Effect of Foot Reflexology Massage on Pain and Anxiety Levels regarding Insulin Injection among Diabetic Children

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Abstract

Background: Anxiety and pain from insulin injections are frequent side effects. Therefore, controlling injection pain aids in reducing anxiety and subsequent health care avoidance behaviors. Foot reflexology massage appears to be useful in decreasing pain and stress as a complementary care that is becoming widely accepted and popular. **Aim**: This study aimed to evaluate the effect of foot reflexology massage on pain and anxiety levels regarding insulin injection among diabetic children. **Design:** A quasi-experimental research design was used to conduct this study. **Setting:** The study was carried out at Pediatric Endocrine Department at Mansoura University Hospital **Subjects and method:** A purposive sample of 100 diabetic children who receiving insulin injection were recruited in this study; the studied children were assigned into two groups, with 50 children in each group (the study and control groups). **Tools:** Three tools were used to collect data: **Tool (1):** A structured interviewing questionnaire. **Tool (II)**: Numeric Pain Rating Scale (NPRS), and **Tool (III):** State-Trait Anxiety Inventory for Children (STAIC). **Results:** The present study revealed that more than half of diabetic children in the study group had mild pain compared to only (8%) in the control group after insulin injection. Moreover, there were highly statistical significant differences post foot reflexology massage among the studied diabetic children regarding anxiety level on STAIC between the study and control groups. **Conclusion**: Foot reflexology massage has an effect on pain and anxiety reduction regarding insulin injection among diabetic children. **Recommendation**: Foot reflexology massage could be applied as a non-pharmacological method and complementary therapy along with routine care to manage insulin injection pain and anxiety among diabetic children.

Keywords: Anxiety, Diabetic children**,** Foot reflexology massage, Insulin injection, Pain.

Introduction

One of the most prevalent chronic diseases in children is type 1 diabetes (T1D), it is an autoimmune disease characterized by progressive pancreatic beta-cell loss resulting in insulin deficiency and hyperglycemia **(Patterson et al., 2019).** The incidence rate of childhood T1D has risen worldwide by 2.8% - 4.0% each year in the past decades. The overall increase in the incidence is around 3% where, globally 78000 children under age 15 years develop T1D **(Mahfouz 2018)**. Approximately 0.25%, that is, around 208 000, of children and adolescents in the world are affected by it. Moreover, the prevalence rate of juvenile diabetes mellitus among school age children in Menoufia governorate was 3.75/1000 **(Hassan et al., 2019).** However, there are few epidemiological studies concerned with T1D in Egypt due to lack of diabetes registries and suboptimal identification of new cases **(Arafa and Alwakeel 2020)**.

Type 1 diabetes management is challenging and complex, requires considerable self-care practices such as frequent daily blood glucose monitoring, injecting insulin around 4 times daily and venipuncture. A needle replacement is necessary at least every two to three days when the child is being treated with an insulin pump, regulating food intake and counting carbohydrate, calculating insulin doses are also necessary. Moreover, the international recommendations also advise performing venipuncture once a year to check blood lipids, thyroid function, and kidney function for the patients of Type 1 diabetes **(Hanberger et al., 2021).**

Pain and anxiety associated with needle procedures especially insulin injections are common in children and adolescents with type 1 diabetes and particularly children are concerned about needle pain. According to the International Association for the Study of Pain, the definition of pain is unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage. It has adverse effects on the body functions, social and psychological well-being. Needle fear and anxiety commonly appears in early childhood, but decreases with age, with a prevalence of 20%–50% in adolescents **(McLenon and Rogers 2019).** According to research, 32% of parents of children with diabetes aged 6 to 17 said that their child was afraid of getting shots **(Cemeroglu et al., 2015).** Pain and anxiety associated with blood-sampling and/or insulin injection carry the risk of disrupting diabetes self-care ability in children and adolescents. Such as avoidance of insulin injections that lead to higher glycated haemoglobin (HbA1c) values and missed insulin doses as well as avoiding blood glucose readings, which occur as a result of needle and injections related fear, pain, and insecurity **(Göthesson et al., 2020).**

The management of diabetes is thought to be too challenging for young children. Children are encouraged to gradually take on more responsibility for diabetes-related tasks as they enter adolescence in order to establish their own self-management practices **(Rankin et al., 2018)**. It is crucial to measure the child's level of pain and anxiety because a child's pain memory can affect their capacity to manage procedures involving needles. In a survey of 501 diabetic patients who used a syringe or pen device to administer insulin, 37% of them reported experiencing pain during the injection. **(Kruger et al., 2015)**. Therefore, controlling injection pain can help to reduce anxiety and the emergence of needle phobias **(McMurtry et al., 2019).**

Reflexology therapy considered as a form of noninvasive and non-pharmacological complementary and alternative methods for managing pain and anxiety. Therefore, used as a way to prevent the unfavorable side effects of analgesic drugs **(Van et al., 2016)**. Reflexology is a science of studying the human health through certain specific reflexology areas quantized on feet, hands, and ears. According to the reflexology hypothesis, the skin on the feet, hands, and ears serves as a representative of the target body parts and impulses generated on these reflexology areas by the external stimulations of definite intensities arrive at the target body organs through the neural pathways or through hormone-like activities. Additionally, it is accompanied by easy acceptance between children and parents, increases the patient's ability to adapt, reduces their anxiety and can be easily used by children **(Ghaljaei and Jalalodini 2021).**

One of the most popular types of reflexology therapy, is foot reflexology which is simple and less expensive**.** The theory of foot reflexology massage **is** based on helping the body to restore its balance naturally. As by touching skin can release the endogenous endorphins of the body that would reduce the stress; therefore, with stress reduction, the pain would consequently have decreased. As well as can relieve the fatigue and anxiety due to applying pressure on hands or feet activate large diameter fibers to close the pain gate, thereby inhibit the transmission of pain **(EL-Fekey 2018).** Furthermore, through the stimulation of cutaneous mechanoreceptors, foot reflexology stimulates large primary afferents that discharge Gamma-Aminobutyric Acid GABA and endorphins **(Jazayeri et al., 2021).** Moreover, the benefits of foot reflexology massage include; increased circulation, which makes the body feel more energized and relaxed this reduces pain perception and anxiety by impacting the cardiovascular, neurological, and locomotor systems as well as the nervous system and also eases muscle tension and pain, which enhances general health and well-being **(Chanif et al., 2019).**

By applying pressure on reflexive points on the foot that correlates to each area of the body, reflexology helps to restore the body's balance and enhance comfort. According to reflexologists, applying pressure to particular reflex points on the sole during disease is believed to break up calcium and uric acid crystals deposited in nerve endings, unblock nerve pathways, and improve blood flow throughout the body **(Ballard et al., 2019).** The advantages of foot reflexology massage have been supported by a number of studies such as, for reducing postoperative pain and anxiety **(Öztürk et al., 2018)**, decreasing fatigue and pain and improve the quality of sleep

in patients with lymphoma **(Rambod 2019)** also, nurses utilized foot reflexology massage in addition to standard care in intensive critical care unit to reduce anxiety and stabilize physiological parameters in patients undergoing coronary artery bypass graft surgery **(Abbaszadeh et al., 2018).**

Nurses play a crucial and effective role in offering counseling, instruction, and advice to guarantee the success of the nursing procedures. Helping patients for minimizing their discomfort, stress, anxiety and pain. So, nurses can use non-pharmacological and alternative therapies such as foot reflexology massage to control injection pain and anxiety because it is simple, inexpensive, and easy to use. Furthermore, it is one of the most significant complementary therapies employed by nurses as a nursing intervention. Additionally, increases the patient's ability to adapt and can be easily used by older children (**Momeni et al., 2020)**

Significance of the study:

The majority of diabetic children are afraid of needles and injection pain. Insulin injection related pain and anxiety are common adverse reactions and influence treatment acceptance **(Taddio et al., 2020).** According to **Hanberger et al., (2021)** one-third of diabetic children perceived substantial pain related to insulin needle procedures. Also, in another study based on the reports of caregivers, 32.7% of children with type 1 diabetes mellitus who required multiple daily injections had needle fear, compared to 22.2% of adolescents as mentioned by **Cemeroglu et al. (2014)**. Because of foot reflexology massage is one of the most essential alternative therapies for pain, it applied in many researches (**Singh & Chaturvedi, 2019**). For instance, the findings of **(Amer et al. 2022)** demonstrated that foot reflexology massage was an effective method to decrease anxiety among patients undergoing coronary angiography. Moreover, **Koraş et al., (2019**) indicated that foot reflexology decreases postoperative pain and the use of analgesics. However, studies for evaluating pain and anxiety together after foot reflexology massage for diabetic children were limited. Therefore, this study was conducted to evaluate the effect of foot reflexology massage on pain and anxiety levels regarding insulin injection among diabetic children**.**

The study aimed to:

Evaluate the effect of foot reflexology massage on pain and anxiety levels regarding insulin injection among diabetic children through:

- Assessing pain levels among diabetic children during and after insulin injection.
- Assessing anxiety levels among diabetic children pre and post-foot reflexology massage.

Research hypothesis:

Diabetic children who receive foot reflexology massage are expected to experience little pain and anxiety regarding insulin injection than those who do not.

Design:

A quasi-experimental research design was applied to carry out this study**.**

Setting:

The study was conducted at the Pediatric Endocrine Department at Mansoura University Hospital Affiliated to the Ministry of Higher Education and Scientific Research.

Subjects and Methods

Subjects:

A purposive sample of 100 diabetic children who are receiving insulin injections were recruited in this study; the studied children were assigned into two groups, with 50 children in each group (the study and control groups). The randomization achieved by asking each child to pick cards with numbers one and two was given to the participants. Children who choose number one were assigned to the study group, while those who choose number two were assigned to the control group. The study group receives foot reflexology massage in addition to routine care and the control group received only routine care from the department as a preparation before insulin injection, other medication, examinations.

Sample size calculation:

The sample size was calculated based on considering the level of significance of power analysis of 0.95(β=1-0.95=0.5) at alpha .05 (one-sided) with a large effect size (0.5) was used as the significance, and 0.001 was used as the high significance.

Inclusion criteria included:

- Children aged 6-17 years
- From both sexes
- Agree to participate in this study

Exclusion criteria included:

- Children are suffering from any mental disease.
- Feet problems
- Local infection of the feet or recent lower limb surgery

Three tools were used:

Three tools were used to collect data for the current study as follows:

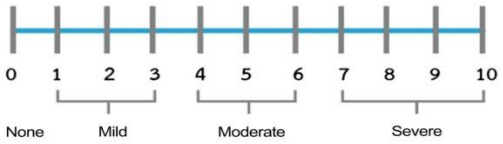
Tool (I): Researchers in the study developed **a structured interview questionnaire** after reviewing the recent related literature and research studies. It included two parts:

Part (1): It included demographic data of diabetic children as age, educational level, and residence.

Part (2): It included items related to the medical history of children as age at diabetes diagnosis and diabetes duration**.**

Tool (II) Numeric Pain Rating Scale (NPRS):

The NPRS was adopted by **McCaffery, et al., (1989):** It used to assess the pain intensity experienced by diabetic children. It contained a blank line anchored at each end of the line by adjectives that describe the extremes of pain. To facilitate measurement, a 10 cm line usually is used. The NPRS is a horizontal bar numbered from zero to ten, which reflects the pain intensity of the respondents. Respondents were asked to select a whole number that best reflects the pain intensity they feel on a scale from 0, "no pain," to 10, "severe pain". A Score given by the respondent was categorized and interpreted as follows: "0" interpreted as "no pain," "1 to 3" as "mild pain," "4 to 6" as "moderate pain," and "7 to 10" as "worst or severe pains. The NPRS was validated earlier and its use for assessing pain intensity had been anticipated.



Tool (III): State-Trait Anxiety Inventory for Children (STAIC) was adopted from **Spielberger (1972)** to measure transitory anxiety state in children. It consists of 20 sentences related to children feeling at a particular time. Scale statements are categorized under five subscales (sadness, worry, fear, uncertainty, and anxiety). Children were instructed to respond according to how they felt about their insulin injections. Children respond to the scale by selecting one of the three alternatives (rarely, sometimes, and often). Response categories were assigned values of one, two, and three respectively.

Scoring system:

The total scores are a summation of the item scores; the total scores were 60. For statistical purposes, scores ranging from 20 to 30 were considered low anxiety, 30–40, indicating average; 40–50, indicating above average; and 50–60 suggesting a very high level of anxiety.

Procedure:

Validity of Tools:

Five professors with more than ten years of experience in the field of pediatric nursing assessed the tools to test the content validity. No modifications for the tools were done according to the experts' judgment on the clarity of sentences, appropriateness of the content, and sequence of items.

Reliability of the tools:

The reliability of tools were tested using Cronbach's alpha. The reliability coefficient for tool II was (0.89), and tool III was (0.87) which means that the tools were reliable.

Pilot Study:

A pilot study was done on 10% of the sample (10 diabetic children) to test the feasibility and applicability of different items of the tool to establish the most practical and comprehensive way of obtaining necessary data.

The participants in the pilot study were included in the main study sample.

Ethical and administrative considerations:

Before the research started, the Approval of the Ethical Research Committee of the Mansoura faculty of Nursing was obtained to conduct the study. The researchers met both medical and nursing directors of the selected setting to clarify the purpose of the study and obtain their approval. Oral consent was obtained from mothers and their diabetic children to gain their cooperation. Data collection was voluntary and confidential. Researchers explained the objective and methodology of the study for all diabetic children. The right to refuse participation in the study was confirmed.

The procedure of Data collection:

The necessary official permissions for data collection were obtained by submitting an official letter issued from the dean of the faculty of nursing to the directors of the study setting. Data were collected within six months from the beginning of March 2021 to the end of August 2021. The researchers visited the study setting two days a week (Sunday and Thursday) from 9:00 am to 1:00 pm. The study was conducted through: preparation, interview and assessment, implementation, and evaluation.

Preparation for the study:

- A thorough review of related recent national and international literatures has been done to construct data collection tools. Also, official permission to conduct the study was obtained from the concerned authorities.
- The researcher has undergone a special training about performing foot reflexology massage for two months under supervision of specialist trainer of the field of physical medicine, rheumatology and rehabilitation to determine the foot's reflection points correctly and learn how to apply pressure. So, the working method was approved. Then apply foot reflexology massage on volunteers, and some of her relative before applying it on diabetic children.
- **The selected points of foot reflexology:** The first one was solar plexus point which located in the distance between the upper and middle third of the sole. It known as relaxation point, this point communicates with the whole nervous system and can trigger a major relaxing effect as well as diminish of both anxiety and stress. The second point was brain point, which is located at the tip of the big toe. It encourages optimal functioning of parasympathetic nervous system which helps the body to cope with the effect of stress and anxiety. Also, it used to decrease pain in the body and enhances the release of endorphins and enkephalins, which are the body's natural pain relievers (**Ruth Hull 2011).** The third point was an adrenal point which is located at halfway between the diaphragm line and waistline just above the kidney point on the foot that assist in reducing pain, as well as helping the body to cope with stress and the fourth one was pituitary point that located in the middle of the big toe, and aid to balance all body hormones by regulating and controlling their activities and help to prevent low energy level of the body **(Elsayed et al., 2019).**

Interview and assessment:

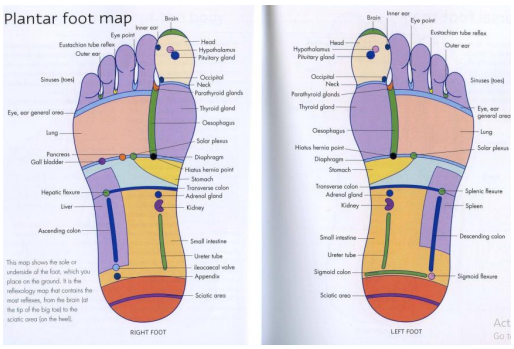
- For the first time, the researcher introduced herself to the studied children and their mothers and explained the purpose of the study then, the subjects were divided into two groups, the control group included 50 diabetic children and the study group included 50 diabetic children.
- After enrollment, the researchers interview each diabetic child with his/her mother individually to obtain data related to demographic data and medical history through using the structured interviewing questionnaire (Tool I). The time taken to complete this assessment was about 15-20 minutes.

Implementation:

- Diabetic children in the control group received routine care according to the hospital protocol of care before the insulin injection. While the diabetic children in the study group received routine care in addition to foot reflexology massage 20 minutes before the insulin injection.

- **For study group,** before applying the foot reflexology massage, the researcher prepared the studied children and the environment as the following:
    - Prepare warm, quite, well ventilated room for foot reflexology massage intervention.
    - Provide a full explanation of the foot reflexology massage procedure as meaning, benefits, duration and the reflexology points for the studied children and their mothers.
    - Ask the diabetic children to wash their feet by soap and warm water before intervention.
    - The researcher should keep her nails short and clean as well as remove any jewelry. Wash and warm her hands, and lubricate them before touching the child. Then get a general overview of the feet, look at the color, feel their temperature and changes in skin texture. Finally, move the feet to check for mobility and flexibility **(Ruth Hull 2011).**
- The researcher sat in fully comfortable and relaxed position in front of the child. Then the child was instructed to lie down in a comfortable, usually supine position. A pillow was placed under the child's foot. Firstly, the child's feet examined for the pain and sensitivity. Then the researcher put a tiny amount of non-therapeutic baby lotion on her hand to facilitate massaging started with the right foot. Followed by performing general massage to warm up the feet. Also, with just one hand's palm and fingers of the researcher, the sole, back, and toes of the child's leg were massaged, these movements repeated several times. This technique enables the children get ready for specific reflexology by relaxing their feet and legs. It took two minutes. **(Mansouri etal., 2017)**
- Then pressure was applied to points on the feet that correspond to the pain and anxiety in the body. These points are four significant points which include solar plexus, brain, adrenal and pituitary. The rotating thumb technique was used as the researcher put four fingers on the dorsal aspect of the child's foot and kept the thumb free to work on the sole. Bend the thumb from the first joint to between a 75 and 90-degree angle to ensure that the thumb nail doesn't dig into the flesh then apply firm pressure with the tip of the thumb to the point to be worked on with rotating the thumb clockwise, then lift the thumb, move to the next point and repeat the procedure. Therefore, the basic movements were; press in, rotate, lift and move. The researcher performed reflexology for 8 minutes on each foot. The cycle of foot reflexology massage was applied in the second foot as the first foot for 10 minutes. Total 20 min for both **(Louise Keet 2008).**

Louise Keet. (2008): The Reflexology Bible: The Definitive Guide to Pressure Point Healing. 1st ed. Octopus Publishing Group ltd 2008. Pp 96-174.



Louise Keet. (2008): The Reflexology Bible: The Definitive Guide to Pressure Point Healing. 1st ed. Octopus Publishing Group ltd 2008. Pp 96-174.

Evaluation:

- State-Trait Anxiety Inventory for Children (Tool III) and Numeric Pain Rating Scale (Tool II) were explained by the researcher to the studied diabetic children on both groups and were scaled for young children by the researcher.
- The severity of anxiety was assessed by (Tool III) by the subjects in the presence of

the researcher for old children but for younger children it was scaled by the researcher. For the study group before and after received foot reflexology massage for 20 minutes (10 min for each foot) in addition to routine care as a preparation before insulin injection, other medication whereas, for the control group, it was estimated before and after received routine care only as a preparation before insulin injection, other medication.

- The intensity of pain level was estimated by Numeric Pain Rating Scale (Tool II) by the subjects in the presence of the researcher during and after insulin injection for both groups.
- Finally, the mean of data was compared between the study and control groups.

Statistical analysis:

Collected data were organized, coded, and entered into a computer. All statistical analyses were performed using a statistical package for social science version 26.0 (SPSS, Chicago, IL). The arithmetic mean and standard deviation were used for quantitative variables to describe the central tendency of observations and to measure the dispersion of results around the mean. The Student's t-test was used for comparison between two variables with continuous quantitative data, while a one-way analysis of variance (ANOVA) test was used for comparison between more than two variables with continuous quantitative data. Chi-square [X2] test was used for the comparison of variables with categorical data. Statistical significance was set at p less than 0.05.

Results:

Table (1): Shows that 52% of the diabetic children participated in the current study were boys in the study group compared to 54% in the control group. Concerning age in years, 41 % of the study group and 42% of the control group, their age was between 10 < and 15. Additionally, 60% of children in the study group compared to 62 % in the control group were at the preparatory educational level. Also, the same table points that nearly three quarters of the studied children were living in urban areas in the study group compared to 70% in the control group. There was no significant difference between the two groups concerning their demographic data.

Table (2): Illustrates that the median age at diabetes diagnosis in years of the studied diabetic children in the study group was 6.2 (0.5-15) compared to 6.4 (0.5-15) in the control group and regarding diabetes duration in years, it was observed that the median diabetes duration was 6.0 (0-16) in both groups.

Table (3): Demonstrates the mean pain scores of (NPRS) in the studied diabetic children during and after insulin injection in the two groups. As shown post-foot reflexology massage intervention for children in the study group, the differences indicated highly statistically significant differences in the pain scores among the studied two groups after insulin injection (P = <0.001).

Figure 1: Highlights the distribution of diabetic children regarding their pain levels after insulin injection among the study group and control group. In the study group, (57%) of diabetic children had mild pain compared to (8%) in the control group. Also, only (8 %) had severe pain in the study group compared to less than three quarters in the control group.

Table (4): Presents that the total mean scores of (STAIC) among the studied diabetic children before using the foot reflexology massage intervention was 41.3±5.4 and decreased to 24.3±1.3 in the study group compared to 39.88±5.03 in the control group following the foot reflexology massage intervention. Significant differences were found between the total mean scores of anxiety in the pre and post the foot reflexology massage intervention in both groups (P = <0.001).

Figure (2): Shows that 8% of the studied diabetic children in study group had a very high level of anxiety on STAIC, whereas the level changed to low anxiety level among 50% of them after foot reflexology massage intervention. Moreover, 22% of the studied diabetic children in study group had above average level of anxiety on STAIC compared to 47% of the studied diabetic children in the control group after foot reflexology massage.

Figure (3): Demonstrates the distribution of the studied diabetic children regarding anxiety level on STAIC in the study and control groups pre and post foot reflexology massage intervention. It was noticed from this figure that in the study and control groups, nearly half of the studied children had above average anxiety level pre the foot reflexology massage intervention. However, post the intervention 50% of the studied children in the study group had low anxiety level compared to 12% in the control group. In addition, there was a highly statistical significant differences post foot reflexology massage among the studied diabetic children regarding anxiety level on STAIC between the study and control groups.

Table (1): Frequency distribution among the studied diabetic children in both groups regarding demographic data

Demographic data	Study group (n=50)		The control group (50)		X2	P-value
	No.	%	No	%		
Gender:						
- Boys	26	52.0	27	54.0	0.31	0.523 NS
- Girls	24	48.0	23	46.0		
Age:						
- 6- < 10	19	38.0	17	34.0		
- 10 < 15	21	42.0	21	42.0	0.83	0.346 NS
- ≥15	10	20.0	13	26.0		
Educational level:						
- Primary level	9	18.0	11	22.0	2.40	0.355
- Preparatory level	30	60.0	31	62.0		
- Secondary level	11	22.0	8	16.0		
Residence:						
- Rural	36	72	35	70	2.0	1.26 NS
- Urban	14	28	15	30		

T-test, x 2 test, NS-non-significant

Table (2): Frequency distribution among the studied diabetic children in both groups regarding the medical history.

Medical history	Study group (n=50)	The control group (50)	t-test	P-value
	Median (Min-Max)	Median (Min-Max)		
Age at diabetes diagnosis in years	6.2 (0.5-15)	6.4 (0.5-15)	0.451	0.534 NS
Diabetes duration in years	6.0 (0-16)	6.0 (0-16)	0.432	0.342 NS

T-test, x 2 test, NS-non-significant

Table (3): Comparison between mean pain scores (NPRS) during and after insulin injection between both study and control groups

Mean pain scores	Study group (n=50)	Control group (n=50)	t-test	P-value
	Mean ±SD	Mean ±SD		
During insulin injection	8.0 ±0.2	8.1 ±0.6	0.443	0.660
After insulin injection	6.4 ±1.1	8.2 ±0.8	5.238	<0.001 *

*Statistically significant level at P < .0001

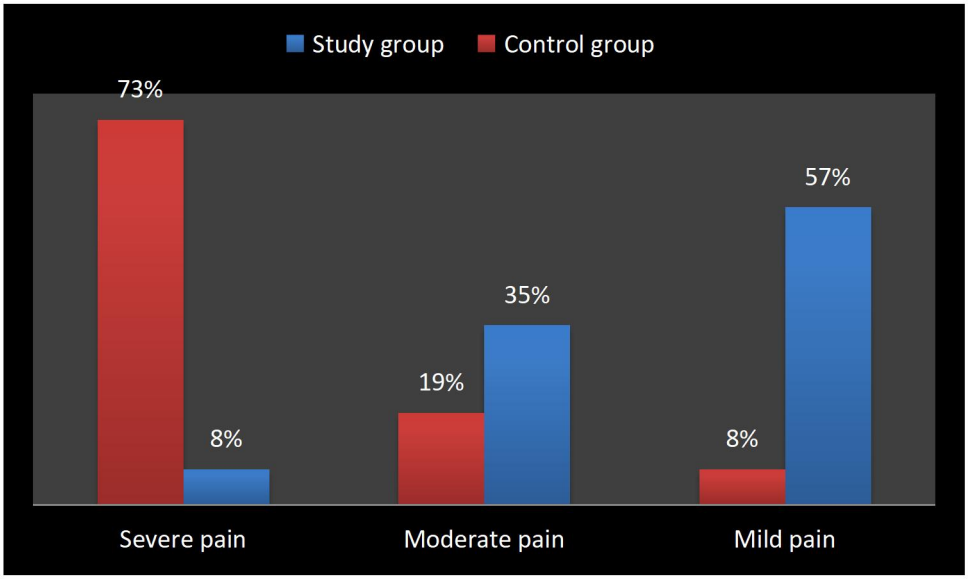


Figure (1): Percentage distribution of diabetic children regarding their pain levels after insulin injection.

Table (4): Differences between the mean score (STAIC) in the studied children for both groups pre and post foot reflexology massage intervention.

Items	Study group (50)	Control group (50)	t- test -P-value
The total mean score of (STAIC) (**Pre intervention**)	41.3±5.4	40.07±5.02	**P- value** 0.660
The total mean score of (STAIC) (**Post intervention**)	24.3±1.3	39.88±5.03	**t-test-** 15.67 **P-value-** P<0.001**

*Statistically significant level at P < .0001

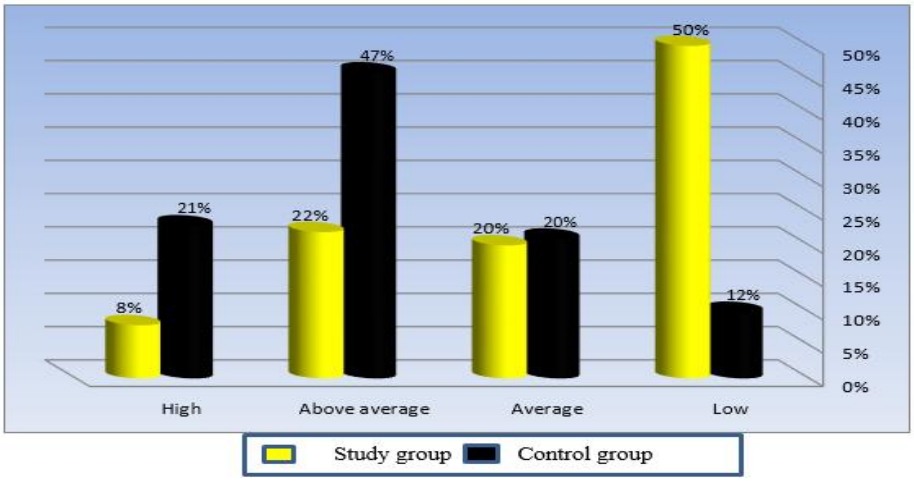


Figure (2): Frequency distribution of anxiety level of the studied diabetic children in the study and control groups after foot reflexology massage intervention.

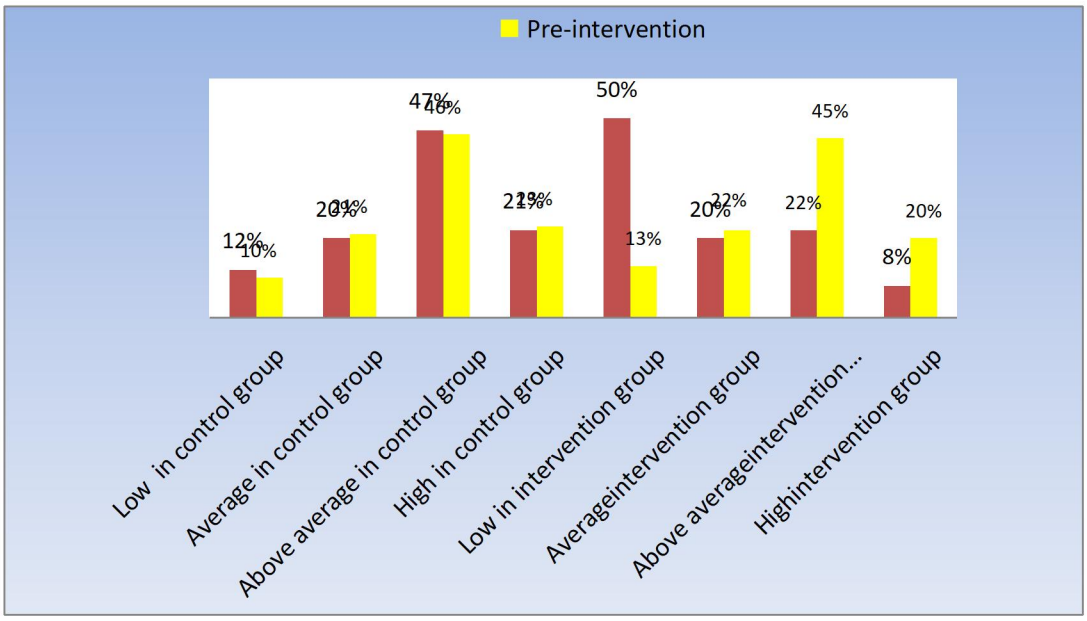


Figure (3): Frequency distribution of anxiety level of the studied diabetic children in the study and control groups pre and post foot reflexology massage intervention.

Discussion:

It is still necessary to assess the best practices for minimizing the psychological effects, painful needle-related experiences, and negative feelings in children with T1D. **Majidi et al., (2015).** Needle procedures related fear may result in increased avoidance behavior and attempts to eliminate any possible exposure to needles. Studies are still being conducted to determine how frequently children should be checked for encounters with needle procedures used in T1D treatment. Nurse plays an important role in teaching and supporting the children and their families as part of the multidisciplinary team that provides pediatric diabetes treatment **(ISPAD Guidelines, 2018).** If anxiety, pain, and coping skills are assessed, support for those who are anxious about needle procedures may be made easier. The availability of methods to reduce fear and pain would increase the opportunities for support **Kleye et al., (2021).** Children with type 1 diabetes who received foot reflexology massage should feel less pain and have less anxiety from insulin injections than those who did not, according to the research hypothesis. Therefore, the study's aim was to evaluate the effect of foot reflexology massage on pain and anxiety levels regarding insulin injection among diabetic children.

The findings of the current study showed that more than two-fifths of the control and study groups were between the ages of 10 and 15. The results of the present study parallel those of Myśliwiec et al., (2019), who investigated " Pediatric diabetes care: inpatient care in the maps of health needs of Poland in 2014" and reported that the age group of the studied children was between 10 to 14 years old accounted for the largest percentage (41%) of patients aged below18 years. In addition, according to the study's findings, there was no significant differences in the demographic data of the two groups. Karamisefat et al., (2021) matched with this result as they showed that children in both groups had no significant differences in terms of demographic characteristics. From the perspective of the researchers, this demonstrated that the baseline of pain and anxiety problems was comparable between the two groups.

According to the current study findings, both study groups' median diabetes duration and age at diabetes diagnosis in years were found to be 6.2 (0.5-15) years and 6.0 (0-16) years, respectively. This concurs with the findings made by **Hanberger et al. (2021),** who investigated "Needle-related pain, affective reactions, fear, and emotional coping in children and adolescents with Type 1

diabetes" and also, came to the same conclusion.

In the present study, foot reflexology massage was shown to reduce pain level as more than half of diabetic children had mild pain in the study group compared to only (8%) in the control group after insulin injection. This result was supported by the finding from a study done by **Bakir et al., (2018)** who showed that foot reflexology applied to rheumatoid arthritis patients is effective in reducing their pain symptoms. Also, the result of the present study was in the same line with those of previous study of **Taheri et al., (2019),** who investigated pain in patients after appendectomy and indicated a positive effect of foot reflexology on pain relief. Furthermore, this was in agreement with other study carried out by **Ghaljaei et al., (2021)** who concluded that that foot reflexology significantly reduced pain mean scores in leukemic children after received 20 min foot reflexology. Reflexology has favorable impacts on lowering pain and anxiety, in the researcher's opinion as vital energy flows along the paths of the feet to all parts of the body. Any kind of barrier in this flowing will eventually lead to illness. Stimulation of specific reflexology points can break these barriers in the canal flow and release energy in each foot, inactivates the pain paths by secreting morphine-like compounds **Karamisefat et al., (2021)**

As regards the mean pain scores, the current study illustrated that the NPRS pain scores were observed to be statistically similar between the two groups during insulin injection while, the pain scores were 6.4 ±1.1 and 8.2 ±0.8 in the study group and control group respectively after insulin injection and the variations between the two groups' pain scores indicated highly statistically significant difference. This is in the same line with **Koç and Gözen (2015)** who mentioned that the FLACC pain score was observed to be statistically similar between groups before vaccination and the pain score was 5.47 ± 2.11 in the reflexology group of the studied infants after vaccination compared by 9.63 ± 0.85 in the control group, therefore they concluded that using foot reflexology before vaccine, reduced the pain level experienced by infants after vaccination. In addition, this result was supported by **Imani et al., (2020)** who conducted a randomized controlled trial to determine the effect of foot reflexology on postoperative pain in patients undergoing tibia plating surgery and found that the baseline pain scores in the intervention and control groups were reported 8.1±0.9 and 8.4±0.9, respectively but, after performing foot reflexology for 10 minutes, one hour before surgery, the pain score in these groups was reduced to 6.9±1.1 and 8.1±1.0, respectively. Besides that, **Ozturk et al., (2018),** was in congruent with the present study finding as they reported that the average pain score of the experimental group was statistically lower than that of the control group in a study entitled "The effects of reflexology on anxiety and pain in patients after abdominal hysterectomy". From the perspective of the researchers the effectiveness of the foot reflexology intervention is suggested and this result supports the study's central hypothesis by demonstrating the beneficial benefits of foot reflexology on patients' pain levels.

In self-care, children found needle procedures like insulin injections to be uncomfortable and reported less emotional resiliency when they experienced more intense pain. Therefore, children and teenagers who displaying distress or anxiety related to needle procedures need support to cope with these emotions that, can be achieved by foot reflexology massage. As in feet reflexology, each part of the body is connected to a certain point at the bottom of the foot, and the pressure applied to these points will result in a relaxed and balanced body as well as help in relieve stress and tension, improve blood flow and promote homeostasis as mentioned by **Ozturk et al., (2018)**. This agree with the present study finding as after applying foot reflexology massage, in the study group half of diabetic children had low anxiety level compared to only 12% in the control group. This result was supported by **Mansouri et al., (2017)** who concluded that foot reflexology massage reduced anxiety level of children with thalassemia undergoing a blood transfusion. In addition, **Levy et al., (2020)** was in the same line with the finding of our study has found that foot reflexology had a positive short-term

anxiolytic effect during labor in primiparas with moderate to severe anxiety.

The current study's findings showed that a little under a quarter of the investigated diabetic children in the study group had high anxiety level on the STAIC, pre foot reflexology massage whereas, less than ten percent of them showed a transition to low anxiety level after receiving foot reflexology massage. It was a confirmation of the application's success in the researchers' view. This is comparable to a study done by **El-Fekey et al. (2018)** who looked at the effect of foot reflexology on stress and anxiety during pregnancy. They discovered that foot reflexology was effective to reduce the level of anxiety during pregnancy and found a statistically significant difference in a level of anxiety between the experimental and control groups in the post-test. This result contradicted with **Kavei et al. (2015)** who concluded that foot reflexology massage had no significant impact on the reduction of anxiety and discomfort of patients undergoing mechanical ventilation after open heart surgery. This discrepancy in the result could be due to the different sample populations and intervention techniques.

The findings of the current study showed that the mean STAIC scores after foot reflexology massage application for the investigated diabetic children in study group were lower than those of the control group. This result matched with what was found by **Bahrami et al., (2019)** as they reported that the mean and standard deviation of the anxiety after foot reflexology was 8.53 ± 3.70 in the intervention group, compared to 11.06 ± 3.19 in the control group. This result demonstrated the usefulness of foot reflexology massage in lowering anxiety levels in diabetic youngsters. Moreover, this result supported by **Bertrand et al., (2019)** who reported that the decrease in the mean of visual analogue scale anxiety score was significant reduced in children suffering from persistent or chronic pain after each session of foot reflexology. Additionally, the findings of the present study were consistent with those of **Erkek and Aktas (2018)** who observed that the mean of 'Spielberger State-trait Anxiety Inventory'' scores were lower in the experimental group that received foot reflexology compared with the control group and this decreasing was statistically significant. From the researcher's view, this due to applying pressure to specific relaxation points on foot such as solar plexus enhances blood flow, permits the release of energy from congested areas of the body, that can help patients to feel better, both physically and psychologically.

Concerning the anxiety level of the studied diabetic children in the study and control groups' pre foot reflexology massage intervention. The results of the current study revealed that were similar anxiety level in the study and control groups before the application of foot reflexology massage and did not show significant differences among the two studied groups. This result was anticipated, because the demographic data of the studied diabetic children and the times at which anxiety levels were measured were similar. These aspects of the study and control groups were homogeneous; therefore, it was crucial for demonstrating how reflexology affects anxiety. This result was supported by **Ramezanibadr et al., (2018)** in a study entitled 'The impacts of foot reflexology on anxiety among male candidates for coronary angiography that was done in Iran on 150 participants. It illustrated that at baseline before foot reflexology, there was no significant difference among the groups regarding the level of state anxiety.

In the current study, the results concluded that there was a highly statistical significant differences post foot reflexology massage application among the studied diabetic children regarding anxiety level on STAIC between the study and control groups. This may have referred to the theory of reflexology which based on the principle that energy flows through vertical zones throughout body from organs toward the head. Therefore, massage and stimulation of nerves cause relaxation, reduce tension and as a result returns balance in the body and decrease anxiety **Kishore et al. (2021)**. This was in agreement with **Abbaszadeh et al. (2018)** who reported that there was a statistically significant difference between intervention and control groups in terms of the level of anxiety. In addition, this result supported by **Abdou and Abd El-Hafez (2018)** who found that there was a statistical

significant differences between the frequencies of anxiety score in both groups and decreased the level of anxiety in intervention group at immediate time, after 15minutes and 45 minutes of applying foot reflexology. This finding conflicted with the result of **Sayari et al. (2021)** who studied the effect of foot reflexology on chest pain and anxiety in patients with acute myocardial infarction, found that severity of anxiety between groups and at different times was not significant.

Conclusion:

Based on the results and hypothesis of the present study, the study findings concluded that foot reflexology massage has an effect on pain and anxiety reduction regarding insulin injection among diabetic children. Also, the study revealed that there was a difference between mean scores that were found statistically significant at $p < 0.05$ level in the study group regarding pain and anxiety levels.

Recommendations:

Based on the findings of this study, the following recommendations are suggested:

- Foot reflexology massage could be applied as a non-pharmacological method and complementary therapy along with routine care as a preparation technique to manage pain and anxiety regarding insulin injection among diabetic children.
- Raising the awareness of pediatric nurses about foot reflexology massage should be integrated and implemented into practice.
- Development and implementation of reflexology training program for mothers and caregivers should be considered
- Replication of the current study on a larger probability sample and in other settings to generalized results

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