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The Efficacy of Foot Reflexology on the Reduction of Peripheral Diabetic Neuropathic Pain

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Abstract

Background: *Diabetes mellitus type 2 is a progressive, degenerative condition where the longer an individual has the condition, the greater the risk of developing serious health complications* ***Aim:*** *Assess the therapeutic efficacy of foot reflexology integrated with medication on the reduction of peripheral diabetic neuropathic pain and glycosylated hemoglobin HA1C for diabetic patients.* ***Design****: quasi-experimental design with a randomized controlled two-group pretest-posttest design* ***Setting****: Outpatient Clinic for Special Medical Hospital at Mansoura University* ***Sample****: 100 patients, the sample size were calculated to be 50 subjects per group (control and study) with 95% confidence level and 90% power.* ***Tools****: Socio-demographic and medical clinical baseline data, Leeds Assessment of Neuropathic Symptoms Pain Scale (LANSS) , Douleur Neuropathies 4 Questions (DN4) Neuropathic Pain Diagnostic Questionnaire, and Brief Pain Inventory Short Form for Diabetic Peripheral Neuropathy.* ***Results:*** *the patients in both the study and the control group were in the same* ***age group*** *with a mean age (45.68±10.52) and (45.32±9.96) respectively. There was a highly statistically significant difference between pre and post intervention regarding LANSS pain scale between study group and control group with (p<0.001).* ***Conclusion:*** *This study strengthened that reflexology therapy in combination with pharmacological therapy is recommended in reducing the diabetic patients' peripheral neuropathic pain.* ***Recommendations:*** *Application of routine foot reflexology to all diabetic patients to decrease the sensation of Peripheral Diabetic Neuropathic pain.*

Keywords: *Efficacy, Reflexology, Peripheral, Diabetic, Neuropathic pain*

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I. Introduction

Diabetes mellitus type 2 (DMT2) develops because of the inability of the body to use insulin effectively, through insulin resistance or impaired pancreatic insulin production and is remarkable by increased the blood glucose levels **(Marquardt, 2007)**. World Health Organization figures reported that diabetes is on the rise, in 2014 the percentage of the worldwide adult population with the condition, diagnosed and undiagnosed, was estimated at 8.4%, 7.3% within the European region, an increase from 1980 of 4.7% and 5.3% respectively **(WHO, 2016)**. Nationally, across Wales, there has been an increase in diagnosed adults from five percent in 2004 to seven percent in 2015 **(Standfield, 2014),** and is estimated to cost ten percents of the National Health Service (NHS) budget **(Hex, et al, 2012).** Global statistics for the breakdown into specific varieties of the diabetes condition do not currently exist **(WHO, 2016)**, although type 2 is considered to account for nearly ninety percent of cases **(Zimmet, et al, 2001).** The WHO has estimated that 180 million people have DM today. The whole variety of people with diabetes and its complications are growing worldwide and is anticipated to rise to 366 million by the year 2030. The DM epidemic can partly be explained by increased average life expectancy, obesity, a sedentary lifestyle, and a changed dietary pattern. The highest increase is projected to be found in the urban population in developing countries, especially in South-Asia. Further, this part of the world features a situation where the diabetes population is relatively young (45-65 years) compared to the West (above 65 years) **(Olokoba, et al, 2012).** DMT2 is a progressive, degenerative condition where the longer an individual has the condition, the greater the risk of developing serious health complications such as cardiac dysfunction **(Jorgenson et al, 2016)**, renal failure **(Dart et al, 2012)**, retinopathy **(Jin et al, 2014)** and peripheral neuropathy **(Nisar et al, 2015)** and recent studies additionally suggests that diabetics are at increased threat of cognitive disorder. Painful diabetic neuropathy (PDN) is considered as a microvascular complication of diabetes mellitus (DM). PDN is a neuropathic pain condition characterized by severe burning pain in the feet and occasionally hands. It has widespread impacts on peoples' mobility, sleep quality and overall quality of life. The personal and societal burden associated with DM and PDN is predicted to rise as prevalence rates increase. The primary symptom of DPN a lack of sensation in the toes which extends to involve the feet and leg in a stocking

distribution. Some patients bitch about numbness and ache, however, most regularly the disease progresses insidiously and undetected. Loss of vibratory, tactile, pain and thermal perception, in addition to abnormal distal lower reflexes and pain or tingling feelings, are early signs of DPN (**Kaur, et al, 2011).**

Painful diabetic neuropathy (PDN) is a commonplace problem of diabetes and the most common reason for all neuropathic pain. About one-third of all diabetes patients suffer from PDN. The reported incidence of PDN varies from eleven percent in Rochester, Minnesota, the USA to 53.7% in the Middle East. One UK study, published in 2011, said that the prevalence of PDN was 21.5% in type 2 diabetes patients and 13.4% in type 1 diabetes patients, ensuing in a usual occurrence of twenty-one percent **(Aslam, 2014).**

Many studies have been found cardiovascular risk factors including old age, diabetes longer duration, overweight, smoking, poor glycaemic control, renal impairment, and high cholesterol to be associated with PDN. This disorder has a huge effect on people's day to day lives each physically and mentally. Despite massive advances in medicine, the treatment of PDN is both challenging for physicians and distressing for patients **(Petropoulos, et al, 2016).** Diabetic neuropathy affects 8.3% to 60% of all diabetic patients. It presents as a feeling of numbness in the symmetrical stocking-glove pattern, with the involvement of distal peripheral nerves. Because of the lack of sensation, subjects are not aware of stepping on sharp objects, having a cut or blister, or touching something too hot or cold. Complications of diabetic neuropathy include pain, ulcers, infections and amputation **(Callaghan, et al, 2012).** Reflexology is taken into consideration as a safe, non-invasive intervention **(Hull et al, 2011)**. Reflexologists believe that by using specialized techniques across reflexes in the feet, which correspond to body organs and systems, normalization of function may be achieved **(Marquardt, 2007).** Reflexology, combined with medication, has been found to have a positive effect on blood glucose levels and quality of life in diabetic adults **(Dalal et al, 2014).**

The aim of the study:
Assess the therapeutic efficacy of foot reflexology integrated with medication on the reduction of peripheral diabetic neuropathic pain and hemoglobin A1C for patients with type 2 diabetes mellitus.

Research hypothesis:
There will be a reduction of Peripheral Diabetic Neuropathic pain and hemoglobin A1C for patients with type 2 diabetes mellitus after implementing foot reflexology among study group than the control group.

II. Subjects and Methods

Research design: quasi-experimental design with a randomized controlled two-group pretest-posttest design.
Setting: The study was carried out at the Outpatient Clinic for Special Medical Hospital at Mansoura University.

Sample: a hundred patients admitted during the period of the beginning of February 2017 to end of May 2017. The sample size was calculated to be 50 subjects per group with a 95% confidence level and 90% power. The subjects were recruited purposively through random sampling and were assigned blindly to both experimental group **(receiving reflexology therapy plus guidelines on foot self-care and conventional therapy)** and control group (**guidelines on foot self-care plus conventional therapy).** Experimental groups received foot reflexology every day for 30 minutes/day for 4 months. All of the patients in both groups received pharmacological treatment of diabetes with either oral medication or insulin injection as prescribed in the treatment plan. Additionally, they were evaluated two times whiles on the study, first times before application of foot reflexology program, the second time three months after receiving the foot reflexology program.

Inclusion criteria:
Eligible people were decided for the study at primarily based on inclusion criteria such as; with type 2 diabetes whose glycosylated hemoglobin (HbA1C) ≥ 8%, and plasma glucose level ≥120mg/decilitre (fasting), received same medication during study, age ≥ 20 years, willing to applying foot reflexology for three months, and able to administer self-care.

Exclusion criteria:
Subjects with end organ damage (gangrene, toes or foot amputation) due to diabetes mellitus or any cause, open wound and skin disease on the leg, history of allergies to lotions or sensitivity to contact with the feet, and diabetic ketoacidosis will be excluded from the study. All the patients were reassessed after three months to assess the effectiveness of the intervention.

Tools of data collection:

Four tools were used for data collection they accomplished after reviewing the recent relevant literature:-

Tool (I): Socio-demographic and medical clinical baseline data:

This tool has been designed by the nursing researchers after reviewing of relevant literature. It was comprised of two parts including:-

Part I: Demographic characteristics questionnaire:

It revealed data about the following items: patient's: age, gender, marital status, level of education, occupation……etc.

Part II: Health history:

It revealed all data about the present, past health history, family history**,** and diagnostic evaluation.

Tool (II): Leeds Assessment of Neuropathic Symptoms Pain Scale (LANSS); (Self-Reported) by (Bennett, M., 2000)

The LANSS Pain Scale: the Leeds assessment of neuropathic symptoms and signs Michael Bennett The LANSS Pain Scale: the Leeds assessment of neuropathic symptoms and signs Michael Bennet This tool used to different NP from non-neuropathic pain. This tool takes half an hour to be applied and is based on the analysis of sensitivity description and on sensory deficits evaluation. Five groups of symptoms are involved, namely dysesthesia, allodynia, paroxysmal pain, autonomic changes and burning sensation at painful site. As regarding physical evaluation, two items are taken into consideration: allodynia and changes in pain threshold at needle pricking.

Scoring system:

Add values in parenthesis for sensory description and examination finding to obtain an overall score. Total score (maximum of twenty-four).

If score less than twelve, neuropathic mechanism are not likely to be a contribution to the patient's pain.

If score equal to or more than twelve, the neuropathic mechanism is likely to be a contribution to the patient's pain.

Tool (III): Douleur Neuropathies 4 Questions (DN4) Neuropathic Pain Diagnostic Questionnaire by (Bouhassira, D., et. al., 2012):-

This is a tool used to screen for Neuropathic Pain. It can be used by specialists and non-specialists. It is compromising of seven items related to symptoms and three items related to physical evaluation. Each item is scored 1 if the answer is fine and zero if poor, leading to a minimum rating of zero and a maximum of 10. The cutoff factor is 4, being that scores same to or above 4 considered NP.

Tool (IV): Brief Pain Inventory-Short Form for Diabetic Peripheral Neuropathy (BPI-DPN) by (Pain Research Group, MD Anderson Cancer Center, 1997):

This scale is used to assess the severity of pain (Severity scale), its impact on daily functioning, and other aspects of pain (e.g., the pain location, relief from medications). The BPI, including the four-item pain Severity scale (Worst Pain, Least Pain, Average Pain, and Pain Now) and the seven-item pain Interference scale (General Activity, Mood, Walking Ability, Normal Work, Relations with Others, Sleep, Enjoyment of Life). Because of the patients age and the possibility of multiple pain co-morbidities, the questionnaire was modified to differentiate between pain due to DPN and pain due to other causes, by adding the words "due to your diabetes" to all items (e.g., "Please rate your pain due to your diabetes at its worst over the past twenty four hours"). Each BPI item uses 0 to 10 numeric rating scale anchored at 0 for "no pain" and ten for "pain as bad as you can imagine" for Severity, and "does not interfere" to "completely interferes" for Interference. The 4 Severity items and the 7 Interference items can also each be averaged to form 2 composite scores, the Pain Severity Index and the Pain Interference Index.

Method:

An official permission to carry out the study was acquired from responsible authorities at the Faculty of Nursing at Mansoura University. Then, the permission becomes obtained from the hospital administrative authority. The aim of the study was described to the patients and their consent to take apart in the study was obtained. They have been additionally confident in their anonymity and the confidentiality in their responses.

Fieldwork:-

The study was done from the beginning of February 2017 to May 2017. Data were collected by the nursing researcher three days per week, during the morning shift out patient's clinic at Special medical Hospital at Mansoura University from 9 am to 2 pm. Data collection consumed four months **as follows:**

Two months from beginning of February 2017to end of March 2017 for collecting baseline date about two groups of the study (control group and study group), an application for the foot reflexology program plus foot self-care guidelines for study group, during this period the researcher educate all subjects at study group how to apply foot reflexology at home correctly and encourage them to perform it daily at least 30 minutes per day. This period considers as pre-intervention phase (pretest) by using all tools mentioned before to reveal the severity of neuropathic pain, level of HbA1C for all patients.

The other 2 months from the beginning of April 2017 to end of May 2017for evaluation of the improvement of neuropathic pain and decrease the level of HbA1C after application of foot reflexology program by using all tools mentioned before, this period consider as post-intervention phase (posttest) for two group of the study.

A pilot study was carried out on ten percents of patients. This number was excluded from the studied sample to identify the obstacles and problems that may be encountered in data collection, applicability, and feasibility of the developed tools.

Mechanism of foot reflexology:

A foot reflexology therapy has been designed to treat the patients holistically. A step-by-step procedure was followed uniformly to stimulate the subsequent reflex regions: energy balance, lymphatic system, solar plexus, adrenal glands, backbone, urinary system, digestive system, brain, other endocrine glands, sciatic nerve, knee, and hip. The researcher depends on the hypothesis that stimulations on these specific areas would establish homeostasis in the functional status of the lymphatic, urinary, digestive and immune systems together with releasing the mental stress, improving the diabetic control, and increasing the lower limb activities. By improving circulation, the body's organs receive sufficient blood supply, the adrenal gland reduces the secretion of epinephrine and norepinephrine hormones, thereby causing the blood vessels to relax as blood pressure is reduced and heart rate decelerates with decreased cortisol secretion resulting in reduced blood glucose and HbA1c.

Reflexology technique:

Firstly, the researcher explains the technique of reflexology and its therapeutic effect on diabetic neuropathy. Prepare massage tools, including wooden sticks for foot reflexology, lotion balm, two towels, and an adjustable couch. **After that,** the patient was placed in supine position and therapist position was sitting in front of the patient's. Previous to the primary techniques, trendy massages to heat changed into completed for one minute. Then, reflexology massages were performed for (the head, pituitary gland, diaphragm, lung, kidney, the solar plexus, brain, pituitary gland, spine, heart, diaphragm, liver, pancreas, adrenal gland, ureter and bladder) for the experimental groups for 10 minutes on the feet in order to re-stimulate the points affecting lower blood glucose stimulate blood circulation can reach the cellular level, thereby resulting in improved nervous and muscular system function,. The locations of the reflection points in exclusive organs have been as follows: the head changed into the bottom of the thumb upwards, within the pituitary gland become the middle pad of the thumb tip, in the diaphragm was along diaphragmatic belt, in the lung was along horizontal lines of the fingers and in the kidneys was inside the edge of large pad under the thumb.

Stimulations are performed in the form of mechanical pressure and relaxation on a particular reflex area by fingers of both the hands of the researcher. The fingers of one hand were used for producing stimulations and the other one for containing the foot firmly towards the utility of strain with tolerable tenderness turned into used to generate simulations. The areas were lubricated with lotion prior to applying stimulation in order to avoid any adverse effect on the skin due to friction. Each reflexology region was stimulated (average) fifteen times of ten minutes duration per session with the understanding that stimulations on particular reflex areas < ten times did not produce any therapeutical impact and an RA would be over stimulated with non-stop stimulations > twenty times. One therapy session took half hour duration of fifteen minutes for each foot, and there were two therapy sessions per day.

Steps of foot reflexology:

- The researcher placed hands on the medial and lateral aspects of the metatarsal bones then applied a rapid back and forth movement of the foot. This movement was performed several times for right and left foot and loosening the ankle.
- After that place hands under the patient's ankle, and applied a firm pressure on the ankle then applied a rapid back and forth movement of the ankle several times for right then for left ankle. Relaxing the toes using the holding hand.
- The researcher placed the thumb on the plantar surface and the index and middle fingers on the dorsal surface while the other hand placed the thumb on the plantar surface, the rest of fingers on the dorsal surface down to the base of the toe, then lifted the toe gently then rotated the toe in a curricular motion both clockwise and counterclockwise then wringing the foot.

- By placing the thumbs on the plantar surface and the other fingers on the dorsal surface, researcher lifted the metatarsal bones gently then rotated them in a curricular motion both clockwise and counterclockwise followed by a spinal twist.
- With hands next to each other on the lateral aspect of the foot, both thumbs on the plantar aspect of the foot and other fingers on the dorsal aspect of the foot, researcher twisted gently back and forth with the hand closer to the toes, the other hand holds the foot stationary and metatarsal kneading. With a hand placed just beneath the toes in the dorsal aspect and the other hand made a fist on the plantar aspect of the foot, researchers applied gentle squeeze under the toes then released the press but still maintained the hand contact.
- Finally, the researcher grasped the toes by one hand, the thumb on the plantar aspect of the toes and the remaining fingers on the dorsal aspect of the foot, the other hand applied pressure by the thumb walking. The pressure was depending on the pain tolerance of the patient; this movement repeated several times rhythmically on right then for the left foot.

Statistical analysis:

Data entry and statistical evaluation have been finished using SPSS 20.0 statistical software packages. In order to assess the independent predictors of the scores of knowledge, practice, and self-care efficacy, multiple linear regression analysis changed into used and analysis of variance for the full regression models done. Statistical significance has been considered at p-value <0.05.

III. Results

Part I: Sociodemographic Characteristics of the studied sample:

Table (1): Frequency distribution of Patients with DM According to Their Socio-Demographic Characteristics (No=100):

	Study(n=50)		**Control(n=50)**		**P. value**
	No.	**%**	**No.**	**%**	
Age	45.68±10.52		45.32±9.96		0.861
sex					
Male	22	44.0	17	34.0	0.206
Female	28	56.0	33	66.0	
Marital Status					
Single	2	4.0	1	2.0	0.480
Married	41	82.0	43	86.0	
Widow	5	10.0	6	12.0	
Divorced	2	4.0	0	0.0	
Educational level					
Illiterate	23	46.0	23	46.0	1.000
Read And Write	11	22.0	11	22.0	
Primary	0	0	0	0	
Secondary	12	24.0	12	24.0	
University	4	8.0	4	8.0	
Occupation					
Worker	18	36.0	13	26.0	0.851
Employee	3	6.0	3	6.0	
House Wife	20	40.0	25	50.0	
Farmer	7	14.0	7	14.0	
Not Working	2	4.0	2	4.0	
Income					
Sufficient	0	0.0	3	6.0	0.121
In sufficient	50	100	47	94.0	
Residence					
Rural	34	68.0	34	68.0	0.585
Urban	16	32.0	16	32.0	
Health insurance					
Yes	0	0.0	3	6.0	0.121
No	50	100	47	94.0	
Disease Duration					
Less than 1 yr	4	8.0	4	8.0	0.911
from1-<5yrs	11	22.0	14	28.0	
From 5<10yrs	27	54.0	28	48.0	
More than > 10yrs	8	16.0	8	16.0	

Table (I): illustrates that the patients in both the study and the control group were in the same **age group** with a mean age (45.68±10.52) and (45.32±9.96) respectively. With regard to **sex,** (56.0%) of the study group and (66.0%) of the control group were female. (82.0%& 86.0) of the study and control groups respectively were

married. (46.0%) of the study group and control group were illiterate with the same percent. (40.0.0%& 50.0%) of the study and control groups respectively were housewives as more than half of patients were female. Regarding residence, (68.0%) of study and control group were from rural areas and (100.0% and 94.0%) of the study and control group respectively had insufficient **income.** In relation to **health insurance,** (100.0% &94.0%) of the study and control group haven't health insurance. Concerning **disease duration**, (54.0%& 48.0%) of the study and control groups respectively had disease duration from 5 years to less than 10 years

Table (2): Frequency Distribution of Patients with DM According to Their Medical History (No=100):

	Study(n=50)		**Control(n=50)**		**P.value**
	No.	**%**	**No.**	**%**	
Treatment					
Insulin	32	64.0	29	58.0	0.803
Tablet	14	28.0	17	34.0	
Both of them	4	8.0	4	8.0	
Diabetic Complication					
hypertension	39	78.0	39	78.0	0.595
Retinopathy	18	36.0	20	40.0	0.418
Neuropathy	50	100.0	50	100.0	------
Delayed wound	0	0.00	0.0	0.00	----
Nephropathy	2	4.0	0	0.00	0.247
Ulcer	0	0	0	0	-----
Diabetes foot	0	0	0	0	0
Ketoacidosis	0	0	0	0	0
Family History					
First Degree	7	14.0	5	10.0	0.380
Non	43	86.0	45	90.0	

Use Pearson chi-square (crosstabs test). *=Significant difference, *p≤0.05 **= highly significance , *p≤0.01 Ns= Non significant difference

Table (2) shows that (64.0%& 58.0%)) of the study and control group respectively administered insulin as a line of treatment of DM, where both groups of studied sample suffering from neuropathy as a complication of DM with the same percent (100.0%).

Table (3):- Comparison between Study Group and Control Group Pretest and Posttest According to Diagnostic Evaluation (N=100).

Diagnostic Evaluation	**Study(n=50)**				**Control(n=50)**				**P.value**
	Pretest		**Posttest**		**Pretest**		**Posttest**		
	No.	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**	
Fasting Blood Glucose									
126mg/dL or higher	50	100	36	72.0	50	100	46	92.0	0.009**
125-100mg/dL	0	0	14	28.0	0	0	4	8.0	
Lower than 100 mg/dL	0	0	0	0	0	0	0	0	
Random Blood Glucose									
200 mg/dL or higher	50	100	34	68.0	50	100	47	94.0	0.001**
140–199 mg/dL	0	0	16	32.0	0	0	3	6.0	
Lower than 140 mg/dL	0	0	0	0	0	0	0	0	
HA1C									
6.5% or higher	50	100	24	48.0	50	100	44	88.0	0.001**
5.7–6.4%	0	0	26	52.0	0	0	6	12.0	
Lower than 5.7%	0	0	0	0	0	0	0	0	

Table (3): shows that there was a highly statistically significant difference between pretest and posttest in the study group and control group regarding the investigation of fasting blood glucose level with (p≤ 0.009), random blood glucose with (p<0.001) and HA1C with (p<0.001).

Table (4): Comparison Between Study Group and Control Group Pretest and Posttest According to The Leeds Assessment of Neuropathic Symptoms and Signs (LANSS Pain Scale) (N=100)

LANSS pain scale	**Study(n=50)**				**p.1**	**Control(n=50)**				**P2**	**P3**
	Pretest Yes		**Posttest Yes**			**Pretest yes**		**Posttest Yes**			
	No	**%**	**No**	**%**		**No**	**%**	**No**	**%**		
A. pain questionnaire											
Your pain feel like strange, unpleasant sensation in your skin	47	94	**20**	40	0.001**	50	100	**41**	82	0.001**	0.001**
Your pain make the skin	25	50	13	2	0.01*	19	38.0	17	34	0.41n	

in the painful area look different from normal.				6						s	0.5ns
Your pain make the affected skin abnormally sensitive to touch	50	100	**23**	46	0.001**	34	68.0	**33**	66	0.500	0.03*
Your pain come on suddenly and in bursts for no apparent reason when you're still	39	78	**15**	30	0.001**	33	66.0	**30**	60	0.33	0.002**
Your pain feel as if the skin temperature in the painful area has changed abnormally	31	62	14	28	0.00**	25	50.0	22	44	0.34ns	0.07 ns
B. Sensory testing											
Yes ,allodynia in painful area only	50	100	**21**	42	0.001**	50	100	**39**	78	0.00**	0.001**
Yes altered pin –prick threshold in painful area	50	100	**23**	46	0.001**	50	100	**40**	80	0.00**	0.001**

Use Pearson chi-square (cross tabs test). *=Significant difference, *p≤0.05 **= highly significance , *p≤0.01 Ns= Non significant difference

- **P1:** comparison between pre and post intervention regarding LANSS pain scale for the study group
- **P2:** comparison between pre and post regarding LANSS pain scale control group
- **P3:** comparison between pre and post regarding LANSS pain scale for study and control groups.

Table (4): shows that there was a highly statistically significant difference between pre and post intervention regarding LANSS pain scale for study group with (p<0.001) & there was a highly statistically significant difference between pre and post intervention regarding LANSS pain scale for control group with (p<0.001) regarding sensory test and only one question of LANSS Pain Scale test. There was a highly statistically significant difference between pre and post intervention regarding LANSS pain scale between study group and control group with (p<0.001).

Table (5):- Comparison of Total the Leeds Assessment of Neuropathic Symptoms and Signs (LANSS) for studied group pretest and posttest

LANSS pain scale	**Study(n=50)**				**Control(n=50)**				**P1**	**P2**	**P3**
	Pretest yes		**Posttest yes**		**Pretest yes**		**Posttest yes**				
	No	**%**	**No**	**%**	**No**	**%**	**No**	**%**			
suggest that it is improbable that pain has neuropathic origin	1	2	30	60	0	0	12	24	0.00	0.00	0.500 Ns
mean that neuropathic mechanisms would be involved in the patient's pain	49	98	20	40	50	100	38	76			0.001**

Use Pearson chi-square (crosstabs test). *=Significant difference, *p≤0.05 **= highly significance , *p≤0.01 Ns= Non significant difference,p>0.05

- **P1:** comparison between pre and post intervention regarding LANSS pain scale for the study group
- **P2:** comparison between pre and post regarding LANSS pain scale control group
- **P3:** comparison between pre and post regarding LANSS pain scale for study and control groups.

Table (5): shows that there was a highly statistically significant difference between pre and post intervention regarding LANSS pain scale of study group with (p<0.001) & there was highly statistically significant difference between pre and post regarding LANSS pain scale control group with (p<0.001) and there was highly statistically significant difference between pre and post regarding LANSS pain scale study and control groups with (p<0.001) but in **first question** there was no statistical significance difference.

Table (6):- Comparison Total the Leeds Assessment of Neuropathic Symptoms and Signs (LANSS) for studied group pretest and posttest (N=100)

LANSS pain scale	**Study(n=50)**		**Control(n=50)**		**P.value**
	Pretest	**Posttest**	**Pretest**	**Posttest**	
	Mean ±SD	**Mean ±SD**	**Mean ±SD**	**Mean ±SD**	
LANSS pain scale	20.38±3.22	9.04±8.11	18.76± 2.05	15.72±6.08	.0001**

(Independent t-test). *=Significant difference, *p≤0.05 **= highly significance , *p≤0.01 Ns= Non significant difference P>0.05

Table (6): shows that there was a highly statistically significant difference between pre and post intervention regarding LANSS pain scale mean and standard deviation between study group and control group with (p<0.0001)**.**

Table (7):- Comparison Douleur neuropathic pain for studied group pretest and posttest (N=100)

Douleur Neuropathies 4 Questions (DN4)	**Study(n=50)**				**Control(n=50)**				**P1**	**P2**
	Pretest		**Posttest**		**Pretest**		**Posttest**			
	No.	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**		
Does the pain have one or more of the following characteristics?										
Burning									0.00**	0. 109
Yes	50	100	**16**	32	25	50	**23**	46		
No	0	0.0	**34**	68	25	50	**27**	54		
Painful cold									0.00**	0.026
Yes	50	100	21	42	13	26	11	22		
No	0	0.00	29	58	37	74	39	78		
Electric shocks									0.00**	0.000
Yes	50	100	**17**	34.0	0	0.0	**0**	0.0		
No	0	0.00	**33**	66.0	50	100	**50**	100		
Is the pain associated with one or more of the following symptoms in the same area?										
Tingling									0.00**	0.000**
Yes	50	100	**23**	46.0	50	100	**45**	90.0		
No	0	0.00	**27**	54.0	0	0.0	**5**	10.0		
Pins and needles									0.00**	0.000
Yes	50	100.0	20	40.0	50	100	40	80.0		
No	0	0.00	30	60.0	0	0.0	10	20.0		
Numbness									0.00**	0.000**
Yes	50	100.0	**22**	44.0	50	100	**42**	84.0		
No	0	0.00	**28**	56.0	0	0.0	**8**	**16.0**		
Itching									0.00**	0.003**
Yes	37	74.0	**11**	22.0	29	58	**25**	50.0		
No	13	26.0	**39**	78.0	21	42	**25**	50.0		
Is the pain located in an area where the physical examination may reveal one or more of the following characteristics?										
Hypoesthesia to touch									0.001**	0.158
Yes	37	74.0	**20**	40.0	30	60	**26**	52.0		
No	13	26.0	**30**	60.0	20	40	**24**	48.0		
Hypoesthesia to pinprick									0.00**	0.00
Yes	50	100	**19**	38.0	50	100	**40**	80.0		
No	0	0.00	**31**	62.0	0	0.0	**10**	20.0		
In the painful area, can the pain be caused or increased by										
Brushing?									0.00**	.000
Yes	50	100	**23**	46.0	50	100	**40**	80.0		
No	0	0.0	**27**	54.0	0	0.0	**10**	20.0		

Use Pearson chi-square (cross tabs test). *=Significant difference, *p≤0.05 **= highly significance , *p≤0.01 Ns= Non significant difference.

- **P1:** comparison between study group pre-post intervention regarding Douleur neuropathic pain
- **P2:** comparison between the study group and control per-post intervention regarding Douleur neuropathic pain

Table (7): shows that there was a highly statistically significant difference between study group pre-post intervention regarding Douleur neuropathic pain with (p<0.000). There was highly statistically significant difference between study group and control per-post intervention regarding Douleur neuropathic pain with (p<0.000) except for Burning and Hypoesthesia to touch there was no significance with (p<0.109) and (p<0.158) respectively.

Table 8: Total Douleur Neuropathies for studied group pretest and posttest:

Douleur Neuropathies	**Study(n=50)**		**Control(n=50)**		**P1**	**P**
	Pretest	**Posttest**	**Pretest**	**Posttest**		
	Mean ±SD	**Mean ±SD**	**Mean ±SD**	**Mean ±SD**		
Douleur Neuropathies	9.48±.504	3.84±3.106	6.94±1.462	5.84±2.485	0.00**	.001 **

Independent t-test used for this comparison *=Significant difference, *p≤0.05 **= highly significance , *p≤0.01 Ns= Non significant difference P>0.05

Table (8): shows that there was a highly statistically significant difference between pre and post intervention regarding Douleur neuropathic pain mean and standard divisions for study group with (p<0.00) & there was a highly statistically significant difference between pre and post intervention regarding Douleur neuropathic pain mean and standard divisions for control group with (p<0.001)**.**

Table (9):- Comparison Brief Pain Inventory-Short Form for Diabetic Peripheral Neuropathy for studied group pretest and posttest (N=100)

Brief Pain Inventory Short Form	**Study(n=50)**		**Control(n=50)**		**P1**	**P2 value**	**P3**
	Pretest	**Posttest**	**Pretest**	**Posttest**			
	Means ±DS	**Means ±DS**		**%**			
Please rate your pain by circling the one number that best describes your pain at its worst in the last week.	8.48±.93	5.72±2.39	7.82±0.77	7.26±1.33	.000**	.012	*0.00.*
Please rate your pain by circling the one number that best describes your pain at its least in the last week	7.46±.67	5.16±2.10	7.26±1.08	6.94±1.49	.000**	.222	*0.00.*
Please rate your pain by circling the one number that best describes your pain on the average.	5.00±.00	3.54±1.63	6.22±.91	5.98±1.23	.000**	.272	*0.00.*
Please rate your pain by circling the one number that tells how much pain you have right now.	8.50±.76	5.90±2.39	7.82±.82	7.06±1.64	.000**	.004	.006
In the last week, how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.	35.60± 16.43	44.58± 16.45	39.20± 20.28	41.80±20.37	.000**	.524	.455
pain has interfered with your: A. General Activity	9.00±.00	6.62±1.80	9.00±.00	8.44±1.18	.000**	.001	*0.00.*
B. Mood	6.94±1.87	5.10±2.25	7.52±1.2	7.10±1.51	.007**	.130	*0.00.*
C. Walking Ability	8.26±1.36	5.86±2.17	8.26±.82	7.80±1.26	0.00**.	.034	*0.00.*
Normal Work (includes both works outside the home and housework(	8.00±.000	5.74±1.86	6.90±1.29	6.46±1.65	0.00**.	.142	.044
E. Relations with other people	5.92±1.68	4.34±2.14	6.14±1.47	5.82±1.49	0.00**.	.283	0.00**.
F. Sleep	6.80±1.01	4.84±2.18	6.22±1.32	5.68±1.88	0.00**.	.102	.043
G. Enjoyment of life	9.00±.000	6.22±1.84	7.00±.00	6.30±1.51	0.00**.	.002	.813

- **P1:** comparison between pre and post intervention regarding Brief Pain Inventory-Short Form for the study group
- **P2:** comparison between pre and post regarding Brief Pain Inventory-Short Form for the control group
- **P3:** comparison between pre and post regarding Brief Pain Inventory-Short Form study and control groups

Independent t-test used for this comparison *=Significant difference, *p≤0.05 **= highly significance , *p≤0.01 Ns= Non significant difference P>0.05

Table (9): shows that there was a highly statistically significant difference between pre and post intervention regarding the Brief Pain Inventory-Short Form for Diabetic Peripheral Neuropathy for studied group pretest and posttest.

Table (10):- Comparison Brief Pain Inventory Short Form (total) for Diabetic Peripheral Neuropathy for studied group pretest and posttest

Brief Pain Inventory Short Form	Study(n=50)		Control(n=50)		P1	P.value
	Pretest	Posttest	Pretest	Posttest		
	Mean ±SD	Mean ±SD	Mean ±SD	Mean ±SD		
Pain	118.96±17.60	103.62±20.86	119.36±20.28	116.64±19.57	.916	.002**

Independent t-test used for this comparison *=Significant difference, *p≤0.05 **= highly significance , *p≤0.01 Ns= Non significant difference

Table (10): shows that there was a highly statistically significant difference between pre and post intervention regarding Brief Pain Inventory Short Form (total) for Diabetic Peripheral Neuropathy for studied group pretest and posttest.

IV. Discussion

The current study results discovered that; the patients in both the study and the control group have the same **age group** with a mean age (45.68±10.52) and (45.32±9.96) respectively. Regarding **sex,** more than half of the study group and control group were female. The majority of the study and control groups were married. Nearly half of the study group and control group were illiterate, housewives. Regarding residence, more than two-thirds of the study and control group were living in rural areas and the majority of study and control group patients had insufficient income and haven't health insurance. Concerning the **disease duration**, more than half of patients in the study group and nearly half of patients in the control groups respectively complaining from diabetes five years to less than ten years ago.

(Tawfik, et al, 2017) was in the same line regarding the age of patients as they mentioned that" regarding the physical characteristics of all patients in both Groups (A & B), the age of patients in the Group (A), ranged from forty-five to fifty-five years with a mean value of (49.8±0.83yrs.). And, the age of patients in the Group (B), ranged from forty-five to fifty-five years with a mean value of (50.93 ± 0.93yrs). The differences concerning age between women of both Groups (A & B) before starting the study were found to be statistically non-significant (p>0.05)".

Also, (**Dalal, et al, 2014**) were agreeing with the study results as they mentioned that "The age (mean ± SD), gender ratio (male: female), the duration of diabetes mellitus [median (range)] and the duration of neuropathy [median (range)], for reflexology group (n = 29) were 56.8 ± 9.7 years; sixteen: thirteen; ten (3–28) years; 5 (1–14) years, respectively. The respective values for control group (n = 29) were 55.9 ± 11.2; fifteen: fourteen; thirteen (4–30); 6 (2–8)".

Additionally (**Mostafa, et al, 2018**) were on the same line as they mentioned that" more than one-third of patients in the study and control group their age was 40- 50 years. Regarding sex, it was found that the highest percentages in both groups (study and control) were female. Regarding marital status, it was found that the highest percentages in both groups (study and control) were married. Regarding education, it was found that more than one-third of the study group was secondary educated while one-third of the control group was not educated. Regarding occupation, it was found that the highest percentages in both groups (study and control) were housewives".

But **(da Silva, et al, 2015)** were disagreeing with the study results regarding the patients' age as reported that "It was found that in the Treated Group, sixty-five percent of participants were female with an average age of sixty-three years old, In the Control Group, sixty-two percent were women, whose average age was sixty years old,. Regarding these variables and those related to race, marital status, education, occupation, smoking, alcohol intake, physical activity, the presence of other chronic disease or presence of acute disease and type of treatment for diabetes mellitus, significant differences were observed between the groups".

More than half of patients in the study and control group administered insulin as a line of treatment of DM, where both groups of studied sample suffering from neuropathy as a complication of DM with the same percent (hundred percent). **(Munshi,2018)** was in the same line as mentioned that "More than half of patients of the study and control group administered insulin as a line of treatment of DM, where all patients at both groups

of studied sample suffering from neuropathy as a complication of DM. Insulin can be considered as preliminary therapy for patients with kind 2diabetes, mainly patients offering with A1C >9 percentage (74. 9 mmol/mol), fasting plasma glucose >250 mg/dL (13.9 mmol/L), random glucose constantly >300mg/dL (16.7 mmol/L), or ketonuria. Because of the subject for hypoglycemia, a few clinicians use insulin most effective for a brief time to counter glucose toxicity. Once insulin sensitivity is restored, the dose may be decreased or changed with metformin or some other oral hypoglycemic agent with a decreased hazard of hypoglycemia".

There was a highly statistically significant difference between pretest and posttest in the study group and control group regarding the investigation of fasting blood glucose level with ($p\leq 0.009$), random blood glucose with ($p<0.001$) and HA1C with ($p<0.001$). **(Gunter, 2017)** was in the same line as mentioned that "Findings, therefore, suggest that regular reflexology treatments in conjunction with conventional medication may decrease blood glucose levels in diabetics with neuropathic pain".

The current study revealed that there was there was highly statistically significant distinction among pre and post-intervention regarding Brief Pain Inventory-Short Form for Diabetic Peripheral Neuropathy for studied group pretest and posttest. **(Devi and Venkatesan, 2018**) were in the same line as they mentioned that" The present study assessed the effectiveness of foot reflexology on peripheral neuropathic pain. The intervention method was used i.e. foot reflexology reduced the level of peripheral neuropathic pain of diabetes patients. The patients have expressed that their pain has been somewhat reduced. A significant level of learning took place among subjects regarding the benefits of foot reflexology and precaution to be taken during the intervention. The study found that in the experimental group, an initial assessment, 14(46.7%) had moderate pain, 15(50.0%) had severe pain and 1(3.3%) had very severe pain. After the intervention, 30(100%) of diabetes patients had mild pain. In the control group, an initial assessment, 21(70%) of the diabetes patients had moderate pain and 9(30%) had severe pain. On second observation 24(80%) of the diabetes patients had reported moderate pain and 6(20%) had severe pain. Hence, the foot reflexology is found to be effective and it can be used in the hospitals among patients with diabetes, to reduced peripheral neuropathic pain".

There was a highly statistically significant difference between study group pre-post intervention regarding Douleur neuropathic pain with ($p<0.000$). There was highly statistically significant difference between study group and control per-post intervention regarding Douleur neuropathic pain with ($p<0.000$) except for Burning and Hypoesthesia to touch there was no significance with ($p<0.109$) and ($p<0.158$) respectively. **(Devi, and Venkatesan, 2018)** reported that" The results revealed that the foot reflexology is effective on peripheral neuropathic pain among diabetes patients".

V. Conclusion

- There was a highly statistically significant difference between pretest and posttest in study group and control group regarding the investigation of fasting blood glucose level, random blood glucose, and HA1C.
- There was a highly statistically significant difference between pre and post intervention regarding LANSS pain scale mean and standard deviation between the study group and control group.
- There has been an enormously statistically widespread difference among pre and post-intervention regarding Brief Pain Inventory-Short Form for Diabetic Peripheral Neuropathy for studied group pretest and posttest.
- There was a highly statistically significant difference between study group per-post interventions regarding Douleur neuropathic pain.
- This study verified thatreflexology therapy further to pharmacological remedy may be endorsed in lowering the peripheral neuropathic pain in diabetic sufferers.

VI. Recommendations

Replication of the same study on larger probability sample at different geographical locations for data generalizability. Application of routine foot reflexology to all diabetic patients to decrease the sensation of Peripheral Diabetic Neuropathic pain.

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