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ORIGINAL ARTICLE

Assessment of diabetic foot Risk factor among patients with diabetes attending to Zagazig university hospital.

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ABSTRACT

Background: Diabetes mellitus is a public and progressively more important chronic disease worldwide. Diabetic foot disease is one of the diabetes complications which most serious and costly. Methods: A cross sectional study was done on 266 diabetic patients at diabetic and vascular clinics in Zagazig university hospitals. The study was done by filling a questionnaire about socio-demographic data, clinical local foot examination for all diabetic patients. Results: The largest percentage of the studied patients were males(62.8%), aged less than 60 years old (62.4%), had education up to level of basic and secondary school education (72.9%), non-workers(28.6%), married(83.1%), with moderate-income (48.9%) and were current smokers(71.1%).On clinical examination of those patients, the largest percentage had abnormal skin(58.6%), absent sweating(54.9%), present fungal foot infection (53.4%), absent sensation has done by10g monofilament test, pinprick test(60.9%) and amputation (15.4%) and most of them had a very high risk of diabetic foot disease. Conclusions: Most of the patients were categorized had a high risk of diabetic foot(68%). It was significantly associated with low education status, prolonged disease duration, insulin treatment, smoking, presence of callus, fungal infections. So we need foot care education for diabetic patients for a high quality of life and improve their awareness of foot care and self-management. Keywords: Footcare, diabetic foot, diabetic foot disease.

INTRODUCTION

Diabetes mellitus one of the most important diseases that are chronically noncommunicable which prevalence has reached an alarming proportion. The prevalence of diabetes mellitus disease has reached in 2015 to 8.8%, which corresponded to 415 million patients. This leads to rising numbers of individuals with foot disease related to diabetes and lower extremity amputations performed in up to75% of those diabetic patients [1].

One of the world's top 10 countries is Egypt which is in terms of the largest number of diabetic patients. The International Diabetes Federation (IDF) estimated that in 2013 (3.81) million people had diabetes mellitus in Egypt. This number is estimated to be almost doubled by 2030. The number of diabetic patients in Egypt is due to rising obesity and physical inactivity prevalence. and rising aging, population growth, urbanization[2]..[

Micro and macrovascular complications of diabetes mellitus including peripheral neuropathy which is the common complication are associated with a high risk of foot disease [3].

Diabetic foot disease is typically defined to include ulcers or infections in the foot of a person with diabetes . Important risk factors for the development of diabetic foot disease include neuropathy, peripheral vascular disease, foot deformity , minor foot trauma, poor glycemic control and decreased resistance to infection. A disabling end-point of diabetic foot ulcer is amputation that has many effects on the diabetic patients' quality of life [4].

Evaluation of foot regularly by a foot specialist is essential to prevent complications of diabetic foot is more important once peripheral neuropathy diagnosis is done[5]. And also foot lesions can be the presenting feature of type 2 diabetes, so any patient with a foot ulcer of undetermined cause should be screened for diabetes [6]. Assessment of biomechanical, neurological and vascular status the foot by comprehensive examination is important to identify patients at risk and to implement the interventions at the appropriate time [2]. This study aimed to improve the quality of life for diabetic patients and decreasing rate of lower limb amputation through examination health status of the foot of patients with diabetics and identifying risk factors of the diabetic foot.

METHODS

Study type and setting:

This study was conducted at Elsharkia governorate in diabetic and vascular clinics at Zagazig university hospitals from March 2018 to December 2018.The study included 266 diabetic patients.

Inclusion criteria:

The patient is known to have type 2 diabetes and been diagnosed with diabetes for at least 6 months, Both males and females.

Exclusion criteria:

The patient is known to have type I diabetes mellitus and gestational diabetes, Patients known to have severe psychiatric disorders or mental retardation and Patients known to have end-stage organ failure.

Sample size:

The Sample size calculated to be 266 patients according to the attendance rate to vascular and diabetic clinics which estimated (1020) diabetic patients during 6 months and prevalence rate of awareness of diabetic patient 62, 8% **[7].** The sample size is calculated by using the Epi 7 program (Open Source Epidemiologic Statistics For Public Health) with a level of confidence (95%).

Sample technique:

Asystemic random sample technique was used to select the study sample. We selected day randomly, based on the interviewers' availability and the day the diabetes clinic was run, then first patient was selected randomly from six patients presented at the clinic after that we select patient every three consecutive who arrived at the clinic was approached in the waiting area. Patients who met the study inclusion criteria were asked if they were willing to participate in the study by completing the questionnaire while they were waiting to see the doctor. A total number of 266 patients were thus included in our study. .

Tools of the study:

1) Structured questionnaire: formed of two domains which were: Socio-demographic data diabetic patients, diabetic history. in Questionnaire which developed in Australia for Diabetic Foot Disease[8] and also Questionnaire of Diabetic Foot Disease and foot care develop in oman[9]were designed To better suit the Egyptian culture and the Egyptian diabetic patients, the Arabic version was modified and validated.

2) Comprehensive foot examination includes a)Assessment of dermatological status.
b)Assessment of musculoskeletal status.
c) Assessment of Neurological Status.
d) Assessment of Vascular status[10].
Pilot study: A pilot study was done on 5 - 10 % of our sample (on 13patients) to test the field of the study and tools. validity was done for the questionnaire by three experts' revision.

Fieldwork:

All patients with diabetes attending diabetic foot and vascular clinics at Zagazig university hospitals were invited and approached consecutively to participate in the study.

On the selected day, based on the interviewers' availability and the day the diabetes clinic was run, every consecutive patient who arrived at the clinic was approached in the waiting area. Patients who met the study inclusion criteria were asked if they were willing to participate in the study by completing the questionnaire while they were waiting to see the doctor. Informed oral consent was obtained from each patient before completing the questionnaire.

The number of questionnaires completed was different each day. On average each interview took 15-20 minutes to complete. When respondents were not able to complete the questionnaire during the time they were waiting for their appointment, the interview was continued after they had seen their doctor.

And also clinical examination of the foot of those patients which includes: Assessment of dermatological status(general inspection of foot should be recorded for nail dystrophy, abnormal erythema, presence of ulceration, paronychia), assessment callus or of musculoskeletal status for muscle wasting or any deformity, assessment of Neurological status using 10 grams monofilament which was put on aspects of plantar surface of heels and digits for pressure sensation testing and using for pinprick test for pain sensation and assessment of Vascular status(palpation of dorsalis pedis pulse in both feet) [10].

Administrative design:

1-Approval was obtained from the family medicine department and the ethical committee in the faculty of Medicine and Zagazig University Institutional Review Board (IRB). 2-An informed verbal consent was also obtained from every patient before filling the questionnaires.

The work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for involving studies humans. An official permission letter was obtained from the faculty of medicine at Zagazig University to the pediatric department (the title and objectives were explained to them to ensure their cooperation. They were reassured about the confidentiality strict of any obtained information, and that the study results would be used only for research. The study procedures were free from any harmful effects on the patients as well as the service provided.

Scoring system:

The patients assigned to a foot risk category once he or she will behave been assessed after a comprehensive examination of the foot as the following **[10]**:

Foot risk category:

a) Low risk (Normal plantar sensation) : category(zero).

b) Moderate risk (loss of protective sensation (LOPS)): category (one).

c) High risk (LOPS with either high pressure or poor circulation or structural foot deformities or onychomycosis): category (two).

d) Very high risk (History of ulceration, amputation or neuropathic fracture): category (three).

Data analysis:

data collection completed, After was questionnaires were translated back into English by the primary investigator. The data were entered into a Microsoft Excel Spreadsheet (Microsoft Excel 2010 program) that was prepared earlier. The data were checked for data entry errors and then rechecked against the hard copies for any other data entry errors. All identified data entry errors were corrected. And managed by using the SPSS program (statistical package for social science) version 14.0.

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Qualitative data were represented as frequencies and relative percentage and Chisquare test(x2) were used to calculate difference qualitative variables. The result measured to be significant if (P-value).was equal to or lower than 0.05.

RESULTS

Table 1 shows that the largest percentage of the studied 266 patients were males (62.8), aged less than 60 years old (62.4), had education up to level of basic and secondary school education(72.9), non-workers(28.6), married(83.1), with moderate-income (48.9)and were current smokers(71.1). Table 2 shows that the largest percentage of 266 diabetic patients had diabetes for 5 to less than 10 years and they also use oral hypoglycemic drugs. Table 3 shows that on clinical examination of the studied 266 patients, the largest percentage of these 266 patients had abnormal skin(58.6), absent sweating(54.9), fungal foot

infection(53.4), the absent sensation has done by10g monofilament test, pinprick test(60.9) and amputation(15.4). Table 4 shows that the largest percentage of our 266 studied patients had very high risk. Table 5 shows that there is a statistically significant difference between risk strata of the studied patients and their age group, gender and education (patients with basic and secondary education had a higher risk). Table 6 shows that in 266 studied patients there is a statistically significant difference between patients' risk level and their disease duration (highest percentage with low risk had DM for less than 5 years) and drug type (about 58.3% of those who had high risk used oral hypoglycemic). Table 7 shows that patients <60 years old, having diabetes for 10 years or less, being female, illiterate, read and write or had basic education were risk factors of diabetic foot.

Table 1. Distribution of the 266 studied patients according to demographic characteristics and special habits

	N (266)	º/₀
Age groups:		
<60 years old	166	62.4
\geq 60 years old	100	37.6
Gender:		
Male	167	62.8
Female	99	37.2
Education:		
Illiterate	12	4.5
Read and write	26	9.8
Basic and secondary school	194	72.9
High education	34	12.8
Occupation:		
Non worker	76	28.6
Farmer	66	24.8
Semiprofessional/professional	69	25.9
Free business	55	20.7
Marital status:		
Single	21	7.9
Married	221	83.1
Divorced	12	4.5
Widow	12	4.5
Income:		
Low	105	39.5
Moderate	130	48.9
High	31	11.6
Smoking:		
No	66	24.8
Current smoker	189	71.1
Ex-smoker	11	4.1

Table 2. Distribution of the 266 studied patients according to disease specific characteristics:

	N (266)	%
Duration:		
<5 years	91	34.2
5-10 years	153	57.5
>10 years	22	8.3
Treatment		
diet control	13	4.9
Oral drugs	168	63.2
Insulin	53	19.9
Combined oral drugs and insulin	32	12

Table 3. Distribution of the 266 studied	atients according to results of clinical examination	ation:
Tuble 5. Distribution of the 200 studied	themes decording to results of chinear examine	mon.

	N (266)	%
Skin status:		
Normal	110	41.4
Abnormal	156	58.6
Sweating:		
Absent	146	54.9
Present	120	45.1
Fungal infection:		
Absent	124	46.6
Present	142	53.4
Ulceration:		
Absent	97	34.6
Present	169	65.4
Callus:	202	
Absent	177	36.5
Present	89	63.5
Deformity:		
Absent	173	65
Present	93	35
Muscle wasting:		
Absent	171	64.3
Present	95	35.7
10g monofilament test		55.1
Absent sensation	162	60.9
Present sensation	104	39.1
Pin prick test:		57.1
Absent sensation	162	60.9
Present sensation	104	39.1
Pulsation:		
Present	266	100
Absent	0	0
Amputation :		v
No	225	84.6
Yes	41	15.4
100	11	10.1

Table 4. Distribution of the studied 266 patients according to International Diabetes Federation(IDF)

 risk stratification

	N (266)	%
Risk strata:		
Low risk	50	18.8
High risk	35	13.2
Very high risk	181	68

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	Low risk	High risk	Very high risk	Total	X^2	Р
	N=50 (%)	N=35 (%)	N=181 (%)	N (%)		
Age group:						
< 60 years old	45 (27.1)	24 (14.5)	97 (58.4)	166(62.4)	22.789	<0.001**
\geq 60 years old	5 (5)	11 (11)	84 (84)	100(37.6)		
Gender:						
Male	39 (23.4)	18 (10.8)	100 (59.9)	167(62.8)	7.199	0.027*
Female	11 (11.1)	17 (17.2)	71 (71.2)	99 (37.2)		
Education:						
-Illiterate	1 (18.3)	4 (33.3)	7 (58.4)	12 (4.5)		
-Read and write	5 (19.2)	3 (11.5)	18 (69.3)	26 (9.8)	16.772	0.01*
-Basic and secondary	31 (16)	22 (11.3)	141 (72.7)	194(72.9)		
education						
-High education	13 (38.2)	6 (17.6)	15 (44.1)	34 (12.8)		
Marital status:						
Single	8 (38.1)	0 (0)	13 (61.9)	21 (7.9)		
Married	39 (17.6)	30 (85.7)	152 (68.9)	221 (83.1)	9.368	0.154
Divorced	1 (8.3)	3 (8.6)	8 (66.7)	12 (4.5)		
Widow	2 (16.7)	2 (5.7)	8 (66.7)	12 (4.5)		
Occupation						
Not working	12 (15.8)	11 (14.5)	53 (69.7)	76 (28.6)		
Farmer	11 (16.7)	8 (12.1)	47 (71.2)	66 (24.8)	5.189	0.520
Professional/semiprofes	12 (17.4)	7 (10.1)	50 (72.5)	69 (25.9)		
sional	15 (27.3)	9 (16.4)	31 (56.4)	55 (20.7)		
Free business						
Income:						
Low	13 (12.4)	13 (12.4)	79 (75.2)	105(39.5)		
Moderate	28 (21.5)	17 (13.1)	85 (65.4)	130(48.9)	6.532	0.153
High	9 (27.3)	5 (16.1)	17 (64.8)	31(11.7)		
Smoking:						
No	15 (22.7)	11 (16.7)	40 (60.6)	66(24.8)		
Current smoker	34 (18)	22 (11.6)	133 (70.4)	189(71.1)	3.041	0.551
Ex-smoker	1 (9.1)	2 (18.2)	8 (72.7)	11(4.1)		
*** <0 001 := +++:+!=+!	1 1 • 1 1 •	·· · C · · · · · ·				

Table 5. Relation between the demographic characteristics of the studied 266 patients and their risk strata

** $p \leq 0.001$ is statistically highly significant

*p<0.05 is statistically significant

Chi-square test(x^2)

Table 6. Relation between the diabetic specific characteristics of the studied 266 patients and their risk strata

	Low risk	High risk	Very high risk	Total	X^2	Р
	N=50 (%)	N=35 (%)	N=181 (%)	N (%)		
Diabetes duration:						
< 5 years	37 (40.6)	14 (15.4)	40 (44)	91(34.2)	50.109	< 0.001**
5-10 years	13 (8.5)	20 (13.1)	120 (78.4)	153(57.5)		
> 10 years old	0 (0)	1 (4.5)	21(95.5)	22 (8.3)		
Treatment						
Diet control.	5 (38.5)	2 (15.4)	6 (46.1)	13 (4.9)		
Oral hypoglycemic	42 (25)	28 (16.7)	98 (58.3)	168 (63.2)	32.256	< 0.001**
Insulin	1 (1.9)	2 (3.8)	50 (94.3)	53 (19.9)		
Oral hypoglycemic and	2 (6.3)	3 (9.4)	27 (84.3)	32 (12)		
insulin						

**p≤0.001 is statistically highly significant

*p<0.05 is statistically significant

Chi-square test(x^2)

Table 7. Logistic regression of variables Independently associated with risk for diabetic foot among the
studied 266 patients

Variables	р	OR	95% C.I.		
			Lower	Upper	
<60 years old	0.001**	0.163	0.054	0.498	
(disease duration <5 years)	0.998	0	0		
Disease duration (5-10 years)	0.998	0	0		
Female gender	0.005*	0.286	0.12	0.684	
Illiterate	0.005*	28.91	2.698	309.83	
Read and write	0.125	3.45	0.709	16.74	
Basic and secondary school education	<0.001**	6.83	2.395	19.49	

**p≤0.001 is statistically highly significant

*p<0.05 is statistically significant

-Confidence Interval (CI). - Odds Ratio (OR).

DISSCUSION

This study showed that the majority (n=166, 62.4%) of patients were between 46-55 years. Male gender was dominating (n=167, 62.8%) with 221 (83.1%) were married. The majority of patients in 194 (72.9%) were educated but the majority (n=142, 53%) were having no job (**table 1**). Male gender

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predominance is consistent with another study done [11]. It is possible to suggest that males are more liable to foot trauma and hence they are commoner in diabetic foot ulceration. These results agree with some published studies where female gender was found to be an independent predictor of good foot self-care[12,13]. About 71.1% of the studied

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diabetic patient are smokers. These patients practice smoking which is a bad habit against the general rules of controlling diabetes mellitus, and so they do with foot care because of lack of information about the hidden risk towards disability or because they think it is much load to take care of feet. This was confirmed by another study showed that smokers had a risk for recurrent ulcers of their foot **[14]**.

Increasing diabetes duration had the greatest impact on increasing the DFU prevalence (table 2). This correlation was in agreement with several other studies [15-18]. Another study found that diabetes duration was not related to the risk of developing a foot ulcer [17]. Diabetic patients taking insulin therapy were not more likely to perform foot care activities, this result may be explained by that patient who is taking insulin have poor metabolic control, and thus are more liable for foot complications[20]. Another study showed that the patients with DFS were 4.5 times more likely to be using insulin [21]. This could be attributed to the fact that the initiation of insulin therapy implies later stages in the natural history of DM. However, in this study combination of diabetes treatment consisting of insulin and oral agents was not found to be associated with foot care. This inconsistency may be due to the low number of participants (12%)that were being treated with a combination of insulin and oral agents.

This study showed that fungal infection and ulceration of the feet were found in 53.4% and 65.4% of the studied group respectively. These findings are higher than those reported from Jordan (35% and 17%) and than what was reported by [22.23]. Callus formation in the feet increased the hazard of foot ulceration in this study (Table 3). While in other studies neuropathy was reported as a risk factor [19,24,25]. Absent peripheral pulsation was not detected in any of our patients. This is lower than that reported from Bahrain (11.8% of 1477 diabetic patients) and Jordan (13% of 1142 diabetic patients). This result less than other studies informed by Bahrain (11.8% of 1477 diabetic patients) and Jordan (13% of 1142 diabetic patients) [26,27].. These differences may be explained by difference in samples of study, assessment methods and disease duration among diabetic patients in the study.

In this study, we used the risk stratification according to IDF [10] using past diabetic history results and clinical foot examination to assess the

risk for diabetic foot (table 4) that showed the largest percentage of studied patients had a very high risk (68%). this result may be due to the limited number of patients and this study done in diabetic foot and vascular clinic where the more diabetic patient came for treatment from already presented foot complications as ulcers or infection. rarely came for follow up or health education. Amputations of the lower limb between diabetic patients can be prevented and professional foot care reached a higher level by using risk stratification of the foot which found to be effective [10]. (Table **5.6**) showed that there is a significant difference. statistically between patients risk level ,disease duration (highest percentage with low risk had DM for less than 5 years), drug type (about 58.3% of those who had high risk used oral hypoglycemic) ,age group, gender and education (patients with basic and secondary education had higher risk) this result in differing from previous study showed there were no significant differences between age, sex. foot infection history, and amputations[28]. logistic regression analysis showed that patients less than 60 years old, being females, with having diabetes for more than 10 years duration, increasing educational level were predictors risk factors of diabetic foot(table 7). These results differ from some published studies where female gender was found to be an independent predictor of good foot self-care [12,13] explained by the fact that women have similar opportunities to attain higher educational status when compared with their male counterpart[9]. Another studies consistent with our study who stated that after analysis using multiple stepwise regression- showed that level of education, diabetes duration, and using educational material about complications of the diabetic foot, are essential factors affecting the improvement of foot disease[29].

CONCLUSION

The issues of loss of protective sensation, vascular insufficiency, deformity, previous amputations, and dermatological abnormalities of the lower limbs were found to be most common among the foot ulceration patients and the largest percentage of our studied diabetic patients had a very high risk of diabetic foot complications(68%). It was significantly associated with low education status, prolonged disease duration, insulin treatment, smoking, presence of callus, fungal infections. We recommend regular foot examination, following basic hygiene habits, encouragement of the use of appropriate footwear, patient education about foot ulcers, and prompt treatment for minor injuries to prevent further ulceration in DM patients which can be done by primary care physicians and family physicians, who have better communication with patients. There were minimal constraints during the study, the illiterate patients could not answer the questionnaire and the investigator had to help them by illustrating the questions and recording their answers. Some patients refused to participate in the questionnaire. This cross-sectional study is limited and also important data of clinical measures not included in this study, such as glycated hemoglobin (A1C) although this study was a focus on care and disease of diabetic foot.

Conflict of interest: Nothing to declare **Financial disclosure**: Nothing to declare

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