

Reliability of the university of Texas classification in predicting the outcomes of diabetic foot in a tertiary Center in Kerala: A prospective observational study



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ABSTRACT

Background: Diabetic foot ulcer (DFU) is one of the most serious complications of diabetes and frequently necessitates amputation, which lowers quality of life with the distressing prospect of re-amputation and increased mortality. The available classifications for a standardized approach to diabetic foot ulceration, though crucial in predicting clinical outcomes, have their limitations. **Aims and Objectives:** This study examined the reliability of the University of Texas (UT) classification system in predicting outcomes of diabetic foot in a tertiary center in Kerala, South India. **Materials and Methods:** In this prospective observational study, 98 DFU patients at Jubilee Mission Medical College and Research Institute, Thrissur, from December 2019 to June 2022 were categorized according to UT classification, and the treatment with outcomes for 6 months was recorded. **Results:** Among the total population, 24.4% of diabetic feet achieved healing without amputation. We observed an increasing incidence of impairment of healing ($P=0.018$) and in the number of amputations in Grades 1, 2, and 3 ($P=0.000$). At 6 months, 52% of diabetic feet, including those who underwent amputation, healed completely. **Conclusion:** DFU in a lower grade but higher stage according to the UT classification showed impaired healing and higher amputation rates as this system includes infection and ischemia. This classification allows reliable categorization and enables re-allocation of grade and stage of diabetic foot during treatment and follow-up, thereby facilitating effective management and predicting outcome.

Key words: Diabetic foot ulcer; University of Texas classification system; Diabetic foot; Foot amputations; Diabetic foot wound

INTRODUCTION

Diabetic foot ulcers (DFU) are one of the most devastating complications of diabetes and the most frequent cause of diabetes-associated hospitalization. It is a full-thickness wound, skin necrosis, or gangrene below the ankle in diabetic patients and is multifactorial in etiology. Studies have shown that diabetics have up to a 25% lifetime risk of developing a foot ulcer.¹ A total of 15–19% of people with diabetes mellitus (DM) are affected by DFU,² which requires long-term multidisciplinary management including medications, daily dressings, offloading, and

surgical interventions. Diabetic ulceration has been shown to precede amputation in up to 85% of cases.³ Despite optimum management, DFU often results in amputation, with a reduction in quality of life, increased mortality, and a propensity for re-amputation. Around 45–85% of amputations in diabetics are preventable with a team approach to wound care.⁴

Classification of DFU based on its characteristics is crucial in planning treatment, monitoring treatment effectiveness, and predicting outcomes. A number of classifications have been proposed for a standardized approach to managing

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DFU and predicting the clinical outcome of these patients. However, each of these classifications has its limitations.

Shea, in 1975, proposed a systematic classification system that included the depth of the ulcer without considering ischemia or infection.⁵ A classification system developed by Meggitt in 1976, after modification in 1981, became known as Wagner’s classification.^{6,7} However, in this system, the ischemic status of the wound is not included.⁸ The Wagner and University of Texas (UT) systems are the most widely used ulcer classification systems.⁹ The UT classification proposed by Lavery et al. includes staging and grading of DFUs in its classification system.¹⁰ The inclusion of stage in the UT system,¹¹ which utilizes wound depth, the presence of infection, and/or peripheral arterial occlusive disease in every category of the wound assessment,⁹ made ulcer depiction more specific, treatment strategies more efficient, and communication more effective. The UT system has been validated and is considered superior to the Meggitt–Wagner system at predicting outcomes, given that wounds with a greater grade and stage are less likely to heal without revascularization or amputation.⁸⁻¹²

There is a paucity of studies from Kerala, India, to evaluate the reliability of the UT wound classification for assessment of DFU, provide appropriate wound care, minimize further complications, including amputations, and predict outcome.

Aims and objectives

The present study was done to assess the reliability of the UT classification in predicting outcomes, including primary healing without amputation and the need for amputation of the diabetic foot in Kerala, South India.

MATERIALS AND METHODS

Study design

This was a prospective observational study with approval from the Institutional Ethics Committee, conducted by consecutive sampling of consenting diabetic foot patients in the General Surgery department of Jubilee Mission Medical College and Research Institute, Thrissur, Kerala, India, from December 2019 to June 2021.

The minimum sample size was determined to be 100 with a 95% confidence level and a 15% relative allowed

error, based on the percentage of diabetic feet that heal completely as reported in the article by Oyibo et al.¹¹

Inclusion criteria

Type 2 DM Patients diagnosed with diabetic foot were included in the study. Patients who provided consent for inclusion in the study were recruited.

Exclusion criteria

Exclusion criteria were as follow: foot ulcers due to causes other than Type 2 diabetes, like neurological and vascular conditions of other etiology, were excluded.

The data for the purpose of this study included socioeconomic parameters, clinical examination findings, the presence of microbiological infection, evidence of osteomyelitis and/or radiological features of bone involvement, features of vascular insufficiency, and features of sensory neuropathy in the Semmes-Weinstein monofilament wire and vibration perception threshold test. Transcutaneous oxygen measurements of <40 mmHg, or an ABPI of <0.9, and duplex ultrasound arterial system findings were also recorded. Clinical data collected prospectively in all patients presenting with foot ulcers was used to classify their ulcers using the UT classification system into different grades and stages.

UT diabetic foot wound classification system

Treatment modalities such as major or minor amputations, minor procedures like incision and drainage, slough excision, fasciotomy, negative pressure dressings, regular dressings, major revascularization procedures, and medical management were recorded.

Outcome measurement

The study subject was followed up for 6 months after discharge. The primary outcome criteria used were the healing of ulcers without amputation and the need for major or minor amputations. The secondary outcomes included the need for minor procedures, major vascular procedures, and non-surgical measures. The outcome criteria used were cross-tabulated with different baseline variables.

Statistical analysis

Data was entered in MS Office Excel and analyzed using IBM SPSS version 25. Numerical variables were expressed

Stage	Grade 0	Grade 1	Grade 2	Grade 3
A	Pre - or Post – ulcerative lesion completely epithelialized	Superficial ulcer not involving tendon, capsule or bone	Ulcer penetrating to tendon or capsule	Ulcer penetrating to bone or joint
B	With Infection	With infection	With infection	with infection
C	With Ischemia	With ischemia	With ischemia	with ischemia
D	With infection and ischemia	With infection and ischemia	With infection and ischemia	with infection and ischemia

as the mean and standard deviation. Categorical variables were expressed as frequencies and percentages. A chi-square test was applied to obtain the association between healing and amputation with study variables. The $P < 0.05$ is considered statistically significant.

RESULTS

A total of 100 consecutive consenting patients who met the inclusion criteria at the Jubilee Mission Medical College and Research Institute, Thrissur, from December 2019 to June 2021 were analyzed. Two patients died during this period, one due to COVID-19 pneumonia and the other due to acute left ventricular failure, and the study continued with 98 patients. Among the total population, 64 (64%) patients were in the age group of 45–65, 26 (26%) in the age group of > 65 , and 10 (10%) patients in the age group of < 45 . The mean age in our study was 59.69 ± 11.59 , and 64 (64%) of the patients were males.

UT grade and stage

Among the total population, 39 (39%) had pre- or post-ulcerative epithelialized lesions or gangrene and were categorised as Grade 0 of the UT classification, while 35 (35%) of the patients with superficial ulcers were classified as UT Grade 1 DFU. The majority of patients in Grade 0 (36 of 39) and Grade 3 (8 of 10) belonged to stage D (Figure 1).

Ischemia, infection and neuropathy

Clinical evaluation revealed that 56 (56%) patients had features of peripheral ischemia, 98 (98%) were found to have signs of infection, and 42 (42% of the patients) had features of neuropathy.

Healing of DFU

Age was not found to be an independent factor in association with ulcer healing or the requirement for

amputation ($P=0.149$ and $P=0.864$, respectively). None of the patients below 45 years showed complete ulcer healing, but this was not statistically significant due to the fewer cases in this age group. Gender was also not found to be an independent factor for association with healing of the DFU and the need for amputation ($P=0.170$ and $P=0.506$, respectively).

Ischemia

Out of the 36 Grade 0 patients, 29 patients and 6 out of 8 Grade 3 patients with ischemia underwent amputation, while none of the patients in Grades 1 and 4 with ischemia underwent amputation. In our study group, 15 of the 43 patients who did not have ischemia showed healing, while only 9 of the 55 patients who were found to have ischemia had ulcer healing without amputation.

Ischemia, as evidenced by clinical examination, USG Doppler arterial system evaluation, and transcutaneous oxygen measurement, was found to impair ulcer healing, and this was statistically significant ($P=0.034$).

Grade and healing

In our patients, 7.7% of Grade 0, 37.1% of Grade 1, 35.7% of Grade 2, and 30% Grade 3 of diabetic feet healed completely. The association of a lower grade of ulcer with healing was found to be statistically significant ($P=0.018$).

Stage and healing

During the study period, 38.6% of Stage B patients as compared to 7% of Stage D patients healed completely, showing that the association of lower stage with healing was of statistical significance ($P=0.003$) (Table 1).

Amputation for DFU

Overall, 42 (42% of the patients) underwent amputation. Across all grades, ray amputations were performed in 32 patients; one patient had a mid-tarsal amputation, five had a below-knee amputation, and four had an above-knee amputation.

Grade-wise ischemia and amputation

Of the ischemic feet, 80.6% belonged to Grade 0 and 75% to Grade 3 underwent amputation. Though it was observed that the highest proportion of amputations for ischemic feet was in Grades 0 and 3, we also observed that an increasing stage across all grades was associated with a higher incidence of amputations and contributed to impair healing as well. The association of ischemia with amputations was statistically significant ($P=0.000$).

Grade and amputation

76.9% of Grade 0 and 60% of Grade 3 patients underwent amputation, while only 11.4% of Grade 1 and 12.5%

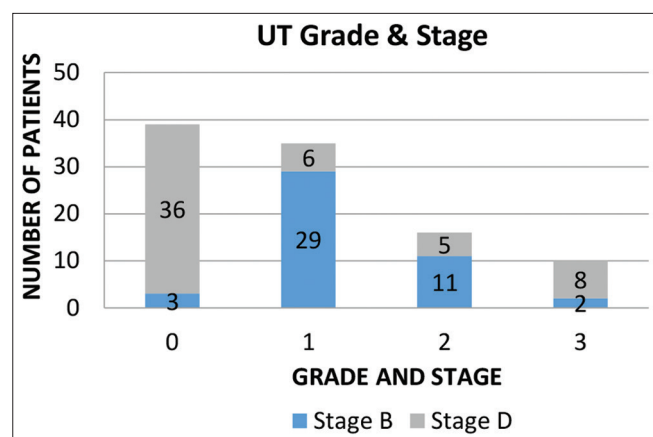


Figure 1: UT classification of the presenting lesions

Table 1: Association of study variables with Healing at 6 months

Variables	Healed				χ^2 -value	P-value
	Yes		No			
	N	%	N	%		
Age						
<45	0	0.0	10	100.0	3.814	0.149
45–65	18	28.6	45	71.4		
>65	6	24.0	19	76.0		
Sex					1.883	0.170
Male	18	29.0	44	71.0		
Female	6	16.7	30	83.3		
Ischemia					4.476	0.034
Present	9	16.4	46	83.6		
Absent	15	34.9	28	65.1		
Infection					0.662	0.416
Present	24	25.0	72	75.0		
Absent	0	0.0	2	100.0		
Neuropathy					0.372	0.542
Present	9	21.4	33	78.6		
Absent	15	26.8	41	73.2		
Grade					10.099	0.018
0	3	7.7	36	92.3		
1	13	37.1	22	62.9		
2	5	35.7	9	64.3		
3	3	30.0	7	70.0		
Stage					8.642	0.003
B	17	38.6	27	61.4		
D	7	13.0	47	87.0		

of Grade 2 required amputation. The association of a lower grade of the ulcer with determining the need for amputation was found to be statistically significant ($P<0.001$).

Stage and amputation

In addition, only 15.7% of the Stage B patients, as compared to 64.8% of patients in Stage D, underwent amputation. This association of the stage of disease with amputation was of statistical significance ($P<0.001$) (Table 2).

Infection

Of the 98 patients with diabetic feet, 96 had evidence of clinical and/or confirmed microbiological infection, of which 24 healed completely, and 41 patients underwent amputation. However, the presence of infection was not statistically significant in determining whether the foot underwent healing ($P=0.416$) or required amputation ($P=0.837$).

Neuropathy

Of the 42 patients with neuropathy, 19 required amputations, and nine healed completely. Of the 56 patients with no neuropathy, 23 underwent amputation, while 15 achieved healing. Neuropathy, diagnosed both clinically and with the monofilament test, was not found to have a statistically significant association with the need for amputation ($P=0.680$) or impaired healing ($P=0.542$).

Table 2: Association of study variables with Amputation at 6 months

Variables	Amputation				χ^2 -value	P-value
	Yes		No			
	n	%	n	%		
Age						
<45	5	50.0	5	50.0	0.292	0.864
45–65	27	42.9	36	57.1		
>65	10	40.0	15	60.0		
Sex					0.443	0.506
Male	25	40.3	37	59.7		
Female	17	47.2	19	52.8		
Ischemia					18.402	<0.001
Present	34	61.8	21	38.2		
Absent	8	18.6	35	81.4		
Infection					0.043	0.837
Present	41	42.7	55	57.3		
Absent	1	50.0	1	50.0		
Neuropathy					0.17	0.680
Present	19	45.2	23	54.8		
Absent	23	41.1	33	58.9		
Monofilament					1.478	0.224
Present	18	36.0	32	64.0		
Absent	24	48.0	26	52.0		
VPT					4.105	0.043
Normal to mild	16	32.0	34	68.0		
Moderate to severe	26	52.0	24	48.0		
Grade					38.464	<0.001
0	30	76.9	9	23.1		
1	4	11.4	31	88.6		
2	2	14.3	12	85.7		
3	6	60.0	4	40.0		
Stage					23.679	<0.001
B	7	15.7	37	84.1		
D	35	64.8	19	35.2		

VPT: Vibration perception test

However, the vibration perception threshold estimation identified a rising trend in amputation with increasing severity of neuropathy ($P=0.042$).

Treatment and outcome

Initially, minor procedures and wound debridement were done for 42 (42% of the patients), while 38 (38% of the patients) required amputations. Routine wound care and dressing were sufficient in 14 (14%) patients, while 6 (6%) patients underwent NPWT during the initial admission. 24.4% of diabetic feet achieved healing without amputation. Of the remaining patients, 4 (4%) patients underwent amputations, 5 (5%) had skin grafting, 3 (3%) had vascular procedures, and 7 (7%) patients underwent wound debridement during the next 6 months.

6 months of follow-up

There were 42 amputations overall, and 29 of them achieved complete healing at 6 months. A total of 52 (52%) patients, including those who underwent amputation, achieved healing.

DISCUSSION

Of the 62 million diabetics currently in India, 25% will develop DFUs, 50% will become infected and require hospitalization, and up to 20% will require amputation. 50% of DFU patients will undergo another amputation within 2 years of the index procedure.¹³ In UT classification system,¹⁰ Stages B, C, and D enhance the characterization of the grade by including infection, ischemia, and both, respectively. Gangrene of the foot falls in Grade 0, but categorised as Stages C or D. Gangrene of the foot will require amputation, which is considered the end point of diabetic foot disease. The UT classification helps us appreciate that the diabetic foot, even in a lower grade can have a grave prognosis on par with a higher grade, as gangrene is assigned to Grade 0.

In this study, of the 100 patients with DFUs classified according to the UT classification system, the highest number of amputations was observed in Grade 0, Stage D (80.6%), which was followed by Grade 3, and Stage D (75.0%). It is important to note that the largest number of patients across all grades belonged to Stage D (64.8%) as it included gangrene of a part of the foot, and in addition, the highest number of patients fell under Grade 0, Stage D. Similar to the reports of Armstrong *et al.*, it was found in our study that patients in Stage D had more amputations.

We observed an increasing trend in amputations for Grades 1, 2, and 3 (11.4% vs. 14.3% vs. 60.0%) after excluding Grade 0. This was also in accordance with the findings reported by Armstrong *et al.*¹⁴ It has been noted that there was a significant overall trend toward an increased prevalence of amputations as wounds increased in both depth and stage. Reports indicate that patients with infection and ischemia are nearly 90 times more likely to receive a mid-foot or higher amputation as compared to patients in less advanced wound stages. Major amputation has been described as 'a marker not just of disease but also of disease management.'¹⁵ Hence, the ability of the UT classification system to predict the possibility of a diabetic foot culminating in amputation is noteworthy.

At 6 months, 52% of the patients had complete wound healing. However, we noted that UT Grade 0 had the least number of healed diabetic feet, followed by Grade 3, which we attribute to both of these groups having the largest number of patients in Stage D.

The ability of the UT classification system to predict diabetic foot healing relies foremost on the inclusion of stage. Oyibo *et al.* pointed out that increasing stage, regardless of grade, is associated with an increased risk of amputation and prolonged ulcer healing time.¹¹ The

UT system has been validated to be generally predictive of outcome given that wounds with a greater grade and stage are less likely to heal without revascularization or amputation.¹² Our study results were in agreement with their conclusions that the UT system is a better predictor of outcome.

Ischemia is considered to be a significant factor affecting wound healing. Our results showed that the presence of ischemia was found to increase the probability of amputation ($P=0.000$), and in the follow-up, it was observed that limbs with ischemia healed poorly or remained unhealed ($P=0.034$), both of these associations being statistically significant. Armstrong *et al.*, in their observations, state that ischemia is the only single disease process that can, by itself, necessitate an amputation. They noted a higher prevalence of amputations in ischemic limbs, and that prevalence of amputation increases considerably in the presence of both ischemia and infection, which was also confirmed by Pecoraro *et al.*¹⁶

In our study, we observed that a diabetic foot with features of infection in combination with ischemia adversely affected healing ($P=0.000$). However, infection alone was not found to be significantly associated with amputation ($P=0.837$), which was in contrast to the report by Armstrong *et al.*¹⁴

A study by Treece *et al.*,¹⁷ found that it was mainly ulcer depth, area, and the presence of arteriopathy (peripheral arterial disease) that significantly contributed as independent variables to outcomes such as healing, non-healing, and amputation. We found that the results of our study were in agreement with their findings. Our observations may be explained by the fact that all infected wounds underwent meticulous wound debridement, regular wound care, and culture-appropriate antibiotics. Thus, intense multipronged management would nearly equate the healing prospects to those of a non-infected wound.

Our patients with severe neuropathy, as confirmed by the vibration perception test (VPT), showed an increased need for amputations, which was statistically significant ($P=0.042$). As reported in earlier studies, VPT might be better than the monofilament test in assessing neuropathy.¹⁸ The weak but significant association noted between neuropathy and outcome has also been observed in a study undertaken by Abbas *et al.* in Tanzania.¹⁹ This highlights the differences that may be found in different populations and also the confounding effect of co-existing arterial disease.

Limitations of the study

A limitation of this study was the small sample size, which may preclude optimal attributable representation and

short-term follow-up. Prospective studies involving larger populations are needed to confirm its applicability as a tool for precise decision-making and prediction. Some of the investigations used in this study are not objective and are therefore unable to provide infallible results. A holistic approach by healthcare professionals of the treatment of complicated diabetic patients is essential in order to identify the high-risk patient. Our predictive model is based on outcomes that can be obtained in developing countries with access to easily available resources. Our results, therefore, are most relevant for DFU patients in developing countries. In future routine toe pressure indices, it may be imperative to understand the benefits of hyperbaric oxygen therapy in the management of diabetic foot with ischemia and its outcomes. This has not been explored in this study and needs consideration.

CONCLUSION

Our study showed that 24.4% of patients with diabetic feet achieved healing without amputation and that infection, together with ischemia, adversely affected healing and increased the need for amputations. We observed that the UT classification system is a simple and reliable wound-based clinical classification tool that includes the presence of infection and ischemia and has potential value in predicting the outcome of diabetic foot wounds, thereby reducing morbidity. This classification is essential for the categorization of diabetic feet and their management. This will have implications for the comparison of the effectiveness of diabetic foot management in different centers and may then be used as the basis for prospective research into optimal wound care in these cases.

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Authors' Contributions:

RRJ- Definition of intellectual content, Literature survey, Prepared first draft of manuscript, implementation of study protocol, data collection, data analysis and manuscript preparation; **ANO**- Concept, design, clinical protocol, manuscript preparation, editing, manuscript revision and submission of article; **AA**- Design of study, statistical analysis and interpretation and review of manuscript; **JT**- Literature survey and preparation of tables and figures, coordination and manuscript revision.

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