RESEARCH ARTICLE

Transcutaneous oxygen tension and ankle brachial pressure index as predictors of outcome in diabetic foot

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ABSTRACT

Background: Diabetic foot ulcer poses a serious threat to patients with Diabetes as the presence of an ulcer further significantly increases the risk of an amputation. Aim and Objectives: The present study was undertaken to assess: Correlation of transcutaneous oxygen tension (TcpO2) and Ankle Brachial Pressure Index (ABPI) in outcome of diabetic foot and severity of neuropathy by grades. Materials and Methods: 30 patients of Type 2 Diabetes Mellitus with foot lesions and 30 healthy controls were selected after obtaining informed consent and ethical committee clearance. Subjects were recruited taking into consideration various inclusion and exclusion criteria. The subjects were assessed for the following parameters: Vibration perception, hot, and cold perception along with TcpO2 and ankle brachial pressure index (ABPI). The test results were compared within the two groups of cases, that is, Group I: Healed ulcer and Group II-Non-healed ulcer. The results of the two groups were compared with 30 healthy controls also. Results: Males were predominant (66.67%) compared to females (33.33%) in the diabetic foot patients. Severe derangements in the sensory modalities were found as observed by the bilaterally reduced values of vibration perception, hot perception and cold perception tests when diabetic foot patients were compared to controls. The values, however, were not significantly different between the two groups of patients of diabetic foot. The values of TcpO2 and ABPI were bilaterally reduced in the cases as compared to controls and amongst the Group I and Group II comparison these values showed a significant difference. A highly significant positive correlation was observed between the TcpO2 and ABPI test results in the diabetic foot patients that indicates both are complimentary tests for diabetic foot outcome prediction. Conclusion: Increased duration of diabetes, high value of Hba1c and presence of neuropathy were found to be important risk predictors for diabetic foot. Early and severe derangement in vibration perception indicated early involvement of large nerve fibers. Heat and cold perception is affected late and less severely, indicating late involvement of small nerve fibers in diabetic polyneuropathy. The positive correlation between TcpO2 and ABPI indicates both are complementary tests for predicting the outcome of diabetic foot. However, TcpO2 being a better predictor maybe incorporated as a routine screening test for diabetic foot risk and outcome predictor in the diabetic foot clinic.

KEY WORDS: Ankle-brachial Pressure Index; Diabetic Foot Ulcer; Transcutaneous Oxygen Tension

INTRODUCTION

India, at present, has a population of 72.96 million diabetics which is expected to rise sharply to about 87 million by 2030. Diabetic peripheral neuropathy (DPN) is the most commonly reported long-term diabetic complication, affecting up to 50 % of type 2 diabetic patients with type 2 diabetes mellitus
The symptoms, pattern of neurologic involvement, course, risk covariates, pathologic alterations, and underlying mechanism of DPN have been seen to be highly variable.\(^1\)\(^{,2}\)\(^{,3}\)

Ulceration is a severe and expensive complication that leads to minor and major amputation in 10–15% of the patients.\(^4\)\(^{,5}\)

The likelihood that patients with diabetes will develop foot ulcers increases in the presence of peripheral neuropathy, peripheral vascular disease (PVD) and poor glycemic control in conjunction with minor foot trauma. The burden becomes more as these ulcers, in turn, often progress to infections of the surrounding tissue, osteomyelitis and amputations.\(^6\)

Frykberg \textit{et al.} and Boyko \textit{et al.} observed that the etiology of diabetic foot ulcers has multiple components.\(^7\)\(^{,8}\)\(^{,9}\) A multicentric study attributed 63% of diabetic foot ulcers to the critical triad of peripheral sensory neuropathy, trauma, and deformity.\(^9\)

Sensory neuropathy reduces the perception of painful thermal and vibration modalities and neuropathic injury results mainly from loss of pain sensation. Acute trauma is more often a result of foreign bodies inside the shoe or the daily repetitive trauma of walking especially if the posture of the foot is abnormal or the shoe fits badly or in case of barefoot walking.\(^9\)

The ankle brachial pressure index (ABPI) is a simple, most reliable, accurate, rapid, inexpensive, non-invasive, quantitative measurement, and the initial test for screening and diagnosing PVD. A high ankle brachial pressure index is associated with increased cardiovascular disease morbidity and lower quality of life because it suggests calcification of arteries.\(^10\) However, in patients with diabetes, both the diagnostic and the predictive value of ABPI may be limited due to a high prevalence of false-negative values as a result of medial artery calcification.\(^11\)\(^{,12}\)\(^{,13}\) Further, ABPI does not reflect microvascular dysfunction, a condition often seen in patients with DFU.

Measurement of transcutaneous oxygen tension (TcPO2) is a non-invasive method reflecting local arterial blood flow and skin oxygenation. Since wound healing depends on an adequate supply of oxygen to the tissues, measurement of TcPO2, may be considered a more reliable method to predict wound healing.\(^14\)

Little research has been performed to investigate the independent roles of multiple potential etiologic factors for DFU, considering the magnitude of this problem. The present study was undertaken to assess: Correlation of TcPO2 and ankle-brachial pressure index (ABPI) in outcome of diabetic foot and severity of neuropathy by grades.

**MATERIALS AND METHODS**

The present study was jointly conducted by Department of Physiology and Center for Diabetes and Endocrinology on patients of T2DM attending Diabetes Clinic of a Government Medical College of Northern India. Institutional Ethical Committee clearance and informed consent from participants was taken before starting the study.

**Study Design**

Observational cross-sectional.

**Study Population**

30 patients of T2DM aged between 29 and 69 years with diabetic foot who met the inclusion and exclusion criteria were selected.

**Inclusion Criteria**

- T2DM patients aged 29–69 years
- Diabetic foot in diagnosed T2DM patients.

**Exclusion Criteria**

- No previous history of any systemic condition related to peripheral neuropathy (e.g. malnutrition, alcoholic neuropathy, end stage renal disease)
- Neuropathies associated with exogenous toxic agents or metals
- Patient on any inflammatory drugs
- Trauma in course of nerve to be examined
- Patient with any other autoimmune disorder, rheumatic diseases or cancer
- Pregnant and lactating females
- Post-menopausal women on HRT (hormone replacement therapy)
- Patients with recent venous thromboembolic episode.

The diagnosis of Diabetes Mellitus was made on the basis of revised American Diabetes Association Criteria.\(^15\)

A detailed history and physical examination was carried out for every subject who entered the study as per a pre-designed proforma.

The selected patients were assessed with Neuropathy Symptom Score (NSS) with symptoms of paresthesias such as burning/numbness/tingling/cramping/aching and clinical examination for Neuropathy Disability Score (NDS). They were assessed for neuropathy using biothesiometry along with heat and cold perception tests.

All the selected patients were divided into two groups on the basis of outcome of the diabetic foot lesion:

- Group I: \((n = 18)\) ulcer healing with treatment/debridement/grafing; healed ulcer
- Group II: \((n = 12)\) non healing ulcers leading to partial limb amputation: Non-healed.
The findings of the two groups were also compared with group of 30 healthy controls.

Measurement of physical parameters: Height (cms), weight (kg) and BMI (kg/cm²).

**Clinical Diagnosis of Diabetic Polyneuropathy**

NSS (maximum score is 9 points).

<table>
<thead>
<tr>
<th>Symptomatology</th>
<th>Maximum score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Burning/numbness/tingling</td>
<td>2 OR</td>
</tr>
<tr>
<td>Fatigue/cramping/aching</td>
<td>1</td>
</tr>
<tr>
<td>Localization</td>
<td></td>
</tr>
<tr>
<td>Feet symptoms</td>
<td>2 OR</td>
</tr>
<tr>
<td>Leg symptoms</td>
<td>1 OR</td>
</tr>
<tr>
<td>Elsewhere</td>
<td>0</td>
</tr>
<tr>
<td>Exacerbation</td>
<td></td>
</tr>
<tr>
<td>Nocturnal exacerbation</td>
<td>2 OR</td>
</tr>
<tr>
<td>Both day/night</td>
<td>1 OR</td>
</tr>
<tr>
<td>Only in day-time</td>
<td>0</td>
</tr>
<tr>
<td>Awakening from sleep</td>
<td>ADD 1</td>
</tr>
<tr>
<td>Symptom improvement on</td>
<td></td>
</tr>
<tr>
<td>Walking</td>
<td>2 OR</td>
</tr>
<tr>
<td>Standing</td>
<td>1 OR</td>
</tr>
<tr>
<td>Sitting or lying down</td>
<td>0</td>
</tr>
</tbody>
</table>

Total score (3 or higher was defined as positive for PNP).

**NDS**

This scoring is based on 4 tests: Vibration perception threshold (VPT); temperature perception on dorsum of foot; pin prick and Achilles tendon reflex.

**VPT and Hot/Cold Threshold**

VPT, Hot threshold and Cold threshold were measured with a biothesiometer (Neuropathy Analyzer model) VIBROTHERM Dx (Diabetic Foot Care, Chennai Engineering Service, India).

**Thermal Perception Threshold (Hot and Cold Threshold)**

Hot and cold threshold values were determined with a microcomputer controlled system. Subjects were initially familiarized with the sensation by holding the probe against the distal palmar surface of hand. Heat and Cold sensation was measured at six sites in each foot: at great toe, at the base of the 1st, 3rd or 5th metatarsals, mid sole and at heel and average of six readings was taken for interpretation.

<table>
<thead>
<tr>
<th>Heat perception (°C)</th>
<th>Interpretation</th>
<th>Cold perception (°C)</th>
</tr>
</thead>
<tbody>
<tr>
<td>42</td>
<td>Normal</td>
<td>20</td>
</tr>
<tr>
<td>43-45</td>
<td>Mild</td>
<td>19-15</td>
</tr>
<tr>
<td>46-48</td>
<td>Moderate</td>
<td>14-10</td>
</tr>
<tr>
<td>49</td>
<td>Severe</td>
<td>9</td>
</tr>
</tbody>
</table>

After assessing for all the above parameters the subjects were staged for polyneuropathy using the following staging criteria:

**Staging of Severity of Diabetic Polyneuropathy**

NO: No objective evidence of Diabetic neuropathy

N1: Asymptomatic polyneuropathy

N1a: No symptoms or signs but neuropathic test abnormalities

N1b: Test abnormalities plus neuropathy impairment on neurological examination.

N2: Symptomatic neuropathy

N2a: Symptoms, signs and test abnormality

N2b: N2a plus significant ankle dorsiflexor weakness.

N3: Disabling polyneuropathy

The grading of diabetic foot lesions was done based on the Wagner-Meggitt grading system of diabetic foot lesions.[16]

- 0 - Intact Skin
- 1 - Superficial ulcer of skin or subcutaneous tissue
- 2 - Deep ulcer extending into tendon, bone, or joint capsule
- 3 - Deep ulcer with abscess, osteomyelitis, or joint sepsis
- 4 - Local gangrene of toes or forefoot or heel
- 5 - Gangrene of entire foot.

Grade 0 and 5 were not considered in our study because grade 0 had no active lesion and Grade 5 lesion posed problem for other tests to be performed.

**TcPO2**

TcPO₂ was measured by Periflux system 5000 equipment PF 5040 TcPO₂/CO₂ Unit (Instrument version 1.70–1.79; manufactured by Perimed AB Jarfalla, Sweden).

**Reference values (Fife et al)[17]**

- 50–70 mmHg Normal
- <40 mmHg Impaired wound healing
- <30 mmHg Critical Limb Ischemia.

**Ankle-Brachial Pressure Index**

The Ankle Brachial Index (ABPI) is the ratio of the blood pressure in the legs to the blood pressure in the arms. The
ABPI is calculated by dividing the highest systolic blood pressure in the arm by the systolic blood pressures at the ankle.

ABPI was measured using the Kodys Auto equipment (Smart-V-Link® Hadeco from Kody Medical Electronics Private Limited, Chennai, India).

**Calculation of ABI**

Pleg is the systolic blood pressure of dorsalis pedis or posterior tibial arteries.

Parm is the systolic blood pressure of the arm in the brachial artery

\[
\text{ABI} = \frac{P_{\text{leg}}}{P_{\text{arm}}}
\]

**Statistical Analysis**

Analysis was performed using IBM Statistical Package for the Social Sciences Statistics 21 statistical package for windows. Continuous variables were expressed as mean ± standard deviation or range, and qualitative data were expressed in percentages. Unpaired ‘t-test’ for independent samples was used in comparing continuous data between two groups. The association between continuous variables was tested using Pearson’s coefficient. All tests were two tailed; confidence intervals were calculated at 95% level and a ‘P < 0.05’ was considered significant.

**RESULTS**

Baseline characteristics of healthy controls and T2DM patients with diabetic foot can be seen in Table 1. No significant difference in the baseline characteristics were seen between the two groups of diabetic patients.

Severity grading of neuropathy in Type 2 Diabetes can be seen in Table 2. 36% patients (n = 11) were in Grade N3 and all belonged to Group II. 27% were in grade N2b (8) and 36% were Grade N2a (11), all in group I. Only 1 patient of group II was N2b grade.

Values of all of the tests done to assess neuropathy in Group I and Group II patients differs significantly when compared to healthy controls. (P < 0.05 being considered significant) [Table 3]. However, no significant difference in the two groups of patients was seen. It was observed that vibration perception is the most severely affected sensory modality followed by heat perception, and the least affected one was cold perception.

The results of TcPO2 and ABPI are shown in Table 4. The test results show a significant decrease in the values of both the tests in Type 2 Diabetic foot patients when compared to controls. A significant difference was seen in both the parameters when comparison was done between the groups (P < 0.05).

A significant positive correlation was seen between TcPO2 and ABPI in the diabetic foot-Pearson’s Correlation coefficient- r value-0.615 (P < 0.05).

**DISCUSSION**

The study was conducted on 30 patients of T2DM with diabetic foot and 30 healthy controls. They were assessed for neuropathy using Biothesiometry and Hot and Cold perception tests. For assessing the vascular status of these subjects TcPO2 and ankle-brachial pressure index (ABPI) tests were done. Most of the subjects were males (67%). There was severe derangement in the sensory modalities examined such as vibration perception and perception of temperature (both hot and cold) in Diabetic patients in comparison to controls. The values of TcPO2 and ABPI were greatly reduced in them and a highly significant positive correlation was seen between the two parameters.
Most of the cases in both groups were in severe grade in our study which shows early loss of vibration perception in type 2 diabetes neuropathy. Hot and cold perception were also tested which shows small nerve fibers involvement. Our findings are consistent with findings in a North Catalonia diabetes study in which it was suggested that we should test temperature and vibration sensation to evaluate small nerve fibers and large nerve fibers respectively.[24-26]

An Indian multi-centric study done by Vishwanathan and Kumpatla has reported high prevalence of amputation rate of 65.2% in diabetics.[27] In the present study, the overall amputation rate was 40% which is much less in comparison, which was probably achieved by well-organized multidisciplinary foot care teams, good glycemic control, offloading, debridement and proper selection of antibiotics and by educating patients on foot care. As 80% of amputations follow a foot ulcer or injury, early recognition of at risk individuals, provision of education, and appropriate foot care may result in a reduced incidence of ulceration and consequently amputation.[28] The risk of amputation was also associated with male sex, a consistent finding in at least two previous prospective studies in American Indians. In the Oklahoma Indian Diabetes Study (n = 875), risk of incidence in men was twice that in women, and in a study on 4,399 Pima Indians, the rate of amputation in men was 2.6 times in comparison to women, adjusted for age and diabetes duration.[29,30]

Several risk factors for amputation among the patients with diabetes have been cited in the literature including age,[30] male sex,[28,29] hypertension,[38,39] neuropathy,[30] and poor glycemic control.[30] Although there are inconsistencies among studies regarding all the various risk factors for amputation, PVD was identified by different researchers as an independent risk factor. In our analysis, presence of PVD also led to a significant higher rate of amputations which was comparable with previous studies.

The presence of vascular disease characterized by disrupted micro-and macro-circulations cause a delay in wound

### Table 3: Results of biothesiometry and hot-cold perception test in Diabetic patients compared with Healthy controls on both the right and left sides. Values are expressed as (mean±SD)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Healthy controls (n=30)</th>
<th>Group I (n=18)</th>
<th>Group II (n=12)</th>
<th>Healthy controls (n=30)</th>
<th>Group I (n=18)</th>
<th>Group II (n=12)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vibration perception</td>
<td>10.23±1.65</td>
<td>45.33±8.02</td>
<td>47.83±4.08</td>
<td>10.47±1.67</td>
<td>45.78±8.31</td>
<td>47.42±5.50</td>
</tr>
<tr>
<td>Hot threshold (°C)</td>
<td>38.73±1.86</td>
<td>48.42±0.81</td>
<td>48.82±1.27</td>
<td>38.60±1.79</td>
<td>48.64±0.77</td>
<td>48.95±0.68</td>
</tr>
<tr>
<td>Cold threshold (°C)</td>
<td>21.73±1.29</td>
<td>11.31±2.57</td>
<td>10.43±1.55</td>
<td>21.86±1.08</td>
<td>10.55±2.58</td>
<td>10.63±1.65</td>
</tr>
</tbody>
</table>

SD: Standard deviation

### Table 4: The comparison of TcPO2 values between the healthy controls and Group I (healed) and Group II (Non-healed). Values are expressed as (mean±SD)

<table>
<thead>
<tr>
<th>Groups</th>
<th>Right</th>
<th>Left</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Values of TcPO2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>63.36±5.9</td>
<td>&lt;0.001*</td>
<td></td>
</tr>
<tr>
<td>Group I</td>
<td>44.5±8.01</td>
<td>44.59±7.71</td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>63.36±5.9</td>
<td>&lt;0.001*</td>
<td></td>
</tr>
<tr>
<td>Group II</td>
<td>24.9±9.19</td>
<td>23.2±8.93</td>
<td></td>
</tr>
<tr>
<td>Values of ABI</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>1.19±0.13</td>
<td>&lt;0.001*</td>
<td></td>
</tr>
<tr>
<td>Group I</td>
<td>0.99±0.13</td>
<td>0.99±0.1</td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>1.19±0.13</td>
<td>&lt;0.001*</td>
<td></td>
</tr>
<tr>
<td>Group II</td>
<td>0.90±0.8</td>
<td>0.89±0.12</td>
<td></td>
</tr>
</tbody>
</table>

*p-value<0.5 is significant, TcPO2: Transcutaneous oxygen tension

Diabetic Foot Ulcer accounts for a major percentage of hospital admissions and is the most important cause of non-traumatic lower limb amputations i.e. about 40–60% worldwide.[18] The induced local metabolic and micro-vascular changes that occur in T2DM patients also lead to another important complication, that is, diabetic peripheral neuropathy.

Many earlier studies like ours suggested male gender predominance.[18-22] The possible explanation for this finding could be involvement of more males in outdoor activities as compared to females predisposing them to foot trauma.[22]

Neuropathy and ischemia, two important complications of Diabetes Mellitus were found to be underlying risk factors for the development of foot ulcers. Patients living in the rural areas and those with poor socioeconomic status often walk bare-foot, having poor knowledge of foot care that puts them at greater risk for development of foot ulceration. Moreover, a severe sensory neuropathy makes it impossible for them to be aware of the trauma that their foot is suffering from, and hence, it adds to the disease burden. These observations are in accordance with the reports of other researchers also.[22-23]
healing in diabetic patients.\[31,32\] Disruption of wound healing results from a decreased blood flow into the ulceration and an aberrant expression of growth factors and cytokines as well. In concordance with our results, previous studies also showed that limb ischemia is associated with an increased risk for amputation.\[33,34\]

In this study of 30 T2DM patients with the diabetic foot, the utility of ABPI and TcPO2 values in predicting wound healing was assessed. A systematic review of various studies by a group of scientists on ulcer healing prediction said that the ABPI values of <0.5 are associated with major amputation and TcPO2 values of >25 mm of Hg are associated with higher chances of healing.\[35\] Another study done in China showed that ABPI (0.45 ± 0.25) and TcPO2 (32.83 ± 18.30 mm of Hg) in the amputation group were significantly lower than that in the other two groups. ABPI and dorsum TcPO2 have been seen to be positively correlated to DFUs prognosis like our study, by multiple regression analysis.\[26\] TcPO2 has in several studies been associated with ulcer healing and cardiovascular events and mortality in patients with type 2 diabetes, but without DFU and/or a history of previous CVD. A 2.8-folded increase in 1-year mortality among patients with TcPO2< 25 mmHg has been observed. Our findings are hence in line with other studies which suggest that the TcPO2 is a better predictor of the outcome of ulcer healing when compared to ABPI.\[35\]

In a study done in Kerala, the mean ABPI in the healed group was 0.96 ± 0.24 and 0.61 ± 0.27 in the non-healed group and the TcPO2 values in the healed and non-healed groups were 33.77 ± 15.51 and 23.29 ± 14.77 mm of Hg respectively.\[36\] Another study done by Kalani et al.\[37\] showed that TcPO2 was a better predictor of diabetic foot ulcer healing when compared to toe blood pressures.

Although the ABPI measurement is a simple non-invasive and reproducible test for assessing the severity of PVD in diabetic patients,\[38\] its use seems to be limited in patients with calcified distally occluded tibial arteries. It may also fail to recognize the underlying problem where an occlusion has a rich collateral network.\[39\] Lauderner et al. evaluated the TcPO2 values for predicting the risk of non-healing and amputation in diabetic foot ulcer and concluded that a significantly decreased probability of healing is seen at values <20 mm of Hg as compared to values >40 mm of Hg.\[40\] The EURODIALE study concluded that the predictors of healing might differ in different cases especially in diabetics with PAD and that infections had a negative impact on wound healing.\[41\]

Since ABPI measures the circulation in medium sized vessels, it well explains the low capillary blood flow and hence, a low transcutaneous pressure of oxygen values. Furthermore, if ABPI is normal there may be presence of skin microcirculation defects in diabetes like chronic capillary ischemia in skin and this is more often seen in T2DM patients with PAD.\[42\]

A significant positive correlation between ABPI and TcPO2 was seen in our study. This is highly suggestive of them being complimentary to each other in predicting the ulcer healing in T2DM patients.

**Limitations**

1. The small sample size in each group (30) can be considered an important limitation of our study. Subjects between 29 and 69 only have been included. We can extend our research by increasing the number of subjects and including subjects younger than 29 and older than 69 years of age.
2. We have included subjects only of Diabetes Mellitus 2. Comparison may be done between patients of Type 1 and Type 2 Diabetes.

**Future Research**

Few studies have been done in Indian subjects that have correlated findings of various sensory tests with tests like ABPI and TcPO2 that may be considered the strength of our study. However, there is a lot of scope for future research:

1. We can extend our study by recording the Nerve Conduction Velocity (sensory and motor) of commonly affected nerves in Diabetics.
2. Correlation may also be done with certain biochemical parameters such as blood glucose level, serum creatinine, urine albumin, and serum lipid profile.

**CONCLUSION**

In our study, severe derangements in the sensory modalities were found as observed by the bilaterally reduced values of vibration perception, heat perception and cold perception tests when diabetic foot patients were compared to controls. The values, however, were not significantly different between the two groups of patients of diabetic foot.

Early and severe derangement of vibration perception indicates early involvement of large nerve fibers. Heat and cold perception are affected late and less severely indicating late involvement of small nerve fibers in diabetic polyneuropathy.

A highly significant positive correlation was observed between the TcPO2 and ABPI test results in the diabetic foot patients that indicates both are complementary tests for diabetic foot outcome prediction. According to the results obtained in the study, TcPO2 seems to be a better predictor of diabetic foot outcome. Thus, it can be incorporated as a routine screening test for diabetic foot risk and outcome prediction in the diabetic foot clinics.
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