RESEARCH
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A STUDY TO ASSESS THE EFFECTIVENESS OF ADJUVANT THERAPIES IN HOME CARE MANAGEMENT OF DIABETIC FOOT ULCER TO REDUCE HEALING TIME AND AMPUTATION RATE AMONG THE DIABETIC PATIENTS RESIDING IN RURAL AREAS OF NELLORE, ANDHRA PRADESH

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Abstract

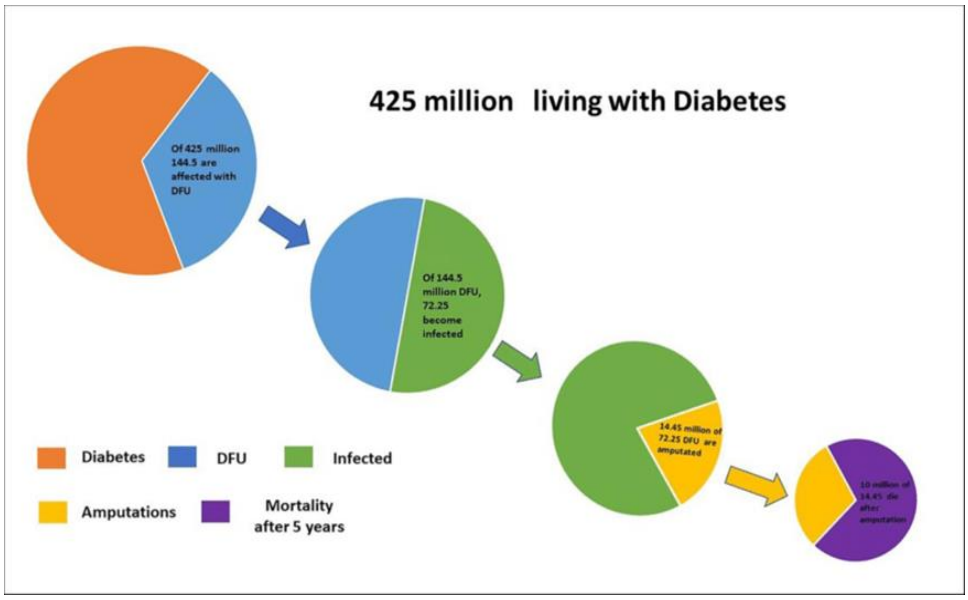
Need for study: Diabetes mellitus (DM) is one of the main problems in health systems and a global public health threat that has increased dramatically over the past 2 decades. According to epidemiological studies, the number of patients with DM increased from about 30 million cases in 1985, 177 million in 2000, 285 million in 2010, and estimated if the situation continues, more than 360 million people by 2030 will have DM. The International Diabetes Federation (IDF) have estimated that 451 million adults live with diabetes worldwide in 2017 with a projected increase to 693 million by 2045 if no effective prevention methods are adopted. The prevalence of both type 1 and type 2 diabetes among children and adolescents has also increased, and the estimates of children and adolescents below age 20 with type 1 diabetes now exceed one million. Diabetic foot ulcers are common and estimated to affect 15% of all diabetic individuals during their lifetime. It is now appreciated that 15 – 20% of patients with such foot ulcers go on to need an amputation. Almost 85% of the amputations are preceded by diabetic foot ulcers. Adjuvant therapies in addition to standard practices in DFU care, there are a wide range of agents available or currently being studied as adjuvant therapies. Hydrogel dressings are a great way to provide hydration to wound. The benefits of using hydrogel-based dressings for wound care are vast by providing excellent source for providing moisture to a dry lesion, hydrogel dressings act fast to help cool down a wound, as well as provide temporary relief from pain for up to six hours. **Objectives:** To assess the effectiveness of adjuvant therapy in home care management of diabetic foot ulcer and to reduce healing time and amputation rate. To find out the association between healing process of diabetic foot ulcer and selected demographic variables among both experimental and control groups. **Material and methods:** A quantitative research approach was adopted .True experimental study was conducted in selected rural areas of Nellore. The sample of 100 diabetic patients having diabetic foot ulcer were selected using simple random method ,out of which 50 were in the experimental group and 50 were in control group. The severity of wound was assessed by Bates-Jenson wound assessment scale. On the first day the demographic variables of the samples were collected by interview method then the Pretest was done to assess the state of the wound by using BWAT scale for both experimental and control groups. For the experimental group intervention that is wound dressing was done with adjuvant therapies by using hydrogel to have debride mentation and honey was applied on the wound and dressing was done with gauze pads. It was continued for 30 days with the help of local health workers. For control group regular dressing procedure was followed. For both the groups health education was given regarding diet, exercises medications to control the confounding variables. The post test was done on 1 5 th and 30thday by using BWAT scale in experimental group and control group. Data obtained was analyzed by using descriptive and inferential statistics and the effectiveness was assessed and tabulated. **Result:** For the experimental group Post hoc multiple comparison of Bonferroni t-test shows the reduction of wound score from pre-test to post-test-I (36.34

± 5.37 vs 28.10 ± 5.44, respectively mean difference is 8.24), which was statistically significant ($p \leq .001$) . After post-test2, intervention further reduces the wound score (36.34 ± 5.37 vs 28.10 ± 5.44, respectively mean difference is 14.58), which was statistically significant reduction from pre-test to post test-II score ($p \leq .001$). Therefore, we can conclude that an adjuvant therapy in home care management reduces the wound score significantly. In the control group Post hoc multiple comparison of Bonferroni t-test shows the reduction of Wound assessment score from pre-test to post-test-I (36.84 ± 4.73 vs 34.08 ± 5.03, respectively mean difference is 2.76), which was statistically significant ($p \leq .01$) . After post-test2, routine care reduces the wound score (36.84 ± 4.73vs 32.54 ± 5.81, respectively mean difference is 4.30), which was statistically significant reduction from pre-test to post test-II score ($p > .05$). Therefore, we can conclude that routine care not reduces the wound score significantly compared to experimental group. **Conclusion:** So adjuvant therapy can be implemented at community, home set up and sub centers especially in rural areas to treat the patients, because it is cost effective and cost beneficial.in rural areas where health care services are not much available and accessible to treat diabetic foot ulcers.

Keywords: Diabetic Foot Ulcer, Adjuvant Therapies, Amputation.

BACKGROUND AND SIGNIFICANCE OF THE PROBLEM

Diabetic foot ulcers are common and estimated to affect 15% of all diabetic individuals during their lifetime. It is now appreciated that 15 – 20% of patients with such foot ulcers go on to need an amputation. Almost 85% of the amputations are preceded by diabetic foot ulcers. Numerous risk factors for the development of foot ulcers have been suggested, the most important being peripheral sensory neuropathy followed by peripheral vascular disease. The proportion of neuropathic, neuro-ischemic, and purely ischemic lesions in diabetics is 54, 34, and 10%, respectively. In India, it is estimated that approximately 40,000 legs are being amputated every year, of which 75% are neuropathic with secondary infection, which is potentially preventable.



Financial Burden Due To DFU in India:

In India diabetic foot ulcer treatment market size is expected to reach USD 361.2 million by 2030, registering a CAGR of 7.82% from 2024 to 2030. The market has been witnessing significant growth, driven by several factors such as the rising prevalence of diabetes, fueled by factors such as sedentary lifestyles, unhealthy dietary habits, and an aging population, which has led to an increase in the incidence

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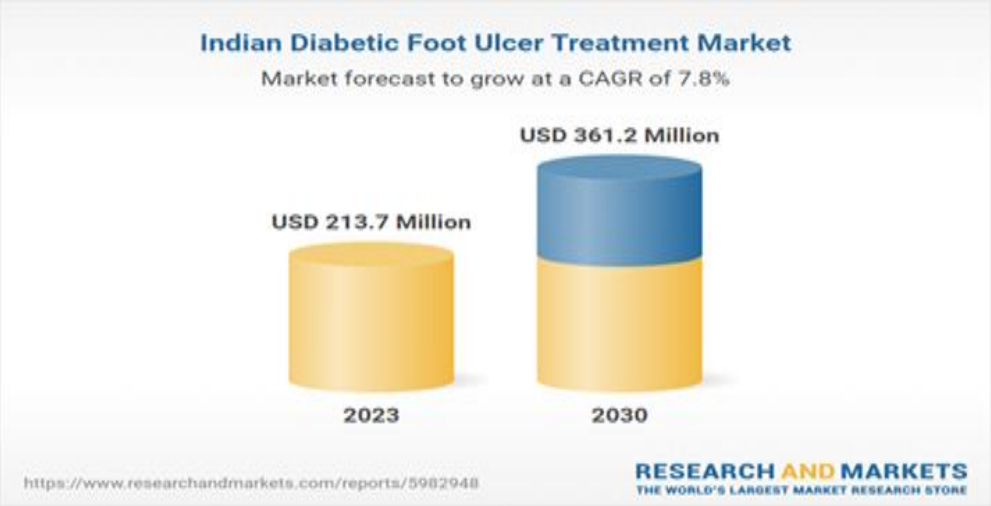
of diabetic foot ulcers. With approximately 77 million diabetic patients in India, the demand for effective treatment options for diabetic foot ulcers is on the rise.



Additionally, increasing awareness about diabetic foot care among patients and healthcare professionals has contributed to the market growth.. Furthermore, government initiatives to improve healthcare infrastructure and increase access to diabetic care services in rural areas are expected to bolster market expansion.

In order to decrease the cost of medical car and financial burden on family and government the best choice is home care management of diabetic foot ulcer . in the present study the researcher used honey and hydrogel .these are local products which are available at low cost with needed medical properties.

Honey is a sweet and viscous fluid produced by bees and other insects from the nectar of flowers. It is composed mainly of a variety of sugars, traces of pollen and water. Honey was used to treat infected wounds as long as 2000 years before bacteria were discovered to cause infection. It has been reported to have inhibitory action to around 50 species of bacteria and fungi (aspergillus, penicillium). The prevalence of antibiotic-resistant microbial species has led to a re-evaluation of the therapeutic use of ancient remedies, including honey. Honey rapidly clears infection from wounds, with no adverse effects to slow the healing process. Honey may actively promote healing. It is being used in treatment of burns. Decubitus ulcers, wounds for many patients which are proven scientifically safe with no side effects

Hydrogel dressings are composed of about 90% water suspended in a gel made up of insoluble hydrophilic polymers which swell up on contact with water. They control the exchange of fluid at the wound-bandage interface, with sodium and other molecules in the wound discharge being exchanged for hydrogel compounds. The success of hydrogel dressings is thought to be due to their ability to maintain an optimum wound healing environment, which is warm and moist, rather than dry whilst keeping out infective agents. Thus, all recent research supports the active use of hydrogels for wound dressing in most types of wounds, as their use leads to the hydration and loosening of necrotic tissue, promoting its autolysis and debridement, and absorbs moderate amounts of sloughing discharge and exudate.

For most of the people residing in rural areas health services are non-accessible in terms of transportation and finance. So that they neglect to have proper diabetic foot care which leads to amputation. This problem can be resolved when we are able to

provide best home remedies which are locally available low cost and effective to enhance healing process of diabetic foot ulcers. Hence the researcher thought to using adjuvant therapies like autolytic debridement hydrogel and honey dressing for diabetic foot ulcer in order to reduce the healing time and amputation rate.

Research Objectives

1. To assess bio- physiological variables among experimental and control groups
2. To assess the status of diabetic foot ulcer among both experimental and control group.
3. To assess the effectiveness of adjuvant therapy in home care management of diabetic foot ulcer and to reduce healing time
4. To assess the effectiveness of adjuvant therapy in home care management of diabetic foot ulcer and to reduce amputation rate.
5. To find out the association between healing process of diabetic foot ulcer and selected demographic variables among both experimental and control groups

Operational Definitions

- **Effectiveness**: It denotes producing a successful result. Outcome of adjuvant therapy on healing process of diabetic foot ulcer among diabetic patients of experimental group
- **Adjuvant therapy**: Adjuvant therapy is the Treatment that is given in addition to the primary (initial) treatment designed to help reach the ultimate goal. Here using autolytic debridement with hydrogel and topical application of honey dressing are used in the experimental group
- **Diabetic foot ulcer:** A non-healing or poorly healing full-thickness wound, through the dermis, below the ankle in an individual with diabetes.
- **Healing:** It is the complex process in which the skin, tissues under it repair themselves after injury in diabetic foot ulcer
- **Amputation:** Surgical removal of a toe, foot or part of a leg due to non-healing diabetic ulcer that causes severe damage to tissues and bone

Assumption:

- Neglected diabetic foot ulcer lead to amputation
- Therapeutic use of adjuvant therapy by using hydrogel and honey reduces healing time and amputation rate
- Diabetic patients in the rural areas accept the adjuvant therapy which is economical and accessible for healing of diabetic foot ulcer

Hypothesis

H_1: There will be difference in the healing of diabetic foot ulcer among diabetic patients in experimental and control group at 0.05 level of significance

H_2: There will be reduction in the amputation rate of diabetic foot among diabetic patients in experimental group than control group at 0.05 level of significance

H_3: There will be significant association in healing time and amputation rate between the experimental and control groups with their selected demographic variables at 0.05 level of significance.

Delimitations

- The study is delimited to 4 weeks
- The study is delimited to patients with DFU grade 1 &2
- The study is limited to people residing in selected rural areas of Nellore

Projected outcome

This study would evaluate the effectiveness of adjuvant therapy in management of DFU in diabetic patients in reducing healing time and amputation rate

RESEARCH METHODOLOGY

Research approach: Quantitative research approach

Research design: True experimental design

Setting of the study: selected rural areas of Nellore

Population:

Targeted population: Diabetic patients with foot ulcer

Accessible population: diabetic patients with foot ulcer in selected areas

Sample: Diabetic patients with foot ulcer in selected villages

Criteria for sample selection

Inclusion criteria

- Diabetic patients with type II diabetes mellitus.
- Diabetic patients with DFU's who were in the age group of 35 to 55yrs
- Both male and female
- Patients with DFU grade 1 and 2
- Diabetic patients with good glycemic control
- Diabetic patients who were willing to participate in the study

Exclusion criteria

- Diabetic patients with type I diabetes mellitus
- Diabetic patients with DFU's aged below 35yrs and above 55yrs
- Patients with DFU grade 3 and 4
- Patients with DFU with gangrene, charcot foot, thromboangitis obliterans (TAO)
- Diabetic patients with poor glycemic control
- Uncontrolled infection
- Patients who have known allergy to honey

Sampling technique: simple random sampling technique

Sample size:.100

The estimated sample for the present study is calculated by using Yemen's formula $n=N/1+N\ (e^2)$

Where n = sample size

N= total number of population = 100 e =

Desired level of precision = 0.05 n = N/1+N

$(e)^2$

$n = 100/1+100(0.05)^2$

100/1.25=80 Hence n = 80

Considering 10% attrition, a sample of 8 is added to the estimated sample size. Hence, a total of samples size is 88. Considering the round figure 100 will be included for the present study.

Independent variable: Adjuvant therapy (Non –surgical debridement with hydrogel and honey dressing)

Dependent variable: Wound status, healing time and amputation rate

Extraneous variables: Diet, physical activity, medications.

Tools for data collection

The tool was prepared by the investigator after extensive study of the related literature and with the guidance of experts. The tool consists of two sections.

Section- A

This section deals with the demographic variables of 16 items. It includes age, gender, educational status, occupational status, marital status, life style ,family history of diabetes, duration of illness, dietary pattern, whether on diabetic diet, habit of smoking, if yes duration of smoking, habit of alcoholism, if yes duration of alcoholism, habit of wearing footwear, if yes type of footwear, and if special footwear its type. No score was allotted, but the data of this section will be used for descriptive analysis.

Section- B

This section deals with the assessment of the diabetic wound status using Bates Jensen Wound assessment tool. It consists of 13 parameters they are size, depth, edges, undermining, necrotic tissue type, necrotic tissue amount, exudate type, exudate amount, skin colour surrounding wound, peripheral tissue oedema, peripheral tissue induration, granulation tissue and epithelialisation.

Scoring procedure

Each parameter had a score from 1-5 depending on the severity of the wound. The minimum and maximum possible score was 13 and 65 respectively. The score interpretation of the wound status will be done as follows:

Score	Diabetic wound status
1-22	Mildly unhealthy
23-44	Moderately unhealthy
45-65	Severely unhealthy

Validity

The validity of the tool was obtained from three experts from nursing field.

Reliability

The reliability of the tool was tested by spilt half method by using Karl Pearson's correlation coefficient.

r=2r/1+r

Feasibility

The feasibility of the study will be tested by conducting pilot study.

Ethical clearance

Ethical clearance was obtained from Narayana Nursing College; Nellore. Clinical trial registration of India (CTRI) was also done as advised by Dr. NTRUHS prior to the data collection process. Permission was obtained from the District Medical health officer, Nellore -to conduct study in selected villages. Informed written consent was obtained individually from the patients, participating in the research study..

Consent

Written consent was taken from participants before going to conducting the study.

Autonomy

All participants were consider to make rational decision and moral choice during the participation of study

Justice

The study will be useful diabetic patients with diabetic foot ulcer

Beneficence

diabetic patients with diabetic foot ulcer Would benefited from the study as they have early wound healing and reduced rate of amputation .

Non malefficence

The study would not be harmful to participants.

Confidentiality

All participants were assured that confidential information would not be shared with others and it is used only for the study purpose.

Veracity

Maintain trust relationship between the investigator & samples

Intervention: Experimental group receives adjuvant therapy i.e.autolytic debridementation using hydrogel and honey dressing. Dressing material pasteurized honey and hydrogel was provided by the investigator for 30 days. Further health education was given regarding diet, exercises, lifestyle modifications, use of medications to prevent extraneous factors in wound healing process.

No intervention or adjuvant therapy is given to control group. The patients will be following regular conventional therapy. But health education was given regarding diet, exercises, lifestyle modifications, use of medications to prevent extraneous factors in wound healing process.

The intervention was implemented as follows for the experimental group.

Day -1:- Interview was done to collect demographic data by using structured questionnaire. The bio-physical parameters were checked. The diabetic foot ulcer status was assessed by using Bates-Jensen Wound assessment tool.(Pre- test)

Day -2:- Demonstrating dressing with the use of hydrogel and honey.

Day -3:- Getting return demonstration from family members under the supervision of health workers.

Day -4:- Giving check list to assess the practice of dressing protocol

Day -15:- Post -test -1 by using Bates-Jensen Wound assessment tool to assess the healing process of ulcer.

Day -30:- Post-test -2 Bates-Jensen Wound assessment tool the healing process of ulcer.

Plan for Data Analysis

The data will be analyzed in the terms of objective of study using the descriptive statistics and inferential statistics. Data analysis as follows

Table 1: Demographic Variables

Demographic variables		Group			
		Experimental(n=50)		Control(n=50)	
		n	%	n	%
Age	30-40 years	12	24.00%	11	22.00%
	41-50 years	14	28.00%	19	38.00%
	>50 years	24	48.00%	20	40.00%
Gender	Male	20	40.00%	28	56.00%
	Female	30	60.00%	22	44.00%
Educational status	Illiterate	18	36.00%	16	32.00%
	Primary education	12	24.00%	10	20.00%
	Secondary education	11	22.00%	18	36.00%
	Graduation and above	9	18.00%	6	12.00%
Occupation status	Un employee	20	40.00%	20	40.00%
	Skilled worker	5	10.00%	4	8.00%
	Daily wage worker	10	20.00%	7	14.00%
	Private or govt employee	15	30.00%	19	38.00%
	Small scale business	0	0.00%	0	0.00%
Type of family	Joint family	25	50.00%	26	52.00%
	Nuclear family	25	50.00%	24	48.00%
Type of Diabetes mellitus	Type IDM	0	0.00%	0	0.00%
	Type IIDM	50	100.00%	50	100.00%
Life style	Sedentary work	19	38.00%	15	30.00%

	Moderate work	23	46.00%	29	58.00%	
	Heavy work	8	16.00%	6	12.00%	
Duration of Diabetes	Less than I year	6	12.00%	5	10.00%	
	1 -3years	14	28.00%	11	22.00%	
	4 -6years	6	12.00%	13	26.00%	
	Above 6 years	24	48.00%	21	42.00%	
Duration of Foot ulcer	1-6 months	47	94.00%	48	96.00%	
	6-12 months	3	6.00%	2	4.00%	
	>1 year	0	0.00%	0	0.00%	
Whether on anti-diabetic treatment	On regular treatment	22	44.00%	28	56.00%	
	On irregular treatment	28	56.00%	22	44.00%	
	No treatment taken	0		0.00%	0	0.00%
Type of treatment	Allopathic treatment	48		96.00%	47	95.92%
	Ayurveda treatment	2		4.00%	2	4.08%
	Combination of allopathic and Ayurveda treatment	0		0.00%	0	0.00%
	Others	0		0.00%	0	0.00%
Habit of smoking	Yes	17		34.00%	19	38.00%
	No	33		66.00%	31	62.00%
IF yes, duration of smoking	Less than I year	0		0.00%	0	0.00%
	I -3years	1		5.88%	1	5.26%
	4 -6years	11		64.71%	9	47.37%
	> 6 years	5		29.41%	9	47.37%
Habit of alcoholism	Yes	17		34.00%	22	44.00%
	No	33		66.00%	28	56.00%
IF yes, duration of alcoholism	Less than I year	0		0.00%	0	0.00%
	I -3years	6		35.29%	7	31.82%
	4 -6years	8		47.06%	7	31.82%
	> 6 years	3		17.65%	8	36.36%
Dietary pattern	Vegetarian	14		28.00%	8	16.00%
	Ova lacto vegetarian	3		6.00%	1	2.00%
	Non-vegetarian	33		66.00%	41	82.00%
Whether on Diabetic diet	Regular diabetic diet	13		26.00%	16	32.00%
	Irregular diabetic diet	14		28.00%	18	36.00%
	No	23		46.00%	16	32.00%
Habit of wearing foot wear	Yes	47		94.00%	48	96.00%
	No	3		6.00%	2	4.00%
If yes, type of foot wear	Slippers	44		91.67%	43	87.76%
	Shoes	0		0.00%	0	0.00%
	Special chappals	4		8.33%	6	12.24%
if yes, special chappals, specify	MCR chappals	0		0.00%	0	0.00%
	Footwear recommended by doctor	2		25.00%	2	11.76%
	Acupressure chappal	6		75.00%	15	88.24%
Source of information on diabetes and diabetic foot ulcer	Family members	21		42.00%	20	40.00%
	Neighbors and friends	14		28.00%	12	24.00%
	Health care professionals	12		24.00%	10	20.00%
	Mass media	3		6.00%	8	16.00%
Do you have acceability and availability of health services in terms of transportation	Yes	23		46.00%	30	60.00%
	No	7		14.00%	5	10.00%

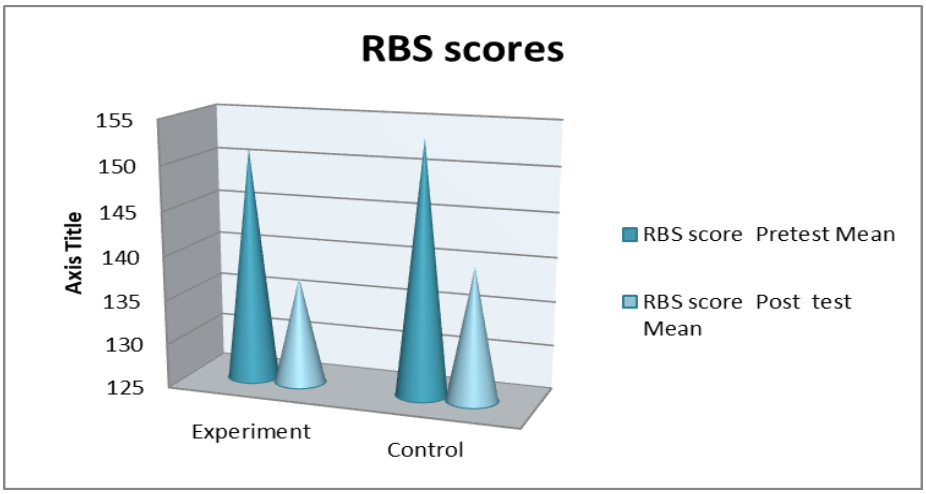
Comparıson of Random Blood Glucose Level Scores Between Experımental and Control Group

Grouop	RBS score				Mean difference	Student paired t-test
	Pretest		Posttest			
	Mean	SD	Mean	SD		
Experimental group	151.30	20.72	137.18	10.67	14.12	t=4.63 p=0.001(S)
Control group	153.40	19.86	140.00	18.28	13.40	t=3.94 p=0.001(S)

P.<0.001 significant S=significant

Statistically there is a significant difference between pretest and posttest

Above table compare the mean RBS score between experiment and control group. IN Experimental group pre test mean was 151.30 in post-test mean was 137.18 with mean difference 14.12 and the 't' value was 4.63 at P.<0.001 which shows significant reduction of RBS in experimental group. In control group are the pre-test mean was 153.40 and post teat mean was 140 with mean difference 13.40 which shows mild reduction in RBS n with 't 'value 3.94 at P.<0.001.



Distribution of Pretest, Posttest-I and Posttest-II Level of wound Ulcer assessment score among Experimental and Control groups of Diabetic patients (N = 50)

Assessment	Level of Wound ulcer healthy status	group				Chi-square value	P Value
		Experimental G (n=50)		Control G (n=50)			
		No.	%	No.	%		
Pretest	Mildly unhealthy	8	16.00%	6	12.00%	0.33	0.56(NS) DF=2
	Moderately unhealthy	42	84.00%	44	88.00%		
	Severely unhealthy	0	0.00%	0	0.00%		
Posttest-I	Mildly unhealthy	21	42.00%	10	20.00%	5.66	**0.05*(S) DF=2**
	Moderately unhealthy	29	58.00%	40	80.00%		
	Severely unhealthy	0	0.00%	0	0.00%		
Posttest-II	Mildly unhealthy	31	62.00%	14	28.00%	11.68	**0.001*** (S) DF=2**
	Moderately unhealthy	19	38.00%	36	72.00%		
	Severely unhealthy	0	0.00%	0	0.00%		

P>0.05 not significant NS= not significant DF= Degrees of freedom

P≤0.05 significant S= significant

Above table compares the level of wound health status score between experimental and control group among diabetic patients.

In pretest, there is no significant difference between experimental and control group of patients. In experimental group, 8 (16%) of them are having mild unhealthy score, 42(84%) of them are having moderately unhealthy score. In control group, 6(12%) of them are having mild unhealthy score, 44(88%) of them are having moderately unhealthy score.

The non-significant P- values 0.33 indicates, the level of wound health score were similar in both the groups.

In posttest-I, in experimental group, 21(42%) of them are having mild unhealthy score, 29(58%) of them are having moderately unhealthy score. In control group, 10(20%) of them are having mild unhealthy score, 40(80%) of them are having moderately unhealthy score .There is a significant difference between experimental and control group of patients. The significant P- values5.66 at 0.05level of significance indicates, the level of wound health score were not similar in both the groups. Where experimental group had improved wound healing than control group.

In posttest-II, in experimental group, 31(62%) of them are having mild unhealthy score, 19(38%) of them are having moderately unhealthy score. In control group, 14(28%) of them are having mild unhealthy score, 36(72%) of them are having moderately unhealthy score. There is a significant difference between experimental and control group of patients. The significant P- values 11.68 at 0.001 level of significance which indicates, the level of wound health score were not similar in both the groups. Experimental group patients are having more mild level of wound score than control group due to usage of adjuvant therapy.

Multiple comparison of wound score between pretest, posttest-I and posttest-II using Bonferroni t-test

	Assessment	Experiment		Repeated ANOVA test score		Bonferroni t- test		
		Mean	SD	F value	P value	Comparison	MD	P value
Experimental	Pretest	36.34	5.37	F=217.79	P=0.001***	Pretest vs post-I	8.24	0.001
	Posttest-I	28.10	5.44			Pretest vs Post-II	14.58	0.001
	posttest-II	21.76	5.74			Posttest I vs Posttest II	6.34	0.001
Control	Pretest	36.84	4.73	F=10.67	P=0.01**	Pretest vs post-I	2.76	0,01
	Posttest-I	33.08	5.03			Pretest vs Post-II	4.30	0.01
	posttest-II	32.54	5.81			Posttest I vs posttest II	0.54	0.26

MD=mean difference P≤0.05 significant P>0.05 not significant P≤0.01 highly significant P≤0.001 very high significant

In experimental group, Repeated measures ANOVA F- test shows that mean wound score difference is statistically significant between pre-test and posttest-II ($F = 217.79$, $p \leq 0.001$).

Post hoc multiple comparison of Bonferroni t-test shows the reduction of wound

score from pre-test to post-test-I (36.34 ± 5.37 vs 28.10 ± 5.44, respectively mean difference is 8.24), which was statistically significant ($p \leq .001$). After post-test2, intervention further reduces the wound score (36.34 ± 5.37 vs 28.10 ± 5.44, respectively mean difference is 14.58), which was statistically significant reduction from pre-test to post test-II score ($p \leq .001$). Therefore, we can conclude that an adjuvant therapies in home care management reduces the wound score significantly.

In control group, Repeated measures ANOVA F- test shows that mean wound score difference is not statistically significant between pre-test and posttest-II ($F = 10.67$, $p \leq 0.01$).

Post hoc multiple comparison of Bonferroni t-test shows the reduction of Wound assessment score from pre-test to post-test-I (36.84 ± 4.73 vs 34.08 ± 5.03, respectively mean difference is 2.76), which was statistically significant ($p \leq .01$) . After post-test2, routine care reduces the wound score (36.84 ± 4.73vs 32.54 ± 5.81, respectively mean difference is 4.30), which was statistically significant reduction from pre-test to post test-II score ($p > .05$). Therefore, we can conclude that routine care not reduces the wound score significantly but it is less than the adjuvant therapies intervention.

Statistical significance was calculated using repeated measures analysis of variance F-test and multiple comparison of pretest and posttest-I differences, pretest and posttest-II differences and are calculated using Bonferroni t-test.

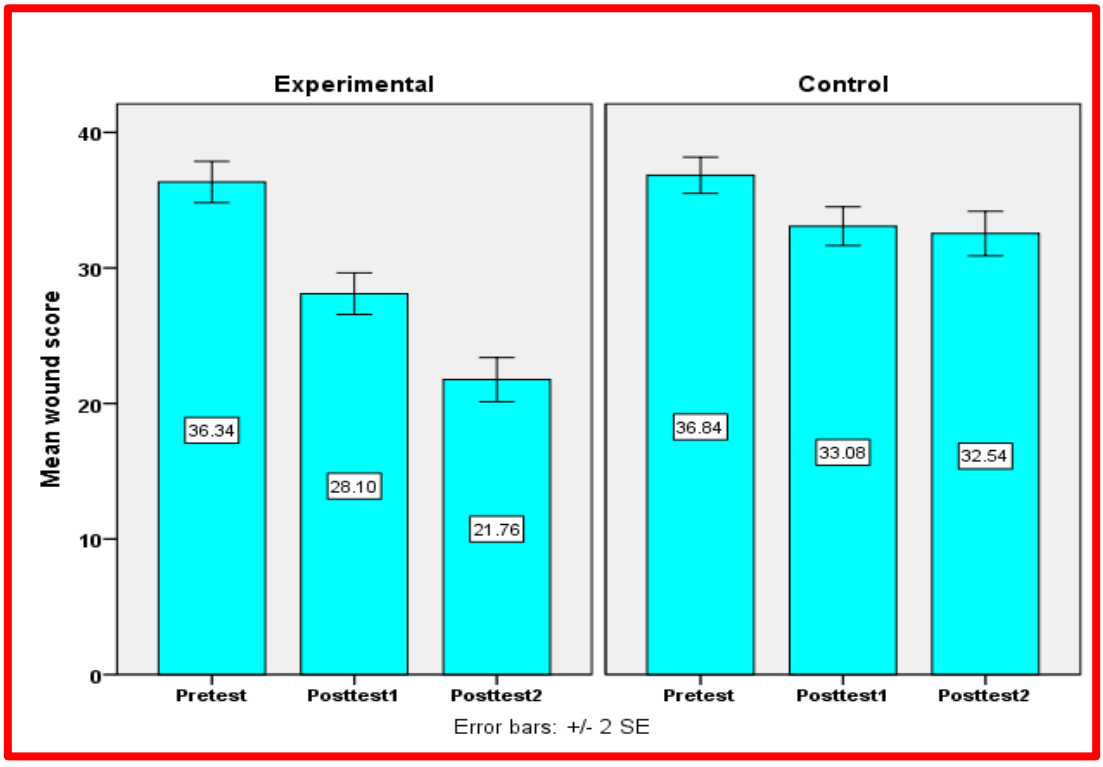


Fig Simple bar with standard error compares the diabetic patients wound score between experimental and control group during pretest, posttest-I and posttest-II

46: 2 x 3 ANOVA with Last Variable as Repeated Measure Test Results for Wound assessment

Source of variation	F value	P value	Repeated contrast test results		
			Assessment Comparison	F value	P value
1) Between comparison Group	65.94	0.001	-	-	-
2) Within comparisons (a) Assessment	516.86	0.001	Pre Vs post-I	421.91	0.001 (S)
			Post-I Vs post-II	187.83	0.001 (S)
(b) Assessment* group	150.39	0.001	Pre Vs post-II	74.08	0.001 (S)
			Post-I Vs post-II	133.05	0.001 (S)

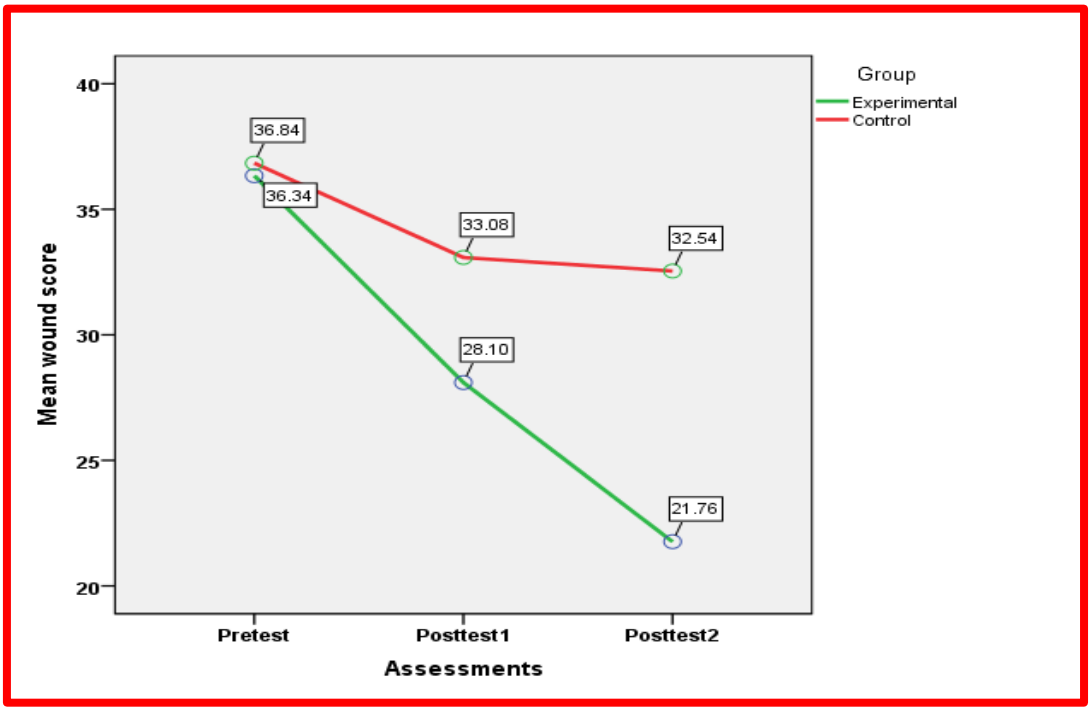


Fig: Line graph shows the pretest, posttest-I and posttest-II of Experimental and Control group wound reduction score

Effectiveness of Adjuvant Therapies and Generalization of Wound Ulcer Reduction Score

		Max wound score	Mean wound score	% of Mean score	Mean Difference of wound reduction score with 95% Confidence interval	Percentage of Wound reduction score with 95% Confidence interval
Experimental	Pretest	65	36.34	55.91%	14.58 (13.63 – 15.53)	22.43% (20.97%– 23.89%)
	Posttest-I	65	28.10	43.23%		
	Posttest-II	65	21.76	33.48%		
Control	Pretest	65	36.84	56.68%	4.30 (3.18 – 5.42)	6.62% (4.89% –8.34%)
	Posttest-I	65	34.08	52.43%		
	Posttest-II	65	32.54	50.06%		

Above table assess the effectiveness of adjuvant therapies in home care management of diabetic foot ulcer to reduce healing time and amputation rate among the diabetic patients residing in rural areas of Nellore, Andhra Pradesh In experimental group, on an average, in posttest, after having intervention patients are reduced 22.43% of wound score than pretest score.

In Control group, on an average, in posttest after having routine care patients are reduced 6.62% of wound score than pretest score

This difference shows the effectiveness of adjuvant therapies than routine care on wound reduction in experimental group.

Differences and generalization of wound assessment reduction score between pretest and posttest score was calculated using and mean difference with 95% CI and proportion with 95%

CI.

SECTION –H

Table 48: Comparision of Amputation Rate among Experimantal and Control Groups

	Experimental group		Control group	
	Number	%	Number	%
Toe amputation	0	0	2	4
Ray amputation	0	0	0	0
Trans metatarsal amputation	0	0	0	0

In experimental group none of them had amputation where as in control group 2(4 %) participants had toe amputation. The mean amputation rat in experimental group was 0% and in control group was 4%. Which indicates that adjuvant therapy was effective to reduce the amputation rate among diabetic patients with foot ulcers.

Major Findings of the Study

Distribution of demographic characteristics of patients with diabemellitus in experimental group and control group

- Distribution of sample with diabetes mellitus according to their age group depicts in experimental group the majority 12(24%) belongs to the age group of 30-40 years, 14 (28%) were in the age group of 41-50 years, 24 (48%) were in the age group above 50years. In the control group 11(22%) belongs to the age group of 30-40 years, 19 (38%) were in the age group of 41-50 years, 20(40%) were in the age group above 50years.
- Percentage distribution of patients with diabetes mellitus in experimental group according to their gender reveals that majority 30(60%) were females, 20 (40%) were males. In control group majority 28(56%) were males, 22 (44%) were females.
- With regard to educational status in experimental group, majority of them 18(36%) were illiterates, 12 (24%) had primary education and 11(22%) had higher secondary education and 9(18%) were graduated. Where as in control group 16(32%) were illiterates, 10 (20%) had primary education and 18(32%) had higher secondary education and 6(12%) had educational status has graduates and above graduation.

- With regard to type of family in experimental group 25(50%) belong to joint family and 25(50%) belongs to nuclear family. Where as in control group 26(52%) belongs to joint family and 24(48%) belongs to nuclear family.
- As per occupation in experimental group majority of patients with diabetes mellitus 20(40%) were unemployed, 5 (10%) were skilled workers, 10 (20%) were daily wage workers, and 15(30%) were government /private employees, and 0(0%) had small scale business. In control group majority of patients with diabetes mellitus 20(40%) were un employees, 4 (8%) were skilled workers, 7(14%) were daily wage workers, 19(38%) were government /private employees, and no one had small scale business.
- With regard to type of diabetes mellitus in experimental group and control group all belongs to Type –II diabetes mellitus
- As per life style in experimental group 19(38%) does sedentary work ,23(46%) does moderate work and 8(16%) does heavy work .In control group 15(30%) does sedentary work ,29(58%) does moderate work and 6(12%) does heavy work
- With regard to Duration of illness majority of the patients with diabetes mellitus 24(48%) were more than 6years, 6(12%) were between the year of 4-6 years, 14(28%) were between 1-3 years, and 6(12%) were less than 1 year. In control group majority of the patients with diabetes mellitus 21(42%) were more than 6years, 13(26%) were between the year of 4-6 years, 11(22%) were between 1-3 years, and 5(10%) were less than 1 year
- With regard to Duration of diabetic foot ulcer majority 47(94%) were between 1-6 months, 3(6%) were between the 6months -1year and none of them were above 1year. In control group majority of the patients had DFU duration as 48(96%) were between 1-6 months, 2(4%) were between the 6months -1year and none of them were above 1year.
- Coming to treatment in experimental group 22(44%) were on regular treatment, 28(56%) were on irregular treatment. In control group 28(56%) were on regular treatment, 22(44%) were on irregular treatment.
- With regard to type of treatment for diabetes mellitus in experimental group 48(96%) were using allopathic tretmment, 2(4%) were under Ayurveda treatment and none of them using combination of both. In control group 47(94%) were using allopathic treatment, 1(2%) were under Ayurveda treatment and 2(4%) were using combination of both.
- With regard to habit of smoking in experimental group 17(34%) were smokers and 33(66%) were non smokers .In control group 19(38%) has the habit of smoking and 31(62%) were not having the habit of smoking.
- With regard to duration of smoking in experimental group no one had less than 1 year, 1(5.88%) had 1-3 years and 11(64.71%) had 4-6 years and 5(29.41%)had above 6 years . In control group no one had less than 1 year ,1(5.26%) had 1-3 years and 9(47.37%) had 4-6 years and 9(47.37%)had above 6 year
- With regard to habit of alcoholism in experimental group 17(34%) were alcoholic and 33(66%) were nonalcoholic .In control group 22(44%) has the habit of taking alcohol and 28(56%) were not having the habit of alcoholism.

- With regard to duration of alcoholism in experimental group no one had less than 1 year, 6(35.29%) had 1-3 years and 8(47.06%) had 4-6 years and 3(17.65%) had above 6 years. In control group 0(0%) had less than 1 year, 7(31.82%) had 1-3 years and 7(31.82%) had 4-6 years and 8(36.36%) had above 6 years.
- Regarding dietary pattern in experimental group 14(28%) were vegetarians,3(6%) were ova lacto vegetarians ,and 33(66%) were non vegetarians .Where as in control group 8(16%) were vegetarians, 1(2%)was ova lacto vegetarians ,and 41(82%) were non vegetarians
- In experimental group 13(26%) were on regular diabetic diet, 14(28%) were on irregular diabetic diet, 23(46%) were not following any dietary restrictions. In control group 16(32%)were on regular diabetic diet ,18(36%) were on irregular diabetic diet ,16(32%) were not following any dietary restrictions
- With regard to habit of wearing footwear 47(94%) has the habit of wearing foot were and 3(6%) has no habit of wearing footwear in experimental group. Among them 44(88%) uses slippers and 3(6%) uses special diabetic footwear and on one uses shoes.
- In control group 48(96%) has the habit of wearing foot were and 2(4%) has no habit of wearing footwear. Among them 43(86%) uses slippers and 5(10%) uses special diabetic footwear and on one uses shoes.
- With regard to source of information in experimental group 21(42%) gets from family members, 14(28%) from neighbors and friends, 12 (24%) from health care professionals and 3(6%) gets information from mass media. In control group 20(40%) gets from family members, 12(24%) from neighbors and friends, 10 (20%) from health care professionals and 8(16%) gets information from mass media.
- In experimental group 23(46%) has accessibility and availability of health services,7(14%) has non availability and 20(40%) had accessibility and availability of health services with great difficulty .In control group 30(60%) has accessibility and availability of health services,5(10%) has non availability and 15(30%) had accessibility and availability of health services with great difficulty

RESULTS

Assessment of Basic Physiological Variables among Diabetic Patients with Dfu Experimental and Control Groups

Systolic blood pressure:

- The level of SBP scores between experimental and control group during pre-test. In experimental group, 42% of them are having normal SBP (<120), 48% of them are having pre hypertension SBP 121-140) and 10% of them are having stage I hypertensive (>140) score. In control group, 36% of them are having normal SBP (<120), 56% of them are having pre hypertension SBP 121-140) and 8% of them are having stage I hypertensive (>140) score. Statistically there is no significant difference between experimental and control group
- In post-test in experimental group, 72% of them are having normal SBP (<120), 26% of them are having pre hypertension SBP 121-140) and 2% of them are having stage I hypertensive (>140) score. In control group, 68% of them are having

normal SBP (<120), 28% of them are having pre hypertension SBP 121-140) and 4% of them are having stage I hypertensive (>140) score. Statistically there is no significant difference between experimental and control group. It was assessed using chi-square test.

- Experimental group are having 140.30 mean score in pre-test and 130.26 mean score in post-test with mean difference 10.04 and the t' value was 3.79 which is significant. In control group are the pre-test mean was 142.50 and post teat mean was 132.30 with mean difference 10.20 which shows significant reduction in hypertension with 't 'value 3.96.

Diastolic blood pressure:

- The level of DBP scores between experimental and control group during pre test. In experimental group, 46% of them are having normal DBP (<80), 44% of them are having pre hypertension DBP (80-89) and 10% of them are having stage I hypertensive (≥90) score. In control group, 44% of them are having normal DBP (<80), 42% of them are having pre hypertension DBP (80-89) and 14% of them are having stage I hypertensive (≥90) score. Statistically there is no significant difference between experimental and control group.
- During post-test in experimental group, 72% of them are having normal DBP (<80), 24% of them are having pre hypertension DBP (80-89) and 4% of them are having stage I hypertensive (≥90) score. In control group, 66% of them are having normal DBP (<80), 28% of them are having pre hypertension DBP (80-89) and 6% of them are having stage I hypertensive (≥90) score. Statistically there is no significant difference between experimental and control group. It was assessed using chi-square test
- Experimental group are having 82.40 mean score in pre-test and 79.86 mean score in post-test with mean difference 2.54 and the 't' value was 1.99 which is significant In control group are the pre-test mean was 83.20 and post teat mean was 80.82 with mean difference 2.38 which shows significant reduction in hypertension with 't 'value 1.96

Random blood sugar levels:

- The level of RBS scores between experimental and control group during pre-test. In experimental group, 26% of them are having normal RBS, 60% of them are having pre diabetic RBS and 14% of them are having diabetic values of RBS. In control group, 24% of them are having normal RBS, 60% of them are having pre diabetic RBS and 16% of them are having diabetic values of RBS. Statistically there is no significant difference between experimental and control group.
- During post-test in experimental group, 84% of them are having normal RBS , 12% of them are having pre diabetic RBS and 4% of them are having diabetic values of RBS. In control group, 78% of them are having normal RBS, 12 % of them are having pre diabetic RBS and 10% of them are having diabetic values of RBS.
- In Experimental group pre-test mean was 151.30 in post-test mean was 137.18 with mean difference 14.12 and the 't' value was 4.63 at P.<0.001 Which shows significant reduction of RBS in experimental group.

- In control group are the pre-test mean was 153.40 and post teat mean was 140 with mean difference 13.40 which shows mild reduction in RBS n with ‘t ‘value 3.94 at P.<0.001
- The level of BMI score between experimental and control group. In experimental group, 70% of them are having normal BMI, 20% of them are having over weight BMI and 10% of them are having obese BMI score. In control group, 64% of them are having normal BMI, 26% of them are having over weight BMI and 10% of them are having obese BMI score .

Assessment of Status of Diabetic Foot Ulcer among Both Experimental and Control Groups

- In pre test experimental group, 16.00% of them are having mild unhealthy score, 84.00% of them are having moderately unhealthy score. In control group, 12.00% of them are having mild unhealthy score, 88.00% of them are having moderately unhealthy score.Statistically there is no significant difference between experimental and control group.
- In pre test Experimental group are having mean value 36.34 with SD 5.37 and control group are having mean value 36.84 with SD 4.73. The mean difference is 0.50 score, this difference is small and it is not statistically significant.
- In posttest-I, in experimental group, 21(42%) of them are having mild unhealthy score, 29(58%) of them are having moderately unhealthy score. In control group, 10(20%) of them are having mild unhealthy score, 40(80%) of them are having moderately unhealthy score .There is a significant difference between experimental and control group of patients.
- In posttest-II, in experimental group, 31(62%) of them are having mild unhealthy score, 19(38%) of them are having moderately unhealthy score. In control group, 14(28%) of them are having mild unhealthy score, 36(72%) of them are having moderately unhealthy score. There is a significant difference between experimental and control group of patients.

Assessment of Effectiveness of Adjuvant Therapy in Home Care Management of Diabetic Foot Ulcer and To Reduce the Healing Time and Amputation Rate

- Considering the pretest score, experimental group of patients are having 36.34 mean wound score and control group of patients are having 36.84 mean wound score, so the mean difference of wound score is 0.50, this difference is small and it is not a statistically significant difference.
- Considering the posttest-I score, experimental group of patients are having 28.10 mean wound score and control group of patients are having 33.08 mean wound score, so the mean difference of wound score is 4.98, this difference is large and it is a statistically significant difference.
- Considering the posttest-II score, experimental group of patients are having 21.76 mean wound score and control group of patients are having 32.54 mean wound score, so the mean difference of wound score is 10.78, this difference is large and it is a statistically significant difference. It was confirmed using independent t test with the value of t=10.78 at P≤ 0.001 level which indicated highly significant difference.

- It shows there is a significant difference between pretest and posttest-II level of wound score. It was confirmed using Extended McNemar's test. Statistical significance (p≤0.001) shows that, posttest-III level of wound reduction score is statistically significant reduction when comparing with pretest level of wound score.
- In experimental group, Repeated measures F-test analysis shows that, mean overall wound healthy score is statistically significant different between pre-test and posttest-II(F = 217.79, P ≤ 0.001). Therefore, we can conclude that a adjuvant therapies in home care management of diabetic foot ulcer to reduce healing time and amputation rate among the diabetic patients.
- Similarly, in control group, Repeated measures F-test analysis shows that, mean overall wound healthy score is statistically significant different between pre-test and posttest-II(F = 0.42, P ≥ 0.05). Therefore, we can conclude that a routine care not reducing healing time and amputation rate among the diabetic patients.
- In experimental group, Repeated measures ANOVA F- test shows that mean wound score difference is statistically significant between pre-test and posttest-II (F = 217.79, $p \leq 0.001$).
- In control group, Repeated measures ANOVA F- test shows that mean wound score difference is not statistically significant between pre-test and posttest-II (F = 10.67, $p \leq 0.01$).
- Post hoc multiple comparison of Bonferroni t-test shows the reduction of Wound assessment score from pre-test to post-test-I (36.84 ± 4.73 vs 34.08 ± 5.03, respectively mean difference is 2.76), which was statistically significant ($p \leq .01$) . After post-test2, routine care reduces the wound score (36.84 ± 4.73vs 32.54 ± 5.81, respectively mean difference is 4.30), which was statistically significant reduction from pre-test to post test-II score ($p > .05$). Therefore, we can conclude that routine care not reduces the wound score significantly but it is less than the adjuvant therapies intervention
- The mean wound score for the experimental group subjects was found to be 36.34 before the intervention. After the intervention, the level of wound was reduced to 28.10 during posttest-I, and further reduced to 21.76 in posttest-II. The mean wound score was found to be 36.84, 33.08 and 32.54 at the pretest, posttest-I and posttest-II for the control group subjects
- In experimental group, On an average, in posttest, after having intervention patients are reduced 22.43% of wound score than pretest score. In Control group, On an average, in posttest after having routine care patients are reduced 6.62% of wound score than pretest score
- This difference shows that adjuvant therapies than routine care on wound reduction in experimental group.
- In experimental group none of them had amputation where as in control group 2(4 %) participants had toe amputation .The mean amputation rat in experimental group was 0% and in control group was 4%., Which indicates that adjuvant therapy was effective to reduce the amputation rate among diabetic patients with foot ulcers.

To Find Out the Association between Healing Process of Diabetic Foot Ulcer and Selected Demographic Variables among Both Experimental and Control Groups

- In experimental group there was a significant association between post test level of wound score and diabetic patients demographic variables like age with chi square value χ**2=8.16 p=0.05*** and regular treatment patients with chi sqare value χ**2=3.88** and habit of smoking χ**2=4.74 p=0.05*, habit of alcoholism** χ**2=4.74**
- In control group there was no association between post test level of wound score of diabetic patients with their selected demographic variables.

CONCLUSION

The present study was conducted to evaluate the effectiveness of adjuvant therapy on reducing the diabetic foot ulcer wound score, and to reduce healing time and amputation rate among diabetic patients residing in rural areas of Nellore. The mean wound score for the experimental group subjects was found to be 36.34 before the intervention. After the intervention, the level of wound was reduced to 28.10 during posttest-I, and further reduced to 21.76 in posttest-II.

The mean wound score was found to be 36.84, 33.08 and 32.54 at the pretest, posttest-I and posttest-II for the control group subjects. In experimental group, Repeated measures F-test analysis shows that, mean overall wound healthy score is statistically significant different between pre-test and posttest-II($F = 217.79$, $P \leq 0.001$). Therefore, we can conclude that adjuvant therapies can be used in home care management of diabetic foot ulcer to reduce healing time and amputation rate among the diabetic patients comparative to regular convention therapies.

Most of the sample in experimental group rejected to participate in the study as they have misconception that use of honey may increase blood glucose level. The researcher explained the metabolism and finally sample gave consent to participate in the study As the study progress experimental group was very happy after noticing the healing process and much cooperation was given by them. It is highly economical as there is no burden of transportation to clinics, it can be done at home setup, dressing can be done by family members. And honey is much cheaper than regular medicines used for dressing. As a researcher and a community health nurse I strongly recommend the study to be implemented at community, home set up and sub centers especially in rural areas to treat the patients, because it is cost effective and cost beneficial.

Therefore there is an imperative need to practice adjuvant therapies in rural areas where health care services are not much available and accessible to treat diabetic foot ulcers to enhance early healing, to reduce amputation rate and to reduce financial burden to family and country.

Nursing Implications

Nursing Practice

- ✓ Nurses can practice honey dressing for ulcers, wound burns as it is a best intervention which promotes early healing
- ✓ Nurses can encourage the local community residents to use adjuvant therapies at home set up to manage minor problems.

- ✓ Nurse can bring awareness among the people about purification process of honey and uses of honey
- ✓ Nurse as the change agent can update knowledge to the nurse on alternative therapies to promote wound healing among diabetes mellitus patients
- ✓ Pamphlets, leaflet about honey properties and action can be made available to public to bring awareness regarding adjuvant therapies

Nursing Education

- ✓ Nursing curriculum should focus on alternative system of medicine along with Allopathy
- ✓ Nursing students should have exposure to AYUSH clinics to know the basic therapies
- ✓ Nursing students can conduct mini projects on effectiveness of adjuvant therapies in treating wounds.

Nursing Administration

- ✓ The nurse administrator should conduct in–service education to nursing personnel regarding updated methods to treat DFU
- ✓ Orientation programs can be planned to nursing staff to ayush clinics
- ✓ Special training can be provided to the nurses working in surgical and medical wards and to nurse educators in nursing educational institution regarding traditional practices and its uses.

Nursing Research

- ✓ As the diabetes is burning problem in the worlds the study finding can be best utilized to treat many patients suffering from different wounds, ulcers, burns etc.
- ✓ The findings can be utilized for further research to improve the knowledge in nursing.
- ✓ This study result will stimulate the new researcher to implement the similar intervention on non- diabetic wounds.

Limitation

- People have misconception that use of honey can increase the blood glucose level. So it was a big hurdle to explain and get the acceptance of sample
- Since the understanding level of patients was different, patients took more time to accept the intervention.
- Most of the people were willing to have allopathic treatment than adjuvant therapy as they have doubt about healing process
- A regular supervision is needed to check dressing process

Recommendations

- ✓ A comparative study can also be done between the effectiveness of various non – pharmacological measures to reduce the severity of wound.

- ✓ A similar study can be conducted on larger samples there by findings can be generalized to a large population.
- ✓ A comparative study can be conducted in urban and rural areas to check the effectiveness and acceptance of people
- ✓ A comparative study can be conducted with Manuka honey and natural honey on reducing severity of wound among patients with diabetes mellitus.
- ✓ A similar study can be conducted at hospital settings

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