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Original Article

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Comparative Study between Mandakini Offloading and Conventional Normal Saline Dressing for Diabetic Foot Ulcer

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ABSTRACT

Background & Objective

This comparative observational trial was carried out to establish the benefits of the 'Mandakini' dressing in comparison with conventional wet gauze dressings, in patients with neuropathic plantar ulcers.

The objective of this study is:

- To compare the effect of mandakini offloading technique over normal saline in diabetic foot ulcer.
- To show the improvement in quality of ulcer healing using mandakini offloading technique.

Methods

Study Design - Hospital based Comparative Observational study.

Period of study – 9 months from September 2021 to May 2022

Place of study: A. J. Institute of Medical Science and research Centre, Mangalore Sample size- Total of 50 patients are taken divided into two groups of 25 each.

The treatment group received 'Mandakini' dressing which was changed every week. Control group received conventional normal saline dressings. Size of the ulcer, grade of the ulcer and wound surface area was assessed at the end of every week up to 6 weeks in both groups. The percentage of wound covered with granulation tissue, the percentage of wound covered with non-viable tissue and the time taken for healing of the ulcer were compared between the two groups

Results: A total of 50 patients were randomized into treatment and control group with 25 patients in each. The 'Mandakini' dressing group had a significant reduction in the wound size compared to the control group). Time taken for healing of the ulcer was significantly less in 'Mandakini' dressing group

Interpretation & Conclusion: Mandakini dressing significantly reduces the wound size and time taken for the healing of plantar ulcer compared to conventional normal saline dressing. Patient acceptability, patient satisfaction, quality of life and cost of the total treatment were better in Mandakini dressing group.

Key Words: *Mandakini dressing, Off-loading presuure techniques, diabetic plantar ulcers*

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INTRODUCTION

The upsurge in the occurrence of type 2 diabetes is related with sedentary lifestyle and obesity. Due to the related risks, mainly the risk of early mortality, type 2 diabetes has been acknowledged as one of the extreme health problems globally [1,2]. The incidence of diabetic patients globally in 2000 was 171 million and is expected to increase three-fold in 2030 [3].

Diabetic foot ulcer is one of the major complications of diabetes mellitus. It occurs in 15 percent of all patients with diabetes and precedes 84 percent of all lower leg amputations[4].

Diabetic foot ulcer is one of the commonest sequelae following trauma or infection in patients with diabetes mellitus, mainly involving the distal ends of limbs where the vascularity is relatively decreased due to effects of diabetes. Despite insulin treatment and a meticulously-controlled diet, approximately 15% of all patients with diabetes will, at some time, have non-healing wounds and this is the leading cause of lower extremity amputation.

Diabetes mellitus impedes wound healing by prolonging the inflammatory phase. Increased glucose in the tissue precipitates infection. Diabetic microangiopathy affects microcirculation. Increased glycosylated haemoglobin decreases the oxygen dissociation. Increased glycosylated tissue protein decreases the oxygen utilization.

Since the last diabetic foot ulcer (DFU) treatment algorithm was published in 2002, new options for diagnostic testing and treatments have been developed. This study seeks to update the DFU treatment algorithm to include new available in approaching new treatment options.

Diabetic foot is a complex pathology with narrow window of opportunity to work. If not dealt with right approach ends up with amputation. It needs special care. A non-healing ulcer on plantar aspect can lead to severe infection[4].

The present study aims to compare the outcome of mandakini offloading technique over normal saline dressing in diabetic foot ulcer. Studies have shown that mandakini offloading technique decreases the pain and plantar pressures over the sole of the foot and also found to be cost effective.

MATERIALS AND METHODS

Source of data:

The study will be conducted in the Department of General Surgery in A.J. Institute of Medical Sciences and Research Centre, Mangalore.

Method of collection of data:

A. **Study Design -** Hospital based Comparative Observational study.
B. **Period of study** – 9 months from September 2021 to May 2022
C. **Place of study**: A. J. Institute of Medical Science and research Centre, Mangalore Sample size- Total of 50 patients are taken divided into two groups of 25 each.
D. **Sampling Technique**: Purposive sampling technique will be adopted to select individuals who meet the inclusion criteria for the study

Inclusion criteria:

1. Diabetic patients of age 18 years and above.
2. Patients having ulcers measuring more than one cm.
3. Patients with controlled blood glucose levels.

Exclusion Criteria:

1. Patients with absent peripheral pulses in dorsal pedis artery, posterior tibial artery and anterior tibial artery.
2. X-rays showing features of osteomyelitis.
3. Malnutrition and uncontrolled diabetes.
4. Patients not giving consent for the dressing.

Methodology:

Two groups with 25 people each will be taken. Group A includes normal saline dressing to ulcer. Group B includes mandakini offloading technique for dressing. Daily dressing is done. Mean area of ulcer is noted before dressing. After 14 days of dressing areas of ulcers are taken in mm square measurements using callipers, compared with normal saline dressing ulcers.

Materials used for preparing mandakini off- loading

DEVICE

1. Used pair of gloves
2. Dynaplast adhesive plaster

Method of preparation and application

1. Paired used gloves are rolled as we do for autoclaving
2. It is placed on adhesive surface of dynaplast and covered circumferentially with dynaplast
3. Edges of dynaplast are approximated by sharp pressure. Now the Mandakini offloading device is ready to place.
4. It acts as a soft air cushion and off loads body weight
5. Fore foot lesions are attended by applying the device proximal to the lesion
6. Hind foot lesions are attended by applying the device distal to the lesion
7. Number of gloves will be decided according to the weight of the patient

Statistical Analysis:

Qualitative data will be represented by percentages. Descriptive data such as mean, range and standard deviation will be used to describe quantitative data. Z test will be used to test significance difference in pain, days of hospital stay and number of dressings needed and plantar pressure between 2 groups.

RESULTS:

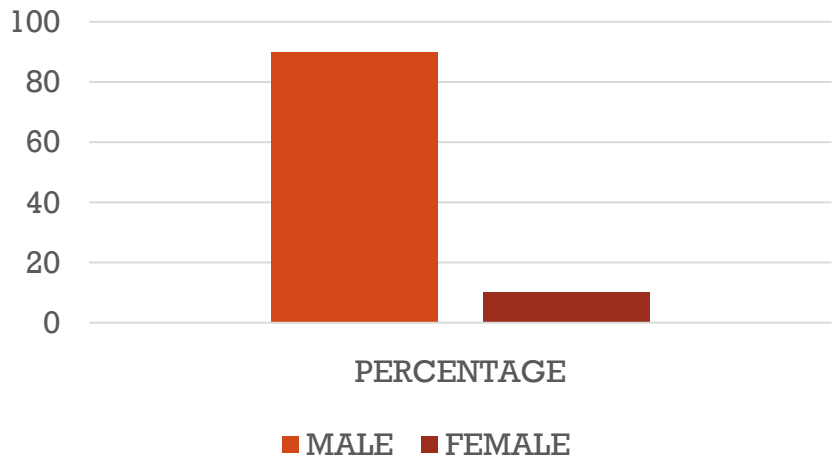
A total of 50 patients were included in the study

These patients were studied, mandakini dressing group included 25 patients and conventional dressing included 25 patients

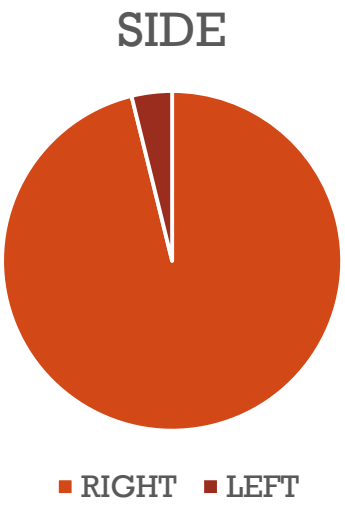
AGE: **GENDER:**

Gender	CASE NO	PERCENTAGE
male	101	89.99%
female	35	31.44%
Total	136	121.43%

age	CASE NO	PERCENTAGE
less than 30 years	0	0.00%
31-40 years	2	4.00%
41-50 years	10	20.00%
51-60 years	20	40.00%
61-70 years	12	24.00%
more than 70 years	6	12.00%
Total	50	100.00%

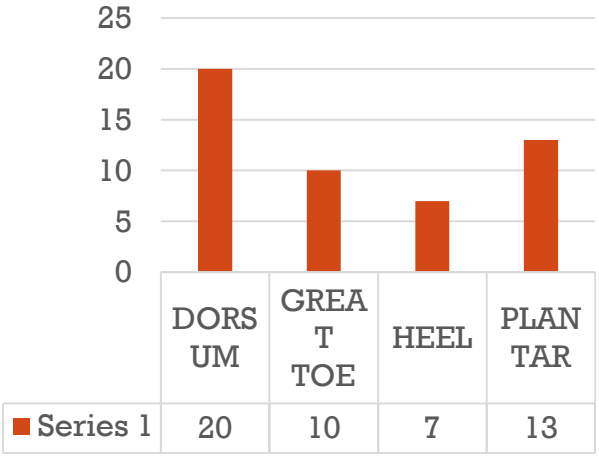


SIDE:



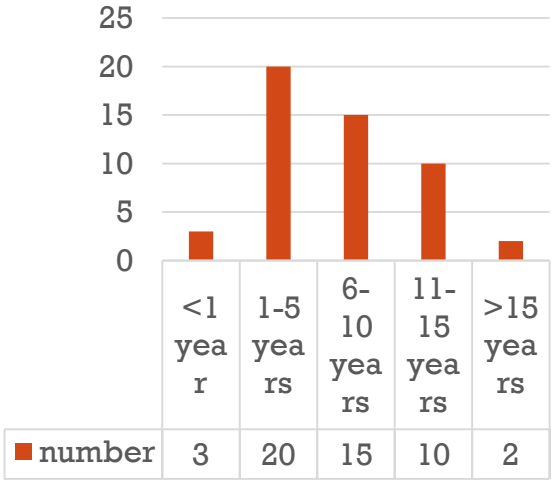
SIDE	CASE NO	PERCENTAGE
RIGHT	40	80.00%
LEFT	10	20.00%

SITE OF PRESENTING LESION:



SITE OF THE PRESENTING LESION	CASE NO	PERCENTAGE
DORSUM FOOT	20	40.00%
GREAT TOE	10	20.00%
HEEL	7	14.00%
FOOT PLANTAR	13	26.00%
TOTAL	50	100.00%

DURATION OF DM:



DURATION OF DM	CASE NO	PERCENTAGE
LESS THAN 1 YEAR	3	6.00%
1-5 YEARS	20	40.00%
6-10 YEARS	15	30.00%
11-15 YEARS	10	20.00%
MORE THAN 15 YEARS	2	4.00%
TOTAL	50	100.00%

RESULTS:

DRESSING	HEALING/ HEALED	NON HEALING/ AMPUTED	TOTAL	X^2	P value
MANDAKINI	20(73.7)	5(26.3)	25		
CONVENTINAL	14(40)	11(60)	25	4.496	0.033
TOTAL	34	16	50		

P<0.05% IS STATISTICALLY SIGNIFICANT

DISCUSSION

Diabetes mellitus is the major healthcare problem worldwide. Diabetes mellitus, the most common endocrine disorder is characterized by metabolic abnormalities due to relative or absolute deficiency of insulin or insulin resistance resulting in hyperglycaemia and associated with micro and macrovascular complications.

In a developing country like India that is nick named as the diabetic capital of the world there are several diabetics who suffer from wound related complications adding to the economic burden they face.

The real burden of the disease is however due to its associated complications which lead to increased morbidity and mortality.

DEMOGRAPHIC DATA

GENDER

In the study the number of males in the study were50 (100%), and number of females were 5(10%). There was no statistical significance between the two groups with a p value more than 0.05 hence the two groups are comparable. Overall male had a higher incidence of diabetic ulcers this is statistically significant with a p value 0.002. This is comparable with study by Ashwath V. H et al[15] 82 (68.3%) were males and remaining 38(31.7%) were females. Shiva Kumar T et al[6] noted that the 81 were male and 19 females.

AGE

In the present study 31-40 years we had 2patients (4%), 41-50 years we had 10 patients (20%), 51-60 years we had 20patients (40%), 61-70 years we had 12 patients (24%) and more than 70 years we had 6 patients (12%).

Shiva Kumar T et al[6] noted the most common age group affected with diabetic foot was 51-60 years followed by 41-50 years with mean age of study group was 57±12 years.

Ashwath V. H et al[5] noted that the mean age in my study population was 50.12±12.88 years. Among the total 120 cases, 10 (8.3%) were less than 40 years of age. 17 (14.2%) were 41-50 yrs. 27 (22.5%) were 51-60 years. 43 (35.8%) were 61-70 years and the remaining 23 (19.2%) were more than 70 years.

SIDE

Number of patients with right side involvement were 40 (80%), and left side involvement were 10 (20%)

SITE OF THE PRESENTING LESION

Site of presenting lesion was dorsum of foot in 20 patients (40%), great toe in 10 patients (20%), heel in 7 patients (14%), and plantar aspect of foot in 13 patients (26%).

DURATION OF DM

Duration of DM was less than 1 year in 3 patients (6%), 1-5 years in 20 patients (40%), 6-10 years in 15patients (30%), 11-15 years in 10 patients (20%) and more than 15 years in 2 patients (4%).

CONCLUSION

- The study was done to give an insight to the depth of diabetic wound management as it has become the foremost problem in the recent times
- Offloading is one of the corner stones of gold standard treatment in diabetic foot ulcer
- The hospital wastes such as used gloves can help us to off load the body weight from ulcer site

- The study shows the fine efficacy of Mandakini offloading device in terms of duration of healing of ulcer, no infection and no recurrence
- It is an ideal offloading device for low socio-economic rural population in developing countries
- It reduces the duration of healing of ulcer when compared to conventional dressing
- It completes the criteria to be called an ideal offloading device

INFORMED CONSENT

A J INSTITUTE OF MEDICAL SCIENCES AND RESEARCH CENTRE, KUNTIKANA, MANGALORE

Informed consent form for the patients of "A.J Institute of Medical Sciences and Research Centre, Mangalore", who will be participating in the research project titled **"COMPARATIVE STUDY BETWEEN MANDAKINI OFFLOADING AND CONVENTIONAL NORMAL SALINE DRESSING FOR DIABETIC FOOT ULCER"**

Name of Principal Investigator	DrNASHI SEMITHA Junior Resident.
Name of Organization	Department of General Surgery, A. J. Institute of Medical Science and Research Centre, Mangalore

This Informed Consent Form has two parts:

- Information Sheet (to share information about the research with you)
- Certificate of Consent (for signatures if you agree to take part)

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet

Introduction

I, DrNASHI SEMITHA, Junior Resident in the Department of General Surgery, A.J Institute of Medical Sciences and Research Centre, Mangalore, am working on my research titled

"COMPARATIVE STUDY BETWEEN MADAKINI OFFLOADING AND CONVENTIONAL NORMAL SALINE DRESSING FOR DIABETIC FOOT ULCER"

. My study subjects will be adults, diagnosed by General Surgery department in A. J. Institute of Medical Sciences and Research Centre, Mangalore.

I am going to give you the information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research. Your decision to participate or not to participate will not have any effect on your treatment in our hospital. There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them and get yourself clarified.

Purpose of the research

The present study aims to compare the outcome of Mandakini offloading technique over normal saline dressing in diabetic foot ulcer.

Type of Research Intervention

It is a hospital-based Comparative Observational study. Patients diagnosed with diabetic foot ulcers in the Department of General Surgery of A. J. Institute of Medical Sciences and Research Centre, Mangalore during two years will be enrolled in this study after providing informed consent to participation.

Participant selection

Patients diagnosed with diabetic foot ulcers in the Department of General Surgery of A. J. Institute of Medical Sciences and Research Centre, Mangalore.

Voluntary Participation

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, it will not affect your treatment in our hospital. You have every right to withdraw at any stage in the research process.

Procedures and Protocol
The present study aims to compare the efficacy of mandakini offloading over normal saline dressing in diabetic foot ulcers
Written informed consent will be obtained from the patients agreeing to participate in the study.
Duration September 2021 to May 2022

Benefits
This study aims to have a better understanding of the effects of mandakini offloading technique.

Reimbursements
You will not be given any money or gifts to take part in this research.

Confidentiality
The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name.

Sharing the Results
The knowledge that we get from doing this research will be shared with you. Confidential information will not be shared. We will publish the results in order that other interested people may learn from our research.

Right to Refuse or Withdraw
You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice and all of your rights will still be respected.

Whom to Contact
This proposal has been reviewed and approved by the Research and Ethical committee of A. J. Institute of Medical Sciences and Research Centre, Mangalore, which is a committee whose task it is to make sure that research participants are protected from harm.
You can ask me any more questions about any part of the research study, if you wish to.

PART II: Certificate of Consent
Title of the study:
"COMPARATIVE STUDY BETWEEN MADAKINI OFFLOADING AND CONVENTIONAL NORMAL SALINE DRESSING FOR DIABETIC FOOT ULCER"

Name of Participant:
Age:
Serial no:
Hospital IP no:
Address:
Tel no/mobile no:
Date of admission:
Date of surgery:
Date of discharge:

Informed consent:

I, give my full, free and voluntary consent to participate in this study and the need for the study has been explained in a language that I understand the best.
After understanding I give my whole consent.
Patient's signature or thumb impression Signature of attesting doctor
Date:
If illiterate a literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.
I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ Thumb print of participant

Signature of witness _____Date _____

Statement by the researcher/person taking consent:

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.
A copy of this informed consent form has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____

LIST OF ABBREVATIONS

ABI- ankle-brachial index
DFU-diabetic foot ulcer
DM- diabetes mellitus
TIA- transient ischaemic attack
CVA-cerebro vascular accident
ACS-acute coronary syndrome
PVD-peripheral vascular disease
ESRD- end stage renal disease
TGF-tumour growth factor
ROS- reactive oxygen species
LDL- low density lipids
PARP- poly adenosine ribose pathway
NGF- nerve growth factor
CGRP-calcitonin gene related peptide
NCS-nerve conduction study
DPA-dorsalispedis artery
PTA-proximal tibial artery

ACKNOWLEDGEMENTS

It gives me great pleasure in preparing this dissertation and I take this opportunity to thank everyone who has made this possible. First and foremost, I thank the Almighty Lord for his blessings on me and my work.

I would like to express my gratitude and love to my Parents and my brother for their constant guidance and support.

I am greatly indebted to the patients, for their co-operation without whom this reasearch would not have been possible and numerous others who have contributed in compilation of this work but whose names do not appear here.

Place: Mangalore
Date: Dr.NashiSemitha

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