

Nursing Guidelines for Diabetic Foot Ulcer Care: An Intervention Study

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Abstract

Background: Diabetic ulceration disturbs the daily life of patients and increases their psychological distress. **Aims:** The main aim of the study is to investigate the effectiveness of a nursing guidelines intervention in improving diabetic ulcers. **Subjects and method:** The study carried out of the vascular outpatient clinic at Alharar hospital, ZagazigSharkia governorate using quasi experimental research design with pre-post assessment on adult's diabetic patients suffering from diabetic foot ulcer. The first part for demographic characteristics of patients, the second part was diabetic details and the third was for recording body weight and height. **Results:** Patient age ranged between 35 and 80 years, most by males (63.3%), (71.7%) illustrates half of them (50%) working, (75%) were rural residents and the majority of patients were either over weight or above, (48.3%), (35%); respectively, approximately two-fifth of them (38.3%) were smoking. The duration of ulcer was mostly (63.3%) less than one year. Sufficient improvement was resolved after the intervention in regular treatment and ulcer care $P < 0.001$, significantly decrease from 346.6 mg/dL to 291.7 mg/dL. Random blood sugar after the intervention ($P < 0.001$), statically significant positive weak correlation between the number ulcer and Wagner grade ($n = 0.291$). **Conclusion and recommendation:** The nursing guidelines applied to patients suffering from diabetic foot are effective in improving their diabetic foot ulcer grades with associated improvements in their blood sugar levels. The study recommends the use of the guidelines and related booklet in those settings should be trained in implementing to measure the long-term effect of such guidelines on patients, diabetic foot state and on their glycemic control.

Keywords: Diabetes, diabetic foot ulcers

INTRODUCTION

Diabetic foot is a complication of diabetes and diabetic foot ulcer is the term used to name the lesions that can occur in a patient's foot (Ahmedani et al., 2019). The annual incidence of diabetic foot ulcer (DFU) worldwide is between 9.1 to 26.1 million (Armstrong et al., 2017). Around 15 to 25% of diabetic patients will develop a diabetic foot ulcer during their lifetime, and 6% of these patients need hospitalization for associated complications (American Podiatric Medical, 2019). As the number of newly diagnosed diabetics is increasing yearly,

the incidence of diabetic foot ulcer is also bound to increase (Singer et al., 2018). Diabetic foot ulcers are among the most common complications of patients who have diabetes mellitus which is not well controlled. It results from poor glycemic control, underlying neuropathy, peripheral vascular disease, or poor foot care (Armstrong et al., 2017). Other common causes are improper foot care, ill-fitting footwear, peripheral neuropathy, and poor circulation (Hanley and Manna, 2018). Around 56% of DFUs become infected (Wu et al., 2017). One of the commonly classifications used is Wagner, which classifies wounds into five grades based on the depth from superficial ulcer to gangrene (Mutluoglu et al., 2012). Treatment strategies include glycemic control, surgical interventions, and patient education for proper foot care (Everett and Mathioudakis, 2018). Exercise and physical activity (Matos et al., 2018) as well as adherence to foot self-care behaviors are effective preventive measures (Zhang et al., 2017). Diabetic foot ulceration disturbs the daily life of patients including changes in sleep pattern, impaired mobility, and interference with certain aspects of life such as sexuality, feelings of loneliness, powerlessness, anxiety and depression. Furthermore, physically restrictive regimes including the use of off-loading measures of the lower limbs could result in increased psychological distress (Prinz et al., 2017; Ahmad et al., 2018). The result of loss of sensation in the foot is repetitive stress, unnoticed injuries, structural foot deformities and eventual tissue breakdown. These factors, combined with poor arterial inflow, confer a high risk of limb loss on the patient with diabetes (Khunkaew et al., 2018). Moreover, once amputated, within 3 years 30-50% undergo amputation of the contra lateral-leg (Cho et al., 2018). With appropriate therapy, foot ulcers heal in many patients, and the need for amputation is averted (Hinchliffe et al., 2016).

Significance of the study: Diabetes Mellitus (DM) is the commonest chronic medical illness. Ulcers of the lower limbs are the most common complications especially those related to the circulatory system and DM. The problem continues to be prevalent despite its preventability. Nursing has an important educational role in the prevention and management of DFUs, and its effectiveness needs to be enhanced.

Aim of the study: To investigate the effectiveness of a nursing guidelines intervention in improving diabetic foot ulcers.

Research hypothesis: The nursing guidelines will lead to improvements in diabetic foot ulcers grades.

SUBJECTS AND METHODS

Research design and setting: This study was conducted using a quasi-experimental research design with pre-post assessment at the vascular outpatient clinic at Alhrar Hospital, Zagazig city, Sharqiah governorate.

Subjects: A purposive sample of 60 adult diabetic patients suffering from diabetic foot ulcer(s) was selected from the setting. Those with arterial occlusion seeking vascular disease treatment, and those with other chronic diseases as liver cirrhosis, cancer, and chronic neurological deficit were excluded. The sample size was estimated to demonstrate an expected decrease in the percent of patients with severe grade of diabetic foot ulcer from a pre-intervention level 50% to 25% after implementation of the intervention at a 95% confidence level and 80% study power. Using Open-Epi software package, the required sample size was 60 after accounting for a dropout rate of about 5%.

Data collection tools: A patient assessment form was adapted by the researchers based on Kaewloet al. (2008). It consisted of a first part for patient demographic characteristics of patients: such as age, gender, level of education, etc. The second part was for diabetic foot details such as ulcers numbers, duration, sites, causes, care, etc. and history of amputation, and smoking. It also involved an assessment of the ulcer grade using Wagner scale for ulcer classification (Wagner, 1987). The third part was for recording body weight and height from which the Body Mass Index (BMI) was calculated by dividing the weight by the squared height, and the laboratory tests results. These included Fasting Blood Sugar (FBS) and Random Blood Sugar (RBS) levels, which were obtained from patients' medical records before and after the intervention. The data collection form was Face and content validated by a jury group of three experts in medical surgical nursing. Minor modifications were done based on their recommendations.

Pilot study: The tool was pilot-tested on 6 patients. It was modified and finalized according to the pilot results. The patients of the pilot study were not included in the study sample.

Fieldwork: Upon obtaining their official permissions, the researchers visited the study setting, met with the directors and head nurses to explain the study aim and procedures, and to gain their cooperation. Then, the sample of patients was recruited. Eligible patients were approached individually; the study purpose and procedures were explained to them to get their oral consent to participate. The fieldwork was conducted out in assessment, planning, implementation, and evaluation phases.

Assessment phase: The patients who consented to participate were interviewed by the researchers using the data collection form. The researchers then explained to each patient what he/she is expected to do in the intervention, and asked him/her to set a convenient time to learn about the nursing guidelines. The foot assessment data and lab results were considered baseline for post-intervention comparisons.

Planning phase: The researcher designed the guidelines with the help of relevant literature and based on patients' needs as identified in the assessment phase. The guidelines were prepared as counseling sessions through an integrated approach to provide proper care for the foot. It provided patients with theoretical and applied knowledge about diabetes mellitus nature, symptoms and signs, complications, management, diabetic foot etiology, symptoms and signs, complications, prevention, management, and diabetic foot ulcer care. It also provided them with practical skills to be able to practice adequate diabetic foot ulcer care. The teaching methods suited small group teaching to facilitate comprehension and integration of theory and practice. Additionally, a booklet was prepared by the researchers for attendants.

Implementation phase: The guidelines program was implemented in theoretical and practical sessions in small 6-patient groups. Adult learning principles with interactions and active participation were followed during the sessions. The researcher used simple language to suit the level of understanding of participants. The practical part was implemented to each patient individually to ensure the acquisition of the skill under training. Additionally, during the practical sessions each patient was assessed as to whether he/she follows the prescribed guidelines or not. By the end of this phase, each participant was given a booklet containing all the information provided during the training sessions.

Evaluation phase: After implementation of the guidelines, an immediate post-intervention evaluation of the effect of the guidelines was carried out using the same patient assessment form.

Administrative design and ethical considerations

Official permissions were obtained from the managers of Zagazig Alhrar Hospital through formal letters from the Dean of Faculty of Nursing, Zagazig University to obtain the approval to conduct the study. These letters explained the aim of the study and its procedures. The research protocol was approved from the research ethics committee at the Faculty of Nursing, Zagazig University. All Helsinki Declaration principles were followed. The researchers obtained informed consent from each patient after clarifying the objectives of the study and its procedures, and informing about the right to refuse participation or to withdraw at any time. Anonymity and confidentiality of data were ensured. The study maneuvers could not lead to any harm on participants, but conversely it was for their beneficence.

Statistical design: Data entry and statistical analysis were done using SPSS 20.0 statistical software package (SPSS Inc., Chicago, IL, USA, 2011). Quantitative continuous data were compared using the non-parametric Mann-Whitney test. Categorical variables were compared using chi-square test. Spearman rank correlation was used for assessment of the inter-relationships among quantitative variables and ranked ones. In order to identify the independent predictors of ulcer grade score, multiple linear regression analysis was used and analysis of variance for the full regression models was done. Statistical significance was considered at p -value <0.05 .

RESULTS

The age of diabetic patients in the sample ranged between 35 and 80 years, with a mean 35.0 years as Table 1 illustrates. They were mostly males (63.3%) and illiterate (71.7%). Half of them (50.0%) were working, and 75.0% were rural residents. Approximately two-fifth of them (38.3%) was smoking. The majority of the patients were either overweight or obese, respectively 48.3% and 35.0%. Table 2 indicates that and slightly less than a half of the patients (48.3%) were having more than one ulcer. In about two-thirds of them (63.3%) the duration of the ulcer was less than one year, mostly with no known cause (66.7%). The ulcer site was single in the majority (83.3%), mostly in the toes (38.3%). Around one half of the patients had were regular in DM treatment and ulcer care. Approximately two thirds (60%) had Wagner ulcer grade “3”, and 30.0% of the patients were having a history of amputation. As described in Table 3, significant improvements were found in patients regular treatment of DM as well as in ulcer care after the intervention ($p<0.001$). Similar improvements were noticed regarding ulcer care ($p<0.001$) and ulcer exudates ($p<0.001$). No changes were observed in the numbers of ulcers or their sites. Meanwhile, the percentages of patients with Wagner Grade 3/4 dropped from 71.7% before the intervention to 8.4% after the intervention. On the other hand, 26.7% improved to Grade 1 after the intervention compared to only 1 (1.7%) before the intervention. Overall, 91.7% of the patients showed post-intervention Wagner grade improvement. Table 4 indicates that the mean RBS significantly decreased from 346.6 mg/dl to 291.7 mg after the intervention ($p<0.001$). However, although the mean level of FBS dropped from 202.1 mg/dl to 188.5 mg/dl, the difference was not statistically significant ($p=0.14$). Table 5 points to statistically significant positive weak

correlation between the number of ulcers and Wagner grade ($r=0.297$), and a moderate correlation with its duration. Meanwhile, the ulcer grade correlated positively with the Fasting Blood Sugar (FBS) and the ulcer duration. The multivariate analysis (Table 6) identified the study intervention as the main statistically significant independent negative predictor of the Wagner ulcer grade. On the other hand, the duration of the ulcer and the Fasting Blood Sugar (FBS) level were positive predictors. The model explains 45% of the variation in ulcer grade.

DISCUSSION

The aim of this study was to evaluate the effectiveness of a nursing intervention on diabetic ulcer grade among patients with diabetic foot ulcer. The results demonstrated significant improvements in diabetic ulcers grades, and thus the research hypothesis is accepted. The study sample included a higher percentage of male patients. This indicates a good representativeness of the sample given the presence of diabetic foot problems. In congruence with this, a study in of the burden of DM in Australia revealed that the risk of developing diabetic foot complications was almost twofold in male diabetic patients in comparison with female ones (Zhang et al., 2020), approximately two-fifth of the diabetic patients of the present study sample reported being currently smoking. Since smoking is very low among females in our rural community, the rate indicates a very high prevalence of smoking among male patients. This is expected in a sample of diabetic patients suffering from diabetic foot problems given the close association between smoking and this complication of DM. In line with this, a review of the effects of smoking in DM, it was shown that cigarette smoking had deleterious effects on wound healing and increased the risk of peripheral neuritis and vasculitis through inducing oxidative stress in the cells (Xia et al., 2019). Overweight and obesity constituted another risk factor of DM among the patients in the current study sample. Overall, more than four-fifth of the sample were overweight or obese, which would have contributed to their disease and associated complications. In agreement with this, Gupta and Bansal (2020) in a study in India found that the overweight or obese individuals have twice the risk of developing DM in comparison with normal weight ones. Moreover, they reported that each 1% increase in the Body Mass Index (BMI) is associated with 1.5% increase in the probability of DM. Similar findings were also revealed by Denova-Gutiérrez et al. (2020) in a study in Mexico. As for the diabetic foot problem among the patients in the current study, the duration of the ulcer was less than one year in approximately two-thirds of them, with a median 0.6 years. This indicates a relatively short duration of the ulcers, which are generally longstanding and resistant to treatment. The long duration of diabetic foot problems and ulcers has been demonstrated in a 7-year long prospective study in India (Zubair and Ahmad, 2019). The relapse of recurrence of infections has been reported as an underlying cause of this long-term trajectory of diabetic ulcers in a study in Switzerland (Gariani et al, 2019). The most common sites of the diabetic foot ulcers among the patients in the present study sample were the toes. This is in fact the commonest site reported in the literature. In most of these diabetic patients, the ulcers were multiple, with advanced Wagner ulcer grade. These problematic conditions of the ulcers might add to long duration and resistance to treatment. In fact, the present study results revealed significant positive correlations between ulcers' duration and their numbers and grade. The findings are in agreement with those of Nur Hilda

Hanina et al. (2015) whose study in Malaysia demonstrated that most diabetic patients presented with Wagner grade III/IV ulcers, and this was mostly in their toes. Similar findings were also reported in a large four European countries study (Sánchez-Ríos et al., 2019). Moreover, approximately one-third of the diabetic patients in the current study sample gave a history of amputation. This is the worst outcome of a diabetic foot problem. It indicates failure of management, which is often related to non-compliance of the patient and lack of glycemic control. In fact, all patients in the sample had Random Blood Sugar (RBS) levels exceeding 200 mg/dl before implementation of the guidelines. Moreover, all of them, except one patient, had their Fasting Blood Sugar (FBS) level exceeding 126 mg/dl, indicating no glycemic control. In support of this, the present study findings showed a significant positive correlation between FBS and ulcer grade. A similarly high rate of amputation due to diabetic foot problems was reported in a study in the Dominican Republic (Bonilla et al, 2019). The current study results indicate that the implementation of the nursing guidelines to the patients suffering from diabetic foot was effective in improving their ulcer grades, which was associated with their significantly better compliance with DM treatment and ulcer care, as well as improved RBS and FBS levels. The independent effect of the intervention was confirmed in multivariate analysis. The success of the nursing intervention could be attributed mainly to its practical component which helped these patients in applying proper foot and ulcer care and corrected their related misconceptions and false practices. In agreement with this, a systematic review provided evidence of educational nursing interventions in improving DFUs (Subrata et al., 2019). The present study findings have also demonstrated significant improvement in the mean RBS after the intervention. In addition, the mean level of FBS declined but not significantly. These improvements in glycemic control were associated with significant improvements in patients' reported practices regarding regular treatment and ulcer care, as well as the ulcer exudates. Moreover, the FBS level was positively correlated with ulcer grade, and even identified as an independent positive predictor of it, indicating that it is a main risk factor for poor ulcer prognosis. In agreement with this, a study in India demonstrated significant improvement in diabetic patients' blood sugar following the implementation of a health education program (Chariwala et al., 2020).

CONCLUSION AND RECOMMENDATIONS

In conclusion, the nursing guidelines applied to patients suffering from diabetic foot are effective in improving their diabetic foot ulcer grades, with associated improvements in their blood sugar levels. The study recommends the use of the guidelines and related booklet in the settings providing care to diabetic patients. The nurses in these settings should be trained in implementing the guidelines and educating patients. Further research is proposed to measure the long-term effect of such guidelines on patient's diabetic foot state and on their glycemic control.

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Table 1: Demographic characteristics of patients in the study sample (n=60)

	Frequency	Percent
Age:		
<60	33	55.0
60+	27	45
Range	35.0-80.0	
Mean±SD	57.6±10.3	
Median	58.0	
Gender:		
Male	38	63.3
Female	22	36.7
Education:		
Illiterate	43	71.7
Educated	17	28.3
Job:		
None	30	50.0
Working	30	50.0
Residence:		
Rural	45	75.0
Urban	15	25.0
Smoking:		
No	37	61.7
Yes	23	38.3
BMI:		
Normal (<25)	10	16.7
Overweight (25-<30)	29	48.3
Obese (30+)	21	35.0
Range	18.6-48.4	
Mean±SD	29.0±5.4	
Median	27.90	

Table 2: Diabetic foot among patients in the study sample (n=60)

	Frequency	Percent
Number of ulcers:		
1	31	51.7
2+	29	48.3
Range	1.0-5.0	
Mean±SD	2.0±1.3	
Median	1.0	
Ulcer duration (years):		
<1	38	63.3
1+	22	36.7
Range	0.01-10.0	

Mean±SD	1.4±2.0	
Median	6.0	
Ulcer cause:		
Unknown	40	66.7
Trauma	16	26.7
Other (thrombus, infection, etc.)	4	6.6
Multiple ulcer sites:		
No	50	83.3
Yes	10	16.7
Ulcer site:		
Toes	23	38.3
Heel	10	16.7
Foot	10	16.7
Other	7	11.7
Multiple	10	16.7
Regular in:		
DM treatment	31	51.7
Ulcer care	30	50.0
Ulcer Wagner grade:		
1	1	1.7
2	16	26.7
3	36	60.0
4	7	11.7
History of amputation	18	30.0

Table 3: Changes in diabetes and diabetic foot care among patients in the study sample before and after the intervention

	Time				X ² test	p-value
	Pre (n=60)		Post (n=60)			
	No.	%	No.	%		
Regular treatment:						
No	29	48.3	0	0.0		
Yes	31	51.7	60	100.0	38.24	<0.001*
Ulcer care:						
No	30	50.0	0	0.0		
Yes	30	50.0	60	100.0	40.00	<0.001*
Number of ulcers:						
Range	1.0-5.0		1.0-5.0			
Mean±SD	2.0±1.3		2.0±1.3		0.02	0.90
Median	1.00		1.50			

Ulcer Wagner grade:						
1	1	1.7	16	26.7		
2	16	26.7	39	65.0	U=52.95	<0.001*
3	36	60.0	4	6.7		
4	7	11.7	1	1.7		
Ulcer Wagner grade:						
Improved by at least 1 grade			55	91.7		
Ulcer site:						
Single	50	83.3	52	86.7		
Multiple	10	16.7	8	13.3	0.26	0.61

(*) Statistically significant at $p < 0.05$

(U) Mann Whitney test

Table 4: Changes in blood sugar among patients in the study sample before and after the intervention

	Time				X ² test	p-value
	Pre (n=60)		Post (n=60)			
	No.	%	No.	%		
Random blood sugar (RBS):						
Range	220.0-650.0		220.0-380.0			
Mean±SD	346.6±85.4		291.7±38.5		U=12.35	<0.001*
Median	350.00		300.0			
Fasting blood sugar (FBS):						
Range	190.0-500.0		180.0-250.0			
Mean±SD	202.1±58.9		188.5±22.0		U=2.18	0.14
Median	190.0		180.0			

(*) Statistically significant at $p < 0.05$

(U) Mann-Whitney test

Table 5: Correlation between patients' number and grade of diabetic foot ulcers and their characteristics

	Spearman's rank correlation coefficient	
	Ulcer No.	Ulcer grade
Grade	.297*	
Age	.001	-.175
Education	-.119	-.121
BMI	.053	-.011
RBS	-.053	.125

FBS	.077	.333**
Ulcer duration	.414**	.445**

(*) Statistically significant at $p < 0.05$ (**) statistically significant at $p < 0.01$

Table 6: Best fitting multiple linear regression model for the ulcer grade

	Unstandardized Coefficients		Standardized Coefficients	t-test	p-value	95% Confidence Interval for B	
	B	Std. Error				Lower	Upper
Constant	2.64	0.33		7.994	<0.001	1.99	3.29
Intervention	-0.88	0.11	-0.55	-7.906	<0.001	-1.10	-0.66
Duration of ulcer	0.086	0.035	0.17	2.459	0.015	0.02	0.16
FBS	0.004	0.001	0.21	3.035	0.003	0.00	0.01

R-square=0.45

Model ANOVA: $F=25.75$, $p < 0.001$

Variables entered and excluded: age, gender, education, residence, number of ulcers, smoking, BMI