

**DISSERTATION ON**  
**“A STUDY TO ASSESS THE EFFECTIVENESS OF 3% CITRIC ACID**  
**DRESSING ON DIABETIC FOOT ULCER AMONG CLIENTS**  
**ADMITTED IN SELECTED WARDS OF RAJIV GANDHI**  
**GOVERNMENT GENERAL HOSPITAL, CHENNAI.”**

**M.Sc (NURSING) DEGREE EXAMINATION**  
**BRANCH –I MEDICAL SURGICAL NURSING**  
**COLLEGE OF NURSING**  
**MADRAS MEDICAL COLLEGE, CHENNAI-03.**



*A dissertation submitted to*  
**THE TAMILNADU DR. M. G. R. MEDICAL UNIVERSITY,**  
**CHENNAI-32**

*In partial fulfillment of the requirements for the degree of*  
**MASTER OF SCIENCE IN NURSING**

**APRIL 2016**

## ***CERTIFICATE***

This is to certify that this dissertation titled **“a study to assess the effectiveness of 3% citric acid dressing on diabetic foot ulcer among patients admitted in selected wards of Rajiv Gandhi Government General Hospital, Chennai”** is a bonafide work done by Ms.R.Krishnaveni, M.sc Nursing Iyear student ,College of Nursing, Madras Medical College, Chennai submitted to The **Tamilnadu Dr.M.G.R.Medical University, Chennai** in partial fulfillment of the requirements for the award of degree of Master of Science in Nursing, Branch I, Medical Surgical Nursing, under our guidance and supervision during the academic period from 2014 – 2016.

**Dr V.Kumari M.Sc(N)., Ph.D**  
**Principal,**  
College of Nursing,  
Madras Medical College,  
Chennai-03.

**Dr.R.Vimala M.D.,**  
**Dean,**  
Madras Medical College,  
Chennai-03.

**“A study to assess the effectiveness of 3% citric acid dressing on diabetic foot ulcer among clients admitted in selected wards of Rajiv Gandhi Government General Hospital, Chennai”**

**Approved by the dissertation committee on**

---

**RESEARCH GUIDE**

---

**Dr. V.Kumari, M.Sc (Nursing),, PhD.,**

Principal,

College of Nursing,

Madras Medical College,

Chennai.

**CLINICAL SPECIALITY GUIDE**

---

**Mrs.A.Thahirabegum, M.Sc (N),, M.Phil., (N),,MBA**

Department of Medical Surgical Nursing.

College of Nursing,

Madras Medical College,

Chennai.

**MEDICAL EXPERT**

---

**Prof. Dr.Dharmarajan M.D., Dip.Diabetology**

Director, Institute of Diabetology,

Rajiv Gandhi Government General Hospital,

Chennai.

*A dissertation submitted to*

**THE TAMILNADU DR. M.G.R. MEDICAL UNIVERSITY**

**Chennai**

*In partial fulfillment of requirements for the degree of*

**MASTER OF SCIENCE IN NURSING**

**APRIL 2016**

### **Acknowledgement**

I wish to express my sincere thanks to **Dr. R.Vimala., MD**, Dean, Madras Medical College, Chennai-03 for providing necessary facilities and extending to conduct this study and for providing necessary arrangements to submit this dissertation in time.

I express my heartfelt thanks to **Dr.V.Kumari, M.Sc (N). PhD.**, Principal, College of Nursing, Madras Medical College, Chennai-03. The success of my work is created to her constant encouragement and valuable suggestions helped in the fruitful outcome of this study.

I express my special and sincere thanks to **Dr.Ms. R. Lakshmi., M.Sc (N), Ph.D., M.BA.. ADME( Nursing)**, Former Principal for their intelligent guidance and constant encouragement which contributed a great deal to give meaning and enrichment of the study.

I deem it a great privilege to express my sincere gratitude and deep sense of indebtedness to my esteemed teacher **Mrs.A.Thahira Begum,M.Sc (N), MPhil,MBA.**, Reader, College of Nursing, Madras Medical College, Chennai-03 for her timely assistance and guidance in pursuing the study.

I render my deep sense of sincere gratitude to **Prof.P.Dharmarajan, M.D., Dip.Diabetology**, Director and Professor, Institute of Diabetology for helping me in constructing tools for the study and completing my study in a successful manner. It is my immense pleasure and privilege to express my gratitude to Staff Nurse for their assistance and help during my data collection.

My immense pleasure to express my sincere gratitude and deep sense of indebtedness to my esteemed teacher **Mrs.Elizabeth Kalavathy, M.Sc(N)**, Reader, College of Nursing, Madras Medical College, Chennai for her timely assistance and guidance in pursuing the study

I would also like to thank **Mrs.Dominic Arockia Mary MSc.,(N)**, Lecturer, **Mrs.K.Shanthi devi M.Sc.,(N)** Lecturer, and **Mrs.K.Saroja M.Sc.,(N)**, Lecturer, College of Nursing, Madras Medical College, Chennai for their valuable support and assistance during this study. It's my great pleasure and privilege to express my deep sense of gratitude to all the faculty members of College of Nursing, Madras Medical College, and Chennai-3 for the support and assistance given by them in all possible manners to complete this study.

I am extremely thankful to, **Mrs.S. Valarmathi Msc. Mphil.** Research officer, Department of Epidemiology, The Tamilnadu Dr.M.G.R. Medical University, Chennai.

I extend my thanks to **Mr.Ravi, B.A, B.L.I.Sc.**, Librarian, College of Nursing, Madras Medical College, and Chennai for his co-operation and assistance which built the sound knowledge for this study.

I am grateful to convey my thanks to all the members of Diabetology and general surgery for the useful information obtained from the department for the study.

Above all, I would like to express my deepest gratitude to all the staff members who worked in the Diabeteology, General Surgery, septic & special wards, who directly and indirectly helped in successful manner to complete this study.

## **Abstract**

**TITLE: “A study to assess the effectiveness of 3% citric acid dressing on diabetic foot ulcer among clients admitted in selected wards of Rajiv Gandhi Government General Hospital, Chennai.”**

Diabetes mellitus is a common disease all over the world and its prevalence and incidence is steadily increasing. However people with diabetes continue to suffer from the complications of the disease. Foot ulceration is one of the most common formidable complications of diabetes

### **Need for the study**

Timely resolution of diabetic foot ulceration is essential if further tissue loss and infection are to be avoided. Current guidelines recommend the use of pressure relieving devices, appropriate dressings to promote healing and prevent infection, and where appropriate, debridement, drainage and revascularization. 3% citric acid dressing treatment for diabetic foot ulcer is simple and effective approach.

### **Objectives**

1. To assess the pre test wound status score of foot ulcer among diabetic client
2. To assess the effectiveness of 3% citric acid dressing on diabetic foot ulcer among experimental group
3. To compare wound status score among experimental and control group.
4. To associate the post test wound status score with selected demographical and physiological variables among experimental and control group

**Key words** –Diabetic foot ulcer, 3% citric acid dressing, and Wound status

### **Research methodology**

Research approach – quantitative approach, Study design – experimental research design, Study setting- medical, surgical, septic and special wards of Rajiv Gandhi Government General Hospital Chennai, Sampling technique– simpling random sampling technique, Tool- Modified Bates Jensen Wound Assessment Tool, Sample size-60.

### **Data collection procedure**

Data collection done after obtained approval from institutional ethics committee & getting written consent from participants, pre test wound status score was assessed by Modified Bates Jesen Wound Assessment tool, applied 3% citric acid soaked gauze dressing on the wound once a day for 14 days and post test effectiveness assessed on 14<sup>th</sup> day by Modified Bates Jesen Wound Assessment tool.

#### **Data analysis:**

The demographical variables were analyzed by using *descriptive (mean standard deviation, frequency and percentage) and inferential statistics (student paired and student independent 't' test and chi-square)*

#### **Study results**

The findings of the study revealed that in experimental group clients were reduced 22.1% of wound score after 3% citric acid dressing. Control group clients were reduced 7.9% of score. This shows the effectiveness of 3% citric acid dressing. Differences between pretest and posttest score was analysed using percentage with 95% CI and mean difference with 95% CI.

#### **Discussion**

Effectiveness of 3% citric acid dressing on diabetic foot ulcer proves that there is significant differences in wound status score among experimental and control group.

#### **Conclusion**

Local application of 3% citric acid dressing can be used as a routine intervention among clients all categories of wound. An extensive experimental study can be conducted for larger number of samples in the health care settings.





## INDEX

### TABLE OF CONTENTS

Chapter	Content	Page No
I	<b>INTRODUCTION</b>	1
1.1	Need for the study	3
1.2	Statement of the problem	5
1.3	Objectives of the study	5
1.4	Operational definitions	5
1.5	Assumptions	6
1.6	Hypothesis	6
1.7	Delimitations	7
II	<b>REVIEW OF LITERATURE</b>	
2.1	Literature reviews related to the study	8
2.2	Conceptual framework	22
III	<b>RESEARCH METHODOLOGY</b>	
3.1	Research Approach	24
3.2	Data collection period	24
3.3	Study setting	24
3.4	Study design	24
3.5	Study Population	25
3.6	Sample size	25
3.7	Criterion for sampling	26
	3.7.1 Inclusion criteria	26
	3.7.2 Exclusion criteria	26
3.8	Sampling technique	26
3.9	Research variables	26
3.10	Development and description of tool	26
	3.10.1 Development of the tool	26
	3.10.2 Description of the tool	27

3.10.3	Intervention protocol	30
3.10.4	Content validity	30
3.11	Ethical consideration	30
3.12	Pilot study	31
3.13	Reliability of the tool	31
3.14	Data Collection Procedure	31
3.15	Data entry and analysis	32
IV	<b>DATA ANALYSIS AND INTERPRETATION</b>	34
V	<b>SUMMARY OF RESULTS</b>	52
VI	<b>DISCUSSION</b>	54
VII	<b>CONCLUSION AND RECOMMENDATION.</b>	61
7.1	Implications of the study	61
7.2	Limitations	62
7.3	Recommendations for further study	62
	<b>REFERENCES</b>	A-G
	<b>APPENDICES</b>	i-xxix

## LIST OF TABLES

S.NO	CONTENTS	PAGE NO
3.1	Distribution of score and interpretation	27
4.1	Distribution of demographical data	32
4.2	Distribution of physiologic Variables	34
4.3	Pretest wound status score among experimental and control group	37
4.4	Effectiveness pf 3% citric acid dressing on diabetic foot ulcer	38
4.5	Comparison of post test wound status score among experiment and control	39
4.6	Comparison of pretest and posttest wound score status of experiment and control group	39
4.7	Pretest & posttest mean percentage of wound score status among experimental group	41
4.8	Percentage distribution of pretest and posttest level of wound status score before and after application of 3% citric acid dressing(experimental Group)	41
4.9	Pretest & posttest mean percentage of wound score status among control Group	43
4.10	Percentage distribution of pretest and posttest level of wound status score before and after application of 3% citric acid dressing(control group)	43

- 4.11 Association between post test wound status score and 45  
demographic and physiologic variables of experimental group
  
- 4.12 Association between posttest wound status score and 47  
demographic and physiologic variables of control group

## LIST OF FIGURES

TABLE NO	FIGURES
2.1	Conceptual framework (Orlando's Deliberative Nursing Process)
3.1	Schematic representation of the study
4.1	Age wise distribution Diabetic foot ulcer patients
4.2	Gender wise distribution Diabetic foot ulcer patients
4.3	Duration wise distribution of history of smoking
4.4	Duration wise distribution of history of diabetic mellitus
4.5	Duration wise distribution of history of diabetic foot ulcer
4.6	Distribution of mean fasting blood sugar level
4.7	Distribution of level of haemoglobin
4.8	Distribution of type of diabetic medication
4.9	Distribution of exercise pattern
4.10	Distribution of dietary pattern

- 4.11 Mean percentage of pre and post wound status score of control and experimental group
- 4.12 Percentage distribution of wound status score before and after application of 3% citric acid dressing(Experiment Group)
- 4.13 Percentage distribution of wound status score before and after routine care (control Group)
- 4.14 Pretest and posttest wound status score among experimental and control group
- 4.15 Association between level of post test wound status score and patients age (experiment group)
- 4.16 Association between level of post test wound status score and history of smoking(experiment group)
- 4.17 Association between level post test of wound status score and diet pattern

## LIST OF APPENDICES

S.NO	TITLE
1.	Certificate approval by Institutional Ethics Committee
2.	Certificate Of Content Validity
3.	Permission Letter For Conducting Study
4.	Study Tool Sec-A Demographical & Physiological Variables Section B- Bates Jesen Wound Assessment Tool
5.	Procedure Protocol
6.	Informed Consent
7.	Coding Sheet
8.	Certificate For English Editing

## LIST OF ABBREVIATION

CA	Citric acid
CI	Confidence interval
CDC	Centers for disease control
DFU	Diabetic foot ulcer
HBO	Hyperbaric oxygen therapy
H	Hypothesis
IGF	Insulin like growth factor
IDF	International diabetes federation
LOPS	Loss of protective sensation
PAD	Peripheral arterial disease
PVD	Peripheral vascular disease
MDI	Maggot debridement therapy
RCT	Randomized control trial
VAC	Vaccum assisted therapy
WHO	World health organization



# CHAPTER-I

## INTRODUCTION

*“Learning is not attained by chance; it must be sought for with ardor and attended to with diligence.” - Abigail Adams*

Encouraging people to adopt healthy life styles and appropriate coping strategies are the key aim in health promotion. Diabetes mellitus, commonly referred to as diabetes was first identified as a disease associated with "sweet urine," and excessive muscle loss in the ancient world. Since, the elevated levels of blood glucose lead to spillage of glucose into the urine, the term is used.

**The International Diabetes Federation (IDF)** Diabetes Atlas, Sixth Edition 2014 provides the latest figures, information and projections on the current and future magnitude of the diabetes epidemic. Approximately 387 million adults have diabetes; by 2035 this will rise to 592 million. The proportion of people with type 2 diabetes is increasing in most countries. 77% of adults with diabetes live in low- and middle-income countries. The greatest number of people with diabetes are between 40 and 59 years of age. 179 million people with diabetes are undiagnosed. Diabetes caused 4.9 million deaths in 2014; every seven seconds a person dies from diabetes.

According to World Health Organization (2009) the total number of people with diabetes worldwide is 171 million in 2000 and is projected to rise up to 366 million in 2030. International working group on the diabetic foot (2005) estimated that each year, around 3.8 million adults die from diabetes related causes, i.e. 6 deaths every minute. It is estimated that 250 million people worldwide have diabetes representing roughly 6% of the adult population (20-79 age group). The number is expected to reach 380 million by 2025, representing 7.1% of the adult population.

According to WHO (2009) the top 10 countries suffering from diabetes are India, China, USA, Indonesia, Japan, Pakistan, Russia, Brazil, Italy and Bangladesh . Recent studies in China, Canada, USA, and several European countries have shown that feasible lifestyle intervention can prevent the onset of diabetes in people at high risk. Overall direct health care cost of diabetes ranges from 2.5% to 15% annual health care budget of a country.

According to Centers for Disease Control and Prevention (CDC - 2009) from 1980 to 2000, the number of Americans with diabetes is more than double. Currently, it is estimated that almost 21 million people in the US are affected by diabetes; by 2030 this figure is expected to exceed 30 million

The development of diabetic foot ulcers (DFUs) typically results from peripheral neuropathy and/or large vessel disease, but most commonly DFUs are caused by peripheral neuropathy complicated by deformity, callus, and trauma. Vascular insufficiency, infection, and failure to implement effective treatment of DFUs are linked to secondary medical complications, such as osteomyelitis and amputation. Approximately 15% of DFUs result in lower-extremity amputation. More than 85% of lower-extremity amputations in clients with diabetes occur in people who have had an antecedent foot ulcer.

According to WHO 2010 studies, 25 % of the clients develop diabetes related complications which are mostly due to poor diabetes control. The elevated blood sugar levels that occur with diabetes mellitus damage blood vessels causing them to thicken and cause poor blood circulation. These ulcers are slow to heal and often become deep and infected. Control of infection and healing of ulcers is difficult in diabetics due to compromised immunity, vasculopathy and neuropathy.

Diabetes Impaired glucose tolerance and impaired fasting glycaemia are risk categories for future development of diabetes and cardiovascular disease. In some age groups, people with diabetes have a two-fold increase in the risk of stroke. Diabetes is the leading cause of renal failure in many populations in both

developed and developing countries. Lower limb amputations are at least 10 times more common in people with diabetes than in non-diabetic individuals in developed countries; more than half of all non-traumatic lower limb amputations are due to diabetes. Diabetes is one of the leading causes of visual impairment and blindness in developed countries. People with diabetes require at least two to three times the health-care resources compared to people who do not have diabetes, and diabetes care may account for up to 15% of national health care budgets. In addition, the risk of tuberculosis is three times higher among people with diabetes.

Diabetic foot is often quite a dreaded disability, with long stretches of hospitalization, and impossible mounting expenses, with ever dangling end result of an amputated limb. The phantom limb plays its own cruel part on the already demoralized psyche.

New treatments for diabetic foot ulcer continued to be introduced. Recent development includes the use of bone marrow derived stem cells, negative pressure dressing, bioengineered skin equivalents and growth factor therapy, hyperbaric oxygen treatment, Maggot or larval therapy. Like wise various modalities are used to treat the diabetic foot ulcer. Moist wound healing is widely accepted concept. Hydrocolloid dressing, enzymatic debridment agents, hydrogel dressings are some examples. Platelet derived growth factor and living skin equivalent products are the newest technological advancement in diabetic foot ulcer care. Though high tech treatments are available today the cost associated with these treatments are very high.

Citric acid treatment for diabetic foot ulcer is simple and effective approach. Citric acid shows promise as it causes a boost in fibroblastic growth and neovascularisation in wounds, aiding the formation of healthy granulation tissue which leads to faster healing and it is economic and affordable to all the population

## **1.1 Need for the study**

The global view, which reveals more than 1 million annual limb amputations—one every 30 seconds—is even more troubling, particularly since the International Diabetes Federation (IDF) 2014 predicts that current global prevalence of diabetes will burgeon from 285 million to reach 435 million by 2030. In the U.S., the burden of diabetes is expected to double from its current prevalence—25.8 million adults and children, or 8.3% of the population—by 2030.

India reveals that 70% of undiagnosed diabetes mellitus, which is higher than expected. In this 25% of those with diabetes may develop diabetes ulcer.

Timely resolution of diabetic foot ulceration is essential if further tissue loss and infection are to be avoided. Current guidelines recommend the use of pressure relieving devices, appropriate dressings to promote healing and prevent infection, and where appropriate, debridement, drainage and revascularization

Citric acid treatment of chronic infected wounds offers excellent results. It has been found effective against a variety of bacteria causing wound infections. In vitro studies have revealed the efficacy of citric acid against bacteria resistant to multiple antibiotics. Citric acid shows promise as it causes a boost in fibroblastic growth and neovascularisation in wounds, aiding the formation of healthy granulation tissue which leads to faster healing.

The high cost to treat the diabetic foot ulcers make it imperative to employ high tech and modern ways of treating it. But in the case of citric acid, it is relatively very low cost and reduces nearly 50 percentage of dressing costs. Clinical results with this treatment showed early formation of healthy granulation tissue and enhancement of the healing process, also it is simple, effective, reliable, non toxic and economic approach to treat the diabetic foot ulcers.

When investigator was posted in the septic ward found that majority of beds occupied with diabetic wound, foul smelling discharge and auto amputation complications effect of diabetes. Though we have high tech treatment and facilities, these treatments are very costly and became unaffordable by the people of middle class society. So the investigator chosen simple, cost effective method of treating clients with diabetic foot ulcer. Treatment with citric acid proves that it is simple, affordable and effective approach for the diabetic foot ulcers.

Considering the above facts the researcher decided to implement the citric acid dressing which is an effective and low cost measure to treat the diabetic foot ulcer.

## **1.2. Statement of the Problem**

**A study to assess the effectiveness of 3% citric acid dressing on diabetic foot ulcer among clients admitted in selected wards of Rajiv Gandhi Government General Hospital, Chennai.**

## **1.3. Objectives:**

1. To assess the pre test wound status score of foot ulcer among diabetic client
2. To assess the effectiveness of 3% citric acid dressing on diabetic foot ulcer among experimental group
3. To compare the wound status score among experimental and control group.
4. To associate the post test wound status score with selected demographical and physiological variable among experimental and control group

## **1.4. Operational definitions**

**Effectiveness**-Refers to the change in wound status brought about by citric acid dressing and also measured in terms of time taken for healing and cost of treatment.

**3% Citric acid-** Refers to the citric acid crystals (Citric acid anhydrous) solution which prepared from dissolving 3 grams of citric acid crystals in 100 ml of sterile water.

**Diabetic foot ulcer** -Refers to the disruption in continuity of skin below the ankle. It refers to partial thickness wound among diabetic clients admitted in Rajiv Gandhi Government General Hospital, Chennai as assessed with Bates Jensen Wound Assessment Tool.

**Diabetic patient**-Refers to clients who are diagnosed as type I and II diabetes mellitus admitted at Rajiv Gandhi Government General Hospital, Chennai.

**Wound Status**-Refers to the condition of the diabetic wound in terms of wound size, presence of infection, depth of wound, presence of necrotic tissue, type and amount of exudates, wound edges, and granulation tissues, measured with Bates Jensen Wound Assessment Tool.

**Application of citric acid dressing**-Refers to the process of application of 20 to 30 ml of citric acid absorbent dressing on diabetic wound once daily.

## **1.5 Assumption**

Antibacterial and healing property in citric acid may promote diabetic wound healing.

## **1.6 Hypothesis**

H<sub>1</sub>: There is difference in wound status score among experimental before and after 3% citric acid dressing

H<sub>2</sub>: There is association between post test wound status score with selected demographical and physiological variables.

## **1.7 Delimitation**

- The data collection period was 4 weeks
- Study findings can be generalized and limited to Rajiv Gandhi Government General Hospital, Chennai.
- Subjects selected within age group of 41-80 years with Diabetic foot ulcer.

## **CHAPTER II**

### **REVIEW OF LITERATURE**

Diabetes mellitus is a multisystem disease related to abnormal insulin production, impaired insulin utilization or both. Diabetes mellitus is a serious health problem throughout the world. Diabetes is the leading cause of heart disease, stroke, adult blindness, foot ulcers and non traumatic lower limb amputations.

The present study aims at bringing about the effectiveness of 3% citric acid dressing on diabetic foot ulcer.

#### **2.1 Review of Literature**

#### **2.2 Conceptual Frame Work**

##### **2.1 Review of Literature**

The review of literature has been done under the following headings:

2.1.1 Literature related to diabetes mellitus.

2.1.2 Literature related to diabetic foot ulcer and its treatments.

2.1.3 Literature related to application citric acid for wound healing.

##### **2.1. Literature related to Diabetes mellitus.**

**Billow., et.al,(2015)** conducted a study to assess the prevalence of metabolic syndrome among patients with type 1 diabetes mellitus(T1DM) and to look at prevalence of diabetes complications in T1DM with and without metabolic syndrome at a tertiary diabetes centre in Chennai, South India. Patients with without metabolic syndrome were older, had longer diabetes duration, acanthosis nigricans, and increased serum cholesterol. In the unadjusted logistic regression analysis, retinopathy, nephropathy and neuropathy were associated with metabolic syndrome. Prevalence of metabolic syndrome is high among Asian Indian T1DM patients, and its presence is associated with increased risk of diabetic retinopathy and nephropathy.

**Bhavana Sosale et.al (2015)** conducted a retrospective crosssectional study to determine the prevalence of CV risk factors, micro and macrovascular



complications in patients with newly diagnosed young onset diabetes across India among seven centers from 2013 to 2015. Patients were evaluated for complications of diabetes and CV risk factors such as body mass index (BMI), hypertension, dyslipidemia, and smoking. In this study demonstrates that patient's with young onset diabetes have micro and macrovascular complications at diagnosis. This study highlights the importance of screening patients with YOD for CV risk factors and micro,macro vascular complications of diabetes at the time of diagnosis.

**Saikat Sen Et.al (2015)** performed a systemic review to evaluate the trends of prevalence, extent of diabetic problem in India based on available literatures over a period of 52 years (1960 to 2011). Pertinent literatures providing details of sample size, age group, along with prevalence of any of the three outcomes of interest, i.e. diabetes mellitus, impaired fasting glucose, impaired glucose tolerance were included. In this report analysed the changes in prevalence of diabetes mellitus and prediabetes in India from 103 potential literatures. A secular trend regarding increase in diabetic prevalence was observed in India, though in rural areas it is slower than urban areas. Extent of lack of awareness and carelessness to undergo screening for diabetes was clearly demonstrated in the recent study. As a conclusion multidisciplinary approach and situation based policy are needed to combat the pandemic.

**Vladimir Vuksan (2013)** was conducted randomized controlled trial to assess the effectiveness of viscous fibre on acute and long term metabolic improvement in type 2 diabetes mellitus such as reduction in hemoglobin A1c,fasting and postprandial giycemia,insulinemia and cardio vascular risk factors.Its is helpful in managing diabetes with positive outcomes on vascular complications and reduced cardio vascular disease risk.

**Mani, Yarde, & Edmonds (2011)** conducted a cohort study to assess prevalence of venous incompetence, impaired calf vein hemodynamic, and loss of micro vascular control in the skin over the dorsum of the foot in an effort to document whether increased retrograde pressure caused due to venous incompetence or loss of sympathetic regulation of the microcirculation is

present in the diabetic patient who is at risk of foot disease. As a conclusion outstanding contribution of this report is the finding of venous incompetence in patients with diabetes results in diabetic foot disease.

**Srivijitkamol, MOUNGGERN & VANNASEANG (2011)** conducted a retrospective study to determine factor(s) associated with reduced assessment of diabetic complication and to determine the prevalence of diabetic complications in type 2 diabetes patients at the out-patient department (OPD) of Internal Medicine at Siriraj Hospital Mahidol University Thailand . There was a high prevalence rate of diabetic complications in patients with type 2 diabetes. Screening for diabetic complications will help to identify patients at high risk of concomitant complications even though some practitioners are not initially aware of the importance of the diabetic complication screening. This study data may help the physician decide to modify treatment to prevent disabilities

**Vishwanathan & Kumpatla (2011)** conducted a study to assess the pattern and causes of amputations in diabetic patients across various parts of India. A total of 1985 type 2 diabetic subjects were selected from 31 centres across India. . The major cause for the occurrence of amputations among the patients was found to be infection. Almost 90 % of the patients had infection. Patients had different types of amputations: major amputations accounting for 29.1 % (n=377) and minor amputations in 70.9 % (n=918) of subjects. Prevalence of neuropathy (82 %) was high and 35 % had peripheral vascular disease due to diabetic mellitus. The study concluded that, foot infection was found to be the major cause of amputation in India.

## **2.2. Literature related to diabetic foot ulcer and its treatments**

**Amit Kumar C. Jain, Viswanath S (2015)** conducted a retrospective study to analyse major amputation occurring in patients with diabetic foot complication through the new principle and practice of diabetic foot at St John's medical college, Bangalore, India. Infected ulcers were the most common cause for major amputation. Most patients who underwent major amputation had a score ranging from 16-20. 11.54% of the patients who

underwent major amputation had osteomyelitis with type 3C diabetic foot osteomyelitis being most common. Majority of the patients who undergo major amputation in India has type 1 diabetic foot complication. Most of the patients undergoing major amputation belong to the high risk category for major amputation.

**Shyam Kishore, et.al. (2015)** conducted a cross-sectional study was to determine the distribution of categories of foot at risk in patients with diabetes, attending a tertiary care hospital and factors that affect it. Foot at risk was classified according to the task force of foot care interest Group of American Diabetes Association. Category of foot at risk was correlated with demographic and clinical feature .Fifty-two percent patients had foot at risk-category 1 and 2. Loss of protective sensation (LOPS) was present in 33% (category 1). Peripheral arterial disease (PAD) was present in 19% (category 2). Both LOP and PAD was present in 10% patients. 95% had never received foot care advice by health professionals, let alone prescriptive footwear or vascular consultation.

**Sukhminder Jit Singh Bajwa, (2015)** conducted a cross sectional study among patients with diabetic foot lesions presenting for amputation suffer from various socio-behavioral, psychological and economic constraints, which have an impact on the care providers of those affected as well. In this study included 171 patients in the age group 29-78 years of either sex who underwent either amputation or debridement, followed by amputation. The clinical status was observed and duly recorded in the performa meant for the study. The socio-behavioral aspects related to diabetic foot were recorded by interview method form patients and their relatives. A higher occurrence of diabetic foot morbidities was found in males (152) than in females (19) with a mean age of 52.64 years at the time of presentation in their study. Socio-behavioral factors such as low literacy levels, treatment by quacks, inadequate foot care and habit of walking barefoot, lack of physician follow-up and association of concomitant risk factors such as smoking and alcoholism and co-morbidities were important triggers for diabetic foot morbidities and subsequent

amputation. These also had psychological impacts on its sufferers. Neuropathy was the main culprit accounting for 88.89% cases, while neuropathy accounted for 11.11% cases.

**Zubair, Malik & Ahmad (2011)** conducted a prospective study to evaluate the incidence and risk factors for amputation among patients with diabetic foot ulcer (DFU) in a multidisciplinary based diabetes and endocrinology centre of Jawaharlal Nehru Medical College of Aligarh Muslim University, India. Detailed history and physical examination was carried out for every subject. Risk factors for amputation were determined by univariate analysis with 95 % of CI. The overall amputation rate was 28.4 %. The risk factors identified for amputation were presence of PVD, leukocytosis, neuropathy, nephropathy, hypertension, dyslipidemia, over use of antibiotics, osteomyelitis, bio film production and higher grade of ulcer.

**Shankhadar (2009)** conducted a study to evaluate the knowledge about foot care, type of footwear used, educational level, association of tobacco abuse and any associated symptoms of foot disease by a structured questionnaire. Clinical evaluation was done by inspection of feet for presence of any external deformities, assessment of sensory function (vibration perception threshold, VPT), vascular status (foot pulses and ankle brachial ratio) and presence of any infection. Average duration of diabetes in the high-risk and low-risk diabetes group was 10.85 and 9.83 years, respectively. In the high- and low-risk diabetic groups, VPT was 11.26 and 10.21V ( $P < 0.02$ ). The study shows, poor knowledge of foot care and poor footwear practices were important risk factors for foot problems in diabetes.

**Bansal & Garg (2008)** carried out a clinical trial on patients with diabetic foot lesions to determine their clinical characteristics, the spectrum of aerobic microbial flora and to assess their comparative in vitro susceptibility to the commonly used antibiotics. A total of 157 organisms (143 bacteria and 14 fungi) were isolated and an average of 1.52 isolates per case was reported. Polymicrobial infection was found in 35 % of the patients. In this study, *Pseudomonas aeruginosa* among the gram-negative (22 %) and *Staphylococcus*

aureus among the gram-positive (19 %) were the predominantly isolated organisms, while Candida was the most predominantly isolated fungus. Neuropathy (76 %) and peripheral vascular disease (57.28 %) was a common feature among the patients. Poor glyceemic control was found in 67 % of the patients. Awareness about lower limb complications of diabetes was very low (23 %) among the patients.

### **Treatments for Diabetic Foot Ulcers**

**Ihtasham Muhammad.et.al (2014)** conducted an experimental study to assess the role of papaya dressings in the management of diabetic foot in terms of healing of ulcers. In this experimental study patients with diabetic foot (n=43) were included. Initial management included empirical antibiotics, surgical debridement or amputation, control of glycemia and then wound care with the help of papaya dressings. Dressings were changed after every 48 hours. The wounds were declared healthy when they were filled with healthy granulation tissue and had epithelial growth on their edges. Topical papaya dressing provides cost effective and favourable outcome in patients with diabetic foot ulcer by decreasing the healing duration, reducing surgical interventions.

**Fujiwara.et.al (2012)** conducted a study to assess the effectiveness of a preventative foot care nursing programme for diabetic patients. The researchers developed a diabetic foot care programme based on the International Working Group on the Diabetic Foot and studied 88 patients who attended foot care programme for 2 years, and collected data from April 2005 to March 2009. Patients were divided into four groups according to the risk classification, and received foot care and evaluated the incidence of foot ulceration or recurrence and non-ulcerated foot condition. The programme reduced the severity score of tinea pedis ( $P < 0.001$ ) and improved callus grade ( $P < 0.001$ ). The researchers found that nurse-based foot care programme is effective in preventing diabetic foot in diabetic patients

**Gottrup&Jorgensen (2011)** conducted a study to assess the efficacy of Maggot debridement therapy (MDT) for treating wound especially diabetic

foot ulcers. Literature and the results demonstrate that Maggot debridement therapy is a safe method with few side effects. Maggot debridement therapy is as good as or better than conventional often surgical debridement, is more selective than surgical debridement, because it decreases time to healing and stays of patients in the ward, and may decrease the risk of major amputations.

**Dumville & Deshpande (2011)** conducted a randomised controlled trial (RCTs) to compare the effects on ulcer healing with hydrogel with alternative wound dressings or no dressing in the treatment of foot ulcers in people with diabetes. The study included 446 participants and the result shows that hydrogel dressings are more effective in healing lower grade diabetic foot ulcers than the basic wound contact dressings.

**Nain, Uppal, Bajaj & Garg (2011)** conducted a study to compare the rate of ulcer healing with the negative pressure dressing technique to conventional moist dressings in the treatment of diabetic foot ulcers. The study was conducted on 30 patients, which were divided into two groups. One group received negative pressure dressing while other group received conventional saline moistened gauze dressing. Results were compared for rate of wound healing. There was a statistically significant difference in the rate of appearance of granulation tissue between the two groups; with granulation tissue appearing earlier in the study group. The study group promised a better outcome (80 % complete responders) as compared to the control group (60 % complete responders). Negative pressure wound therapy has a definitive role in healing of diabetic foot ulcers.

**Nather (2010)** conducted a prospective study to determine the effectiveness of vacuum-assisted closure (VAC) therapy in the healing of chronic diabetic foot ulcers. An electronic vacuum pump was used to apply controlled negative pressure evenly across the wound surface. Changes in wound dimension, presence of wound granulation and infection status of diabetic foot ulcers in 11 consecutive patients with diabetes were followed over the course of VAC therapy. Healing was achieved in all wounds. The average length of treatment with VAC therapy was 23.3 days. Ten wounds showed

reduction in wound size. All wounds were satisfactorily granulated and cleared of bacterial infection at the end of VAC therapy. VAC therapy also provides a sterile, more controlled resting environment to large, exudating wound surfaces. Large diabetic foot ulcers were thus made more manageable.

**Abdelatif.M.et.al. (2008)** conducted a prospective pilot study on safety and efficacy of a new honey ointment on diabetic foot ulcers. The objective was to study the effectiveness and safety of pedyphar ointment, a new ointment prepared from natural royal jelly and panthenol in an ointment base in the treating patients with limb-threatening diabetic foot infections. They found out that 96% of the patients responded well, with a complete cure, defined as complete closure of the ulcer without signs of underlying bone infection and concluded that pedyphar ointment is a promising, safe conservative local treatment.

**Tiaka, Papanas & Manolakis (2008)** investigated the use of Hyperbaricoxygen (HBO) in addition to standard treatment of the diabetic foot for more than 20 years. Evidence suggests that Hyperbaricoxygen reduces amputation rates and increases the likelihood of healing in infected diabetic foot ulcers, in association with improved tissue oxygenation, resulting in better quality of life. Nonetheless, Hyperbaricoxygen represents an expensive modality, which is only available in few centers. The study shows that, Hyperbaricoxygen appears promising, but more experience is needed before its broad implementation in the routine care of the diabetic foot.

**Duckworth WC.,et.al.,(2004)** conducted a study to assess wound healing process by several agents such as insulin-like growth factor (IGF) and human acidic fibroblast growth factor (rh-aFGF). In vivo studies have shown that IGF can stimulate the proliferation and differentiation of endothelial cells and fibroblasts and promote granulation tissue regeneration to contribute to wound healing. Ever since Bunting's discovery of insulin in 1921, many benefits beyond blood glucose regulation have been documented. Preclinical and clinical studies have demonstrated positive effects of insulin on wound healing, but no suitable method for routine clinical use of topically applied insulin has

been reported. Hence we have decided to study the effect of insulin on healing on diabetic foot and to develop an appropriate method for topical application of insulin.

### **2.3 Literature Related To Application Of Citric Acid For Wound Healing.**

**Vinod Prabhu et.al (2014)** conducted a end pilot study to look for cost effective method for dressing wounds to minimize loss of working hours in Bharati Vidyapeeth University, Sangli, Maharashtra, India. Three percent citric acid solution (CA) was used for dressing on necrotic lower limb diabetic ulcers with the object of pH modulation of wounds at an early stage and to evaluate its effects on wound healing. Appearance of healthy granulation was the end point of the study. An unicentric randomized double blinded study with a parallel design was used to compare patients treated with 3% CA and Eusol solutions, respectively. It is concluded that 3% CA solution forms a good alternative for wound dressings that acts by modulating the wound pH to acidic levels thereby contributing to wound healing by increased fibroblast proliferation and probably increasing local oxygen concentration and reducing microbial growth and virulence.

**Thool .V,U, et.al (2014)** conducted an experimental study in the backdrop managing of MRSA and VISA infections in Orthopaedic patients, Sevadal Mahila Mahavidyalaya, Nagpur, India .Citric acid was found to be an effective permeabilizer and potentiating agent for VISA/MRSA isolates. All the VISA isolates (n=9) were susceptible to citric acid except one. Of the 16 MRSA isolates tested for potentiating activity of citric acid, 14 isolates showed an increase in zone diameter size. Two isolates showed an exceptional resistance to citric acid. Citric acid offers a novel prophylactic approach for controlling MRSA and VISA infections of wounds from orthopaedic patients. The use of citric acid may prevent the development of infections that will minimize antibiotic use, prevent development of resistance as well as promote healing.



**Nagoba B, (2012)** conducted a prospective open study to assess for simple and effective approach for the treatment of traumatic wounds in non-diabetic patients. An attempt was made to develop a simple and effective treatment modality by using citric acid as the sole antimicrobial agent to control bacterial infections of traumatic wounds. Citric acid ointment (3%) was applied to traumatic wounds to determine its efficacy in their treatment of traumatic wounds. Citric acid ointment was found effective in controlling infections. Out of 259 cases, 244 (around 95%) were healed completely in 5-25 applications of 3% citric acid. As citric acid has antibacterial activity and wound-healing property; hence it is the best alternative for the treatment of traumatic wounds. Besides these properties, citric acid has no adverse effects and it is a good dressing agent.

**Hartalkar Amol1, et.al (2012)** reported *a case from MIMSR Medical Collge, Maharastra, India. A case of 45 years-old male patient with a large non-healing ulcer over right leg and also known case of chronic liver disease and was having multiple underlying problems. The ulcer was not responding to conventional treatment for more than one month. This non-healing ulcer was treated simply by local application of three percent citric acid ointment every day for a month, which led to complete healing of the ulcer without any complications.*

**Wadher et.al (2011)** conducted a clinical trial study to determine efficacy of 3% citric acid on surgical site infections. A total of 70 cases of surgical site infections not responding to conventional treatment modalities were included in the present study. Three per cent citric acid ointment was applied to the wound daily once until it healed completely or showed formation of healthy granulation tissue. Application of 3% citric acid to wounds resulted in complete healing of postoperative wounds or formation of healthy granulation tissue in 6 to 25 applications in 69 cases (98.57%). Citric acid treatment was found to be safe and useful in the treatment of surgical site infections. Hence, the topical use of citric acid is recommended, especially when the treatment of surgical site infections is a matter of great concern. These

infections are difficult to control and, if not treated in time, increase further morbidity. In the present study, an attempt was made to develop simple and effective treatment modality by using citric acid as a sole antimicrobial agent to control surgical site infections.

**Vinayak Vaghav, et.al (2011)** reported a case of non-healing sinus in mid tarsal region of foot, which did not respond to conventional antimicrobial treatment and local care combined for years, but was treated successfully by using three percent citric acid as a sole topical antimicrobial agent. In the present study, they used citric acid for the treatment of chronic sinus successfully. The sinus, which did not respond to anti-Koch's treatment or loads of antibiotics, healed completely in 11 (one application a day) applications of citric acid. Hence, we can safely suggest the use of citric acid in the treatment of a chronic sinus when other conventional modalities are exhausted.

**Gandhi (2010)** conducted an experimental study to develop a simple and effective treatment modality using citric acid as a sole antimicrobial agent to control infections in burn patients not responding to conventional treatment. Forty-six cases with 5-60 % superficial to deep burns in a study group and 20 cases with 10-70 % superficial to deep burns in a control group were investigated for culture and susceptibility. Application of citric acid to burn wounds resulted in complete healing in 40 (86.95 %) cases in 7-25 applications (P value 0.145); however, in a control group conventional antibiotic therapy and local wound care resulted in complete healing in nine (45 %) patients only. Citric acid treatment was found effective in the control of burn infections as compared to conventional therapy. Complete healing in 86.95 % cases as compared to 45 % in a control group indicates that citric acid is nontoxic, economical and quite effective in the management of burn infections

**Gutyon (2009)** conducted a comparative study to assess the efficiency of citric acid as a dressing in comparison with silver sulfadiazine gauze dressing. In 52 patients treated with citric acid and the 91 percent of wounds were rendered sterile within 7 days. In 52 patients treated with silver

sulfadiazine, 7 % showed control of infection within 7 days. Healthy granulation tissue was observed earlier in patients treated with citric acid (mean 7.4 versus 13.4 days). In control group only 10 % of wounds healed within 15 days. It shows citric acid as an ideal dressing in the treatment of wound healing.

**Ormerod& Shah (2008)**, conducted a clinical trail at University of Wisconsin School of medicine and public health to identify the low cost effectiveness of citric acid based dressing for treating diabetic ulcers. The experimental group receives citric acid based gauze dressings on the diabetic wound for duration of 1 month. At the end of second week granulation tissues appeared at a period of 2 to 4 weeks the ulcers resolved completely. It shows citric acid based dressing has excellent track on wound healing.

**Allen (2008)** conducted an extensive study to evaluate the efficacy of citric acid application in the treatment of wound healing. Literature review was carried out form July 2000 to July 2008. The 5 observational studies with 165 patients and 245 cases in 10 controlled trials where 42patients were treated with citric acid. Most of the patients reported 95 % of complete wound healing within 3- 8 weeks in observational and 62 % in controlled trails.

**Nagoba et.al. (2008)** conducted a study to develop an approach, using citric acid as a sole antimicrobial agent, for the treatment of chronic wound infections caused by multiresistant *Escherichia coli* (MAREC). A total of 34 cases of chronic wound infections yielding MAREC isolates on culture were studied. The antibacterial effect of citric acid against MAREC was evaluated in vitro by broth dilution method. Three percent citric acid gel was applied to each wound once daily until it healed completely. All 34 isolates were inhibited by citric acid with minimum inhibitory concentrations in the range of 1500-2000 microg/ml. Topical application of 3 % citric acid to wounds 7-42 times resulted in elimination of MAREC from infected sites and successful healing of wounds in all 34 patients. This treatment modality was simple, reliable, non-toxic and effective. Hence, the use of citric acid for the cost-effective treatment of wound infections caused by MAREC is recommended.

**Nagoba (2007)** conducted a study to prove the effect of Citric acid treatment for postoperative wound healing in MIMSR medical college, Maharashtra. A 40-year-old female presented with history of swelling at the upper and middle of the left leg since 6 months was confirmed as post cancer surgery non healing wound not responding to conventional antibiotic therapy and local wound care in an operated case of synovial sarcoma of the knee, monophasic fibrous type with no lung metastasis. Post surgical non healing wound not responding to conventional therapy was treated successfully with local application of 3 % citric acid ointment for 25 days. And the researcher found that treating post surgical wounds with 3 % citric acid is a useful measure in the clinical areas.

**Hess (2005)** reported in his study, in tissue repair vitamin C directly affects the normal production and maintenance of matrix materials especially collagen. Vitamin C also strengthens and promotes the formation of new blood vessels. With vitamin C deficiency even superficial wounds fail to heal and the walls of the blood vessels become fragile and are easily ruptured.

**Van et.al (2003)** conducted a randomized clinical trials on diabetic foot ulcer patients and found that a novel formulation of metal ions and citric acid reduces reactive oxygen species in vitro which plays an important role in wound healing. Reactive oxygen species react with nitric oxide produced by macrophages to form preoxynitrate, another strong oxidant with detrimental effects on surrounding tissue. This study investigated whether samples of metal ions and citric acid are able to reduce levels of reactive oxygen species. Samples of materials were tested in assays by checking inhibition of reactive oxygen species production by poly morphonuclear neutrophils (PMN), antioxidant activity and inhibition of human complement. The result shows that the citric acid was found to cause significant reduction of super oxide thus promoted wound healing.

## **2.2 Conceptual frame work**

### **Modified Orlando's Theory of Deliberative Nursing Process (1990)**

Orlando was one of the earliest nurse theorist and one of the first people to develop nursing inductively from the empirical study of nursing practice. Orlando's theory has radically shifted the nurse's focus from medical diagnosis, to the nursing diagnosis that is finding and meeting the client's immediate needs.

Orlando's nursing process is composed of the following basic elements

1. Client's behaviour
2. Reaction of the nurse
3. The Nursing activities which are designed for the clients distress

Orlando says that nurses should help in relieving the physical and mental discomfort and should not add to the client's distress.

In this theory, Nursing process is used by nurses to meet the clients needs. Meeting the needs improves the clients's behaviour. Client's behaviour can be increased body temperature, rigor, vomoting, body pain, fatigue, dis comfort. Nurse reacts to the client's behaviour and act accordingly. After completion, the nursing action is evaluated for its effectiveness.

#### **Patient Behaviour**

Patient need is to improve wound status which is caues by Diabetic melitus. The client who cannot resolve a need feels helpless and the person's behaviour reflects this feelings. Patient behaviour can be verbal ( expressed by language such as complaints of foot ulcer) or non verbal ( manifestation like edema,exudate,discomfort,immobility).

## **Nurse Reaction**

Nurse perceives the clients behaviour (demographical and physiological variable) and feels that the client has some needs to be met validating the same by communicating with the client, the nurse investigator assesses the pre assessment level of wound score by Bates Jensens Wound Assessment Scale.

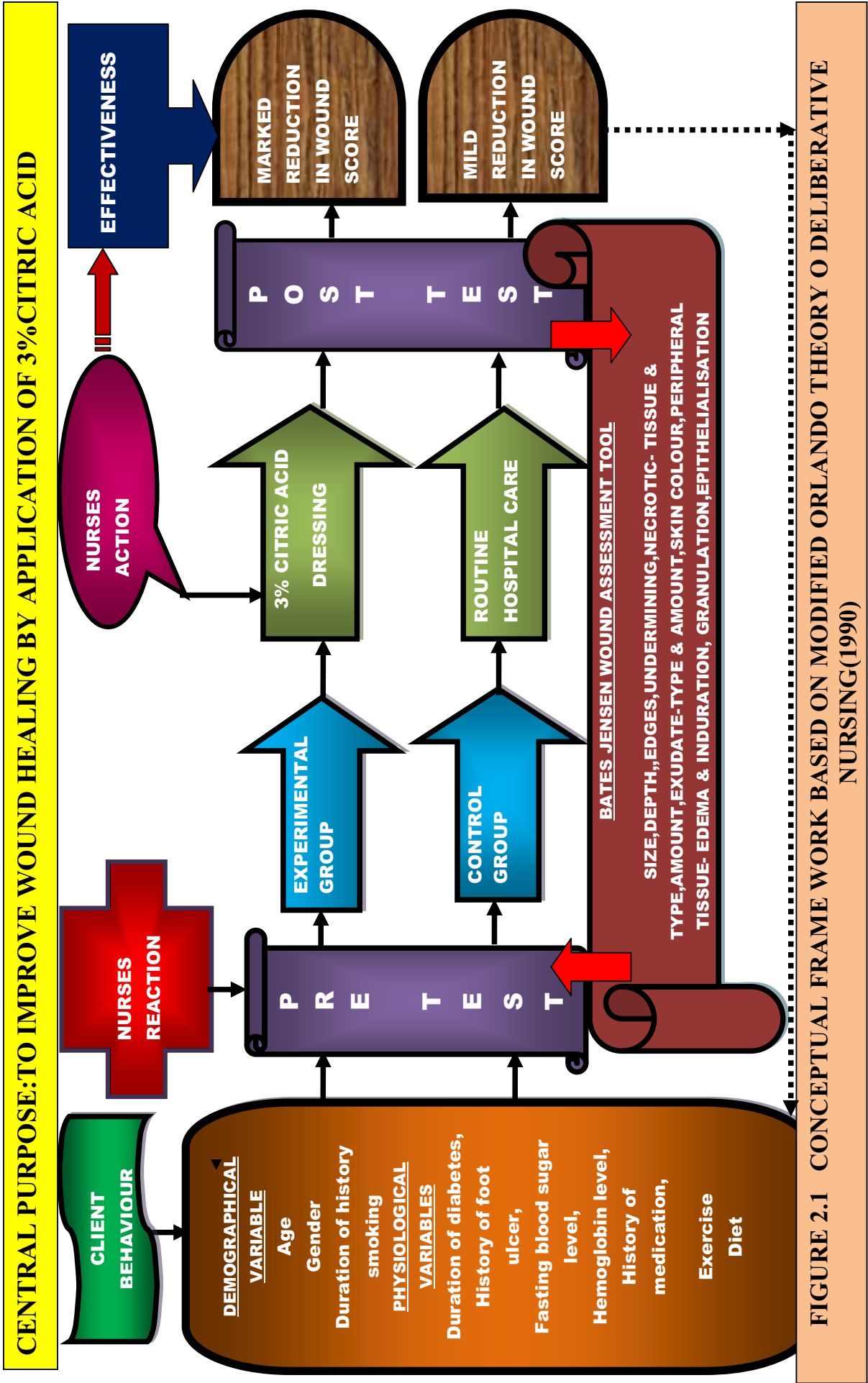
## **Nurse Action**

Nurse activity can be automatic or instinctive, deliberative.

In automatic nurse actions includes decided on for reasons other than the patient's immediate need include giving medication and performing routine patient care for control group.

Deliberative nurse actions involving exploring the meaning (wound status) and relevance of an action to the patient ( 3% citric acid dressing) and actions are evaluated for effectiveness after completion (post test).

In deliberative nurse actions involves exploring the meaning (verifying) and identifying the need of the client. The nurse investigator's activity is in planning and implementing the nursing action for meeting the client's needs or improving the client behaviour ( improve wound healing). Here the nurse action is application of 3% citric acid dressing for 14 days for experimental group and post assessment done on 14th day to find out effectiveness of nurse action. If there is marked reduction in wound score, encourage to follow the therapy.



**FIGURE 2.1 CONCEPTUAL FRAME WORK BASED ON MODIFIED ORLANDO THEORY O DELIBERATIVE NURSING(1990)**

## **CHAPTER III**

### **METHODOLOGY**

This chapter deals with the methodology to assess the effectiveness of 3% citric acid dressing on diabetic foot ulcer among patients admitted in selected wards of Rajiv Gandhi Government General Hospital, Chennai.

Research methodology includes the research approach, Research design, Duration of the study, study settings, study population, sample size, sample selection criteria, sampling technique, Research variables of the study, setting, population, sample, criteria for sample selection, sampling technique, Development and description of the tool, scoring procedures, intervention protocol, content validity, pilot study, reliability of the tool, procedure for data collection and plan for statistical analysis.

#### **3.1. Research approach**

The quantitative research approach was used to evaluate the effectiveness of 3% citric acid dressing on diabetic foot ulcer among patients admitted in selected wards of Rajiv Gandhi Government General Hospital, Chennai.

#### **3.2 Data collection period**

The study was conducted for the period of four weeks (from 16.7.2015 to 15.8.2015)

#### **3.3 Study setting**

The study was conducted in selected wards of Rajiv Gandhi Government General Hospital, Chennai Tamilnadu. It is one of the biggest hospitals in South East Asia with 3000 beds and funded & managed by state government of Tamil Nadu. It has all specialities and super specialities services are rendered by the hospital. The hospital is treating about 10,000 to 12,000 out patients every day.

The Department of General surgery was started in the year 1960 and it has been upgraded as a Institute of general surgery on Feb 2, 2014. The current bed strength of the Institute of General Surgery is 200, which includes General



wards,Special,Septic wards & intensive care units.This is one of the largest department in a Government Hospital among India.Dr Ragumani MS,is Director & Professor of Institute of the General Surgery.There are 7 units in this Department and admissions are done throughout the week, 3-5 diabetic wound debridement/day, 3 amputation/week are carried.Those affected with diabetic foot ulcers are treated in the surgical wards and special & selected wards of Rajiv Gandhi Government General Hospital, Chennai.In 2015 current out patient census was 50,000 in which 1/3 patient was diabetic foot ulcer.

### 3.4 Study design

The research design used in the study is experimental design. In experimental design Pretest –Post test control group design.

Experimental group	O <sub>1</sub>	X	O <sub>3</sub>
Control group	O <sub>2</sub>	---	O <sub>4</sub>

Keys:

- O<sub>1</sub> Observation on experimental group before intervention
- O<sub>2</sub> Observation on control group before intervention
- X Intervention
- O<sub>3</sub> Observation on the experimental group after intervention
- O<sub>4</sub> Observation on the control group intervention
- Routine management

### 3.5 Study population

The target population of the present study is the adults between the age group of 41-80 years patients with diabetic foot ulcer admitted at Rajiv Gandhi Government General Hospital, Chennai.

### 3.6 Sample size

The study sample comprises of 41- 80 years male and female diagnosed to have Diabetic foot ulcer admitted in selected wards of Rajiv Gandhi Government General Hospital, Chennai.The sample size for the study was 60.

Out of which 30 samples who receive 3% citric acid dressing belong to the experimental group and 30 samples who do not receive 3% citric acid dressing belong to the control group.

### **3.7. Criterion for selection of samples**

#### **3.7.1. Inclusion Criteria:**

- ❖ Patients who are willing to provide informed consent
- ❖ Patients with type I and type II diabetes mellitus who are admitted with diabetic wound/ diabetic foot ulcer
- ❖ Patients who are in the age group of 41-80 years of either sex
- ❖ Patients who are present at the time of data collection period
- ❖ Patients who can understand and read English or Tamil.

#### **3.7.2. Exclusion Criteria:**

- ❖ Clients who are critically ill
- ❖ Clients who are on treatment with corticosteroids, radiation therapy and immunosuppressive drugs.
- ❖ Clients with protein energy malnutrition as diagnosed by physician.
- ❖ Clients with vascular and neurological problem.

### **3.8 Sampling technique**

The samples were selected by simple randomized sampling technique based on the inclusive criteria.

### **3.9 Research variables.**

- ❖ *Independent Variable* - 3% citric acid dressing
- ❖ *Dependent variable* – Client with the diabetic foot ulcer

### **3.10 Development and Description of tool**

After an extensive review of literature and discussion with the experts the following tools are prepared to collect data.

#### **3.10.1 Development of tool**

Appropriate tool was selected with the help of review of literature. Obtained expert opinion and content validity from Diabetology and nursing statistics department and constructed tool. Pre testing of tool was done during

pilot study. Direct assessment of clients was performed during the data collection.

### **3.10.2 Description of the tool**

#### **Tool Consists Of Two Sections: A& B**

**Section A:** *Demographic& Physiologic Variable Profoma*-Demographic& Physiologic data was collected from the patients and hospital records which include age, gender, and history of smoking, duration of diabetes mellitus, history of foot ulcer, fasting blood sugar and hemoglobin levels, medication, dietary pattern, exercise.

**Section B:** *Modified Bates Jensen Wound Assessment Tool (2001)*-Bates Jensen Wound Assessment Tool is a standardized tool developed in the year 1995 by Barbara Bates Jensen and revised in 2001. The Bates Jensen wound assessment tool contains 13 characteristics which assess the wound status. These characteristics included location and shape of the wound, size in centimeters square, depth, appearance of edges, undermining or tunneling, necrotic tissue type and amount, exudate type and amount, surrounding skin condition, peripheral tissue edema and induration, granulation tissue appearance and epithelialization (Bates-Jensen & MuNees, 2001)

#### **Scoring and interpretation of the *Modified Bates Jensen Wound Assessment Tool (2001)*:**

In the BWAT, 13 characteristics of wound status are scored using a Likert-type scale; a score of **1** - indicates the healthy wound and **5** - indicates the most unhealthy wound attribute for each characteristics. Item sub scores are added to obtain a total score. The scores range from 13-65 with the higher number demonstrating a worse condition of the wound.

The Bates Jensen wound assessment scale (2001) has internal consistency and reliability obtained for this tool is 0.91 and yielded high correlation.

#### **Administration of the Tool.**

1. Size: a sterile metric scale was used to measure the longest and widest aspect of the wound surface.

2. Depth: depth is identified by the most appropriate wound description of the following and 1 to 5 scores are given respectively
  - ❖ Tissues damaged but no break in skin
  - ❖ Superficial, abrasion, blister, or shallow crater.
  - ❖ Deep crater with or without undermining of adjacent tissue
  - ❖ Visualization of the wound is obscured by necrosis
  - ❖ Supporting structures include tendon, joint capsule are also involved.
3. Edges : edges of the wound is identified and scored by the following guideline:
  - ❖ Indistinct- wound outline is unable to clearly distinguish.
  - ❖ Attached - flat or even wound base
  - ❖ Not attached - base of the wound is deeper than the edge
  - ❖ Rolled under, thickened -soft to firm and flexible to touch
  - ❖ Hyperkeratosis - callous like tissue formation around wound and at edges.
  - ❖ Fibrotic, scarred -hard to touch
4. Undermining: undermining refers to the deep tissue damage around the wound margin, and it is assessed by inserting cotton tipped applicator at the wound edges and scored as per the guideline in the tool.
5. Necrotic tissue type: necrotic tissue of the wound is identified according to colour, consistency and adherence.
6. Necrotic tissue amount: transparent metric measuring scale with concentric circles divided into 4 (25 %) pie shaped quadrants to determine percent of wound involved.
7. Exudates type: whether the exudate is bloody, serosanguineous, serous, purulent, foul or foul purulent is assessed.
8. Exudates amount: a transparent metric measuring scale with concentric circles divided into 4 (25 %) pie- shaped quadrants is used to determine the exudates amounta and according to the percentage it is determined that the amount of exudates is scant, small, moderate, or large.
9. Skin colour surrounding wound: the colour of the tissues with in 4 cm of wound edge is assessed.

10. Peripheral tissue edema: the edema of the peripheral tissue is assessed with in 4 cm of wound edge. Non pitting edema appears as skin that is shiny and taut. Pitting edema is identified by firmly pressing a finger down in to the tissues and waiting for 5 seconds, on release of pressure, tissues fails to resume previous position and indentation appears. A metric scale is used to find how far the edema is spread to the surroundings.
11. Peripheral tissue induration: it is assessed by gently pinching the tissues. Induration results in an inability to pinch the tissues. A metric scale is used to find how far the induration is spread.
12. Granulation tissue: it is identified by visualising the wound. When the tissue is bright, beefy red, shiny, and granular with a velvety appearance it is said to be healthy. Poor tissue health appears as pale pink or blanched to dull, dusky red colour.
13. Epithelialisation: a transparent metric measuring scale with concentric circles divided into 4 (25 %) pie shaped quadrants to determine percentage of wound involved.

The scores obtained are interpreted as; increase in the wound status score indicates the wound degeneration and poor wound healing. Decrease in the wound status score indicates the wound regeneration and tissue healing.

**Table 3.1 Score Interpretation**

<b>S.NO</b>	<b>SCORE</b>	<b>RESULT</b>
1	50-60	Unhealthy
2	40-49	Moderate
3	30-39	Mild
4	20-29	Good
5	<19	Healthy

### 3.10.3 Intervention protocol

Protocol	Experimental group	Control group
• Place	Surgical, Spetic and special wards	Surgical ,Spetic and special wards
• Dosage	20-30 ml gauze soaked 3 % citric acid dressing	Routine ward care
• Duration	14 days	14 days
• Frequency	Once in a day	Once in a day
• Time	30 Minutes/day	30 minutes/day
• Administrationby	investigator	investigator

### 3.10.4 Content Validity

Content validity was determined by experts from Nursing and Medical and Statistician .Experts's suggestions are incorporated in the tool.After the modifications they agreed this tool for assessing effectiveness 3% citric acid on diabetic foot ulcer among patients admitted in selected wards of Rajiv Gandhi Government General Hospital, Chennai

### 3.11 Ethical considerations

The study was conducted after the approval and ethical clearence of the Institutional ethics committee, Madras Medical college and Rajiv Gandhi Government General Hospital,Chennai. The investigator was instructed to follow the guidelines of the ethical committee.All subjects were carefully informed about the purpose of study, ensure confidentiality of the study result.The freedom was given to the patient to leave the study at his/ her will without any reason, no routine care was altered or withheld.The investigator followed the ethical guidelines which were issued by the research committee. Informed written consent was received from all the patients.Obtained from

each study participant after giving full information about the study. Anonymity was assured to each participant and maintained by the researcher.

### **3.12. Pilot Study**

Pilot study was conducted in Rajiv Gandhi Government General Hospital, Madras Medical College Chennai for a period of five days. Simple random sample of 10 diabetic foot ulcer patients were selected, five were assigned to experimental group and five assigned to control group randomly. Bates Jensen wound assessment scale was used to assess the wound status. Assessment was done every day before each dressing. The result revealed that there is a significant improvement in the status of wound after the application of 3% citric acid dressing. Pilot study participants are not included in the main study.

### **3.13. Reliability of the tool**

After pilot study reliability of the tool was assessed by using Split of method and its correlation coefficient  $r$  value was 0.83. This correlation coefficient was very high and it was good tool for assessing effectiveness 3% citric acid dressing on diabetic foot ulcer among patients admitted in selected wards of Rajiv Gandhi Government General Hospital, Chennai.

### **3.14. Data Collection Procedure**

The investigator obtained permission from the Director, Professor and Head of the department Institute of General surgery and Institute of Diabetology. Rapport was established after a brief introduction about the study. Informed consent was obtained from each study participants after getting full information about study. Anonymity was assured to each participants.

Collected demographical & physiological variables from diabetic patients and also pretest assessment of wound status done by using Bates Jensen Wound Assessment Tool. Study samples were selected by simple random sampling technique and samples were divided into two groups based on lottery method, odd numbers as experimental group and even number as control group.

Application of 3% citric acid dressing to experimental group and routine care for control for control group for 14 days followed by post assessment done on 14 th day by using Bates Jensen Wound Assessment Tool. The investigator followed all ethical principles for collecting the data. The procedure is recorded and reported.

### **3.15. Data entry and analysis**

The data were analyzed using *descriptive statistics, inferential statistics.*

#### ***Descriptive statistics***

- ❖ Frequency and percentge to describe demographical & Physiological variables of diabetic clients with diabetic foot ulcer.

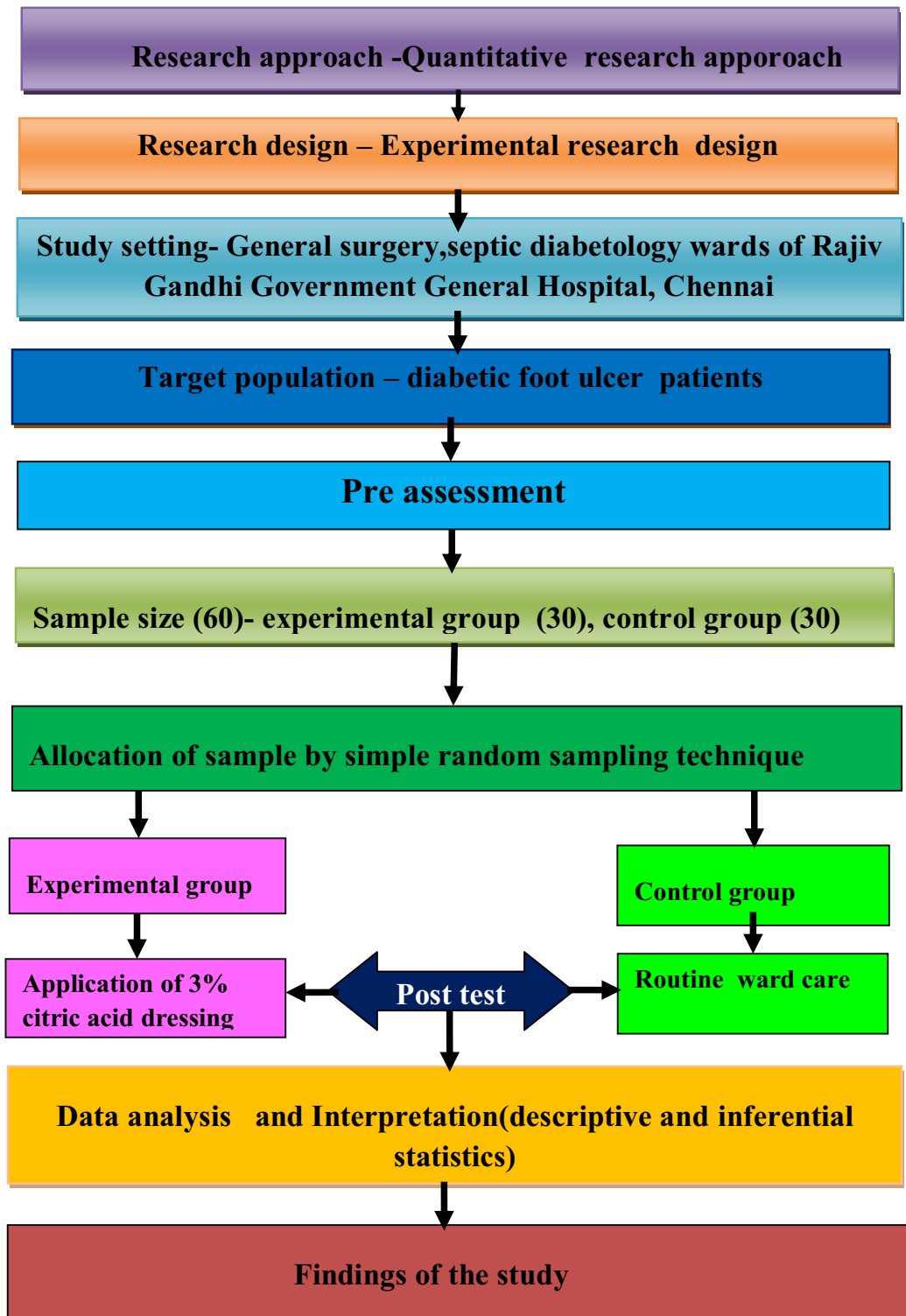
#### ***Inferential statistics***

- ❖ Student paired-‘t’ test to assess the effectiveness 3% citric acid dressing on diabetic foot ulcer among experimental and control group.
- ❖ Student independent- ‘t’ test to compare the effectiveness of 3% citric acid dressing on diabetic foot ulcer between experimental and control group.
- ❖ Chi - square test associate the effectiveness of 3% citric acid dressing with selected demographical & physiological variables.



**Figure 3.1**

**Schematic Representation of Research Methodology**



## CHAPTER IV

### DATA ANALYSIS AND INTERPRETATION

This chapter represents the method of analysis and interpretation of the data. The study was conducted to assess the effectiveness of 3% citric acid dressing on diabetic foot ulcer. Data was collected from 60 samples, divide into control and experimental group for implementation of intervention. The findings were tabulated analyzed and interpreted in this chapter. The data was analyzed using descriptive and inferential statistics.

#### **Organization data**

- **Section I :** Assessment of demographic and physiological variables of client's with diabetic foot ulcer
- **Section II:** Assessment of pretest wound status score of diabetic foot ulcer among experimental and control group before intervention.
- **Section III:** Assessemnt of effectiveness of 3% citric acid dressing among group
- **Section IV:** Compare the wound status score of diabetic foot ulcer among experimental and control group.
- **Section VI:** Associate post test wound status score with selected demographical & physiological variables

**Section-I Assessment of demographical and physiological variables of clients with diabetic foot ulcer**

**Table 4.1 Distribution of demographical data**

S. No	Demographic variables		Group				Total	Chi square test
			Experiment(n=30)		Control(n=30)			
			f	(in%)	f	(in%)		
1	Age	41-50 years	5	16.7	9	30	14	$\chi^2=3.01$ p=0.39
		51-60 years	15	50	11	36.7	26	
		61-70 years	7	23.3	9	30	16	
		71-80 years	3	10	1	3.3	4	
2	Gender	Male	20	66.7	20	66.7	40	$\chi^2=0.00$ p=1.00
		Female	10	33.3	10	33.3	20	
3	Duration of History of smoking	Non smoker	13	43.3	11	36.7	22	$\chi^2=0.45$ p=0.79
		1 - 10 years	11	36.7	11	36.7	24	
		>10 years	6	20.0	8	26.6	14	

Significant at  $P \leq 0.05$  \*\*

Highly significant at  $P \leq 0.01$  \*\*\*

Very high significant at  $P \leq .001$  \*\*\*

Table 4.1 reveals the distribution of age, gender and history of smoking.

**In regarding age**, in experimental group 16.7 % of participants were between 61-70 years of age, 50.0% participants were 51-60 years, 23.3% participants were 61-70 years and 10% were 71-80 years. Regarding age, in control group 30 % of participants were between 61-70 years of age, 36.7% participants were 51-60 years, 30% participants were 61-70 years and 3.3% were 71-80 years.

**In regarding gender**-In the case of gender, in experimental group 66.7 % were male and 33.3 % were female. In control group 66.7 % were female and 33.3 % were female.

**In regarding history of smoking**-History of smoking in experimental group shows that 43.3 % were non smokers and 36.7 % were smokers for 1- 10 years and 20 % were smokers for more than 10 years. In control group 36.7 % were non smokers and 36.7 % were smokers for 10 years and 26.6 were more than 10 years.

**Table 4. 2 Assessment of Physiologic Variables of client's with diabetic foot ulcer**

S. no	Physiologic Variables		Experimental Group		Control Group		Total	Chi Square Test
			f	(in %)	f	(in %)		
1	Duration of diabetic mellitus	<1yrs	7	23.3	5	16.7	12	$\chi^2=0.46$ p=0.97
		1 – 3 yrs	7	23.3	7	23.3	14	
		4 – 6 yrs	8	26.7	9	30	17	
		7 – 9 yrs	2	6.7	2	6.7	4	
		≥10 yrs	6	20	7	23.3	13	
2	Duration of History of food ulcer	<1month	11	36.7	9	30	20	$\chi^2=2.71$ p=0.44
		1 month	4	13.3	7	23.3	11	
		2months	5	16.7	8	26.7	13	
		>2month	10	33	6	20	16	
3	Mean fasting blood sugar (mg/dl)	80 –120	7	23.3	3	10	10	$\chi^2=3.80$ p=0.28
		121 -160	11	36.7	8	26.7	19	
		161 -200	9	30.0	13	43.3	22	
		>200	3	10.0	6	20	9	
4	Hemoglobin level (gm/dl)	9.0 -10.0	11	36.6	9	30	20	$\chi^2=0.68$ p=0.7
		10.111.0	9	30.0	8	26.7	17	
		11.1-12.0	5	16.7	6	20	11	
		>12.0	5	16.7	7	23.3	12	
6	Medication	OHA	15	50	12	40	27	$\chi^2=0.60$ p=0.43
		Insulin	15	50	18	60	33	
7	Exercises	Regular	10	33.3	10	33.3	20	$\chi^2=0.00$ p=1.00
		Irregular	20	66.7	20	66.7	40	
8	Diet pattern	Regular	17	56.7	12	40	29	$\chi^2=1.66$ p=0.19
		Irregular	13	43.3	18	60	31	

Significant at  $P \leq 0.05$  \*\* Highly significant at  $P \leq 0.01$  \*\*\* Very high significant at  $P \leq .001$ \*\*\*

**In duration of diabetes mellitus** among experimental group 23.3% were less than one year, 23.3% were 1-3 years, 26.7% were 4-6 years, 6.7% were 7-9 years, 20% were more than years. In control group 16.7% were less than one year, 23.3% were 1-3 years, 30% were 4-6 years, 6.7% were 7-9 years, 23.3% were more than years.

**In the case of duration of diabetic foot ulcer**, among experimental group 36.7% participants were less than one month, 13.3% were one month, 16.7% were two months, 33% were more than two months. In control group 30% participants were less than one month, 23.3% were one month, 26.7% were two months, 20% were more than two months.

**Regarding mean fasting blood sugar** in experimental 23.3% mean blood sugar ranging between 80-120 mg/dl, 36.7% were ranging between 121-160 mg/dl, 30% were ranging between 161-200 mg/dl and 10% ranging between were > 200mg/dl. In control group 10% were ranging between 80-120 mg/dl, 26.7% were ranging between 121-160 mg/dl, 43.30% were ranging between 161-200 mg/dl and 20% ranging between were > 200mg/dl.

**In the case of level of hemoglobin** among experimental group 36.6% were between 9- 10 gm/dl 30% were between 10.1-11 gm/dl, 16.7% 11.1-12 gm/dl and 16.7 were >12 gm/dl. In control group 30% were between 9- 10 gm/dl 26.7% were between 10.1-11 gm/dl, 20% 11.1-12 gm/dl and 23.3% were >12 gm/dl

**Regarding type of consuming diabetic medication** in experimental group 50% were on insulin, 50% were on oral hypoglycemic agent. In control group 60% (18) were on insulin and 40% were on oral hypoglycemic agent.

**Regarding exercise pattern** in experimental group in experimental group 33.3% were on regular exercise pattern, and 67.7% were on irregular exercise pattern. In control group 33.3% were regular exercise pattern, 66.7% (20) were on irregular exercise pattern

**Regarding dietary pattern** in experimental group 56.7% were regular dietary pattern and 43.3% were on irregular pattern, in control 40% were on regular dietary pattern and 60% were irregular dietary pattern.

**Section II-Assessment pre test wound status score  
of experimental and control group**

**Table 4.3-Pretest wound status score among experimental group  
control group**

Test	Group	Wound score		Mean difference	Student independent t-test
		Mean	SD		
Pretest	Experiment	33.33	3.22	0.26	t=0.31 p=0.75
	Control	33.07	3.41		

\*significant at  $P \leq 0.05$  \*\*

highly significant at  $P \leq 0.01$  \*\*\*

very high significant at  $P \leq .001$  \*\*\*

Table 4.3 shows the mean pre test wound status score of clients with diabetic foot ulcer, in experimental group 33.33, in control group 33.07. The mean difference was 0.20 and the calculated 't' value was 0.31. There is no statistically significant ( $p=0.75$ ) difference between wound status between control and experimental group.



**Section-III Assessment of effectiveness of 3% citric dressing acid on diabetic foot ulcer clients**

**Table 4.4 Effectiveness of 3% citric acid on diabetic foot ulcer**

Group		Maximum Score	Mean wound score	Mean difference in wound score with 95% confidence interval	Percentage of wound score with 95% confidence interval
Experiment	Pretest	60	33.33	13.27	22.1%
	Posttest	60	20.07	(11.91 – 14.63)	(19.9%-24.4%)
Control	Pretest	60	33.07	4.77	7.9 %
	Posttest	60	28.30	(2.71 – 6.82)	(4.5% –11.3%)

Table 4.4 shows that on an average, experimental group clients were reduced 22.1% of wound score after 3% citric acid dressing. Control group reduced 7.9% of score. This shows the effectiveness of 3% citric acid dressing. Differences between pretest and posttest score was analysed using percentage with 95% CI and mean difference with 95% CI.

**Section IV-Compare the post test wound status score of diabetic foot ulcer among experimental and control group.**

**Table 4.5 Comparison of post test wound status score among experiment and control**

Test	Group	Wound score		Mean difference	Student independent t-test
		Mean	SD		
posttest	Experiment	20.07	3.59	8.23	<b>t=6.59</b> <b>p=0.001***</b>
	Control	28.30	5.82		

\*significant at  $P \leq 0.05$  \*\*

highly significant at  $P \leq 0.01$  \*\*\*

very high significant at  $P \leq .001$  \*\*\*

Table 4.5 In the comparison of post test mean wound status score of experiment group was 20.07% and in control group was 28.30% respectively. Mean difference between post test score of experimental and control group was 8.23. There is a statistically very high significant difference ( $p=0.001$ \*\*\*) in the wound status among experimental and control group after intervention.

**Table 4.6 Comparison of pretest and posttest wound score status of experiment and control group**

Group	Test	Wound score		Mean difference	Student paired t-test
		Mean	SD		
Experiment	pretest	33.33	3.22	13.27	<b>t=19.97</b> <b>p=0.001 ***</b>
	posttest	20.07	3.59		
Control	pretest	33.07	3.41	4.77	<b>t=2.09</b> <b>p=</b> <b>0.05**</b>
	posttest	28.30	5.82		

significant at  $P \leq 0.05$  \*\*, highly significant at  $P \leq 0.01$  \*\*\*, very high significant at  $P \leq 0.001$

Table 4.6 shows the comparison of overall pretest and posttest.

In the comparison of overall pretest and posttest, in experimental group pretest and post test scores were 33.33% score and 20.07% respectively and difference is 13.27 score. The calculated 't' value was 19.97. There is a statistically very high significant difference ( $p=0.001$  \*\*\*) in wound status among experimental group before and after application of citric acid

Considering control group, in pretest and post test scores were 33.07% and 28.30 respectively. Difference is 4.77 score. The calculated 't' value was 2.09. There is a statistically significant difference ( $p=0.05$  \*\*) in wound status among experimental group before and after routine care.

**Table 4.7 comparison of pretest and posttest mean percentage of wound status score among experimental group**

Diabetic foot ulcer	Maximum score	Wound score		% of wound score	Percentage Difference
		Mean	SD		
Pretest	60	33.33	3.22	55.6	23.5%
Posttest	60	19.27	2.01	32.1	

Table 4.7 shows the percentage of client's with diabetic foot ulcer in experimental group before starting the intervention was 55.6% and the final score decreased to 32.1% and the difference between pretest and post test was 23.5%.

**Table 4.8 Percentage distribution of pretest and post test level of wound status score before and after 3% citric acid dressing (experimental group)**

Score Interpretation	Pretest		Posttest		Chi square test
	f	(in%)	f	(in%)	
Very good	0	0.0	17	56.7	$\chi^2=52.59$ <b>P=0.001***</b>
Good	0	0.0	11	36.7	
Mild	25	83.3	2	6.6	
Moderate	5	16.5	0	0.0	
Poor	0	0.0	0	0.0	
Total	<b>30</b>	<b>100.0%</b>	<b>30</b>	<b>100.0%</b>	

\*significant at  $P \leq 0.05$  \*\*

highly significant at  $P \leq 0.01$  \*\*\*

very high significant at  $P \leq .001$  \*\*\*

Table 4.8 shows that, in pre test percentage distribution of wound status score among experimental group, 83.3% of them had mild score, 16.5% of them had moderate score . In post test percentage distribution of wound status

score among experiment, 56.7% of them had very good score, 36.7% of them had good score, 6.6% of them are having mild score. The calculated 'Chi square test' value was 52.59. There is a statistically very high significant difference (**p=0.001 \*\*\***) in wound status among experimental group before and after 3% citric acid dressing.

**Table 4.9 Pretest & posttest mean percentage of wound status score among control group**

Diabetic foot ulcer	Maximum score	Wound score		% of wound score	Percentage difference
		Mean	SD		
Pretest	60	33.07	3.41	55.1	7.9%
Posttest	60	28.30	5.82	47.2	

Table 4.9 shows the percentage of clients with diabetic foot ulcer in control group before starting the intervention was 55.1% and the final score decreased to 47.2% and the difference was 7.9% which shows that there is mild changes wound status after routine dressing.

**Table 4.10 Percentage Distribution of pretest and posttest level of wound status score before and after routine care (control group)**

	Pretest		Posttest		Chi square test
	f	(in %)	f	(in%)	
<b>Very good</b>	0	0.0	2	6.7	<b><math>\chi^2=13.55</math> P=0.01**</b>
<b>Good</b>	0	0.0	6	20	
<b>Mild</b>	26	86.7	20	66.6	
<b>Moderate</b>	4	13.3	2	6.7	
<b>Poor</b>	0	0.0	0	0.0	
<b>Total</b>	30	100	30	100	

\*significant at  $P \leq 0.05$  \*\* highly significant at  $P \leq 0.01$  \*\*\*

very high significant at  $P \leq .001$ \*\*\*

Table 4.10 shows in pretest percentage distribution of wound status score among control, 86.7% of them had mild score ,13.3% of them had moderate score.

In post test percentage distribution of wound status score among control, 6.7% of the clients had very good wound score, 20.0% of them had good score, 66.6% of them had mild score, 6.7% of them were having

moderate score. The calculated 'Chi square test' value was 13.55. There is a statistically highly significant difference ( $p=0.001$  \*\*\*) in wound status among experimental group before and after routine dressing.

**Section IV-Association between post test wound score status score with demographical,physiological variable**

**Table 4.11 Association between post test wound status score with demographic and physiological variables (experimental group)**

S.no	Demographical And Physiological Variable		Level of wound score				Total	Chi square test
			Below Average ( $\leq 13.27$ )		Below Average ( $> 13.27$ )			
			f	(in %)	f	(in%)		
1	Age	41-50 yrs	1	20	4	80	5	$\chi^2=10.03$ $p=0.01^{**}$
		51-60 yrs	5	33.3	10	66.7	15	
		60-70yrs	6	85.7	1	16.3	7	
		71-80 yrs	3	100	0	0	3	
2	Gender	Male	9	45	11	55	20	$\chi^2=6.70$ $p=0.03^*$
		Female	6	60	4	40	10	
3	Duration of smoking	Non smoker	3	23.1	10	76.9	13	$\chi^2=5.40$ $p=0.02^*$
		1 - 10 years	8	72.7	3	27.3	11	
		>10 years	4	66.7	2	33.3	6	
4	Duration of diabetic mellitus	< 1 yr	4	57.1	3	42.9	7	$\chi^2=8.37$ $p=0.06$
		1 - 3 yr	1	14.3	6	85.7	7	
		4 - 6 yrs	6	75.0	2	25	8	
		7 - 9yrs	2	100.	0	0	2	
		> 10 yrs	2	33.3	4	66.7	6	
5	Duration of diabetic foot ulcer	< 1 month	6	54.5	5	45.5	11	$\chi^2=0.29$ $p=0.96$
		1 month	2	50.0	2	50	4	
		2 month	2	40.0	3	60	5	
		> 2month	5	50.0	5	50	10	
6	Mean fasting blood sugar level	80	2	28.6	5	71.4	7	$\chi^2=1.82$ $p=0.61$
		81- 120	6	54.5	5	45.5	11	
		121- 160	5	55.6	4	44.4	9	
		161 -200	2	66.7	1	33.3	3	
7	Haemoglobin (Gm/dl)	9.1 - 10.0	5	45.5	6	54.5	11	$\chi^2=3.09$ $p=0.38$
		10.1 -11.0	3	33.3	6	66.7	9	
		11.1 -12.0	3	60.	2	40	5	
		> 12.0	4	80	1	20	5	
8	Medication	on OHA	7	46.7	8	53.3	15	$\chi^2=3.09$ $p=0.38$
		on insulin	8	53.3	7	46.7	15	
9	Exercises	on regular	2	20	8	80	10	$\chi^2=5.40$ $p=0.02^*$
		Irregular	13	60	7	35	20	
10	Diet pattern	regular	5	29.4	12	70.6	17	$\chi^2=6.65$ $p=0.01^*$
		Irregular	10	76.9	3	23.1	13	

\*significant at  $P \leq 0.05$  \*\* highly significant at  $P \leq 0.01$  \*\*\* very high significant at  $P \leq .001$ \*\*\*



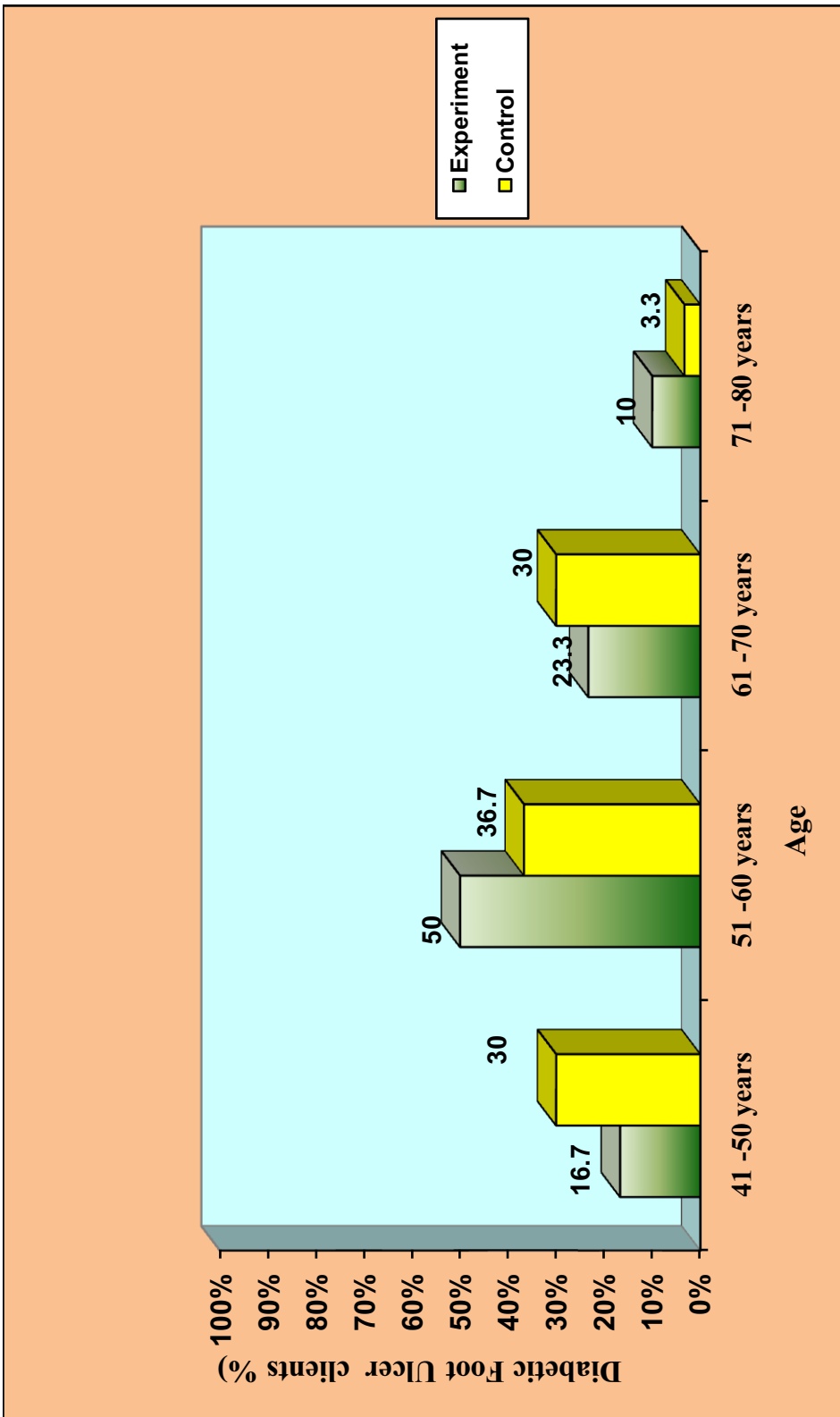
Table 4.10 shows the association between the demographic variables and physiologic variables with post test wound status score of diabetic foot ulcer among patients of experimental group. There is association exists between the ages, gender, history of smoking and regular exercise pattern and dietary of the patients and final wound status score. Younger; non smokers, regular exercise and regular diet pattern patients are benefitted more than others. Statistical significance was calculated using chi square test.

**Table 4.12 Association between post test wound status score with demographic and physiological variables (control group).**

S.no	Demographical and physiological variable		Level of wound score				Total	Chi square test
			Below Average ( $\leq 13.27$ )		Below Average ( $> 13.27$ )			
			f	(in%)	f	(in %)		
1	Age	41-50 yrs	4	44.4	5	55.6	9	$\chi^2=1.33$ $p=0.71$
		51-60 yrs	6	54.5	5	45.5	11	
		60-70yrs	4	44.4	5	55.6	9	
		71-80 yrs	1	100	0	0	1	
2	Gender	Female	10	50	10	50	20	$\chi^2=0.00$ $p=1.00$
		Male	5	50	5	50	10	
3	Duration of smoking	Non smoker	3	23.1	10	76.9	13	$\chi^2=3.56$ $p=0.17$
		1 - 10 years	8	72.7	3	27.3	11	
		>10 years	4	66.7	2	33.3	6	
4	Duration of diabetic mellitus	< 1 yr	4	57.1	3	42.9	7	$\chi^2=4.88$ $p=0.30$
		1 - 3 yr	1	14.3	6	85.7	7	
		4 - 6 yrs	6	75	2	25	8	
		7 - 9yrs	2	100	0	0	2	
		> 10 yrs	2	33.3	4	66.7	6	
5	Duration of diabetic foot ulcer	< 1 month	6	54.5	5	45.5	11	$\chi^2=0.75$ $p=0.86$
		1 month	2	50	2	50	4	
		2 month	2	40	3	60	5	
		> 2month	5	50	5	50	10	
6	Mean fasting blood sugar level	80	2	28.6	5	71.4	7	$\chi^2=0.91$ $p=0.86$
		81- 120	6	54.5	5	45.5	11	
		121- 160	5	55.6	4	44.4	9	
		161 -200	2	66.7	1	33.3	3	
7	Haemoglobin (G/DL)	9.1 - 10.0	7	77.8	2	22.2	9	$\chi^2=4.56$ $p=0.21$
		10.1 - 11.0	3	37.5	5	62.5	8	
		11.1 - 12.0	3	50	3	50	6	
		> 12.0	2	28.6	5	71.4	7	
8	Medication	on OHA	6	50	6	50	12	$\chi^2=0.00$ $p=1.00$
		on insulin	9	50	9	50	18	
9	Exercises	on regular	4	40	6	60	10	$\chi^2=0.60$ $p=0.43$
		Irregular	11	55	9	45	20	
10	Diet pattern	regular	5	41.7	7	58.3	12	$\chi^2=0.55$ $p=0.45$
		Irregular	10	55.6	8	44.4	18	

\*significant at  $P \leq 0.05$  \*\* highly significant at  $P \leq 0.01$  \*\*\* very high significant at  $P \leq .001$ \*\*\*

Table 4.11 shows the association between post test wound status score with demographic and physiological variable. There is no association exists between post test wound status score with demographic physiological variable, none of the variables are significant. Statistical significance was calculated using chi square test.



**Figure 4.1 Age wise Distribution of Diabetic foot ulcer clients**

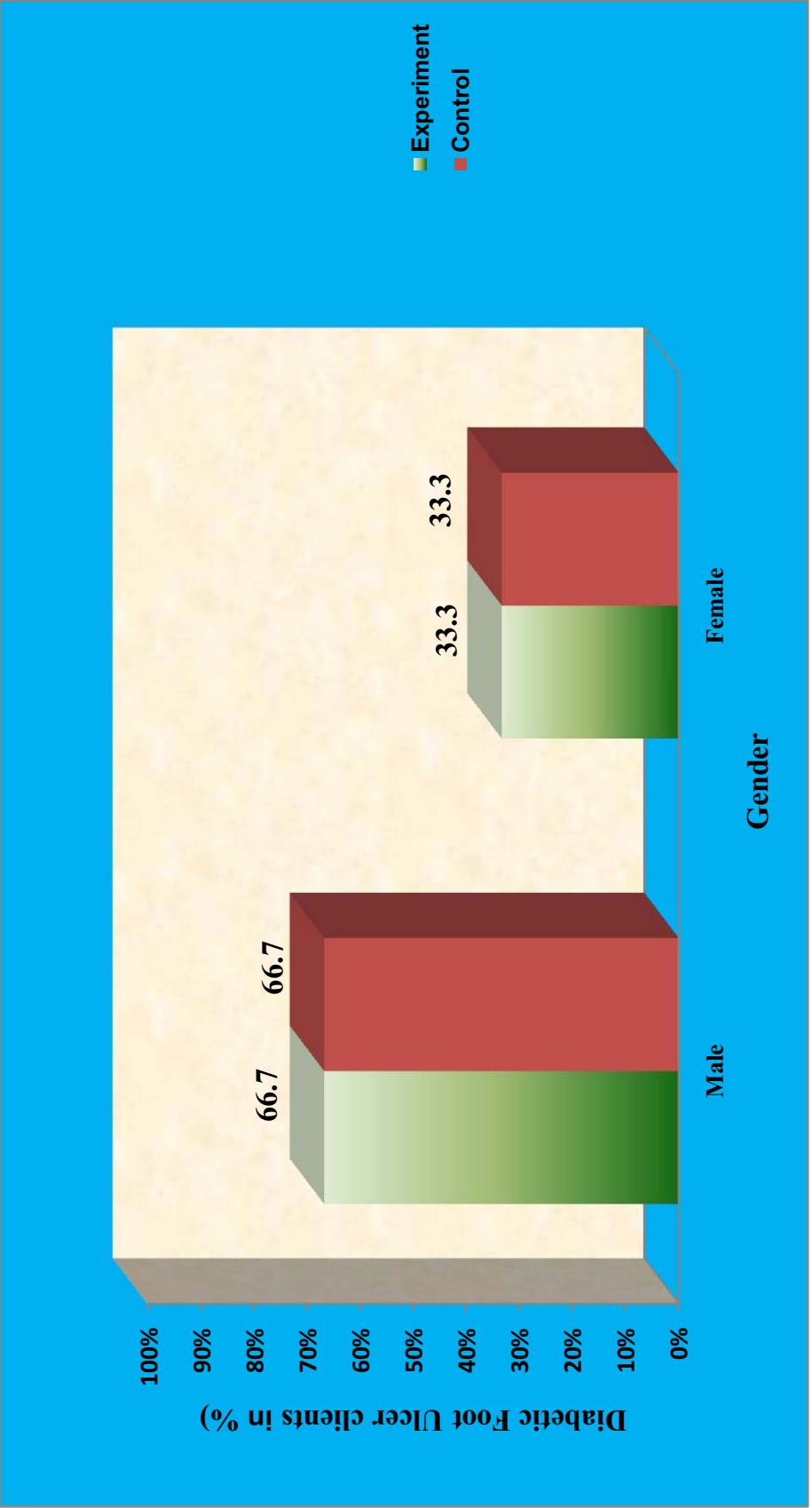
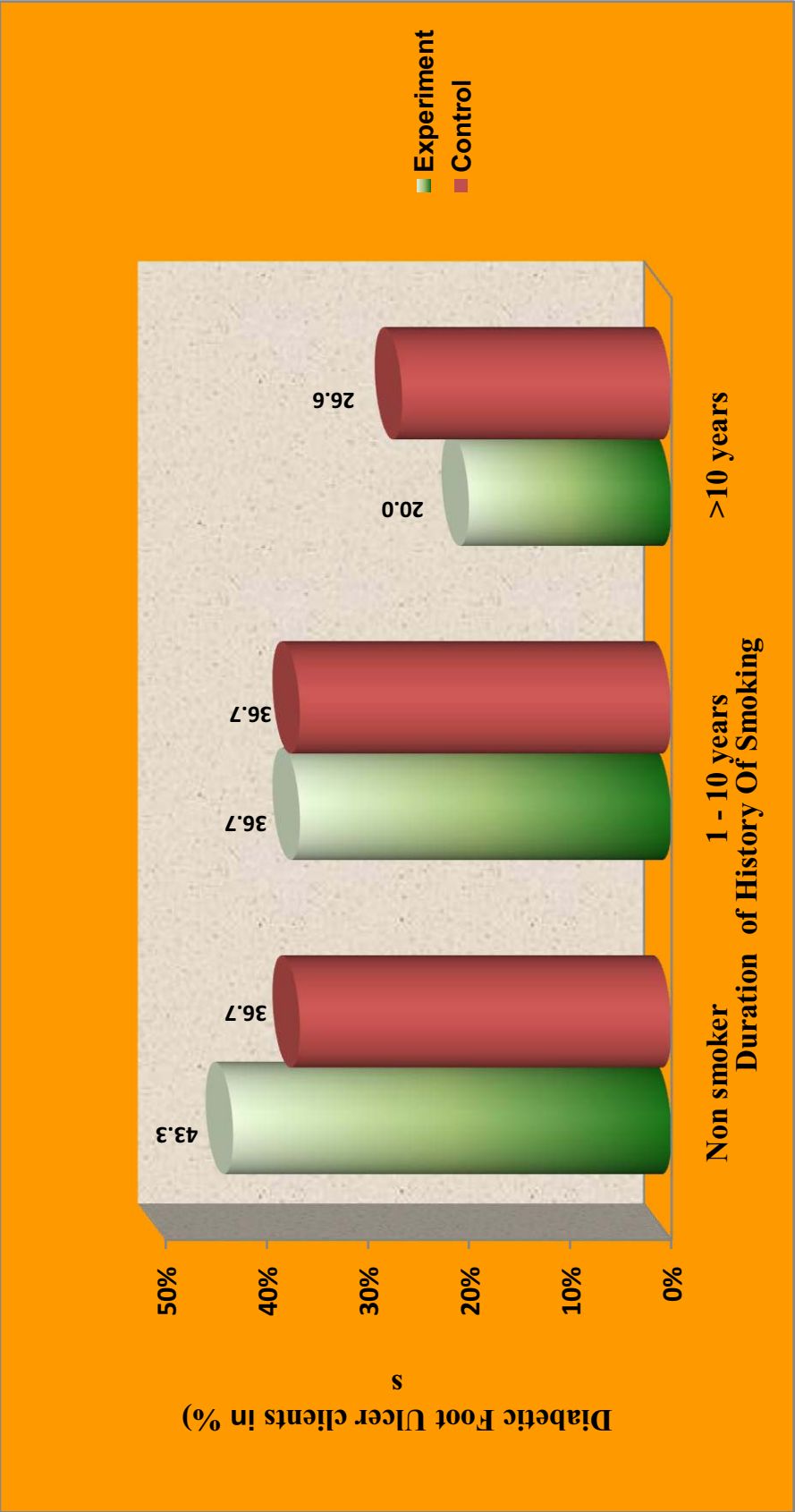


Figure 4.2 - : Gender wise Distribution of Diabetic foot ulcer



**Figure 4.3: Duration Wise Distribution of History Of Smoking**

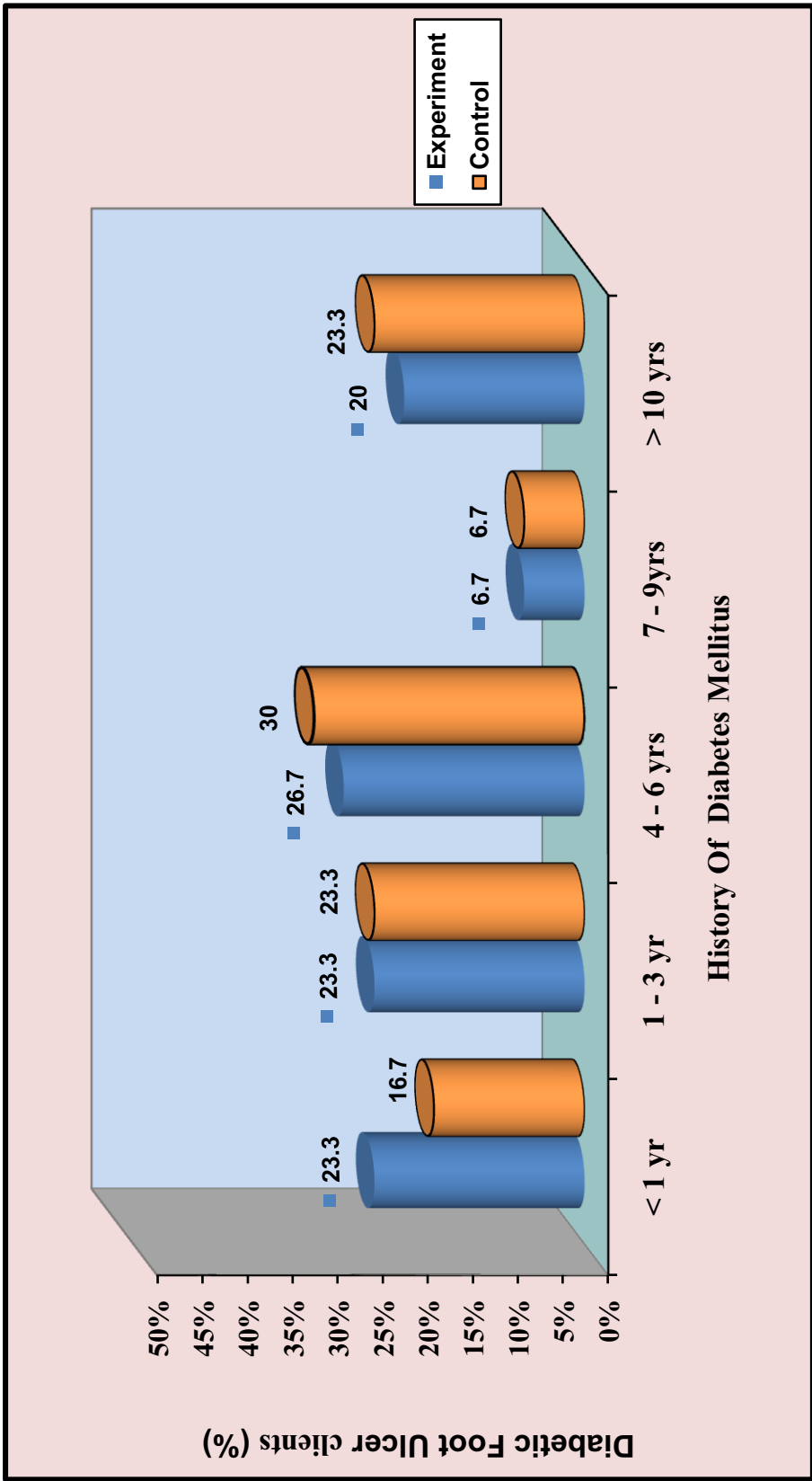


Figure 4.4: Duration Wise Distribution of History of Diabetes Mellitus

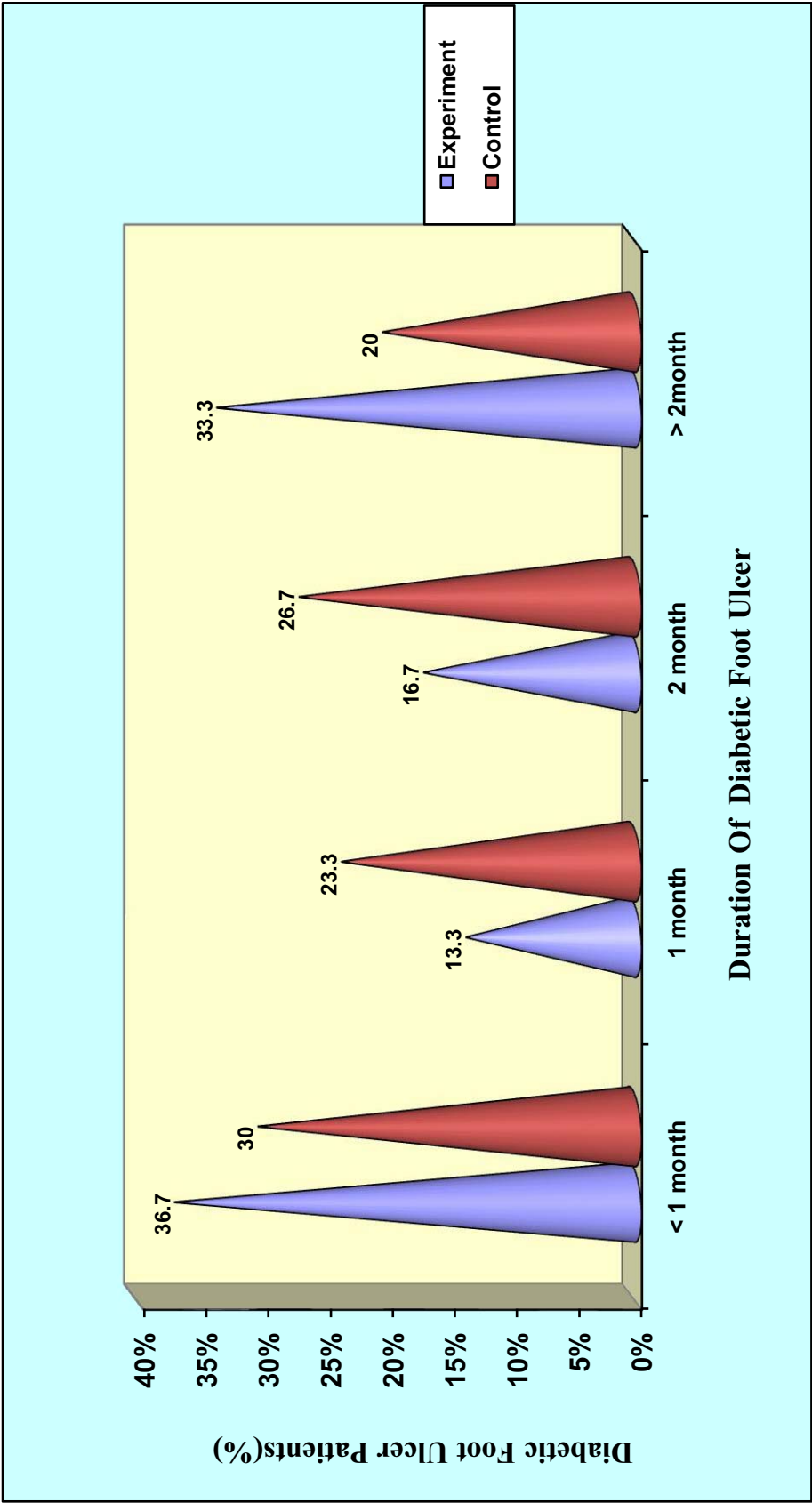


Figure 4.5: Duration wise Distribution of Diabetic Foot Ulcer





**Figure 4.6: Distribution of Mean Fasting Blood Sugar Level**

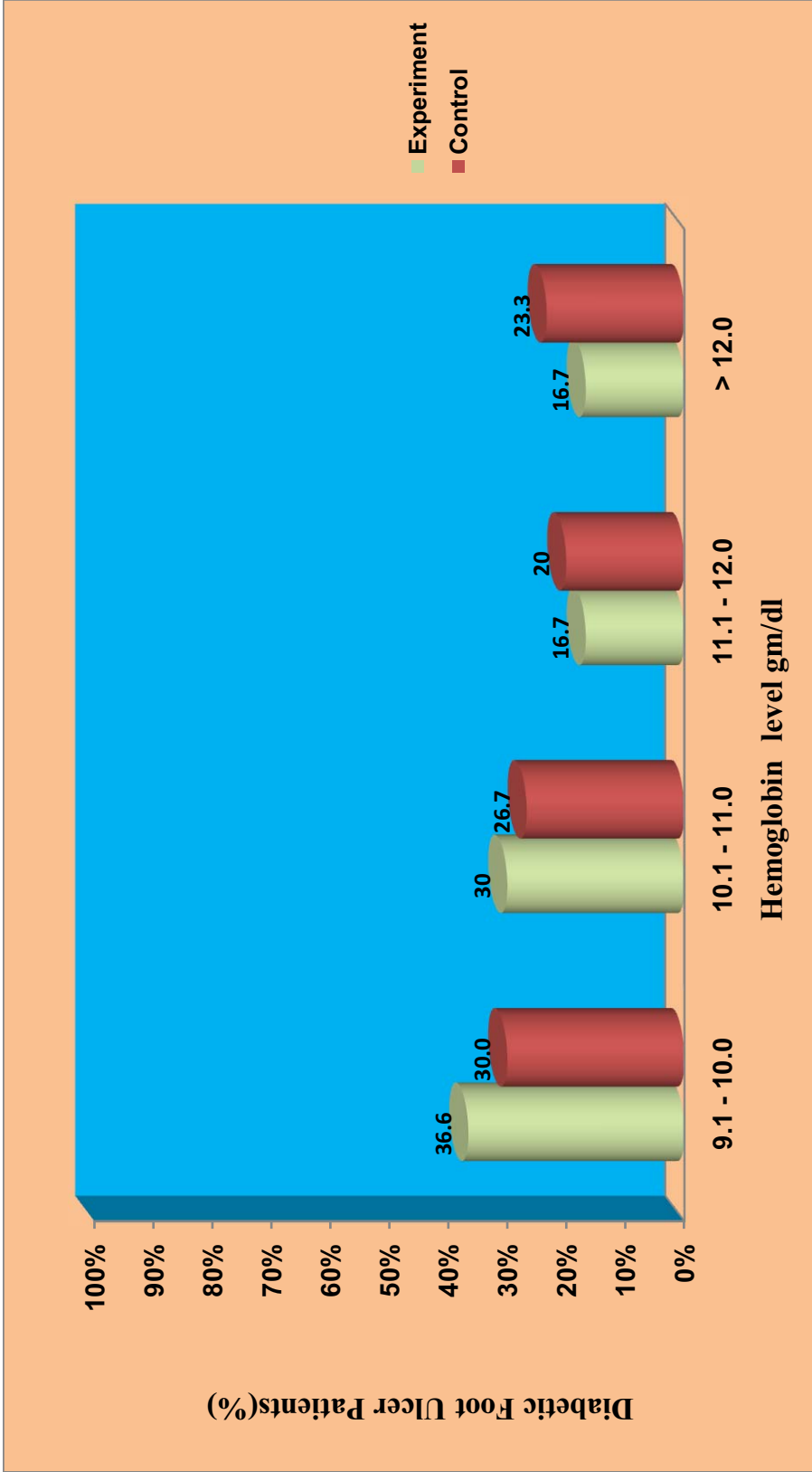


Figure 4.7: Distribution of Hemoglobin Level

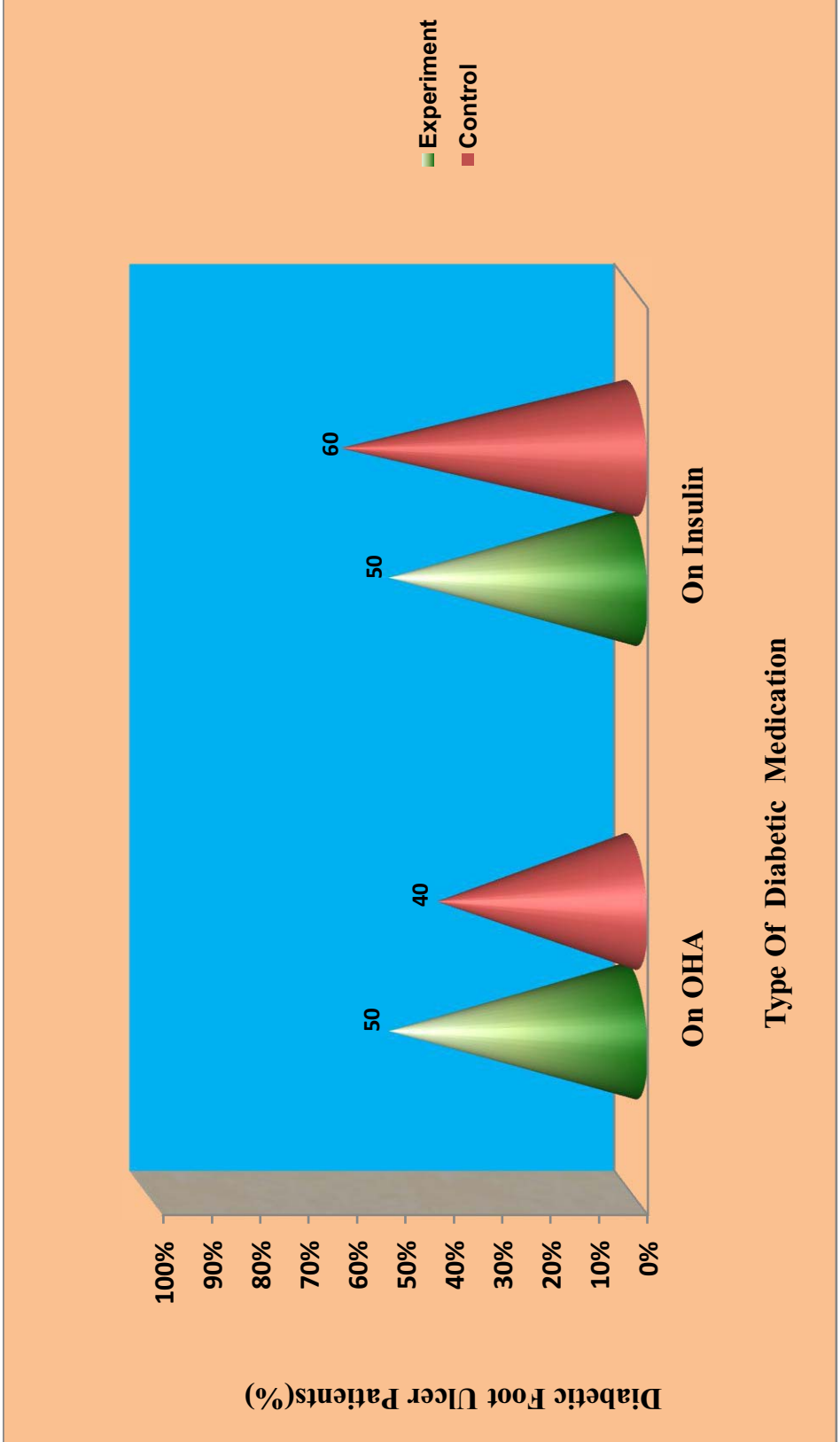


Figure 4.8: Distribution of Type Diabetic medication

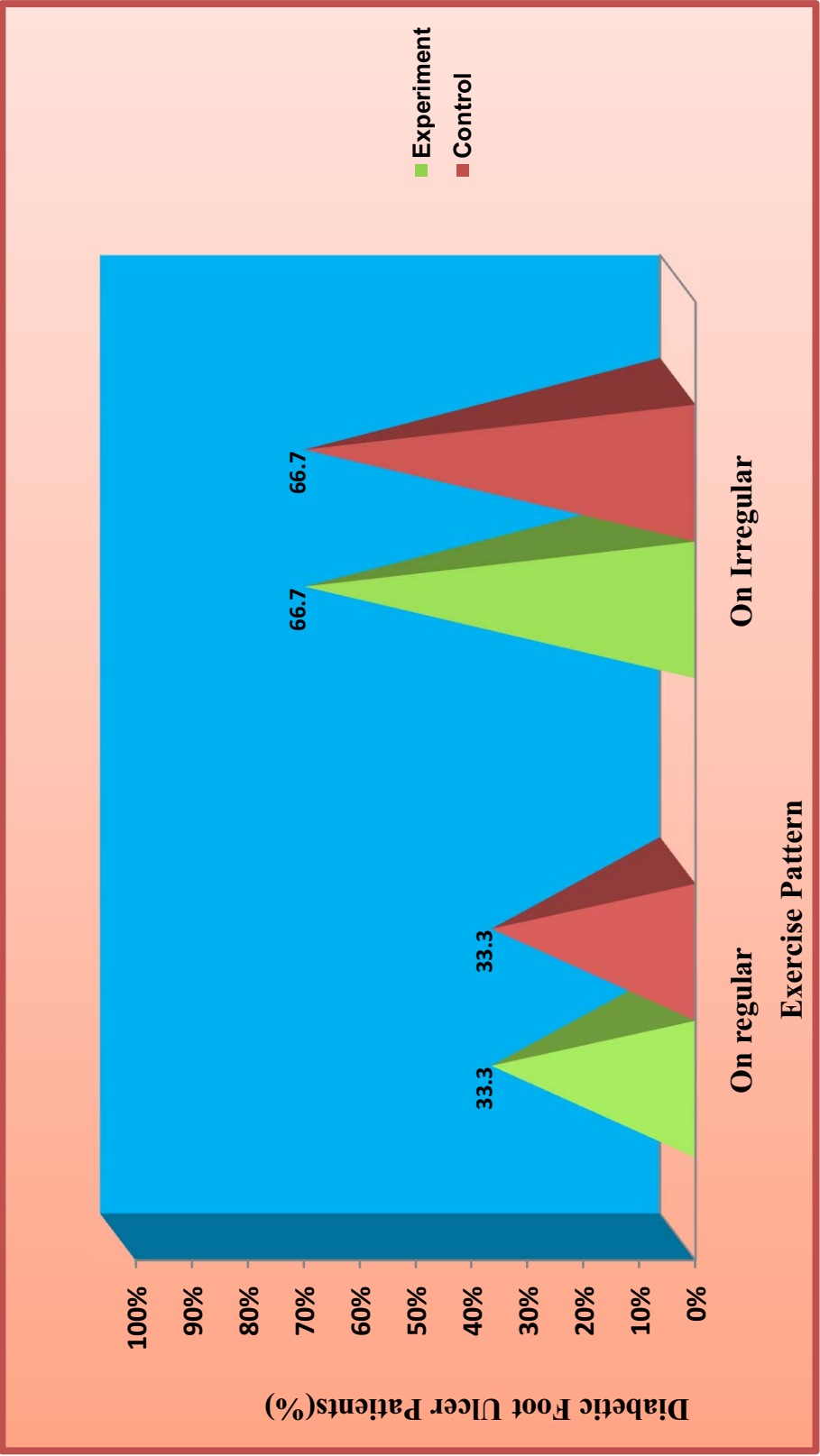


Figure 4.9 Distribution of Exercise Pattern

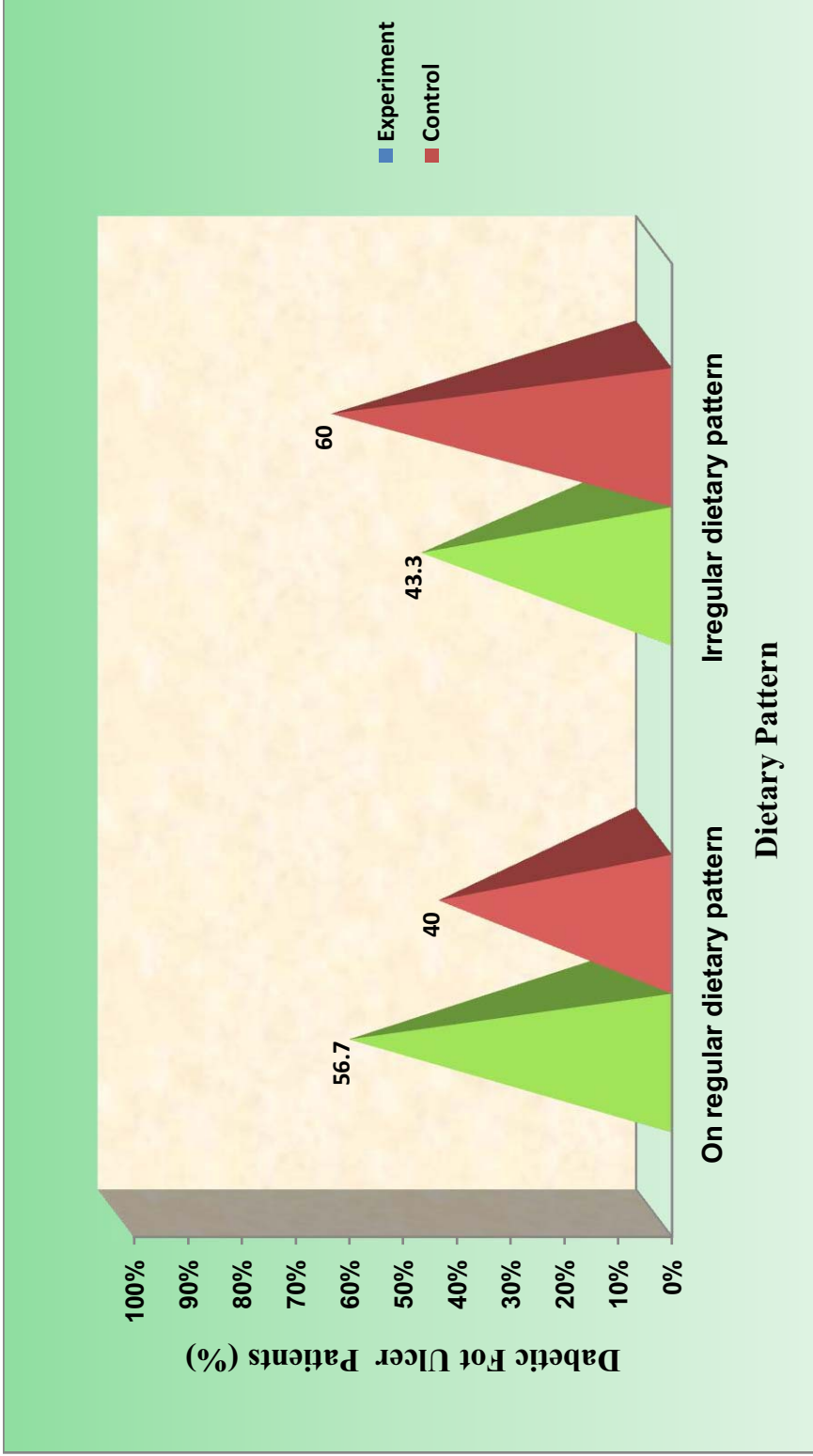
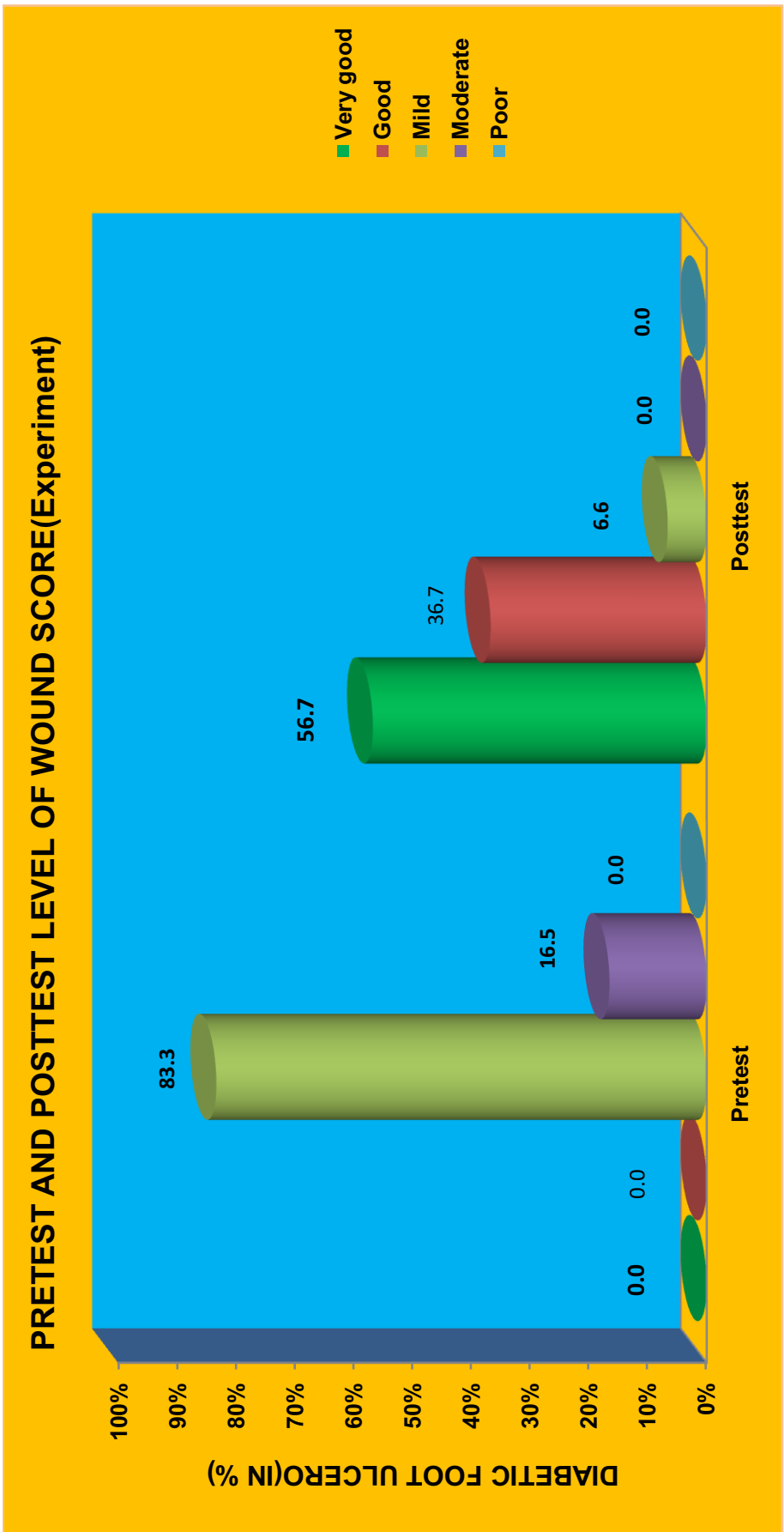
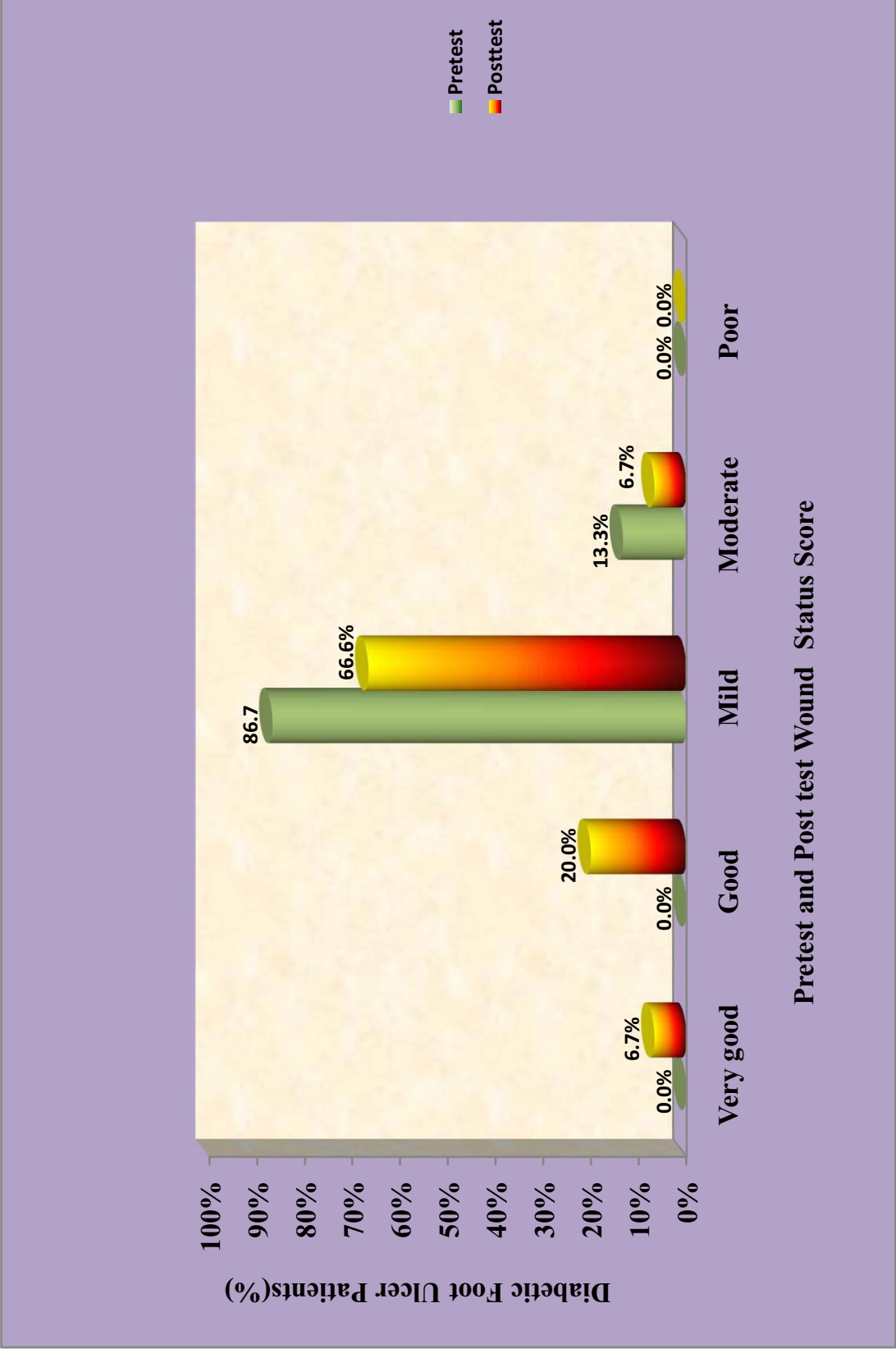


Figure 4.10: Distribution of Dietary Pattern



**Figure 4.12:**Percentage distribution of wound status score before and after application of 3% citric acid dressing(Experiment Group)



**Figure 4.13:** Percentage distribution of wound status score before and after routine care (control Group)

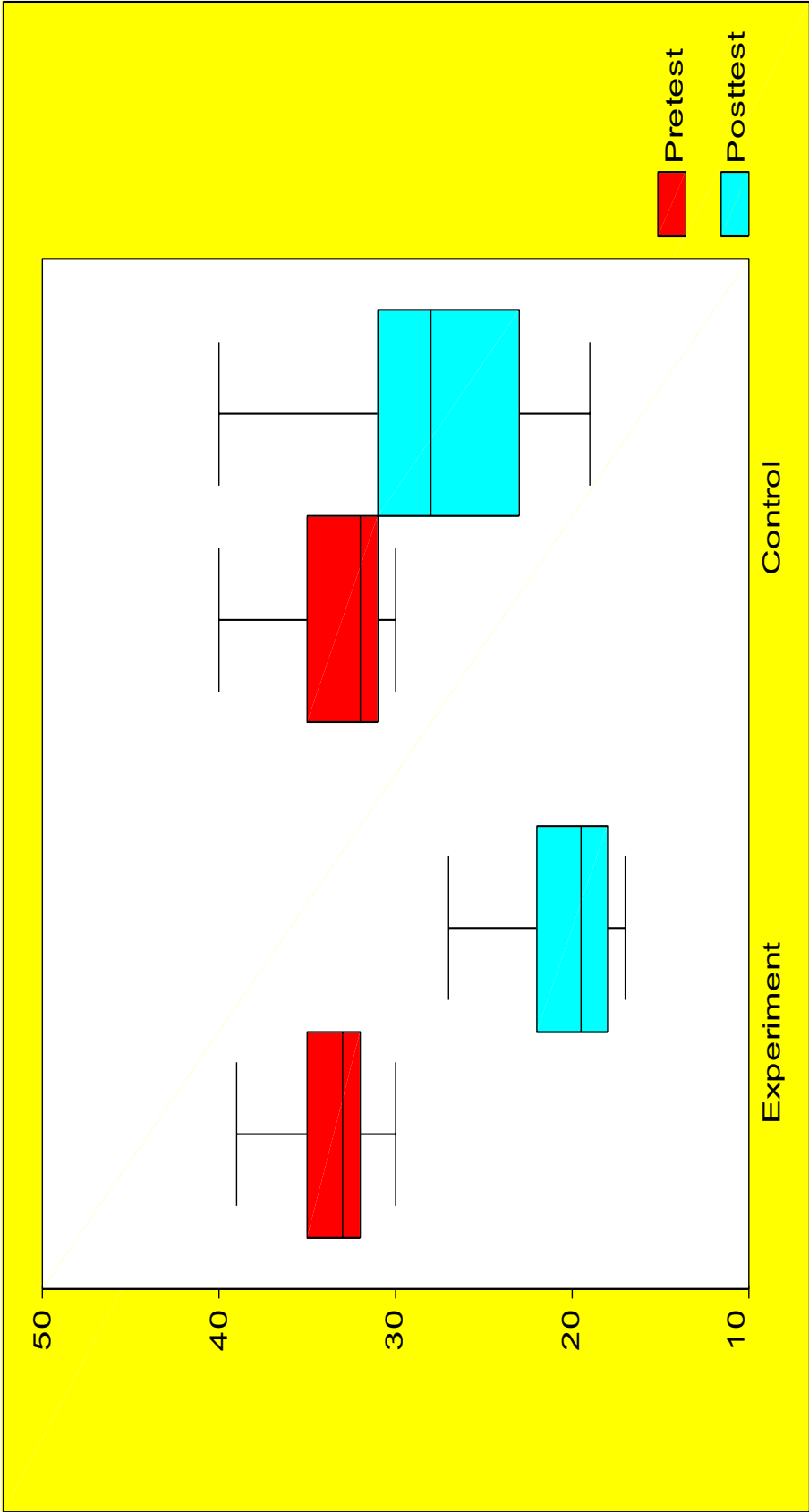
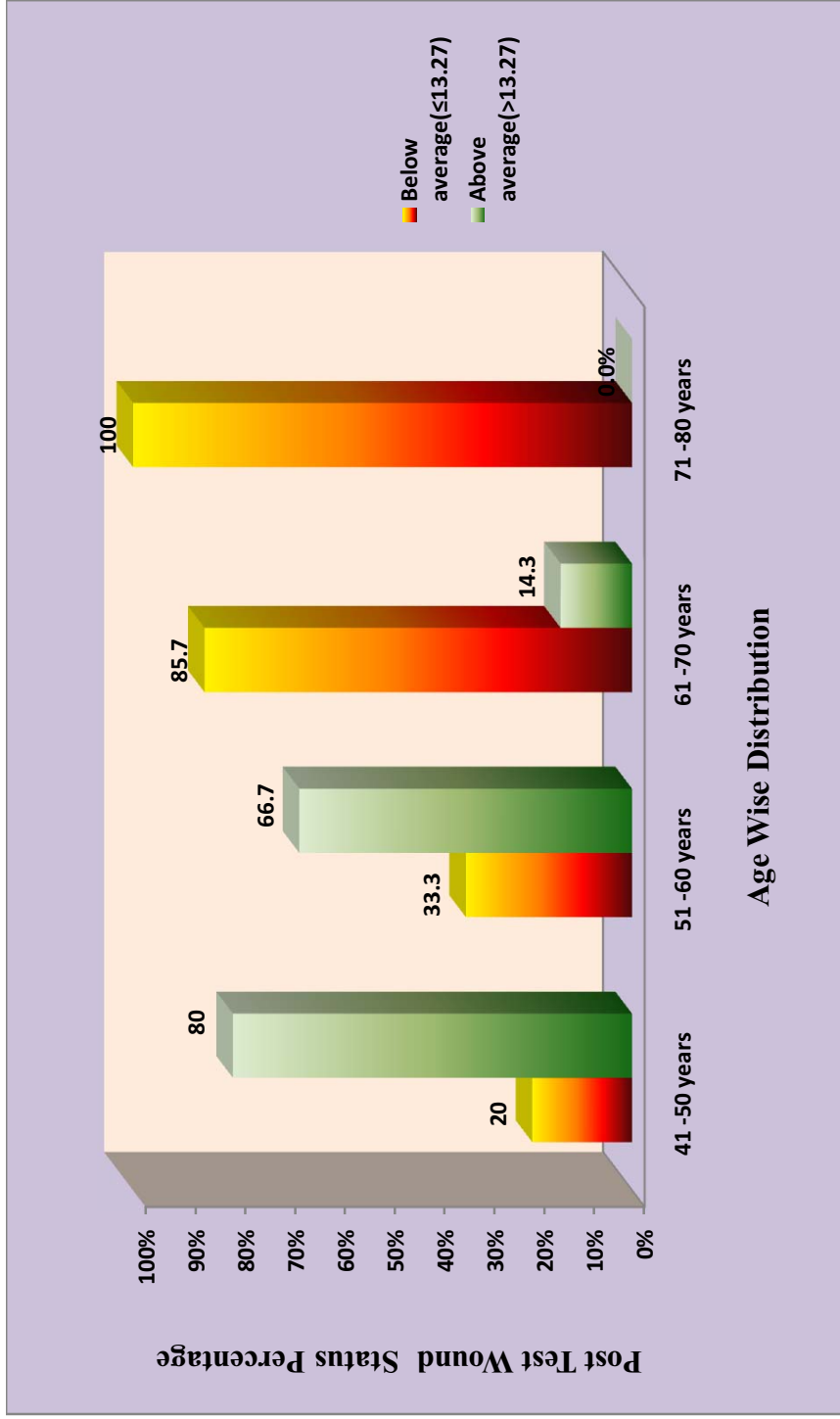


Figure 4.11: Box plot shows the pretest and posttest wound score among experiment and control group





**Figure 4.14: Association between Post test wound status score and age**

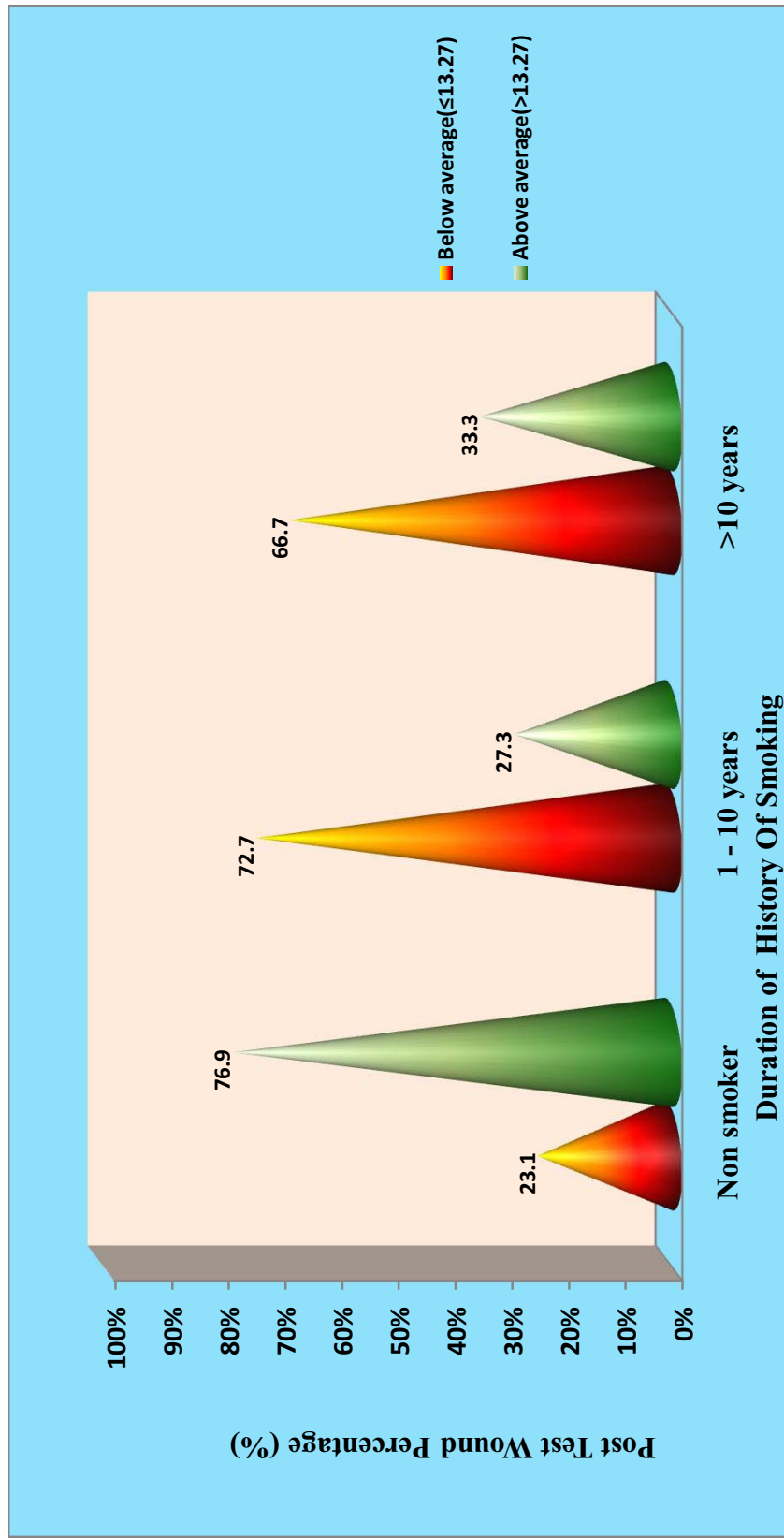


Figure 4.15: Association between Post Test Wound Status Score and Smoking

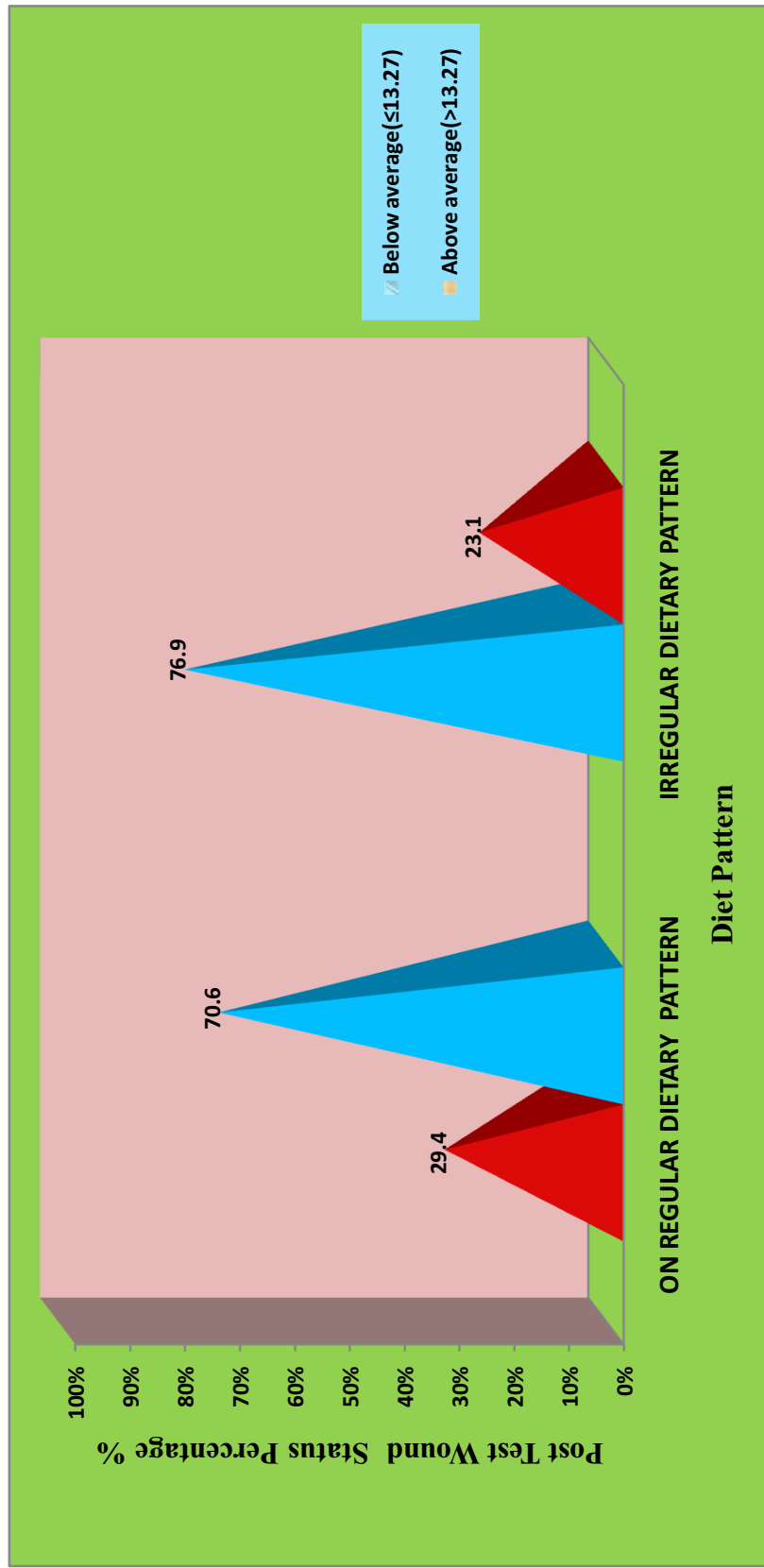


Figure 4.16: Association between Post Test Wound Status Score and Diet Pattern



## **CHAPTER V**

### **SUMMARY OF THE RESULTS**

The purpose of the study was “a study to assess the effectiveness of 3% citric acid dressing on diabetic foot ulcer among clients admitted in selected wards of Rajiv Gandhi Government General Hospital, Chennai”. 60 subjects between the age group of 41 to 80 years with Diabetic foot ulcer were selected by simple random sampling technique and assigned 30 subjects to experimental group and 30 to control group for each on the basis of inclusion criteria. 3% Citric acid dressing was done for the experimental group and routine dressing was done for the control group. Demographic & physiologic variables were collected and the wound status was assessed for both experimental and control group with the help of Bates Jensen Wound Assessment Tool. The results of both groups were compared, interpreted and summarized in this chapter.

#### **Summary of the demographical variables**

- **In demographical variables** among the study participants majority of the subjects were in the age group of 51-60 years (43.3%). Regarding gender majority of subjects were male (66.6%). Regarding history of smoking, majority were 1- 10 years smokers (40%) and non smokers (40%).
- **In physiological variable** regarding history duration of diabetic mellitus, majority were 4-6 yrs of illness (28%). Regarding duration of diabetic foot ulcer, majority were < 1 month (33.3%). Majority people mean fasting blood glucose level were 161-200mgdl (36.6%). Majority people hemoglobin level were 9.1- 10 grms.(33.3%). Regarding type of

diabetic medication, majority were in insulin (55%).Majority people were in irregular exercise pattern (66.6%).Majority people were in irregular dietary pattern (51.6%).

- Regarding pretest wound status assessment of experimental and control group shows that there is no significant difference (  $p = 0.75$  )
- Regarding pre test percentage distribution wound status of experimental group shows that,83.3% clients had mild and 16.5 % clients had moderate level of diabetic foot ulcer.
- Regarding pre test percentage distribution of wound status of control group shows that, 86.7% clients had mild,13.3% clients had moderate level of diabetic foot ulcer .
- Regarding post test wound status assessment of experimental group shows that 56.7% clients had healthy wound status.
- Regarding post test wound status assessment of control group shows that most of the patient (66.6%)had mild wound healing status.
- Regarding percentage difference between pre and post test mean wound status score of experimental group was 23.5%.
- Regarding mean percentage difference between pre and post test mean wound status score of control group was 7.9%.
- Comparison of pre and post test assessment wound status score shows that statistically significant of intervention.3 %Citric acid dressing was found to be effective in treating the diabetic foot ulcer than routine ward care.
- Regarding effectiveness of 3% citric acid dressing on diabetic ulcer shows that 22.1% wound score reduction.
- Regarding effectiveness of routine ward care on diabetic ulcer shows that 7.9 % wound score reduction.

- The correlation between the selected demographic and physiologic variables with effectiveness of 3% citric acid dressing shows the following results: There was association exists between the age, gender, history of smoking and regular exercise pattern and dietary of the clients and effectiveness of 3% citric acid dressing.

## CHAPTER VI

### DISCUSSION

This chapter concentrates on the findings of this study derived from the statistical analysis and its pertinence to the objectives set for the study. The collected data was collected in two sections. Section A: Demographic and Physiological data, section B: Assessment of wound status.

#### 5.1 Findings related to demographic and physiological variables

##### Age.

Study results shows that majority of clients were between 51-60 years of age, in experimental group 50 % (15), in control group 36.7 % (11).

*A study was conducted by Desai (1997)* revealed that age related cellular defects are shown by a decrease in the absolute number of cells, the number of hair follicles in growth phase, the diminished production of macro molecules which results in diminished production of collagen from the dermis are the major causes related to delay in wound healing among older adults.

##### Gender

In the case of gender males were majority, in experimental group 66.7% (20) were male, in control group 66.7% (20) were male.

*A study conducted by Desiree & Tania (2006)* reveals that elderly men heal more slowly than elderly women.

##### History Of smoking

Regarding history of smoking majority of clients were non smoker and habit of smoking for about 10 yrs, in experimental group 43.3% (13) were non smokers, 36.7 % (11), in control group 36.7 % (11) were non smokers and 36.7 % (11) were smokers for 10 years.

*Miller & Sandra (2002)* explains that smoking delays wound healing and the reason for this is smoking causes vasoconstriction and lack of oxygen



reaching to the skin cells, decreased collagen synthesis, and delayed growth of new blood vessels within the wound.

### **Duration of Diabetic Mellitus**

Regarding duration of diabetes mellitus, majority of clients were in diabetic mellitus for 4-6 years 26.7% (8) were in experimental group, 30% (9) were in control group.

*A study was conducted by Bennett (2004)* reveals a duration of diabetes mellitus increases wound status score increasing indicating a slower wound healing.

### **Duration of Diabetic Foot Ulcer**

In the case of duration of diabetic foot ulcer, majority of clients had diabetic foot ulcer for > 1 month, in experimental group 36.7% (11), in control group 30.0% (9).

*David, Lynne, Ole & Jesse (2002)* conducted a cohort study among > 3100 individuals with diabetic neuropathic foot ulcer. The result showed that longer duration of wound is one of the factors associated with wound healing process by 20 week of care.

### **Mean Fasting Blood Sugar Level**

Results regarding mean fasting blood sugar shows majority were between 121-160 mg/dl, in experimental group 33.3% and in control group 43.3%.

*A study conducted by Martson (2006)* shows that there is a high level of positive correlation exists between wound healing and hyperglycemia. The two serious consequences of elevated blood sugar levels are a reduction in the function of neutrophils as phagocytes and alteration in the deposition of collagen by fibroblasts with subsequent reduction in the wound strength.

### **Hemoglobin Level**

Regarding hemoglobin level majority were 9.1-10.mgdl, in experimental group 36.6 %( 11), in control group 30 %( 9).

*Sussman & Jensen (2007)* stated that Hemoglobin level less than 12 g/dl in an important risk factor for wound healing

### **Medication**

Regarding type of diabetic medication majority clients were on insulin, in experimental group 60% (18), in control group 50% (15).

*A study conducted by Koblik, Sieradzki, and Sendur&Biernat (2001)* shows that subcutaneous insulin injection improves the post ischemic skin blood flow in ulcerated feet and they had clinically proven that the time needed for healing is highly significant.

### **Exercise Pattern**

Regarding exercise pattern majority people were irregular exercise pattern, in experimental 66.7 %( 20) in control 66.7 % (20).

*A study conducted in saskatoon health region(2011)* proves that exercise can improve joint mobility, increase blood flow and in decrease insulin production and cortisol activity there by wound healing.

### **Dietary Pattern**

Regarding dietary pattern majority people were irregular dietary pattern, in experimental 33.3 %( 13) in control 60 % (18)

*Nancy Collin, Collen Solan (2013)* conducted studies that prove that comprehensive diet and nutrition management have been shown to promote optimal glycemic control and facilitate wound prevention and healing.

## **5.2 Findings based on objectives**

**Objective-I: To assess pretest wound status score of foot ulcer among diabetic clients .**

With regard to effect of citric acid dressing 60 clients with diabetic foot ulcer were randomly assigned to experimental and control group. Wound status

was assessed with Modified Bates Jensen Wound Assessment Tool both experimental and control group.

The mean difference of initial wound status score of experimental and control group was 0.26 and the calculated 't' value (0.31) which is not significant at  $p=0.75$  level of significance. So it is proved that there is no significant difference in wound status among the experimental and control group before starting the treatment.

***Objective-II: To assess the effectiveness of 3% citric acid dressing on diabetic foot ulcer among experimental group***

The mean score of clients with diabetic foot ulcer in experimental group before starting the intervention was 33.33 and the final score decreased to 20.07 and the mean difference was 13.27. The calculated 't' value of experimental group was 19.97 which shows the effectiveness of 3% citric acid dressing on diabetic foot ulcer.

In experimental group mean difference in wound score with 95% confidence interval was 13.27. Percentage distribution of wound score with 95% confidence interval was 22.1% which shows that on an average, experimental group reduced 22.1 % of wound score after 3% citric acid dressing.

Thus, "There is a statistically very high significant difference in wound status among experimental group before and after 3 % citric acid dressing" is accepted.

**Vinod Prabhu et.al (2014)** conducted a end pilot study to look for cost effective method for dressing wound .Three percent citric acid solution (CA) was used for dressing on acute lower limb diabetic ulcers with the object of pH modulation of wounds at an early stage and to evaluate its effects on wound healing. Appearance of healthy granulation was the end point of the study. It is concluded that 3% CA solution forms a good alternative for wound dressings that acts by modulating the wound pH to acidic levels thereby contributing to

wound healing by increased fibroblast proliferation and probably increasing local oxygen concentration and reducing microbial growth and virulence.

**Objective III: *To compare post test wound status score among experimental and control group.***

#### **Comparison of pretest and posttest wound status score**

In the comparison of overall pretest and posttest, considering experiment group pretest and post test mean score were 33.33% and 20.07% respectively. Difference is 13.27 score and calculated 't' test value 19.97 which shows statistically very high significant at  $p=0.001^{***}$ .

In control group, in pretest and post test scores were 33.07 and 28.30 respectively and difference was 4.77 score. The calculated 't' test value was 2.09 which shows statistically significant at  $p=0.05^*$

In the comparison of post test wound status score of experiment and control group were 20.07 % and 28.30% respectively. Difference between post test wound status score of experimental and control score is 8.23 and calculated 't' value was 6.59 which shows statistically very high significant at  $p=0.001^{***}$

In comparison of mean difference before and after citric acid dressing of experimental group was 13.27 and the mean difference before and after routine wound dressing of control group was only 4.77. This clearly depicts that application of citric acid has made an impact in healing of the wound of experimental group clients faster than the control group clients

This proved that there is a significant difference between experimental group and control group after treatment. So citric acid dressing is effective in treating the diabetic foot ulcer.

**Gutyon (2009).**, included 104 cases of superficial burn injury to assess the efficiency of citric acid as a dressing in comparison with silver sulfadiazine gauze dressing. In 52 clients treated with citric acid and the 91 percent of wounds were rendered sterile within 7 days. In 52 clients treated with silver

sulfadiazine, 7 % showed control of infection within 7 days. Healthy granulation tissue was observed earlier in clients treated with citric acid (mean 7.4 versus 13.4 days). In control group only 10 % of wounds healed within 15 days. It shows citric acid as an ideal dressing in the treatment of wound healing.

**Thus “There is a significant difference in wound status among experimental and control group after application of citric acid ”is accepted**

**Objective IV: *To find association between selected demographic and physiologic variables with final wound status score of control and experimental group.***

**Association between selected demographic and physiologic variables with post test wound status score of experimental group.**

There is association exist between the demographic and physiologic variables with post test wound status score of diabetic foot ulcer among clients of experimental group. There is association exists between the ages, gender, history of smoking, regular exercise pattern and dietary of the clients with final wound status score. Younger, non smokers, regular exercise and regular diet pattern clients are benefitted more than others. Statistical significance was calculated using chi square test..

The association of post test wound status score with age ( $\chi^2=10.03$   $p=0.01^{**}$ ) shows that statistically high significant. Which proves “When the age advances the wound status score also increases which indicates that there is a delay in wound healing”. Carrel & Nouy (1997) first time reported in the early 1920s the delay in wound healing is associated with ageing. It has also been reported that complications of wound healing such as wound dehiscence, are more common in older people.

The association of post test wound status score with gender ( $\chi^2=6.70$   $p=0.03^*$ ) shows that statistically significant. Sukhminder Jit Singh

**Bajwa, (2015)** A higher occurrence of diabetic foot morbidities was found in males than in female.

The association of post test wound status score with smoking ( $\chi^2=5.40$   $p=0.02^*$ ) shows that statistically significant. Which proves “smoking delays the wound healing process”. According to a study conducted by **Silverstein (1992)** the documented effects of the toxic constituents of cigarette smoke-- particularly nicotine, carbon monoxide, and hydrogen cyanide-- suggest potential mechanisms by which smoking may undermine expeditious wound repair. Nicotine is a vasoconstrictor that reduces nutritional blood flow to the skin, resulting in tissue ischemia and impaired healing of injured tissue.

The association of post test wound status score with exercise pattern ( $\chi^2=5.40$   $p=0.02^*$ ) which shows statistically significant. *A study conducted in saskatoon health region(2011)* proves that exercise can improve joint mobility, increase blood flow and in decrease insulin production and cortisol activity there by wound healing.

The association of post test wound status score with dietary pattern ( $\chi^2=6.65$   $p=0.01$ ) which shows that statistically significant. Which proves “when the fasting blood sugar level increased”. **Apelqvist&Agardh(1992)** investigated the association between the risk factors and outcome of diabetic foot ulcers and the result shows that there is significant association exists with glycemic control by diet with the number of days needed for the healing of foot ulcers.

Thus “**There is a association between post test wound status score with selected demographical and physiological variables**” is accepted.

## **CHAPTER VII**

### **CONCLUSION AND RECCOMMENTATION**

Diabetic foot infections are the major cause of morbidity. Inappropriate treatment and infections is the common sequel of diabetic foot ulceration that leads to delayed wound healing. Diabetic foot ulcers at its later stages highly affect the persons' quality of life and image.

This chapter explains about implications in the field of , nursing practice,nursing adminstration,nursing education,nursing research, limitations, recommendation for further study.

The study is to identify the effectiveness of 3% citric acid dressing on diabetic foot ulcer among diabetic patients. The study design was one group pre test and post test with control group. The data was collected for a period of 4 weeks at Rajiv Gandhi Government General Hospital, Chennai. The study was conducted on 60 patients, 30 each were randomly assigned to experimental and control group. 3% Citric acid dressing was done for the experimental group and routine dressing was done for patients of control group once a day for 14 days. The wound status was assessed by Bates Jensen Wound Assessment Tool.

#### **7.1. Nursing implications**

##### **7.1.1. Nursing Practice**

The nurse working in the surgical unit should be trained in implementing citric acid dressing as complementary therapy to bring out positive physical and psychological responses as an adjunctively to other pharmacological treatment to promote comfort and well being among the diabetic foot ulcer patients.

##### **7.1.2. Nursing Adminstration**

Nursing adminstration focus towards the alternative therapy for diabetic foot ulcer / foot care should be included in nursing practice other than routine care.Nursing in service programme should be conducted for staff nurses

about peripheral vascular complication and screening and preventive measures. Nursing administrator should monitor new changes in foot care ..

### **7.1.3. Nursing Education**

People with diabetic foot ulcer receive various methods of treatment. To manage the symptoms effectively many are turning to alternative therapies like herbal medicines and various other topical agents. Among these therapies citric acid dressing is one of the alternative treatments. In the field of nursing education, topical application of citric acid dressing for diabetic wound is concerned with holistic care of patients. Thus, it is appropriate to incorporate alternative therapies like citric acid dressing into nursing curriculum.

### **7.1.4 Nursing Research**

The nursing research need to focus more on the evidence based and holistic practice through understanding the various techniques that can bring about significant positive and psychological outcomes for patients with diabetic foot ulcer.

The nursing research intended to offer upto date suggestions in implementing the alternative treatments like citric acid dressing application as one of the nursing intervention for the foot ulcer which is an affordable and effective way of treating foot ulcers.

## **7.2. Limitations of the study**

1. The study was conducted on less number of subjects.
2. No comparison was done with specific topical agents used for wound dressing.

## **7.3. Recommendations for further study**

1. Local application of citric acid dressing can be used as a routine intervention among patients with diabetic wound in hospitals.
2. An extensive experimental study can be conducted for larger number of samples in the health care settings.



3. Further research can be conducted with the help of other wound assessment scale.
4. A study can be conducted to find out effectiveness of citric acid dressing in the healing of burns wound.
5. A comparative study can be conducted with other products used for wound dressing.

Citric acid is a product which contains the healing properties and anti microbial properties and it is effective in the successful management of foot ulcers in an affordable and simple way.

## REFERENCES

### JOURNAL REFERENCE

1. Aggarwal, K. (2004). Foot Complications in Diabetes. *Asian Journal of Diabetology*, 3(3), 22-23.
2. Akram T Kharroubi and Hisham M darwish (2015). Diabetes mellitus: The epidemic of the century. *World Journal of Diabetes*. Jun 25; 6(6): 850–867.
3. Allen, V. (2008). Citric Acid Treatment for Diabetic Foot Ulcer. *Journal of Burns And Wound* , 3(1), 45-46.
4. Amit Kumar C. Jain, Viswanath S( 2015) .Studying major amputations in a developing country using Amit Jain’s typing and scoring system for diabetic foot complications - time for standardization of diabetic foot practiceint. *Surgical journal of india* :26-30
5. Amy, Ranjit Mohan Anjana, Viswanathan Billow (2015) Prevalence And Clinical Profile Of Metabolic Syndrome Among Type I Diabetes Mellitus In India, *Journal Of Diabetes And Its Complication* , july vol 29 659- 664 .
6. Bates-Jensen, B., & munees, P. (2001). Toward an Intelligent Wound Assessment System. *Ostomy/Wound Management*, 41(7a), 80-87.
7. Boulton, A., Vilekeite, L., & Ragnarson, T. (2009). The Global Burden of Diabetic Foot Disease. *Lancet*, 366, 1719-24.
8. Blount MH, Cullen M, Nester CJ, William AE. The assessment and management of diabetes related lower limb problems in India: an action research approach to integrating best practice. *J Foot Ankle Res*. 2014;7:30
9. Basavraj S. Nagoba, phd; Namdev M. Suryawanshi, MD; Bharat Wadher, phd; Sohan Selkar, mpht .(2015), Acid environment and wound healing- a view Volume 27 - Issue 1

10. Culleton, J. (1999). Preventing diabetic foot complications. Tight G... [Postgrad Med.1999] - pubmed - NCBI. *National Center for Biotechnology Information*.
11. Desai, J. (1997). Ageing and wound healing in old age. *Journal of wound care*, 6(5),237-9.
11. Desiree, M. O., & Tania, T. J. (2006). Sex Hormones and Wound Healing: Androgens and Wound Healing. *Wounds*, 18(1), 8-18.
12. Femiano, F., Rullo, R., & Lanza, a. (2010). A Comparison of Salivary Substitute Versus Citric Acid in Patients Complaining of Dry Mouth: A Clinical Randomized Controlled Study. *Journal of Oral Surgery and Medicine*, 10(12),134-35.
13. Fujiwara, Y., Kishida, K., Terao, M., Takahara, M., Matsuhisa, M., & Funahashi, T. (2011). Beneficial Effects of Foot Care Nursing For Peopl... [J Adv Nurs. (2011)] - pubmed - NCBI. *National Center for Biotechnology Information*.
14. Gandhi, R. (2010). Simple, Effective And Affordable Approach For The Treat...[Burns. 2010] – pubmed – NCBI. *National Center for Biotechnology Information*.
15. Guptha, S., Sing, Z., Purty, A. J., Kar, M., & Maharajan, P. (2010). Diabetes Prevalance and Riskfactors in Rural area of Tamilnadu. *Diabetes Research and Clinical Practice*, 33, 180-83.
16. Harris, C., Bates-Jensen, B., Parslow, N., Raizman, R., & Singh, M. (2009). The Bates-Jensen Wound Assessment Tool (BWAT): Development of a Pictorial Guide for Training Nurses. *Wound Care Canada*, 7(2), 33-38.

17. Lickman., Fontento, J., & Rahnema, R. (1995). Citric Acid and Hyaluronic Acid Based Gel Dressing for Diabetic Foot Ulcer . *Diabetes Care*, 35(4), 23-24.
18. Koblik, T., Sieradzki, J., Sendur, R., & Biernat, J. (2001). The Effect of Insulin and Sulodexide (Vessel Due F) on Diabetic Foot Syndrome: Pilot Study in Elderly Patients. *Journal of Diabetes Complications*, 15(2), 69-74.
19. Nagoba, B. (2010). Citric Acid Treatment of Necrotizing Fasciitis: a Report of Two Cases - Nagoba - 2010 - International Wound Journal - Wiley Online Library. *Wiley Online Library*.
20. Nagoba BS, Deshmukh SR, Wadher BJ,etal. Treatment of superficial pseudomonal infections with citric acid: an effective and economical approach. *J Hosp Infect*. 1998;40(2):155-157.
21. Nagoba BS, Gandhi RC, Wadher BJ, Deshmukh SR, Gandhi SP. Citric acid treatment of severe electric burns complicated by multiple antibiotic resistant Pseudomonas aeruginosa. *Burns*. 1998;24(5):481-483.
22. Nagoba BS, Kulkarni PB, Wadher BJ, Kulkarni UP, Mahabaleshwar L. Citric acid treatment of diabetic foot: a simple and effective approach. *J Assoc Physicians India*. 2000;48(7):739-741.
23. Nagoba BS, Gandhi RC, Wadher BJ, Rao AK, Hartalkar AR, Selkar SP. A simple and effective approach for the treatment of diabetic foot ulcers with different Wagner grades. *Int Wound J*. 2010;7(3):153-158.
24. Nagoba BS, Gandhi RC, Hartalkar AR, Wadher BJ, Selkar SP. Simple, effective and affordable approach for the treatment of burns infections. *Burns*. 2010;36(8):1242-1247.
25. Nagoba BS, Wadher BJ, Chandorkar AG. Citric acid treatment of non-healing Ulcers in leprosy patients. *Br J Dermatol*. 2002;146(6):1101.

26. Nagoba BS, Wadher BJ, Rao A, Selkar SP, Gandhi RC. Treatment of Lepromatous ulcers using citric acid as a sole antimicrobial agent. *Int Wound Journal*.2012;9(5):553-556.
27. Nagoba B, Raju R, Wadher B, et al. Citric acid treatment of surgical site infections: a prospective open study. *Wound Pract Res*. 2011;19(2):82-86.
28. Nagoba B, Rao A, Wadher B, Gugale D, Mantri S. A simple and effective approach for treating non-healing ulcers after a snakebite. *WOUNDS*. 2011;23(8):252–255.
29. Nagoba B, Gandhi R, Wadher B, Rao A, Selkar S. Simple and effective approach for the treatment of traumatic wounds in non-diabetic patients: a prospective open study. *Int Wound J*. 2013;10(5):585-589
30. Nagoba BS, Gandhi RC, Wadher BJ, Gandhi SP, Selkar SP. Citric acid treatment of necrotizing fasciitis: a report of two cases. *Int Wound J*. 2010;7(6):536-538.
31. Nagoba BS, Wadher BJ, Rao AK, Kore GD, Gomashe AV, Ingle AB. A simple and effective approach for the treatment of chronic wound infections caused by multiple antibiotic resistant Escherichia coli. *J Hosp Infect*. 2008;69(2):177-180.
32. Nagoba, B. (2007). Microbiological, Histopathological and Clinical Changes in Chronic Infected Wounds After Citric Acid Treatment. *Journal of Medical Microbiology*.
33. Nain, P., Uppal, S., Bajaj, K., & Garg, S. (2011). Role of Negative Pressure and Wound Therapy in Healing of Diabetic Foot Ulcers. *Journal of Surgical Technique and Case Report*, 3(1), 17-22.
34. Nather, A. (2010). Effectiveness of Vacuum-Assisted Clos... [Ann Acad Med Singapore. 2010] - pubmed - NCBI. *National Center for Biotechnology Information*.

35. Martson. (2006). Slow Wound Healing Due to Elevated Blood Sugar. *Nutrition Supplements News*.
36. Position Statement - Type 2 Diabetes in Young People | International Diabetes Federation. (2010). *International Diabetes Federation*.
37. Sosale B, Sosale AR, Mohan AR, Kumar PM, Saboo B, Kandula S. Cardiovascular risk factors, micro and macrovascular complications at diagnosis in patients with young onset type 2 diabetes in India: CINDI 2. *Indian J Endocr Metab* [serial online] 2016 [cited 2016 Jan 30];20:114-8
38. Seema Abhijeet Kaveeshwar 2014The current state of diabetes mellitus in India *Australas Medical Journal* . 7(1): 45–48.
39. Sriwijitkamol, A., Mounngern, Y., & Vannaseang, S. (n.d.). Assessment and prevalences of diabetic comp... (J Med Assoc Thai. 2011) - PubMed - NCBI. *National Center for Biotechnology Information*.
40. Shyam Kishore, Ashish D. Upadhyay (2015) Categories Of Foot At Risk In Patients Of Diabetes At Atertiary Car Centre :Insight Into Need Foot Care . *Indian. Journal of endocrinology and metabolism* May-Jun 19(3) 405-410.
- 41 Sussman, C., & Jensen, B. M. (2007). *Wound Care: a Collaborative Practice Manual* (3rd Ed.,). Philadelphia, Pa.: Lippincott Williams & Wilki
41. Taylor, R., Taylor, A., & Smith, J. (2002). Using an artificial Neural Network to Predict Healing Times and Risk Factors for Venous Leg Ulcers. *Journal of Wound Care*, 11(3), 101-105.

42. The International Diabetes Federation Diabetes Atlas, Sixth Edition  
2014
43. Vinod Prabhu, Sadan and Prasadi (2014) Does wound pH modulation with 3% citric acid solution dressing help in wound healing: A pilot study *Saudi surgical journal* volume 2 page no 36-48
44. Vishvanathan, V., & Kumpatala, S. (2011). Pattern and Causes of Amputation in Diabetic Patients - A Multicentric Study from India. *Journal of Association of Physicians India*, 59, 148-51.
45. Zazgornik, J. (2011). Citric Acid Inhibits Growth of Helicobacter Pylori *In Vitro*: A New Strategy for Eradication. *Journal of Wound Care*, 123(1-2), 38-40.
46. Zubair, M., Malik, A., & Ahmad, J. (2011). Incidence, Risk Factors for amputation among Patients with Diabetic Foot Ulcer in a North Indian Tertiary Care Hospital. *Foot (Edinb)*, 2, 132-34.

#### **BOOKS REFERENCE**

1. Altman, Buchel Coxon (2000). *Fundamentals & Advanced Nursing skill* (1<sup>st</sup> edition). Canada: Thomson learning publication
2. Barbara Lauristen Christensen. Elaine Kockrow (1995). *Foundations Of Nursing* (1<sup>st</sup> edition) Missouri: Mosby
3. Black M. Joyce (2005). "Medical Surgical Nursing Clinical Management for positive outcomes". Saint Louis. Elsevier.
4. Brunner and Suddarth (2001). *Medical and Surgical Nursing*. 8<sup>th</sup> edition . Philadelphia. J.B. Lippincott
5. Carol Taylor et al (2008) "Fundamentals Of Nursing" (1<sup>st</sup> edition). New Delhi: Wolters Kluwer .

6. Julia M. Leaky, practicia E. Kililay (1998). “*Fundamentals of Nursing Practice*”(1<sup>st</sup> edition) Pennislavania : W.B.Saunders company .
7. Julia B.G. (2006). “*Nursing Theories the base for Professional Nursing practice appletion*”(1<sup>st</sup> edition), Lange Publication .
8. Lewis et al (2007) .“*Text Book Of Medical Surgical Nursing*”, 8<sup>th</sup> edition, Mosby publications.
9. Luckmann’s (1996) “ *Core Principles And Practice Of Medical Surgical Nursing*” (1<sup>st</sup> edition). Philadelphia: W.B. Saunders company .
10. Lippincott., (1982). “*Manual of Nursing Practice*” (5<sup>th</sup> edition) , U.S.A: Lippincott publications.
11. Polit. D.I & Hungler. P(1999). *Principles and methods of Nursing Research & method* (6<sup>th</sup> edition) . philadelphia : Lippincott company.
12. Potter & Perry (2005). “*Fundamentals of Nursing*” (6<sup>th</sup> edition) Missourie: Mosby.
13. Ruth F Crares , Censtance (2003). “*Fundamentals of Nursing*” (4<sup>th</sup> edition) , Philadelphia: J.B.Lippincott company.
14. Rao .(2004). “*Methods of Biostatistics*”.(2<sup>nd</sup> edition) . Hyderabad : Paras Medical Publications.
15. Smeltzer C, Bare G, Hinkel, L & Cheever H. Brunner & Suddardh’s (2008). *Text book of Medical Surgical Nursing* , (11<sup>th</sup> edition). New Delhi: Wolter Kluwer pvt.Ltd.



## NET SOURCES

1. [Http://www.ncbi.nlm.nih.gov](http://www.ncbi.nlm.nih.gov)
2. [Http://care.diabetesjournals.org](http://care.diabetesjournals.org)
3. [Http://www.ncbi.nlm.nih.gov](http://www.ncbi.nlm.nih.gov)
4. [Http://www.nutralegacy.com](http://www.nutralegacy.com)
5. [Http://jmm.sgmjournals.org](http://jmm.sgmjournals.org)
6. [Http://www.idf.org/position-statement-type-2-diabetes.org](http://www.idf.org/position-statement-type-2-diabetes.org)

**INSTITUTIONAL ETHICS COMMITTEE**  
**MADRAS MEDICAL COLLEGE, CHENNAI-3**

EC Reg No.ECR/270/Inst./TN/2013  
Telephone No. 044 25305301  
Fax : 044 25363970

**CERTIFICATE OF APPROVAL**

To  
Mrs. R KRISHNA VENI  
M.Sc., (Nursing)  
College of Nursing  
Madras Medical College,  
Chennai – 600 003.

Dear Mrs. R KRISHNA VENI,

The Institutional Ethics Committee has considered your request and approved your study titled **A STUDY TO ASSESS THE EFFECTIVENESS OF 3% CITRIC ACID ON DIABETIC FOOT ULCER AMONG PATIENTS ADMITTED IN SELECTED WARDS OF RAJIV GANDHI GOVERNMENT GENERAL HOSPITAL, AT CHENNAI. No.29102014.**

The following members of Ethics Committee were present in the meeting held on 21.10.2014 conducted at Madras Medical College, Chennai-3.

- |  |                      |
|--|----------------------|
| 1. Dr.C.Rajendran, M.D.,   | : Chairperson        |
| 2. Dr.R.Vimala, M.D., Dean, MMC, Ch-3  | : Deputy Chairperson |
| 3. Prof.B.Kalaiselvi, M.D., Vice-Principal, MMC, Ch-3                              | : Member Secretary   |
| 4. Prof.R.Nandhini, M.D., Inst.of Pharmacology, MMC                                | : Member             |
| 5. Prof.K.Ramadevi, Director i/c, Inst.of Biochemistry, MMC                        | : Member             |
| 6. Prof.Saraswathy, M.D., Director, Pathology, MMC, Ch-3                           | : Member             |
| 7. Prof.S.G.Sivachidambaram, M.D., Director i/c,<br>Inst.of Internal Medicine, MMC | : Member             |
| 8. Dr.Balakrishnan, M.S., Director, Inst.of Surgery, MMC                           | : Member             |
| 9. Thiru S.Rameshkumar, Administrative Officer                                     | : Lay Person         |
| 10.Thiru S.Govindasamy, B.A., B.L.,  | : Lawyer             |
| 11.Tmt.Arnold Saulina, M.A., MSW.,   | : Social Scientist   |

We approve the proposal to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study and SAE occurring in the course of the study, any changes in the protocol and patients information/informed consent and asks to be provided a copy of the final report.

Member Secretary, Ethics Committee

**MEMBER SECRETARY**  
**INSTITUTIONAL ETHICS COMMITTEE**  
**MADRAS MEDICAL COLLEGE**  
**CHENNAI - 600 003**

### CERTIFICATE FOR CONTENT VALIDITY

This is to certify that a tool prepared by **Ms.R.Krishnaveni**, studying M.Sc Nursing, II Year, College of Nursing, Madras Medical College, undertaking a research study on "A STUDY TO ASSESS THE EFFECTIVENESS OF 3% CITRIC ACID ON DIABETIC FOOT ULCER AMONG PATIENTS ADMITTED IN SELECTED WARDS OF RAJIV GANDHI GOVERNMENT GENERAL HOSPITAL, AT CHENNAI." has been validated by me and is found to be valid up to date and she can proceed with this tool to conduct the main study

Name : DR. TAMILARASI. B

Designation : PRINCIPAL

Date : 15.07.2015

Place : CHENNAI.



  
PRINCIPAL  
MADHA COLLEGE OF NURSING  
MADHA NAGAR, KUNDRATHUR,  
CHENNAI - 600 069  
PHONE : 24780736

**CERTIFICATE FOR CONTENT VALIDITY**

This is to certify that a tool prepared by **Ms.R.Krishnaveni**, studying M.Sc Nursing, II Year, College of Nursing, Madras Medical College, undertaking a research study on **“A STUDY TO ASSESS THE EFFECTIVENESS OF 3% CITRIC ACID ON DIABETIC FOOT ULCER AMONG PATIENTS ADMITTED IN SELECTED WARDS OF RAJIV GANDHI GOVERNMENT GENERAL HOSPITAL, AT CHENNAI.”** has been validated by me and is found to be valid up to date and she can proceed with this tool to conduct the main study

Name : *D. P. SHARMANAN*

Designation : *Director + Prof*

Date : *16/7/2015*

Place : *CHENNAI - 3.*

*[Handwritten Signature]*  
*16/7/2015*

SIGNATURE WITH SEAL

Director and Professor,  
Institute of Diabetology,  
Madras Medical College,  
Rajiv Gandhi Government General Hospital  
Chennai - 600 003

**PERMISSION LETTER**

From

**Ms.R.Krishnaveni**  
M.Sc (Nursing) II Year,  
College of Nursing,  
Madras Medical College,  
Chennai – 3.

To

**The Director,**  
Institute of General Surgery,  
Rajiv Gandhi Government General Hospital,  
Chennai - 3.

Through Proper Channel,

Respected Sir / Madam,

**Sub : Requesting Permission to conduct a Research study – Reg.**

I, **Ms.R.Krishnaveni**, studying M.Sc Nursing II Year, College of Nursing, Madras Medical College, request you to kindly grant me permission for the study proposed to conduct on the topic **“A STUDY TO ASSESS THE EFFECTIVENESS OF 3% CITRIC ACID ON DIABETIC FOOT ULCER AMONG PATIENTS ADMITTED IN SELECTED WARDS OF RAJIV GANDHI GOVERNMENT GENERAL HOSPITAL, AT CHENNAI -03**, to fulfill the requirement of data collection. I assure you that it will not interfere with routine activities of the study settings.

*Permitted  
21.02.15  
Forwarded  
Jehi  
01/07/15*

Thanking you,

Date: 11/7/2015

Place: Chennai

Yours sincerely,

*R. Krishna Veni*

(R.Krishna veni)

*Permitted to  
conduct study on  
DFS pts in IGS ward 30/6  
- to vistmak for name of pt  
for formal to concerned  
with chief  
Ph  
8.7.15*

**DR. P. RAGUMANI, M.S**  
DIRECTOR  
Institute of General Surgery  
Madras Medical College,  
CHENNAI-600 003.

PERMISSION LETTER

From

**Ms.R.Krishnaveni,**  
M.Sc (Nursing) II Year,  
College of Nursing,  
Madras Medical College,  
Chennai – 3.

To

**The Director,**  
Institute of General Surgery,  
Rajiv Gandhi Government General Hospital,  
Chennai - 3.

Through Proper Channel,

Respected Sir / Madam,

**Sub : Requesting Permission to conduct a Research study – Reg.**

I, **Ms.R.Krishnaveni**, studying M.Sc Nursing II Year, College of Nursing, Madras Medical College, request you to kindly grant me permission for the study proposed to conduct on the topic **“A STUDY TO ASSESS THE EFFECTIVENESS OF 3% CITRIC ACID ON DIABETIC FOOT ULCER AMONG PATIENTS ADMITTED IN SELECTED WARDS OF RAJIV GANDHI GOVERNMENT GENERAL HOSPITAL, AT CHENNAI -03,** to fulfill the requirement of data collection. I assure you that it will not interfere with routine activities of the study settings.

Thanking you,

Yours sincerely,

*R. Krishnaveni*

**(R.Krishnaveni)**

*Forwarded  
Del.  
01/07/15*

*Forwarded  
Del.  
01/07/15*

Date: 1/7/2015

Place: Chennai

*7/7/15  
May be printed after  
Dean/CC approval*

*[Signature]*  
7/7/15

Director and Professor,  
Institute of Diabetology,  
Madras Medical College,  
Rajiv Gandhi Government General Hospital,  
Chennai - 600 003

## TOOL FOR DATA COLLECTION

### DEMOGRAPHIC AND PHYSIOLOGIC VARIABLE PROFOMA

#### PART- A

1. Sample number :
2. Date :
3. Age
  - a) 41-50
  - b) 51-60
  - c) 61-70
  - d) 71 -80
4. Gender
  - a) Male
  - b) Female
5. History of smoking
  - a) Non smoker
  - b) 1- 10 yrs
  - c) > 10 yrs
6. Duration of diabetes Mellitus
  - a) < 1 yr
  - b) 1-3 yr
  - c) 4- 6 yrs
  - d) 7-9yrs
  - e) > 10 yrs
7. History of diabetic foot ulcer
  - a) < 1 month
  - b) 1 month
  - c) 2 month

d) > 2month

8. Fasting blood sugar level mg/dl :

Date:									
FBS:									

a) 80 mg/dl

b) 81- 120 mg/dl

c) 121- 160 mg/dl

d) 161 -> 200 mg/dl

8. Hemoglobin level

a) 9.1-10 gm/dl

b) 10.1-11 gm/dl

c) 11.1-12 mg/dl

d) > 12 gm/dl

9. Medication

a) on OHA

b) on insulin

10. Exercise :

a) on regular

b) irregular

11. Dietary pattern

a) on regular dietary pattern

b) on irregular dietary pattern



## பகுதி அ

சுய மற்றும் உடலியல் சார்ந்த விவர படிவம்

1.ஆய்வு எண்:

2. தேதி:

3.வயது:

அ) 41-50 வயது வரை

ஆ)51-60 வயதுவரை

ஆ)51-60 வயதுவரை

இ)61-70 வயதுவரை

ஈ)71-80 வயதுவரை

4.பாலினம்:

அ)ஆண்

ஆ) பெண்

5. புகை பழக்கம் உள்ளதா?

அ) இல்லை

ஆ)ஆம் எனில் எத்தனை வருடம்?

1)10 வருடத்திற்குள்ளாக

2)10 வருடத்திற்கு மேல்

6.சர்க்கரை நோயின் காலம்:

அ)1 வருடத்திற்குள்

ஆ)1-3 வருடம்

இ)4-6 வருடம்

ஈ)7-9 வருடம்

உ)10 வருடத்திற்கும் மேல்

7.சர்க்கரை நோயினால் ஏற்பட்ட பாதபுண் ?

ஆம் எனில்?

அ) 1 மாதம்

ஆ) 2 மாதம்

இ) 2 மேல்

8. சராசரி இரத்த சர்க்கரையின் அளவு:

அ)81-120 மேல்

அ)80-120 வரை

ஆ)121-160 வரை

இ)161-200 வரை

9.இரத்த ஹீமோகுளோபின் அளவு:

அ)9.1-10 கிராம்

ஆ)10.1-11 கிராம்

இ)12 க்கும் மேல்

10. மருந்துகள் எடுத்து கொண்டதன் விவரம் எந்த வகையான சர்க்கரை மாத்திரை எடுத்துக்கொள்கிறீர்கள்?

அ)மாத்திரை

ஆ)இன்சலின்

11. உடற்பயிற்சி செய்பவரா?

அ) ஆம்

ஆ)இல்லை

12. உணவு கட்டுப்பாட்டில் உள்ளீர்களா?

அ)ஆம்

ஆ)இல்லை

**Part : B****MODIFIED BATES-JENSEN WOUND ASSESSMENT TOOL(2001)**

ITEM	ASSESSMENT	DATE: SCORE:	DATE: SCORE:
<b>1.Size</b>	1=Length x width <4 sq cm 2=Length x width 4--<16 sq cm 3=Length x width 16.1--<36 sq cm 4=Length x width 36.1--<80 sq cm 5=Length x width >80 sq cm		
<b>2. Depth</b>	1=Non-blanchable erythema on intact skin 2=Partial thickness skin loss involving epidermis &/or dermis 3=Full thickness skin loss involving damage or necrosis of subcutaneous tissue; may extend down to but not through underlying fascia; &/ormixed partial & full thickness &/or tissue layers obscured by granulation tissue 4=Obscured by necrosis 5=Full thickness skin loss with extensive destruction, tissue necrosis or damage to muscle, bone or supporting structures		
<b>3.Edges</b>	1=Indistinct, diffuse, none clearly visible 2=Distinct, outline clearly visible, attached, even with wound		

	base 3=Well-defined, not attached to wound base 4=Well-defined, not attached to base, rolled under, thickened 5=Well-defined, fibrotic, scarred or hyperkeratotic		
<b>4.Under-mining</b>	1=None present 2=Undermining < 2 cm in any area 3=Undermining 2-4 cm involving < 50% wound margins 4=Undermining 2-4 cm involving > 50% wound margins 5=Undermining > 4 cm or Tunneling in any area		
<b>5.Necrotic Tissue Type</b>	1=None visible 2=White/grey non-viable tissue &/or non-adherent yellow slough 3=Loosely adherent yellow slough 4=Adherent, soft, black eschar 5=Firmly adherent, hard, black eschar		
<b>6. Necrotic Tissue Amount</b>	1=None visible 2=< 25% of wound bed covered 3=25% to 50% of wound covered 4=> 50% and < 75% of wound covered 5=75% to 100% of wound covered		

<b>7. Exudate Type</b>	<p>1=None  2=Bloody  3=Serosanguineous: thin, watery, pale red/pink  4=Serous: thin, watery, clear  5=Purulent: thin or thick, opaque, tan/yellow, with or without odor</p>		
<b>8. Exudate Amount</b>	<p>1=None, dry wound  2=Scant, wound moist but no observable exudates  3=Small  4=Moderate  5=Large</p>		
<b>9. skin Color surrounding Wound</b>	<p>1=Pink or normal for ethnic group  2=Bright red &amp;/or blanches to touch  3=White or grey pallor or hypopigmented  4=Dark red or purple &amp;/or non-blanchable  5=Black or hyperpigmented</p>		
<b>10. Perpheral Tissue Edema</b>	<p>1=No swelling or edema  2=Non-pitting edema extends &lt;4 cm around wound  3=Non-pitting edema extends ≥4 cm around wound  4=Pitting edema extends &lt; 4 cm around wound</p>		

	5=Crepitus and/or pitting edema extends $\geq$ 4 cm around wound		
<b>11. Peripheral Tissue Induration</b>	1=None present 2=Induration, < 2 cm around wound 3=Induration 2-4 cm extending < 50% around wound 4=Induration 2-4 cm extending $\geq$ 50% around wound 5=Induration > 4 cm in any area around wound		
<b>12. Granulation Tissue</b>	1=Skin intact or partial thickness wound 2=Bright, beefy red; 75% to 100% of wound filled &/or tissue overgrowth 3=Bright, beefy red; < 75% & > 25% of wound filled 4=Pink, &/or dull, dusky red &/or fills $\leq$ 25% of wound 5=No granulation tissue present		

<p><b>13. Epithelialization</b></p>	<p>1=100% wound covered, surface intact  2=75% to &lt;100% wound covered &amp;/or epithelial tissue extends &gt;0.5cm into wound bed  3=50% to &lt;75% wound covered &amp;/or epithelial tissue extends to &lt;0.5cm into wound bed  4=25% to &lt; 50% wound covered  5=&lt; 25% wound covered</p>		
	<p>TOTAL SCORE</p>		
	<p>SIGNATURE</p>		



### SCORE INTERPRETATION

S.NO	SCORE	RESULT
1	50-60	Unhealthy
2	40-49	Moderate
3	30-39	Mild
4	20-29	Good
5	<19	Healthy

## WOUND DRESSING PROTOCOL

STEPS	RATIONALE
1.Explain the procedure to the patient and get consent	To get co-operation
2 Assess the client’s level of comfort and check the need for assistance	Removal of dry dressing can be painful, client may require pain medication. Assistance may be needed to open the sterile pack.
3. Instruct the client not to touch the wound area and sterile supplies.	Result in contamination of wound and supplies
4. Close room or cubicle curtains	Provide privacy and reduces airborne microorganisms.
5. Position the client on supine position or lateral position or as comfortably for wound dressing	Provides access to the wound
6. Apply face mask and protective wear , and wash hands thoroughly	Protects researcher from splashes. Reduces transmission of pathogens to exposed tissues.
7. Put on clean gloves and remove the dressing and dispose.	Prevents transmission of infectious organisms from soiled dressing to nurse’s hands.
8. Assess the wound status with the help of Bates Jensen Wound Assessment Tool	Provides the assessment and scoring of the wound condition.
9. Remove gloves and dispose	
10. Keep sterile dressing tray on bedside table.	Sterile dressing remain sterile while on or with in sterile surface.
11. Apply sterile gloves	Allows handling sterile supplies without contamination.

12. Open the tray and pour 50 ml of citric acid solution with a sterile syringe	
13. Clean the wound from least to most contaminated area with citric acid solution.	Assists in debridement and cleans wound of debris.
14. And apply citric acid soaked gauze on the wound and cover with gauze pads and tape over dressing. In the case of circumferential dressing apply gauze roll and secure it with adhesive tapes.	Protects wound from the entrance of microorganism. Secures dressing in place.
15. Remove gloves and dispose. Clean the area and replace articles	Reduces transmission of infection.
16. Assist client to comfortable position	Promotes sense of well being to the client and enhances comfort.
17. The procedure is recorded and reported.	Recording and reporting is essential for ethical and legal concerns and also for future reference.

(Taylor,2010 & Potter & Perry,2009)

## INFORMATION TO PARTICIPANTS

**Title of the study** : “A study to assess the effectiveness of 3% citric acid dressing on diabetic foot ulcer among patients admitted in selected wards of rajiv gandhi government general hospital, chennai-03”.

**Name of the Participant** :

**Date** :

**Age/sex** :

**Investigator** : Miss. R KRISHNA VENI

**Name of the institution** : Rajiv Gandhi Government General Hospital,  
Chennai-3

**Enrollment No** :

You are invited to take part in this study. The information in this document is meant to help you decide whether or not to take part. Please feel free to ask if you have any queries or concerns.

You are being asked to co-operate in this study being conducted in Rajiv Gandhi Government General Hospital, Chennai-3.

### **What is the Purpose of the Research (explain briefly)**

This research is conducted to evaluate the effectiveness of 3% citric acid on diabetic foot ulcer among patients admitted in Rajiv Gandhi Government General Hospital, Chennai-3. We have obtained permission from the Institutional Ethics Committee.

### **Study Procedures**

- ❖ The study will be conducted after obtaining approval from Institutional Ethics Committee.

- ❖ Patients with diabetic foot ulcer will be explained about the study procedures and purpose.
- ❖ Informed consent will be obtained from those who are willing to participate.
- ❖ Those who fulfil the inclusion criteria will be enrolled and randomised to either experimental or control group.
- ❖ Pre test assessment score of diabetic foot ulcer is been assessed by Bates jenson wound assessment scale . The experimental group will receive 3 % citric acid so dressing. The control group will undergo ordinary saline dressing.
- ❖ Assessment of the final wound status score on the 14 th day of treatment by Bates johnson wound assessment scale.

#### **Possible Risks to you**

No risks involved.

#### **Possible Benefits to you**

After finishing this study, investigator will provide information that the effectiveness of 3% citric acid on diabetic foot ulcer patients

#### **Possible benefits to other people**

The result of the research may provide benefits to the patients with diabetic foot ulcer and also empathetic care to them by investigator.

#### **Confidentiality of the information obtained from you**

You have the right to confidentiality regarding the privacy of your personal details. Your privacy in the study will be maintained throughout the study in the event of any publication or presentation resulting from the research, no personally identifiable information will be shared. The information

from this study, if published in scientific journals or presented at scientific meetings, will not reveal your identity.

**How will your decision not to participate in the study affect you?**

Your decisions not to participate in this research study will not affect your activity of daily living, medical care or your relationship with investigator or the institution.

**Can you decide to stop participating in the study once you start?**

The participation in this research is purely voluntary and you have the right to withdraw from this study at any time during course of the study without giving any reasons.

However, it is advisable that you talk to the research team prior to stopping the treatment.

Signature of Investigator  
Participants

Date:

Signature of

Date:

## INFORMED CONSENT

**Title of the study** : “A study to assess the effectiveness of 3% citric acid dressing on diabetic foot ulcer among patients admitted in selected wards of rajiv gandhi government general hospital, chennai-03”.

**Investigator** : R. Krishna veni

**Name of Participant** :

**Age/sex** :

**Date** :

**Name of the institution** : Rajiv Gandhi Government General Hospital,  
Chennai-3

**Documentation of the informed consent:** (legal representative can sign if the participant is minor or competent).

- I \_\_\_\_\_ have read/it has been read for me, the information in this form. I was free to ask any questions and they have been answered. I am over 20 yrs of age and exercising my free power of choice, hereby give my consent to be included as a participant in the study.
- I have read and understood this consent form and the information provided to me.
- I have had the consent document explained in detail to me.
- I have been explained about the nature of my study.

- My rights and responsibilities have been explained to me by the investigator.
- I agree to cooperate with the investigator
- I have not participated in any research study at any time.
- I am aware of the fact that I can opt out of the study at any time without having to give any reason
- I hereby give permission to the investigators to release the information obtained from me as a result of participation in this study to the regulatory authorities, government agencies and Institutional ethics committee.
- I understand that they are publically presented; my identity will be kept confidential.
- I am aware that I have any question during this study; I should contact the concerned investigator.

Signature of Investigator

Signature of Participants

Date

Date



## ஆராய்ச்சி ஒப்புதல் படிவம்

ஆராய்ச்சி தலைப்பு : மூன்று சதவீத சிட்ரிக் அமிலக்கரைசல் கொண்டு சர்க்கரை  
நோயினால் ஏற்படும் பாதபுண் ஆற்றுவது பற்றிய ஆய்வு

ஆய்வாளர் பெயர் : இரா. கிருஷ்ண வேணி

பங்கேற்பாளர் பெயர் :

தேதி :

வயது/பால் :

- ஆய்வாளர் மேற்கொள்ளும் ஆராய்ச்சியில் பங்கேற்க யாருடைய கட்டாயமுமின்றி முழுமனதுடனும் சுயநினைவுடனும் சம்மதிக்கிறேன்.
- ஆய்வாளர் மேற்கொள்ள போகும் பரிசோதனைகளை மிக தெளிவாக விளக்கிக்கூறினார்.
- எனக்கு விருப்பமில்லாத பட்சத்தில் ஆராய்ச்சியிலிருந்து எந்நேரமும் விலகலாம் என்பதையும் ஆய்வாளர் மூலம் அறிந்து கொண்டேன்.
- இந்த ஆராய்ச்சி ஒப்புதல் கடிதத்தில் உள்ள விவரங்களை நன்கு புரிந்துகொண்டேன். எனது உரிமைகள் மற்றும் கடமைகள் ஆராய்ச்சியாளர் மூலம் விளக்கப்பட்டது.
- நான் ஆராய்ச்சியாளருடன் ஒத்துழைக்க சம்மதிக்கிறேன். எனக்கு ஏதேனும் உடல்நலகுறைவு ஏற்பட்டால் ஆராய்ச்சியாளரிடம் தெரிவிப்பேன்.
- நான் வேறு எந்த ஆராய்ச்சிலும் தற்சமயம் இடம்பெறவில்லை என்பதை தெரிவித்துக்கொள்கிறேன்.
- இந்த ஆராய்ச்சியின் தகவல்களை வெளியிட சம்மதிக்கிறேன். அப்படி வெளியிடும்போது என் அடையாளம் வெளிவராது என்பதை அறிவேன்.
- எனக்கு இந்த ஒப்புதல் கடிதத்தின் நகல் கொடுக்கப்பட்டது.

ஆய்வாளர் கையொப்பம்

பங்கேற்பாளர் கையொப்பம்

தேதி

தேதி

## ஆராய்ச்சி தகவல் தாள்

ஆராய்ச்சி தலைப்பு : மூன்று சதவீத சிட்ரிக் அமிலக்கரைசல் கொண்டு சர்க்கரை

நோயினால் ஏற்படும் பாதபுண் ஆற்றுவது பற்றிய ஆய்வு

ஆய்வாளர் பெயர் : இரா. கிருஷ்ண வேணி

பங்கேற்பாளர் பெயர் :

தேதி :

வயது/பால் :

ஆய்வாளர் மேற்கொள்ளும் ஆராய்ச்சியில் பங்கேற்க யாருடைய கட்டாயமுமின்றி முழுமனதுடனும் சம்மதிக்கலாம். இதில் பங்கேற்பதன் நோக்கம் இந்த ஆராய்ச்சியில் தகவல்களை தெரிந்து கொள்வதற்காகவும். அதனை பயன்படுத்துவதற்காக மட்டும் தான்.

இந்த ஆராய்ச்சியின் நோக்கம், மூன்று சதவீத சிட்ரிக் அமில நீர்க்கரைசல் கொண்டு சர்க்கரை நோயினால் ஏற்படும் பாதபுண் ஆற்றுவது பற்றிய ஆய்வு மற்றும் பயன்படுத்தும் முறைகளை பற்றி கற்றுதருவது,

ஆராய்ச்சி மேற்கொள்ளும் முறை

இந்த ஆராய்ச்சியில் பாதபுண் உள்ள சர்க்கரை நோயாளிகளுக்கிடையே ஆய்வாளர் தயார் செய்த மூன்று சதவீத சிட்ரிக் அமில நீர்க்கரைசல் கொண்டு சர்க்கரை நோயினால் ஏற்படும் பாதபுண் ஆற்றுவது மற்றும் ஆராய்ச்சிக்கு முன்பும் மற்றும் பின்பும் பாதபுண் நிலையை அறியலாம்

இதனால் ஆய்வாளருக்கான பயன்

இந்த ஆய்விற்குபின் மூன்று சதவீத சிட்ரிக் அமில நீர்க்கரைசல் கொண்டு சர்க்கரை நோயினால் ஏற்படும் பாதபுண் ஆற்றுவதை அறிவது மற்றும் இதை தினசரி பயன்பாட்டிற்கு உகந்தது என நிரூபித்தல்.

இதனால் பங்கேற்பாளருக்கான பயன்

இந்த ஆய்வு சர்க்கரை நோயினால் ஏற்படும் பாதபுண் ஆற்றுவது மற்றும் ஏற்படும் பின்விளைவுகளை தவிர்க்க, அவரின் அறிவு திறனை மேம்படுத்துகிறது.

ஆராய்ச்சியில் பங்கேற்கவில்லை என்றாலும், உங்களின் சராசரி வாழ்கைமுறை, மருத்துவரின் ஆலோசனை மற்றும் சிகிச்சை முறையில் எந்த வித மாற்றமும் ஏற்படாது என்பதை தெரிவிக்கிறேன்.

இந்த ஆராய்ச்சியில் பங்கேற்க விருப்பம் இல்லை என்றால் உங்களின் முழுமனதுடன் நீங்கள் இந்த ஆராய்ச்சியில் இருந்து விலகி கொள்ளலாம் என்பதை தெரிவிக்கிறேன்.

இந்த ஆராய்ச்சியில் உங்களின் மருத்துவதகவல்களை பாதுகாப்பாக வைத்துக்கொள்கிறேன் என்பதை தெரிவிக்கிறேன்.

இந்த ஆராய்ச்சியின் தகவல்களை வெளியிடும் போது, உங்களை பற்றிய அடையாளங்கள் வெளிவராது என்பதை உறுதி கூறுகிறேன்.

ஆய்வாளர் கையொப்பம்

பங்கேற்பாளர் கையொப்பம்


தேதி

தேதி

## CERTIFICATE OF ENGLISH EDITING

This is to certify that the dissertation work topic “**A study to assess the effectiveness of 3% citric acid dressing on diabetic foot ulcer among patients admitted in selected wards of Rajiv Gandhi Government hospital at Chennai**” done by **Ms. Krishnaveni. R, MSc (N) second year** student of College Of Nursing, Madras Medical College , Chennai -03 is edited for English language appropriateness .

Date : 10.2.16

  
**A. ARULRAJ**, M.A., B.Ed., M.Phil.,  
B. T. Asst. in English  
Govt. High School,  
Munjurpet - 632 011, Vellore Dist.,



