

Predicting The Diabetic Foot Ulcer Risk Using Sensory Monofilament Test Among Diabetic Patients At Benha University Hospitals

Sarah Reda Shohood*, Wafaa Ismail Shrief**, Marwa Mosaad Ali***.

*Clinical Instructor –Faculty of Nursing Damanhour University, ** Medical Surgical Department-Faculty of Nursing –Mansora University. *** Medical Surgical Department, Faculty of Nursing-Benha University

Abstract

Diabetes mellitus continues to grow in global prevalence and to consume health care resources. One of the key areas of morbidity associated with diabetes is the diabetic foot. Many cohort prospective studies considered that 5.07/10g Semmes Weinstein Monofilament test is a significant predictor of loss of protective sensation, peripheral diabetic neuropathy, future ulcer and likely lower extremity amputation. **This study aimed** to predict the diabetic foot ulcer risk using sensory monofilament test. **Methods:** Quasi-experimental design was conducted at Benha University Hospitals. Purposive sample of 60 diabetic patients admitted to medical department, Benha University Hospitals with inclusion criteria: Patients' age ranges from 21-60 years, intact foot skin, exclusion criteria: Patients with diabetic foot ulcer & anticipatory reaction. Data were collected using **three tools I**"Structured Questionnaire" which includes 2 parts: part I: "Socio demographic data"& patient's life style. Part II: Medical data. Tool **II** "Neurovascular Foot Assessment Sheet" which includes 2 parts; part I "Sensory assessment sheet". Part II: "foot assessment sheet". Tool **III** "foot Ulcer Assessment Sheet" for 2nd and 3rd assessment. **Results** loss of protective sensation has increased from one quarter to more than one third after six months for RT& LT feet using sensory monofilament test, one fifth of sample were high risk group for diabetic foot, after six months. One sixth of diabetic foot ulcer risk group had foot ulcer. **Conclusion:** Semmes Weinstein Monofilament is an evidence based procedure used in identifying loss of protective sensation, diabetic neuropathy consequently diabetic foot ulcer risk. **Recommendations:** Instruct patients to use 5.07/10g nylon Semmes Weinstein Monofilament to test their feet for neuropathy & recommendations for nurses to use the test in outpatient clinics as a routine procedure.

Key words: foot ulcer, peripheral neuropathy, Sensory monofilament test, 5.07/10g Semmes Weinstein Monofilament..

Introduction

Diabetes mellitus (DM) is a medical problem with high variable prevalence among different population and constantly increases with aging. It represents one of the major challenges, which limit individual function, work capacity and affect quality of life. Despite

being a non communicable disease, currently is placed at front of public health challenges facing the world. It also consumes time, effort& cost of health care institution (Abd El Hafiez & Alan, 2013). (Donna & Linda, 2013).

Diabetes Mellitus is a chronic metabolic diseases characterized by

hyperglycemia, which is a common effect of uncontrolled diabetes and over time leads to serious damage to many of the body's systems, especially the nerves and blood vessels, due to defects in insulin secretion, or its action, or both (**World Health Organization, 2014**).

Diabetic peripheral neuropathy (DPN) is the presence of symptoms and signs of peripheral nerve dysfunction in patients with diabetes after exclusion of other causes. This condition affects 30%-50% of the patient population with diabetes and this prevalence tends to increase proportionally with the duration of diabetes. Neuropathy often presents with a loss of protective sensation, defined as a level of sensory deficit (**Alexander et al., 2014**).

Because of chronicity of disease, the incidence of complications increases among diabetic patients. Diabetic foot ulcer & amputation are the most dramatic & sometimes fatal complications of DM. These complications are the leading cause of hospitalization among diabetic patients (**Saleh et al., 2012**).

Diabetic foot problem goes to ulceration and infection due to diabetic peripheral neuropathy and loss of protective sensation (LOPS) which complicated by trauma, foot deformity, peripheral vascular insufficiency, infection, lack of diabetic foot care & failure to implement effective treatment for diabetic patient worsen the problem (**El Sayed, 2012**).

Monofilament test is a portable, inexpensive, easy to use, has no hazard accurate assessment device for the loss of protective sensation. Diabetic neuropathy can be detected using the 5.07 monofilament (this filament bends with the application of a 10-g force). Once the patient is assessed using monofilament and his response was no sensation he should be assigned to a foot risk category (**Abd El Azeem, 2013**). Therefore, this

study was conducted to determine the effectiveness of sensory monofilament test in identifying loss of protective sensation and predicting the diabetic foot ulcer risk patients.

Significance of the study

It estimated that currently 387 million people worldwide have diabetes in 2014 and this number is predicted to grow up to 592 million by the year 2035. The greatest number of people with diabetes is between 20 and 79 years (**International Diabetes Federation (IDF), 2014**). The prevalence of type 2 diabetes is growing rapidly world wide as it accounts for 90 to 95% of diabetes as a result of an aging, increasing urbanization, changes in dietary pattern, physical activity and scourge of obesity (**Kumar et al., 2016**).

Diabetes caused 4.9 million deaths in 2014 IDF estimates more than 37 million people in Middle East & North Africa region have diabetes in 2013 and by the year 2035 this will rise to 68 million (**Sherwani et al., 2016**).

Egypt is currently in the top 10 countries with the highest number of people with diabetes; it became the 9th in the global prevalence of DM with 8.5 million patients in 2017 (**World Health Organization, 2014**). Egypt is one of the 19 countries and territories of the IDF MENA Region. 425 million people have diabetes in the world and more than 39 million people in the MENA Region; by 2045 this will rise to 67 million. There were 8,222.6 cases of diabetes in Egypt in 2017. Total adult population: (54,44), Prevalence of diabetes in adults : (15.1) Total cases of diabetes in adults : (8,222.6) (**International Diabetic Federation, 2017**). Informal statistics mentioned that 8500 cases were admitted to Benha University hospitals, surgical department in 2016. Nearly, 400 case were admitted with diabetic foot ulcer.

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It is estimated that about 5% of all patients with diabetes present with a history of foot ulceration, while the lifetime risk of diabetic patients developing this complication is 15%. The majority (60–80%) of foot ulcers heal, while 10–15% of them will remain active, and 5–24% of them finally lead to limb amputation within a period of 6–18 months after the first evaluation (Alexiadou & Doupes, 2012).

Foot ulceration results in longer days of hospitalization and higher mortality rates in diabetic patients due to complication with healing failure. Somewhere in the world, a leg is lost due to diabetes every thirty seconds. It is well accepted that peripheral neuropathy is a risk factor for developing foot ulceration, thus early detection and meticulous foot care can reduce lower extremity amputation (LEA) rates by about 50-85% (Narres et al., 2017).

Several studies suggest that patient education about foot care is effective in prevention of diabetic foot ulcers. Nurses can teach patients how to perform physical examination and take care of their feet on a daily basis. For instance, nurses can encourage patients to carry out a series of simple rules in order to help prevent foot ulcers or recurrence, such as checking the shoes before wearing, keeping feet clean and continuing care of the skin and nails. Training about choosing the right shoes is essential as well (Aalaa et al., 2012).

Concerning screening role; Careful inspection of the diabetic foot on a regular basis is one of the easiest, least expensive and most effective measures for preventing foot complications. Prevention of diabetic foot ulcers begins with screening for loss of protective sensation, which is best accomplished in the primary care setting with a brief history, foot examination and the

Semmes-Weinstein monofilament
(Alexander et al., 2014).

The aim of the study

This study aimed to predict the diabetic foot ulcer risk using sensory monofilament test among diabetic patients at Benha University hospitals.

Research hypothesis was:

Sensory monofilament test is an effective method (procedure) used in identifying the loss of protective sensation and predicting the diabetic foot ulcer risk.

Subjects and methods

Research Design:

Quasi-experimental design was conducted to predict the diabetic foot ulcer risk patients using sensory monofilament test.

Research Setting:

This study was conducted in Medical Department (fifth and sixth floor) which classified into 3 wards each ward includes 6 beds, at Benha University Hospitals from December 2016 to May 2017.

Subjects:

Purposive sample of 60 patients with history of diabetes mellitus type 1 & type 2 diabetes admitted to medical department at Benha University Hospitals their feet were assessed & tested for peripheral neuropathy using sensory monofilament test based on "A sample of 60 diabetic patients were required to estimate an average accuracy of Monofilament test as a diagnostic procedure for predicting diabetic foot ulcer risk = 60.2% assuming monthly rate of new cases about 50 cases (finite

population) with precision of 10% (based on attached paper), using alpha error = 0.05 and 95% confidence level"

The sample size was calculated using STATA 11 software.

Inclusion criteria were as follow:

- Patients with: age ranges from 21-60 years old, Intact foot skin, no wound.

Exclusion criteria:

- Patients with diabetic foot ulcer, Patients with anticipatory reaction.

Tools of Data Collection:

Three tools were used to collect data -pertinent to the study- all of them filled by the investigator, those were:

✗ **Tool I "Structured questionnaire"** it was developed by the investigator to assess two aspects ; a) Socio-demographic data sheet & Patient life style sheet.

✗ b) Medical data which include: type of diabetes, duration, glycemc control (controlled or uncontrolled), treatment and any associated disease (liver, heart, respiratory, kidney & others).

Tool II "Neurovascular Foot Assessment Sheet" it was used to assess two aspects: a) **Sensory Assessment Sheet**, this tool was adopted from (Abd-El Azeem, 2013) and one item adapted by the investigator, filled by asking the patient if he felt the Monofilament or no when the investigator applying pressure by 5.07/10g Semmes-Weinstein Monofilament in both RT and LT foot. The monofilament was used to apply light pressure on seven sites of the patient's feet; The planter aspect of the first, third, and fifth toes and over the skin overlying first, third, and fifth metatarsal heads & the heel.

Scoring System:

- Score=out of (7) for each foot.
- Insensation at one site means loss of protective sensation.

b) **Foot Assessment Sheet** which includes assessment of skin condition for (callous, redness, swelling, previous ulcer, dryness, hotness and pain). Foot deformities for (hammer toes, claw toes, bony prominence, and Charcot foot). Movement for (flexion, extension and rotation). Nails for (thickness, ingrown, deformed and improperly cut). Vascular assessment for (pulses, capillary refill) and footwear assessment for (size, selected material). (Boulton et al., 2008).

Scoring System:

For skin assessment, foot deformity& nail assessment each item was assessed and scored in terms of (Yes) = (2), or (No) = (1).

While foot movement, footwear assessment& vascular assessment were scored in terms of (Yes) = (1), or (No) = (2).

Then the patient was categorized according to risk category score; intact protective sensation (0) should be seen after one year, loss of protective sensation (1) seen after 6 months, loss of protective sensation & presence of foot deformity or vascular problems (2) seen after 3 months, loss of protective sensation and/or history of planter ulcer (3) seen after 1-3 months.

Tool III "Foot Ulcer Assessment Sheet "Filled By the Investigator during Second and Third Assessment Interview: Which designed by the investigator to assess presence or absence of foot ulcer at the second assessment

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after three months or the third assessment
after six months from the first assessment
according to risk category score.

Scoring System:

Presence of ulcer scored as (Yes)
= (2) or absence of ulcer as

(No)= (1) in both right & left foot.

If foot ulcer present it was classified according to Wagner Grading System for diabetic foot infection (intact skin (0), superficial ulcer of skin or sub coetaneous tissue (1), Ulcers extended to tendons and bone (2), History of deep ulcer with osteomyelitis or abscess planter ulcer (3), Gangrene of toes or forefoot(4), gangrene of the foot(5)).

Preparatory phase

- An official approval for conducting the study was obtained from faculty of nursing Benha University.
- An official approval for conducting the study was obtained from administrative personnel of medical department Benha university hospitals.
- The study was done in medical department at Benha University to collect data of the current study during morning & afternoon shifts for six consequential months from December 2016 to May 2017.

Pilot Study:

It was conducted on 10% of study' subjects (6 patients). Needed modifications were done according to the result of pilot study. Modifications were minor so the subjects who shared in the pilot study were included in the actual sample.

Field Work

The procedure was done by the investigator:

- 1- The patient was asked to remove his footwear along with socks and a careful inspection and assessment of the feet was carried out, because inappropriate footwear and foot deformities are common contributory factors in the development of diabetic foot ulceration.
- 2- Dermatological foot assessment, foot deformities, nail assessment, foot movement, footwear and its suitability& vascular assessment were done.
- 3- The monofilament was shown to the patient and touch it to his/her hand or arm so that he/she knows it does not hurt.
- 4- The patient was asked to close his/her eyes and Monofilament was applied perpendicular to the skin surface and with sufficient force so that it bends or buckles as "C" shape. Total duration of skin contact of the filament was approximately 2 seconds.
- 5- Don't apply the filament on an ulcer site, callus or necrotic tissue.
- 6- Don't allow the filament to slide across the skin or make repetitive contact at the test site
- 7- The patient was asked to say whether he can feel the pressure applied (yes/no) and in which foot.
- 8- The monofilament was used to apply slight pressure on seven sites of the patient's feet: the planter aspect of the first, third, and fifth toes and over the skin overlying first, third, and fifth metatarsal heads& the heel.
- 9- Once the patient was assessed using monofilament and his response was no

sensation in at least one site he was assigned to be interviewed according to risk category.

Based on risk category score "12" patients were interviewed after 3 months from first assessment as they had loss of protective sensation in addition to foot deformity or vascular problems and the last cases were assigned to be seen after 6 months due to duration of data collection.

In the second and third assessment neurovascular foot assessment, assessment of foot ulcer occurrence and its degree if present were done.

Tools validity and reliability

After modification of Tool II "Neurovascular Assessment Sheet" by the investigator, these tools were examined by panel of (5) experts in the field of medical surgical nursing to measure validity of the tools and necessary modifications were done accordingly.

Reliability of Tools:

Tools were tested for its reliability using Cronbach's Alpha Coefficient Statistical test which revealed that the reliability of tool II was (0.59).

Ethical Consideration:

- An oral consent was taken from the patients before inclusion in the study.
- The aim of study was explained to subjects, confidentiality was assured through coding the data and it would be used only for the research purpose.
- The investigator emphasized that participation is voluntary and each patient have the right to withdraw from the study at any time.

Results:

Table (1) this table revealed that (78.3%) were more than 50 yrs, (58.3%) were female, regarding place of residence (76.7%) of them were from rural area. It is also illustrated that majority of them were married (80%), (41.7%) of them were illiterate and (73.3%) were not working while (25%) of them their work need prolonged standing.

Table (2) indicated that (81.7%) of patients didn't do any type of exercise, in addition (51.7%) of patients spent less than 30 minutes /day in performance of daily living activity.

Table (3) It illustrated that (73.3%&71.7%) of studied patients had intact protective sensation for RT& LT foot respectively in the first assessment (monofilament score=7), compared to (65%&66.7%) for RT& LT foot respectively in assessment after 6 months, In second assessment after 3 months, subjects were 12 according to risk category (the diabetic foot ulcer risk group).The table showed that (16.7%) of patients had intact of protective sensation for RT& LT foot, while (83.3%) RT& LT foot had loss of protective sensation (risk group) SWM score was less than (7).

Figure (1) this figure concluded that loss of protective sensation has increased from (26.7%&28.3%) to (35%&33.3%) respectively after six months for RT< feet using monofilament test.

- This figure confirms the hypotheses that monofilament test can identify LOPS and consequently diabetic neuropathy.

Table (4) it revealed that (48.3%&46.7%) of studied patients had pain in RT& LT foot respectively in the first assessment, followed by (35%) had planter hotness followed by dryness (33.3%) in RT& LT foot, compared to (51.7%&50%) for RT& LT foot respectively for pain,(35%) for hotness &

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(33.3%) for dryness in assessment after 6 months.

For second assessment the table showed that (66.7%) had RT< dryness, followed by (66.7%&58.3%) for pain RT& LT foot respectively, followed by (41.7%) for hotness.

Table (5) this table showed that (15%&13.3%) respectively of study sample had bunions in RT& LT foot in the first assessment, followed by (5%) for hammer toe. Compared to (16.7%&15%) respectively for bunions in RT& LT foot, followed by (5%) for hammer toe in assessment after 6 months.

For second assessment this table showed that (33.3%) had RT< bunions, followed by (8.3%) for hammer toe.

Table (6) it showed that (10% & 11.7%) respectively Rt & Lt of sample had delayed capillary refill in first & after 6 months assessment, while (6.7% & 15%), (8.3% & 15%) had unpalpable dorsalis pedis & posterior tibial pulse respectively after 6 months. This table confirms the hypothesis that the main reason for DFU was neurogenic not ischemic.

Figure (2) this figure concluded that (20%) of patients were at risk for diabetic foot ulcer (12 cases) in first assessment, this percentage increased to (21.7%) after 6 months.

*This figure confirms the hypotheses that sensory monofilament test can identify diabetic foot ulcer risk group.

Table (7) It revealed that; patients who had intact protective sensation (Monofilament score was 7/7) had decreased from (33.3% & 16.7%) for Rt & Lt foot respectively to (16.7% & 8.3%)

*This table confirms the hypotheses that sensory monofilament test can identify loss of protective sensation & neuropathy.

Figure (3) it revealed that; after 6 months from first assessment (16.7%) from diabetic foot ulcer risk group had superficial foot ulcer according to wagner scale for foot ulcer.

This figure confirms occurrence of diabetic foot ulcer for risk group & this enhances the hypotheses.

Section I: Socio-Demographic Characteristics

Table (1): Distribution of studied patients regarding socio-demographic characteristics.

Socio demographic characteristics	No=60	%
Age Code		
<30	4	6.7
30-50	9	15.0
>50	47	78.3
x±sd	54.06+11.19	
Gender		
Male	25	41.7
Female	35	58.3
place of residence		
Urban	14	23.3
Rural	46	76.7
Marital status		
Single	3	5.0
Married	48	80.0
Widowed	9	15.0
Educational level		
Illiterate	25	41.7
Read & write	14	23.3
Secondary	18	30.0
Baccalaureate	3	5.0
Occupation		
Not working	44	73.3
Work need prolonged standing	15	25.0
Work need prolonged sitting down	1	1.7

Table (2): Distribution of studied patients regarding patient lifestyle (exercise).

Exercise& daily living activity	No=60	%
practice any type of exercise		
NO	49	81.7
-15 minutes/ day	1	1.7
-30 minutes/ day	1	1.7
-60 minutes/ day	2	3.3
- Once/ week	4	6.7
-Twice/ week	3	5.0
Total time spent in performance of daily living activity		
>15 minutes/day	13	21.7
15-30 minutes/ day	31	51.7
30-60 minutes/ day	9	15.0
More than 60 minutes/ day	7	11.7

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Table (3): Distribution of studied patients regarding neurological foot assessment sheet.

Monofilament test score	1 st time				After 3 months				After 6 months			
	Rt		Lt		Rt		Lt		Rt		Lt	
	No=60	%	No	%	No=12	%	No	%	No=60	%	No=6	%
1.00	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	1	1.7
3.00	3	5.0	1	1.7	2	16.7	1	8.3	3	5.0	2	3.3
4.00	0	0.0	1	1.7	0	0.0	1	8.3	0	0.0	0	0.0
5.00	5	8.3	2	3.3	3	25.0	1	8.3	6	10	4	6.7
6.00	8	13.3	12	20.0	5	41.7	7	58.3	12	20	13	21.7
7.00	44	73.3	43	71.7	2	16.7	2	16.7	39	65	40	66.7

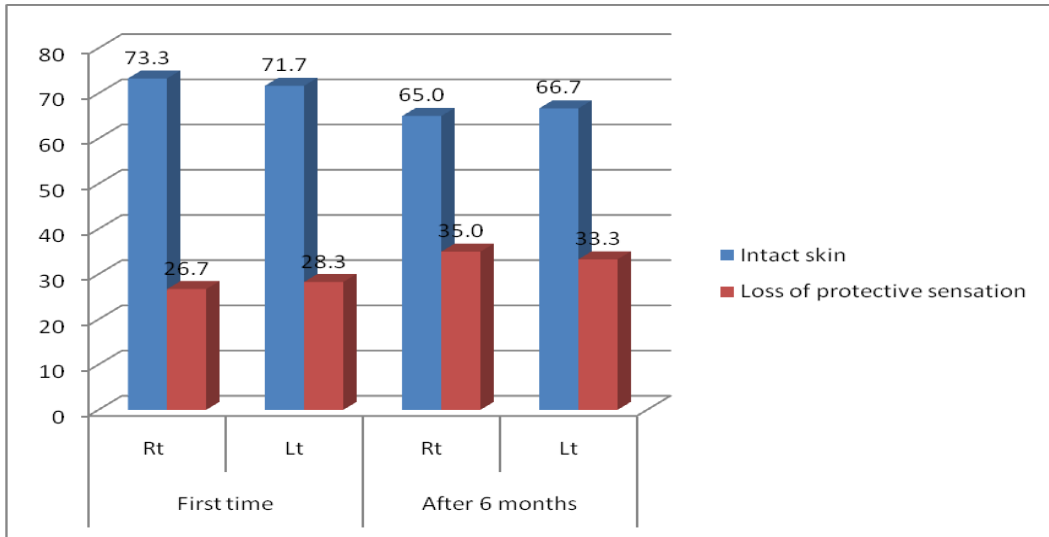


Figure (1): Distribution of studied patients monofilament score in first & after 6 months assessment.

Table (4): Distribution of studied patients regarding response (yes) for skin assessment.

Dermatological assessment	1 st Assessment				After 3 months				After 6 months			
	Rt		Lt		Rt		Lt		Rt		Lt	
	No=60	%	No=60	%	No=12	%	No=12	%	No=60	%	No=60	%
Callous	1	1.7	1	1.7	0	0.0	0	0.0	2	3.3	3	5.0
previous ulcer	1	1.7	1	1.7	0	0.0	0	0.0	1	1.7	1	1.7
Redness (2)	7	11.7	7	11.7	0	0.0	0	0.0	7	11.7	7	11.7
Swelling	6	10.0	5	8.3	2	16.7	1	8.3	10	16.7	8	13.3
Pain	29	48.3	28	46.7	8	66.7	7	58.3	31	51.7	30	50.0
Hotness	21	35.0	21	35.0	5	41.7	5	41.7	21	35.0	21	35.0
Maceration	1	1.7	1	1.7	0	0.0	0	0.0	1	1.7	1	1.7
Dryness	20	33.3	20	33.3	8	66.7	8	66.7	20	33.3	20	33.3

Table (5): Distribution of studied patients regarding response (yes) for foot deformities.

Foot deformities	1 st time				After 3 months				After 6 months			
	Rt		Lt		Rt		Lt		Rt		Lt	
	No=60	(%)	No=60	%	No=12	%	No=12	%	No=60	%	No=60	%
Hammer toes	3	(5.0)	3	5.0	1	8.3	1	8.3	3	5.0	3	5.0
Claw toe	1	(1.7)	1	1.7	0	0.0	1	8.3	1	1.7	1	1.7
Bunions	9	(15.0)	8	13.3	4	33.3	4	33.3	10	16.7	9	15.0
Charcot foot	1	(1.7)	1	1.7	1	8.3	1	8.3	2	3.3	2	3.3

Table (6): Distribution of studied patients regarding response (No) for vascular assessment.

Vascular assessment	1 st time				After 3 months				After 6 months			
	Rt		Lt		Rt		Lt		Rt		Lt	
	No=60	%	No=60	%	No=12	%	No=12	%	No=60	%	No=60	%
DorsalisPedis Pulse	4	6.7	7	11.7	3	25.0	4	33.3	4	6.7	9	15.0
Posterior Tibial Pulse	5	8.3	7	11.7	2	16.7	3	25	5	8.3	9	15.0
Capillary Refill	6	10.0	7	11.7	5	41.7	6	50	6	10	7	11.7

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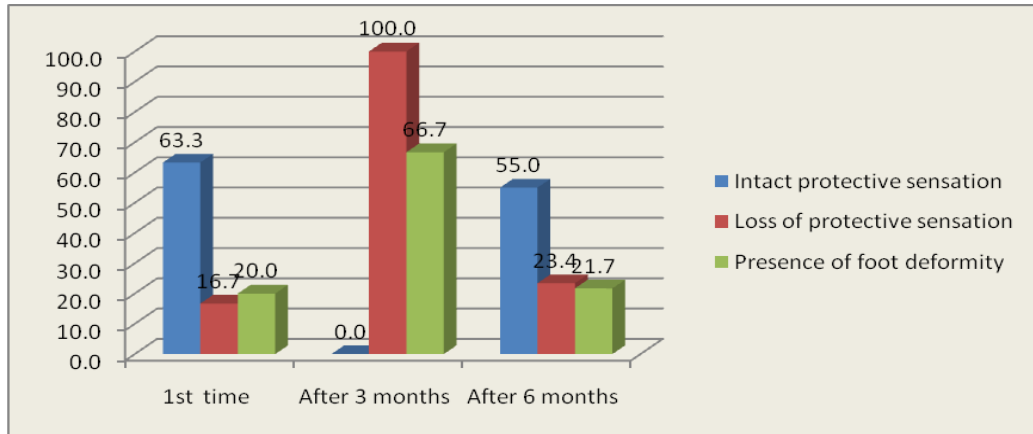


Figure (2): Frequency distribution of studied patients regarding risk category score.

Table (7): Distribution of diabetic foot ulcer high risk group regarding first, second & third neurological foot assessment.

Mon o- filam int score = (7)	1 st assessment				2 nd assessment				3 rd assessment			
	Rt		Lt		Rt		Lt		Rt		Lt	
	No=12	%	No	%	no=12	%	No=12	%	No=60	%	No=60	%
3	2	16.7	1	8.3	2	16.7	1	8.3	2	16.7	2	16.7
4	0	0.0	1	8.3	0	0.0	1	8.3	0	0.0	0	0.0
5	3	25.0	0	0.0	3	25.0	1	8.3	3	25.0	2	16.7
6	3	25.0	8	66.7	5	41.7	7	58.3	5	41.7	7	58.3
7	4	33.3	2	16.7	2	16.7	2	16.7	2	16.7	1	8.3

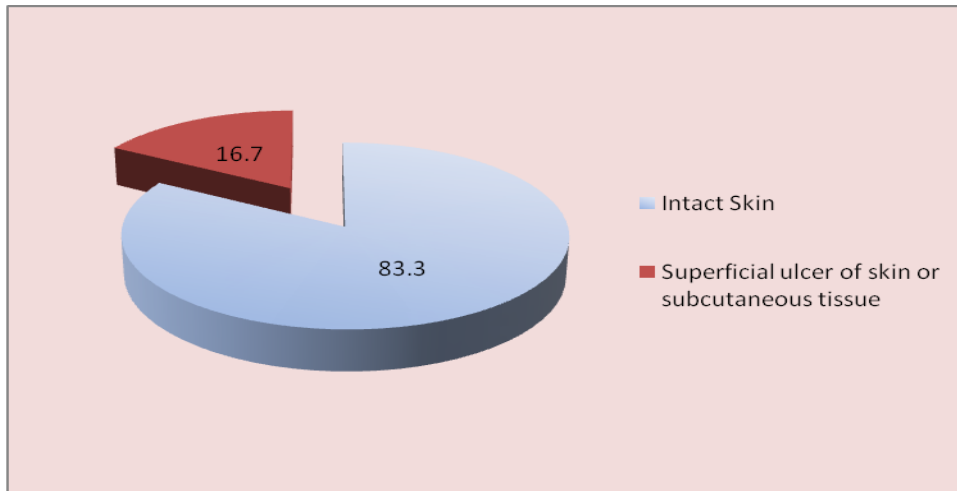


Figure (3): Distribution of studied patients regarding Maggitt-wagner scale for presence of diabetic foot ulcer in high risk group after 6 months.

Discussion

Foot ulcer is a significant complication of diabetes and often precedes lower extremity amputation. The ulcer is susceptible to infection once the wound is present, so one of the most challenges of DFU prevention depending on DFU risk identification.

The findings of this study revealed that more than three quarters of studied subjects were more than 50 years old (54 ± 11.9). This is in accordance with **Al Shabrawy (2015)** in her study about "assessment of insulin injection complications among patients with type I diabetes and suggested guide lines", this study revealed that more than half of study subjects were 50 years old. It was in contrary with **Riaz et al., (2014)** his average age was (17.9 ± 6.4).

Regarding gender results of present study, it showed that female patients represented more than half of study sample this finding was in agreement with **Allam (2017)** in her study about "Self-Efficacy Among Patients With Diabetes Mellitus", also **Rashwan (2016)**, **Hirsch(2012)** and **Mostafa (2011)** all reported that more than half of

studied patients were females but these results weren't in accordance with **Abd-El Ghaffar (2003)** who found that higher incidence was among males. These differences may be due to change in settings & most of sample were type 2 DM.

Concerning place of residence the present results revealed that more than three quarters of the study subjects were from rural, this finding was in the same line with **Alshabrawy (2015)**, **Galal (2012)** & **Abd El-Aziz (2007)** who's study revealed that more than half of their subjects were from rural areas. But this result was in contrary to finding of **Allam (2017)**, **Abd El Rohman (2017)**, **Abd El Azeem (2013)**, **Attia (2012)** & **Mostafa, (2011)** who reported that most of their subjects were living in urban area this difference may be due to difference in setting of study (this study was done at Benha university hospitals, while Abd El Azeem's study was done at National Institute of Diabetes & Endocrine Glands) in Cairo.

In relation to marital status the study showed that majority of subjects were married this finding was in agreement with **Alshabrawy (2015)** this may be due to the same setting of the study. Also, **Allam (2017)** & **Rashwan (2016)** reported majority of them were married.

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Concerning educational level, the study showed that nearly two third of the subjects were illiterate & read and write. This finding was in agreement with **Allam (2017)**, **Alshabrawy (2015)** & **Aziz (2010)** who reported in a study for clarification of association between high risk foot, retinopathy & HbA1c in Saudi Arabia that there was significant association between illiteracy and incidence of foot ulcer. This contrary with **Odume et al., (2015)** who reported that subjects with type 2 DM were found in highly educational levels rather than low educational level.

In relation to occupation the relatively high percentage nearly three quarters of patients were not working (house wife & retired) this may be due to being females more than half of studied patients & the others were retired. This finding was in accordance with **Ahmed (2017)** who found that three quarters of her subjects were not working in her study about "assessment of barriers to self-management among patients with Type 2 DM at specialized medical hospital Mansoura University". **Allam (2017)** & **Abd El Rohman (2017)** agree with that. While quarter of the studied sample's work needed prolonged standing up (teacher, grocer, cloth trader & technician". This finding was in agreement with **Stoppler et al (2016)** who said that: "injury to nerves, including prolonged pressure on a nerve or group of nerves, is a common cause of neuropathy. Decreased blood flow (ischemia) to the nerves can also lead to long-term damage" in her review about neuropathy.

Despite importance of exercise & its effect on lowering blood glucose level and reducing cardiovascular risk factor, three quarters of subjects didn't do daily or weekly exercise. This result was coordinated with **Alshabrawy, (2015)** who found that majority of patients had no exercise regimen. This may be due to cultural habits that ignore importance of exercise plus co-morbidity which lead to bed rest. This finding was consistent with many researches that denote poor physical exercise practice among diabetic patients **Ahmed,**

(2017) & **Abd El Rohman (2017), Belal (2015)**. But **Chipkin et al., (2001)** considered exercise potential to worsen neuropathy & retinopathy.

Regarding total time spent in daily living activity (DLA) half of studied subjects had spent only (15-30) minutes for routine activity which indicate short time spent in DLA this may be due to co-morbidity & age. While **Venemol et al (2013)** concluded that "repeated bouts of DLA during prolonged sedentary behavior forms a valuable strategy to improve postprandial glucose handling in patients with type 2 diabetes".

Regarding Neurological foot assessment using 5.07/10g SWM test, to test loss of protective sensation (LOPS) in 7 sites the first, third, fifth toes & its metatarsals and heel. It showed that less than three quarters of patients had intact protective sensation (IPS) for RT & LT foot in the first assessment (monofilament score =7), while the other more than quarter had LOPS (monofilament score was less than 7). This finding was in the same line with **Abd El Alzeem (2013)** who found that half of sample had IPS in her study about predicting diabetic foot ulcer using sensory monofilament test at Cairo university, also **Abd El Rohman, (2017)** found that less than two thirds of patients had weak sensation in her study about "factors affecting development of diabetic foot among diabetic patients at specialized medical hospital, Mansoura University", compared to two thirds of subjects had IPS in assessment after 6 months. This finding indicated increase risk of LOPS & their by increase risk of foot ulcer. Also the incidence of loss of protective sensation was higher in left foot.

*This result confirms the hypotheses that SWM Test can identify loss of protective sensation.

In second assessment after 3 months, subjects were 12 according to risk category. Interviewed patients were 100% risk, majority of them had loss of protective sensation for RT & LT foot (monofilament score less than 7).

Regarding dermatological foot assessment, nearly half of studied subjects had pain in RT& LT foot followed by hotness & dryness in first & after six months assessment times. This finding was agree with **Papanas et al., (2010)** who found association between elevated temperature, sudomotor dysfunction & neuropathy risk. Also **Heitzman (2010)** found in his study about foot care for patients with diabetes that dryness is significant predictor of foot ulcer.

On the other hand, **Baker & Fowler, (2007)** found that most of their subjects had callus in their study for examining the diabetic foot in general practice.

Regarding foot deformities two thirds of studied subjects had no foot deformities this result was consistent with **Abd EL Azeem (2013)** who found that majority of patients had no foot deformity. Also in this study bunions had the high percentage among foot deformities but **Michiel (2017)** said that, "bunions and hammertoes are genetic, certain shoes can make the problem worse if patients already have them but shoes won't cause them so it can't cause DFU if appropriate shoes. On the other hand, **Damir (2011)** mentioned that claw toe & hammertoe are associated with DPN.

Concerning the high risk group in second assessment they showed that bunions followed by charcot foot & hammer toe were the most appearant foot deformities but this finding was in contrary to **Michiel, (2017)** while, **Martinez et al., (2011)** in their study about biomechanics in diabetic patients ; found that there was no association between foot deformity & DPN and subsequent DFU.

Regarding risk category in relation to ulcer: in the first assessment nearly two third of subjects had IPS, while one fifth of subjects were assigned to be the risk group as they had LOPS, foot deformity & vascular problems or previous ulcer formation. After first assessment the risk group for diabetic foot ulcer was seen after three months, they were 100% at risk. After other three months, the risk increased that one sixth of the risk group had superficial foot

ulcer. This finding was in accordance with **shahbazian et al., (2013)**. Who told that increasing age, duration of diabetes & uncontrolled diabetes increases the risk of diabetic foot ulcer occurrence for risk group in their study "Risk assessment of patients with diabetes for foot ulcers according to risk classification consensus of International Working Group on Diabetic Foot", also, **Criage et al (2014)** considered monofilament a gold stander in predicting foot ulcer risk patient in their study about " foot sensation testing in the patient with diabetes: introduction of the quick and easy assessment tool, while this result was not agree with **El Nahas et al., (2009)** who found that there is no relation between foot ulcer & LOPS in Egypt, in their study about "The prevalence of risk factors for foot ulceration in Egyptian diabetic patients at Al Mansoura university hospital". This may be due to low percentage of foot ulcer occurrence (one sixth) from risk group.

*After 6 months from first assessment one sixth of risk group had foot ulcer this confirms the hypotheses that SWM test can predict diabetic foot ulcer, this result was in the same line with **Alexander et al (2014)** who said that "The Semmes-Weinstein monofilament examination, a reproducible, valid, and generalizable test of foot sensation, is recommended as the screening procedure of choice for examining diabetic feet".

Conclusion

Based on findings the study concluded that Semmes Weinstien Monofilament Test is an evidence based procedure effective in identification loss of protective sensation, diabetic neuropathy consequently diabetic foot ulcer risk. So it is very helpful in early detection of foot ulcer risk and there by early management will be conducted. This will decrease effort & cost on health care staff and institution.

Recommendation

Based on Findings of the Current Study, It is Suggested That:

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- 1- Instruct patients to use 5.07/10g nylon Semmes Weinstein Monofilament to test their feet for neuropathy.
- 2- Instruct patients with foot ulcer to follow up every month.
- 3- Development of an educational program for patients with diabetes mellitus about early detection and prevention of diabetic foot ulcer.
- 4- Provide standard guidelines about using SWMT as a routine screening test for nurses in order to enhance their practice in diabetic foot out-patient clinics.

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