Original Article

Transcutaneous oxygen pressure (TcPO$_2$) and ulcer outcome in diabetic patients: Is there any correlation?

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ABSTRACT

Background: Due to poor blood circulation, the prevalence of foot ulcer is extensively reported among diabetic patients. Diabetic neuropathy is the critical factor of diabetes that can affect the nerves.
Objective: To examine the outcomes and correlation between TcPO2 and ulcer outcomes among diabetic patients.
Material and methods: A prospective cohort design has been employed to compare and correlate TcPO2 group with ulcer outcomes. A total of 192 patients were enrolled, who underwent diagnosis for ulcer outcome. Descriptive analysis and Pearson Correlation were used for data analysis via SPSS version 20.
Results: The prevalence of minor amputation among diabetic patients in 25—40 mmHg 75 (85.22%) and >40 mmhG 73 (84.88%) group is reported for ulcer outcome. Mostly diabetic patients were healed with intact skin (male = 36, female = 73), and improved ulcer healing (male = 23, female = 43). Correlation between ulcer size (p = .016), ABI (p = .044), TBI (p = .000), Adiponectin (p = .009), HbA1c (p = .033), and S. creatinine (p = .025) was significant with TcpO2 group.
Conclusions: The study concluded that there is a positive and significant correlation between TcPO2 group and ulcer outcome. There is a positive association between TcPO2 baseline and degree of ulcer healing with intact skin.

1. Introduction

Diabetes Mellitus has affected more than 370 million people across the globe. By 2030, this figure is expected to be increased to about 552 million people [1]. Diabetes is a common healthcare issue that occurs as a result of high Body Mass Index (BMI), high blood pressure, and obesity. There are many symptoms associated with diabetes, like frequent urination, increased hunger and thirst. Persistent diabetes over a period of time can lead to chronic renal diseases, cardiovascular diseases, strokes, diabetic retinopathy (damage to the eyes), and foot ulcers due to poor blood circulation. The most common complication of diabetes is diabetic neuropathy as it damages and blocks the nerves of the body. The symptoms of neuropathy are tingling, numbness, and pain that lead to damaged skin tissues. It can ultimately lead to diabetic foot ulcers or cutaneous ischemia that are extremely difficult to treat and cure. Normal wound healing process of the body does not occur among patients suffering from diabetes. It can lead to the formation of foot ulcers and ultimately to amputation. Foot ulcer is characterized as a disabling long-term complication of diabetes. The exact reasons of physiological disorder, causing ulcer are not known to researchers. There are various risks associated with ulcer; such as, ischemia and neuropathy. The patients that are diagnosed with these symptoms, are at a higher risk of having foot ulcer [2]. The major causes of diabetic foot ulcers are infection, injury, neuropathy, and hypoxia or ischemia. Despite successful revascularization and the use of other conventional therapies, patients might have to undergo minor amputations. The causes for undergoing amputation may be diminished by wound healing from osteomyelitis, pervasive limb ischemia, and soft tissue infection.

Transcutaneous oxygen measurement method, also known as transcutaneous oximetry, establishes the amount of oxygen that is circulating in the blood capillaries. It is a non-invasive approach and is measured through electrodes placed on the skin. It reveals that whether the blood vessels are damaged or blocked. Londahl and Katzman [3] revealed that foot ulcer healing was very significant with TcPO2 findings than with Toe Blood Pressure (TBP) or

Ankle-Brachial Index (ABI) measurements. TcPO2 comprises of various measures; such as local tissue perfusion pressure, local oxygen consumption, arterial oxygen content, arterial pressure and neurovascular function. Therefore, it provides both micro as well as macro circulation aspect and is reliable measure in the healing process of foot ulcers in diabetic patients.

TcPO2 technique is applied during arteriopathy, and also used for monitoring and assessing ischemia of limbs [1]. This technique is useful in quick healing of the patients. Various tests are conducted to keep the measurements constant in the range of around 10–30 mmHg. The decision about revascularization is made on the basis of results of TcPO2 technique. Transcutaneous oxygen pressure is used to diagnose foot disorders prevalent among patients, suffering from diabetes [4]. The prevention of foot ulcers and amputation of lower extremity or the limb is possible, and it can be achieved by educating diabetic patients. They should be educated on proper care like wearing the comfortable and the right sized shoes. Additionally, blood sugar levels must be strictly monitored, medications must be taken on time, and sugar levels must be maintained within the normal range. Smoking should also be avoided or controlled. Unfortunately, if the foot ulcers occur, then their management will also provide the much-needed relief to the diabetic patient. It can be done by the use of appropriate footwear, the proper treatment of any peripheral artery insufficiency, and the control of hyperglycemia.

Diabetic peripheral neuropathy and diabetic foot ulcers are a result of underlying arterial blockage or damage. They can occur due to various metabolic abnormalities, some on which are low density lipoprotein levels, inhibition of prostacyclin synthesis, increased platelet adhesiveness, and elevated plasma levels. Diabetic neuropathy can cause loss of coordination between the muscles of leg and foot. Moreover, it leads to the loss of skin sensation and numbness and increased mechanical stress during any movement. If the treatment of foot ulcerations is delayed, it can lead to non-traumatic lower extremity amputations. The major cause of premature death amongst patients with diabetic foot ulcers is ischemic heart disease [5]. The onset of diabetic foot ulcer or deformity happens approximately about 10 years after the occurrence of peripheral neuropathy.

Foot ulcer is prevalent among diabetic patients that poses a lifelong threat, causing various complications. The ulcer and TcPO2 has become a global phenomenon among diabetic patients. The diabetic metabolism complications occur due to the disturbances in vascular system. TcPO2 and ulcers are correlated in the treatment of diabetes as the higher level of transcutaneous oxygen level could be associated with foot ulcers. According to a recent research; almost 40% of health facilities are used in developing nations and nearly 15% in developed nations for resolving foot infections [6]. The sepsis related to foot infections or ulcer has mortality rate of 12% across the globe. It has become imperative for healthcare institutions or networks to control the prevalence. Concerning the same issue, the present study will investigate the outcome and correlation between TcPO2 and ulcer among the diabetic patients. Although, TcPO2 is proven to be much superior to ABI and TBP measurements; there are limitations and problems, when using transcutaneous oximetry. The accuracy of the measurements can be affected by various physiological factors; like skin thickness of patients and skin oxygen consumption. Amongst diabetic patients; foot ulcers are found to be the major cause for increased rate of hospitalization [7]. TcPO2 is used for managing vascular diabetic foot ulcer in the clinical practice as it helps in determining the level of amputation, evaluates wound healing, and procedure of revascularization. However, ability of TcPO2 to detect mortality in diabetes is also unknown. Therefore, the present study has mainly focused on the outcomes and correlation between TcPO2 and ulcer among diabetic patients.

2. Material and Methods

2.1. Study design

The study has employed a prospective cohort hospital based-study that has quantitatively compare and correlate TcPO2 with ulcer outcomes. The study has followed the procedures of previous studies to identify the developed outcomes of interest and to research particularly addressed in this study. The study design tends to identify a cohort of individuals at a point before they reveal the anticipated outcomes [2,5,8].

2.2. Study participants

The study has recruited 192 diabetic patients from Rajiv Gandhi Centre for Diabetes and Endocrinology, of Jawaharlal Nehru Medical College Hospital, Aligarh Muslim University, and Aligarh, India, who had ulcer or ulcers in their foot during the period December 2010–2016. The patients on basis of their foot ulcers were characterized into three groups; impaired ulcer healing, improved ulcer healing, healed with intact skin. Whereas, complete healed foot is the end-point followed in the study.

2.3. Inclusion and exclusion criteria

The study was carried out in accordance with principles of Declaration of Helsinki as revised in 2001. The patients suffering from diabetes mellitus II were included in the study. Patients with inflammatory or infectious diseases, autoimmune and rheumatic diseases, cancer, hematological diseases, severe renal or liver failure, as well as those who were under treatment with anti-inflammatory drugs, were excluded. The patients with recent venous thromboembolism were also excluded.

2.4. Clinical evaluation

The medical records of all the patients were evaluated to confirm the diagnosis after obtaining consent from them. Detailed history and physical examination was carried out for every subject including their age, sex, weight, BMI, HbA1c, blood pressure, heat shock protein 47 and 70, serum creatinine levels, ADP levels, lipid profile, and neuropathy (absence of perception of the Semmes-Weinstein monofilament at 2 of 10 standard plantar sites on either foot). Coronary artery disease was determined on the basis of history of physician-diagnosed angina, myocardial infarction, or any previous revascularization procedure assessed by questionnaire.

All patients had blood pressure, serum glucose, serum cholesterol, triglyceride, LDL-cholesterol, HDL-cholesterol levels and urinary albumin excretion (UAE) values measured on first day of admission to the hospital. Duration of ulcer, site, and size of ulcer, history of smoking, history of previous amputation, and clinical outcome were noted in every patient. Clinical assessment for signs of infection (swelling, exudates, surrounding cellulitis, odor, tissue necrosis, crepitation and pyrexia) was made by one researcher, classifying the ulcers and determining the presence of clinical signs of infection.

Along with ABI (ratio of systolic blood pressure in brachial artery), TcPO2 was evaluated as reported by Ref. [9]. The measurements of TcPO2 were taken at the foot dorsum (2 cm proximal to basis of third toe by avoiding the areas of superficial veins and overlying bone. Moreover, the study also investigated the

probability of healing of ulcer among the diabetic patients. The Kaplan-Meier curve has been used to represent the time from foot ulcer to its complete healing based on the three groups.

2.5. Statistical analysis

The obtained data was evaluated using Statistical Package of Social Sciences (SPSS) version 20.0, which would include descriptive analysis and Pearson Correlation.

3. Results

The results have shown demographic and baseline characteristics for age, gender, Wagner grade, HbA1c, and lipid profile based on TcPO2 groups. The results have been categorically analyzed these variables using descriptive analysis and reported significant correlation between Wagner grades (2.28 ± 1.112; p = .000) and HbA1c (9.69 ± 2.055; p = .033) with TcPO2 groups. In contrast, results have shown insignificant correlation of age (48.03 ± 12.737; p = .231), sex (1.65 ± 0.478; p = .442), and lipid profile (423.78 ± 120.84; p = .410) with TcPO2 groups (Table 1). Table 2 has illustrated the percentage of ulcer outcome (Impaired, Improved and Healed) among diabetic patients. The results have shown that mostly diabetic patients were healed with intact skin (male = 36, female = 73), improved ulcer healing (male = 23, female = 43) and impaired ulcer healing (male = 8, female = 9). In terms of ABI, results have shown that improved ulcer healing is found among diabetic patients (1.761 ± 9.601). Similarly, results have shown that there was no existence of impaired ulcer healing (1.75 ± 9.55) and healing with intact skin (1.771 ± 9.652) in diabetic patients. However, the correlation between ABI and ulcer outcomes was insignificant (p = .295). A slight significant association was observed among the patients with impaired ulcer healing (50.60 ± 18.76), improved ulcer healing (50.74 ± 18.81), and healed ulcer with intact skin (50.834 ± 18.77) with p-value .049 (Table 2).

In terms of TBI, results have shown that diabetic patients mostly healed with intact skin (0.982 ± 0.310). Similarly, results have further shown that improved ulcer healing (0.9799 ± 0.311) and impaired ulcer healing (0.975 ± 0.313) were witnessed. However, the correlation between TBI and ulcer outcomes is significant (p = .000). In terms of LDL-C, results have shown that diabetic patients mostly improved ulcer healing (76.11 ± 18.33). Similarly, results have shown that impaired ulcer healing (75.90 ± 18.46) and

healed with intact skin (75.81 ± 18.64) were not witnessed. However, the correlation between ABI and ulcer outcomes was insignificant (p = .072). ROC curve for TcPO2 is given in Fig. 1. The probability of healing of ulcer for diabetic patients is illustrated in Fig. 2.

Table 3 has shown correlation between TcPO2 and data. The results have identified significant correlation between ulcer size (r = −0.173, p = .016), ABI (r = 0.146, p = .044), TBI (r = 0.486, p = .000), Adiponectin (r = 0.187, p = .009), HbA1c (r = 0.155, p = .033), and S. creatinine (r = −0.162, p = .025) with TcPO2 group. In contrast, HSP-70 (r = 0.020, p = .784), HSP-47 (r = −0.009, p = .897), Cathepsin D (r = −0.084, p = .246), 25 (OH)-D (r = 0.060, p = .409), Smoking habit (r = 0.046, p = .523), HDL-C (r = 0.035, p = .634), LDL-C (r = 0.057, p = .435), WBC(x109/L) (r = −0.019, p = .789), Total Serum proteins (r = 0.050, p = .491), SA (r = −0.026, p = .723), and SG (r = 0.017, p = .813) were insignificantly correlated with TcPO2 group (Fig. 3).

4. Discussion

The results have examined correlation between ulcer outcomes and TcPO2 groups among diabetic patients. The findings have shown significant correlation of Wagner grade and HbA1c with TcPO2 groups. A total of 109 diabetic patients were healed with intact skin, 66 diabetic patients were grouped into improved ulcer outcome, and 17 diabetic patients were grouped into impaired ulcer group. These findings have been supported with the outcomes of Caselli et al. [10]. Caselli et al. [10] scrutinized transcutaneous oxygen tension following percutaneous trans luminal angioplasty in diabetic foot ulcer patients. A total of 43 patients, who had undergone revascularization, were chosen for the study; out of which, 20 had undergone unsuccessful revascularization. Transcutaneous oxygen tension was measured before and after surgery. TcPO2 gradually improved in SR group, showing the best reading four weeks after the surgery. Additionally, there was a marked decrease in the transcutaneous carbon dioxide tension levels soon post-surgery, reaching lowest levels at the end of three weeks. However, in the UR group, TcPO2 levels did not show any significant rise after surgery and consequently, remained similar through the observation period and TcPO2 levels remained unchanged. The percentage of patients, who had undergone percutaneous trans luminal angioplasty and had TcPO2 levels that were equal to or more than 30 mmHg, were about 39% a week after the surgery.

Table 1
Demographic data and baseline characteristics.

Factors	TcPO2 groups			All patients	P value
	Group 125 mmHg	Group 225-40 mmHg	Group 3 > 40 mmhG		
Age (years)	48.5 ± 11.5924	49.13 ± 11.755	48.96 ± 11.754	48.03 ± 12.737	.231
BMI (kg/sq mt)	21.33 ± 4.542	20.46 ± 4.075	19.82 ± 4.080	20.10 ± 4.139	0.912
Systolic BP (mmHg)	132 ± 16.416	128.43 ± 17.901	132.36 ± 18.977	131.60 ± 18.495	0.010
Diastolic BP (mmHg)	87.05 ± 11.37	80.06 ± 10.364	86.19 ± 17.552	85.17 ± 16.011	0.011
HbA1c (%)	9.67 ± 2.095	9.657 ± 2.0738	9.671 ± 2.085	9.69 ± 2.055	.033
Serum creatinine (mg/dL)	1.24 ± 0.436	1.29 ± 0.572	1.21 ± .457	1.22 ± .477	0.018
LDL-C (mg/dL)	76.48 ± 18.27	72.91 ± 20.308	76.62 ± 17.994	75.93 ± 18.419	0.023
HDL-C (mg/dL)	34.62 ± 3.138	34.49 ± 2.694	34.65 ± 3.691	34.61 ± 3.458	0.000
Total cholesterol (mg/dl)	137.14 ± 12.289	137.20 ± 12.459	136.74 ± 14.762	136.87 ± 14.054	0.000
Triglycerides (mg/dL)	93.76 ± 18.463	98 ± 26.348	95.54 ± 20.328	95.79 ± 21.277	0.000
CAD	502.861 ± 139.729	534.27 ± 175.47	520.417 ± 176.384	521.026 ± 171.977	0.245
Wagner Grade of ulcer					
1	4 (16.6%)	27 (30.68%)	22 (37.2%)	53 (27.60%)	.000
2	8 (33.3%)	30 (34.09%)	30 (50.8%)	68 (35.41%)	
3	9 (37.5%)	19 (21.5%)	19 (32.2%)	47 (24.47%)	
4	2 (8.3)	6 (6.81%)	5 (8.47%)	13 (6.77%)	
5	1 (4.1%)	6 (6.81%)	4 (6.77%)	11 (5.72%)	

HDL-C: High-density lipoprotein, LDL-C: Low-density lipoprotein, BMI: Body mass index, CAD: coronary artery disease.

Table 2
Outcome data.

Demographic data	Impaired ulcer healing (109 patients)	Improved Ulcer Healing (66 patients)	Healed with intact skin (17 patients)	P value
TcPO2 (mmHg)	50.60 ± 18.76	50.74 ± 18.81	50.834 ± 18.77	.049
ABI	1.75 ± 9.55	1.761 ± 9.601	1.771 ± 9.652	.295
TBI	0.975 ± 0.313	0.9799 ± 0.311	0.982 ± 0.310	.000
HbA1c %	9.681 ± 2.052	9.679 ± 2.058	9.68 ± 2.065	.460
HDL-C (mg/dL)	34.62 ± 3.464	34.61 ± 3.476	34.64 ± 3.497	.788
LDL-C (mg/dL)	75.90 ± 18.46	76.11 ± 18.33	75.81 ± 18.64	.072

HDL-C: High-density lipoprotein, LDL-C: Low-density lipoprotein, BMI: Body mass index, CAD: coronary artery disease, ABI: ankle-brachial index, TBI: toe-brachial index, HbA1c: glycated hemoglobin.
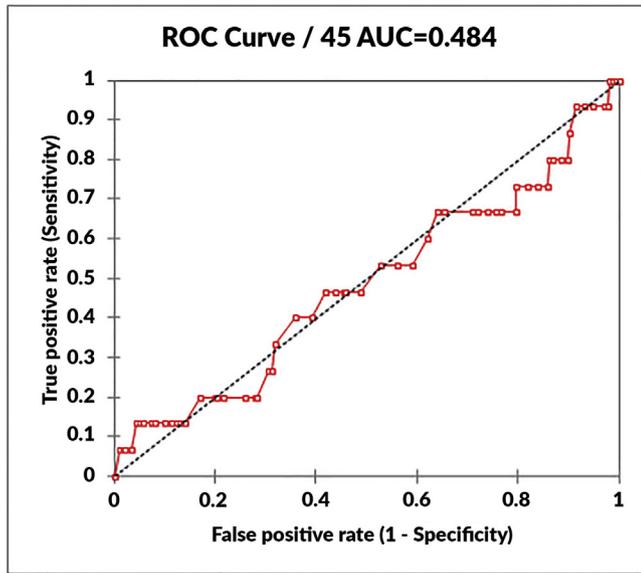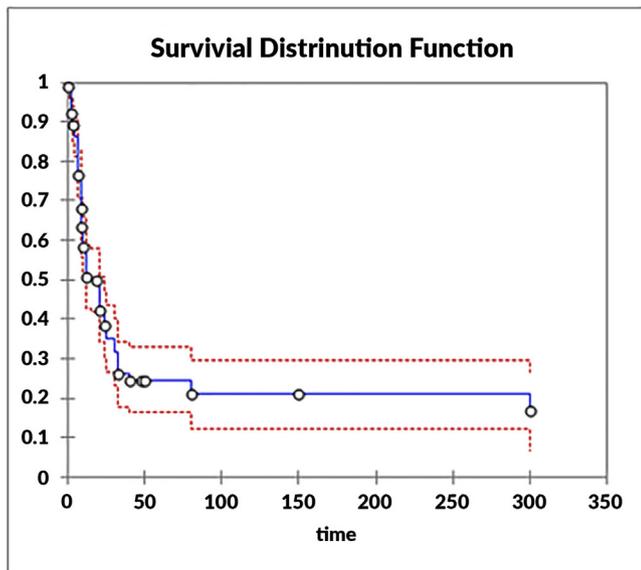

Fig. 1. ROC curve for TcPO2.

Fig. 2. Kaplan-meier probability curve.

Subsequently, the level of TcPO2 increased to 75% at the end of three weeks. The study concluded that within 3−4 weeks after successful revascularization, cutaneous oxygenation levels were improved considerably. Alternatively, transcutaneous carbon

Table 3
Correlation of TcPO2.

Data	TcPO2	
	r	p
Ulcer Size (cm^2)	–.173	.016
ABI	.146	.044
TBI	.486	.000
HSP-70 (pg/ml)	.020	.784
HSP-47 (ng/ml)	–.009	.897
Adiponectin (ng/ml)	.187	.009
Cathepsin D (RFU/ml)	–.084	.246
25(OH)-D (ng/ml)	.060	.409
HbA1c %	.155	.033
Smoking habit	.046	.523
HDL-C (mg/dL)	.035	.634
LDL-C (mg/dL)	.057	.435
Total Cholesterol (mg/dL)	.015	.832
WBC(x10^9/L)	–.019	.789
S. Creatinine (mg/dL)	–.162	.025
Total Serum proteins (gm%)	.050	.491
Serum Albumin (SA) (gm%)	–.026	.723
Serum Globulin (SG) (gm%)	.017	.813

HDL-C: High-density lipoprotein, LDL-C: Low-density lipoprotein, BMI: Body mass index, CAD: coronary artery disease, ABI: ankle-brachial index, TBI: toe-brachial index, HbA1c: glycated haemoglobin, HSP70: Heat shock protein 70, HSP47: Heat shock protein47, WBC: White blood cells.

dioxide tension monitoring was suggested to find the negative consequence of revascularization [10].

When ischemia, infection, and neuropathy coexist with a diabetic foot ulcer, hyperbaric oxygen therapy is suggested by clinicians before going in for invasive amputations. Subsequently, controlled trials have also proven to show positive outcomes of hyperbaric oxygen therapy. Prior to hyperbaric oxygen therapy, transcutaneous oxygen measurements are taken to ascertain the need for hyperbaric oxygen therapy. Diabetic patients with transcutaneous oxygen levels of over 50 mmHg in normobaric pure oxygen or with peri-wound transcutaneous oxygen tensions that are over 400 mmHg in 2.5 hyperbaric oxygen are recommended to go for hyperbaric oxygen therapy in addition to undergoing conventional therapy [11].

Another study conducted by Ruangsetakit et al. [12] examined transcutaneous oxygen tension levels of patients, who were suffering from critical limb ischemia and had recently undergone amputation of their gangerous toes. Fifty patients participated in the study. The average age of the patients was 67 years. Their baseline ulcers and ankle brachial pressure index were measured, and their demographic data was gathered. Patients with chronic ischemic ulcers endured amputation of their gangerous toes. Their transcutaneous oxygen tension levels were measured with a thirty-degree elevation of the leg in a supine position. The consequence of surgery exhibited two categories of ulcer prognosis, namely; healing and non-healing ulcers. The healing ulcers showed granulation at the base and the edges resulting in good prognosis.
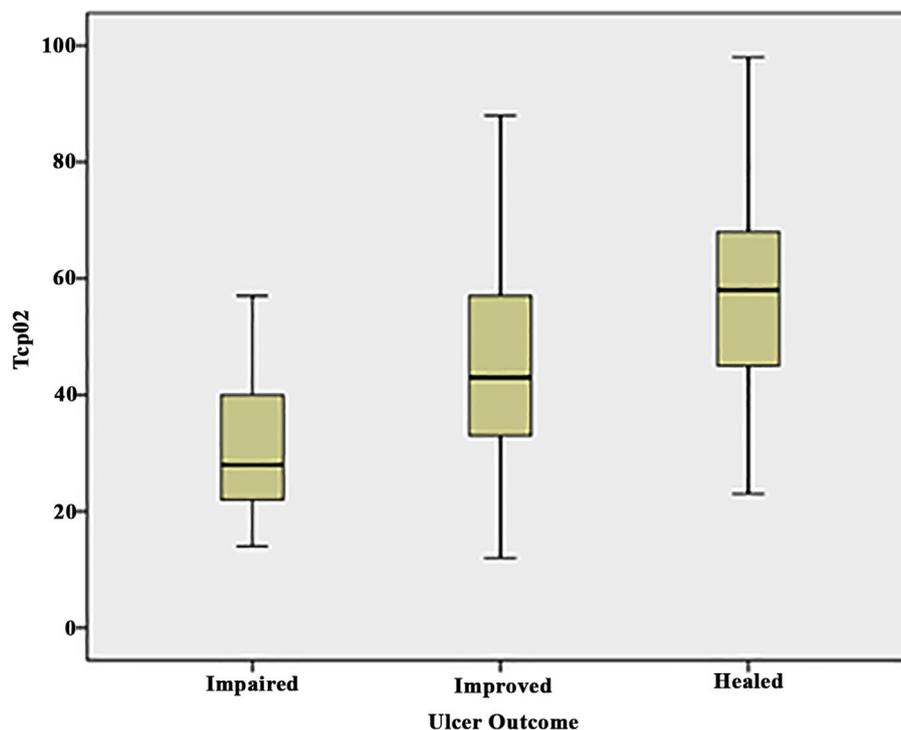
Fig. 3. Box plot of TcPO2 in diabetic ulcer patients showing median values and 10th, 25th, 75th, and 90th percentiles.

Conversely, poor granulation and less tissue formation was observed in non-healing ulcers resulting in worsening of the ischemic ulcers. It was concluded that, TcPO2 assisted in the prognosis of healing of amputated gangerous toes and ischemic ulcer healing [13].

5. Conclusion

The study aimed to examine the outcomes and correlation between TcPO2 and ulcers among diabetic foot patients. The study has solely focused on ulcer outcomes among diabetic patients with several prevalence factors. Among these factors, it has been identified that diabetic patients positively improve their ulcer outcomes that are healed with intact skin. Similarly, fewer patients were diagnosed in the major amputation rate as compared to minor amputation rate. There is a positive association between TcPO2 baseline and degree of ulcer healing with intact skin. Lastly, the study has reported significant correlation between ulcer size, TBI, Adiponectin, S. creatinine, and HbA1c with TcPO2 groups at 5% level of significance. However, other prevalent factors were insignificantly reported with TcPO2 groups among diabetic patients. The findings have introduced a platform for future studies to examine these insignificant factors among diabetic patients to control the extent of ulcer outcome. Moreover, future researches should examine the status of mortality among patients and compare it with the amputation rates. It particularly gives a predicted estimation of patients undergone different diagnosis techniques.

Declarations

Ethical approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Competing interest

The author declares no competing interest.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.dsx.2018.12.008.

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