

Is Toe Brachial Index a Better Tool than Ankle Brachial Index for Predicting Outcomes in Diabetic Foot Patients?

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ABSTRACT

Introduction: Diabetes accounts for more than 50% of lower extremity amputation, of which 85% of lower limb amputation in diabetic patients are preceded by foot ulcers. The increasing prevalence of ischaemic ulcers has made ischaemia probably the most important cause of Diabetic Foot Ulcers (DFUs) today. Modalities for assessment of vasculopathy include clinical examination of pulses, Ankle Brachial Pressure Index (ABI), Toe Brachial Pressure Index (TBI), Transcutaneous partial pressure of Oxygen (TcPO₂), Duplex imaging, Magnetic Resonance (MR) and Computed Tomography Angiography (CTA).

Aim: This study was aimed at evaluation of ABI and TBI in assessment of vasculopathy in DFUs and their association with the various surgical outcomes.

Materials and Methods: This study was done as a cross-sectional study on 100 patients with diabetic foot, from December 2016 to April 2018, with prospective follow-up till the outcome of "ulcer healed", "minor/major amputation" with healing of the amputation stump, was achieved. The multimodality approach for treatment of DFU was taken. Variables like age, gender, duration of present ulcer, previous history of ulcers and interventions, comorbidities, history of smoking and duration of diabetes were recorded and assessed. The examination included examination of peripheral pulses, presence of neuropathy, measurement of ABI and TBI. Investigations included HbA1c levels, swab or pus cultures from the ulcers, objective evaluation of Peripheral Arterial Disease (PAD) by Duplex Ultrasonography and CT Angiography where an intervention was contemplated. The data was entered in MS Excel spreadsheet and analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0.

Results: The mean age was 62.55±9.21 years, with maximum patients belonging to the age group 61-70 years (38%) followed by 51-60 years age group (33%). Smoking as a risk factor was present in 59% of all the patients. A total of 53 patients underwent amputation among which 28 were smokers (52.8%). Neuropathy was present in 47.22% (n=51), with 60.87% of all patients with neuropathy undergoing amputation which was significant (p-value=0.005). When defined by ABI alone (ABI <0.9), 46.3% patients had PAD, however, using TBI <0.7 for defining PAD, incidence of PAD increased to 68.31% patients. Thus identifying 21 more patients with PAD as compared to ABI. Poor glycaemic control was significantly associated with poor outcome in the form of amputation (p<0.001). Patients who underwent major amputation had a mean ABI of 0.54±0.22, for minor amputation the mean ABI was 0.85±0.19 and for those who had healed ulcers, had a mean ABI of 0.61±0.27. The cut-off value for ABI to predict amputation was >0.51 with a sensitivity of 77.14 and a specificity of 56.1, which was not found to be significant (p-value=0.0796). The mean TBI for the diabetic feet was 0.25±0.12 for major amputation, 0.42±0.26 for minor amputation and 0.61±0.19 for ulcer healed. With a cut-off value of ≤0.3, the sensitivity and specificity for predicting amputation were 68.75 and 88.68 respectively which was found to be significant (p<0.001).

Conclusion: The ABI has been found to under-report ischemia as compared to TBI in diabetic patients. TBI also correlates better with the outcome of a DFU. Thus, making TBI a part of assessment of vasculopathy in DFU patients who have not undergone toe amputations, would help in correctly identifying ischemia and early institution of possible intervention in such patients.

Keywords: Ankle brachial pressure index, Diabetic mellitus, Peripheral arterial occlusive disease, Toe brachial pressure index

INTRODUCTION

It is estimated that diabetes accounts for more than 50% of lower extremity amputation [1], of which 85% of lower limb amputation in diabetes patients are preceded by foot ulcers [2]. The DFUs are usually classified as neuropathic, neuroischaemic or ischaemic ulcers. The prevalence of neuroischaemic and ischaemic ulcers has been rising to become probably the most common aetiology of DFUs [3-7].

The International Working Group on the Diabetic Foot (IWGDF) suggest, in addition to a thorough history taking for symptoms of PAD and palpation of pulses in the lower limb (including posterior tibial and dorsalis pedis arteries), a hand-held doppler evaluation of the flow signals from both foot arteries and a measurement of the ABI should be included in the evaluation of patients with DFUs. The PAD is likely when the patient has claudication or rest pain, both foot pulses are absent at palpation,

or absent or monophasic. Doppler signals are obtained from one or both foot arteries. An ABI <0.9, is a sign of PAD. In case of diagnostic uncertainty, measurement of the TBI or TcPO₂ may provide additional diagnostic value [8]. The TBI measurement is recommended for evaluation of foot circulation, especially when the ABI values are falsely high as toes are significantly less affected by media sclerosis and also when the ABI is >0.6 or ankle pressure is >70 mmHg as their predictability of healing is poor at these levels [9]. Various studies revealed that ABI in DFUs patients tend to under-report PAD [9,10]. Also, TBI correlated better than ABI in predicting an outcome of DFU [9,11].

The aim of this study was to evaluate ABI and TBI in assessment of vasculopathy in a setting of diabetic foot and to study their association with the various surgical outcomes. Indian study [9] are scarce in this respect although the country has one of the highest population of diabetics second only to China.

MATERIALS AND METHODS

The study was designed as a cross-sectional (observational) study on patients with diabetic foot, with prospective follow-up till the outcome of ulcer healed, minor and major amputation with healing of the amputation stump, was achieved. A total of 100 patients with 108 affected legs with diabetic foot who met the inclusion criteria were studied. The study was initiated after obtaining permission from the institutional Ethical Committee of Army Hospital Research & Referral (IEC Regn No. 74/2016) and was conducted in Department of Vascular surgery, Army Hospital Research and Referral, New Delhi, India from December 2016 to April 2018.

Sample size calculation: Based on the previous study of Kalani M et al., the sensitivity and specificity of Toe Blood Pressure (TBP)/TBI for predicting ulcer healing was 15% and 97%, respectively [12]. Taking these values as reference, the minimum required sample size with desired precision of 15%, 95% power of study and 5% level of significance was 94 patients. To reduce margin of error, total sample size taken was 100.

Inclusion criteria: Patients with DFUs who presented at the surgery/vascular surgery department were included. They were further classified under Wagner Grade-1-5 [13], University of Texas Stages A-D and Grades 0-3 [14] and PEDIS (perfusion (arterial supply), extent, depth, infection and sensation) Grades 1-4 [15].

Exclusion criteria: Patient with non diabetic vasculopathies like those caused by autoimmune diseases, rheumatic diseases, malignancies, renal or liver failure, haematological diseases or treatment with anti-inflammatory drugs, were excluded and those patients who did not follow-up were also excluded.

Study Procedure

A self-reporting questionnaire to record the demographic variables and relevant history was filled by patient, which included age, gender, duration of present ulcer, previous history of ulcers and interventions for the same, Other co-morbid conditions, history of smoking: patients were designated as smokers or non smokers as per National Health Interview survey (NHIS)[16]. According to this criterion if a person has smoked more than 100 cigarettes/bidis in life time and continues to smoke, is termed as current smoker. Duration of diabetes mellitus was also noted since diagnosis. After taking the history, patients were thoroughly examined which included a general physical examination and local examination of the lower limbs. General physical examination included body mass index, weight in kg/height in m², pulse including palpation of peripheral pulses namely carotid, brachial, radial, ulnar, femoral, popliteal, dorsalis pedis, anterior tibial and posterior tibial arterial pulsations on both sides, Blood pressure in both upper limbs, presence of pallor, pedal oedema. Local examination of the ulcer and the limb includes number, location, exudation (+/-), presence of neuropathy: sensory examination using Semmes Weinstein 10g nylon filament was done. Patient was also evaluated for any motor weakness and signs of autonomic disturbances.

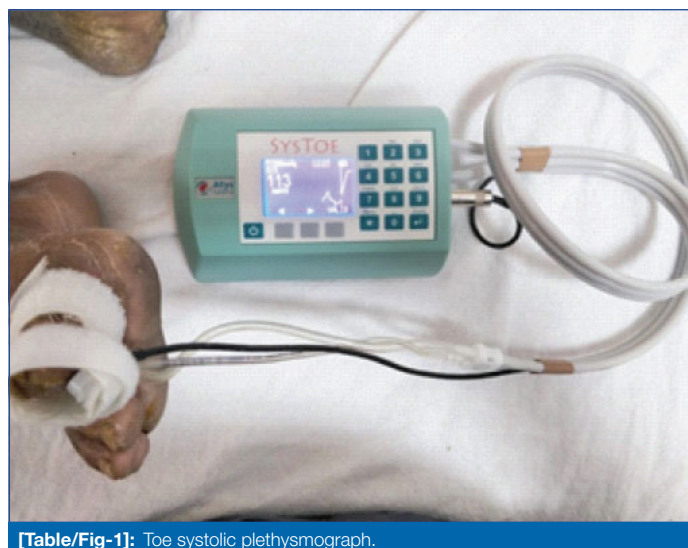
Ankle Brachial Index (ABI): Defined as maximum distal artery pressure at ankle/greater of the brachial pressures [17]. The pressures were recorded using a handheld doppler.

Toe Brachial Index (TBI): Defined as toe pressure measured by plethysmography/greater of the brachial pressures [Table/Fig-1] [17].

Investigations pertaining to the cases were sent as under:

1. HbA1c levels
2. Swab or pus culture from the ulcer
3. Objective evaluation of PAD by Duplex ultrasonography
4. CT Angiography of the peripheral arterial tree where a revascularisation procedure was contemplated

A patient was considered to have peripheral arterial disease if ABI: <0.9 and/or TBI: <0.7 [17]. Patients received treatment with



[Table/Fig-1]: Toe systolic plethysmograph.

debridement, revascularisation procedures and amputation or a combination of these and other measures as per the multidisciplinary approach for treatment of Diabetic foot.

The surgical outcomes were documented as:

1. Ulcer healed: complete epithelialisation of the ulcer.
2. Minor amputation: Amputations distal to the ankle joint have been termed as minor amputations.
3. Major amputation: Amputations at or above ankle joint have been termed as major amputations.

The demographic study of the DFUs was done with respect to age of the patient, sex, duration of diabetes, duration of ulcer, glycaemic control, grade of DFU at presentation.

The various risk factors like duration of diabetes, poor glycaemic control, smoking, presence of infection, presence of neuropathy were studied and vasculopathy parameters like ABI and TBI were studied and compared with each other in predicting the outcome of the disease.

STATISTICAL ANALYSIS

Categorical variables were presented in number and percentage (%) and continuous variables were presented as mean±SD and median. Normality of data was tested by Kolmogorov-Smirnov test. If the normality was rejected then non parametric test was used.

Statistical tests were applied as follows:

1. Quantitative variables were compared using Analysis of Variance (ANOVA)/Kruskal Wallis test.
2. Qualitative variables were correlated using Chi-Square test/Fisher-exact test.
3. Receiver operating characteristic curve was used to find out cut-off point of parameters for predicting amputation.

A p-value of <0.05 was considered statistically significant. The data was entered in MS Excel spreadsheet and analysis was done using SPSS version 21.0.

RESULTS

A total of 100 patients with 108 affected legs were included in the study. The patient's age in the present study varied from 41 years to 86 years. The average age was 62.55±9.21 years. The maximum numbers of patients were in the age group 61-70 years. Out of the 100 patients studied, 93 (93%) were males and 7 (7%) were females [Table/Fig-2].

Average duration of diabetes for the study population at presentation was 10.15±5.24 years. All the co-morbid conditions were noted and analysed for their frequency in the study population. A total of 61% (n=61) patients had at least one co-morbidity other than diabetes. Hypertension was the most common co-morbid condition, present in 39% (n=39) patients, followed by coronary artery disease in 18% (n=18). There were 37% (n=37) patients who had a past history of

Age (in years)	Female, n (%)	Male, n (%)	Total (n)	p-value
41-50	0	11 (100%)	11	0.235
51-60	1 (3.03%)	32 (96.97%)	33	
61-70	3 (7.89%)	35 (92.11%)	38	
>70	3 (16.67%)	15 (83.33%)	18	
Total	7 (7.00%)	93 (93.00%)	100	

[Table/Fig-2]: Distribution of the population (total and gender wise) into age groups (p-value by Chi-square test).

foot ulcers of which three had bilateral disease, making number of feet with past history of ulcers as 40. Among these, nine ulcers healed completely, eight with dressings alone and one after endovascular intervention. There were 26 feet which underwent minor amputations, five of which after endovascular intervention. In remaining five cases, the patients underwent major amputations, with three of these after endovascular intervention as in [Table/Fig-3].

Variables	Dressings (n)	Endovascular (n)	Endovascular+ Amputation (n)	Amputation (n)	Total (n)
Ulcer healed	8	1	-	-	9
Minor amputation	-	-	5	21	26
Major amputation	-	-	3	2	5
Total					40

[Table/Fig-3]: Past history of ulcers, interventions and outcome.

Ulcer characteristics: Ulcer characteristics of the various DFUs in terms of their side, site, number and exudates were noted for descriptive purpose as in [Table/Fig-4].

Ulcer characteristics	Variable	Total (n)	Percentage (%)
Side	Right	45	41.67
	Left	63	58.33
Site	Foot	104	96.29
	Involving Leg	04	3.71
Number	Solitary	66	61.11
	Multiple	42	38.89
Exudate	Present	24	22.22
	Absent	84	77.78

[Table/Fig-4]: Ulcer characteristics.

Classification of the diabetic foot: The diabetic feet were distributed as per Wagner's grade as depicted in [Table/Fig-5] [13].

Wagner's grade	Frequency (n)	Percentage (%)
1	11	10.19
2	31	28.70
3	25	23.15
4	26	24.07
5	15	13.89
Total	108	100

[Table/Fig-5]: Distribution of feet as per Wagner's grading system.

The feet were also classified as per University of Texas staging and grading system as shown in [Table/Fig-6,7] [14].

Stage (University of Texas)	Frequency (n)	Percentage (%)
A	0	0.00
B	5	4.63
C	49	45.37
D	54	50
Total	108	100

[Table/Fig-6]: Classification of feet as per University of Texas staging system.

Grade (University of Texas)	Frequency (n)	Percentage (%)
0	0	0.00
1	9	8.33
2	37	34.26
3	62	57.41
Total	108	100

[Table/Fig-7]: Classification of feet as per University of Texas grading system.

The feet were also classified as per PEDIS classification as in [Table/Fig-8].

Duration of DFU at the time of presentation was noted in months. The average duration of symptoms at presentation was 2.32 ± 0.95 months. Posterior tibial artery pulse was the most commonly absent pulse (n=95, 87.96%) [Table/Fig-9].

The outcomes were classified as ulcer healed, minor amputation or major amputation. Their frequency is depicted in [Table/Fig-10].

PEDIS grade	Frequency (n)	Percentage (%)
1	11	10.19
2	32	29.63
3	49	45.37
4	16	14.81
Total	108	100.00

[Table/Fig-8]: Classification of feet as per PEDIS grading system.

	Fem A	Pop A	ATA	DPA	PTA
Pulse absent	8.33% (n=9)	55.56% (n=60)	85.19% (n=92)	86.11% (n=93)	87.96% (n=95)

[Table/Fig-9]: Distribution of absent pulses.

Outcome	Frequency (n)	Percentage (%)
Major amputation	25	23.15
Minor amputation	28	25.93
Ulcer healed	55	50.93
Total	108	100.00

[Table/Fig-10]: Frequency of various outcomes of the diabetic foot.

Demographic Variables and their Impact on Outcome

Age: The distribution of age was studied under headings of each outcome and has been depicted in [Table/Fig-11].

Sex: Gender distribution for various outcomes is depicted in [Table/Fig-12].

Duration of diabetes: Duration of diabetes was found to significantly impact the outcome [Table/Fig-13,14] (p-value=0.006).

Age (in years)	Outcome			p-value
	Major amputation (n=25)	Minor amputation (n=28)	Ulcer healed (n=55)	
Mean±Std	63.24±10.39	61.71±8.5	62.56±8.84	0.83
Median	65	63	61	
Min-Max	48-85	43-75	42-86	
Inter quartile range	56-70.250	55.500-68.500	56.250-68.750	

[Table/Fig-11]: Age distribution for each outcome (p-value by ANOVA test).

Sex	Outcome			n (%)	p-value
	Major amputation n (%)	Minor amputation n (%)	Ulcer healed n (%)		
Female	3 (42.86)	2 (28.57)	2 (28.57)	7 (100)	0.366
Male	22 (21.78)	26 (25.74)	53 (52.48)	101 (100)	
Total	25 (23.15)	28 (25.93)	55 (50.93)	108 (100)	

[Table/Fig-12]: Sex distribution with outcome (p-value by Chi-Square test).

Duration of diabetes (in years)	Major amputation (n=25)	Minor amputation (n=28)	Ulcer healed (n=55)	p-value
Mean±SD	12.08±4.73	10.86±5.39	8.56±5.02	0.006
Median	11	10	8	
Min-Max	4-22	2-22	2-24	
Inter quartile range	8.750-15	7-14.500	5-12	

[Table/Fig-13]: Duration of diabetes as distributed under outcome (p-value by Kruskal wallis test).

Duration of symptoms (months)	Major amputation (n=25)	Minor amputation (n=28)	Ulcer healed (n=55)	p-value
Mean±SD	2.4±1.12	2.29±0.85	2.33±0.96	0.998
Median	2	2	2	
Min-Max	1-5	1-4	1-5	
Inter quartile range	2-3	2-3	2-3	

[Table/Fig-14]: Duration of symptom as distributed under outcome (p-value by Kruskal Wallis test)

Duration of symptoms: Duration of symptoms was not found to significantly affect the outcome. (p-value=0.998) [Table/Fig-14].

Risk Factors and their Impact on Outcome

Smoking: Total 59 patients in this study were smokers, three of whom had bilateral disease, making the legs involved in smokers as 62. However, as a risk factor for the outcomes, it was not found to be statistically significant (p-value=0.636), as depicted in [Table/Fig-15].

Smoking	Outcome			Total	p-value
	Major amputation n (%)	Minor amputation n (%)	Ulcer healed n (%)		
No	12 (26.09)	13 (28.26)	21 (45.65)	46 (100)	0.636
Yes	13 (20.97)	15 (24.19)	34 (54.84)	62 (100)	
Total	25 (23.15)	28 (25.93)	55 (50.93)	108 (100)	

[Table/Fig-15]: Smoking distributed under outcomes (p-value by Chi-Square test).

Neuropathy: Neuropathy was present in 47.22% (n=51) of the legs and it was found to significantly affect the outcome (p-value=0.005) [Table/Fig-16].

Type of neuropathy	Outcome			Total	p-value
	Major amputation n (%)	Minor amputation n (%)	Ulcer healed n (%)		
Sensory neuropathy	4 (17.39)	4 (17.39)	15 (65.22)	23 (100)	0.005
Motor+sensory neuropathy	7 (35.00)	10 (50.00)	3 (15.00)	20 (100)	
Motor, sensory and autonomic neuropathy	4 (50.00)	2 (25.00)	2 (25.00)	8 (100)	
No neuropathy	10 (17.54)	12 (21.05)	35 (61.40)	57 (100)	
Total	25 (23.15)	28 (25.93)	55 (50.93)	108 (100)	

[Table/Fig-16]: Presence of neuropathy (p-value by Chi-Square test).

Glycaemic control: Glycaemic control, as quantified by HbA1c levels had a significant bearing on the outcome of the patients with DFUs (p-value <0.001) [Table/Fig-17].

Presence of infection: Presence of infection was found to significantly impact outcome (p-value=<0.001) [Table/Fig-18].

Ischaemia: It was defined by ABI <0.9 and/or TBI <0.7. With definition of ABI, PAD was present in 46.30% (n=50) population. Defining PAD by TBI <0.7, the incidence of PAD was found to be 68.31% (n=69) in the study population. As the great toe was missing in seven patients, TBI could be taken only in 101 patients, however, an additional 21 patients with PAD were identified by TBI

HbA1c (gm%)	Major amputation (n=25)	Minor amputation (n=28)	Ulcer healed (n=55)	p-value
Mean±SD	6.5±0.73	5.78±0.56	5.34±0.42	<0.001
Median	6.7	5.8	5.2	
Min-Max	5.2-7.9	4.9-7.2	4.5-6.5	
Inter quartile range	6-6.950	5.350-6	5.100-5.400	

[Table/Fig-17]: Distribution of HbA1c levels in various outcome groups (p-value by Kruskal Wallis test).

Presence of infection	Outcome			Total	p-value
	Major amputation n (%)	Minor amputation n (%)	Ulcer healed n (%)		
No	2 (4.26)	10 (21.28)	35 (74.47)	47 (100)	<0.001
Yes	23 (37.70)	18 (29.51)	20 (32.79)	61 (100)	
Total	25 (23.15)	28 (25.93)	55 (50.93)	108 (100)	

[Table/Fig-18]: Presence of infection distributed under outcomes (p-value by Chi-square test).

criteria. Also, the percentage of neuroischaemic ulcers increased from 22.22% (n=24) to 37.03% (n=40).

Further distribution of ABI and TBI were studied for their impact on outcome as in [Table/Fig-19,20].

The ABI and TBI were compared for their sensitivity and specificity in predicting a poor outcome in the form of amputation as shown in [Table/Fig-21].

ABI	Major amputation (n=25)	Minor amputation (n=28)	Ulcer healed (n=55)	p-value
Mean±SD	0.54±0.22	0.85±0.19	0.61±0.27	0.079
Median	0.54	0.9	0.5	
Min-Max	0.3-1.15	0.4-1.1	0.16-1.16	
Inter quartile range	0.400-0.600	0.715-1	0.425-0.880	

[Table/Fig-19]: ABI as distributed under outcomes (p-value by Kruskal Wallis test).

TBI	Major amputation (n=22)	Minor amputation (n=26)	Ulcer healed (n=53)	p-value
Mean±SD	0.25±0.12	0.42±0.26	0.61±0.19	<0.001
Median	0.2	0.3	0.6	
Min-Max	0-0.6	0.1-1	0.2-0.9	
Inter quartile range	0.200-0.300	0.200-0.600	0.500-0.800	

[Table/Fig-20]: TBI as distributed under outcomes. As the great toe was missing in 7 patients, TBI could be taken only in 101 patients, (p-value by Kruskal Wallis test).

	Area under the ROC curve (AUC)	Standard error	95% Confidence interval	p-value	Cut-off	Sensitivity	Specificity
ABI	0.615	0.065	0.496 to 0.724	0.079	>0.51	77.14	56.1
TBI	0.825	0.043	0.737 to 0.894	<0.001	≤0.3	68.75	88.68

[Table/Fig-21]: ABI and TBI in predicting unfavourable outcome.

DISCUSSION

The mean age of our study population was 62.55±9.21 years. The mean age at presentation in the present study was comparable to other studies like Global Epidemiology of DFU study by Zhang P et al., where the mean age at presentation was 61.7± 3.7 years [18]. However, Indian study of self-reported DFU cases by Pendsey SP revealed mean age of presentation as 53.55 years as compared to 68 years in western population [19]. Most of the Indian studies including this study, are studies based on self-reported cases and not population-based studies leading to variations in the prevalence.

Males were more affected than females in the present study as seen in other studies. In study by Al-Rubeaan K et al., males were affected more than females presented by 68.57% and 31.43% [20]. Epidemiological study by Pendsey SP of self-reported DFU patients revealed a sex ratio M/F of 3:1 [19]. The present study was predominated by males as this was a self-reported study, conducted in service hospital where servicemen and their dependent are treated, females tend to under-report. However, neither age nor sex was significant in predicting the outcome of the disease. Average duration of diabetes at presentation in the present study was 10.15 ± 5.24 years which was comparable to study done by Zhang P et al., where patients with DFUs had longer duration of Diabetes 11.3 ± 2.5 years [18]. The duration of diabetes was found to be significantly associated with outcome (p -value=0.006). Association of duration of diabetes with poor outcome was similar to that found in study by Saleem S et al., where longer duration of diabetes (>10 years), was significantly associated with poor outcome $p < 0.001$ [21].

Smoking is a known risk factor in development of diabetes, DFUs and PAD. Smoking was a risk factor present in 59 patients with involvement of 62 legs. Among 53 patients who underwent amputation, 28 were smokers (52.8%), however smoking was not found to be a good predictor of poor outcome in the present study, (p -value= 0.636). This is similar to the findings of Apelqvist J et al., in which the smoking was not found to predict amputations [22]. However, in study by Anderson JJ et al., it was found that greater number of diabetics who smoked, underwent amputation as compared to those who did not smoke which was statistically significant ($p=0.038$) [23].

Neuropathy was evaluated with presence of sensory, motor, autonomic neuropathy or a combination of these. A 47.22% of patients were found to have neuropathy. The findings were similar to that found in study by Margolis DJ et al., where 50% of all the ulcers were neuropathic [24]. The PAD was defined in the study population as ABI of <0.9 and/or TBI <0.7. A 53.7% patients had PAD, when defined by ABI alone which was similar to the Eurodial study, where almost 48% of patients with DFU had PAD [20]. Also, in the large Swedish study by Gershater MA et al., almost 50% had PAD [6]. In this study, 22.22% of the study population had both ischemia and neuropathy co-existing, close to the finding by Margolis DJ et al., where incidence of neuroischaemia ulcers was about 30% [24].

However, when TBI (<0.7) was used for defining PAD, the incidence of PAD increased to 68.31% patients, identifying 21 more patients with PAD as compared to ABI. Further the incidence of neuroischaemic ulcers increased from 22.22- 37.03%. This shows defining PAD with TBI is better than ABI in diabetics as also brought about in study by Karunakaran K et al., [9].

The average HbA1c of the study population was 5.75 ± 0.73 gm%. Poor glycaemic control was significantly associated with poor outcome in the form of amputation, (p -value <0.001). This was similar to the findings of the meta-analysis done by Zhou ZY et al., which revealed a statistically significant association between high HbA1c and lower extremity amputations, ($\chi^2=65.51$, p -value=0.0001) [25].

Presence of infection is another independent risk factor for poor outcome of DFUs. A total of 56.48% legs had infection associated with the DFU. This was similar to study by Avery LA et al., where the incidence of infection in DFUs was about 61% [26]. It was found to be statistically significant in predicting a poor outcome for the disease (p -value=<0.0001), similar to the findings of Oyibo SO et al., where risk of amputation increased with infection ($p < 0.001$) [14].

Most common pulse to be absent in the study population with PAD was posterior tibial artery pulse (87.96%) followed by dorsalis pedis artery pulse (86.11%) and closely followed by anterior tibial artery pulse (85.19%). This was similar to the findings that tibial and peroneal artery pulsations are the commonest involved in diabetic foot as found in study by Boulton AJ et al., [27].

The assessment parameters for vasculopathy were further compared with each other and it was found that TBI correlated better with prediction of a poor outcome (AUC- 0.825) as compared to ABI (AUC-0.615). These findings were similar to the studies by Karunakaran K et al., which revealed that TBI correlated better than ABI in predicting poor outcome in a case of DFU [9]. This study caters to the most common cause of lower limb amputations in elective setting. India has one of the largest population of diabetics and thus patients with DFUs, making it a significant cause of morbidity and cost to state. A significant difference was achieved between the sensitivity and specificity of TBI and ABI in predicting the outcome of DFUs. This study caters to the most common cause of lower limb amputations in elective setting. India has one of the largest population of diabetics and thus patients with DFUs, making it a significant cause of morbidity and cost to state. A significant difference was achieved between the sensitivity and specificity of TBI and ABI in predicting the outcome of DFUs.

Limitation(s)

The study includes measurement of TBI which requires specialised instrument, toe photo-plethysmograph which is not readily available in all clinics over the country. It is impossible to measure TBI for legs with prior amputation of the great toe. A higher sample size would bring down the margin for error even further.

CONCLUSION(S)

In present study, neuropathy was found in almost half of the study population as was PAD and about a quarter of the population had both the risk factors. However, using TBI rather than ABI to define PAD, the incidence of ischaemic ulcers increased to almost 2/3rd of the presenting population. ABI in Diabetic patients can be wrongly high because of calcified arterial walls, making an accurate evaluation of vasculopathy, very difficult. The TBI, which involves measurement of toe systolic pressure, better assesses the vasculopathy as the distal arteries are much less affected by medical calcific sclerosis in diabetes. The TBI was a better predictor of outcome of DFUs than ABI. TBI will prove to be an invaluable clinical tool in management and to prognosticate DFUs.

REFERENCES

- [1] Rose GA, Blackburn H, Gillum RF, Prineas RJ. Cardiovascular Survey Methods. 2nd edn. Geneva: World Health Organization, 1982.
- [2] Smith SR, Reed JF. Prevalence of mixed infections in the diabetic pedal wound: A perspective based on a national audit. *Int J Low Extrem Wounds*. 2002;1:125-28.
- [3] New JP, McDowell D, Burns E, Young RJ. Problem of amputations in patients with newly diagnosed diabetes mellitus. *Diabet Med*. 1998;15:760-64.
- [4] Edmonds M. Experience in a multi-disciplinary diabetic foot clinic. In: Boulton AJM, Connor H, Ward JD, editors. *The Foot in Diabetes*. 1st ed. Chichester, UK: Wiley. 1987:121-33.
- [5] Ndip A, Jude EB. Emerging evidence for neuroischemic diabetic foot ulcers: Model of care and how to adapt practice. *Int J Low Extrem Wounds*. 2009;8(2):82-94.
- [6] Gershater MA, Londahl M, Nyberg P, Larsson J, Thorne J, Eneroth M, et al. Complexity of factors related to outcome of neuropathic and neuroischemic/ischemic diabetic foot ulcers: A cohort study. *Diabetologia*. 2009;52(3):398-407.
- [7] Prompers L, Schaper N, Apelqvist J, Edmonds M, Jude E, Mauricio D, et al. Prediction of outcome in individuals with diabetic foot ulcers: Focus on the differences between individuals with and without peripheral arterial disease. *The EURODIAL Study*. *Diabetologia*. 2008;51(5):747-55.
- [8] Frykberg RG, Zgonis T, Armstrong DG, Driver VR, Giurini JM, Kravitz SR, et al. *Diabetic Foot Disorders: A Clinical Practice Guideline*. *The Jour of Foot and Ankle Surg*. 2006:49s.
- [9] Karunakaran K, Sathyapriya B, Rajkiran T, Anandan H. Efficacy of diagnosing vascular occlusion in diabetic foot patients to improve the outcome. *Int J Sci Stud*. 2016;4(6):19-22.
- [10] Elhadd T, Robb R, Jung R, Stonebridge P, Belch J. Pilot study of prevalence of asymptomatic peripheral arterial occlusive disease in patients with diabetes attending a hospital clinic. *Pract Diabetes Int*. 1999;16:163-66.
- [11] Wang Z, Hasan R, Firwana B, Elraiyah T, Tsapas A, Prokop L, et al. A systematic review and meta-analysis of tests to predict wound healing in diabetic foot. *J Vasc Surg*. 2016;63:29S-36S.
- [12] Kalani M, Brismar K, Fagrell B, Ostergren J, Jörneskog G. Transcutaneous oxygen tension and toe blood pressure as predictors for outcome of diabetic foot ulcers. *Diabetes Care*. 1999;22(1):147-51.
- [13] Wagner FW Jr. The dysvascular foot: A system for diagnosis and treatment. *Foot Ankle*. 1981;2(2):64-122.

- [14] Oyibo SO, Jude EB, Tarawneh I, Nguyen HC, Harkless LB, Boulton AJ. A comparison of two diabetic foot ulcer Classification Systems, The Wagner and the University of Texas wound classification systems. *Diabetes Care*. 2001;24(1):84-88.
- [15] Lipsky BA, Berendt AR, Cornia PB, Pile JC, Peters EJ, Armstrong DG, et al. Infectious diseases society of America. Clinical practice guidelines for the diagnosis and treatment of diabetic foot infections. *Clin Infect Dis*. 2012;54:132-73.
- [16] National Center for Health Statistics. Survey Description, National Health Interview Survey, 2017. Hyattsville, Maryland.
- [17] Hirsch AT, Haskal ZJ, Hertzner NR, et al. ACC/AHA 2005 Practice Guidelines for the management of patients with peripheral arterial disease (lower extremity, renal, mesenteric, and abdominal aortic): A collaborative report from the American Association for Vascular Surgery/Society for Vascular Surgery, Society for Cardiovascular Angiography and Interventions, Society for Vascular Medicine and Biology, Society of Interventional Radiology, and the ACC/AHA Task Force on Practice Guidelines (Writing Committee to Develop Guidelines for the Management of Patients With Peripheral Arterial Disease): endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation; National Heart, Lung, and Blood Institute; Society for Vascular Nursing; Trans-Atlantic Inter-Society Consensus; and Vascular Disease Foundation. *Circulation*. 2006;113:e463-654.
- [18] Zhang P, Lu J, Jing Y, Tang S, Zhu D, Bi Y. Global epidemiology of diabetic foot ulceration: A systematic review and meta-analysis. *Ann Med*. 2017;49(2):106-16.
- [19] Pendsey SP. Epidemiological aspects of diabetic foot. *Int J Diabetes*. 1994;14:37-38.
- [20] Al-Rubeaan K, Al Derwish M, Ouizi S, Ouizi S, Youssef AM, Subhani SN, et al. Diabetic foot complications and their risk factors from a large retrospective cohort study. *PLoS One*. 2015;10(5):e0124446.
- [21] Saleem S, Hayat N, Ahmed I, Ahmed T, Rehan AG. Risk factors associated with poor outcome in diabetic foot ulcer patients. *Turk J Med Sci*. 2017;47:826-31.
- [22] Apelqvist J, Agardh CD. The association between clinical risk factors and outcome of diabetic foot ulcers. *Diabetes Res Clin Pract*. 1992;18(1):43-53.
- [23] Anderson JJ, Boone J, Hansen M, Spencer L, Fowler Z. A comparison of diabetic smokers and non-smokers who undergo lower extremity amputation: A retrospective review of 112 patients. *Diabet Foot Ankle*. 2012;3.
- [24] Margolis DJ, Malay DS, Hoffstad OJ, Leonard CE, MaCurdy T, de Nava KL, et al. Prevalence of Diabetes, diabetic foot ulcer, lower extremity amputation among Medicare beneficiaries, 2006-2008. *Diabetic Foot Ulcers, Data Points #1; AHRQ Publication No. 10 (11)-EHC009-EF*. Rockville, MD: Agency for Healthcare Research and Quality. 2011.
- [25] Zhou ZY, Liu YK, Chen HL, Yang HL, Liu F. HbA1c and lower extremity amputation risk in patient with diabetes: A meta-analysis. *Int J Low Extrem Wounds*. 2015;14(2):168-77.
- [26] Avery LA, Armstrong DG, Wunderlich RP, Mohler MJ, Wendel CS, Lipsky BA. Risk factors for foot infections in individuals with diabetes. *Diabetes Care*. 2006;29(6):1288-93.
- [27] Boulton AJ, Armstrong DG, Albert SF, Frykberg RG, Hellman R, Kirkman MS, et al. Comprehensive foot examination and risk assessment. *Diabetes Care*. 2008;31(8):1679-85.

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