Factors associated with severity and anatomical distribution of Diabetic Foot Ulcer in Uganda: A multicenter cross-sectional study

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Abstract

Background: Diabetic foot ulcer (DFU) is a devastating complication of diabetes mellitus (DM) associated with high mortality and morbidity including amputations of lower extremities; and a high economic burden especially in low-income countries like Uganda. The aim of this study was to identify the factors associated with severity of DFU and assess the anatomical distribution of DFU among patients in Uganda.

Methodology: This was a multicenter cross-sectional study conducted in 7 selected referral hospitals in Uganda. 117 patients with DM type 1 and 2 and foot ulcers were enrolled for this study from January to March 2021. Using the Wagner classification, patients were categorized as less severe DFU (grade 1 and grade 2) and severe DFU for grade 3 and above. A pre tested questionnaire was used to collect data. Data were analyzed using STATA Version 14 with significance at 95% and p-value of <0.05.

Results: Out of 117 patients with DFU, 70 (59.8%) had severe DFU and 47 (40.2%) had less severe DFU. Mean age in years was 57.5 (SD15.2) among all study participants in general. The right foot was affected in (47.9%) of cases and the most frequent ulcer was found on the plantar of the foot (44.4%). Majority of the patients had one ulcer (50.4%) and the most frequent ulcer size was >5 cm (47.9%). Majority (61.5%) of the participants were female. Majority of participants, 90 (76.9%) also had uncontrolled blood sugars and 27(29.1%) had normal glycemia

Severity of DFU was 3.4 more prevalent among patients with mild neuropathies (p=0.003), and 2.7 more prevalent for those with moderate neuropathies (p=0.005). Also, severity of DFU was 1.5 more prevalent in patients with an ulcer 5-10 cm of diameter (p=0.047) and 2.5 more prevalent in those with foot ulcer of more than 10 cm of diameter (p=.000).

Conclusion: The study showed that most of the DFU patients have severe diabetic foot ulcer and uncontrolled glycemia. Neuropathies and ulcers more than 5cm wide are precipitating factors to severity of DFU and, therefore, early management is important to reduce the burden of the disease.

Background

Diabetic Foot Ulcer (DFU) is an advanced consequence of diabetes mellitus (DM). There is a 15% lifetime chance of developing ulcer among diabetic patients, and when it occurs, it is associated with high mortality [1]. The 5 years survival rate varies between 25% and 45% among patients with DFU worldwide [2-4]. Globally, DFU has become one of the leading causes of lower limb amputation with over 1 million patients amputated annually, an average of a limb amputation every 20 seconds somewhere in the world [5]. (Hingorani, 2016). Following amputation due to DFU, 85% of patients will still develop chronic infection and other forms of gangrene which lead to poor quality of life and financial stress [6-7]. One third of the management costs for diabetes is estimated to be linked to foot ulcers as compared to patients without DFU, and the cost of care is estimated to be 5.4 and 2.6 times higher in the year of first episode and second episode respectively [8]. Costs for treatment of patients with highest grade ulcers are

eight times higher compared to those with lowest grade DFU [7]. (IDF, 2017). In addition to high management costs, the severity of DFU ultimately leads to high mortality and poor quality of life [9]; however, factors precipitating the progression of DFU to severe form are not yet fully assessed in Uganda.

The prevalence of diabetic foot has been reported to be higher among people with type 2 diabetes, compared to people with type 1 diabetes worldwide [10].

Globally the prevalence of DFU averages at 6.4% with a higher predilection in men compared to women [8] (IDF, 2019). This prevalence varies between 3% in Oceania to 13% in North America, 7.2% across African continent, and in Uganda it varies from 1 to 4% [10]. In Ethiopia, a prevalence of 13.6% of DFU was reported among type II diabetes mellitus patients and it was associated with rural residence, poor foot self-care practice, overweight, obesity, and neuropathy [11].

Studies have shown that factors usually associated with occurrence of DFU include; older age, longer diabetic duration, hypertension, diabetic retinopathy and smoking history [12]. Peripheral neuropathy, peripheral vascular disease, and foot trauma were also reported risk factors in the pathophysiology of foot ulcer [13]. Other factors include patient educational status, body mass index (BMI) patient habits of foot self-care practice, and the presence of complicated peripheral neuropathy [14-16]; However, these factors may differ basing on the patient's socio-economic status, demographic characteristics and the evolution of DFU within the facility [11].

The management of DFU requires the participation of the patient [17]. Self-management of DM has significant impact on the outcome of controlling blood sugar levels and their complications like diabetic foot ulcer [17]. Several researches have shown that DFU management outcome is related to patient awareness and self-foot care behavior [18-20]. The DFU has been largely studied in developed countries showing that Wagner grades 3 and 4 are the most common and the metatarsal region is the most affected [21-22]. To date, the literature about the anatomical distribution and its relation to the severity of DFU is still lacking in developing countries like Uganda

Although DFU and associated factors have been largely studied in developed countries, there is paucity of data about DFU in LMICs like Uganda including factors associated with severity of the diabetic foot ulcer. An evidence-based understanding of the factors associated with severity of DFU is necessary in developing countries in order to establish effective control measures to reduce its burden. The purpose of this study, therefore, was to determine factors associated with severity of DFU and its anatomical distribution among patients with DM in Uganda.

Methods

Study design and setting

This multicenter cross-sectional study was conducted in seven [7] hospitals in Uganda (Kampala International Teaching Hospital, Kitagata General Hospital, Mbarara Regional referral Hospital, Fortportal

Regional referral Hospital, Hoima Regional referral Hospital, Jinja Regional referral Hospital and Kirudu specialized Hospital), whose location is shown in Figure 1.

Study participants and recruitment

All patients aged 18 years and above with DM type 1and type 2 and having a wound which is located below the ankle of the foot attending the surgical Department and DM clinics of selected hospitals in Uganda were recruited by purposive consecutive sampling method from September 2021 to January 2022. The patients provided written informed consent to participate in the study.

The DFU patients with difficulty in communicating, such as those with severe cognitive impairment or who could not consent were excluded from the study.

The required sample size for study patients with DFU was calculated using Kish Leslie (1965) formula stated as:

$$n = \frac{z^2 \rho(1-\rho)}{r^2}$$

The prevalence of DFU in a cross-sectional study done in Egypt of 8.7% among adult patients aged 18 year and above attending Alexandria University teaching Hospital Diabetic clinic was used to determine the sample size [23] resulting in a calculated sample size of 122 participants.

Study procedure

Data was collected using a questionnaire developed after reviewing literature and based on available data and piloted. This questionnaire was translated into the local languages (Luganda/Lusoga, Runyakore/Rukiga and Runyoro/Rutoro) by languages expert. A medical doctor, a nurse and one surgery resident were recruited as research assistants in every selected hospital and the data collection was supervised by the principal investigator. The key variables included about the general characteristics of the patients such as type of DM, duration of DM, history of trauma, duration of the diabetic foot ulcer, type of therapy; sociodemographic variables such as age, sex, occupation, monthly income, tribe and residency; and Behaviour factors such as history of smoking, alcohol intake, type of diet, frequency of consulting the diabetic clinic, foot care and life style.

Blood samples were collected from the veins (radial and ulnar) in a gray vacutainer for testing the HbA1c in the laboratory of Kampala International University Teaching Hospital (KIU-TH).

Body Mass Index (BMI) which is a ratio of the patients' weight in kilogram to the square value of the height in meters was determined using a calibrated weighing scale and wall mounted station meter manufactured by Southern Early Child Association (SECA®). Weight estimation by a subtraction method using a wheel chair was used in determining the patient weight as well as a tape measure for height

determination for those who could not stand. Normal BMI was defined as less than 24.9, overweight from 25 to 29.9, obesity from 30 and above [24]. Blood pressure was taken by using a manual Sphygmomanometer with appropriate cuff sizes for the patient arms. High blood pressure was defined as systolic blood pressure ≥ l40 mmHg or diastolic pressure ≥ 90 mmHg (European Society of Cardiology/European Society of Hypertension, 2018).

The patients were subjected to a physical and neurological examination. Pressure sensation was assessed using 10g monofilament (Semmes westein test) at 4 of the 10 standard sites of the sole of the feet (plantar base of the big toe, 2nd and 5th toes and at the heel), avoiding areas with callosity. Vibration sense was elicited using a 128 Hz tuning fork at the hallux of the big toe [25-26]. Patients' feet were also examined in this study to determine the characteristics of the foot ulcer: number of ulcers, size of ulcers, and location. The ulcer was classified using the Wagner classification [22] (Table 1).

Fasting blood sugar (FBS) and HbA1c were determined using four (4) milliliters (ml) of blood withdrawn from the anterior cubital fossa of each subject using a sterile disposable syringe and needle after cleaning the site with a swab soaked in 70% alcohol. The blood sample was collected in both Ethylene diamine triacetic acid (EDTA) grey top vacutainer for blood sugar tests and glycosylated hemoglobin (HbA1c) [21,27].

HbA1c was screened by using a Ichroma II Machine (2017) and results were interpreted as follows: <6.5% HbA1c were considered as controlled DM and those with HbA1c of 6.5% and above were uncontrolled DM [28]. Each study participant received a printed copy of their results.

Table 1: Wagner classification of diabetic foot ulcer

Grade	Lesion
0	No open wounds but cellulitis or deformity may be present
1	Superficial wound and wound may be partial or full thickness
2	Ulcer extends to involve structures such as; ligaments, tendons, joint capsule, or deep fascia. No abscess or osteomyelitis present
3	Deep ulcer and demonstrates abscess, osteomyelitis or joint sepsis
4	Localized gangrene of part of the forefoot or heel; Involved areas include part of the forefoot or heel
5	Gangrene is extensive and involves the entire foot

The participants were classified into two 2 categories [28]:

Less severe DFU: participant with grade 1 and grade 2 foot ulcer using Wagner classification

Severe DFU: participant with grade 3 and above using the Wagner classification.

Data processing and analysis

The raw data was entered in MS Excel spreadsheet software, cleaned and later exported to stata version 15 (Stata Corp®) for summary statistics and analysis. All categorical variables were summarized and were presented in figures and tables with their frequencies, percentages, and for the continuous variables by means and standard errors. Bivariate and multivariable analysis was done using Poisson regression to assess the likelihood between severity of the DFU and study factors with significance determined at $p<0.05$. Variables which had a p-value <0.2 in bivariate analysis were considered for multivariable analysis.

Poisson regression was chosen to obtain Prevalence Risk Ratios (PRR) over logistic regression to avoid over estimation of the prevalence ratios, allow appropriate control of confounding variables and because the later poorly estimates the standard errors of the estimated risk ratios especially when dealing with Severe DFU which is a common outcome of interest among patients with DFU [29].

Ethical consideration

Ethical approval was granted by the Research Ethics Committee of Kampala International University (KIU), reference KIU-REC-2021-57 and permission was obtained from management of the selected hospitals before data collection.

Results

Among 122 targeted study sample, data from 117 patients with DFU (96%) were analysed after data cleaning. Five (4%) of the DFU patients had incomplete data and were, therefore, excluded from further analysis.

Among the 117 participants with DFU who formed the definitive sample size, majority (59.8%) had severe DFU and 40.2% less severe DFU. The majority of the participants (61.5%, n=117) were female. Mean age of study participants was 57.1 (49.5 for less severe; 67.5 for severe DFU). Majority of the participants (76.9%; n=117) had poor glycaemic control and 29.1% had normal glycemia.

Classification of DFU Using the Wagner classification among study participants

Most of studied patients (44%; n=117) had Grade 3 diabetic foot ulcer according to the Wagner classification (Figure 2).

The above graph is demonstrating that majority of the study participants 59.8% (n = 117) had severe DFU with 95% CI-(50.4-68.8) (Figure 3).

Socio demographic characteristics

Most of the participants were in the age-group between 50-59 years 39 (33.3%); and the majority were from rural areas 87 (74.4%). (Table 2). Age group of 70-95 years was associated with severe DFU

(p=0.02).

Table 2. Socio demographic characteristics of participants

Variables	Less severe DFU (G1 & G2	Severe DFU (G3, G4, & G5)	Total	p-value
Age group in years				
18-39	10 (21.3)	4 (5.7)	14 (12.0)	
40-49	7 (14.9)	8 (11.4)	15 (12.8)	
50-59	13 (27.7)	26 (37.1)	39 (33.3)	
60-69	12 (25.5)	13 (18.6)	25 (21.4)	
70-95	5 (10.6)	19 (27.1)	24 (20.5)	
				0.026
Sex				
Female	28 (38.9)	44 (61.1)	72 (61.5)	
Male	19 (40.4)	26 (37.1)	45 (38.5)	
				0.720
Residence				
Urban	13 (27.7)	17 (24.3)	30 (25.6)	
Rural	34 (72.3)	53 (75.7)	87 (74.4)	
				0.682
Region				
Western	33 (70.2)	51 (72.9)	84 (71.8)	
Central	6 (12.8)	12 (17.1)	18 (15.4)	
Eastern	7 (14.9)	5 (7.1)	12 (10.3)	
Non-Ugandan	1 (2.1)	2 (2.9)	3 (2.6)	
				0.555

Socioeconomic characteristics among study participants

The majority (59.8%; n=117) of study participants were peasant farmers and most of them had a monthly income that ranged from <10,000 – 500,000 Ugandan shillings (Table 3).

Table 3. Socioeconomic factors among study participants

Variables	Less severe (G1 & G2	Severe (G3, G4, & G5)	Total	p-value
Occupation, n (%)				
Peasant farmer	28 (59.6)	42 (60.0)	70 (59.8)	
Business/self employed	11 (23.4)	13 (18.6)	24 (20.5)	
Non-employed	7 (14.9)	9 (12.9)	16 (13.7)	
Formerly employed	1 (2.1)	6 (8.6)	7 (6.0)	
				0.502
Average monthly income				
< 10,000	15 (31.9)	21 (30.0)	36 (30.8)	
10,000-100,000	16 (34.0)	14 (20.0)	30 (25.6)	
100,001-500,000	14 (29.8)	22 (31.4)	36 (30.8)	
500,001-1M	1 (2.1)	9 (12.9)	10 (8.5)	
Above 1M	1 (2.1)	4 (5.7)	5 (4.3)	
				0.144

Medical characteristics among study participants

As shown in Table 4, the majority (94.9%) of participants had type 2 DM; were taking insulin as treatment 76 (65%), had been living with DM for more than 9 years 61 (55.0%); and had been with DFU for more than 6 months.

Table 4. Medical characteristics among participants

Variables	Less severe (G1 & G2	Severe (G3, G4, & G5)	Total	P-value
Type of DM				
Type 1	4 (8.5)	2 (2.9)	6 (5.1)	
Type 2	43 (91.5)	68 (97.1)	111 (94.9)	0.174
Duration of DM in years, mean (SD)	12.2 (11.0)	10.0 (8.8)	10.9 (9.7)	0.236
Duration of DM in years				
0-3	12 (25.5)	19 (27.1)	31 (26.5)	
4-8	10 (21.3)	11 (15.7)	21 (17.9)	
9 and above	25 (53.2)	40 (57.1)	65 (55.6)	0.744
Method of treatment				
Insulin				
No	17 (36.2)	24 (34.3)	41 (35.0)	
Yes	30 (63.8)	46 (65.7)	76 (65.0)	0.834
Herbal Medicine				
No	26 (55.3)	45 (64.3)	71 (60.7)	
Yes	21 (44.7)	25 (35.7)	46 (39.3)	0.330
Oral hypoglycemic agents (OHA)				
No	20 (42.6)	28 (40.0)	48 (41.0)	
Yes	27 (57.4)	42 (60.0)	69 (59.0)	0.783
Not on any treatment				
No	45 (95.7)	68 (97.1)	113 (96.6)	
Yes	2 (4.3)	2 (2.9)	4 (3.4)	0.683
Number of therapies received				
0	2 (4.3)	2 (2.9)	4 (3.4)	
1	20 (42.6)	39 (55.7)	59 (50.4)	
2	17 (36.2)	13 (18.6)	30 (25.6)	
3	8 (17.0)	16 (22.9)	24 (20.5)	0.173

Duration of DFU in months, mean (SE)	4.9 (10.1)	4.2 (7.3)	4.5 (8.5)	0.670
Duration of DFU in months				
Less than 1	17 (38.6)	19 (28.4)	36 (32.4)	
1-6	22 (50.0)	39 (58.2)	61 (55.0)	
Over 6	5 (11.4)	9 (13.4)	14 (12.6)	0.527
History Of Trauma on Affected Foot				
No	40 (85.1)	57 (81.4)	97 (82.9)	
Yes	7 (14.9)	13 (18.6)	20 (17.1)	0.604
History of previous DFU				
No	36 (76.6)	50 (71.4)	86 (73.5)	
Yes	11 (23.4)	20 (28.6)	31 (26.5)	0.535
History of Amputation due to DFU				
No	40 (85.1)	55 (78.6)	95 (81.2)	
Yes	7 (14.9)	15 (21.4)	22 (18.8)	0.375

Behavior characteristics among patients with DFU

Results showed that only 17.1% (n=117) attended twice monthly the diabetes clinic, 22 (18.8%, n=117) do regular physical exercise, and majority had good foot care (59.8%, n=117), history of smoking, not doing physical exercises and eating a mixture of foods are associated with severity of the DFU with a p-value of 0.04, 0.02 and 0.01, respectively (Table 5).

Table 5. Behavior characteristics among participants

Variables	Early (G1 & G2	Late (G3, G4, & G5)	Total	P-value
Taught About Complication DM				
No	20 (42.6)	37 (52.9)	57 (48.7)	
Yes	27 (57.4)	33 (47.1)	60 (51.3)	0.274
Counselled About Risk of DFU When You Have DM?				
No	14 (29.8)	26 (37.1)	40 (34.2)	
Yes	33 (70.2)	44 (62.9)	77 (65.8)	0.411
Counselled by friend,				
No	31 (66.0)	41 (58.6)	72 (61.5)	
Yes	16 (4.3)	29 (51.4)	45 (38.5)	0.707
Counselled by HW				
No	30 (63.8)	37 (52.9)	67 (57.3)	
Yes	17(6.4)	33 (47.1)	50 (42.7)	0.480
counselled by social media				
No	31 (66.0)	41 (58.6)	72 (61.5)	
Yes	16 (34.1)	29 (41.4)	45 (39.0)	0.707
How Often Do You Attend the DM Clinic?				
Never	13 (27.7)	25 (35.7)	38 (32.5)	
Once monthly	22 (46.8)	28 (40.0)	50 (42.7)	
Every 2 months	7 (14.9)	13 (18.6)	20 (17.1)	
Once yearly	5 (10.6)	4 (5.7)	9 (7.7)	0.577
Smoking status				

Non smoker	44 (93.6)	56 (80.0)	100 (85.5)	
Ever smoked	3 (6.4)	14 (20.0)	17 (14.5)	0.040
Alcohol consumer				
No	38 (80.9)	53 (75.7)	91 (77.8)	
Yes	9 (19.1)	17 (24.3)	26 (22.2)	0.512
Foot care score				
1	12 (25.5)	25 (35.7)	37 (31.6)	
2	5 (10.6)	5 (7.1)	10 (8.5)	
3	30 (63.8)	40 (57.1)	70 (59.8)	0.464
Type of shoes worn				
Open shoes	30 (63.8)	47 (67.1)	77 (65.8)	
Any type of shoes	12 (25.5)	17 (24.3)	29 (24.8)	
Don't wear shoes	5 (10.6)	6 (8.6)	11 (9.4)	0.908
How Often Do You Cut Your Nails Since Are Known With DM?				
Always	14 (29.8)	22 (31.4)	36 (30.8)	
Occasionally	32 (68.1)	45 (64.3)	77 (65.8)	
Don't	1 (2.1)	3 (4.3)	4 (3.4)	0.791
Who cuts your nails				
Self	30 (63.8)	46 (65.7)	76 (65.0)	
Other people	17 (36.1)	24 (34.3)	41 (35.0)	0.762
What do you use to cut your nails (multiple answers)				
Nail cutter				

No	33 (70.2)	43 (61.4)	76 (65.0)	
Yes	14 (29.8)	27 (38.6)	41 (35.0)	0.329
Razor blade				
No	14 (29.8)	30 (42.9)	44 (37.6)	
Yes	33 (70.2)	40 (57.1)	73 (62.4)	0.152
Knife				
No	46 (97.9)	68 (97.1)	114 (97.4)	
Yes	1 (2.1)	2 (2.9)	3 (2.6)	0.807
How often do you do exercises				
Always	8 (17.0)	14 (20.0)	22 (18.8)	
Occasionally	27 (57.4)	39 (55.7)	66 (56.4)	
Never	12 (25.5)	17 (24.3)	29 (24.8)	0.529
Work in the garden				
No	27 (57.4)	37 (52.9)	64 (54.7)	
Yes	20 (42.6)	33 (47.1)	53 (45.3)	0.921
Walk at least 30 minutes a day				
No	25 (53.2)	47 (67.1)	72 (61.5)	
Yes	22 (46.8)	23 (32.9)	45 (38.5)	0.625
House work				
No	38 (80.9)	56 (80.0)	94 (80.3)	
Yes	9 (19.1)	14 (20.0)	23 (19.7)	0.128
Jogging				
No	40 (85.1)	67 (95.7)	107	

			(91.5)	
Yes	7 (14.9)	3 (4.3)	10 (8.5)	0.910
Don't do any				
No	36 (76.6)	57 (81.4)	93 (79.5)	
Yes	11 (23.4)	13 (18.6)	24 (20.5)	0.044
Diet of the patient (multiples responses)				
Vegetables				
No	22 (46.8)	17 (24.3)	39 (33.3)	
Yes	25 (53.2)	53 (75.7)	78 (66.7)	0.526
Fruits, n (%)				
No	21 (44.7)	17 (24.3)	38 (32.5)	
Yes	26 (55.3)	53 (75.7)	79 (67.5)	0.011
Mixture of all				
No	34 (72.3)	58 (82.9)	92 (78.6)	
Yes	13 (27.7)	12 (17.1)	25 (21.4)	0.021
Lipids				
No	26 (55.3)	32 (45.7)	58 (49.6)	
Yes	21 (44.7)	38 (54.3)	59 (50.4)	0.174
Proteins				
No	22 (46.8)	22 (31.4)	44 (37.6)	
Yes	25 (53.2)	48 (68.6)	73 (62.4)	0.308
Carbohydrate				
No	20 (42.6)	23 (32.9)	43 (36.8)	

Yes	27 (57.4)	47 (67.1)	74 (63.2)	0.092

Comorbidities linked with DM Among patients with DFU

The study showed that most DFU patients (47.9%) had normal weight and hypertension (59.0%), moderate kidney failure (19.7%), moderate neuropathy (37.6%) and severe neuropathy (32.5%) being associated with severe DFU (p-value 0.01); while Hba1C levels above 6.5% were found in 76.9%, compensated heart disease 18.8% and decompensated heart disease 4.3% of the study patients. Furthermore, Claudication (24.8%) was the most common Peripheral Vascular Disease among DFU patients, followed by gangrene (6.0%) and the least being Deep Venus Thrombosis (DVT) (4.3%) (Table 6).

Table 6. Comorbidities among patients with DFU

Variables	Early (G1 & G2	Late (G3, G4, & G5)	Total	p-value
Neuropathy				
Absent	16 (34.0)	8 (11.4)	24 (20.5)	
Mild	3 (6.4)	8 (11.4)	11 (9.4)	
Moderate	18 (38.3)	26 (37.1)	44 (37.6)	
Severe	10 (21.3)	28 (40.0)	38 (32.5)	0.013
Peripheral Vascular Disease				
No disease	35 (74.5)	41 (58.6)	76 (65.0)	
Claudication	10 (21.3)	24 (27.1)	34 (29.1)	
Gangrene	0 (0.0)	7 (10.0)	7 (6.0)	
DVT	2 (4.3)	3 (4.3)	5 (4.3)	0.103
Hba1C, mean (sd)	8.3 (2.6)	8.8 (2.6)	8.6 (2.6)	0.158
Hba1C 6.5%,				
Less than 6.5%	14 (29.8)	13 (18.6)	27 (23.1)	
6.5 % and above	33 (70.2)	57 (81.4)	90 (76.9)	0.158
BP class,				
Normal	19 (40.4)	28 (40.0)	47 (40.2)	
Hypertension	28 (59.6)	41 (58.6)	69 (59.0)	
Hypotension	0 (0.0)	1 (1.4)	1 (0.9)	
BMI, mean (sd)	25.9 (6.7)	25.0 (5.2)	25.3 (5.9)	0.393
BMI group				
Underweight <18.5	3 (6.4)	5 (7.1)	8 (6.8)	
Normal 18.5 - 24.9	21 (44.7)	35 (50.0)	56 (47.9)	
Pre-obesity 25.0 - 29.9	16 (34.0)	22 (31.4)	38 (32.5)	
Obesity Class I 30.0 - 34.9	3 (6.4)	6 (8.6)	9 (7.7)	
Obesity Class II 35.0 - 39.9	2 (4.3)	0 (0.0)	2 (1.7)	
Obesity Class III 40 and above	2 (4.3)	2 (2.9)	4 (3.4)	0.614

Anatomical distribution of foot ulcer among study participants

Most of the study participants (47.9%, n=117) had DFU located on the right foot, with the majority on the dorsum of the foot (54.7%, n=117); location of the ulcer on the plantar (p=0.01), having more than 4 ulcers (p=0.01) and size of ulcer of >10 cm of diameter (p=0.00) were associated with severity of the DFU (Table 7).

Table 7. Anatomical distribution of the DFU among study participants

Variables	Early (G1 & G2): n (%)	Late (G3, G4, & G5)	Total	p-value
Foot Affected By DFU				
Right	23 (48.9)	33 (47.1)	56 (47.9)	
Left	20 (42.6)	27 (38.6)	47 (40.2)	
Both	4 (8.5)	10 (14.3)	14 (12.0)	0.633
Location of DFU				
Heel				
No	38 (80.9)	52 (74.3)	90 (76.9)	
Yes	9 (19.1)	18 (25.7)	27 (23.1)	0.409
Dorsum				
No	26 (55.3)	27 (38.6)	53 (45.3)	
Yes	21 (44.7)	43 (61.4)	64 (54.7)	0.074
Plantar				
No	33 (70.2)	32 (45.7)	65 (55.6)	
Yes	14 (29.8)	38 (54.3)	52 (44.4)	0.009
Toes				
No	22 (46.8)	31 (44.3)	53 (45.3)	
Yes	25 (53.2)	39 (55.7)	64 (54.7)	0.788
Number of Ulcer				
1	29 (61.7)	30 (42.9)	59 (50.4)	
2	14 (29.8)	15 (21.4)	29 (24.8)	
3	4 (8.5)	22 (31.4)	26 (22.2)	
4	0 (0.0)	3 (4.3)	3 (2.6)	0.010
Size of DFU in cm, n (%)				
1 to 5	34 (72.3)	22 (31.4)	56 (47.9)	
5 to 10	13 (27.7)	29 (41.4)	42 (35.9)	
Over 10	0 (0.0)	19 (27.1)	19 (16.2)	0.000

Bivariate and multivariable Analysis using Prevalence Risk Ratios (PRR) of developing severe DFU.

The patients with mild neuropathy (aPRR = 3.4; 95% CI =1.51 - 7.63; p-value= 0.003) and moderate neuropathy (aPRR = 2.65; 95% CI =1.34 - 5.23; p-value= 0.005) were at risk of developing severe DFU as compared to those with normal foot sensations, when other factors were held constant. However, at bivariate analysis, the patients with severe form of neuropathy were 2 times more likely (95% CI= 1.21 - 4.03, p =0.009) to develop severe DFU as compared to those with normal foot although this turned out not to be a significant risk factor at multivariable analysis. In addition, the size of the ulcer of more than 5cm was associated ($p < 0.05$) with severe DFU (Table 8).

Table 8. Bivariate and multivariable Analysis for patients with DFU

Variable	DFU		Bivariate analysis		Multivariable analysis	
	Less severe	severe	c.PRR (95%CI)	P-Value	a.PRR (95%CI)	P-Value
Age	47 (40.2)	70 (59.8)	1.01(1.01-1.02)	0.003	1.02(1.01-1.03)	0.001
Age group in years						
18-39	10 (21.3)	4 (5.7)	1		1	
40-49	7 (14.9)	8 (11.4)	1.87(0.72-4.87)	0.202	-	-
50-59	13 (27.7)	26 (37.1)	2.33 (0.99 -5.52)	0.054	-	-
60-69	12 (25.5)	13 (18.6)	1.82 (0.73 - 4.54)	0.199	-	-
70-95	5 (10.6)	19 (27.1)	2.77 (1.18 - 6.53)	0.020	-	-
Sex						
Female	28 (59.6)	44 (62.9)	1		1	
Male	19 (40.4)	26 (37.1)	0.95 (0.69 - 1.29)	0.724	-	-
Residence						
Rural	34 (72.3)	53 (75.7)	1		1	
Urban	13 (27.7)	17 (24.3)	0.95 (0.69 - 1.29)	0.724	-	-

Profession						
Peasant farmer	28 (59.6)	42 (60.0)	1		1	
Business/self employed	11 (23.4)	13 (18.6)	0.9 (0.6 - 1.37)	0.630	0.84 (0.43 - 1.66)	0,621
Non employed	7 (14.9)	9 (12.9)	0.94 (0.58 - 1.51)	0.790	1.02 (0.61 - 1.71)	0,939
Formerly employed	1 (2.1)	6 (8.6)	1.43 (1 - 2.05)	0.052	1.13 (0.5 - 2.53)	0,773
Education level						
No formal	3 (6.4)	12 (17.1)	1		1	
Primary	29 (61.7)	40 (57.1)	0.73 (0.52 - 1)	0,052	0.58 (0.38 - 0.89)	0,011
Secondary	14 (29.8)	14 (20.0)	0.63 (0.4 - 0.98)	0,041	0.53 (0.29 - 0.97)	0,039
Tertiary	1 (2.1)	4 (5.7)	1 (0.6 - 1.66)	1,000	0.45 (0.18 - 1.17)	0,102
Religion						
Moslem	4 (8.5)	9 (12.9)	1		1	
Christian	43 (91.5)	61 (87.1)	0.8 (0.52 - 1.38)	0.506	0.9 (0.54 - 1.45)	0.629
Average monthly income in Ug shx						
< 10,000	15 (31.9)	21 (30.0)	0.73 (0.43 - 1.23)	0,234	0.42 (0.13 - 1.33)	0,142
10,000-100,000	16	14	0.58 (0.33 -	0,071	0.39 (0.12 -	0,128

	(34.0)	(20.0)	1.05)		1.31)	
100,001-500,000	14 (29.8)	22 (31.4)	0.76 (0.46 - 1.28)	0,303	0.47 (0.16 - 1.42)	0,181
500,001-1,000,000	1 (2.1)	9 (12.9)	1.13 (0.69 - 1.83)	0,635	0.8 (0.3 - 2.14)	0,650
Above 1M	1 (2.1)	4 (5.7)	1	.	1	.
Smoking status						
Non smoker	44 (93.6)	56 (80.0)	1	.	1	.
Ever smoked	3 (6.4)	14 (20.0)	1.47 (1.11 - 1.95)	0,007	1.08 (0.68 - 1.71)	0,751
Vegetables						
No	22 (46.8)	17 (24.3)	1	.	1	.
Yes	25 (53.2)	53 (75.7)	1.56 (1.06 - 2.3)	0,026	1.4 (0.63 - 3.12)	0,406
Fruits						
No	21 (44.7)	17 (24.3)	1	.	1	.
Yes	26 (55.3)	53 (75.7)	1.5 (1.02 - 2.21)	0,040	0.67 (0.26 - 1.7)	0,395
Dorsum						
No	26 (55.3)	27 (38.6)	1	.	1	.
Yes	21 (44.7)	43 (61.4)	1.32 (0.96 - 1.81)	0,086	1.32 (0.88 - 1.98)	0,176
Plantar						
No	33 (70.2)	32 (45.7)	1	.	1	.
Yes	14 (29.8)	38 (54.3)	1.48 (1.1 - 2)	0,009	1.46 (0.89 - 2.38)	0,135
Number of locations for one Ulcer						
1	29 (61.7)	30 (42.9)	1	.	1	.
2	14 (29.8)	15 (21.4)	1.02 (0.66 - 1.57)	0,938	0.52 (0.32 - 0.86)	0,011

3	4 (8.5)	22 (31.4)	1.66 (1.23 - 2.25)	0,001	0.57 (0.27 - 1.21)	0,145
4	0 (0.0)	3 (4.3)	1.97 (1.53 - 2.53)	0,000	0.72 (0.33 - 1.6)	0,421
Visual Loss						
Normal	8 (17.0)	18 (25.7)	1	.	1	.
Mild	7 (14.9)	14 (20.0)	0.96 (0.65 - 1.43)	0,853	0.55 (0.28 - 1.08)	0,084
Moderate	15 (31.9)	23 (32.9)	0.87 (0.61 - 1.26)	0,470	0.48 (0.29 - 0.78)	0,003
Severe	17 (36.2)	15 (21.4)	0.68 (0.43 - 1.06)	0,090	0.31 (0.17 - 0.54)	0,000
Neuropathy						
Normal	16 (34.0)	8 (11.4)	1	.	1	.
Mild	3 (6.4)	8 (11.4)	2.18 (1.11 - 4.28)	0,023	3.4 (1.51 - 7.63)	0,003
Moderate	18 (38.3)	26 (37.1)	1.77 (0.95 - 3.29)	0,070	2.65 (1.34 - 5.23)	0,005
Severe	10 (21.3)	28 (40.0)	2.21 (1.21 - 4.03)	0,009	2.06 (0.96 - 4.43)	0,063
Peripheral Vascular Disease						
No disease	35 (74.5)	41 (58.6)	1	.	1	.
Claudication	10 (21.3)	19 (27.1)	1.21 (0.87 - 1.7)	0,259	1.39 (0.88 - 2.2)	0,162
Gangrene	0 (0.0)	7 (10.0)	1.85 (1.51 - 2.28)	0,000	1.26 (0.71 - 2.24)	0,424
DVT	2 (4.3)	3 (4.3)	1.11 (0.53 - 2.35)	0,781	1.74 (0.44 - 6.89)	0,433
Hba1C 6.5%, n (%)						
Less than 6.5%	14 (29.8)	13 (18.6)	1	.		
6.5 and above	33 (70.2)	57 (81.4)	1.32 (0.86 - 2.01)	0.205	-	-
BP class						

Normal	19 (40.4)	28 (40.0)	1	.	1	.
Hypertension	28 (59.6)	41 (58.6)	1 (0.73 - 1.36)	0,987	1.05 (0.64 - 1.73)	0,851
Hypotension	0 (0.0)	1 (1.4)	1.68 (1.33 - 2.13)	0,000	1.93 (0.56 - 6.64)	0,296
Size of DFU in cm						
1 to 5	34 (72.3)	22 (31.4)	1	.	1	.
5 to 10	13 (27.7)	29 (41.4)	1.76 (1.2 - 2.58)	0,004	1.51 (1.01 - 2.27)	0.047
Over 10	0 (0.0)	19 (27.1)	2.55 (1.84 - 3.53)	0,000	2.46 (1.38 - 4.39)	0.002
Ankle Brachial Index						
Normal (1.0 to 1.4)	9 (19.1)	9 (19.1)	1	.	1	.
Acceptable (0.9 to less 1.0)	4 (8.5)	4 (8.5)	0.63 (0.26 - 1.55)	0.315	0.66 (0.21 - 2.09)	0.474
Some Arterial Disease (0.8 to less 0.9)	1 (2.1)	1 (2.1)	0 (0 - 0)	0.000	0 (0 - 0)	0.000
Moderate (0.5 to less 0.8)	0 (0.0)	0 (0.0)	1.47 (1.14 - 1.9)	0.003	1.52 (0.61 - 3.81)	0.373
Severe (Less than 0.5)	2 (4.3)	2 (4.3)	0 (0 - 0)	0.000	0 (0 - 0)	0/000
Not assessable	31 (66.0)	31 (66.0)	0.88 (0.64 - 1.21)	0.429	0.71 (0.5 - 1.01)	0.053

Discussion

This study assessed the factors associated with severity of diabetic foot ulcer in Uganda. The Burden of DM and DFU is increasing worldwide and especially in developing countries [8]. The prevalence of DFU in Uganda is estimated at 4%, and an adult patient has a 10 - 15% risk of developing DFU during their diabetic life time [1,30].

This study revealed that the majority of patients with DFU were female (61.5%) although the sex difference was not significant (p>0.05). These results are similar to those reported by Agwu [30] in Uganda that showed 55.4% for female predominance. However, our results differ with the most common findings concerning sex distribution of diabetic foot ulcer reported in the world wide systematic and meta-analysis review in which the males were the most affected by diabetic foot ulcer (4.5%, 95%CI: 3.7–5.2%) than in females (3.5%, 95%CI: 2.8–4.2%) [1]. Similarly, Bekele and others reported higher cases of DFU among the males (55.7%) [31]. The reason why DFU was more prevalent in females than males in our study could be explained by the poor health care behaviour that commonly occurs in our communities where majority of the patients with DFU consult first traditional healers and seek for medical care in hospitals very late [32].

The majority (90%) of patients with DFU in this study had poor sugar control although this did not appear as a risk factor associated with severe ulcer. This result is similar to what has commonly been found in DFU patients as reported in a recent systematic review [31].

Among study participants, approximately 60% had severe DFU. Our results were contrary to the findings of Jalilian and others in a systematic review that reported a higher prevalence of 62% for less severe DFU [9]. This could probably be due to delayed consultation of better health care by patients with DM and DFU just after treatment from traditional healers.

The majority (44%) of the participants had Grade 3 DFU according to Wagner classification, which is in agreement with results of a study in Sri Lanka (40.7%, n=91) [21]. Other studies, however, have reported Grade 2 DFU to be the most common among diabetic patients in Ethiopia (31%) and India (35%) [33-35].

Results showed that the anatomical distribution of the ulcer among the study participants was found mostly (47.9%) on the right foot and the ulcer located on the plantar of the foot (44.4%, n=117) (p-value =0.009). Our results are at variance with those reported in Korea and Sri Lanka where the commonest location of the ulcer were the toes (56.2%, n=60) and (31.9%, n=91), respectively [21,34].

The majority of the study participants had one ulcer 59 (50.4%) and also most of them had an ulcer measuring 1-5 cm2 56 (47.9%), followed by that measuring 5-10 cm2 42 (35.9%) and over 10 cm2 19 (16.2) (Table 7).

We can deduce that the severity of DFU at the time of admission varies by region depending on the education level, therefore, emphasis be placed on early consultation when the foot of DM Patient is affected to avoid inherent complication to severe DFU.

The size of the DFU found in this study is similar to that reported in India where the ulcer <4 cm^2 was observed in 21.8% patients, between 4-8 cm2 in 30.9%, 8 – 12 cm2 in 21.8% and > 12 cm2 in 25.4% patients [35].

Poor blood sugar (cPPR: 1.32 (95% CI: 0.86 - 2.01) and history of smoking (aPR 1.08 (95% CI:0.68 - 1.71) were not associated with severity of the DFU in this study although they are commonly known as factors associated with development of the diabetic foot ulcer. It was also noted in this study that poor blood sugar control was common to all types of DFU regardless the severity.

High BMI has been reported to be associated with occurrence of DFU and with severe DFU (37 latest); however, our results did not support this association. This could be explained by the finding that most (47.9%, n=117) of our study participants had normal BMI.

Many factors have been reported to be associated with the severity of the diabetic foot ulcer. In this study, a number of factors were identified to be associated with severe DFU and included neuropathies and the size of the ulcer. Patients with mild or moderate neuropathy were 3.4 times (p-value = 0.003, 95% CI: 1.51 – 7.63) and 2.7 times (p-value = 0.005, 95% CI: 1.34 - 5.23) more likely to have severe diabetic foot ulcer, respectively. This result is similar to a study in Ethiopia where neuropathies were 4 times likely in patients with severe diabetic foot [36].

Severe diabetic foot was 1.5 times and 2.5 times more prevalent among patients with diabetic ulcer on their foot measuring 5-10cm^2 or 10cm^2 (p=0.047 and p=002), respectively.

Patients with ulcer on their foot measuring 5-10cm^2 were 1.5 times more prevalent with severe diabetic foot with a p-value of 0.047 (1.01 - 2.27) at 95% confidence Interval and those with a size of more than 10cm2 were 2.46 more prevalent with severe DFU with a p-value of 0.002 (1.38 - 4.39) at 95% confidence interval. Therefore, this study shows that the larger the ulcer the more risk for severity, so the DFU should be treated early and effectively to avoid progression towards severity.

Ambageda in Sri langa did not find any statistically significant association between any factor with severity of the ulcer, However Stom in Norway found duration of ulcer with the severity with p-value of = 0.042 [21,27,37].

In a systematic review, the relationship between wound location (plantar ulcer) and wound severity was also reported (hazard ratio=1; 95% CI) [9].

Some limitations of this study were noted. The study was conducted in hospitals and clinics and this limits the results to be generalized to entire Ugandan population. The other limitation is the nature of being a cross sectional study, the causal relationship between the contributing factors and the severity of DFU could not be established.

The strength of this study is that it is a multi-center study and data was collected concurrently so there is a possibility of generalizing to the catchment of the study area. However, a prospective study on severity of the DFU and outcomes in the region is proposed.

Conclusion

Most patients were from western Uganda and have poor health seeking behaviors leading to late consultation in diabetic clinics when the condition is rather severe. Majority of participants had severe DFU and Grade 3 was the most common grade identified. The dorsum of the right foot was the most affected with ulcers and the majority of patients with DFU had poor blood sugar control. There is an association between neuropathies, ulcer size of more than 5cm and severity of the DFU.

Therefore, there is a need to control blood sugar, effectively treat as early as possible the neuropathies, and focus more on education of patients to consult early to prevent the complications inherent to severity of the DFU.

Declarations

Availability of data

The data used to support the findings of this study are available from the corresponding authors upon request.

Ethics approval and consent to participate

This clinical trial has been approved by Kampala International University Research Ethics Committee (KIU-REC) under the number (KIU-REC-2021-57). Informed consent was obtained from all the participants in the current study. All methods were carried out in accordance with relevant guidelines and regulations.

Consent for publication

Informed consent was obtained from all the participants in the current study.

Competing interests

Authors declare no competing interest.

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Authors' contributions

GWN and AN conceived the concept. BMV wrote the main manuscript. BMV, RS, GWN and AN designed the survey and critically reviewed the manuscript. FKS, IN, IM, AN, RS and TP collected data. YM analyzed the data. FKS, FXO, RS, AN, PK, SJ, GA and GWN reviewed the manuscript development, revised the methodology and critically reviewed the manuscript. All authors reviewed and approved the final manuscript.

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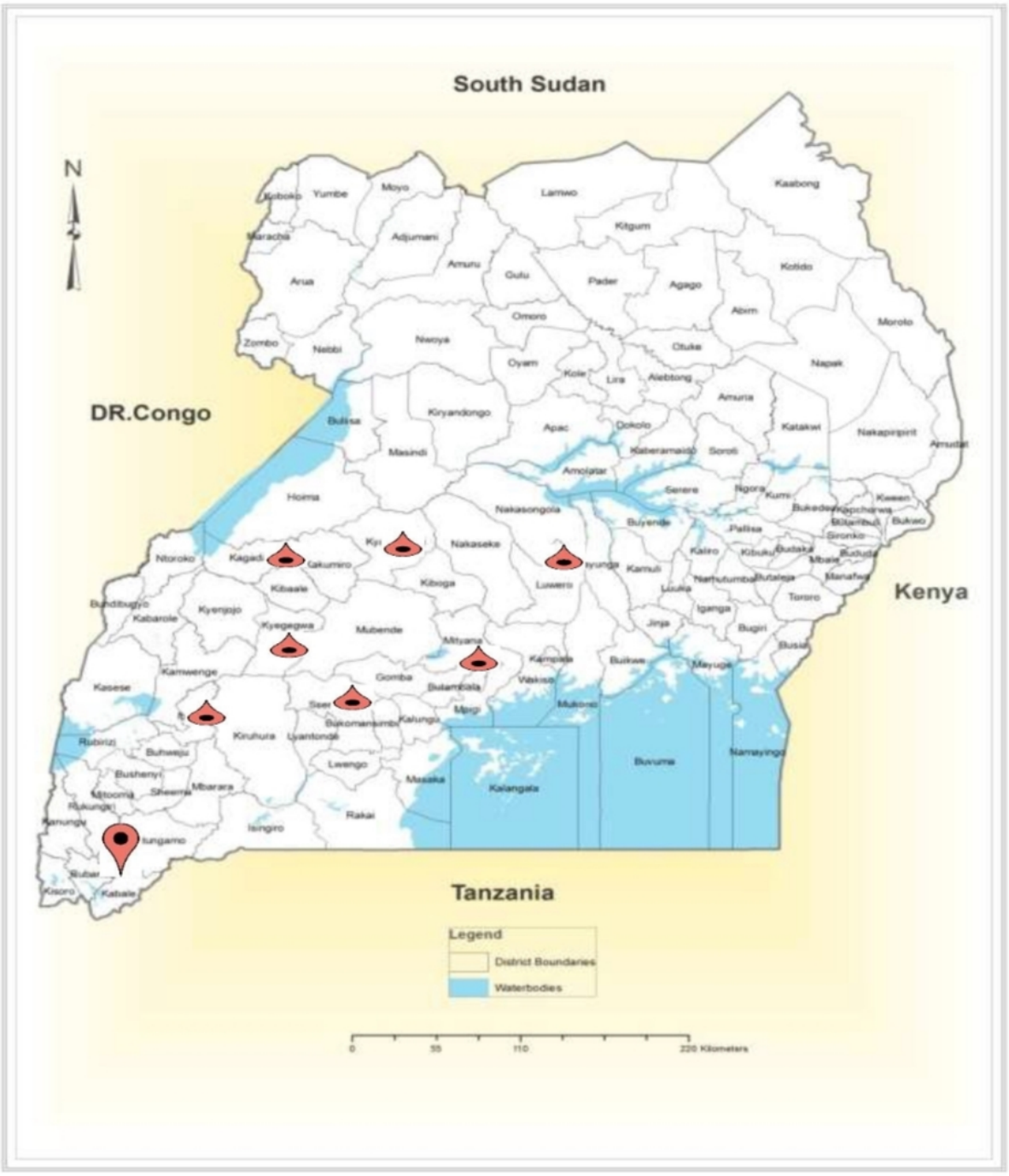
Figures



Uganda map with location of study site

Figure 1

Distribution of study sites according districts.

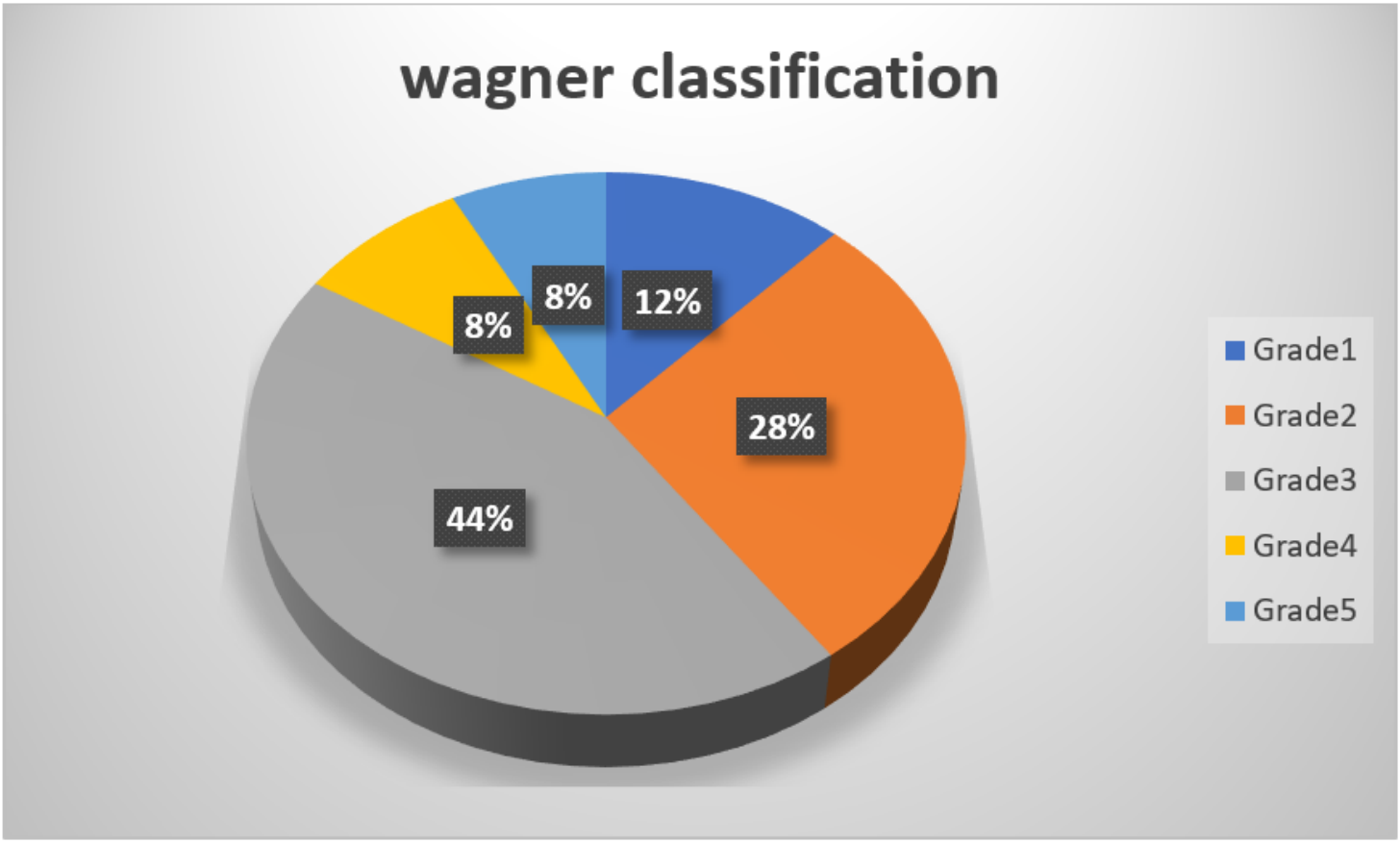


Figure 2

Grade of foot ulcer according to Wagner classification

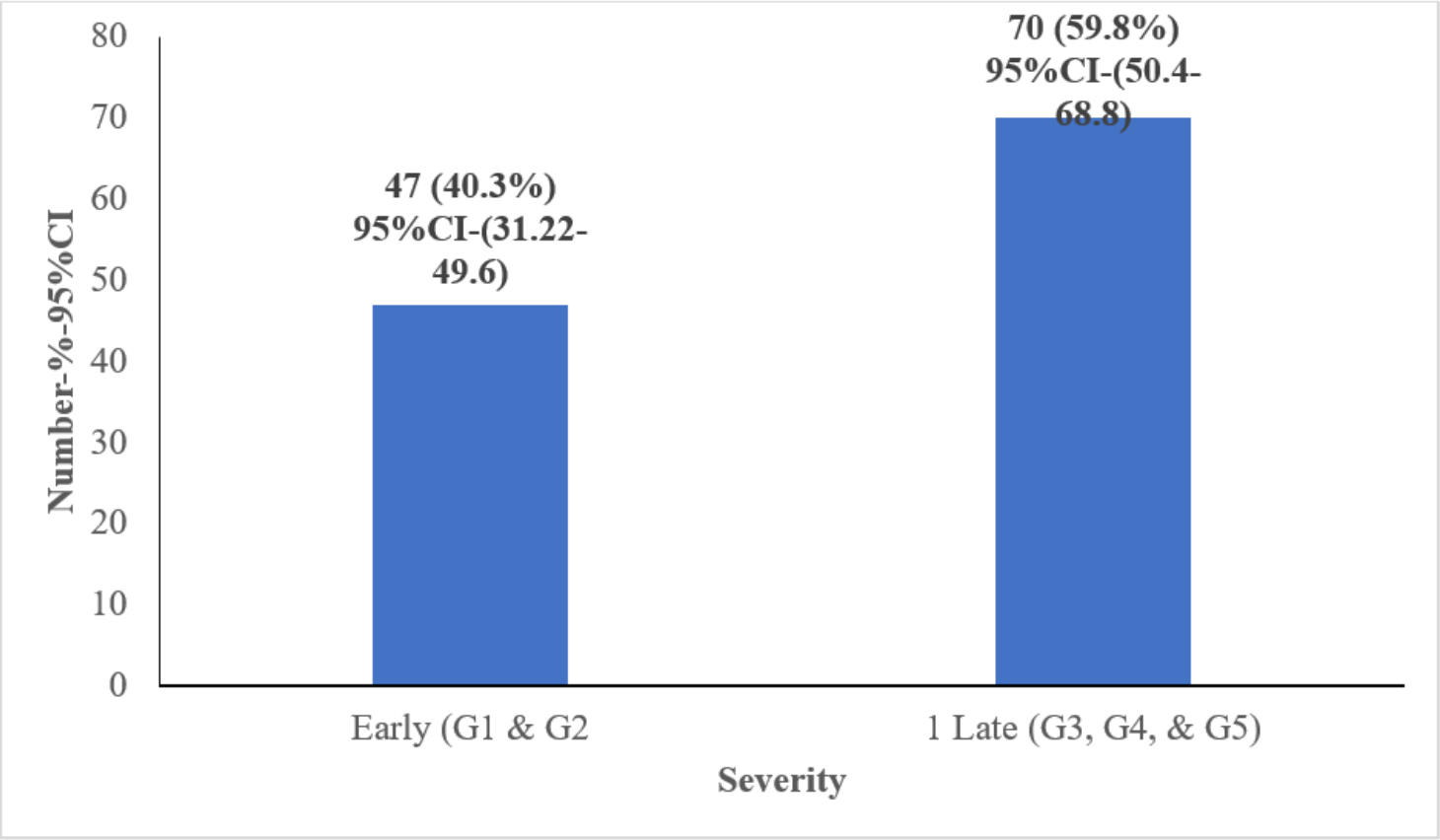


Figure 3

Classification of DFU into severe and less severe