A Study to Assess the Effectiveness of Topical Application of Amla Juice on Wound Healing Among Clients with Diabetic Foot Ulcer Admitted at Selected Hospital, Tiruvannamalai, India

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KEYWORDS
Diabetic Foot Ulcers, Experimental Investigation, Modified Bates-Jensen Wound Assessment, Amla Juice, Wound Healing and Statistical Significance

ABSTRACT
On 60 clients with diabetic foot ulcers who were admitted to the medical as well as surgical wards of TNK Hospital in Tiruvannamalai, an experimental research study has been undertaken. The clients were categorized as control and experimental groups (30 in each category) using a simple random sampling procedure. The Modified Bates-Jensen Wound Assessment instruments were utilized for finding the degree of diabetic foot ulceration in the control and experimental group, respectively. The gauze impregnated with 10–15 millilitres amla juice was applied to the wounds of clients in experimental group daily for a week. Upon comparing the level of wound healing at the post-test between the experimental and control group in clients with foot ulcers caused by diabetes, the computed unpaired 't' value, t = 5.380, was determined to reach $p<0.001$ statistical significance. The study's findings showed that topical application of Amla juice to diabetic foot ulcer in the experimental group significantly improved the degree of wound healing.

1. Introduction

Between 40 and 60 million individuals worldwide suffer from diabetes. According to World Health Organization (WHO), diabetes might rank seventh among all causes of death worldwide by 2030. [1] The International Diabetes Federation (IDF) projects that by 2045, there will be 700 million individuals worldwide, aged 20 to 79, who have diabetes. Currently, 463 million adults worldwide live with the disease. Compared to countries with higher incomes, the prevalence has been growing steadily in nations with lower or middle incomes. [2] The World Health Organisation (2020) estimates that throughout 2016 and 2030, the number of diabetes-related fatalities will nearly double and that 80% of those fatalities are recorded in nations with low to middle incomes. By 2045, it is probably going to rise another 1.84 times, or 134.3 million. India projected that by 2030, there would be 87 million diabetics, up from 51 million in 2010—a 58% rise. [3].Diabetes is rapidly being seen as a potential epidemic in India. India has the second-highest clientele, with 77 million affected customers. Type-2 diabetes affects up to 50 million people in India, making it the "Diabetes Capital" of the world. It is projected that 79.4 million Indians may develop diabetes mellitus by 2030. [4] According to INDIAB study of Indian Council of Medical Research. (ICMR), diabetes mellitus is a non-communicable disease (NCD) that has been steadily increasing in Tamil Nadu over the past couple of decades, with a predicted incidence of 10.4%.[5]The research, titled "Secular Trends in Diabetes in India (STRiDE-I): Change in prevalence in ten years among urban and rural populations in Tamilnadu," reported by the Times of India (2021), found that although there was an upsurge throughout sectors, the increase was more notable in town and peri-urban regions. A survey published in 2016 by the Deccan Chronicle states that one in ten people in Tamil Nadu has diabetes and likewise Hindu magazine in 2020, stated that the number of individuals with diabetes in rural Tamil Nadu had skyrocketed. Diabetes is a leading

source of substantial complications over time, such as kidney failure, damage to the eyes, lower limb amputation, strokes, and coronary artery disease. [6–8] Diabetic foot illness is a significant challenge for health facilities and practitioners. A frequent, serious, and persistent complication of diabetes is diabetic foot ulcer. [9] A foot ulcer might occur at any moment in the course of life for up to 25% of individuals with diabetes. Thirty percent of diabetic patients often need hospitalisation due to diabetic foot ulcer. [10]. Twenty percent of infections end in an amputation, and over 50% of all foot ulcers get infected and need hospitalisation. [9] In India, the incidence of patients with diabetes foot is rising in rural as well as urban areas, accounting for 85% of all amputations. In India, an estimated 100,000 legs are amputated annually, and the number is rising. [11]Healing these wounds is hampered by diabetes-related immune system dysfunction and harm done to blood vessels. [10]. Amputations occur 10–20 times more often in diabetics than in non-diabetics. [9–10]. As to the International Diabetes Federation (IDF) estimations, diabetes-related limb loss occurs somewhere on the globe every 30 seconds. [12]. Amputations and persistent ulcers greatly decrease the standard of living and raise the chance of dying young. There are several obstacles to overcome, ranging from foot ulcers to peripheral vascular disease and nerve damage, which may lead to amputations and even premature deaths. [13–16].The site of diabetic foot ulcer injury is abundant in oxidising agents, primarily H2O2, which are provided by neutrophils and macrophages.[17–18].Diabetes foot treatment is important since it is based on techniques to enhance the standard of care for patients who have been hospitalised with diabetic foot. [19–20] In order to avoid diabetic foot and successfully treat this illness, it is necessary to raise awareness of the problem and put foot care techniques into practice. [21–22]. Amla, alternatively referred to as the Indian gooseberry, Phyllanthus emblica, or Emblica officinalis, is a plant that includes ascorbic acid, emblicanin A and B, which have powerful antioxidant properties and have been shown to have advantages that accelerate the healing of wounds. [23–24]Tissue healing is aided by the addition of antioxidants to the wounded surroundings. Consuming amla or using it on a daily basis guards against several viral, bacterial, and fungal illnesses. Due to its cooling qualities, amla juice is perfect for healing chronic ulcers and a wide range of skin conditions. High antioxidant qualities help protect the heart, brain, lungs, skin, and wounds that become infected. [25–26] Indian gooseberry or amla is one of the many significant therapeutic herbs in Indian traditional medicine systems. Significant substances found in amla, as revealed by phytochemical research, include tannins, alkaloids, polyphenols, vitamins, and minerals. [26]. It has been discovered that ascorbic acid, gallic acid, ellagic acid, emblicanin A and B, phyllembein, quercetin, and others are physiologically beneficial. Moreover, amla is said to have strong immune-modulatory, free radical scavenging, antioxidant, anti-inflammatory, and anti-mutagenic characteristics that make it useful in both the management and avoidance of diabetes. [27] Emblica shield cells from harm by free radicals, promote proliferation of cells, and cross-link collagen at the site of wounds, as seen by a rise in extracellular activity. [28] Therefore, emblica used topically aids in hastening the curing of diabetic wounds via contraction and closure. [29] Researchers discovered that a high percentage of individuals with diabetes mellitus had diabetic foot ulcers, which led to frequent hospital stays. As a safe and affordable alternative to surgery that speeds up the healing process of wounds, amla can help lower the monetary cost of hospital stay. This inspired the investigators to carry out a study whose objective was to evaluate the impact of amla juice treatment on the degree of wound healing in clients with diabetic foot ulcer.

2. Objectives of the Study

1. To evaluate the level of wound healing with in the experimental and control group of clients with Diabetic foot ulcer before and after the intervention.
2. To evaluate the level of wound healing between the experimental and control group of clients with Diabetic foot ulcer after the intervention.
3. To determine the association in the pre and post test mean differed level of wound healing among Diabetic foot ulcer clients with their selected demographic variables in experimental and control

group.

Hypotheses.

H_1: There is a significant difference between the pre and post test level of wound healing among clients with Diabetic foot ulcer with in experimental and control group at $p<0.05$.

H_2: There is a significant difference in the post test level of wound healing among clients with Diabetic foot ulcer between experimental and control group at $p<0.05$.

H_3: There is a significant association in the pre and post test mean differed level of wound healing among Diabetic foot ulcer clients with their selected demographic variables in experimental and control group at $p<0.05$.

3. Materials and Methods.

Research Design and Methodology: A quantitative research methodology was used. True experimental two group before - after research design was adopted.

Study settings: TNK Hospital's Medical and Surgical Unit in Tiruvannamalai served as the study's location.

Sample and Sample Size: Clients who met the inclusion criteria and had a diabetic foot ulcer made up the research participants. A 5% attrition rate and two population proportion formulas were used to identify the sampling range of sixty. Thirty of the sixty diabetic clients with diabetic foot ulcers were allotted to the interventional group, and the other thirty to the control group.

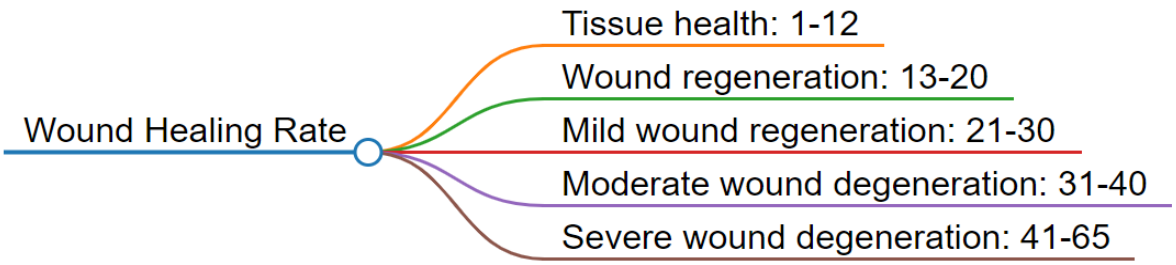
Sampling technique: For this investigation, a simple random sampling procedure using a lottery method was used to draw the participants.

Development and description of tools used for the study:

Section A: This segment contain socio-economic factors including age, gender, religion, education, occupation, family income, type of family, diet pattern, type of work, type of diabetes mellitus, habits of smoking, alcohol intake, exercise, and family history of diabetes mellitus. It also includes: nature of treatment, site (location) concerned, type of wound phase, duration of diabetic foot ulcer, and dressing duration.

Section B: Modified Bates-Jensen the Wound evaluation or examination Tool is a diabetic foot ulcer examination tool used to examine the degree of wound healing before and after the intervention. The evaluation comprise of size and depth of wound , and edges, under-mining , presence of necrotic tissue, type and amount of exudates, skin coloration surrounding the wound, peripheral tissue edema and indurations, granulation tissue and epithelialization.

Degree of wound healing Score:



Content validity: To illustrate the tool's content validity, six nursing professionals, one dietician, and two medical experts gave their comments.

Reliability of Tool: The study was able to proceed as the reliability score of r = 0.96 determined by

inter-rater reliability, indicated good tool reliability.

Pilot study: Based on pilot study findings, no major change were found in the degree of wound healing for the control group . In the experimental group, the degree of wound healing improved significantly at $p<0.001$ level , which suggested the feasibility of the research study.

Statistical Testing: The statistical testing has been done using IBM SPSS version 21. Descriptive statistics were utilised, namely frequency and percentage (%) distribution, used for analysing the variables of clients with diabetic foot ulcer. The mean and SD (σ) were used to determine the wound healing level both before and after the intervention in clients with diabetic foot ulcer. Inferential statistics namely, an unpaired "t" test were employed to evaluate the pre- and post-test levels of wound healing between the experimental and control group, while a paired "t" test was used to compare the levels of wound healing within the experimental and control group. An ANOVA was used to determine the association of the differed pre and post-test score of wound healing with the selected demographic factors of clients with diabetic foot ulcer. It was based on a 95% confidence interval. The significant level at a P value of <0.05 were considered to evaluate the difference.

Procedure for Data Collection

The collection of the data was done for the period of six weeks. Confidentiality was assured and the study aim and objectives, purpose and risk of the research study were communicated after obtaining approval from the hospital administration. The participants were given a short introduction by the investigators along with details about themselves and the purpose of the research. The investigators built a relationship with the participants and gave them the assurance that they would not suffer any physical or psychological harm throughout the study. After receiving their explicit permission, both in writing and verbally by taking the informed consent to take part in the research study, the investigators collected the socio-demographic variables and administered the pre-test by using the Modified Bates-Jensen wound assessment tool to measure the degree of wound healing. Data were gathered in both groups using the observational and interview methods, which took around 25 to 30 minutes. For the experimental group, an amla juice dressing consisted of 10-15ml of amla juice-impregnated gauze applied to the diabetic wound, one time daily for seven days during the evening hours. Routine measures done by hospital were adhered for the control group. Using the same wound assessment tool, a post-test was administered to both groups on the seventh day after the intervention. When gathering the data, the investigators followed ethical principles.

4. Result

The tables below display the data that were analysed:

Table 1: Frequency and percentage distribution of the pre and post-test degree of wound healing in the experimental and control group clients with diabetic foot ulcer

N=60

S.No	Group	Assessment	Tissue health 1-12		Wound regeneration 13-20		Mild wound regeneration 21-30		Moderate wound degeneration 31-40	
			F	%	F	%	F	%	F	%
1	Experimental	Pre-test	-	-	-	-	22	73.33	8	26.67
		Post test	2	6.67	18	60.0	10	33.33	-	-

2	Control	Pre-test	-	-	-	-	24	80.0	6	20.0
		Post test			2	6.67	23	76.67	5	16.67

Table 2: Comparisons of the pre and post-test degree of wound healing with in the experimental and control group clients with diabetic foot ulcer

N=60

S.No.	Group	Assessment	Mean	S.D (σ)	Paired‘t’ Value
1	Experimental	Pre-test	27.93	2.74	t=7.591*** p=0.000 , S
		Post test	21.16	4.95	
2	Control	Pre-test	27.63	2.82	t=2.408* p=0.023, S
		Post test	26.97	3.21	

***p<0.001, *p<0.0, S-Significant

Table 3: Comparisons of the pre and post-test degree of wound healing between the experimental and control group clients with diabetic foot ulcer

N=60

S.No.	Group	Assessment	Mean	S.D (σ)	Un paired‘t’ Value
1	Experimental	Pre-test	27.93	2.74	t=0.418 p=0.678, N.S
		Post test	27.63	2.82	
2	Control	Pre-test	21.16	4.95	t=5.380*** p=0.000, S
		Post test	26.97	3.21	

***p<0.001 , S-Significant , N.S-Non Significant

Table 4: Association of the mean pre and post test differed wound healing score among diabetic foot ulcer clients with their selected demographic characteristics

There was a statistically significant association existed with regard to the habit of smoking and family history of diabetes mellitus at p<0.05 and p<0.001 levels, respectively in the experimental group . A statistically less significant association existed with regard to gender , exercise, and family history of diabetes mellitus at p<0.05 level and marital status at p<0.01 level in the control group . However, there is no such association found with other demographic characteristics in both experimental and control group.

5. Discussion

The 1st objective was to evaluate the degree of wound healing in the experimental as well as control group clients with diabetic foot ulcers before and after the intervention. 22 (73.33%) of the experimental group's participants had mild wound regeneration, and 8 (26.67%) had moderate wound degeneration, according to the pre-test assessment of the wound healing degree. Pre-test results for wound healing in the control group showed that 6 subjects (20.0%) and 24 subjects (80.0%) had moderate wound degeneration and mild wound regeneration, respectively. Analysis of the

experimental group's post-test degree of wound healing showed that 2 subjects (6.67%) had tissue health, 10 subjects (33.33%) had mild wound regeneration, and 18 subjects (60.0%) had wound regeneration.

The post-test, wound healing degree in the control group showed that 23 subjects (76.67%) had mild wound regeneration, 5 subjects (16.67%) had moderate wound degeneration, and 2 subjects (6.67%) had wound regeneration. (Figure 1).The results of this study were consistent with those of other research evaluating the benefits of gooseberry, or amla, on individuals with diabetes mellitus. [30–31]

N=60

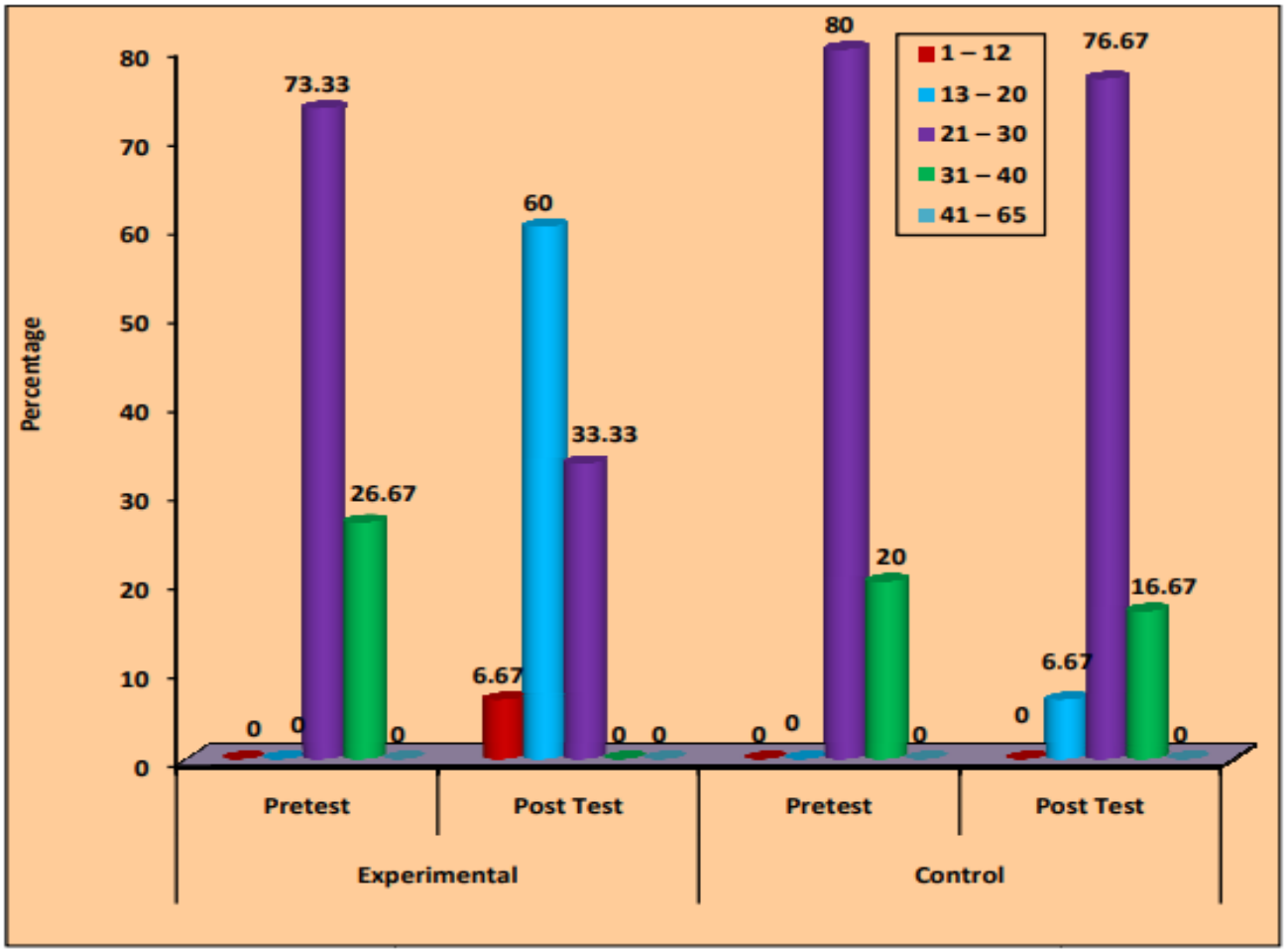


Fig.1. The percentage distribution of the experimental and control group's pre and post-test level of wound healing.

The subsequent 2nd objective was to compare the degree of wound healing in the experimental and control group clients with diabetic foot ulcer before and after the intervention.

The mean value as well as the SD (σ) of the degree of wound healing in the experimental group was 27.93 and 2.74 for the pre-test analysis, as well as 21.16 and 4.95 for the post-test analysis. The estimated paired t' value of 7.591 was observed to be significant at the $p<0.001$ level. The pre-test mean and SD (σ) for the control group's degree of wound healing were 2.82 and 27.63, respectively. On the degree of wound healing, the post-test mean and SD (σ) were 3.21 and 26.97, respectively. At the $p<0.05$ level, the calculated "t" value of 2.408 was observed to be significant. (Figure 2) Thus, the previously mentioned research hypothesis (H1) denotes that **"there is a significant difference between the pre and post test level of wound healing with in experimental and control group at P < 0.05"** was accepted.

The results of this investigation were consistent with those of previous research assessing the impact of amla and its potential as an antioxidant for preventing ulcers in individuals with diabetes. [32–33]

N=60

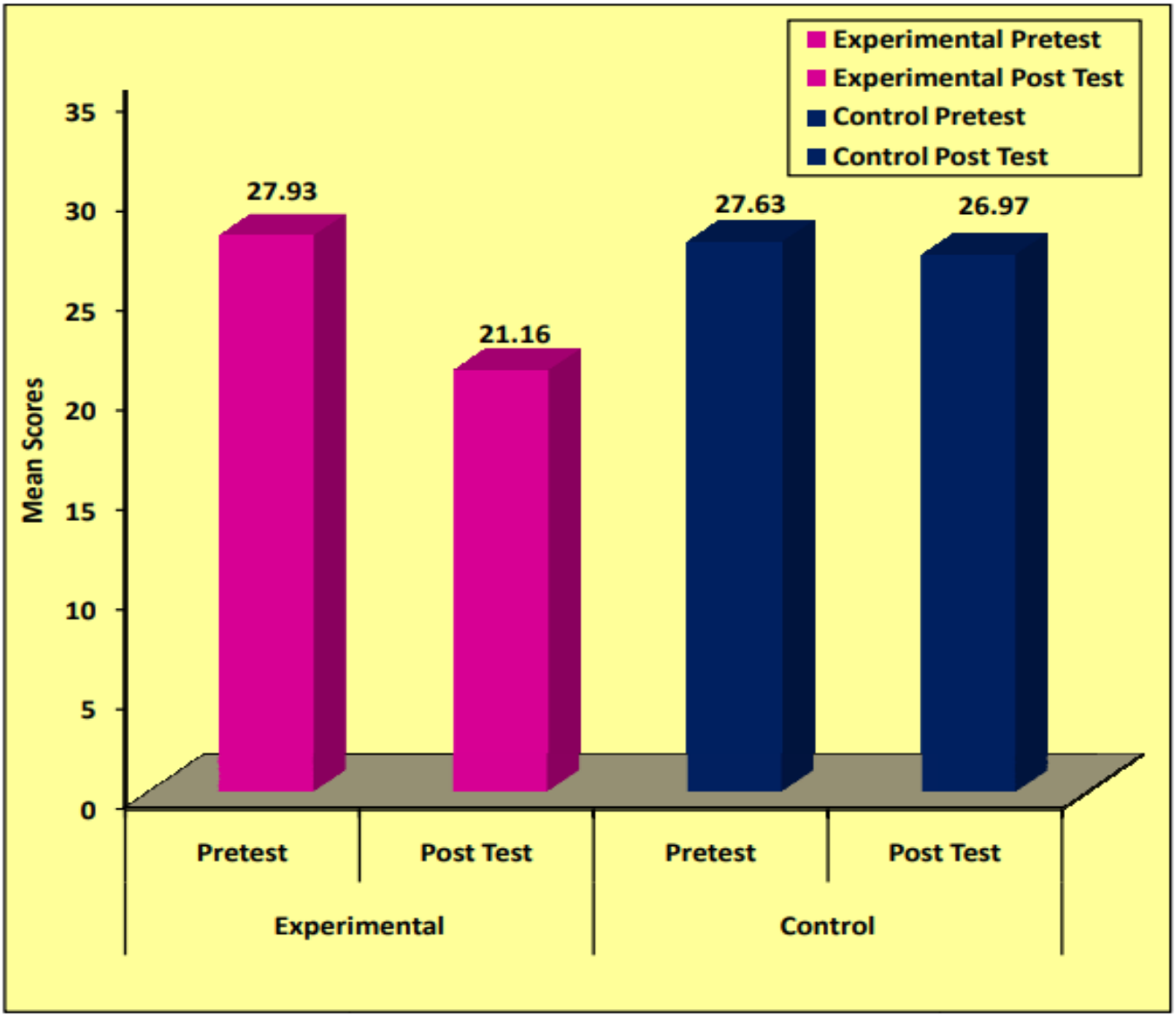


Fig.2: Comparison of the pre and post-test level of wound healing in experimental and control group clients with diabetic foot ulcer

The 3rd objective has been to compare the pre and post interventional level of the wound healing among clients with diabetic foot ulcer in the experimental and control group yielded a calculated unpaired "t" value of 0.418 for pre-test analysis between the experimental and control group , which was found to be non-significant at the $p<0.05$ level. The calculated unpaired "t" value, 5.380, was found to be significant at the $p<0.001$ level when comparing the post-test findings on the level of wound healing between the experimental and control group. (Figure 3). There was a significant variation in the post-test level of wound healing between the two group, which indicates that topical application of amla juice over the diabetic foot ulcer accelerated the pace of wound healing in the experimental group. Thus, it was decided to accept the previously mentioned study hypothesis (H2), which claims that

"there is a significant difference in the post test level of wound healing among clients with Diabetic foot ulcer between experimental and control group at p<0.05" was accepted. The results of the research aligned with those of the research carried out by Vidushan et al., in which 30 individuals with diabetes mellitus who were between the ages of 31 and 65 were treated with Amla dressing in comparison with 30 controlled dressing group (povidone iodine followed by normal saline) for diabetic foot ulcers. The Amla dressing group showed a substantial improvement in ulcer healing, with 52% exhibiting mild wound regeneration and 12.6% displayed moderate wound regeneration at the p<0.001 level.

N=60

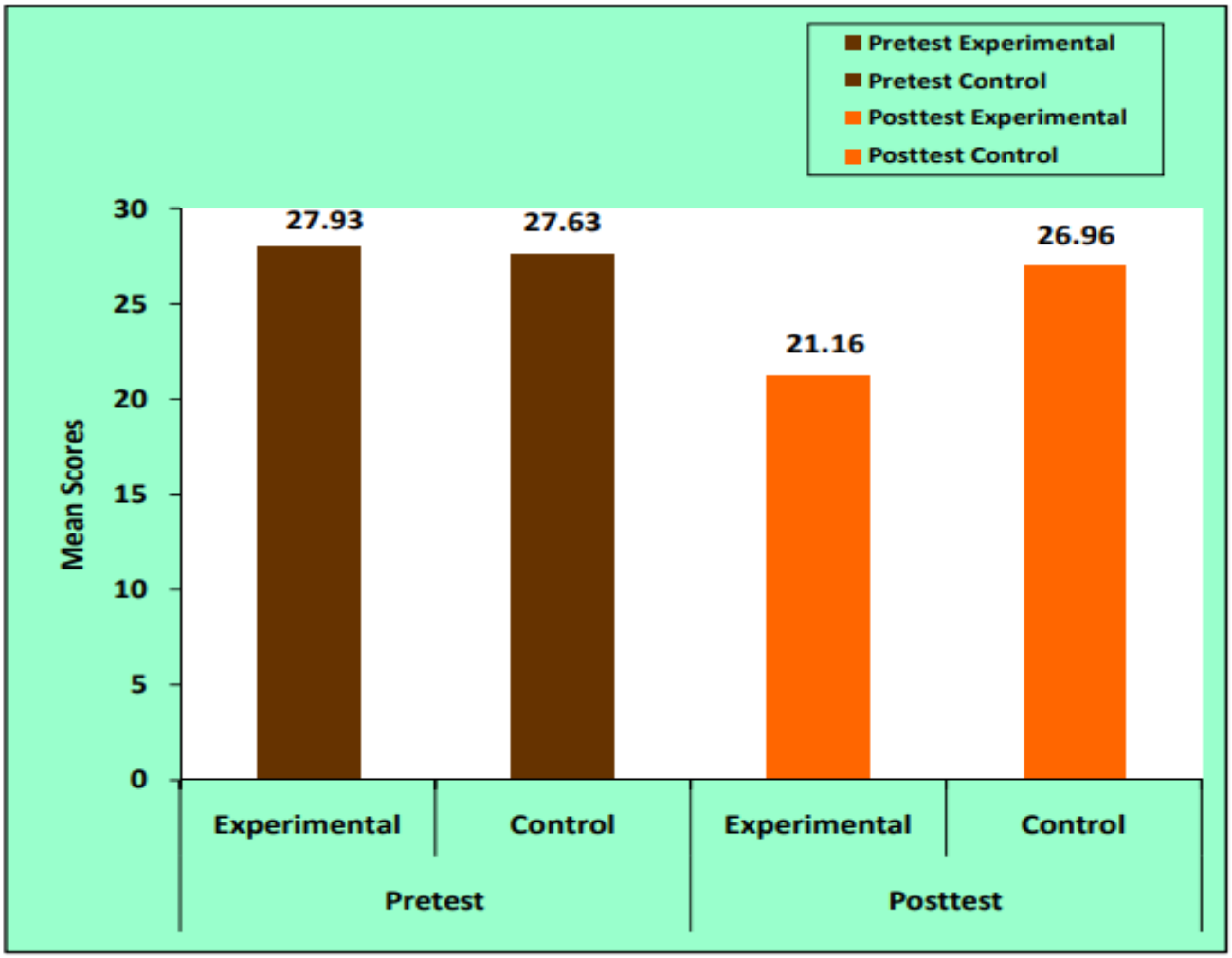


Fig.3: Comparison of the pre and post-test level of wound healing between experimental and control group clients with diabetic foot ulcer

The 4th objective was to determine the association in the mean differed pre and post-test degree of wound healing in clients with diabetic foot ulcer with their selected demographic variables in experimental and control group. Based on the statistical findings , the previously mentioned research hypothesis (H3) which states that **"there is a significant association in the pre and post test mean differed level of wound healing among Diabetic foot ulcer clients with their selected demographic variables in experimental and control group at p<0.05"** was accepted for the experimental group with regard to the habit of smoking and family history of diabetes mellitus and in control group , the formulated hypothesis was retained for gender, exercise, marital status and family history of Diabetes Mellitus.The hypothesis was rejected for other demographic variables in the experimental and control

group.

6. Conclusion

The present study concluded that, amla juice application over the diabetic wound for the individuals with diabetic foot ulcer in the experimental group had a significantly improved post-test degree of wound healing when .compared to individuals in the control group who were only provided with routine measures by hospital. In order to enhance the healing of wounds in clients with foot ulcers caused by diabetes, the topical application of amla juice may be used as an alternative therapy that is safe, affordable, and free of negative effects. [25–27] It is also important for minimising the size and depth of wounds, as well as for accelerating the healing process, which shortens the duration of therapy and shortens hospital stay. [28–29]

7. Implications for Clinical Practice

According to the research, health professionals are essential in playing a pivotal role by providing topical amla juice application for diabetic clients with foot ulcer . Also further research studies are suggested to determine the effect of amla juice on a daily basis as a regular non-pharmacological treatment for individuals with varied degrees of diabetic foot ulcer . [26–27]. To assess the efficacy of topical administration of Amla juice for diabetic foot ulcer among diabetic patients, appropriate research could additionally be undertaken with a large number of participants and in various contexts, such as communal homes or additional medical centres.

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