

Efficacy of Faradism under Pressure Technique in Diabetic Foot: A Randomized Control Trial

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DOI: <https://doi.org/10.52403/ijrr.20220329>

ABSTRACT

Background: Chronic edema is a distressing chronic symptom that is the result of several conditions including chronic venous disease, immobility, and obesity. Patients with diabetes are at increased risk of developing neuropathy, peripheral arterial disease, and infections.

Objective: The study aimed to find the effectiveness of faradism under pressure in the participants with diabetic foot and determine the better of these for benefit of patients.

Study Design: A randomized controlled trial

Methods: In a 4-week intervention study, 30 participants with features of diabetic foot were studied. They were divided into 2 groups by simple random sampling; Group A: Faradism under Pressure and Group B: Control Group. Pre- and post-treatment data were collected and analyzed using SPSS 22.0. Paired and unpaired t-tests were used to find out the significance of the treatment.

Results: A significant improvement in pain and swelling ($p < 0.05$) after the treatment was found. Greater statistically significant improvement was seen in Group A as compared to Group B.

Conclusion: The study concluded that Faradism Under Pressure program was more effective when compared to the control group in treating patients with Diabetic Foot.

Keywords: Diabetic Foot, Faradism Under Pressure, Swelling, Edema, Girth Measurement.

CTRI NUMBER: CTRI/2021/11/038313

INTRODUCTION

Diabetes is a serious, long-term condition with a major impact on the lives

and well-being of individuals, families, and societies worldwide. It is among the top 10 causes of death in adults, and was estimated to have caused 4 million deaths globally in 2017. Three main types of diabetes are – Type 1 Diabetes Mellitus (T1D), Type 2 Diabetes Mellitus (T2D), and Gestational Diabetes Mellitus (GDM). (1)

Peripheral edema is an accumulation of fluid in the interstitial space that occurs as the capillary filtration exceeds the limits of lymphatic drainage, producing noticeable clinical signs and symptoms. (2)

Chronic edema is a distressing chronic symptom that is the result of several conditions including chronic venous disease, immobility, and obesity. It has been estimated that 1.33:1000 of the population is affected by chronic oedema and this prevalence increases to 5.4:1000 in those over 65 years of age. The prevalence is also higher in women. (3)

The prevalence of diabetes worldwide was estimated at 131 million in 2000 and is forecast to increase to 366 million by 2030. (4) In the UK, 2.8 million people were registered as having diabetes in 2010. (5) Patients with diabetes are at increased risk of developing neuropathy, peripheral arterial disease, and infections. (6)

The postural regulation of blood flow is impaired in patients with diabetic neuropathy. This disturbance is compatible with a loss of sympathetic vascular tone and arteriovenous shunting. (7, 8) In particular,

the capability of effective pre-capillary vasoconstriction on standing is reduced. This exposes the capillary bed to a high hydrostatic load, resulting in hyperperfusion and increased shear force in the microcirculation on dependency which in turn leads to thickening of the capillary basement membrane and oedema of the feet and lower legs. (9)

Faradic current is a short-duration interrupted direct current with a pulse duration ranging from 0.1 to 1 ms with a frequency of 50 to 100 Hz. Faradic current is surged to produce tetanic contraction and relaxation of the muscle. Treatment with faradic current also known as faradism. (10)

Faradism under pressure method is used in the treatment of edema to increase the venous and lymphatic drainage from the edematous area. The faradic current is applied along with an elastic bandage such as elastocrepe bandage and body part, which is to be treated, is kept elevated during treatment. Applied for 15 to 20 minutes only.[11]

Hypothesis: Null hypothesis [H0]: There will be no significant effect of Faradism under pressure on Diabetic Foot. Alternative hypothesis [H1]: There will be significant effect of Faradism under pressure on Diabetic Foot.

REVIEW OF LITERATURE

Noha Amin, et al (2016) conducted study on diabetic foot disease from the evaluation of “foot at risk” to the novel diabetic ulcer treatment modalities and concluded that diabetic foot ulceration is generally preventable. The first step in ulcer prevention is the careful screening for foot problems & detection of patients at high risk.

Tae Hwan park, et al (2016) conducted a study on “Management of diabetic foot Brief synopsis for busy orthopedist” and concluded that numerous, treatment methods including vacuum drainage systems, skin substitutes especially apligraf; blood bank platelet concentrate, hyperbaric oxygen therapy, pulsed electro-

magnetic fields, gene therapy using synthetic growth factors, & stem cells therapies have been proposed for local wound care of diabetic foots, suggesting that no single effective methods have surfaced as the accepted standard.

Chelcy S Jaju, et al (2020) Conducted a study on “Effectiveness of Faradism under pressure vs subjects with peripheral oedema” and concluded that Faradism under pressure is beneficial in oedematous condition

John T. Farrara, et al (2001) conducted a Randomised control trial on “Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale” on 2724 subjects to investigate the clinical importance of the NPRS scale on pain intensity and concluded that PI-NRS that best represents a clinically important improvement.

MATERIALS AND METHODS

Research design: A randomized controlled trial

Sample design: Simple Random Sampling (Lottery method)

Study population: Participants with Diabetic Foot.

Sample size: 30 Participants Group A: 15 Participants (Faradism under pressure) Group B: 15 Participants (Control Group)

Study setting: Nootan College of Physiotherapy, Visnagar, Gujarat.

Study duration: 6 months (September 2021 to February 2022).

Treatment duration: 4 Weeks

Inclusion criteria:

- Age 40-60 years.
- Both male and female.
- Participants with diabetes.
- Participants who are willing to be a part of the study.
- Participants having pain and oedema.

Exclusion criteria:

- Excluded (ulcer).
- Fracture of foot, ankle, tibia.

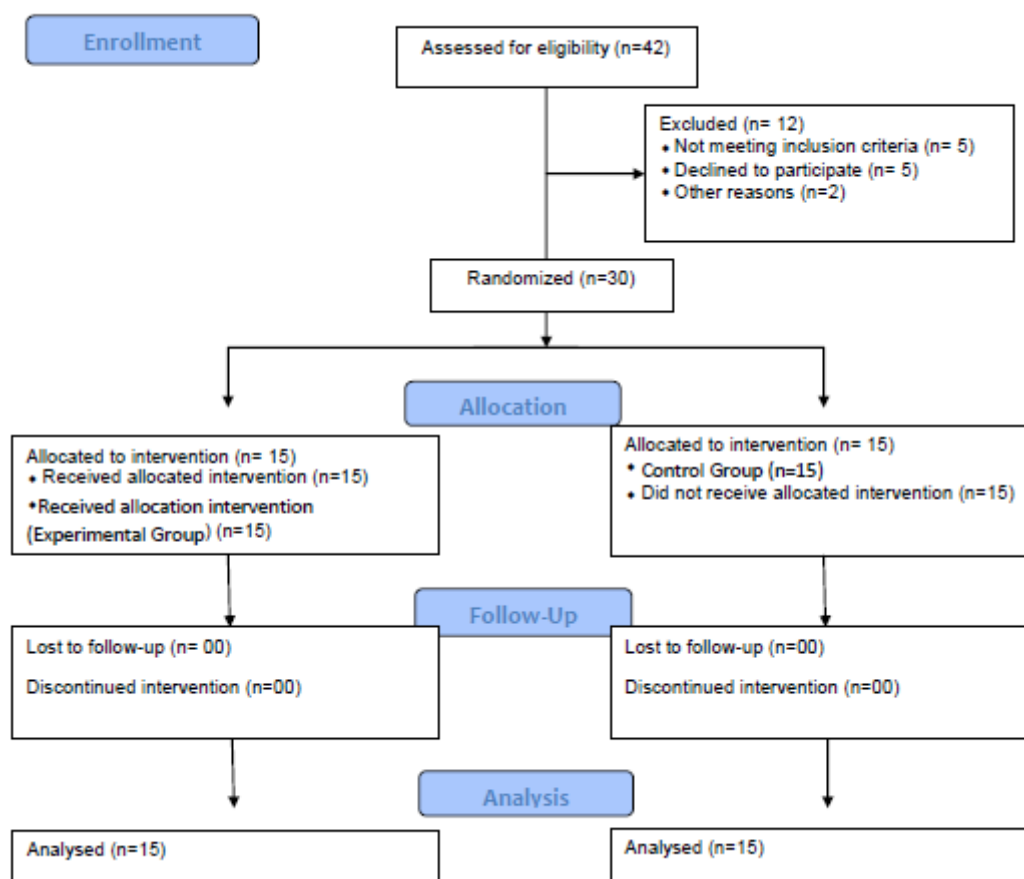
- Infection.

Ethical approval was generated from the Institutional ethical committee and the participants gave an informed written consent signed. All thirty participants' demographic data were recorded. The

participants were divided into two groups i.e., Group A and Group B by simple randomize sampling by lottery method.

Group A will be given Faradism under pressure & Group B as they are in the control group.

Randomization:



Intervention design [For 4 weeks (4 days/week)]:

Faradism under pressure method is used in the treatment of oedema to increase the venous and lymphatic drainage from the oedematous area. Usually, In diabetic foot patients, severe oedema and pain are present so, Faradism under pressure can be effective for the patients.

The first participant was in supine lying. The participant's leg was in a relaxed position and clean the affected area was. Anode (red electrode) on the sole of the foot. Cathode (Black electrode) placed at calf muscle. Fix the pad in position firmly,

with straps, if necessary, test the contraction produced. Then apply a crepe Bandage, starting distally it should be firm but not too tight, avoid gaps between the turns of the bandage. Elevate the leg above the heart level. In treatment, the pulse duration is 0.1 to 1ms with a frequency of 50 Hz for 15 minutes. The treatment was applied 4 days per week for 4 weeks.

Data collection procedure: Data will be collected at baseline and at the end of 4 weeks training. Follow up will be taken at 6 months. The participants underwent a detailed pre evaluated assessment which

obtained information about demographic data, examination and functional outcomes.

- **Outcome measures:** Numerical Pain Rating Scale (NPRS)
Girth measurements

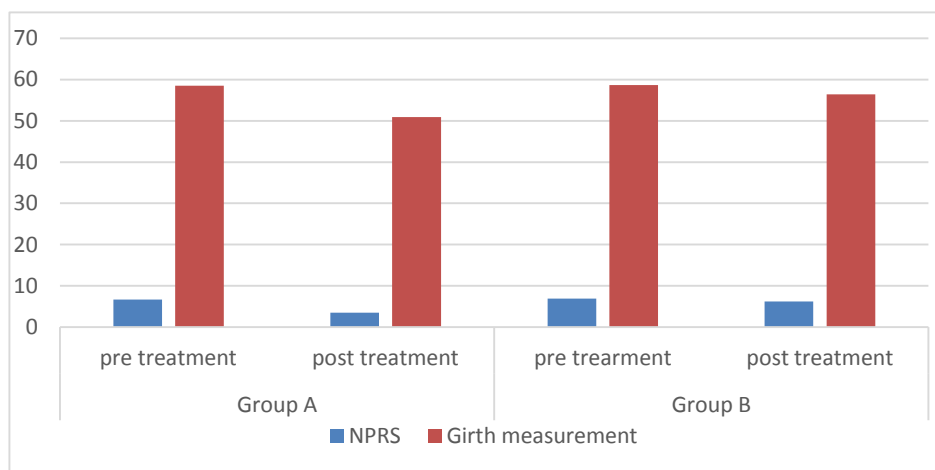
Statistical Analysis:

The data were tabulated and participated to statistical analysis using SPSS 22.0 software for windows and analysed with paired t test and unpaired t test. After treatment the result showed a significant improvement ($p < 0.05$) in terms of reduce swelling.

RESULT

[Table no.1 Intragroup comparison of pre –post treatment of both groups]

Outcome	Group A				Group B				
	Pre-Treatment Mean SD	Post-Treatment Mean SD	t value	p-value	Outcome	Pre-Treatment Mean SD	Post-Treatment Mean SD	t value	p-value
NPRS	6.66 ± 1.04	3.53 ± 1.18	12.25	0.00	NPRS	6.93 ± 0.96	6.26 ± 0.79	5.29	0.00
Girth measurement	58.53 ± 3.66	50.93 ± 3.36	26.25	0.00	Girth measurement	58.66 ± 4.11	56.40 ± 4.15	12.47	0.00



[Graph-Intragroup comparison of pre –post treatment of both groups]

Pre and post treatment data of participants of both groups were noted. All statistical analysis was done using SPSS 22.0 software. Descriptive analysis was obtained by using Mean & SD. The intergroup comparison between group A and B of pre-post treatment of outcomes were done by unpaired t test. The intragroup comparison between both group of pre post treatment of outcomes were done by paired t test.

DISCUSSION

The results found in this study disclosed after a four weeks treatment program, both groups, Group A who received faradism under pressure and Group

B is control group, a significant improvement in the reduce swelling in the participants with diabetic foot.

Diabetic foot is one of the most significant and devastating complications of diabetes, and is defined as a foot affected by ulceration that is associated with neuropathy and peripheral arterial disease of the lower limb in a patient with diabetes. In the acute stage of diabetic foot, the pain, inflammation, swelling commonly seen.

The main purpose of the treatment is to reduce pain and swelling of the affected foot in the participants of diabetic foot.

In the acute diabetic foot may present with different clinical symptoms. Patients may describe it as symptoms of

unpleasant sensations such as tingling, burning, prickling. Although the sensory nerve fibers are the most commonly affected fibers, motor nerve fibers are sometimes affected too, leading to muscle denervation. During the early course of the disease, the muscle power is preserved except mild muscle weakness in the toe extensors.

In the recent years, apart from the standard diabetic foot treatment modalities have been developed. Faradism under pressure useful in the participants with acute diabetic foot to reduce pain and swelling in the foot.

The physiological effects of faradism under pressure include the increase venous return, lymphatic drainage improve blood flow and helps to reduce pain and swelling. An acute condition of diabetic foot classified as pain, inflammation and swelling of the foot. Faradism under pressure helps to reduce pain and swelling, improve blood flow and lymph drainage.

This study was conducted on thirty participants. The participants were divided into two groups; Group A received faradism under pressure and Group B is control group for 1 session/day and 4 days/week for 4 weeks. In this study Numerical Pain Rating Scale (NPRS), Girth measurement were used as outcome measures. The results showed a significant improvement in the outcome measures in post-treatment stage as compared to the pre-treatment stage.

Though a significant improvement was found after treatment in Group A showed greater improvement in the NPRS Score and Girth measurement. (p value < 0.05).

Thus, the alternative hypothesis [H11] is accepted.

The above exposed statement suggests that faradism under pressure is the effective management of participants with diabetic foot to reduce pain and swelling.

Limitation

1. The study includes treatment period of 4 weeks only.

2. The study involves small sample size.
3. The study includes participants with diabetic foot.

Suggestions and recommendations:

1. The study can be done with longer treatment duration.
2. Further studies can be done using the same intervention procedures for reducing pain and swelling of foot.
3. Further studies can be taken up with different intervention parameters for reducing pain and swelling of foot.
4. Further studies can be done using the same intervention procedures for reducing pain and swelling of foot in case of diabetic foot.

CONCLUSION

In the Randomized Control Trail conditions used in the study, both the groups showed significant improvement in reduced pain and swelling. The use of Faradism under pressure a significantly greater improvement in reducing pain and swelling, when compared to control group (Group B).

ACKNOWLEDGEMENT

A successful outcome in any research Endeavour attributes itself to the selfless guidance of the mentor. I would like to express my deep appreciation and gratitude to my guide Dr. Nidhi Vedawala. I am so fortunate that I got to work under the guidance of such a person who gave me valuable advices, intellectual guidance and all the help that I needed in making of this dissertation. I am thankful to her for giving me the opportunity to explore new things on my own and at the same time guiding me and making me understand things whenever I was wrong. I thank her for her constant motivation; patience and support that helped me complete this dissertation. Her consistent efforts to make me use proper sentences, careful reading and revising the dissertation and her advice in statistical analysis and data presentation has helped me to learn a lot of things.

My heartfelt thanks to my parents and my family members for their interest in my academic excellence, for their constant love, encouragement and providing supportive and cheerful environment which made this work easy. I am also thankful to my friends for their support, help and constant motivation for completion of this work.

Lastly, I honor all the participants of the study for participating in this study and helping me.

Conflict of Interest: None

Source of Funding: None

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How to cite this article: Shrimali N, Vedawala N. Efficacy of faradism under pressure technique in diabetic foot: a randomized control trial. *International Journal of Research and Review*. 2022; 9(3): 249-254. DOI: <https://doi.org/10.52403/ijrr.20220329>
