the skin. The inability to perceive pinprick over either hallux would be regarded as an abnormal test result. Ankle reflexes: Ankle reflexes can be tested with the patient either kneeling or resting on a couch/table. The total absence of ankle reflex either at rest or upon reinforcement is regarded as an abnormal result. VPT testing: The biothesiometer (or neurothesiometer) is a simple handheld device that gives a semiquantitative assessment of VPT. This process should initially be demonstrated on a proximal site, and then the mean of three readings is taken over each hallux. A VPT >25 V is regarded as abnormal and has been shown to be strongly predictiveof subsequent foot ulceration.

Vascular assessment

Peripheral arterial disease is a component cause in approximately one-third of foot ulcers and is often a significant risk factor associated with recurrent wounds. A vascular examination should include palpation of the posterior tibial and dorsalis pedis pulses, which should be characterized as either "present" or "absent". Diabetic patients with signs or symptoms of vascular disease or absent pulses on screening foot examination should undergo ABI pressure testing and can be considered for a possible referral to a vascular specialist. An ABI >0.9 is normal, <0.8 is associated with claudication, and <0.4 is commonly associated with ischemic rest pain and tissue necrosis. ABI measurements may be misleading in diabetes because the presence of medial calcinosis renders the arteries incompressible and results in falsely elevated or supra-systolic ankle pressures. In the presence of incompressible calf or ankle arteries (ABI >1.3), measurements of digital arterial systolic pressure (toe pressure) or transcutaneous oxygen tension may be performed.

Risk classification and referral/follow-up

These categories are designed to direct referral and subsequent therapy by the specialty clinician or team and

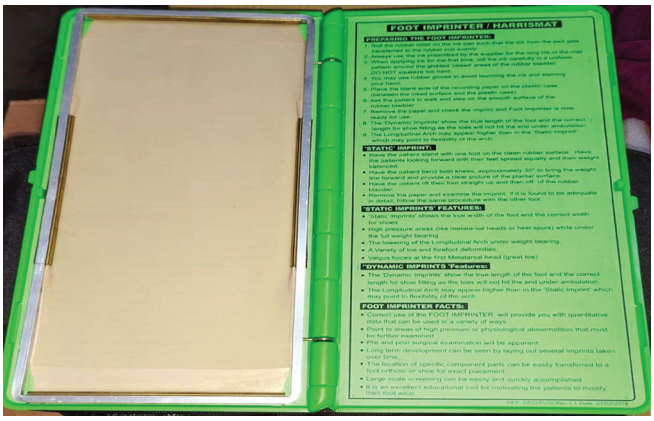

Figure 1: Harris mat

Risk classification based on the comprehensive foot examination			
Risk category	**Definition**	**Treatment recommendations**	**Suggested follow-up**
0	No. LOPS no PAD, no deformity	Patient education including advice on appropriate footwear	Annually (by generalist and/or specialist)
1	LOPS±deformity	Consider prescriptive or accommodative footwear	Every 3–6 months (be generalist or specialist)
2	PAD±LOPS	Consider prescriptive or accommodative footwear Consider vascular consultation for combined follow-up	Every 2–3 months (by specialist)
3	History of ulcer or amputation	Same as category 1 Consider vascular consultation for combined follow-up If PAD is present	Every 1–2 months (by specialist)

LOPS: Loss of protective sensation, PAD: Peripheral artery disease

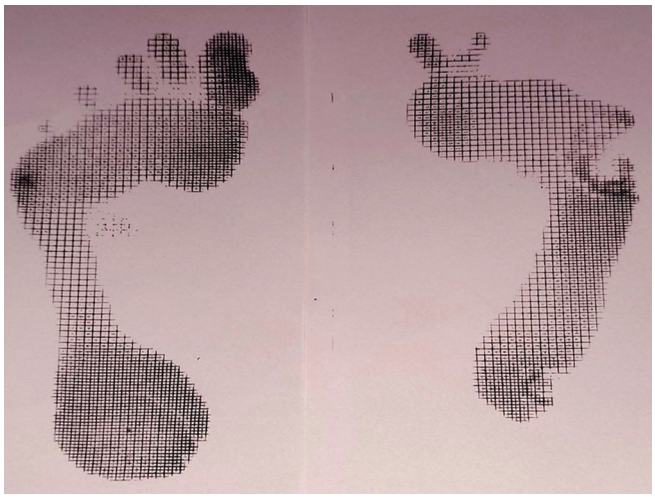

Figure 2: Risk classification based on the comprehensive foot examination

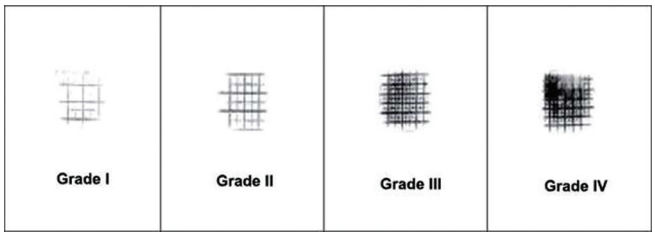

Figure 3: The print patterns and corresponding values were analyzed based on the Silvino, Ewanskie, and Waugh study findings.

Figure 4: Diabetic Foot.

frequency of follow-up by the generalist or specialist. An increased category is associated with an increased risk for ulceration, hospitalization, and amputation.

Harris mat

Print patterns and the respective pressure values according to Silvino. Evanski e Waugh's study was analyzed as follows.

Early identification of feet at risk for ulceration is important in preventing plantar lesions. In diabetic patients with pre-sensitive

foot. Effective screening for high plantar pressure in diabetic patients could have a major injury on the incidence of DFU.

RESULTS

The study's demographic analysis (Table 1) revealed that most participants were aged 51–60 years (39%), with a male predominance (63%), suggesting a higher prevalence of diabetic neuropathy in middle-aged to older adults. Occupational data (Table 2) indicated a majority of farmers (36%) and housewives (29%), reflecting socioeconomic factors potentially impacting healthcare access. Clinical examination (Table 3) showed 49% had dry skin, 25% calluses, and 13% fissures, with 100% exhibiting Loss of Protective Sensation (LOPS) and 13% having absent pulses, highlighting neuropathy and vascular involvement in diabetic foot complications. Correlation data (Table 4) demonstrated that grade III/IV pressure points and temperature differences >2°C were strongly linked to diabetic foot ulcers (DFUs). Among patients with DFUs, 88% had grade III/IV pressure points, and 72% exhibited a temperature difference >2°C (Table 5), emphasizing the efficacy of temperature monitoring and footprint analysis for early detection and prevention of DFUs.

Foot imprinter Harris Mat FM 1111 is a simple, inexpensive, and practical foot pressure measurement device intended for routine clinical use.

IR thermometer non-contact

Temperature is measured on the sole of the foot (1st, 3rd, and 5th) metatarsal head great toe, central midfoot, and heel and dorsum of the foot.

If the temperature corresponding side on left and right foot different by >2°C patients were advised to contact the doctor and reduce the number of steps taken in the following days until the temperature difference was <2°C.

Table 1: Age and sex distribution

Age (in years)	Male	Percentage	Female	Percentage	Total (%)
20–30 years	2	2	4	4	6
31–40 years	3	3	3	3	6
41–50 years	13	13	14	14	27
51–60 years	25	25	14	14	39
61–70 years	11	11	1	1	12
71–80 years	8	8	1	1	9
81–90 years	1	1	0	0	1
Total	63	63	37	37	100

Table 2: Occupation

Occupation	Number of patients	Percentage
Businessmen	7	7
Clerk	7	7
Ex-servicemen	1	1
Farmer	36	36
Fruit seller	1	1
Housewife	29	29
Laborer	15	15
Tailor	1	1
Teacher	4	4
Total	100	100

Table 3: Clinical examination

Clinical exam	Number of patients	Percentage
Dermatological changes		
Callus	25	25
Dry skin	49	49
Fissure	13	13
Nail dystrophy	2	2
Musculoskeletal at deformity		
Hammer toe	1	1
Claw toe	1	1
Neurological assessment		
LOPS	100	100
Vascular assessment		
Pulses absent	13	13
Pulses present	87	87

LOPS: Loss of protective sensation

Table 4: Correlation of diabetic foot ulcer with respect to grades of pressure points and temperature difference

Grade of pressure points	Diabetic foot ulcer (n=50)	Temperature		
		<1.5	1.5–2	>2
Grade I/II	6	6	0	0
Grade III/IV	44	0	8	36
Total	50	6	8	36

Early diagnosis and treatment are advised for the healing of diabetic foot lesions.

Technical specification

1. Simple, one-handed
2. Non-contact, IR method

Table 5: Foot ulcer developed in diabetic neuropathy patients and its correlation with grades of pressure points and temperature difference

Grade of pressure points	Diabetic neuropathy (n=50)	Temperature			Foot ulcer developed
		<1.5	1.5–2	>2	
Grade I/II	30	20	8	2	1
Grade III/IV	20	0	0	20	14
Total	50	20	8	22	15

The P<0.00001

3. Laser targeting
4. $3^{1/2}$ digit LCD display
5. Resolution 0.1°C
6. Accuracy±0.4°C
7. Response time <1 s
8. Power-9v dry cell
9. Measuring distance <1 cm
10. °C/°F. Display selection
11. Automatic power off.

Statistical analysis

The data were summarized as mean values with standard deviations. The statistical analysis was performed using chi-square test. The SPSS 21.0 for Windows computer software (SPSS Inc., Chicago, IL) was used for statistical analysis. P<0.05 was considered significant.

Management of diabetic foot

Limb salvage program

The limb salvage program in diabetic ulcers with early debridement might significantly reduce the need for amputations to some extent. However, prevention of ulcer formation needs to be given priority in Diabetic foot management. Consideration of social and psychological implications is also important in planning strategies for the prevention of ulcer recurrences. Since the DFU has developed into a public health problem, it deserves a holistic approach including socio-economic planning and rehabilitation.

In our study, cost-effective reliable tools, such as hand-held IR thermometer and Harris mat are used and studied their

efficacy in identifying high-risk individuals and preventing DFU among them. 100 Patients with type 2 diabetes with peripheral neuropathy were selected for the study. 50 patients who had already developed DFU and the other 50 patients with type 2 diabetes with peripheral neuropathy who have not developed foot ulcer.

Cisneros et al.,[7] evaluated the inter- and intra-examiner reliability of footprint pattern analysis in diabetic patients using the Harris mat. The study included 41 subjects, with assessments performed by three independent examiners and repeated by one examiner after one week. The kappa coefficient (Kw) was greater than 0.80, indicating high reliability for analyses involving one or multiple examiners. Similarly, our study of footprint analysis using the Harris mat aligns with the findings of this research.

DISCUSSION

Madhale et al.,[8] studied dynamic foot measurement in diabetic patients and also indigenously developed a low-cost lightweight foot pressure scanner. In our study, Harris mat is used to study the footprints, which was found significantly helpful in identifying the high-risk diabetic neuropathy patients and thus help in preventing DFU.

Lavery et al.,[9] studied home monitoring foot skin temperatures to prevent ulceration. The study comprised of 2 study groups, a standard therapy group with 44 subjects (suitable footwear, diabetic foot education, regular foot evaluation by podiatrist) and an Enhanced therapy group with 41 subjects (hand-held IR thermometer for measuring foot skin temperature in addition to the standard therapy). The study concluded that over the 6-month follow-up 20% of the standard therapy subjects developed foot ulcers and only 2% of the enhanced therapy subjects developed foot ulcers. Hence, at-home self-monitoring with daily foot temperature may be an effective tool to prevent foot complications in individuals at high risk for foot lower extremity ulceration and amputation.

In our study maximum no of patients are in the age group of 51–60 years which is in accordance with Madhale et al.,[8] study and also with many other studies. The maximum number of patients are farmers by occupation. 44% of patients had blood sugar values between 200 and 300 mg/dL. 72% of the patients had Hemoglobin A1c level >9. Out of 50 diabetic ulcer patients, 44 had grade 3 and grade 4 out of which 36 patients also had a temperature difference of >2°C which is in accordance with Lavery et al.,[14] study in which high-risk individuals with temperature difference >2.2°C developed foot ulcer. In this study, out of 50 diabetic neuropathy patients 20 had grade 3 and grade 4 pressure points and 20 patients had a temperature difference of >2°C, 15 had developed DFU over the follow period. Out of the 15 patients 14 had temperature difference of >2°C and 15 had grade 3 and grade 4 pressure points. That is 30% of the patients developed DFU over the follow-up period of 5 months which is in accordance with Lavery et al.,[9] study in which 20% had developed DFU after standard therapy.

Limitations of the study

The study's limitations include a small sample size and short follow-up duration of 5 months, which may not fully capture long-term outcomes or the recurrence of diabetic foot ulcers. Additionally, the reliance on cost-effective tools like the infrared thermometer and Harris mat, though practical, might lack the precision of advanced diagnostic methods. The study's single-center design and exclusion of patients with critical illnesses or comorbidities limit its generalizability to a broader population. Finally, self-monitoring for temperature differences by patients introduces potential reporting bias.

CONCLUSION

- In our study, 50 patients are diabetic neuropathy patients who had developed DFU, out of which 88% of patients had grade 3 and grade 4 pressure points and 72% of the patients had foot temperature gradient of >2°C
- 50 patients are diabetic neuropathy patients without foot ulcers, out of which 40% had grade 3 and grade 4 pressure points, and 60% of the patients had grade 1 and grade 2 pressure points. 44% of patients had a foot temperature gradient of >2°C, and 34% of patients had a foot temperature gradient of 0.6–1°C
- 50 diabetic neuropathy patients after 5 months of follow-up out of 20 grade 3 and grade 4 patients 14 had developed DFU which is 70%. 22 patients with temp >2°C out of which 14 patients had developed foot ulcer that is 64%
- Foot temperature monitoring and footprint study together have 67% efficacy in determining the type 2 diabetic neuropathy patients developing DFU
- Hence, these two methods are efficacious in preventing DFU by identifying high-risk individuals and offloading the pressure points by advising suitable footwear
- Out of 50 diabetic neuropathy patients without foot ulcer over the 5-month follow-up 15 patients had developed DFU which is 30%. Hence, regular foot temperature and footprint monitoring of high-risk individuals can prevent DFU by proper footwear and offloading of the pressure points
- Thus according to this study foot temperature monitoring and footprint study together can prevent

DFU and decrease the incidence of foot amputation and morbidity due to foot ulcer.

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MAK, SK, ASY, MA- Concept and design of the study, prepared first draft of manuscript; interpreted the results; reviewed the literature and manuscript preparation; Concept, coordination, preparation of manuscript and revision of the manuscript.

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