

University of Kerbala College of Nursing

Effect of Using Apple Cider Vinegar on Foot ulcer Healing of Diabetic Patients

A Thesis Submitted By:

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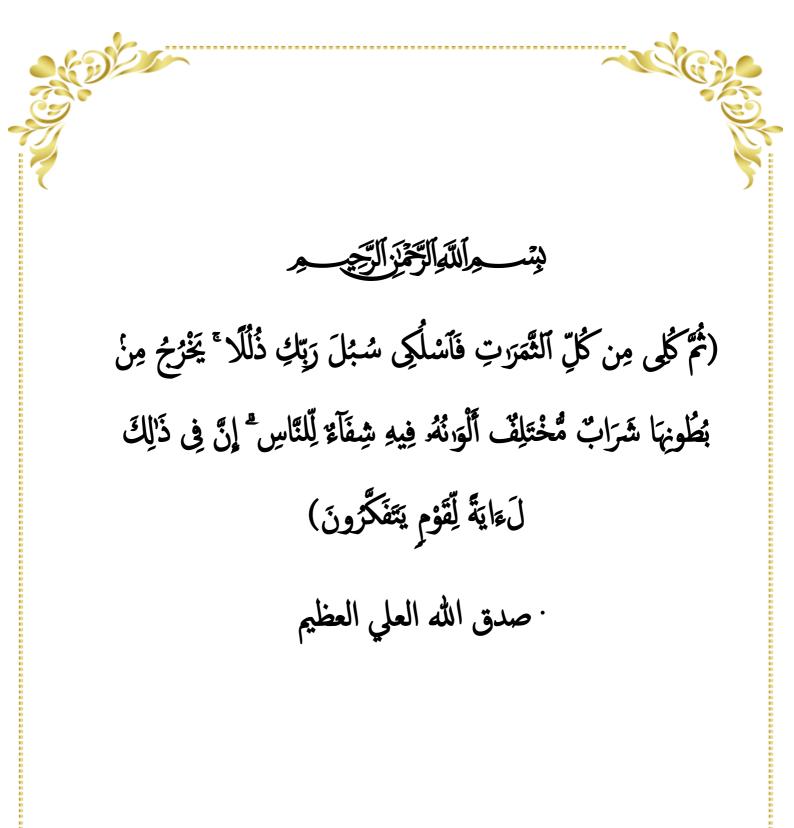
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Dedication

- To my dear parents, many thanks for giving me the support to reach my dreams. Accomplishing this would hopefully make you proud of me as much as I am proud of having you as my parents. I love you my father and mother.
- To my love, my dear and my life partner... My husband for his support and encouragement.
- To my lovely children Yasmeen, Masara, and Ali
 who bring the joy to our life.
- To my brother and sister for their love, support, and encouragement.

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Abstract

Background: Foot ulcers are one of the usual and dangerous complications that occur in patients with diabetes. Apple vinegar dressing has antimicrobial properties and other clinical therapeutic consequences. This study was performed to examine the apple cider vinegar's impact on foot ulcer healing in diabetes mellitus patients.

Methods: A quasi-experimental study was conducted at the Imam Al-Hassan Center for Endocrinology and Diabetes from September 26, 2022, to July 25, 2023. A purposive sample include of sixty patients with diabetic foot ulceration who they were separated randomly into intervention and control group. Patients in the intervention group were instructed to perform dressing soaked with apple cider vinegar (1-5%) acetic acid concentration once a day for 21 days, while only routine care was provided to the control group. The study instrument included socio-demographic and clinical data of participants, Meggitt-Wagner classification system, and the DMIST for observing the process of healing from a diabetic foot ulcer. The instruments were validated by a panel of experts, and it is reliability was verified through a pilot study. Both a descriptive analysis procedure and an inferential analysis procedure; a p-value of <0.05 was determined to be statistically relevant.

Results: The study group outperformed the control group in diabetic foot ulcer healing, with 80% obtaining excellent healing compared to 16.7% (p 0.001). Furthermore, the grade of diabetic foot ulcers improved in the study group, with 63.3% having superficial ulcers compared to 23.3% in the control group (p 0.01).

Conclusions: This study found that using an apple cider vinegar dressing to diabetic foot ulcer improves wound healing.

Recommendations: It is recommended that apple cider vinegar dressing be used on a regular basis and changed one time per day.

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List of abbreviations and symbols

Items	Meaning
ABI	Ankle-Brachial Index
ACV	Apple cider vinegar
ADA	American Diabetes Association
ANOVA	Analysis of Variance
AD	Anno Domini
AV	Apple vinegar
BC	before Christ
COA	Charcot osteoarthropathy
CVR	Content Validity Ratio
CWD	continuous wave Doppler
DFU	diabetic foot ulceration
DKA	Diabetic ketoacidosis
DM	Diabetes mellitus
DPN	diabetic peripheral neuropathy

FVI	Face Validity Index
GRAS	Generally Recognized as Safe
HO	Null Hypothesis
H1	Alternative Hypothesis
HbA1c	Glycated Hemoglobin
I-CVI	Item Level Content Validity Index
IDDM	Insulin-dependent Diabetes Mellitus
IDF	International Diabetes Federation
I-FVI	Item Face Validity Index
IWGDF	International Working Group on the Diabetic Foot
LOPS	Loss of Protective Sensation
MH	Marginal Homogeneity Test
MODY	maturity-onset diabetes of the young
MS	Mean of Score
NE	Number of Experts in Agreement
NIDDM	Non-insulin-dependent diabetes mellitus
NO.	Number
NPWT	Negative Pressure wound therapy
P value	Probability Value
PAD	peripheral arterial disease
QOL	Lower Quality of Life
S-CVI/Ave	Scale-Level Content Validity Index Based on an Average Method
S-CVI/UA	Scale Level Content Validity Index Based on the Universal Agreement
SARS	severe acute respiratory syndrome
SD	Standard Deviation
S-FVI	Scale Face Validity Index
SGLT2	Sodium-glucose co-transporter-2
Sig.	Level of Significance
SIM-Card	Subscriber Identity Module Card
SPSS	Statistical Package for Social Science
t	Independent Sample t Test
T1DM	Type 1 diabetes mellitus
T2DM	Type 2 diabetes mellitus
TBI	Toe-Brachial Index
TCC	Total Contact Casting
U	Mann-Whitney Test
UA	Universal Agreement
UK	United Kingdom
USA	United states America

USD	United States Dollar
VEGF	Vascular Endothelial Growth Factor
X2	Chi-Square Test
τ	Kendal-Taue Test
&	And
<	< Less than
\leq	Equal or less than
< < > >	Equal or more than
>	More than
et al.	Et alia
etc.	Et cetera
f	Frequency
%	Percent
*	P-value equal or less than 0.05
**	P-value less than or equal to 0.01

Chapter One

Introduction

Chapter One Introduction

1.1 Introduction:

Diabetes mellitus (DM) is a metabolic disorder that results in unusually high levels of blood sugar. Type 1, type 2, maturity-onset diabetes of the young (MODY), gestational diabetes, and neonatal diabetes are the several subtypes of DM (Sapra et al.,2023). Diabetic foot ulcers are a common complication for those with poorly managed type 2 DM. The most frequent causes include poor glycemic control, peripheral vascular disease, insufficient foot care, and underlying neuropathy. It's also a common cause of foot osteomyelitis and lower extremity amputation. These ulcers generally occur where the foot is subjected to repeated pressure and injury. Every year, there are 9.1 to 26.1 million diabetic foot ulcers worldwide. In the course of their lives, 15 to 25% of people with diabetes mellitus will develop a diabetic foot ulceration. Diabetic foot ulcers are projected to become more common as the number of persons newly diagnosed with diabetes rises each year (Oliver et al., 2022).

Diabetes mellitus is becoming more common worldwide, and diabetic patients are living longer lives, hence the prevalence of diabetic foot problems has increased as well. According to a Boulton et al.,2005, a lower leg is amputated every 30 seconds owing to diabetes, with an average annual treatment cost of 8659 Dollar per patient for diabetic foot issues. Medical care costs for diabetic foot diseases range from 9-13 billion dollar in the United States alone. The International Diabetes Foundation is actively increasing public awareness of diabetic foot problems, owing to the considerable social, medical, and financial difficulties connected with this illness (Zhang et al., 2017).

Foot ulcers are a major source of worry in diabetic patients, accounting for nearly 85% of amputations due to acute gangrene or infection

caused by these ulcers. Diabetes problems such peripheral arterial disease (PAD) led to diabetic foot ulceration and amputation, which is a cardiovascular condition when blood flow to the lower limbs is decreased by constricted arteries.

Poor oxygen circulation and medicine delivery can arise from this, which can hinder healing and raise the risk of ulcers. In diabetes, PAD is a discrete risk factor for ulceration and limb loss. It is present in 50% of diabetic foot ulcer (DFU) patients, a figure that may be increasing.14, 15 DFU and PAD patients have a lesser chance of healing and a higher chance of having an amputation. Therefore, it is crucial that PAD be detected in all diabetic patients (Registered Nurses' Association of Ontario [RNAO], 2013).

Neuropathy, which occurs when the peripheral nerves are damaged owing to the effects of diabetes, is another key consequence of diabetes that leads to foot ulcers. This syndrome can include foot numbness, skin abnormalities, deformities, and limited joint motion. These neuropathic alterations, when combined with other contributing factors such as poor selfcare, poor glycemic control, poor footwear, obesity, and a lack of early medical attention, can lead to the development of foot ulcers. It is critical to address these risk factors in order to effectively prevent and manage diabetic foot ulcers (Bodman et al., 2022).

Furthermore, any foot ulcer in a diabetic person has a chance of becoming infected. Medical intervention for diabetic foot infections can range from mild (debridement, antibiotics, etc.) to major (resection, amputation) (Lipsky et al., 2015). Huge societal expenses are associated with ulcers and amputations, including missed pay, lost employment, extended hospital stays, protracted rehabilitation, and a rise in the demand for home care and social services.

Care of individual with diabetic foot ulceration necessitates a coordinated, multidisciplinary approach from healthcare providers given the

statistics on the burden of illness and the severe long-term health consequences (International Working Group on the Diabetic Foot [IWGDF], 2011).

A mix of aerobic and anaerobic bacteria frequently causes infection of diabetic foot ulcers or chronic sores. This combination of infections resulted in the development of antibiotic resistance, so the need for new antimicrobial agents has resulted in the resurgence of therapies that have been used for centuries but fell out of favor during the antibiotic era but are safe, widely effective, and have a low propensity to cause resistance. Debridement is slipping away of devitalized and polluted tissue from wounds in order to show good tissue and aid recovery (Al-Duboni, 2015).

The fermentation of apple fruits into alcohol or acetic acid produces apple vinegar (AV). It may be produced from a variety of apple varieties using either the classic Orleans process or the quick (or submerged) technique frequently used in the sector. (Kara et al., 2021). Notably, vinegar, particularly apple vinegar, is considered a food production that is safe and all-natural, with no artificial additives added, according to the Generally Recognized as Safe (GRAS) label. Numerous researches have demonstrated its impact on blood glucose regulation, anticancer characteristics, cancer, diabetes, obesity, and other health issues (Baldas et al., 2018).

Apple cider vinegar is valued for its various antimicrobial properties, which have clinical therapeutic implications. It is commonly used for washing and taking against conditions including warts, head lice, and nail fungus due to its potential effectiveness in combating these issues. Furthermore, Apple cider vinegar is well known for its effectiveness as a fruit and vegetable surface disinfectant. It may be utilized as a natural preservation strategy, successfully preventing the growth of harmful bacteria that cause foodborne illness in food items. These attributes make apple vinegar a versatile and natural option for both therapeutic and food-related applications (Yagnik, et al., 2018). Additionally, treating ear infections,

Chapter one: Introduction

otitis, and myringitis with a low vinegar concentration irrigation of the ear canal produces favorable results (Kara, et al., 2021). Apple cider vinegar has significant concentrations of organic acids, phenolic compounds, tannins, flavonoids, and carotenoids, which provide it antioxidant and antibacterial capabilities against a range of pathogenic agents (Ozturk, et al., 2015).

1.2 Importance of the study:

Due to its increasing prevalence worldwide, diabetes has become one of the most serious and challenging health issues affecting the human population

in the modern era. Diabetes is becoming more common in much of the world as a result of the rapid economic expansion that has led to urbanization and the adoption of modern living styles (Blas and Kuru, 2010). Consequences of foot ulcers include decline in functional status, infection, hospitalization, lower-extremity amputation, and death. The lifetime risk of foot ulcer is 19% to 34%, and this number is rising with increased longevity and medical complexity of people with diabetes. Morbidity following incident ulceration is high, with recurrence rates of 65% at 3–5 years, lifetime lower-extremity amputation incidence of 20%, and 5-year mortality of 50–70%. New data suggest overall amputation incidence has increased by as much as 50% in some regions over the past several years after a long period of decline, especially in young and racial and ethnic minority populations (Dermott et al.,2023).

The risk for amputation is one of the most serious side effects of DFU. Amputations not only have a significant negative effect on patients' physical and mental health, but they significantly raise mortality rates (Morey-Vargas et al., 2015). As a considerable portion of the entire expense of diabetes in both developed and developing countries, diabetic foot ulcers have a significant financial impact (De Lima et al., 2022). A multidisciplinary approach is currently used to manage DFUs and includes various conventional techniques like surgical debridement, dressings to keep the wound moist, off-loading techniques, vascular evaluations, and infection and glucose control (Everett et al., 2018).

Even though these techniques have shown some promise, there is still an urgent need for therapies that quicken wound healing, lower the risk of infection, and ultimately improve patient outcomes. The use of apple cider vinegar dressing as an adjuvant therapy for diabetic foot ulcers is the main focus of this investigation. Due to its many health advantages, particularly its antibacterial characteristics brought on by its high acetic acid content, apple cider vinegar has become increasingly popular. Acetic acid can efficiently inhibit, inactivate, and break down haemagglutinin glycoproteins, potentially preventing the transmission of infectious diseases (Yagnik et al., 2018).

Additionally, it has been discovered that several microbiological strains, including bacteria and fungi, which are frequently linked to diabetic foot ulcer infections, are negatively impacted by the acidic environment provided by apple cider vinegar dressing. An attractive possibility for enhancing DFU healing rates is provided by apple cider vinegar dressing, which offers a natural and affordable method of treating wound infections. By giving new proof supporting the viability of apple juice vinegar dressing, the examination could prompt a change in outlook in the way to deal with DFU care. The expense reserve funds related with this intercession could reach out to medical care frameworks and emergency clinics, easing the stress on clinical assets and financial plans (Nasiri et al., 2015).

Furthermore, quicker mending times and decreased removal rates could prompt superior patient personal satisfaction and in general prosperity (Morey-Vargas et al., 2015). Due to its increasing prevalence worldwide, diabetes has become one of the most serious and challenging health issues affecting the human population in the modern era. Diabetes is becoming more common in much of the world as a result of the rapid economic expansion that has led to urbanization and the adoption of modern living styles (Blas and Kuru, 2010).

Therefore, the present study has huge importance because of the lifetime risk of foot ulcer is 19% to 34%, and this number is rising with increased longevity and medical complexity of people with diabetes. Morbidity following incident ulceration is high, with recurrence rates of 65% at 3–5 years, lifetime lower-extremity amputation incidence of 20%, and 5-year mortality of 50–70%. In addition to the high risk of leg amputation, all of this poses a risk to a diabetic foot patient (Dermott et al.,2023). Therefore, it is important to study this problem and investigate and provide evidence about the current non pharmacological intervention in order to alleviate the suffering of these patients and enhance their health status and QO.

1.3 Problem Statement:

Diabetic foot ulcers are a significant condition that can be very expensive and have long-term negative effects. Additionally, these foot ulcers significantly lower quality of life (QoL). For instance, the lack of mobility caused by foot ulcers affects patients' capacity to do normal tasks and partake in recreational activities. Sadness and a low quality of life are two outcomes of foot ulcers, among others (Vileikyte, 2001).

Diabetic foot ulcers (DFUs) are a significant morbidity and mortality concern connected with diabetes. The death rate is estimated to be 5% in the first year following the commencement of a DFU and 42% in the first five years. Techniques used often in DFU treatment include surgical debridement, dressings to maintain a moist wound environment and regulate exudate, wound off-loading, vascular assessment, infection and glucose control, and wound debridement. To coordinate these operations, a multidisciplinary diabetic foot wound clinic is the best location. (Everett et al., 2018).

Diabetic patients are exposed in their lives to diabetic foot ulcers, which are a chronic wound that delays healing, which affects the quality of life of the patient and his coping with the disease in particular. The high prices of diabetic foot care products and the delays healing time of the wound, all of this constitutes a burden on the patient and the health care system. Therefore, providing a low-cost product that is effective in healing ulcers has become very necessary. Therefore, this study will provide evidence to support the use of apple cider vinegar as an antimicrobial agent and healing assistance in DFUs administration. The focus of the current study revolves around investigating the impact of utilizing apple cider vinegar in the management and wound healing of DFUs among patients with diabetes mellitus.

1.4. The study objectives:

1.4.1 Determine the effect of using apple cider vinegar on wounds healing among patients with diabetic foot ulcers.

1.4.2 Find out the relationship between the effect of apple cider vinegar on wounds healing of diabetic foot ulcer patients with their socio-demographic data and clinical information.

1.5 Hypotheses:

a. H0: The application of apple cider vinegar doesn't have a significant improvement in wound healing among individuals with diabetic foot ulcer.

b. H1: The use of apple cider vinegar has a notable positive effect on enhancing wound healing among patients with diabetic foot ulceration.

1.6 Definition of the terms:

1.6.1. Effect:

a. Theoretical definition:

It refers to the end conclusion or consequence of a certain cause, which can be an illness or a therapeutic strategy used to produce the observable effect (Kumar, 2011).

b. **Operational** definition:

The extent or level of impact achieved when applying an apple cider vinegar to improve wounds healing among patients with diabetic foot ulcers.

1.6. 2. Apple cider vinegar:

a. Theoretical definition:

"Is a type of vinegar made with rushed apples. It's used as an ingredient in foods like salad dressings, pickles, and marinades. For many years, people

have also used it as a home remedy for everything from fighting germs to preventing heartburn" (Benisek, 2022).

b. Operational definition:

This particular vinegar is produced with apple juice. Foods like marinades, pickles, and salad dressings all contain it as an ingredient .For a long time, people have also utilized it as a natural cure for anything from reducing heartburn to eradicating infections so, it is soak with dressing for patients with diabetic foot ulcers at Imam Al-Hassan Center for Endocrinology and Diabetes in Kerbala city.

1.6.3. Diabetic foot ulcers:

a. Theoretical definition:

A diabetic foot ulcer (DFU) is chronic foot inflammation which is a non-healing or poorly healing wound below the ankle. It can occur when nerves in the feet are damaged from diabetes, resulting in the loss of protective sensation and may lead to amputation (Mark et al., 2018).

b. Operational definition:

A full-thickness wound, through the dermis, below the ankle on a weight-bearing or exposed surface in an individual with diabetes. These ulcerations can have a prolonged period to heal. DFUs are categorized as being purely neuropathic, purely ischemic, or neuroischemic (mixed).

Chapter two

Literature Review

Chapter two Literature Review

2.1 Historical overview of diabetes mellitus:

Diabetes mellitus is a metabolic condition caused by a variety of factors that is defined by persistent hyperglycemia and abnormalities in the balance of proteins, carbohydrates, and fats as a result of problems with insulin production, action, or both (Ning et al., 2022). While errors in insulin action are typically linked to peripheral tissue resistance to insulin, abnormalities in insulin secretion are caused by improper functioning of the pancreatic beta cells (Toelsie et al., 2013). The final effect is always inadequate insulin availability. Typical symptoms of diabetes mellitus include thirst, polyuria, blurred vision, loss of weight, and when untreated, a non-ketotic hyperosmotic syndrome or ketoacidosis that can cause stupor, coma, and finally death (Balaji et al., 2019).

One of the earliest human diseases known to science is diabetes mellitus, which has plagued societies for millennia. Hesy-Ra of the Third Dynasty, an Egyptian physician, penned The Ebers Papyrus around 1552 before Christ (BC), is generally acknowledged to include the first accounts of symptoms similar to those of diabetes, such as increased fluid consumption and urine output (Mohajan and Mohajan, 2023). The German Egyptologist Georg Ebers found this text in 1862, and it also includes a list of treatments for "the sickness of the flowing of too much urine." (Toelsie et al., 2013).

The first person to notice a connection between high urine glucose levels and a disease characterized by sweet-tasting pee that draws dogs and flies was the Chinese physician Zhang Zhongjing in 229Anno Domini (AD) (Wu et al., 2021). Additionally, these researchers looked at the relationship between the disorder's early and late onsets, inherited factors, obesity, a sedentary lifestyle, and certain dietary practices (Ali et al., 2006). Diabetes mellitus long -term involve retinopathy, which may cause blindness, nephropathy, which may end in renal failure, and/or neuropathy, which raises the risk of foot ulcers and amputation as well as signs of autonomic dysfunction, such as sexual dysfunction (Tripathi and Srivastava, 2006 and Dandona and Dhindsa, 2011).

2.2. Type of DM

2.2.1. Type 1 diabetes:

About 5–10% of all incidents of diabetes are T1DM, also known as type 1 diabetes mellitus (DM), insulin-dependent diabetes mellitus (IDDM), or juvenile-onset diabetes. It is an autoimmune disorder characterized by the pancreatic beta-cells' T-cell-mediated apoptosis, which results in a lack of insulin and ultimately causes hyperglycemia. (Toren et al., 2021). Although the etiology of this autoimmune is yet unknown, it has been established that both inherited and environmental factors have a role. The rate of development of this pancreatic -cell-specific autoimmunity and the sickness itself is rapid, most commonly occurring in newborns and children (juvenile onset). However, it may appear gradually in maturity (late onset) (Kahaly and Hansen, 2016).

Variations in the rate of immune-mediated death of pancreatic betacells frequently influence the disease's eventual course. Children and teenagers are particularly vulnerable to rapid beta-cell loss, which can result in diabetic ketoacidosis (DKA), which can be the disease's first sign (Anindya et al., 2023). Others, particularly in the presence of physiological stress, serious diseases, or the development of additional difficulties, may develop a severe hyperglycemic form with or without ketoacidosis. In such circumstances, the disease progresses slowly, with a gradual increase in fasting blood glucose levels. on the other hand, adults may have beta-cells that continue to operate and secrete enough insulin to keep ketoacidosis at bay for an extended period of time (Kahaly and Hansen, 2016). However, with the development of severe hyperglycemia and eventual ketoacidosis, these people become insulin-dependent due to a gradual insulin deficit. Despite the varying course of this kind of diabetes, those who are affected develop severe or complete insulin deficiency early, midway through, or even later in life, making them dependent on insulin therapy for survival. No matter what age it occurs, this severe or extreme insulin insufficiency appears as low or undetectable plasma C-peptide levels (Mujeeb et al., 2021).

2.2.2 Type 2 diabetes:

The term T2DM, also known as adult-onset diabetes or non-insulindependent diabetes mellitus (NIDDM), used to describe 90–95% of all cases of diabetes. The two main insulin-related problems that characterize this kind of diabetes are insulin resistance and -cell dysfunction (Sanz-Cánovas et al., 2022). Insulin resistance results from disruptions in a variety of cellular pathways, which lowers the sensitivity of cells in peripheral tissues, including those in the muscle, liver, and adipose tissue, to insulin. Reduced insulin sensitivity in the early stages of the illness causes -cells to hyperfunction in order to achieve a compensatory increase in insulin production to maintain normo-glycemia (Umpierrez and Korytkowski, 2016).

Thus, hyperglycemia is prevented by the greater amounts of circulating insulin (hyperinsulinemia) (Suvarna et al., 2023). However, over time, the -cells' enhanced insulin production cannot entirely compensate for the decreased insulin sensitivity. Additionally, -cell performance begins to decline, and -cell malfunction ultimately leads to an insulin shortage. As a result, hyperglycemia develops and normoglycemia becomes unstable. Despite the fact that insulin levels are decreased, the release of insulin is typically sufficient to prevent the onset of DKA (Fadini et al., 2017). However, severely stressful situations, such as those brought on by infections or other pathophysiological conditions, might result in DKA. Several

medicines, including second-generation antipsychotics, corticosteroids, and sodium-glucose co-transporter-2 (SGLT2) inhibitors, can result in DKA. Patients with T2DM typically may not require any insulin medication when their ailment first manifests or even later in life, in the absence of any significant physiological stress situations (Fadini et al., 2017).

This kind of diabetes has a complex etiology and pathophysiology that is brought on by a variety of known and unknowable factors such as a mix of hereditary (polygenic) predispositions and significant environmental impacts (Yuen and Wong, 2015). More commonly than other risk factors, aging, obesity, a family history of diabetes, sedentary lifestyles, preceding GDM in women, and pathophysiological disorders including hypertension and dyslipidemia have all been associated to T2DM. It occurs more commonly among members of particular racial or ethnic groups, such as Native Americans (American Indians), Asian Americans, African Americans, Hispanics, and Latinos (Hedderson et al., 2010).

Type 2 diabetes mellitus is prevalent in the aforementioned racial or ethnic groupings, and its strong link with first-degree blood relations strongly implies that genetic variables, while complex and largely unknown, play a part in the origin of this condition. Contrary to T1DM, no link has been found between this condition and genes associated with the immune response, including autoimmune. There is therefore no immune-mediated apoptosis of pancreatic cells (Noctor et al., 2016).

2.3 Complications of diabetes mellitus:

Diabetes-related complications are divided into two categories: acute (short-term) and chronic (long term) (Munawar et al., 2022).

2.3.1 Short term complications:

Short-term blood glucose abnormalities can lead to acute problems such hypoglycemia, hyperglycemia, and diabetic ketoacidosis (DKA) (Brunner and Suddarth, 2018).

2.3.2 Long Term Complications:

Chronic (long-term) problems often appear 10 to 15 years after diabetes mellitus first manifests. These issues consist of the items that follow:

• Macrovascular (big vessel) disease: has an impact on the cerebral, peripheral, and coronary circulations.

• Microvascular (small vessel) disease: Chronic exposure to hyperglycemia affects the microvasculature, eventually leading to diabetic nephropathy, retinopathy and neuropathy with high impact on the quality of life and overall life expectancy. Sexual dysfunction is an often-overlooked microvascular complication of T2DM, with a complex pathogenesis originating from endothelial dysfunction. Diabetic nephropathy and retinopathy affect approximately 25% of patients with T2DM; diabetic neuropathy is encountered in almost 50% of the diabetic population, while the prevalence of erectile dysfunction ranges from 35-90% in diabetic men. The duration of T2DM along with glycemic, blood pressure and lipid control are common risk factors for the development of these complications. Criteria for the diagnosis of these conditions are well established, but exclusion of other causes is mandatory (Faselis et al.,2020).

• **Neuropathic disease**: leads to issues including erectile dysfunction and foot ulcers by affecting sensory, motor, and autonomic neurons (Brunner and Suddarth, 2018).

2.4 Overview about diabetic ulcer:

Diabetes foot ulcer (DFU) It defines a break in the skin of the foot in a person with diabetes that does not heal right away but says nothing about the sort of break that is present. In addition, once an ulcer has developed, a number of factors inhibit the skin break from healing fast (Dixon and Edmonds, 2021). The causes of the skin break vary from person to person, and the causes of the healing delay evolve with time in addition to between individuals: At different phases of the healing process, different variables could predominate and hinder recovery. The physician must be aware of the factors that are most significant at any given moment in order to effectively treat each individual ulcer. They must also choose the best course of action (Matilde et al., 2020).

One of the most significant complications of diabetes is diabetic foot, which frequently necessitates extended hospital stays and lower limb amputation (Anselmo et al., 2010). diabetic foot affects more than 15% of patients with diabetes (Leone et al., 2012). There are between 25 and 80 percent more cases of diabetes foot each year (Fahmida et al., 2014). According to reports, 4 to 27% of people globally have diabetes-relate foot problems (Nasiri et al., 2015).

In developed nations, 20% of healthcare budgets are allocated to the treatment of diabetic foot, which affects more than 5% of patients with diabetes.

The cost of a diabetic foot for one person in the United State of America (USA)ranges from 7,000 to 10,000 USD in the year, and in difficult instances requiring amputation, this cost rises to 65,000 USD, illustrating the enormous expenditures of healthcare (Aalaa, et al., 2012). Ischemia, neuropathy, and infection cause diabetic foot. Despite recent breakthroughs in medicine and surgery, diabetic foot issues remain the most significant side effects of diabetes. It is still regarded as the biggest risk factor for non-traumatic foot amputation and has persisted as a health problem (Kalish and Hamdan, 2010).

Failure to treat a diabetic foot can lead to gangrene, infection, amputation, and even death (Snyder and Hanft, 2009). Diabetes foot seldom heals, which has an impact on patients' quality of life, lifestyle, social interactions, and health (Vileikyte ,2008). Additionally, it may raise the expense of healthcare. Blood sugar management, antimicrobial therapy, wound cleaning, hyperbaric oxygen, negative pressure, electrical

stimulation, and growth hormone use are all part of the treatment for diabetic feet (Wang et al., 2018).

The mortality and disability of patients with diabetes are significantly influenced by diabetic foot. Despite significant improvements in diabetes diagnosis and management, the problem of diabetic foot remains unresolved (Edmonds et al., 2021). Numerous people have diabetic feet to some extent, and as a result, they need drug therapy. Surgery is a possibility for individuals after unsuccessful medical therapy. The treatment of these lesions is one of the most difficult procedures in diabetic foot care. Several treatments are used to treat diabetic feet, and numerous researches have looked into the efficacy and efficiency of these items. Honey and olive oil are two examples of this type of commodity (Tian et al., 2014).

2.5 Incidence and prevalence of diabetic ulcer:

Due to neuropathy (nerve damage), vascular disease, or trauma, people with diabetes are more susceptible to develop skin sores, especially chronic ulcers. Diabetes patients frequently develop peripheral neuropathy, which causes nerve damage in the foot, as well as peripheral artery disease. Unknown immune system deficiencies in diabetes patients make it difficult for them to prevent or treat diseases. Diabetes patients frequently experience foot ulcers since they are more likely to develop in those with the illness (Aynalem and Zeleke, 2018). According to estimates, a person with diabetes has a 25% lifetime risk of getting a foot ulceration, which in 2008 cost 10,000 Euro (EUR) for an ischemic ulcer that is untreated and 17,000 EUR for an uninfected ulcer (Endris et al., 2013).Diabetic foot ulcer prevalence was 6.3% (95%CI: 5.4-7.3%), which was higher in males (4.5%, 95%CI: 3.7-5.2%) than in females (3.5%, 95%CI: 2.8-4.2%), and higher in type 2 diabetic patients (6.4%, 95%CI: 4.6-8.1%) than in type 1 diabetics (5.5%, 95%CI: 3.2-7.7%). North America had the highest prevalence (13.0%, 95% CI: 10.0-15.9%), Oceania had the lowest (3.0%, 95% CI: 0.9-5.0%), and the prevalence in Asia, Europe, and Africa were 5.5% (95%CI: 4.6-6.4%), 5.1% (95%CI: 4.1-6.0%), and 7.2% (95%CI: 5.1-9.3%), respectively. Australia has the lowest (1.5%, 95%CI: 0.7-2.4%) and Belgium has the highest prevalence (16.6%, 95%CI: 10.7-22.4%), followed by Canada (14.8%, 95%CI: 9.4-20.1%) and USA (13.0%, 95%CI: 8.3-17.7%). The patients with diabetic foot ulcer were older, had a lower body mass index, longer diabetic duration, and had more hypertension, diabetic retinopathy, and smoking history than patients without diabetic foot ulceration. (Zhang et al.,2017).

2.6. Risk factors and causes of diabetic ulcer:

2.6.1. Risk factors:

2.6.1.1 Neuropathy:

Diabetic foot ulcers are closely correlated with the existence of numbness or discomfort, which are common symptoms of any kind of diabetic neuropathy, but notably polyneuropathy, which is distinguished by altered vibration, position, and temperature sensations (Casadei et al., 2021). Patients are more likely to develop a lesion that might progress into an ulcer because there is a gap between their sensations and the real state of their limbs (Centers for Disease Control and Prevention, 2017).

2.6.1.2 Peripheral vascular disease (PAD):

The outcome of peripheral vascular disease is inadequate blood flow, particularly in the lower limbs. Threats from necrosis and infection might be raised by the resultant ischemia. Surgery can be done to assist restore sufficient blood flow (Nussbaum et al., 2018). Peripheral arterial disease accounts for up to 50% of diabetic foot ulcers and acts as an independent risk factor for the development of these ulcers. The higher prevalence of PAD in diabetic patients is noted, with up to 11% of diabetic patients being affected when compared to 4% of non-diabetics. Moreover, PAD was more prevalent

in diabetic foot cases complicated with foot ulcers with prevalence rate of 30% and amputations with 54% (Altoijry et al., 2021).

2.6.1.3 Presence of pre-ulcerative lesions:

Preventing foot ulcers in diabetic people requires early detection of new lesions. Ulcers commonly form as a result of calluses, especially hemorrhagic calluses, and locations that are subject to recurrent shear or stress. Using a pressure platform and in-shoe pressure sensors, stress sources may be found so that the best shoes (which reduce the chance of developing lesions) can be chosen (Raghav et al., 2018).

2.6.1.4 Hypertension:

More than half of diabetics who develop foot ulcers also have high blood pressure This condition can be controlled by combining oral medicines with insulin therapy (Armstrong et al., 2018). hypertension (HTN) or elevated systolic and diastolic pressures are also major risk factors for the nephropathy, proteinuria and end stage renal disease ESRD. HTN and Atherosclerotic cardiovascular disease (ASCVD) are also leading cause of morbidity and mortality among diabetics, coexisting with diabetic kidney disease (DKD) (Aziz et al.,2021).

2.6.1.5 Gender and age:

Male patients with diabetes are more than twice as likely (more than two-thirds) to develop foot ulcers than female ones. In addition, the bulk of them are in their 40years to 70years. Patients beyond the age of 6 years have a lot more issues than those under 6years (Armstrong et al., 2018).

2.6.1.6 Smoking:

Smoking has been associated to the development of foot ulcers and gangrene as well as other concomitant illnesses such arterial and vascular disease and chronic obstructive pulmonary disease. These problems impede healing and may cause lesions to linger and may develop into ulcers (Al-Rubeaan et al., 2015).

2.6.1.7 Charcot joint:

This ailment, also known as neuropathic joint or Charcot (neuro/osteo) arthropathy, is a gradual degenerative and destructive joint disorder that occurs in patients with aberrant pain sensation and proprioception. Diabetes mellitus is by far the most common cause of Charcot joints in modern western countries, with patient demographics mirroring those of elderly diabetics. The severity of diabetes mellitus influences the prevalence of this illness (Bhattacharya et al., 2023). If Charcot foot causes change in shape of the foot or ankle, that put too much pressure on areas of foot. This can lead to open ulcers or sores that increase risk for infections. Foot ulcers have been reported as one of the most common complications after diabetic Charcot foot, occurring in 11–60% of cases.5,6,8,10 The need for surgery and amputation at the DCF site was also observed during follow-up (Rahman et al.,2020).

2.6.1.8 Other risk factors:

The most significant known risk factors for developing foot ulcers are those that have already been mentioned. However, there are additional variables that, although carrying a lower risk, can still contribute to the eventual formation of an ulcer. These risk factors include the duration of the patient's diabetes, which means the longer someone has diabetes, the higher the risk of developing foot ulcers. Reduced vision, which can lead to increased chances of trauma and injury to the feet, is another contributing factor (Rastogi et al., 2020). Furthermore, chronic renal illness, obesity, and continuous uncontrolled hyperglycemia are additional risk factors that can increase the likelihood of foot ulcers. Chronic kidney disease can affect blood circulation and healing processes, while obesity places extra pressure on the feet and makes them more susceptible to injury (Alavi et al., 2014).

2.6.2 Causes of diabetic foot ulcer:

There are various reasons, which may be categorized into two main causes of diabetic foot ulceration in DM individuals, namely:

2.6.2.1 Peripheral neuropathy (sensory, motor, autonomic):

They are the primary and highest significant contributing elements. Before suffering a loss of protective sense that makes a person more susceptible to thermal and physical damage and raises the likelihood of developing foot ulcers, sensory neuropathy is typically very advanced (>50%) (Khursanova et al., 2023). Proprioception, or the sense of foot position, has also vanished along with the sensation of pain and pressure. All the muscles in the legs are impacted by motor neuropathy, which causes aberrant bones to protrude, changes to the normal foot architecture, and recognizable deformities as hammer toes and hallux rigidus (Sharma, 2021). Regarding autonomic neuropathy or autosimpatectomy, the foot is particularly sensitive to minor damage because of the dry skin, lack of perspiration, and increased secondary capillary filling caused by arteriovenous malformations in the epidermis (Fahrun, 2016).

2.6.2.2. High foot plantar pressure:

It is second-most important cause-and-effect factor. Numerous studies have revealed that individuals with diabetic peripheral neuropathy (DPN) and those who have a history of diabetic foot ulcers (DFUs) have elevated plantar pressures. It has been suggested that individuals with DPN are more likely to acquire DFUs if their plantar pressure is high. Therefore, to lower the risk of developing DFUs, current international standards recommend attaining at least a 30% reduction in maximal plantar pressure. (Fernando et al., 2016).

2.6.2.3 Trauma:

Particularly recurrent trauma, 21% trauma from footwear friction, 11% owing to foot injuries (mainly from falls), 4% cellulitis due to problems from tinea pedis, and 4% due to incorrect fingernail cutting (Fahrun, 2017).

2.6.2.4 Atherosclerosis:

The most significant contributing factor is peripheral vascular disease caused by atherosclerosis, particularly with relation to the femoropopliteal blood arteries and the tiny blood vessels below the knee. People with diabetes have a twofold increased risk of developing ulcers compared to patients without diabetes (Fahrun, 2017).

2.7 Pathophysiology of diabetic ulcer:

The main risk factors for the development and progression of diabetic foot ulcers include peripheral neuropathy, peripheral vascular disease, and impairment of the immune system's response to infection. These conditions are more prevalent in patients with DM. Additionally, DM suffers from a wound-healing dysfunction that increases the risk of infection (Wild et al., 2010; Sharp and Clark, 2011). Neuropathy impacts the autonomic, sensory, and motor systems in DM. Damage to the innervation of the leg muscles causes an imbalance in leg extension and flexion, leading to deformity and changed pressure points. Ulcers will eventually develop as a result of the cumulative skin damage. Due to the autonomic neuropathy, the sweat and oil glands produce less, making the foot less moist and more prone to damage. Because sensory neuropathy decreases the pain threshold, often, a wound is not detected until it progresses (Clayton and Elasy, 2010).

Due to endothelial dysfunction, blood vessel muscle, and decreased endothelial production of vasodilators, hyperglycemia causes constriction of the peripheral arteries (Nieves-Cintrón et al., 2021). Diabetes mellitus (DM) thromboxane A2 augmentation, namely vasoconstrictor and aggregate platelet aggregation, increases the risk of plasma hypercoagulability (Kryukov et al., 2021). Hypertension and dyslipidemia both have an impact on peripheral arterial disease. The aforementioned explanation will lead to the development of occlusive artery disease, which will then cause ischemia of the lower limbs and an increased risk of ulcers (Aziz et al., 2021).

According to Clayton and Elasy (2010), the newly formed ulcers will spread swiftly, develop gangrene, and necessitate amputating the lower leg (below the knee). Ulcers develop as the capacity of peripheral soft tissues to heal decreases with DM. Blood glucose control is no longer adequate to management advanced diabetes when the structure of skin tissue, nerves, blood vessels, and other support tissues has been destroyed (Pirri et al., 2021). Slow wound healing in DM increases the risk of wound complications, which further impede wound healing. Gangrene, septicemia, and various infections (including cellulitis, abscesses, and osteomyelitis) are some of these adverse effects (Wild et al., 2010; Sharp and Clark, 2011).

2.8 Assessment of diabetic ulcer:

The American Diabetes Association (ADA) suggests a yearly, thorough foot examination that includes a general check and an evaluation of the pedal pulses. Additionally advised are general foot self-care instruction and peripheral arterial disease screening. Referrals to foot care experts should be made for smokers, those with foot abnormalities, and anyone with a history of problems in the lower extremities (American Diabetes Association [ADA], 2010). A history, general inspection, dermatologic, musculoskeletal, neurologic, and vascular assessments are important aspects of a thorough foot examination (Boulton, et al., 2008).

2.8.1 Patient history:

Even if the patient's history is an important part of risk assessment, a thorough foot examination is still necessary to determine a patient's overall risk for foot ulcers. An important aspect of the history is any foot ulceration or amputation in the past (Lin et al., 2020). Neuropathic or peripheral vascular symptoms, decreased eyesight, or renal replacement treatment are additional crucial considerations in the history. The use of cigarettes should also be noted because it increases the chance of developing neuropathy as well as vascular disease (Boulton et al., 2008).

2.8.2 General Inspection:

The level of risk can be determined by inspection based on the sock, feet, and legs, hygiene, toenails, pulses, ankle strength, movement, and sensitivity. This information is used to identify patients who are at risk for foot alteration and to start protective measures that help prevent lower extremity amputation (Pérez-Panero, 2019).

2.8.3 Dermatologic and Musculoskeletal Assessment:

In terms of dermatology, the majority of studies analyzed alterations in skin temperature, color, hardness, and turgor as well as common skin conditions like diabetic dermopathy, necrosis lipoidica diabetorum, and diabetic bullae, which are prevalent in diabetic patients and have a high potential for developing into limb-threatening issues like ulceration and infection. Most research in the musculoskeletal component concentrated on muscular strength, gait patterns, and foot abnormalities, particularly Charcot osteoarthropathy (COA), the most severe musculoskeletal consequence of diabetes (Shirazi et al., 2016).

2.8.4 Neurologic Assessment:

Simple tests that can be used to detect Loss of Protective Sensation (LOPS) include the following:

1- Pressure evaluation using the Semmes-Weinstein monofilament test using nylon filament.

2- A 128-Hz tuning fork was used to assess vibration.

3- Checking for a pinprick feeling.

4- Evaluation of ankle reflexes.

5- Biothesiometer testing for vibration perception threshold.

Each test has been evaluated in prospective clinical studies, and is capable of detecting LOPS. To rule out LOPS, use the monofilament test (which is the most widely utilized test) in addition to any other test. LOPS would be indicated by an abnormal finding for either test (Boulton et al., 2008). The following procedure is used to identify clinically significant large-fiber neuropathy using the monofilament test's pressure assessment: When 10 g of force is applied perpendicular to the skin, a 5.07 monofilament will buckle. The monofilament is released as soon as buckling takes place within one second. The patient indicates if the nylon probe is touching skin by saying "yes" or "no" while keeping their eyes closed. The location of the monofilament installation should be visible to the patient. On each foot, four to ten locations should be examined. 90% of patients with LOPS may be detected with testing on the great toe's dorsal surface and at the bases of the first, third, and fifth metatarsals. It's also advised to test up to 10 sites altogether, in any sequence. An entry on the chart marked "positive" or "negative" denotes the presence of sensation or its absence, respectively. Avoid using on areas with calluses or scar tissue (Boulton et al., 2008).

At the end of each foot's great toe is a 128-Hz tuning fork that vibrates. It is an inappropriate reaction if the examiner can still feel the vibration after the patient stops feeling it. In the pinprick test, With the patient's eyes closed, a pin is gently placed on the dorsal surface of the great toe to depress the skin. An abnormal test result would be if the patient was unable to detect their depression (Boulton et al., 2008). The Achilles tendon must be stretched until the ankle is in a neutral posture in order to trigger the ankle reflex. An aberrant outcome of a tendon hammer strike is complete lack of response. The last test makes use of a biothesiometer, a portable instrument that can measure the vibration perception threshold. Once the great toe has been touched with the stylus, the amplitude is increased until the patient feels the vibration. This yields a quantifiable test, and an abnormal

result is a vibratory perception threshold larger than 25 volts (Boulton et al., 2008).

2.8.5 Vascular Assessment:

Diabetes patients and anyone at risk for peripheral arterial disease (PAD) must have a lower limb vascular evaluation. There is proof that common evaluation methods, such the ankle-brachial index (ABI), may be less useful in diabetics (Jakubiak et al., 2020). Other widely used tests, such as continuous wave Doppler (CWD) and the toe-brachial index (Tehan et al., 2015).

2.9. Management of diabetic ulcer:

Closing the wound is the major objective in the treatment of diabetic ulcers.Patients with DM get ongoing treatment for DFU wounds, with the course of treatment varying based on the ulcer's severity and if ischemia is present or not. Necrotomy/debridement, unloading, managing the infection by identifying the kind of bacteria, giving the appropriate antibiotics, and ulcer management using clean, moist wound dressing are the cornerstones of DFU therapy (Mc Intosh and Kelly, 2009).

2.9.1 Debridement:

Debridement refers to the process of removing non-living objects, foreign materials, and diseased tissues from vulnerable areas to prevent harm (Shankhdhar, 2011). In the case of chronic wounds, debridement is essential to eliminate dead tissue and debris (Lebrun et al., 2010). This procedure involves the removal of aberrant injuries' base, wound edge tissue like epidermal hyperkeratosis (callus), necrotic dermal tissue, debris, and bacterial components that may hinder wound healing.Numerous clinical trials and investigations have shown that debridement plays a crucial role in promoting wound healing by facilitating the development of granulation tissue. By transforming the local environment of a chronic wound into an acute wound, debridement accelerates the healing process of the lesion, making it an essential step in managing diabetic foot ulcers (Van Baal, 2009).

According to Frank et al.'s theory, debridement of diabetic foot ulceration can raise vascular endothelial growth factor (VEGF) levels since debridement causes fresh wound bleeding (Cardinal, 2009). While regular debridement of diabetic foot ulcers may expedite wound healing, there is limited data to fully support this claim (Edwards, 2010). Individuals with foot ulcers must offload in order to transfer their center of gravity away from the lesion spot. This unloading procedure is intended to reduce wound healing time and tissue damage (Wu et al., 2007).

Offloading is a vital component in the treatment of diabetic ulcers. Foot ulcers usually form in high-pressure areas of the foot. The most effective unloading technique is total contact casting (TCC). It entails precisely molding casts to shift the patient's weight away from the ulcer area while still allowing the patient to move around while receiving therapy. TCC helps to reduce swelling, which can hinder wound healing. Despite being difficult and time-consuming, TCC has yielded remarkable results, with 73-100% of ulcers healing when used.

total contact casting does have some drawbacks, such as the need for expertise and time, the possibility of plaster irritation leading to new injuries, constraints in daily wound monitoring, dressing changes, and infection detection, as well as the rising usage of cast walkers that can be detached. Additional unloading alternatives include bed rest, wheelchairs, walkers, and custom-made shoes (Snyder and Hanft, 2009).

According to Webster et al. (2012), infection prevention ulcers brought on by diabetes make a wound susceptible to bacterial infection. Due to the high frequency of infection in diabetic ulcers, a comprehensive approach is required for a complete assessment. Erythema, edema, pain, softness, warmth, and pus discharge are the main clinical signs of infection. The severity of the infection must be determined. According to infectious illnesses, the American society divides wound infections into three groups:

(1) Mild infections: if erythema is obtained < 2 cm,

(2) Moderate infection: if erythema is > 2 cm and

(3) Severe infection: systemic infection (Zakariah et al., 2020).

Diabetic ulceration is divided into two groups, namely:

(a) Cellulitis that is less than 2 cm in diameter and does not reach joints or bones is a non-limbal hazard.

(b) Cellulitis that is more than 2 cm long, has affected the joints and bones, and is systemically infected. Only clinical experience-based research is currently available on the take of antibiotics as a medication for diabetic ulceration. The effectiveness of an antibiotic's toxicity should be determined by the results of bacterial culture (Webster et al., 2012).

Staphylococcus and streptococcus often produce non-limbthreatening infections. For polyclinics, oral antibiotics such cephalexin, Amoxilin-clavulanic acid, moxifloxin, or clindamycin can be used to treat mild to moderate infections (Webster, et al., 2012). Staphylococcus, streptococcus, Enterobacteriaceae, pseudomonas, enterococcus, and anaerobic bacteria like Bacteroides, Pepto cocci, and Pepto streptococci are some examples of polymicrobial organisms that can cause serious illnesses. Hospitalization is recommended for serious infections, along with the use of both aerobic and anaerobic antibiotics. Ipenem-cilastatin, B-lactam Lactamase (ampicillin-sulbactam and piperacilintazobactam), and broadspectrum cephalosporin are options for intravenous antibiotics for serious infections (Stillman, 2008).

2.9.2 Dressing:

A dressing is a material that is applied topically to the region to protect and aid in the healing of the wound. In order to prevent direct dressing contact with the wound, plaster acts as a barrier. The many types of dressings include film, composite, hydrogel, hydrocolloid, alginate, foam, and other absorptive dressings including negative pressure wound therapy (NPWT) (Leonget al., 2012). The main purpose of a closed-clean wound or granulated wound is to provide a moist healing environment that encourages cell migration and prevents dry sores. The right dressing is chosen based on the type and amount of exudate that is present in the wound. Hydrogel dressing, film, and composite use are best suited for cuts with a little amount of exudate. Alginate, foam, and NPWT are widely used for wounds with exudate levels, whereas hydrocolloids are used for wounds with exudate amounts. Injuries with a lot of necrotic tissue need to be cleaned up before a dressing is put on (Leong et al., 2012).

2.10 Using of cider vinegar:

The French terms vin and aigre, which both indicate sour wine, are the origin of the word "vinegar." (Lim et al., 2019). Vinegar was originally known as alegar in England where it was created from soured malt liquors. The manufactured vinegar may be divided into grain vinegar and fruit vinegar depending on the raw materials utilized (Bansal et al., 2020). The red apples are used to make apple cider vinegar. It is a two-stage fermentation process in which yeasts, often of the Saccharomyces genus, convert fermentable carbohydrates to ethanol in the first step and bacteria, typically of the Acetobacter genus, oxidize the ethanol in the second (Bansal et al., 2020).

The first antibiotic that was perhaps known to man was vinegar. In 400 B.C., Hippocrates used it on his patients. He advised using concentrated vinegar in the form of washes and vapor to cure "lichen" and warts. He advised using concentrated vinegar in cases of vitiligo, leprosy, and psoriasis (Maheswari and Mahendran, 2023). It is generally known that criminals used vinegar to prevent infection when vandalizing and robbing goods from the dead corpses of plague victims during the great plague of Europe (Tanturri, 2023). Consuming vinegar is thought to increase fullness and reduce the

appetite for following meals, which can help with weight reduction and obesity management. By significantly lowering systolic blood pressure, vinegar has a beneficial effect on cardiovascular illnesses. Leukemia cells undergo apoptosis, and cancer cells are prevented from proliferating (Bansal et al., 2020).

2.11 Effects of apple cider vinegar for diabetic foot ulcer:

Healing wounds is a difficult process. Both intrinsic and external variables impact anything. The wound's pH has an impact on oxygen release, angiogenesis, and protease toxicity of microorganisms and activities. Chronic wounds that won't heal have an alkaline pH, and the majority of harmful bacteria need a pH level greater than 6. In an acidic environment, healing happens more easily. The pH of the wound is lowered with acetic acid, which lessens bacterial protease activity. Additionally, it increases the activity of macrophage fibroblasts and lessens bacterial byproducts' toxicity. A rapid disinfection with improved granulation is the result of all these processes. Furthermore, due to its impact on biofilm, it is therapeutically effective against multi-drug resistant Pseudomonas aeruginosa and Staphylococcus aureus and speeds up wound healing by reducing wound contamination and infection (Bansal et al., 2020).

2.11.1 Mechanism of action:

Acetic acid is a weak organic acid that quickly penetrates cell membranes. They are in equilibrium because of their ionized and nonionized states, the latter of which easily traverses hydrophobic membranes. When proton gradients, necessary for ATP synthesis, collapse, the microorganism perishes. Its efficiency against a range of bacteria has been shown in studies conducted both in vivo and in vitro (Halstead et al., 2015).

2.11.1.1. Antibacterial effect:

In a different study, Halstead et al.,2015 found that acetic acid had good activity against most of the organisms tested, including Proteus vulgaris, P. aeruginosa, A. baumannii, ß-haemolytic Streptococci A and B, S. epidermidis, S. aureus, and Enterococcus faecalis, which were all eliminated after only 30 minutes of exposure (Bjarnsholt et al., 2014). 0.5% and 1% acetic acid completely eradicated the biofilms of P. aeruginosa and S. aureus, respectively (Bjarnsholt et al., 2014). Additionally, acetic acid is a potent tuberculocidal disinfectant. Also, a 30-minute exposure to 6% acetic acid led to an 8-log10 decrease in live Mycobacterium tuberculosis (Cortesia et al., 2014).

2.11.1.2 Antifungal effect:

Acetic acid produced anti-fungal action against Candida Spp in a denture stomatitis infection model that was equivalent to nystatin in reducing microbial adherence and eradication. C. albicans' ability to proliferate on culture plates was constrained by 5% acetic acid. In a disc diffusion experiment, Aspergillus Niger and Saccharomyces cerevisiae showed high sensitivity to 25% acetic acid. (Gopal et al., 2019).

2.12.1.3 Antiviral effect:

The CoV-2 virus that causes severe acute respiratory syndrome (SARS) has demonstrated extraordinary antiviral activity in the presence of vinegar and its active component, acetic acid. By producing a low pH-dependent conformational shift, acetic acid inactivates and disaggregates haemagglutinin glycoproteins, which are present on the surface of influenza viruses. It breaks down the viral envelope and prevents viral spread (Pianta, et al., 2020). Vinegar works by reducing the virus's titer in the nasopharyngeal swab by 90%, which inhibits the virus's ability to infect. Additionally, a modest concentration (0.34%) of vinegar fumigation reduced the signs and symptoms of a moderate SARS-CoV-2 infection more quickly (Pagani et al., 2020).

Foot ulcers, which afflict up to 2% of the people and are chronic nonhealing sores, continue to be difficult for clinicians to treat (Shubhangi, 2013). For those with diabetes, impaired wound healing is a common and expensive issue. Approximately 15% of all diabetes patients may get one or more-foot ulcers, and 15–25% of them will eventually need to have their feet amputated. 25–50% of all diabetes hospital admissions and the bulk of the 60,000–70,000 amputations carried out annually in the U.S. are due to non-healing diabetic foot ulcers (Al-Duboni, 2015).

The need for new antimicrobial agents as bacterial resistance to antibiotics continues has resulted in the resurgence of therapies that have been used for centuries but fell out of favor throughout the age of antibiotics. These treatments are risk-free, widely successful, and unlikely to lead to resistance. Debridement, according to is the process of removing sick and contaminated tissue from wounds in order to show healthy tissue and hasten healing (Eriksson et al.,2022). Due to its antimicrobial properties, in numerous hospitals all around the world, vinegar debridement therapy was employed to treat infections of the bones and soft tissues. Additionally, it has been used as an antibiotic for wound dressing and other purposes, leading to suggestions that vinegar can treat or be an ingredient in treatments for the majority of human and many animal diseases (Al-Duboni, 2015).

2.12 Theoretical framework:

Complete research requires the selection of a suitable nursing theory. The researcher chose Lydia E. Hall's Theory as the theoretical framework for this study after doing an exhaustive search and review of several nursing theories. This selection was made because Hall's theory strongly correlates with the research method and shares substantial parallels with the research domains. Using this theoretical framework, the researcher hopes to give enough attention to the study's specific topic while also ensuring consistency with established nursing principles and concepts. The application of Lydia E. Hall's Theory will aid in gaining a better knowledge of the research topic and will improve the overall efficacy of the study's findings.

2.12.1 Lydia E. Hall theory core, care and cure model:

In accordance with Hall's theory, nursing is described as "participation in care, core, and cure components of patient care, where care is the primary responsibility of nurses, whereas core and cure are shared with other members of the health team." The primary objective of care is to establish a rapport with the individual that will foster the development of their core values (Priyadarshini, 2021).

2.12.2 Lydia E. Hall Theory Major Concepts:

Individual:

According to Touhy and Birnbach (2001), the emphasis of nursing care in Hall's work is the individual human who is 16 years of age or older and has advanced through the acute stage of a long-term disease. Healing is fueled and motivated by the individual receiving care, not by the healthcare provider. Hall emphasizes the importance of the individual as unique, capable of development and learning, and requiring a whole-person approach.

Health:

Health can be defined as a state of self-awareness in which people intentionally adopt behaviors that are most advantageous to their well-being. According to Hall, it is critical to assist individuals in investigating the importance of their behaviors, allowing them to identify and confront concerns while cultivating self-identity and maturity. Individuals can strive for optimal health and well-being through cultivating self-awareness and deliberate decision-making (Touhy and Birnbach, 2006).

Society and Environment:

Within Hall's theory, the concept of society or environment is inextricably tied to the individual. Hall is credited for creating the Loeb Centre concept, which was inspired by her belief that the hospital setting during acute sickness treatment might result in difficult psychological experiences for patients. The Loeb Centre emphasizes the necessity of establishing an environment that encourages self-development. In such a context, nurses' priorities the individual's requirements and any actions made affecting society or the environment are targeted at assisting the individual in accomplishing their personal goals. The emphasis remains on the individual's well-being and growth within the context of their environment (Jarrar, et al., 2021).

Nursing:

Nursing is defined as involvement in the care, core, and cure components of patient care (Priyadarshini, 2021).

2.12.3 Lydia E. Hall theory aspects (Sub-concepts):

The care circle:

According to the notion, nurses are devoted to the noble task of caring patients. Nurses' primary focus is on nurturing patients via care and comfort, similar to the concept of mothering (Jose Lanithottam and Parappallil 2019). This caring process includes factors such as care and comfort, as well as providing teaching-learning activities to assist the patients' well-being and growth. The basic purpose of nursing is to give compassionate care and support, similar to a mother's nurturing role, ensuring the patients' physical and emotional requirements are addressed while fostering an environment favorable to learning and healing (Wei and Horton-Deutsch, 2022).

The Core Circle:

The patient getting nursing care is at the center of Hall's theory. The core acts in accordance with his or her feelings and ideals and sets objectives for himself or herself rather than according to anybody else. This entails the therapeutic use of oneself and is communicated to other healthcare professionals (Touhy and Birnbach, 2006).

The Cure Circle:

The concept of "cure" in nursing, according to this theory, refers to the administration of medications and therapies (Jose Lanithottam and Parappallil Jacob, 2019). The "cure" part of nursing, according to Hall's

approach, is a joint endeavor undertaken by nurses and other healthcare professionals such as physicians and physical therapists. This means that nurses collaborate with these specialists to carry out the essential medical interventions and treatments to promote the patients' recovery and wellbeing. The "cure" circle emphasizes the necessity of collaboration and teamwork in providing holistic treatment to those in need (Priyadarshini, 2021).

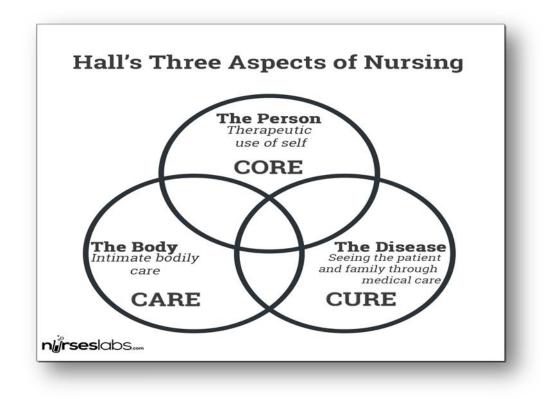


Figure 2-1: Hall's three aspects of nursing (Sumarno, 2019).

2.12.4. The practical application of theory in the present study:

Among the three main components—the patient (core), the body (care), and the nursing attitude (cure), different diseases may cause the patient to experience a range of different feelings and behaviors, necessitating the nurse's implementation of the necessary procedures and nursing care in consideration of these variations. In this clinical trial, diabetic patients are exposed in their lives to diabetic foot ulcers, which are a chronic wound and delay in healing time, which affects the quality life of the patient and his coping with the disease in particular. By applying apple cider vinegar dressing on diabetic foot, patients could control their own feelings, motives, goals and ultimately exert their self-potentials to the greatest extent. Thus, the goal of rehabilitation can be achieved successfully.

• Care: The researcher tries to assist the patient to reduce the severity of diabetic foot ulcer grade and accelerate wound healing level through implementing apple cider vinegar dressing for 21 days.

• Core: The patients that diagnosed with diabetes mellitus and were confirmed to have diabetic foot ulcer.

• Cure: The researcher solved the patients' problems including severity of diabetic foot ulcer grade and wound healing level through the application of an interventional protocol using apple cider vinegar dressing.

2.13 Previous Related Studies:

First study:

Budak et al., (2021) conducted study in turkey, using the antimicrobial disc diffusion method, evaluate the antimicrobial activity of various vinegars (apple, grape, hawthorn, sour cherry, and pomegranate) produced using the conventional method against some significant foodborne pathogens (Escherichia coli, Enterococcus faecalis, Staphylococcus aureus, and Campylobacter jejuni). In addition, the vinegar's organic acid content, antioxidant potential, and phenolic components were studied, as well as their connection to the antibacterial impact. They came to the conclusion that vinegar's antibacterial activity is effectively mediated by its antioxidant, phenolic, and organic acid content. In this study, apple vinegar and pomegranate vinegar were found to have the strongest antibacterial activity against gram-positive and gram-negative microorganisms, respectively.

Second study:

Bansal et al., (2020) review article research to ascertain the current uses of vinegar in India, ranging from dermatology to scullery. They came to the conclusion that vinegar has been utilized as a food preservation and flavoring ingredient. Despite being used as medicine for more than a century, vinegar is still a viable therapeutic choice for the treatment of a number of dermatoses (Aquatic and marine dermatoses, Fungal infections, Warts, Chronic papillomatous dermatitis, Alkali burns, Photodamaged skin, Hair growth, Sclerosant, and Melasma) as a stand-alone therapy or as a supplement to other treatments. The benefits of utilizing vinegar include its ease of availability, affordability, and ease of preparation, which makes it a sustainable medicine option.

Third study:

Agrawal et al., (2018) conducted a study to determine the benefits of acetic acid dressing for managing wounds This is a prospective review of 100 patients with infected wounds who received care at a tertiary care facility in India from October 2013 to October 2015 over a period of two years. The majority of the research participants had already received treatment using tried-and-true methods including saline, povidone-iodine, eusol, and hydrogen peroxide. The inclusion criteria took into account the referring doctor's unsuccessful attempt to eliminate wound infection using conventional methods. Patients with systemic infection symptoms were not included in the research. The study took into account the rests of all wounds.

The result of study showed mean age of patients treated was 33 years (range 9–60 years) with 70% were male. Patients were treated for a variable period of 7–21 days. Following acetic acid therapy, there was a reduction in wound size, along with surrounding inflammation and induration, which is suggestive of wound healing. The discharge, odor, and granulation tissue all significantly improved. There were no notable negative consequences associated with using acetic acid as dressings, except from the stinging feeling that some patients reported upon administration. Additionally, after being treated with 1% acetic acid, the quantity of soakage at infected skin grafting donor sites decreased and they naturally healed without the need for

grafting. The wound with better granulation tissue had a pH of 7, whereas the typical pH of infected wounds was alkaline (pH 9 or higher).

Fourth study:

Yagnik et al., (2017) in vivo study design conducted a study in England, UK.to see if methicillin-resistant Staphylococcus aureus and resistant Escherichia coli are eliminated by antibacterial apple cider vinegar. Alternative therapies are essential since therapy entails repeated courses of ineffective antibiotics as well as undesirable side effects. looked at whether apple cider vinegar (ACV), a naturally occurring, vegan substance with strong antibacterial action, may help these resistant bacteria. Additionally, they have a high rate of morbidity and death due to failed treatments.

Fifth study:

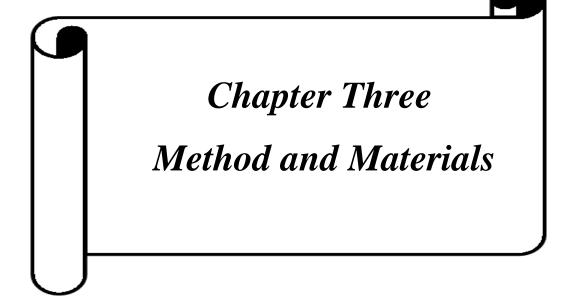
Al-Duboni, (2015) carried out a research project to evaluate the effectiveness of vinegar treatment on bacterial development during the course of treating diabetic foot ulcers. Thirty patients with non-healing ulcers were separated into three groups; standard therapy was used on ten wounds, vinegar therapy on ten wounds, and hypertonic saline on ten wounds at College of Medicine in Baghdad Iraq. According to the study, necrotic tissue has not changed much. The necrotic tissue did not significantly debride during the first 14 days of standard treatment, and several infections, primarily Staphylococci, Streptococci, and Pseudomonas, grew rapidly. Necrotic tissue reduced by 4.1 cm² on average during the same time period with vinegar treatment (P = 0.02). While vinegar-treated wounds were totally debrided (P = 0.001) and 70% of cultures were negative after just 3 weeks of therapy, traditionally treated wounds still had 41% of their surface covered in necrotic tissue and continued to proliferate various infections. Additionally, vinegar treatment was linked to faster rates of wound healing and accelerated proliferation of granulation tissue.

Sixth study:

Nagoba et al., (2013) conducted a study in India to review previous studies examining the effect of acetic acid on pseudomonal wound infections. Skin and soft tissue infections, as well as burn wound infections, are frequently caused by Pseudomonas aeruginosa. Controlling wound infection requires antiseptic treatment, which is a crucial component of the infection control in wounds. Questions have been raised despite the widespread employment. According to experimental evidence now available, several commonly used antiseptic substances may be damaging to the cells involved in wound healing and may also obstruct the process of spontaneous tissue restoration. The current study described the many organic acids frequently used as a substitute for antibacterial agents to prevent pseudomonal wound infections, with particular reference to acetic acid and their role in the healing process of wounds. When infection is brought on by several P. aeruginosa strains that are resistant to various antibiotics, acetic acid should be kept in mind as an option. The importance of topical treatments like acetic acid should not be overlooked at a time when microorganisms are developing antibiotic resistance is a growing source of worry.

2.14 Literature synthesis:

From reviewing the previous studies, it is evidenced showed vinegar treatment was linked to faster rates of wound healing and accelerated proliferation of granulation tissue and effective in elimination different type of bacteria primarily Staphylococci, Streptococci, and Pseudomonas. vinegar dressing treatment was more successful and effective in diabetic foot healing. The vinegar can be safely, effectively and very economically used in elimination of multiple antibiotic resistant strains of P. aeruginosa from soft tissue infected wounds. From this studies revision, it was found that following using acetic acid therapy, there was a reduction in wound size, along with surrounding inflammation and induration, which is suggestive of wound healing. The discharge, odor, and granulation tissue all significantly improved. There were no notable negative consequences associated with using acetic acid as dressings. Additionally, after being treated with 1% acetic acid, the wound that need graft naturally healed without the need for grafting. The vinegar dressing treatment will change the ph. of the wound which makes it antibacterial to some degree. Additionally, it is found that wound with better granulation tissue had a pH 7.



Chapter three

Method and materials

Each and every one of the research methodologies used in this study will be covered in great detail in this chapter. Study design, administrative arrangements, ethical considerations, study locations, sample selection techniques, study phases, inclusion/exclusion criteria, instrumentation, data collecting techniques, and data analysis were all incorporated in these processes.

3.1. Design of the Study:

In the current investigation, a quasi-experimental approach was employed. It was employed to determine how applying apple cider vinegar dressing on wounds healing among patients with diabetic foot ulcers. This study was initiated from 26 September 2022to 25 July 2023.

3.2. Administrative arrangements:

Before gathering the data from the following institutions, formal administrative approval was requested to perform this study.

1- Official permission from University of Kerbala / Collage of Nursing council (Appendix AI).

2- Official permission from Iraqi Ministry of Health / Kerbala Health Directorate /Research Committee Decision of Training and Human Development Center (Appendix AII).

3- Official permission was obtained from Iraqi Ministry of Health/ Training and Human Development Center/ Kerbala Health directorate (Appendix AIII).

3.3. Ethical consideration:

It is shown in appendix BI, the University of Kerbala College of Nursing /research ethics committee approved the secrecy and anonymity of the participant identities. The participants willingly consented to participate orally and in writing as shown in appendix BII. They were fully informed of the present investigation and its objectives, and it was made clear to them that they had the right to withdraw from the study at any moment. Furthermore, the investigator took precautions to protect the anonymity of the data gathered during the investigation.

3.4. Settings of the Study:

This research is carried out in diabetic foot consultant to the Imam Al-Hassan Center for Endocrinology and Diabetes in Kerbala city which established in 2011 contains adult medical consultant clinic, Children's diabetes consultant clinic, children growth hormone consultant clinic, nutrition consultant clinic, endocrine glands consultant and diabetic foot consultant clinic. In 2022, the center received (21,600) visitors, in the diabetic foot clinic alone, which received (700) visitors during the year.

3.5. Sample size:

The sample size was selected to be sixty diabetic people who were admitted or taking follow up appointments in Imam Al-Hassan Center for Endocrinology and Diabetes in Kerbala city divided into two groups. There were 30 patients in each of the control and study groups. The study group was exposed to an interventional protocol while the control group was not. The sample was selected by using a purposive non random sampling technique in which this method (sometimes known as judgment, selective, or subjective sampling) refers to a sampling approach where an investigator uses his or her own discretion while selecting individuals of the population to take part in the study.

3.6. Sample of the Study:

Patients who were admitted or taking follow up appointments in Imam Al-Hassan Center for Endocrinology and Diabetes in Kerbala city in the diabetic foot consultant clinic were the sample was chosen using a purposive nonrandom sampling method. A control group of thirty patients was selected, and a study group of thirty patients was must-have to take part. The intervention protocol was given to the study group (foot dressing contain apple cider vinegar).

3.6.1. Inclusion Criteria:

Patients with diabetic foot ulcer in grades 3 and 4 according to Meggitt-Wagner system.

3.6.2. Exclusion Criteria:

The following were all eliminate by the researcher, as indicated in figure (3-1)

- ◆ Patients with foot ulcer in grade 0,1,2 according to Meggitt-Wagner system.
- Patients with foot ulcer in grade 5according to Meggitt-Wagner system who need foot amputation.
- ✤ Patients who have vinegar allergy in medical history.

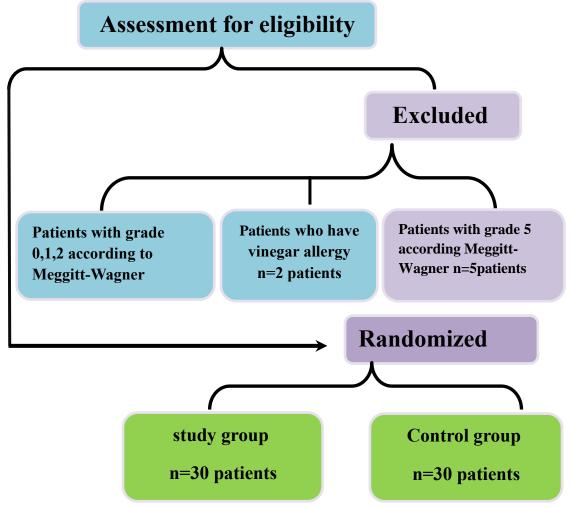


Figure 3-1: Flowchart of the eligibility and exclusion criteria.

3.7. Steps of the Study:

This research is performed as the following steps:

3.7.1. Intervention protocol:

Patients in the study group were instructed to perform foot ulcer dressing once a day for 21 days, while patients in the control group received the routine care only that include povidone-iodin dressing. This intervention is intended to determine how to lessen the severeness and facilitate the healing process of DFU by using apple cider vinegar dressing, in this group, every patient received instructions. to perform ulcer cleansing with normal saline, irrigation with apple cider vinegar, dressing the wound with apple cider vinegar-soaked gauze and cover with sterile dressing. The researcher starts by evaluating diabetic foot ulcer healing by using the DMIST scale and classification according to the Meggitt-Wagner classification system for DFU as a pre-test evaluation procedure before the application of the intervention. The ulcer is then cleaned and irrigated with normal saline. The ulcer was irrigated with 1-5% apple cider vinegar, and then the wound was cover with sterile dressings.

Apple cider vinegar was examined to ensure the appropriate concentration for dressing diabetic foot ulcers. The examination process was carried out by an assistant professor of organic chemistry at the College of Nursing, Al-Ameed University (Appendix A-V), and examined by specialists in the laboratories of the Iraqi Biotechnology Company in Basra Governorate to ensure the toxicity rate on human cells. The results of the examination showed that apple cider vinegar was safe for human cells at this concentration (Appendix A-IV). The patients were followed up on by the researchers once a day to ensure the patient perform ulcer cleansing with normal saline, dressing the wound with apple cider vinegar-soaked gauze and cover with sterile dressing and. The follow-up strategy involved creating communication groups on social media services (WhatsApp and Telegram) and using the phone to make follow-up calls by communicating with patients through (SIM-card). During this follow-up, the researchers monitored the patient's adherence and responses to the intervention. Patients in the control group just received the routine care provided to all patients in the study setting. The data collection process was carried out from January 12th to April 19th, 2023. The ulcer in both groups was evaluated every week for 21 days to identify the degree of healing.

3.7.2. The study instruments:

The researcher employed a suitable questionnaire with three elements to accomplish the goals of the study:

3.7.3.1. First part (Socio-demographic data and clinical information):

This section provides patient sociodemographic and clinical information, such as ages, genders, marital status, educational level, residency, occupation, smoking status, history of diabetes diagnosis, type of diabetes, type of treatment used, chronic diseases, duration of diabetic foot ulcer disease, Ankle-brachial pressure index ratio, and cumulative sugar test (HbA1c).

3.7.3.2. Second part (Meggitt-Wagner classification system for diabetic foot ulcers):

A tool to determine the degree of diabetic foot ulcers designed by Meggitt & Wagner (Monteiro-Soares et al, 2020). This scale includes six grades that can measure the degree of foot ulcers (from 0 to 5 grades) according to the severity of the ulcer. The degree is 0 for intact skin, 1 for superficial ulcers, 2 for ulcers that penetrate tendon or joint capsules, 3 for lesions affecting deeper tissues, 4 for forefoot gangrene, and 5 for whole foot gangrene affecting more than two thirds of the foot.

3.7.3.3. Third part (diabetic foot ulcer healing scale):

A DMIST scale for measuring the healing of diabetic foot ulceration will be use, it was designed by Oe et al., (2020) this scale consists of seven domains: depth, maceration, inflammation/infection, size, tissue type of the wound bed, type of wound edge, and tunneling/undermining. The term "DMIST" was chosen for this scale using the first letters of the seven domains, if total points of the score is (0-11), the healing rate is (good), if the total points are (12-23), the healing rate is (medium), and if the total points are (>23), the healing rate is weak or late.

3.8. Evaluating the validity and reliability of the instruments: **3.8.1.** Study instrument validation:

The instrument validation describes how well it captures or measures the phenomenon under study. The validation process is the outcome of research. The level to which an experimental study validates a hypothesis is called the degree of hypothesis examination. support for the study's theoretical foundation and premise (Gray et al., 2016). The study instrument and interventional procedure have been revised by a panel of 17 specialists. The study instrument's content, simplicity, relevance, style, and application were all requested to be evaluated by each expert participant.

3.8.1.1. The content validation:

The content validation defined as the relationship and representation of the targeted construct in the questionnaire items for the purpose of a specific evaluation (Yusoff, 2019). Using this reference, the researcher carried out content validation and a content validity index. Both diabetic foot ulcer healing scale and Meggitt-Wagner classification system for diabetic foot ulcers. The back translation model developed by Brisilin translated the tool into Arabic. The following actions were done in order to implement the content validity process:

1) Creating the validation based on the evaluation of experts who had a good knowledge of the procedure and expectations.

2) The researcher gave questions to ten experts who each had more than ten years of professional experience in their respective fields. These experts included three from the University of Baghdad's college of nursing, one from the University of Kerbela's college of nursing, one from the University of Babylon's college of nursing, two from the University of Kufa's college of nursing, one expert from the college of nursing/ University of Warith Al-Anbiyaa, one from the College of Nursing at the University of Al-Ameed, and one from the College of Nursing at Al-Safwa University College.

3) The content validity process involved face-to-face meetings between researcher and experts as well as the online distribution of a questionnaire form to the experts.

4) The experts were given the review items in a clear manner, and they scored each one and offered comments on some of them, which the researcher took into account. The expert-provided ratings on each independent item were calculated using appropriate scales.

5)Calculate the content validity index (CVI) before concluding.

diabetic foot ulcer healing scale (DMIST): There were ten specialists. There were (10,9,10,10,9,10,10) experts who agreed on each question. Each item had a (1,0,1,1,0,1,0,1) universal agreement (UA). Item Level Content Validity Index (I-CVR) values for each item were (1,0.9,1,1,0.9,1 and 1). This scale's S-CVI-Ave score was 9.74, which is within the allowed range for the Content Validation Index (CVI). Scale-Level Content Validity Index Based on the Universal Agreement Method, or S-C.VI.UA, was defined as having a value of (0.71) (Yusoff, 2019). According to Appendix J-II, the proportion of every item that 10 experts agreed were relevant was on average (1.83).

Meggitt-Wagner classification system for diabetic foot ulcers: Ten specialists were present. The number of experts that agreed on each issue was (10,10,9,9,10,10,10). There was (1,1,0,1,1,1) universal agreement (UA) for each item. Item Level Content Validity Index (I-CVR) values were (1,1,0.9,1,1,1 and 1) for each item. The scale's S-CVI-Ave (Levels of Content Validation Index (CVI) Based on an Average Method) value was 9.3, and the CVI considered this value acceptable. S-CVI-UA, or Scale-

Level Content Validity Index Based on the Universal Agreement Method, was defined as having a value of (0.83) (Yusoff, 2019). The proportion of all elements that were considered significant on average by the 10 experts was (0.98) (Appendix J-II).

3.8.1.2. Face validity:

Face validity is the degree to which test takers interpret an instrument's and its items' content as relevant to the field in which the instrument is being utilized. Additionally, according to some studies, face validity is the extent to which raters' opinions about an assessment instrument's items are evaluated in terms of whether or not they are suited to the desired concept and evaluation objectives. The test takers themselves, non-professional users who are interpreting test findings, and the general public make up the face validity raters (Yusoff, 2019). There are six steps of response validity process as follow:

The response validity procedure consists of the following six steps:

1-The first phase involved preparing appropriate replies for raters who understood the procedure and had a clear idea of what to anticipate.

2-The researcher distributed questionnaires to seven experts with ten years or more of relevant professional experience. These experts included (2) faculty members from the College of Nursing at the University of Kerbala, (1) from the Imam Al-Hassan Center for Endocrinology and Diabetes, (1) from the College of Nursing at the University of Al-Ameed, and (3) from the College of Nursing at Al-Safwa University College.

3-The response validity procedure, which can be done using an online or face-to-face evaluation approach.

4-The panel of raters received the domain of the objects at this point. Before providing their evaluation of these things, reviewers were requested to do so. Reviewers are asked to provide a written critique in order to make each thing more understandable and clearer .

5-The reviewers were requested to provide the scores for all things after thoroughly reviewing each item. The reviewers then provided ratings of replies to the researcher.

6-The Face Validity Index (FVI) came in two different forms: I-FVI for the items and S-FVI for the scale and items. percentage of reviewers (S-FVI/UA) who completed comprehension measures and gave it a three or four on the clarity scale. The Face Validity Index (FVI) was computed in this final step: **diabetic foot ulcer healing scale (DMIST):** There were 7 raters in all. There was consensus among the raters for each question (7, 7, 7, 7, 7, 7, and 6). For each item, there was universal agreement (UA), which was (1, 1, 1, 1, 1, and 0). Item Face Validity Index (I-FVI) values were 1, 1, 1, 1, 1, and 0.8 for each item. According to Yusoff (2019), the S-FVI average of this scale was (0.97), which was suitable for FVI. The S-FVIUA was (0.85). The average percentage for the seven experts' evaluations of the item's understanding and clarity was (0.97) (Appendix J-II).

Meggitt-Wagner classification system for diabetic foot ulcers: There were seven raters in all. There was consensus among the raters for each question (7, 7, 7, 7, 7, and 7). For every item, there was (1, 1, 1, 1, 0, and 1) universal agreement (UA). Item Face Validity Index (I-FVI) values were (1, 1, 1, 1, 0.8, and 1) for each item. According to Yusoff (2019), the S-FVI average of this scale was (0.97), which was suitable for FVI. The S-FVIUA was (0.83). The average percentage for the seven experts' evaluations of the item's understanding and clarity was (0.97) (Appendix J-III).

3.8.2. Pilot Study:

Department of Health in Kerbala. The researcher conducted a pilot study on 8 patients who satisfied the same criteria as the research sample from 16 January to 28January at the Imam Al-Hassan Center for Endocrinology and Diabetes in Holy Kerbala city. Purposive non-random sampling was used to gather it. The original research samples were not included in the pilot study samples.

3.8.2.1. The aims of the pilot study are to:

1. To test the feasibility and to determine the time required to fill the questionnaire.

2. To assess the clarity and comprehensiveness of the content of the questionnaire by the participants.

3. To find out the reliability of the questionnaire.

4. To detect the total time required for each patient.

3.8.2.2 .Findings from the pilot study :

1. Indicate that study instrument was clear and understandable.

2. The socio-demographic and clinical information sections, along with the three scales, took between 15 and 20 minutes to complete.

3.8.3. Reliability of the questionnaire format items:

The questionnaire is a significant and widely used instrument for information gathering. The degree to which a phenomenon measurement provides a fair and consistent result is referred to as reliability. One of the dependability interests is repeatability. For instance, a scale or test is deemed dependable if repeated measurements using it under consistent conditions result in the same conclusion. Testing for reliability is essential since it deals with how well a measuring questionnaire's components work together (Taherdoost, 2016). The results calculation in table (3-1) demonstrates that the instrument was effective and significant to the research topic of (Effect of Using Apple Cider Vinegar on Foot ulcer Healing of Diabetic Patients). The accepted coefficient's reliability of the used study questionnaire regarding internal consistency (Alpha Cronbach) is 0.70.

 Table (3-1): Internal consistency of a studied questionnaire as measured

 by the reliable coefficient (Alpha Cronbach)

Reliable coefficient of researching questionnaire	Alpha (Cronbach - α)	Standard lower value	Assessment
DMIST	0.79	0.70	Verified
Meggitt-Wagner system	0.71	0.70	Verified

3.9. Data Collection:

The researchers independently measured the degree of diabetic foot ulcer healing and the grade of the ulcer and recorded those values in the study instrument as part of the data collecting process. Data for the research sample were gathered between January 30 and April 19, 2023. As illustrated in figure (3-2), data were gathered four times every week for 21 days.

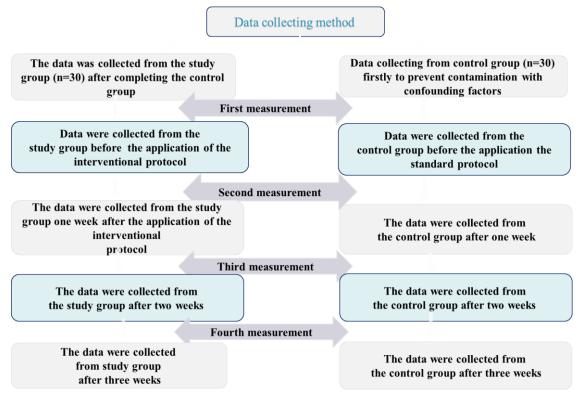


Figure (3-2): Flowchart of the data collection method

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3.110 Rating and scoring:

The following patterns resulted from the data rating and scoring: **3.10.1 Ankle brachial index (ABI):**

In this test, the blood pressure in the upper and lower limbs is compared. It is computed by subtracting the blood pressure in the arm from the blood pressure in the ankle artery.

Ankle brachial index ABI=ankle systolic pressure /arm systolic pressure Whereas ABI result was categorized as follows:

Normal =1.0-1.4

Acceptable=0.9-1.0

Some arterial disease =0.8-0.9

Moderate arterial disease =0.5-0.8

Severe arterial disease =less than 0.5.(Crawford et al., 2016)

3.10.2 Rating and scoring for glycated hemoglobin (HbA1c):

A blood test called HbA1c indicates how effectively controlled blood sugar during the last three months. It calculates the amount of hemoglobin that is coated with glucose, a protein found in red blood cells that transports oxygen. the results of the HbA1 test were classed as follows:

Normal =below 5.7%

Prediabetes =5.7%-6.4%

Diabetes =6.5% or higher. (Sherwani, et al., 2016)

3.10.3 Rating and scoring for diabetic foot ulcer healing scale:

The development of a monitoring instrument for the diabetic foot ulcer (DFU) wound-healing process. Seven domains are included in it: depth, maceration, inflammation/infection, size, tissue type of the wound bed, type of the wound edge, and tunneling/undermining.

The result of measurement can be categorized according to:

If the total of the points of the score is (0-11), the healing rate is (good).

If the total points are (12-23), the healing rate is (medium).

If the total points are (>23), the healing rate is (weak or late).

3.10.4 Rating and scoring for Meggitt-Wagner classification system for diabetic foot ulcers):

A tool to determine the degree of diabetic foot ulcers designed by this scale includes six grades that can measure the degree of foot ulcers (from 0 to 5 grades) according to the severity of the ulcer.

The six grades include:

1-Skin that is undamaged is considered to be degree 0.

2-Surface ulcer is referred to as degree 1.

3-Degree 2 refers to an ulcer that penetrates the joint capsule or a tendon.

4-Deeper tissue injuries are classified as degree 3 lesions.

5-Forefoot gangrene is described as degree 4.

6-Whole foot gangrene affecting more than two thirds of the foot is classified as degree 5 (Monteiro-Soares et al, 2020).

3.11 Statistical data analysis:

The following descriptive and inferential statistical analysis techniques were used to analyze data using the application SPSS Version 26:

3.11.1. Descriptive statistical analysis:

Include frequencies and percentages (%) in descriptive statistical analysis. The value of the percentages (%) was determined using the following formula: % is equal to (Frequency/Sample Size) x 100.

3.11.2. Inferential statistical analysis

3.11.2.a. Researcher can assess if the means of several measurements collected from the same subject are similar or different using the analysis of variance (ANOVA) statistic, sometimes referred to as the repeated-measures analysis of variance (RMANOVA).

3.11.2.b The statistical method employed to assess the connections between the independent variables and the interventional procedure's influence was chi-square analysis.

3.11.2.c Significance levels According to Abd El Aziz et al. (2016), a probability value of 0.05 was deemed statistically significant. According to Al-Kerety (2017), the approved probability range for significance values was between 0.05% and > 0.01%, with 0.01% denoting results that are statistically highly significant. According to Nieswiadomy (2012), the significance level is "the probability value of rejecting a null hypothesis when it is true".

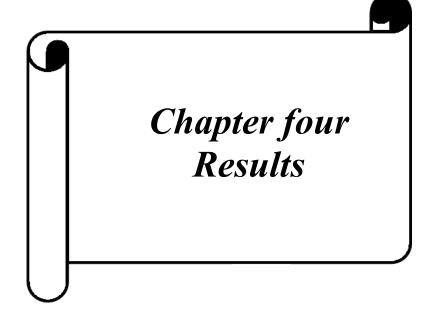
3.12 Limitations:

This study has a number important limitations, including:

1. Due to the nature of the topic being examined, there was a scarcity of samples during sample collecting. Due to the limited number of patients, it is clear that a bigger sample size will be needed for future research.

2. Because the research is distinctive and unique, the researcher experienced a shortage of references. The absence of information in this article about how apple cider vinegar affects the healing of diabetic foot ulcers made it extremely difficult to compare the results.

3. It took a long time to follow up on developments for each research group since each patient was measured using the study equipment every week for three weeks.



Chapter four

Results

In this chapter, the researcher gives detailed findings generated from thorough data analysis, which effectively correlate to the previously mentioned research objectives. The findings have been painstakingly organized and presented in this manner to aid in the comprehension of the research findings.

Table (4-1): Distribution of participants according to their socio-demographic characteristics:

		Con	trol group	Stud	y group	n-			
Socio-dem	ographic characteristics		n=30		n=30	p- Value			
		F	%	F	%	, and			
	20-39 years	6	20.0	3	10.0				
Age groups	40 - 59 years	20	66.7	22	73.3	0.354			
	≥60 years	4	13.3	5	16.7				
	M±SD			49.2	±9.73				
Gender	Male	23	76.7	22	73.3	0.770			
	Female	7	23.3	8	26.7				
	Single	2	6.7	1	3.3				
Marital status	Married	23	76.7	23	76.7	0.647			
	Widower	4	13.3	5	16.7				
	Divorced	1	3.3	1	3.3				
	Does not read or write	5	16.7	3	10.0				
	Reads and writes	6	20.0	4	13.3				
Educational	Elementary school and	16	53.3	22	73.6	0.680			
Level	Middle school								
	Preparatory school	2	6.7	1	3.3				
	Collage or above	1	3.3	3	10.0				
Residence	Urban	26	86.7	26	86.7	1.00			
Restuctive	Rural	4	13.3	4	13.3	1.00			
	Gainer	15	50.0	14	46.7				
Occupation	government employee	5	16.7	6	20.0	0.839			
occupation	Retired	3	10.0	2	6.7	0.002			
	House wife	7	23.3	8	26.7				
	Yes	10	33.3	7	23.3				
Smoking	No	14	46.7	14	46.7	0.296			
	Previously	6	20.0	9	30.0				

f. (frequency); % (percentage)

66.7% of patients in control group aged of 40 - 59 years, and 73.3% of them in study group with mean of age are 49.2 years and standard deviation is 9.73 years. Regarding gender of participants, 76.7% and 73.3% of them are male in control and study group respectively as mentioned in table (4-1).

A 76.7 % of patients are male in two groups as a marital status. As educational level 53.3% and 73.6% of patients had elementary school in control and study group respectively. The same percentage of urban living between control and study group is 86.7%. A 50% of patients in control group are gainer occupation and 46.7% of patients in study group as well as. A 46.7% of patients in two groups are not smoked.

() / / / /	ποαιιοπ ο <u>ς</u> ραπιειραι	Control	0	Study	
Clin	nical data	n= 3	80	n =	
		F	%	F	%
	<5 years	0	0	3	10.0
Duration of DM	5-9 years	9	30.0	6	20.0
	10- 14 years	14	46.7	8	26.7
	15 years and above	7	23.3	13	43.3
Type of DM	Type 1	1	3.3	2	6.7
Type of DM	Type 2	29	96.7	28	93.3
	Diet	0	0	2	6.7
Type of treatment used	Hypoglycemic tablets	14	46.7	14	46.7
	Insulin	16	53.3	14	46.7
CI .	Heart disease	7	23.3	9	30.0
Chronic	kidney failure	1	3.3	2	6.7
diseases	None	22	73.3	19	63.3
D	< 4 months	29	96.7	25	83.3
Duration of	4-6 months	1	3.3	3	10.0
diabetic foot	≥7 month	0	0	2	6.7
	Normal	13	43.3	12	40.0
	Acceptable	8	26.7	7	23.3
Ankle-brachial	Some arterial disease	7	23.3	5	16.7
pressure index ratio	Moderate arterial disease	1	3.3	5	16.7
	Severe arterial disease	1	3.3	0	0
	Normal	1	3.3	0	0
HbA1c	prediabetes	23	76.7	19	63.3
	Diabetes	6	20.0	11	36.7

Table (4-2): Distribution of participants according to their clinical data:

f. (frequency); % (percentage)

Regarding the clinical data, as shown in table (4-2) the result exposed that 46.7% of patients in control group had DM for 10- 14 years ago while 43.3% of them in study group had DM for 15 years and above. A 96.7% and 93.3% of patients in control and study group respectively have type 2DM.

Concerning treatment of DM these results reported that 53.3% of patients in control group and 46.7% of them in study group treated with insulin. 73.3% and 63.3% of patients in control and study group respectively did not have any chronic diseases other than DM. A 96.7% of patients in control group and 83.3% of them in study group are newly in diabetic foot (< 4 month ago).

Regarding ankle-brachial pressure index ratio, 43.3% and 40.0% of patients in control and study group respectively, had 1.0-1.4mmhg. A76.7% of patients in control group 63.3% of them in study group had reading of HbA1c is (5.7 to 6.4).

Control group Study group Measure Measure Measure Measure Measure Measure Measure Measure Variables 2 2 4 3 4 3 f. f. f. f. % f. % % % f. % f. % f. % % Diabetic **Degree0** 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 foot 0 0 0 0 0 0 0 0 0 0 0 23.3 19 63.3 Degree1 0 7 ulcer grade 23 3.3 3.3 93.3 93.3 76.7 Degree2 0 0 0 0 28 28 11 36.7 1 1 27 90.0 86.7 27 90.0 6.7 **Degree3** 90.0 27 26 2 2 6.7 0 0 0 0 10.0 3 10.0 2 0 Degree4 3 3 10.0 6.7 0 0 0 0 0 0 0 0 Degree5 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 Good 5 0 0 0 16.7 0 0 6.7 16 53.3 80.0 0 0 0 2 24 Level of diabetic 14 21 70.0 21 70.0 22 73.3 20 20 66.7 23 76.7 46.7 Moderate 66.6 6 20.0 foot ulcer **Bad** or healing 9 30.0 30.0 26.7 5 16.7 10 33.3 16.7 9 8 5 0 0 0 0 late

Table (4-3): Distributions of diabetic foot ulcer healing and diabetic foot ulcer grade for the study and control groups:

f: frequency; %: percentage; Measure 1: before implementing the intervention; Measure 2: one week after implement intervention, Measure 3: two weeks after implement intervention; Measure 4: three weeks after implement intervention.

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At four different measurement intervals, Table (4-3) compares diabetic foot ulcer grade and diabetic foot ulcer healing level between the study and control groups. The results show significant disparities in the outcomes observed in the two groups over time.

At the third measurement period, 53.3% of the patients in the study group had a good level of diabetic foot ulcer healing, but none of the patients in the control group had such progress. Furthermore, the fourth measurement period results show a significant improvement in the study group, with 80% of patients displaying good diabetic foot ulcer healing. In the control group, only 16.7% of patients had a similar good reaction, as illustrated in figure (4-6).

In terms of diabetic foot ulcer grade, the third measurement period revealed that 76.7% of the patients in the study group had "Ulcer penetrating to tendon or joint capsule," while 23.3% had "Superficial ulcer." In comparison, 86.7% of patients in the control group were classified as having "Lesion involving deeper tissues."

Moving on to the fourth measurement period, it was discovered that the study group improved in diabetic foot ulcer grade. In particular, 36.7% of patients in the research group were defined as having "Ulcer penetrating to tendon or joint capsule," whereas 63.3% were diagnosed as having "Superficial ulcer." Meanwhile, the control group demonstrated a notable proportion of 90% of patients with "Lesion involving deeper tissues."

Table (4-4): The difference between the mean of diabetic foot ulcer healing and diabetic foot ulcer grade results of the Control and Study group:

Variables		N	Mean	Std. Deviation	Mean Difference	t	Sig.
Diabetic foot ulcer healing	Control group	30	2.21	.434	. 441 4.11		.000
	Study group	30	1.77	.395	. 441	4.11	.000
Diabetic	Control group	30	4.07	.301	.258	3.53	.001
foot ulcer grade	Study group	30	3.81	.262	.238	5.55	.001

It is clear from the results of table (4-4) that the mean of diabetic foot ulcer healing of control group is (2.21) with a standard deviation of (.43417) and the mean of diabetic foot ulcer healing of study group is (1.77) with a standard deviation of (.395) with mean difference is (.44167). The result of the t-test (4.11) with a probability value of (0.000) is smaller than the level of significance (0.05). Therefore, decided that there are statistically significant differences at the level of significance (0.05) between the mean of diabetic foot ulcer healing of control group and study group in favor of patients of the study group and this is mentioned in figure (4-8).

This study indicate that the mean of diabetic foot ulcer grade of control group is (4.07) with a standard deviation of (.301) and the mean of diabetic foot ulcer grade of study group is (3.81) with a standard deviation of (.262) with mean difference is (.258). The result of the t-test (3.53) with a probability value of (0.001) is smaller than the level of significance (0.05). Therefore, reported that there are statistically significant differences at the level of significance (0.05) between the mean of diabetic foot ulcer grade of control group and study group in favor of patients of the study group, shown in figure (4-9).

Table (4-5): Pairwise comparisons of the diabetic foot ulcer healing readings under the effect of using apple cider vinegar on wounds healing between the four measurements periods among the study group:

(I) time	(J) time	Mean Difference (I-J)	Std. Error	p-value	Sig.
1	2	.241	.081	.006	HS
	-3	.862	.065	.000	HS
	4	1.138	.082	.000	NS
2	1	241	.081	.006	HS
	3	.621	.092	.000	HS
	4	.897	.058	.000	HS
3	1	862	.065	.000	HS
	2	621	.092	.000	HS
	4	.276	.084	.003	HS
4	1	-1.138	.082	.000	NS
	2	897	.058	.000	HS
	3	276	.084	.003	HS

*Based on estimated marginal means the mean difference is significant at the 0.05 level. NS: Non-Significant (P value >0.05); S: Significant (P value $\leq 0.05 - > 0.01$); HS : Highly Significant (P value ≤ 0.01).(I) time = The measurement to which it is compared. (J) time = Measurements that compare to the main measurement.

The pairwise comparisons in table(4-5) shows that there was a highly significant difference in diabetic foot ulcer healing readings under the effect of using apple cider vinegar on wounds healing between the periods of the first measure (before application of dressing with using apple cider vinegar) and second measure (one week after application of dressing with using apple cider vinegar) at P-value of 0.006, it represents that the diabetic foot ulcer healing mean before applying the interventional protocol was greater than one week after applying it, which can be seen from mean difference (I-J) column.

A highly significant difference in diabetic foot ulcer healing readings between the periods of the first measure and third measure (two weeks after application of dressing with using apple cider vinegar) at P-value of 0.000, it represents that the diabetic foot ulcer healing mean before applying the interventional protocol was greater than two weeks after applying it, which can be seen from mean difference (I-J) column. Also, there was also a highly significant difference in diabetic foot ulcer healing readings between the periods of the first measure and fourth measure (three weeks after application of dressing with using apple cider vinegar) at P-value of 0.000, it represents that the diabetic foot ulcer healing mean before applying the interventional protocol was greater than three weeks after applying it, which can be seen from mean difference (I-J) column.

Table (4-6): Pairwise comparisons of readings under the effect of using apple cider vinegar on diabetic foot ulcer grade between the four measurements periods among the study group:

(I) time	(J) time	Mean Difference (I-J)	Std. Error	p-value	Sig.
1	2	.000	.000		
	3	.310	.087	.001	HS
	4	.724	.084	.000	HS
2	1	.000	.000		
	3	.310	.087	.001	HS
	4	.724	.084	.000	HS
3	1	310	.087	.001	HS
	2	310	.087	.001	HS
	4	.414	.093	.000	HS
4	1	724	.084	.000	HS
	2	724	.084	.000	HS
	3	414	.093	.000	HS

*Based on estimated marginal means the mean difference is significant at the 0.05 level. NS: Non-Significant (P value >0.05); S: Significant (P value $\leq 0.05 - > 0.01$); HS : Highly Significant (P value ≤ 0.01).(I) time = The measurement to which it is compared. (J) time = Measurements that compare to the main measurement

The pairwise comparisons table above shows that there was no statistic significant difference in diabetic foot ulcer grade readings under the effect of using apple cider vinegar on wounds healing between the periods of the first measure (before application of dressing with using apple cider vinegar) and second measure (one week after application of dressing with using apple cider vinegar), it represents that the mean diabetic foot ulcer grade before applying the interventional protocol was equal than one week after applying it, which can be seen from mean difference (I-J) column. While there was a highly significant difference in diabetic foot ulcer grade readings between the periods of the first measure and third measure (two weeks after application of dressing with using apple cider vinegar) at P-value of 0.001, it represents that the diabetic foot ulcer grade mean before applying the interventional protocol was greater than two weeks after applying it, which can be seen from mean difference (I-J) column. Also, there was also a highly significant difference in diabetic foot ulcer grade readings between the periods of the first measure and fourth measure (three weeks after application of dressing with using apple cider vinegar) at P-value of 0.000, it represents that the diabetic foot ulcer grade mean before applying the interventional protocol was greater than three weeks after applying it, which can be seen from using apple cider vinegar) at P-value of 0.000, it represents that the diabetic foot ulcer grade mean before applying the interventional protocol was greater than three weeks after applying it, which can be seen from mean difference (I-J) column.

Socio-dei	nographic	Levels	of diabetic for healing	oot ulcer	χ2			
charac	teristics	Good %	Moderate %	Bad or late %	χ2 – value	p- value	Level of Sig.	
	20-39 years	33.3	66.7	0				
Age	40 - 59 years	68.1	31.9	0	10,426	.236	NS	
	≥60 years	60	40	0				
Gender	Male	63.6	36.4	0	5,162	.271	NS	
Gender	Female	62.5	37.5	0	5,102	.271	115	
	Single	0	100	0				
Marital	Married	78.3	21.7	0	19,026	.048	S	
status	Widower	20	80	0	17,020		~	
	Divorced	0	100	0				
	Does not read or write	33.3	66.7	0				
	Reads and writes	75	25	0				
Educational	Elementary school	61.5	38.5	0	13.547	.375	NS	
level	Middle school	66.7	33.3	0				
	Preparatory school	66.7	33.3	0				
-	Collage or above	100	0	0				
Residence	Urban	61.5	38.5	0	14,753	753 .005	S	
	Rural	75	25	0	,. 00		2	

Table (4-7): Association between patients' levels of diabetic foot ulcer healing with their socio-demographic characteristics posttest:

Chapter Four: Result

							0/	
	Earner	57.1	42.9	0				
Occupation	government employee	83.4	16.6	0	9,065	.697	NS	
	Retired	50	50	0				
	House wife	62.5	37.5	0				
	Yes	57.2	42.8	0				
Smoking	No	71.4	28.6	0	7,660	.467	NS	
	Previously	55.5	44.5	0				

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Sig.: significancy, S: significance, NS: non significance, X²: chi-square

Outcomes of chi-square test from this table shows that there is a statistically significant difference between levels of diabetic foot ulcer healing and marital status; since chi-square had p-value (0.048) less than (0.05), that means that levels of diabetic foot ulcer healing differed by marital status ($\chi^2 = 19.026$, p = 0.048). All single patients were in moderate level of diabetic foot ulcer healing and 78.3% of married patients had good level of diabetic foot ulcer healing, while 80% of widower and 100% of divorced had moderate level of diabetic foot ulcer healing.

Result if this table also exposed that there is a statistically significant difference between levels of diabetic foot ulcer healing and residence; since chi-square had p-value (0.005) less than (0.05), that means that levels of diabetic foot ulcer healing differed by residence ($\chi 2 = 14.753$, p = 0.048). A 61.5% of patients who are living in rural and 75% of them who are living in urban had good level of diabetic foot ulcer healing.

Table (4-8): Association between patients' diabetic foot ulcer grade with patients' socio-demographic characteristics posttest:

Socio-demographic characteristics			diabetic foot ulcer grade							χ2		
		Degree0	Degree1	Degree2	Degree3	Degree4	Degree5	χ2 - value	p- value	Level of Sig.		
	20-39 years	0	0	33.3	66.7	0	0					
Age	40 - 59 years	0	0	68.2	31.8	0	0	7,06	.315	NS		
	≥60 years	0	0	60	40	0	0					
Gender	Male	0	0	54.5	45.5	0	0	3,235	.357	NS		
Genuer	Female	0	0	87.5	12.5	0	0	3,233	.557			
	Single	0	0	0	100	0	0		.534			
Marital	Married	0	0	69.5	30.5	0	0					
	Widower	0	0	60	40	0	0	8.000		NS		
Status	Divorced	0	0	0	100	0	0					
Educations	Does not read or write	0	0	66.7	33.3	0	0					
Educational level	Reads and writes	0	0	75	25	0	0	19.85 .048	.048	S		
	Elementary school	0	0	61.6	38.4	0	0					

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Chapter Four: Result

-						69				
	Middle school	0	0	66.7	33.3	0	0			
	Preparatory school	0	0	61.6	38.4	0	0			
	Collage or above	0	0	0	100	0	0			
Residence	Urban	0	0	61.6	38.4	0	0	21.22	.050	S
Residence	Rural	0	0	75	25	0	0	- 21.23		3
	Gainer	0	0	50	50	0	0			
Occupation	government employee	0	0	66.7	33.3	0	0	11,123	.267	NS
_	Retired	0	0	50	50	0	0			
	House wife	0	0	66.7	33.3	0	0			
	Yes	0	0	85.7	14.3	0	0			
Smoking	No	0	0	64.3	35.7	0	0	3,786	.706	NS
	Previously	0	0	63.3	36.7	0	0			

Sig.: significancy, S: significance, NS: non significance, X²: chi-square

Results of chi-square test from table (4-8) shows that there is a statistically significant difference between diabetic foot ulcer grade and educational level; since chi-square had p-value (0.048) less than (0.05), that means that levels of diabetic foot ulcer grade differed by educational level ($\chi^2 = 19.85$, p = 0.048). 75% of patients who reads and writes, 61.6%

of them who had elementary school, 66.7% of them had preparatory school, and 61.6% of them that had middle school were in (degree2) of diabetic foot ulcer grade. While all patients who had collage or above were in (degree3) of diabetic foot ulcer grade. Also exposed that there is a statistically significant difference between of diabetic foot ulcer grade and residence; since chi-square had p-value (0.050) equal than (0.05), that means that of diabetic foot ulcer grade differed by residence ($\chi 2 = 21.23$, p = 0.050). A 61.6% of patients who are living in rural and 75% of them who are living in urban had (degree2) of diabetic foot ulcer grade.

		Level	s of diabetic foo healing	ot ulcer		χ2		
clini	cal data	Good %	Moderate %	Bad or late %	χ2- value	p- value	Level of Sig.	
	<5 years	100	0	0				
Duration of	5-9 years	83.3	16.7	0				
DM	10- 14 years	62.5	37.5	0	9,388	.669	NS	
	15 years and above	46.2	53.8	0				
Type of DM	Type 1	50	50	0	1,684	.794	NS	
	Type 2	64.2	35.8	0	1,004	.//+	110	
Type of	Diet	50	50	0		.071		
treatment used	Hypoglycemic tablets	64.3	35.7	0	14,449		NS	
	Insulin	63.3	36.7	0				
Chronic	Heart disease	22.2	77.8	0				
diseases	kidney failure	50	50	0	20,456	.009	S	
	None	84.2	15.8	0				
Duration of	< 4 months	64	36	0		.207		
diabetic	4-6 months	66.7	33.3	0	10,907		NS	
foot	7 month and above	50	50	0				
	Normal	83.3	16.7	0				
Ankle-	Acceptable	85.7	14.3	0				
brachial pressure	Some arterial disease	40	60	0	25,136	.067	NS	
index ratio	Moderate arterial disease	20	80	0				
	Severe arterial disease	0	0	0				
HbA1c	Normal	0	0	0				
IIDAIC	Prediabetes	84.2	15.8	0	10,560	.032	S	
Cia air	Diabetes	27.3	72.7	0				

Table (4-9): Association between levels of diabetic foot ulcer healing with patients' clinical data posttest:

Sig.: significancy, S: significance, NS: non significance, X²: chi-square

Outcomes of chi-square test from table (4-9) shows that there is a statistically significant difference between levels of diabetic foot ulcer healing and chronic diseases; since chi-square had p-value (0.009) less than (0.05), that means that levels of diabetic foot ulcer healing differed by chronic diseases (χ^2

= 20.456, p = 0.009). 77.8% of patients who had heart disease, 50% of them who had kidney failure, while 84.2% of them who had no any disease were had good level of diabetic foot ulcer healing. Also exposed that there is a statistically significant difference between levels of diabetic foot ulcer healing and HbA1c reading; since chi-square had p-value (0.032) less than (0.05), that means that levels of diabetic foot ulcer healing differed by HbA1c reading ($\chi 2 = 10.560$, p = 0.032). An 84.2% of patients who had HbA1c reading of (prediabetes) had good level of diabetic foot ulcer healing, while 72.7% of them who had HbA1c reading of (diabetes) had moderate level of diabetic foot ulcer healing.

	clinical data		Diabo	etic foot ulo	cer grade (%	%)		X ²		
cim	ical data	Degree0	Degree1	Degree2	Degree3	Degree4	Degree5	X ² - value	p- value	Level of Sig.
	<5 years	0	0	66.7	33.3	0	0			
Duration	5-9 years	0	0	83.3	16.7	0	0			
of DM	10- 14 years	0	0	62.5	37.5	0	0	5,865	.753	NS
	15 years and above	0	0	53.9	46.1	0	0			
Type of	Type 1	0	0	50	50	0	0	1,684	.794	NS
DM	Type 2	0	0	64,2	35,8	0	0	1,004	.794	110
Type of	Diet	0	0	50	50	0	0	1,701	.945	
treatment	Hypoglycemic tablets	0	0	71,5	28,5	0	0			NS
useu	Insulin	0	0	57,1	42,9	0	0			
Chronic	Heart disease	0	0	33.3	66.7	0	0			
diseases	kidney failure	0	0	0	100	0	0	13.704	.003	S
	None	0	0	84.2	15.8	0	0			
Duration	< 4 months	0	0	64	36	0	0			
of diabetic	4-6 months	0	0	100	0	0	0	15.600	.016	S
foot	\geq 7 months	0	0	0	100	0	0			
Ankle- brachial	Normal	0	0	0	100	0	0			
pressure index	Acceptable	0	0	88.3	11.7	0	0	27.200	.007	S
ratio	Some arterial disease	0	0	71.4	28.6	0	0			

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						— 74				
	Moderate arterial disease	0	0	60	40	0	0			
	Severe arterial disease	0	0	20	80	0	0			
HbA1c	Normal	0	0	0	0	0	0	10,519	.015	S
	Prediabetes	0	0	84.2	15.8	0	0			
	Diabetes	0	0	27.3	72.7	0	0			

Sig.: significancy, S: significance, NS: non significance, X²: chi-square

Results of chi-square test from table (4-10) shows that there is a statistical significance difference between diabetic foot ulcer grade and chronic diseases; since chi-square had p-value (0.003) less than (0.05), that means that of diabetic foot ulcer grade differed by chronic diseases ($\chi^2 = 13.704$, p = 0.003). 66.7% of patients who had heart disease, 100% of them who had kidney failure had (degree3) of diabetic foot ulcer grade, while 84.2% of them who had no any disease had (degree3) of diabetic foot ulcer grade.

Regarding duration of diabetic foot, this table shows that there is a statistical significance difference between diabetic foot ulcer grade and duration of diabetic foot; since chi-square had p-value (0.016) less than (0.05), that means that of diabetic foot ulcer grade differed by duration of diabetic foot ($\chi 2 = 15.600$, p = 0.016). 64% of patients who had diabetic foot for period of < 4 month and 100% of them who had diabetic foot for period of 4-6 months had (degree2) of diabetic foot ulcer grade, while 100% of them who had diabetic foot for period of \geq 7 month had (degree3) of diabetic foot ulcer grade.

Concerning ankle-brachial pressure index ratio these results reported that there is a statistical significance difference between diabetic foot ulcer grade and Ankle-brachial pressure index ratio; since chi-square had p-value (0.007) less than (0.05), that means that diabetic foot ulcer grade differed by Anklebrachial pressure index ratio ($\chi 2 = 27.200$, p = 0.007). all patients who had d ankle-brachial pressure index ratio level (normal)had (degree3) of diabetic foot ulcer grade, while 88.3 % of them who had d ankle-brachial pressure index ratio level (acceptable)and 71.4 of them who had d ankle-brachial pressure index ratio level (some arterial disease) were suffering from (degree2) of diabetic foot ulcer grade.

Result of this table also exposed that there is a statistical significance difference between diabetic foot ulcer grade and HbA1c reading; since chisquare had p-value (0.015) less than (0.05), that means that of diabetic foot ulcer grade differed by HbA1c reading ($\chi 2 = 10.519$, p = 0.015). An 84.2% of patients who had HbA1c reading of (prediabetes) had (degree2) of diabetic foot ulcer grade, while 72.7% of them who had HbA1c reading of(diabetes) had (degree3) of diabetic foot ulcer grade.

Chapter Five

Discussion

Chapter five

Discussion

The fifth chapter gives a well-structured and systematic discussion of the data reported in the fourth chapter. The discussion is structured in such a way that it provides incisive insights into the research findings and their ramifications. It dives into the significance and relevance of the findings, drawing parallels with the research objectives and hypotheses. Furthermore, the discussion is backed by relevant literature and studies connected to the research issue, which enriches the analysis and reinforces the findings' reliability.

5.1 Discussion of socio-demographic data of the study and control groups:

The results of the present study showing that majority of the participants for each group (study and control) are aged of 40 - 59 years. The study also showed that most of the study sample are male in both control and study group. These findings come with agreement of these of Eltokhy, et al., (2016), They conducted an interventional study to evaluate using vinegar as a basic pseudomonas dressing infected wound at Faculty of Medicine, Al-Azhar University in Egypt. Their sample's gender was male more than female. This gender distribution breakdown sheds information on the representation of male and female participants in both groups, providing vital insights into the research population's demographic characteristics

In investigations by Rovan et al. 2017, and Stoekenbroek et al. 2017, shows that the majority of persons with diabetes were women, which contradicted the findings of the current study. In terms of marital status, around two-thirds of patients in both the control and research groups were married. Furthermore, almost one-third of the control group members had finished primary school certification, with a similar proportion in the study group. Furthermore, a sizable proportion of patients in both groups lived in cities.

In terms of occupation, around half of the patients in both the control and research groups worked as earner. Furthermore, approximately half of both groups' members stated that they did not smoke. The study's findings revealed a comparison between the study and the control groups. with homogeneous characteristics of age, gender, marital status, residency and smoking condition for both groups and these results didn't align with Polikandrioti, 2022 findings. The researcher observed that diabetes foot ulcers were highly correlated with both occupation (p=0.018), age (p=0.020), and marital status (p=0.016).

The results of the study showed a comparison between the study and the control group with homogeneous characteristics of age, gender, marital status, residency and smoking condition for both groups (Researcher).

5.2 Discussion the participants clinical data of study and control groups:

Through the assessment of the participants' clinical information, it was revealed that about a half of patients in the control group had infected with DM for whom with 10- 14 years before, while those in the study groups had DM for 15 years and above for a semi ratio. Similarly, Bekele et al., 2020 in their study which was performed in Ethiopia reveled that approximately half of the patients in the control group had had diabetic mellitus (DM) for 10 to 14 years before to the trial.

Participants in the study group, on the other hand, had had diabetes for at least 15 years. High ratios of patients in both control and study groups have respectively infected with DM type II. Concerning type of treatment used for DM, these results reported that more than a half of patients in control group and less than a half of them in study group treated with insulin. The majority of patients in control and study groups respectively did not have any chronic diseases other than DM this is going with Nasiri et al., 2015, who found that all the patients complaining diabetic foot ulcer are free from any chronic diseases.

On the other hand, Fernández-Montequín et al., 2007 demonstrated that the about 30% of the participants of the study were having a history of heart diseases. A high rate of patients in both control and study group has diabetic foot less than four months ago). Regarding ankle-brachial pressure index ratio, almost a half of patients in control and study groups had 1.0-1.4mmhg. More than two thirds of patients in control group and above a half of them in study group had HbA1c ranges of (5.7 to 6.4).

The researcher sees that the results of the study showed a convergence in proportions between the study and the control group data.

5.3 Discussion Distributions of level diabetic foot ulcer healing and diabetic foot ulcer grade for the study and control groups:

Analytical procedures show the different levels of diabetic foot ulcer healing and diabetic foot ulcer grade between the study and control groups. The results show that, at third measure on patients within the study group (two weeks after implement intervention) was in good level of diabetic foot ulcer healing, while there is no any patient in the control group, these results agree with Park et al., 2019. The results of the fourth measures (three weeks after implement intervention) indicate that majority of patients within the study group were in good level of diabetic foot ulcer healing measure facing little number of patients within the control group. In diabetic foot ulcer grade, the results of the third measure exposed that most of patients within the study group were in (degree2) and about a quarter of them in the (degree1), majority of them have (degree3) within the control group. Concerning the results in the fourth measure, results revealed that about a third of patients within the study group were in (degree2) and the other two thirds of them at the (degree1). A high ratio of them in (degree3) within the study group, as well as for those within the control group.

The researcher sees that application apple cider vinegar dressing on diabetic foot ulcer level of healing and grade of ulcer was effective.

5.4 Discussion of the difference between the mean of diabetic foot ulceration healing and diabetic foot ulceration grade results of the Control and Study groups:

The findings in Table demonstrate that the mean of diabetic foot ulcer healing levels within study group is higher than the mean of diabetic foot ulcer healing levels within control group. Also, the t-test when performed, value for the diabetic foot ulcer healing scores a high probability value of (0.000). This interprets the high effect of apple cider vinegar on wounds healing that was applied on within the study group patients. Those findings are supported with these of Al-Duboni, et al., (2015) study. They conducted an interventional study to evaluate the vinegar therapy's effectiveness in preventing bacterial development while treating diabetic foot ulcers in Diyala, Iraq. They came to the conclusion that vinegar therapy was related with decreased bacterial growth rates and was more successful and efficient at debriding non-healing foot and leg ulcers in diabetes patients than ongoing standard care.

Also, the results of table (4-4) showed that the mean of diabetic foot ulcer grade within study group is higher than the mean of diabetic foot ulcer grade within control group. The result of the t-test (3.539) with a probability value of (0.001) is smaller than the level of significance (0.05). Therefore, we reported that differences with the appropriate level of significance (0.05) are statistically significant between the mean of diabetic foot ulcer grade of control group and study group in favor of patients of the study group.

At Hospital University Sains Malaysia, Shukrimi et al. (2008) conducted control trial research to examine the effectiveness of honey and

povidone iodine as dressing solutions treating Wagner type II diabetic foot ulcers. They discovered that applying honey to wounds can help manage diabetic foot ulcers, speed up wound healing, and more effectively reduce edema and odor.

5.5 Discussion of comparisons of the diabetic foot ulcer healing readings under the effect of using apple cider vinegar on wounds healing between the four measurements periods among the study group:

Findings showed that there was a highly significant difference in diabetic foot ulcer curing readings under the effect of using apple cider vinegar on wounds healing between the periods of the first measure (before application of dressing with using apple cider vinegar) and second measure (one week after application of dressing with using apple cider vinegar). It represents that the diabetic foot ulcer curing score mean before applying the interventional protocol was greater than one week after applying it, which can be seen from mean difference in the table 4.

There was also a highly significant difference in diabetic foot ulcer curing score readings between the periods of the first measure and third measure (two weeks after application of dressing with using apple cider vinegar), it represents that the diabetic foot ulcer curing score mean before applying the interventional protocol was greater than two weeks after applying it. Also, there was also a highly significant difference in diabetic foot ulcer healing readings between the periods of the first measure and fourth measure (three weeks after application of dressing with using apple cider vinegar) at P-value of 0.000, it represents that the diabetic foot ulcer healing score mean before applying the interventional protocol was greater than the diabetic foot ulcer healing score mean before applying the interventional protocol was greater that the diabetic foot ulcer healing score mean before applying the interventional protocol was greater than three weeks after applying it.

A study by Allawi, et al., (2019) is being undertaken at the College of Veterinary Medicine, University of Mosul, Mosul, Iraq to look at the impact

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of apple cider vinegar on the healing of experimentally produced wounds infected with Pseudomonas aeruginosa. They found that increasing the quantity of apple cider vinegar led to faster and better healing of the diabetic infected ulcer wounds. These findings align with Novianty et al.,2021 results in which he used tetracycline in comparison of apple a cider vinegar and the results showed that apple vinegar caused inhibition of staphylococcus aureus and the grade of the ulcer was similar to ours. Jabir et al., 2011 They conducted an interventional experimental study to assess in clinical isolates of otomycosis, apple cider vinegar and acetic acid had greater antifungal properties than fluconazole. at Al-Habboobi Hospital, Dhi-Qar, Iraq. They concluded that apple cider vinegar was effective on inhibiting the bacterial infection on wounds of diabetic ulcer and it accelerates the healing process.

5.6 Discussion comparisons of diabetic foot ulcer grade readings under the effect of using apple cider vinegar on degree of diabetic foot ulcer between the four measurements periods among the study group:

Finding showed no difference in diabetic foot ulcer grade readings under how utilizing apple cider vinegar affects the speed of wound healing between the periods of the first measure (before application of dressing with using apple cider vinegar) and second measure (one week after application of dressing with using apple cider vinegar), While there was a highly significant difference in diabetic foot ulceration grade readings between the periods of the first measure and third measure (two weeks after application of dressing with using apple cider vinegar) at P-value of 0.001,.Also, there was also a highly significant difference in diabetic foot ulceration grade readings between the periods of the first measure and fourth measure (three weeks after application of dressing with using apple cider vinegar) at P-value of 0.000, it represents that the diabetic foot ulcer grade mean before applying the interventional protocol was greater than three weeks after applying it .Surahio, et al., (2014) conducted prospective observational research to assess the function of honey in diabetic foot wound dressing ulcer at Al-Noor Specialist Hospital in Saudi Arabia. They came to the conclusion that applying honey to chronic diabetic foot ulcers considerably lowers the rate of amputation and enhances wound healing.

From These findings the researcher sees that application of the apple cider vinegar dressing on wounds was affecting in progress through the four measurements periods, where the fourth measurement period for healing process and reducing degree of foot ulcer was much better than the first period.

5.7 Discussion of statistical association between patients' levels of diabetic foot ulcer healing with patient's-demographic characteristics posttest:

The result in tables (4-7) reveals a non-significant statistical association was found between level of diabetic foot ulcer healing and the Socio-demographic Characteristic of age, gender, educational level, occupation, and smoking at p-value >0.05. while a significant difference was found between levels of diabetic foot ulcer healing and the Socio-demographic Characteristic of marital status. Also, it told that there is a statistical significance between levels of diabetic foot ulcer healing and residency at $p. \le 0.05$. This result is similar to that revealed by Yimam et al., 2021 that found also relation between healing of ulcer and residency. Also Ahmed et al., 2023 reported that marital status and educational level have an effect on the healing of the ulcer.

The researcher observed that level of diabetic foot ulcer healing differed by residence, the patient who living in urban had good level of diabetic foot ulcer healing. While the patient who living in rural, they had a lower level of diabetic foot ulcer healing

5.8 Discussion of statistical association between patients' diabetic foot ulcer grade with patients' socio-demographic characteristics posttest:

The result in tables (4-8) reveals a non-significant statistical association was found between diabetic foot ulcer grade and the Sociodemographic Characteristic of age, gender, marital status, occupation, and smoking at p-value >0.05. while a significant difference was found between diabetic foot ulcer grade and socio-demographic characteristic of educational level. Also, it was clear that there is a statistical relationship between diabetic foot ulcer grade and residency at $P \le 0.05$. Yekta et al.,2011 found in their investigation that high-grade ulcers determined by Wagner's classification are significantly related with low educational level and residency in urban places.

The researcher observed that diabetic foot ulcer grade differed by residence, the patient who living in urban had higher diabetic foot ulcer grade. While the patient who living in rural, they had a lower level of diabetic foot ulcer healing

5.9 Discussion of statistical association between levels of diabetic foot ulcer healing with patients 'clinical data posttest:

Findings showed that there is a non-significant statistical difference was found between level of diabetic foot ulcer healing and the clinical data of duration of DM, type of DM, type of treatment used, duration of diabetic foot, ankle brachial pressure index ratio at p-value >0.05. while there is a statistical significance difference between levels of diabetic foot ulcer healing and chronic diseases characteristic. It is also found that there is a statistical significance difference between levels of diabetic foot ulcer healing and HbA1c reading at $p \le 0.05$ level. In Jamshoro, Pakistan, Makhdoom, et al.2019 carried out an experimental study design to assess the management of diabetic foot with natural honey. They came to the conclusion that using natural honey improved recovery and reduced the number of leg and foot amputations.

The researcher observed that level of diabetic foot ulcer healing differed by chronic disease, the patient who have heart disease and kidney disease had low (22.2% and 50%) percentage of them good level of healing While the patient who don't have any disease had higher (84.2%) percentage of them good level of diabetic foot ulcer healing.

In term of HbA1c reading the researcher observed that level of diabetic foot ulcer healing differed by HbA1c reading, the patient who have diabetes reading (≥ 6.5) had low (27.3%) percentage of them good level of healing. While the patient who have prediabetes reading (5.7t06.4) had higher (84.2%) percentage of them good level of diabetic foot ulcer healing.

5.10 Discussion of statistical association between diabetic foot ulcer grade with patients 'clinical data posttest:

Findings showed that there is a non-significant statistical difference was found between diabetic foot ulcer grade and the clinical data of duration of DM, type of DM, type of treatment used at p-value >0.05. while there is a statistical significance difference between diabetic foot ulcer grade and chronic diseases, duration, ankle -brachial pressure index ratio, and HbA1c reading at $p \le 0.05$ level. Ugwu et al., 2019 demonstrated that the ulcer grade and infection duration are in significant relation and the study findings are similar to them.

Concerning ankle-brachial pressure index ratio, findings reported that there is a statistical link between diabetic foot ulcer grade and Ankle-brachial pressure index ratio $p \le 0.05$ level. Ankle-brachial pressure scores were strongly associated with the extent of diabetic foot ulcers (p = 0.025; r = 0.258) according to correlation test results according to Kristianto et al., 2021. It is also a statistical significance between levels of diabetic foot ulcer grade and HbA1c reading $p \le 0.05$ level, and this result align with Din et al., 2023 findings which show a statistically significant link among the grades of diabetic foot ulceration and the patients' HbA1c levels (p-value 0.001). This data implies that there is a strong relationship between the severity of diabetic foot ulcers and the patients' long-term glycemic management, as measured by HbA1c levels.

Chapter six

Conclusion and recommendations

Chapter six

Conclusion and Recommendations

6.1 Conclusion:

This study's results conclude that:

- 1. Application of apple cider vinegar dressing reduced the grade severity and enhanced wounds healing of diabetic foot ulcers. And the progress through the four measurements periods, where the fourth measurement period for healing process was much better than the first period.
- 2. There is a statistical significance difference between levels of diabetic foot ulcer healing and patients' marital status and residency. Also, there is a statistical significance difference between diabetic foot ulcer grade and patients' educational level and residency.
- 3. There is a statistical significance difference between levels of diabetic foot ulcer healing and chronic diseases characteristic and HbA1c reading. also, there is a statistical significance difference between diabetic foot ulcer grade and chronic diseases, duration of diabetic foot infected, ankle-brachial pressure index ratio, and HbA1c reading.

6.2. Recommendations:

The following recommendations are made based on the study's results and conclusions:

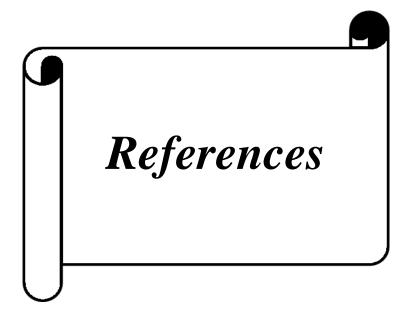
1- Regular patient education: It is critical to offer patients with diabetic foot ulcers with consistent and ongoing instructions on foot care with apple cider vinegar dressing. Making sure patients are well-informed on correct foot care procedures will help them manage their condition more effectively.

2- Increased emphasis on prevention and education: Nursing staff should place a greater emphasis on diabetic foot ulcer prevention, early identification, management, and infection control. Additionally, patient education about diabetic foot care should be prioritized in order to empower people in managing their condition.

3- Optimal use of apple cider vinegar dressing: It is recommended to use apple cider vinegar dressing on a daily basis, with dressing changes made once daily. This strategy has the potential to lower the total burden of diabetic foot ulcer complications as well as treatment expenses for both patients and healthcare facilities.

4- Conduct bigger-scale studies: Future study should focus on bigger sample size studies to examine the efficacy of apple cider vinegar for frequent usage in diabetic foot care products. Investigating its effect on the healing process, healing level, and ulcer grade could provide useful information for improving diabetic foot ulcer therapy.

5-Examine the long-term outcomes: It is critical to look into the long-term effects of utilizing apple cider vinegar dressing on diabetic foot ulcer healing. evaluating its long-term advantages can assist healthcare practitioners in developing effective treatment techniques.



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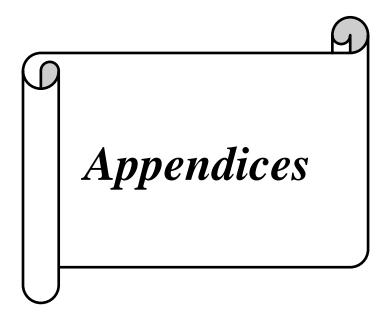
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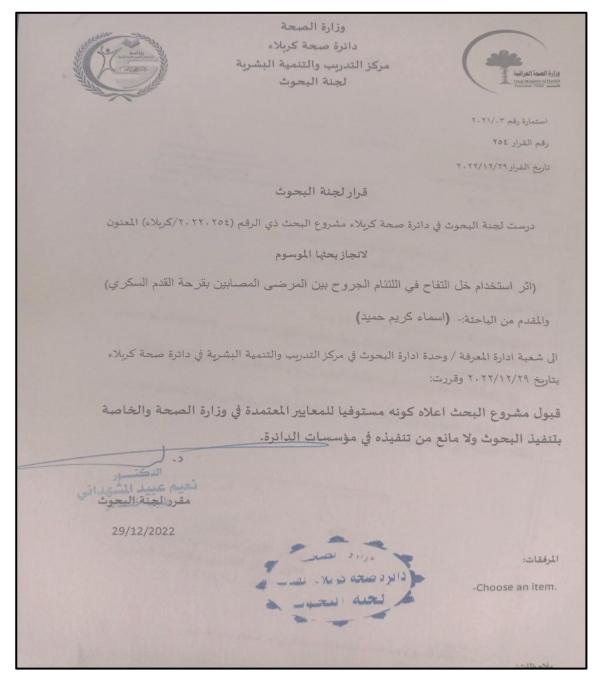
Appendix A-I

Official permission from Nursing College Council/ University of Kerbala

جمهورية العراق وزارة التعليم العالي والبحث العلمي المعة كربلاء كلية التمريص شعبة الدر اسات العليا التاريخ: 28 / (/ 2022 12831 Fas : 1283 الى / دائرة صحة كربلاء/ مركز التدريب و التنمية البشرية د/ تسهيل مهمة تحية طيبة... يرجى التفضل بالموافقة على تسهيل مهمة طالبة الماجستين السيدة (أسماء كريم حميد) في مركز الإمام الحسن "عليه السلام" للغدد الصم و السكري لإنجاز رسالتها الموسومة : Effect of Using Apple Cider Vinegar on Wounds Healing among Patients with Diabetic Foot Ulcers. أثر استخدام خل التفاح في التنام الجروح بين المرضى المصابين بقرحة القدم السكري. وهي احدى طلبة الدراسات العليا / الماجستير في كليتنا / للعام الدراسي (2022-2023) التقدير ... LUES -R أ.م.د. سلمان حسين قارس الكريطي 14731 c. معاون العميد الشوون /العلمية و الدر اسات العليا 2022 / 11/ 98 نسخة منه الى :-- مكتب السيد المعاون العلمي المحترم. - شعبة الدراسات العليا.

Appendix A-II

Official permission from Iraqi Ministry of Health/ Decision of the Research Committee in Kerbala Health Department



Appendix A-III

Official permission from Iraqi Ministry of Health/ Training and Human Development Center/ Kerbala Health directorate

جمهورية العراق محافظة كربلاء المقد دائرة صحة كريلاء المقدسة مركز التدريب والنتمية البشرية شعبة ادارة المعرفة / وحدة ادارة البحوث Holy Karbala governorate Karbala Health Department General manager's office Training and Human Development 4 < . -العدد: Center التاريخ / ۲۰۳۰ 1=/19 الى / جامعة كربلاء المقدسة / كلية التمريض الموضوع /تسهيل مهمة تحية طيبة كتابكم المرقم د.ع. / ٢٨٣ في ١ / ١ / ١ / ٢ . ٢ نود إعلامكم بأنه لا مانع لدينا من تسهيل مهمة طالبة ماجستير (اسماء كريم حميد) لإنجاز بحثها الموسوم: (اتر استخدام خل التفاح في اللتنام الجروح بين المرضى المصابين بقرحة القدم السكرى) في مؤسستنا الصحية وبأشراف الدكتور (ضياء العقابي) على ان لا تتحمل دائرتنا اي نفقات مادية مع الاحترام . . 2 الدكتورة [ا تقوى خضر عبد الكريم مدير مركز التدريب والتنمية البشرية Y. YY/1 C/ 2 نسخة منه الى مركز الامام الحسن (عليه السلام) للغدد الصم والسكري اجراء اللازم مع الاحترام ٠٠

Appendix A-V

The result of an examination of the percentage of acetic acid concentration in apple cider vinegar at Al-Ameed University/College of Nursing



Appendix A-VI

The Result of The Toxicity of Apple Cider Vinegar on Human Cells



Appendix B-I Ethical Considerations

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patients with diabetic foot ulcers.	anong among
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Appendix B-II

Consent Form

صفحة موافقة المبحوث

التئام الجروح ة)حيث اطلعني مشاركتي هذه كما ان بأمكاني اجيب على أي اجيماني أي معلومات الناتجة وان هذه	ميد) بشرح 5 في تسهيل فماد جديد نم المشاركة كان ،او ان لا يي ، كما ان ال ها أي شخص	كريم ح للتفاح بة .كما سبب ك مشارك طلع علي راسة .	موافقة خطية للمشا نوقيع اسفل الصفحة كي تشهد بان : عد ان قامت طالبة الماجستير (أسماء تت بحثه الموسوم (تأثير استخدام خل رضى المصابين بقرحة القدم السكري: وع مني وبمحض ارادتي وان باستطاء مشاركتي في الدراسة متى شئت ولأي و مسائلة من شأنها الضرر بمهنتي او ه اركتي سوف تعامل بسرية تامة ولن يم اركتي في أي منشور عن هذه الد ل او عائلتي في أي منشور عن هذه الد	التساؤلا بين الم صاحب هي تطر سؤال لا نفقات ا المعلوم شخصي
			بذا فأني أوقع على مشاركتي في هذا البحث نابة التاريخ بجانب التوقيع	
	2023/	/	مشارك التاريخ	توقيع ال
	2023/	1	باحث التاريخ	توقيع ال

Appendix C-I

The study Instrument Sociodemographic and Clinical Data



Appendix C-II

Diabetic Foot Ulcer Healing Scale (DMIST)

الثاني)	(الجزء
القياس	ادوات

) الاول: مقياس الشفاء من قرحة القدم السكري(DMIST)	المقياسر
ن: قياس عمق الجرح (أعمق نقطة في الجرح).	١ .العمؤ
سليمة	
الطبقة السطحية / البشرة	۲.
تحت الجلد / الأدمة إلى الأنسجة الدهنية	۳.
الأوتار	.£
نسيج اللفافة و / أو العضلات	.•
العظام	۰.
ف: يعرف الضعف بأنه تلف الجلد حول الجرح بسبب الرطوبة الزائدة / الإفرازات. كما	٢ الضع
حيط الجلد بأنه ٢ سم حول حافة الجرح.	يُعرَّف
لايتنيع	
طفيف: فقط عند حافة الجرح	
معتدل: محيط الجلد: بعد محيط الجلد	
هاب / عدوى: قياس التهاب المنطقة التهاب العظم والنقي من خلال الملاحظات	
ريرية أو من خلال المعلومات من السجلات السريرية.	الس
· · · · · · · · · · · · · · · · · · ·	.•
علامات الالتهاب (مثل الدفء، الاحمرار، التورم، الألم)	
علامات العدوى الموضعية (مثل تصلب، صديد، رائحة كريهة)	۲.
التهاب العظم والنقي	
التهاب العظم والنقي وعلامات العدوى الموضعية	
عدوى جهازية (حمى، تعفن الدم)	
مجم: حجم الجرح يقاس بالطول × العرض. يُعرَّف الطول بأنه قياس للجرح طوليا؛ يُعرَّف	٤. ا لـ
ض بأنه قياس متعامد مع الطول ويكون عرضيا للجرح. يجب استبعاد الاحمرار المحيط	
جرح. إذا كان هناك نوعان أو أكثر من القرحات التي نشأت من نفس السبب وتشترك في	بال
ں خصائص الجرح، فيجب أن يكون "الحجم" مجموع أحجام الجرح. إذا كان حجم الجرح	نفس
مكن قياسه بدقة، على سبيل المثال، بسبب الأنسجة الميتة أو شكل الجرح غير المنتظم،	
ب إضافة "S" بعد التصنيف.	فيج
سليمة	
≥ 1سم ^۲	.۱
\leq 1 سنم ` - 4 سنم ` \geq	۲.
\leq 4 سنم 2 – 9 سنم 2	۳.
\leq^2 ستم ' -16 ستم \leq	. ٤
\leq^2 سم ' - 25 سم \leq^2	
≤ 36- ۲ سم ² ≤ 36 سم ² ≤ 36	۲.
≤ 2 سم ' 49- ' سم $36 <$	۰.
< 64 - ۲ سم ² ≤ 49 سم ² ≤ 64 × 64 × 64 × 64 × 64 × 64 × 64 × 64	.^

۹. > 64 سم ²
 الصفة السريرية لنسيج الجرح: إذا كان هناك مزيج من عدة أنواع من الأنسجة، فيجب
اختيار النسيج السائد او الأكثر وضوحا على للجرح ١. سليمة
• •
٢. لا يمكن تقييم النسيج الحبيبي أو التحبيب لأن الجرح ملتئم أو ضحل جدًا ٣. نسيج منخر أبيض، أصفر و / أو رمادي
· · · سنيني منصر ابيص ، مصر و / أو رماني ٤. الأنسجة الميتة السوداء
ه. الغرغرينا
م. المراحرية ٦. نوع حافة الجرح: إذا كان هناك مزيج من عدة أنواع من حافة الجرح، يتم اختيار نوع
الحافة السائدة أو الأكثر وضوحا.
. استكمال النسبيج الظهاري
 میزة غیر خاصة / صُحلةً جدًا بحیث لا یمکن تقییمها
۲. فرط تقرن / بطانة / إيببول
٣. أحمر الحواف
٤. غير واضح أو غير قادر على التقييم بسبب العدوى وما إلى ذلك.
 v. نفق أو تقويض: (حدوث حفرة عميقة طولية داخل الجرح) يجب قياس ذلك في أطول نقطة
في النفق أو التقويض.
١. لا يوجد
۲. 1 سم ≥
≤ 1 سنم 4 سنم 2 سنم 2 .۳
٤. 4 سم > 8 سم ≥
ه. <u>8 سم ></u>
مجوع النقاط
الحبد ١- ١١) (متوسط ١٢-٢٣) (ضعيف أو متأخر ٢٣٧)

للجيد ١٠- ١١) (متوسط ٢٢-٢٣) (ضعيف أو متأخر >٢٣)

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Appendix C-III

Diabetic Foot Ulcer Classification System (Meggitt-Wagner

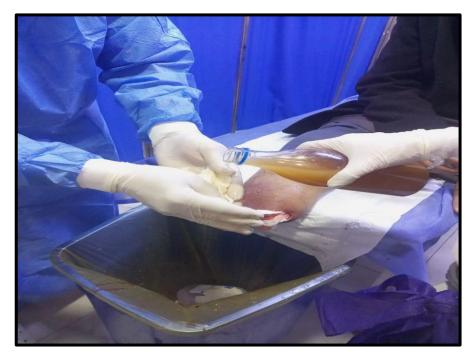
System)

لمقياس الثاني: مقياس درجة قرحة القدم السكري (<mark>Meggitt-Wagner system</mark>)		
الدرجة	الوصف	
•	الجلد سليم	
١	قرحة سطحية	
٢	قرحة عميقه	
٣	قرحة تتضمن إصابة العظام	
٤	موت او تآكل انسجة القدم الأمامية	
0	موت او تآكل انسجة القدم الكاملة التي تصيب أكثر من ثلثي القدم	

Appendix -D

Steps to implement the intervention protocol by the

researcher







Appendix-E

Pictures of diabetic foot ulcer Before and After Applications of Interventional Protocols (Apple cider vinegar dressing)



After





Before

Appendix-E

Pictures of diabetic foot ulcer Before and After Applications of Interventional Protocols (Apple cider vinegar dressing



Before

After



Before

After

Appendix-E

Pictures of diabetic foot ulcer Before and After Applications of Interventional Protocols (Apple cider vinegar dressing)



Before



Appendix F-I Experts' List

الغرض	مكان العمل	سنوات الخبرة	التخصص	اللقب العام	اسم الخبير	ت
	كلية التمريض /جامعة بغداد	، لعبر د ۳٤ سنة	تمريض صحة البالغين	<u>العلمي</u> استاذ	د. وداد کامل محمد	۰.
	كلية التمريض / جامعة بابل	۲۴ سنة	تمريض صحة البالغين	استاذ	د. سحر أدهم علي	۲.
	كلية التمريض / جامعة كربلاء	۲۰ سنة	تمريض صحة البالغين	استاذ مساعد	د. حسن عبد الله عذبي	۳.
	كلية التمريض /جامعة بغداد	۱۷سنة	تمريض صحة البالغين	أستاذ مساعد	د. وفاء عبد علي	<u>۔</u> ٤
idity	كلية التمريض /جامعة العميد	١٦سنة	تمريض صحة البالغين	أستاذ مساعد	د. ضياء کريم عبد علي	۰.
Content validity	كلية التمريض / جامعة الكوفة	٥ اسنة	تمريض صحة البالغين	أستاذ مساعد	علي د. محمد عبد الکريم مصطفی	۲.
Conte	كلية التمريض / جامعة الكوفة	۱۳ سنة	تمريض صحة البالغين	استاذ مساعد	د <u>.</u> جهاد جواد کاظم	.~
	كلية التمريض /جامعة وارث الأنبياء	۱۳ سنة	تمريض صحة البالغين	استاذ مساعد	د <u>.</u> نسیم سمیر صقر	.^
	كلية التمريض / جامعة بغداد	۱۲ سنة	تمريض صحة البالغين	استاذ مساعد	د. صادق عبد الحسين حسن	٩.
	كلية التمريض /كلية الصفوة الجامعة	۱۰سنة	تمريض صحة البالغين	مدرس دکتور	د. علي سلام عبيد	۱.
	كلية التمريض /جامعة كربلاء	۳۰سنة	تمريض صحة نفسية وعقلية	أستاذ	د. علي کريم خضير	۱۱
alidity)	كلية التمريض /جامعة كربلاء	۳۲سنة	تمريض صحة مجتمع	أستاذ مساعد	د. سلمان حسين فارس	١٢
ponse process validity	كلية التمريض/كلية الصفوة الجامعة	ه ۲ سنة	تمريض صحة البالغين	أستاذ مساعد	د. جمعة جبر عبد الرضا	١٣
onse p	كلية التمريض/كلية الصفوة الجامعة	۲۳سنة	تمريض صحة البالغين	مدرس دکتور	د. عامر محمد غبیش	١٤
	كلية التمريض /كلية الصفوة الجامعة	٨سنة	علوم كيمياء -حياتية سريرية	مدرس دکتور		10
Face validity (res	كلية التمريض /جامعة العميد	٢سنة	تمريض صحة البالغين	مدرس دکتور	د. احمد محمد جاسم	١٦
Face v	مدينة الامام الحسين(ع) الطبية التعليمية /مركز الامام الحسن (ع) للغدد الصم والسكري	۱۸ سنة	طبيب اختصاص جراحة العظام والكسور/جراحة القدم السكري	دکتوراه (بورد)	د. ضیاء حسین علوان	١٧

Appendix F-II

Content validity of diabetic foot ulcer healing scale (DMIST)

Exper Item	t	1	2	3	4	5	6	7	8	9	10	Ne	N	I-CVI	UA
Q1		1	1	1	1	1	1	1	1	1	1	10	10	1	1
Q 2		1	1	1	1	1	1	1	1	1	0	9 10 0.9		0	
Q 3		1	1	1	1	1	1	1	1	1	1	10	10	1	1
Q 4		1	1	1	1	1	1	1	1	1	1	10	10	1	1
Q 5		1	1	1	1	1	1	1	1	1	0	9	10	0.9	0
Q 6		1	1	1	1	1	1	1	1	1	1	10	10	1	1
Q 7		1	1	1	1	1	1	1	1	1	1	10	10	1	1
Proportion relevance	1	1	1	1	1	1	1	1	1	1	0.71				
								S- (CVI/	UA					0.71
								S-	CVI/	Ave					9.74
															1.83
		$i-CVI = CVR = (ne - N/2) / (N/2), S- CVI/Ave = (\sum CVR/N), UA = Universal agreement, Content Validity Ratio CVR = I- CVI (item level content validity index), S-CVI\Ave = scale-level content validity index, ne = number of experts agreement, ne = The number of experts who rated an item as "essential", N the total number of experts.$													alidity perts in

Appendix F-III

Face validity of diabetic foot ulcer healing scale (DMIST)

Raters Item	1	2	3	4	5	6	7	RA	UA	N	I-FVI								
Q1	1	1	1	1	1	1	1	7	1	7	1								
Q 2	1	1	1	1	1	1	1	7	1	7	1								
Q 3	1	1	1	1	1	1	1	7	1	7	1								
Q 4	1	1	1	1	1	1	1	7	1	7	1								
Q 5	1	1	1	1	1	1	1	7	1	7	1								
Q 6	1	1	1	1	1	1	1	7	1	7	1								
Q 7	1	1	1	1	1	0	1	6	0	7	0.8								
Proportion clarity and comprehension	1	1	1	1	1	0.8	1												
					S-	CVI/	UA					0.85							
S-FVI/Ave																			
Average proportion of items judged as clarity and comprehension across the seven experts 0.97												0.97							
I-FVI = (agreed it)	em)	/ (n	umbe	r of r	ater),	S-F	FVI/	Ave =	= (sum	of I	-FVI scores)/(number o	f item), S-							
FVI/UA = (sum of	f U	A sc	cores)	/(num	ber o	f item	ı), L	$\mathbf{J}\mathbf{A} = \mathbf{U}$	Univer	sal a	greement = raters in agr	eement, I-							
FVI = item face validity, S-FVI =scale face validity.																			

Appendix F-IV

Content validity Of Meggitt-Wagner classification system for

diabetic foot ulcers

Expert Item	1	2	3	4	5	6	7	8	9	10	Ne	N	I-CVI	UA
Q1	1	1	1	1	1	1	1	1	1	1	10	10	1	1
Q 2	1	1	1	1	1	1	1	1	1	1	10	10	1	1
Q 3	1	1	1	1	1	1	1	1	1	0	9	10	0.9	0
Q 4	1	1	1	1	1	1	1	1	1	0	10	10	1	1
Q 5	1	1	1	1	1	1	1	1	1	1	10	10	1	1
Q 6	1	1	1	1	1	1	1	1	1	1	10	10	1	1
Proportion relevance	1	1	1	1	1	1	1	1	1	0.83				
														0.83 9.3
													0.98	
	I-CVI = CVR=(ne $- N/2$) / (N/2), S- CVI/Ave= (Σ CVR/ N) , UA = Universal agreement, Content Validity Ratio CVR= I- CVI (item level content validity index), S-CVI\Ave =scale-level content validity index, ne= number of experts in agreement , ne = The number of experts who rated an item as "essential" , N = the total number of experts.												n level x, ne=	

Appendix F-V

Face validity of Meggitt-Wagner classification system for

diabetic foot ulcers

Raters Item	1	2	3	4	5	6	7	RA	UA	N	I-FVI					
Q1	1	1	1	1	1	1	1	7	1	7	1					
Q 2	1	1	1	1	1	1	1	7	1	7	1					
Q 3	1	1	1	1	1	1	1	7	1	7	1					
Q 4	1	1	1	1	1	1	1	7	1	7	1					
Q 5	1	1	0	1	1	1	1	6	0	7	0.85					
Q 6	1	1	1	1	1	1	1	7	1	7	1					
Proportion clarity and comprehension	1	1	0.83	0.83 1 1 1 1												
					S-0	CVI/U	A					0.83				
S-FVI/Ave																
Average proportion of items judged as clarity and comprehension across the seven experts 0.97																
I-FVI = (agreed item)/ (number of rater), S-FVI/Ave = (sum of I-FVI scores)/(number of item), S-FVI/UA = (sum of UA scores)/(number of item), UA = Universal agreement = raters in agreement, I-FVI = item face validity, S-FVI = scale face validity.																

Appendix – G

The Statistician's Opinion

جمهورية العراق 14 وزارة التعليم العالي والبحث العلمي جامعة كربلاء Republic of Iraq Ministry of higher education & scientific research كلية التمريض University of Kerbala الدر اسات العليا College of Nursing اقرار الخبير الاحصانى اشهد بان الرسالة الموسومة : (تأثر استخدا) حل ، لنفاع في تسعل التسام الجوح من المرض المصابين يقرحة القرم السكري : طريقة مخاد (· map قد تم الاطلاع على الاسلوب الاحصائي المتبع في تحليل البيانات واظهار النتائج الاحصائية وفق مضمون الدراسة ولأجله وقعت. توقيع الخبير الاحصائى: الاسم واللقب العلمى: ١٠ ح ٢ الاختصاص الدقيق: 5 re مكان العمل: جامعة كربلاء / كلية لرم - م المد التاريخ: 1/ 1 / 2023

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Appendix – H

The Linguistics' Opinion

جمهورية العراق Republic of Iraq وزارة التعليم العالى والبحث العلمي Ministry of higher education & scientific research جامعة كربلاء University of Kerbala كلية التمريض College of Nursing الدر اسات العليا اقرار الخبير اللغوي The effect of using Apple Cider Vinegario Facilitate Wounds Healing among Patients, With Diabetic Foot Olcers: New Pressing. Method) قد تم جرى مرجعتها من الناحية اللغوية بحيث اصبحت بأسلوب علمى سليم خال من الأخطاء اللغوى ولأجله وقعت. توقيع الخبير اللغوي: الاسم واللقب العلمي: ج الاختصاص الدقيق: رد مكان العمل: جامعة كربلاء / كلية ع الذرا المن التاريخ: 3/ 8/ 2023

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Appendix – I Signed official approval permit the use of the Diabetic Foot Ulcer Healing Scale (DMIST)

Date: October 13, 2022

To: Asmaa Kareem Hameed

From: Makoto Oe, PhD, RN & Hiromi Sanada, PhD, RN, WOCN, FAAN

Re: Permission to use the DMIST

As holders of the official copyright for the DMIST for evaluating the healing process of patients with diabetic foot ulcers, we hereby grant permission for the use of the DMIST in your clinical agency.

makoto Qe

Makoto Oe, PhD, RN

Professor

Kanazawa University

H. Samad

Hiromi Sanada, PhD, RN, WOCN, FAAN President Ishikawa Prefectural Nursing University Professor Emeritus The University of Tokyo

الخلاصة

الخلفية العلمية: قرحة القدم هي واحدة من المضاعفات المعتادة والخطيرة التي تحدث في مرضى السكري. ضماد خل التفاح له خصائص مضادة للميكروبات وعواقب علاجية سريرية أخرى. تم إجراء هذه الدراسة لفحص تأثير ضماد خل التفاح على التئام قرحة القدم لدى مرضى السكري.

المنهجية: أجريت دراسة شبه تجريبية في مركز الإمام الحسن (ع)للغدد الصماء والسكري في الفترة من 26ايلول 2022للى 25 تموز 2023. تشمل العينة الهادفة ستين مريضا يعانون من تقرح القدم السكري الذين تم فصلهم عشوائيا إلى مجموعة التدخل والسيطرة. تم توجيه المرضى في مجموعة التدخل الضماد المنقوع بخل التفاح الي يكون فيه تركيز حمض الخليك (١-٥٪) مرة واحدة يوميا لمدة ٢١ يوما، بينما تم تقديم الرعاية الروتينية فقط للمجموعة الضابطة. تضمنت أداة الدر اسة البيانات الاجتماعية والديموغرافية والسريرية للمشاركين، ونظام تصنيف محموة البيانات وTMIST لمراقبة عملية الشفاء من قرحة القدم السكرية. تم التحقق من صحة الأدوات من قبل فريق من الخبراء، وتم التحقق من موثوقيتها من خلال در اسة تجريبية. كل من إجراء التحليل الوصفي وإجراء التحليل الاستدلالي؛ تم تحديد قيمة p البالغة <٠,٠٠ لتكون ذات صلة إحصائية.

النتائج: تفوقت مجموعة الدراسة على المجموعة الضابطة في شفاء قرحة القدم السكرية، حيث حصل 80٪ على شفاء ممتاز مقارنة ب16.7. ٪ (ص0,001). علاوة على ذلك، تحسنت درجة قرح القدم السكرية في مجموعة الدراسة، حيث كان63,3 ٪ يعانون من قرح سطحية مقارنة ب23,3 ٪ في المجموعة الضابطة (0.01 p).

الاستنتاجات: وجدت هذه الدراسة أن استخدام ضمادة خل التفاح لقرحة القدم السكرية يحسن التئام الجروح.

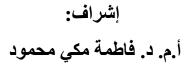
ا**لتوصيات:** يوصبي باستخدام ضماد خل التفاح بشكل منتظم وتغيير ها مرة واحدة في اليوم.



جامعة كربلاء كلية التمريض

تأثير استخدام خل التفاح على التئام قرحة القدم لمرضى السكري

الى مجلس كلية التمريض / جامعة كربلاء وهي جزء من متطلبات نيل درجة الماجستير في علوم التمريض



تموز _ ۲۰۲۳ م

محرم _ ٥٤٤٥هـ