Study on the Management of Diabetic Foot Ulcers in Diabetic Patients at a Tertiary Care Hospital

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ABSTRACT

AIM: To study the treatment pattern of diabetic foot ulcer and to assess the effect of patient counselling on diabetic foot ulcer patients.

OBJECTIVE:

1. To study the various modalities of treatment used for Diabetic Foot Ulcer patients in a tertiary care hospital.
2. To assess the effect of patient counselling on diabetic foot ulcer patients with standard questionaries

METHODS:

The protocol was reviewed, revised, and approved by the Institutional Review Committee of MVJ Medical College and Research Hospital before commencement of the study. Over the course of six months, a tertiary care hospital conducted prospective research. Following the giving of written informed permission, diabetic patients with foot ulcers of both genders who were visiting the hospital were invited to participate and enrolled. A total of 150 patients participated in the study. The patients were recruited according to the inclusion and exclusion criteria mentioned. The study was attempted to improve the patient's knowledge and attitude towards the self-management of diabetic foot ulcer. And thus, patient counselling is an essential component of clinical pharmacy practice in hospital.

RESULTS:

In this study, majority of the study participants belonged to the age group 61-70 years (30.7%) of age. 22% of the study participants were of the age group between 51-60 years of age. Majority (64.7%) of the study participants were males. In this study, Nottingham Assessment of Functional Footcare (Revised 2015) was used and an improvement in the total score was found i.e., from 18.27 ± 5.85 before counselling jym oof ff\c b to 44.07 ± 4.70 post counselling which was found to be statistically significant (P<0.001). Thus, a proper foot care education program has been shown to reduce the risk of ulceration.

CONCLUSION:

The present study was conducted to study the effect of patient counselling on diabetic foot ulcer patients using NAFFC score. Majority in the study belonged to 61-70 years and were males. Most of them had type 2 DM and grade 1 foot ulcer. In this study, Nottingham Assessment of Functional Footcare (Revised 2015) was used and an improvement in the total score was found i.e., from $18.27+5.85$ before counselling to $44.07+4.70$ post counselling which was found to be statistically significant (P<0.001). NAFFC score played an important role in the study to assess the functional outcome among diabetics with foot ulcers. Though there is development of new therapies for the management of diabetic foot ulcers, a high rate of failure ending with amputation still exists. Hence a counselling session to the diabetics with foot ulcers

can prevent further complications.

KEYWORDS: Diabetic Foot Ulcer, Diabetic Mellitus, NAFFC, Management of Diabetic Foot, Patient counselling, Meggitt-Wagner.

INTRODUCTION

Diabetes mellitus defines as a group of metabolic disorders with the main feature of chronic hyperglycaemia. It is caused by either decreased insulin effectiveness or insulin secretion, or it may be both [1,2]. It is estimated that about 1% of the individual suffer from diabetic mellitus. Every tissue and organ in the body endures biochemical and structural changes as an outcome of hyperglycaemia, which is what causes the majority of diabetes complications, which can be either acute metabolic or chronic systemic.

There are several classification systems for diabetes mellitus, but one of the most used is based on etiology and includes the following main types:

Type 1 Diabetes (T1DM):
The pancreatic beta cells that produce insulin are destroyed by the immune system. This usually occurs in early adulthood or youth. Require ongoing insulin treatment.

Type 2 Diabetes (T2DM):
Insulin resistance and relative insulin deficiency. Usually advance in adulthood but can occur in younger individuals. Managed through lifestyle modifications, oral medications, and sometimes insulin.

Gestational Diabetes Mellitus (GDM):
High blood sugar levels that first occur during pregnancy. During pregnancy. Managed through diet, exercise, and sometimes insulin.

Other Specific Types of Diabetes:
This category includes various less common forms of diabetes with specific etiologies, includes monogenic diabetes (Maturity-Onset Diabetes of the Young or MODY) and secondary diabetes related to certain medical conditions, medications, or genetic syndromes.

- **DM Epidemiology:**

According to International Diabetes Federation figures from 2019, around 537 million people worldwide have diabetes. In 2020, diabetes ranked as the ninth most prevalent cause of mortality globally, leading nearly 2 million deaths annually from the illness and renal disease associated with it

Type 1 DM
Evidence from extensive epidemiologic studies around the globe show that the incidence of T1DM has been growing by 2-5% globally, and that the prevalence of T1DM in the United States by the age of 18 is roughly 1 in 300[3].

Type 2 DM
In 2017, 462 million people globally (i.e., 4.4% of people in the 15–49 age group, 15% of people in the 50–69 age group, and 22% of people in the 70+ age group) had type 2 diabetes, that corresponds to an average rate of 6059 instances per 100,000 people. The global prevalence of type 2 diabetes is expected to climb to 7079 people per 100,000 by 2030, showing a consistent increase across the world [4].

- **DM Etiology**

Type 1 Diabetes

Type 1 diabetes results from autoimmune demolition of the β cells of the pancreas. There are various indicators of immunological damage of the β cell, such as antibodies to insulin, glutamic acid decarboxylase, and islet cells. This type of diabetes may occur at any age, although it often affects children and teenagers [5].

Type 2 Diabetes

Insulin resistance and relatively insufficient insulin production, with gradually decreasing insulin secretion over time, are the characteristics of this type of diabetes. Insulin resistance is a result of abdominal obesity, which is seen in the majority of people with type 2 diabetes. In addition, these individuals frequently exhibit high levels of plasminogen activator inhibitor type 1 (PAI-1), hypertension, and dyslipidaemia [6].

- **Clinical Presentation**

Table 1: Clinical Presentation of T1DM & T2DM

Characteristic	Type 1 DM	Type 2 DM
Age	<30 years	>30 years
Onset	Abrupt	Gradual
Body Habitus	Lean	Obese or history of obesity
Insulin Resistance	Absent	Present
Autoantibodies	Often present	Rarely present
Symptoms	Symptomatic	Often asymptomatic
Ketones at diagnosis	Present	Absent
Need for Insulin therapy	Immediate	Years after diagnosis
Acute complications	Diabetic ketoacidosis	Hyperosmolar hyperglycaemic state
Microvascular complications at diagnosis	No	Common
Macrovascular complications at or before diagnosis	Rare	Common

- **DM Pathogenesis**

Type 1 DM

This type is an autoimmune disease that primarily affects pancreas, leading to the destruction of beta cells in the islets of Langerhans which produces insulin. Here is an overview of the steps in the development of type 1 diabetes:

1. **Genetic Predisposition:** Individuals with a family history of type 1 diabetes have an increased risk of developing this condition. Specific genetic markers, like certain HLA genes, are strongly associated with an increased risk of type 1 diabetes. However, having these genetic markers alone is not sufficient

to trigger the disease.

2. **Environmental Triggers:** It is believed that environmental factors triggers the autoimmune response in genetically predisposed individuals, which may include viral infections, dietary factors, and other environmental exposures.

3. **Autoimmune Response:** The autoimmune process begins when the immune system misinterprets the beta cells that produce insulin as foreign intruders. This can occur due to molecular mimicry, where a viral protein or other environmental factor resembles a beta cell antigen. Once the immune system recognizes these antigens as threats, it mounts an immune response.

4. **Immune Cell Infiltration:** Immune cells, particularly T lymphocytes, migrate to the pancreas and infiltrate the islets of Langerhans. These T cells release inflammatory cytokines and cause direct damage to the beta cells.

5. **Loss of Insulin Production:** As beta cells are progressively destroyed, the pancreas does not produce sufficient insulin. This results in a relative or absolute insulin deficiency.

Type 2 DM

In terms of the pathophysiology of the condition, elevated glucose levels in the blood result from a disruption of the feedback loops between the action and secretion of insulin. The reduced insulin release resulting from malfunctioning -cells limits the body's ability to maintain physiological glucose levels. On the other hand, IR promotes glucose production in the liver while reducing glucose absorption in the liver, muscle, and adipose tissue. -cell dysfunction is generally more severe than IR, despite the fact that all of these processes take place early in the pathophysiology and lead to the disease's presentation [7].

- **DM Diagnosis**

The identification of a glycaemic cut point that distinguishes normal individuals from diabetic patients is necessary for the diagnosis of the disease [8,9].

Table 2: Criteria for the Diagnosis of Diabetes Mellitus

Criteria for the Diagnosis of Diabetes Mellitus
Symptoms of diabetes plus casual plasma glucose concentration ≥200 mg/dL (11.1 mmol/L) or Fasting c plasma glucose ≥126 mg/dL (7.0 mmol/L) or 2-hour post load glucose ≥200 mg/dL (11.1 mmol/L) during an OGTT
OGTT, oral glucose tolerance test.

- **Complications of DM**

Acute complications

The acute complications of DM are diabetic keto acidosis (DKA) and non-ketonic hyper-osmolar state (NKHS). Volume depletion altered mental state, and absolute or relative lack of insulin are associated with both conditions.

Chronic complications

Chronic complications can be classified into vascular and nonvascular complications. The vascular complications are further subclassified into microvascular (retinopathy, neuropathy, and nephropathy) and macrovascular complications (coronary artery disease, peripheral vascular disease, and cerebrovascular disease). Nonvascular complications include problems such as gastroparesis, sexual dysfunction, and skin changes [10].

- **Diabetic Foot Ulcer**

15% of individuals with diabetes have diabetic foot ulcers, which are open wounds or sores that typically develop on the bottom of the foot. Diabetic foot ulcers are among the most common complications of poorly managed diabetes mellitus. Poor foot care, peripheral vascular disease, underlying neuropathy, and poor glycaemic control are the usual causes. In addition, it frequently results in lower extremity amputation and foot osteomyelitis. These ulcers typically appear in areas of the foot that are frequently under strain and tension. Staphylococcus is the infecting agent that is most common.

Figure 1: Diabetic Foot Ulcer of Patient 1

- **Precipitating Factors of DFU**

If a diabetic person has one or more of the following, their chance of getting foot ulcers is quite high:
  - Peripheral artery disease (PAD) reduces blood flow to the legs, arms, hands, and feet.
  - Varicose vein history
- Extreme temperatures can worsen a circulation condition called Raynaud's illness.
- Calluses and corns on the feet.
- Skin that is too dry (which makes it vulnerable to bacterial invasion).
- Being sedentary and having little mobility.
- High amounts of blood sugar
- Older than 40

- 10 years or more of continuous diabetes history
- High blood pressure, or hypertension
- Bunions and club feet are examples of acquired or congenital foot abnormalities.
- Smoking
- Instances of foot ulcers in the past
- Amputation of a foot or limb in the past.
- Poor foot care

- **Epidemiology of DFU**

A diabetic's lifetime chance of developing DFU is 15%, although it may reach 25%. The incidence is approximately 3% every year. DFU has been found to be the primary cause of hospitalisation for diabetic people. According to estimates, people with diabetes account for 25% of all hospital admissions [11].

- **Etiology of DFU** [12]

Diabetes patients may develop diabetic foot ulcers for an assortment of reasons, but there are two main causes that stand out, namely:

- **CAUSATIVE FACTOR**

Peripheral neuropathy: Prior to losing protective feeling and becoming more susceptible to thermal and physical damage, sensory neuropathy is typically profound (>50%), which raises the risk of developing foot ulcers. Proprioception, or the sense of one's own foot location, diminishes along with the perception of pressure and pain.

High foot plantar pressure: This situation is related to two things: limitations of joint mobility and foot deformities.

Trauma: Especially recurring trauma, 21% trauma from friction from footwear, 11% due to foot injuries (mostly due to fall), 4% cellulitis due to tinea pedis complications and 4% due to fingernail cut errors.

- **CONTRIBUTIVE FACTOR**

Atherosclerosis: This is due to PAD, especially regarding the blood vessels of femoropopliteal and small blood vessels below the knee, is the most important contributing factor.

Diabetes: Leads to intrinsic wound healing, including collagen cross-linking disorders, metric proteinase matrix functional disorders and immunologic disorders, especially impaired PMN function.

- **Pathophysiology of DFU**

Any inframalleolar infection in a diabetic with diabetes mellitus is simply called a diabetic foot infection. Among them are osteomyelitis, tendonitis, septic arthritis, paronychia, cellulites, myositis, abscesses, and necrotizing fasciitis. The infected diabetic "mal perforans" foot ulcer, however, is the most prevalent and traditional lesion. The primary cause of ulceration resulting from trauma or excessive pressure on a malformed foot lacking protective sensation is neuropathy, which is characterised by disruptions in sensory, motor, and autonomic processes. Bacterial colonisation can occur in underlying tissues when the skin's protective barrier is compromised. By contiguous extension, the infection may spread to deeper tissues and turn this wound into an actively infected lesion. This series of events, particularly in an

ischemia limb, can happen quickly, spanning hours or even days. Some diabetic individuals may be affected by a variety of poorly defined immunologic abnormalities, particularly those involving polymorph nuclear leucocytes, which are likely to enhance the risk and severity of foot infections.

- **Diabetic Foot Ulcer Evaluation**

Management of any ulcer should be guided by a comprehensive evaluation. Enough details on the characteristics of the ulcer, including its size, depth, location, and look, allow for mapping of the ulcer's progress throughout treatment. The evaluation should determine the cause of the ulcer and ascertain whether the lesion is neuropathic, ischemic, or neuro ischemic. Peripheral sensory neuropathy and loss of protective feeling have been shown to be associated with the inability to feel the pressure of 10-g monofilament.

Neurological reflex hammer and a standard tuning fork, which operates at 128 cycles per second, are two more common techniques that may detect insensibility.

The doctor uses a blunt, sterile probe to inspect the ulcer after describing its size and look. Soft probing can identify the development of sinus tracts, erosion of ulcer edges, and ulcer dissection into bone, joints, or tendon sheaths. Osteomyelitis is highly predictive of a positive probe-to-bone result. Wound healing frequently fails when the underlying osteomyelitis is not diagnosed. It is necessary to record the presence and number of cellulites, as well as any smells or exudates.

- **Classification of DFU**

Table 3: Meggitt-Wagner's Classification of DFU [13]

Meggitt-Wagner's Classification	
Grade 0	Pre- or post-ulcerative lesion completely epithelialized
Grade 1	Superficial, full-thickness ulcer limited to the dermis, not extending to the subcutis
Grade 2	Ulcer of the skin extending through the subcutis with exposed tendon or bone and without osteomyelitis or abscess formation
Grade 3	Deep ulcers with osteomyelitis or abscess formation
Grade 4	Localized gangrene of the toes or the forefoot
Grade 5	Extensive Gangrene

- **Management of DFU [14]**

STANDARD OF CARE

Dr. Frederick Treves (1853–1923) established three key DFU treatment proposals that are now the cornerstone of contemporary care: off-loading, sharp debridement, and diabetic foot education. These three concepts fundamentally altered the way DFUs were managed. presently the pillars of therapy are based on these concepts and include vascular evaluation, treatment of active infection, glycaemic management, dressings that promote a moist wound environment, wound off-loading, and local wound care with surgical debridement.

Surgical debridement

Debridement of a wound includes the removal of surrounding callus as well as any necrotic tissue that is not supportive to healing. This procedure lowers plantar pressures in callused regions and encourages the production of granulation tissue and re-epithelialization [15]. Debridement also has a significant impact on infection management because devitalised tissues hinder the immune system's ability to combat infection, operate as a physical barrier to antibiotics, and provide a nidus for bacterial growth [16].

Choice of dressing

Due to the heterogeneity of DFUs, no single dressing works best for any type of wound. The general consensus is that the purpose of a dressing should be to provide a moist environment that fosters angiogenesis, autolytic processes, granulation, and faster migration of epidermal cells across the base of the wound. The dressing that is chosen must be suitable for controlling excessive wound exudates.

Wound off-loading

Plantar shear stress, the horizontal strain exerted on the foot, and to a lesser extent, vertical pressure on the sole of the foot, are significant variables that contribute to the development and prolonged healing of DFUs [17]. Alleviating the pressure and friction on the plantar area of a DFU is crucial for effective wound management, as it facilitates the healing process and reduces the likelihood of the lesion reoccurring [18]. Numerous techniques, including as booties, orthotic walkers, and shoe modifications, can be used to accomplish off-loading. The site of the wound and any history of peripheral vascular disease (PAD) should be taken into consideration while selecting the technique. Surgical off-loading need to be reserved for high-risk patients whose conservative therapy has failed [19].

Vascular assessment

Co-morbid DFU and PAD patients recover more slowly, have a higher major amputation rate, and perish at a greater rate [20]. It is recommended that individuals with DFUs have their ankle brachial index (ABI) or pedal pulses palpated in order to determine whether they have PAD. ABI values less than 0.7 are associated with a certain level of arterial insufficiency, while ABI values less than 0.4 are indicative of severe PAD. Due to vascular calcifications, patients with an ABI higher than 1.4 most likely have non-compressible arteries near the ankle. This is frequently seen in diabetic patients and in those with renal impairment [21].

Treatment of active infection

Accurate diagnosis of diabetic foot infections and appropriate antibiotic treatment are essential for improved outcomes. One of the consequences of abusing medicines to reduce bacterial load or avoid sickness is antibacterial resistance. The IDSA has provided specific guidelines for the management of diabetic foot infections. The IDSA recommends treating wounds which exhibit at least two signs of inflammation (erythema, warmth, tenderness, pain, induration) or purulent discharge. Before starting antibiotic therapy, a deep tissue culture should be obtained via curettage or biopsy after debridement.

It is recommended that clinical diabetic foot infections be treated with narrow spectrum antibiotics for the shortest period of time feasible in order to prevent antibacterial resistance and other adverse treatment outcomes.

Figure 2: Diabetic Foot Ulcer of Patient 2

Glycaemic control

To promote wound healing and reduce negative effects on cellular immunity and infection, blood glucose optimisation is strongly advised. Several observational studies have discovered favourable associations between glycaemic control and wound healing, despite the absence of RCTs in the latest Cochrane review making it impossible to determine if intensive glycaemic control had a beneficial or deleterious influence on the treatment of DFUs. In addition, a different Cochrane analysis evaluating the impact of glycaemic goals in type 2 diabetes discovered that those with strict glycaemic control had a 35% decreased chance of amputation of the lower extremities.

Multidisciplinary care

Diabetes foot care is becoming the latest standard of care in areas where the resources are available. For the treatment of DFUs, the majority of guidelines now advise referral to a multidisciplinary care facility. Amputation rates, severity of amputation, and wound healing periods have all decreased with multidisciplinary treatment, according to a number of studies and systematic reviews. Although there are many different definitions of multidisciplinary diabetic foot care in the literature, it often involves a general, vascular, or orthopaedic surgeon together with a podiatrist, diabetes expert, physical therapist, and wound care nurse.

- **Impact of Patient Education on the Management of Diabetic Foot Care**

Patient education plays an important role in the management of diabetic foot care. Here are some of the key impacts:

1. **Prevention of Complications:** Patient education helps individuals with diabetes understand the importance of regular foot care. They learn to inspect their feet daily, which can lead to the early detection of wounds or infections. Early intervention can prevent complications like foot ulcers or gangrene.

2. **Improved Self-Care:** Education empowers patients to take responsibility for their foot health. They learn how to clean and moisturize their feet, trim nails properly, and select appropriate footwear, reducing the risk of injuries or pressure sores.

3. **Enhanced Blood Sugar Control:** Proper education on diet and medication adherence can help patients maintain better blood sugar levels. Improved glycaemic control can reduce the risk of nerve damage and poor circulation, which are factors contributing to diabetic foot problems.

4. **Increased Awareness:** Patients become more aware of the potential dangers, like numbness or tingling in their feet, and can report these symptoms to their healthcare providers promptly. Early recognition of issues leads to early treatment.

5. **Reduced Hospitalizations:** Effective patient education can decrease the frequency of hospital admissions due to diabetic foot complications, resulting in cost savings and improved quality of life.

6. **Quality of Life:** When patients are educated about diabetic foot care, they are more likely to engage in regular physical activity and maintain a healthier lifestyle. This can enhance their overall quality of life and well-being.

7. **Long-Term Outcomes:** The long-term impact of patient education is evident in better foot health, fewer amputations, and an improved prognosis for individuals with diabetes.

Figure 3: Patient Counselling Session

AIM AND OBJECTIVES
AIM:
To study the treatment pattern of diabetic foot ulcer and to assess the effect of patient counselling on diabetic foot ulcer patients.

OBJECTIVES:
PRIMARY OBJECTIVE:
• To study the various modalities of treatment used for diabetic foot ulcer patients in a tertiary care hospital.

SECONDARY OBJECTIVE:

• To assess the effect of patient counselling on diabetic foot ulcer patients with standard questionnaires.

METHODOLOGY

The study was conducted to study the management of diabetic foot ulcer in diabetic patient visiting MVJ MEDICAL COLLEGE AND RESEARCH HOSPITAL, BANGALORE. The study was attempted to improve the patient's knowledge and attitude towards the self-management of diabetic foot ulcer. And thus, patient counselling is an essential component of clinical pharmacy practice in hospital. Counselling enhances the patients' understanding for their illness and its treatment and may improve adherence and therapeutic outcome and to prevent other complications and future hospitalization.

- **Human ethical approval:**

A study protocol was presented to the MVJ Medical College and Research Hospital's ethics committee members in Bangalore for permission regarding human subjects' treatment. The board members approved the study, and a certificate of ethical clearance was granted.

- **Study design:** Prospective Observational Study
- **Study period:** Six months
- **Study site:** Department of General Medicine and General Surgery, MVJ Medical College and Research Hospital, Bangalore.
- **Study population:** The study population included patients with diabetic foot ulcer, diabetic patients, neuropathy of foot.
- **Sample size:** 150 patients

- **Sample Size Calculation:**

The sample size was calculated using the formula: $Z^2 \times P(1-P) / d^2$

Z^2 = Standard normal variate (at 5% type 1 error (p<0.05) it is 1.96)

P = Expected proportion in population based on previous studies

D = Absolute error on precision

Sample size = $1.96^2 \times 0.11(1-0.11) / 0.05^2 = 150$

- **Study criteria**

Inclusion Criteria:

- Patient diagnosed with T1DM or T2DM with co-morbidities.
- Patient with newly diagnosed, previously diagnosed, and recurrent episodes of DFU.
- Diabetic Foot ulcer patients of either sex.
- Patient aged between 21-90 years.
- Patient at risk for DFU.

Exclusion Criteria:

- Patient diagnosed with gestational diabetes.
- Patients aged below 20 years.
- Non-diabetic related ulcers.
- Patient unwilling to participate in the study.

- **Study Material/Instrument:**
- Informed consent form
- Patient data collection form
- Nottingham Assessment of Functional Footcare (NAFF) questionaries (revised 2015).

- **Study procedure:**
1. A prospective observational study is planned to be conducted at MVJ Medical College and Research Hospital in Bangalore, South India.
2. The Institutional Ethical Committee of MVJ Medical College reviewed and approved the study before it began.
3. The study aims to enroll all eligible patients in the surgery and general medicine wards with Diabetic Foot Ulcer, who give their consent to participate.
4. The patients were considered into the study after verbally explaining the need of the study, the procedure involved and obtaining the informed consent form from the patients.
5. The series of patient history interviews and medication history interview was performed among the patients who are enrolled in the study and the details are documented.
6. The researchers will assess the patients' knowledge about diabetic foot ulcer through a set of questions. [Nottingham Assessment of Functional Footcare (NAFF) questionaries]
7. Patients will receive counseling on self-management and precautions for their diabetic foot ulcer, as well as dietary and pharmacological counseling.
8. Each patient was followed up over a period of 15-18 days and during the follow up NAFF questionaries was brought to the context to evaluate the knowledge and attitude of the study subjects after counseling the compelled data was analyzed.
9. Finally, the data collected at MVJ Medical College and Research Hospital will be systematically compiled and statistically analyzed to identify any trends or patterns.

- **Assessment of management of DFU**

Age, gender, educational status, occupational status, DM type, DM duration, social status, family history with DM, co-morbidities, other complication of DM, FBS, RBS, DFU duration, pain assessment, clinical classification of DFU, organisms isolated from the wound, DFU treatment (Standard of care, class of drugs, antidiabetic drugs).

- **Assessment of patient education**

Each question answered by the patients regarding their knowledge about diabetic foot ulcer before counselling and after counselling was compared and scored. The questionnaire consists of 15 questions. The positive answers are scored as three, moderate answers are scored as two or one and negative answers are scored as zero.

Note on scoring- calculate the total score.

In order to compare the score obtained with data on the NAFF 29, multiply the score by 1.115 to obtain 29 equivalents.

NEED FOR STUDY

The prime cause of non-traumatic limb amputation is diabetic foot ulcers. Based to current evidence, up to 34% of individuals with type 2 diabetes are thought to have diabetic foot ulcers at some point in their lives [22].

In India, DFUs affect around 15% of diabetics during their lifetime. Out of 62 million diabetics in India, 25% develop DFUs, of which 50% become infected, requiring hospitalization while 20% need amputation [23].

The diabetic foot has become one of the most common and serious complications of diabetes mellitus and is a frequent cause of hospitalization and disability [24].

Patient counselling is a vital element of clinical pharmacy practice in hospital. Counselling encourages the patients understanding for their disorder and its management and may improve adherence and therapeutic outcome.

Considering the various barriers of patients counselling, a simple and systemic counselling is provided to the patients to enhance their knowledge and attitude towards the diabetic foot ulcer.

Patient counselling helps the patients to undergo more effective drug treatment, improved quality of life, improved medication adherence and better copping strategies for medication-related adverse effects.

This study also helps to observe the various modalities of treatment in the management of diabetic foot ulcer.

RESULTS

Out of 150 patients, 2 (1.3%) were in the age group of 21-30 years, 9 patients (6.0%) were in the age group 31-40 years, 29 patients (19.3%) were in the age group 41-50 years, 33 patients (22.0%) were in the age group 51-60 years, 46 patients (30.7%) were in the age group 61-70 years, 26 (17.3%) patients were in the age group 71-80 years and 5 patients (3.3%) were in the age group 81-90 years. The majority of the patients affected were in the age group of 61-70 years (Table 4; Figure 4).

Table 4: Age wise Distribution

Sl. No	Age in Years	Frequency (N=150)	Percentage (%)
1.	21-30 years	2	1.3
2.	31-40 years	9	6.0
3.	41-50 years	29	19.3
4.	51-60 years	33	22.0
5.	61-70 years	46	30.7
6.	71-80 years	26	17.3
7.	81-90 years	5	3.3
Total No. Of Patients		150	

Figure 4: Distribution of Age

N=150

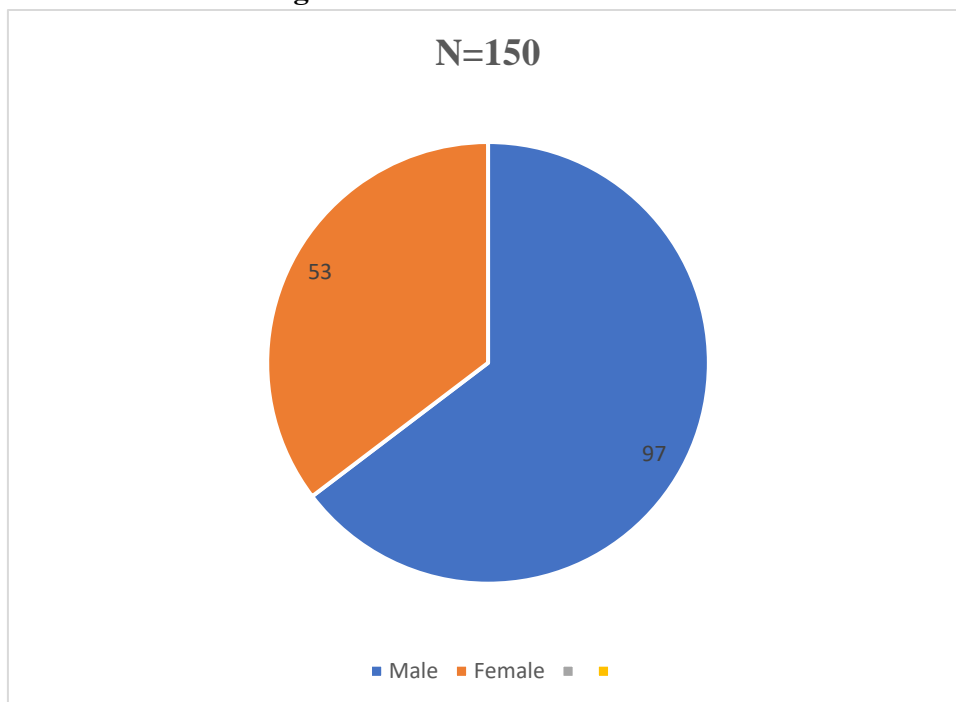■ 21-30 ■ 31-40 ■ 41-50 ■ 51-60 ■ 61-70 ■ 71-80 ■ 81-90
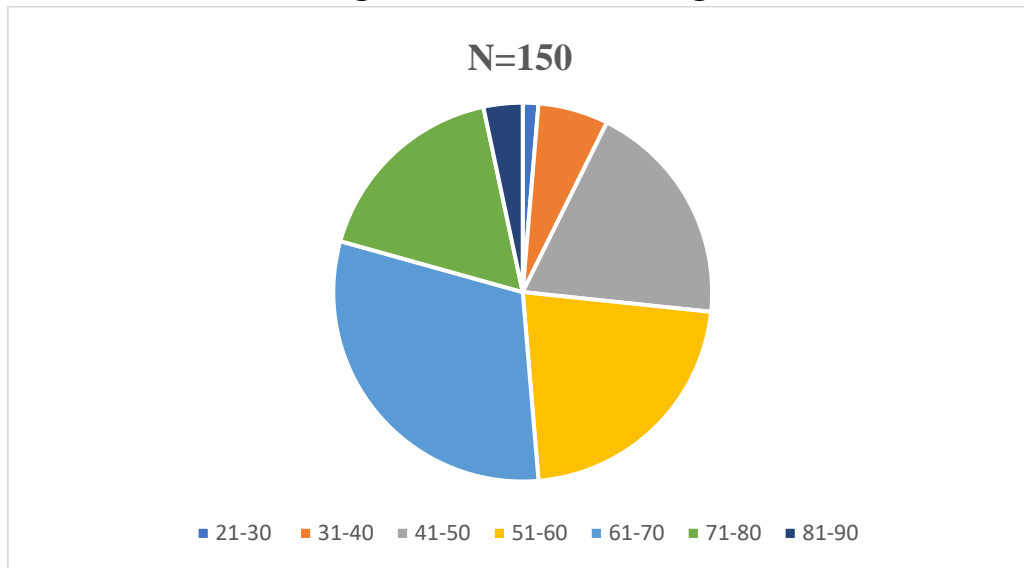
Out of selected 150 patients, 97 patients (64.7%) were male and 53 patients (35.3%) were female. (Table 5; Figure 5)

Table 5: Gender wise Distribution

Sl. No	Gender distribution	Frequency (N=150)	Percentage of patients (%)
1.	MALE	97	64.7%
2.	FEMALE	53	35.3%
Total No. of Patients		**150**	

Figure 5: Distribution of Gender

N=150

■ Male ■ Female ■ ■

Out of selected 150 patients, the foot ulceration with diabetes was most seen in 82 patients who were illiterates. This concludes that the patients with no formal education were recorded the highest with 54.7% (Table 6; Figure 6)

Table 6: Distribution of Educational Status

Sl. No:	Educational Status	Frequency (N=150)	Percentage (%)
1	Degree graduate	17	11.3
2	Illiterate	82	54.7
3	PUC	19	12.7
4	SSLC	32	21.3
Total No. of Patients		**150**	

Figure 6: Distribution of Educational Status
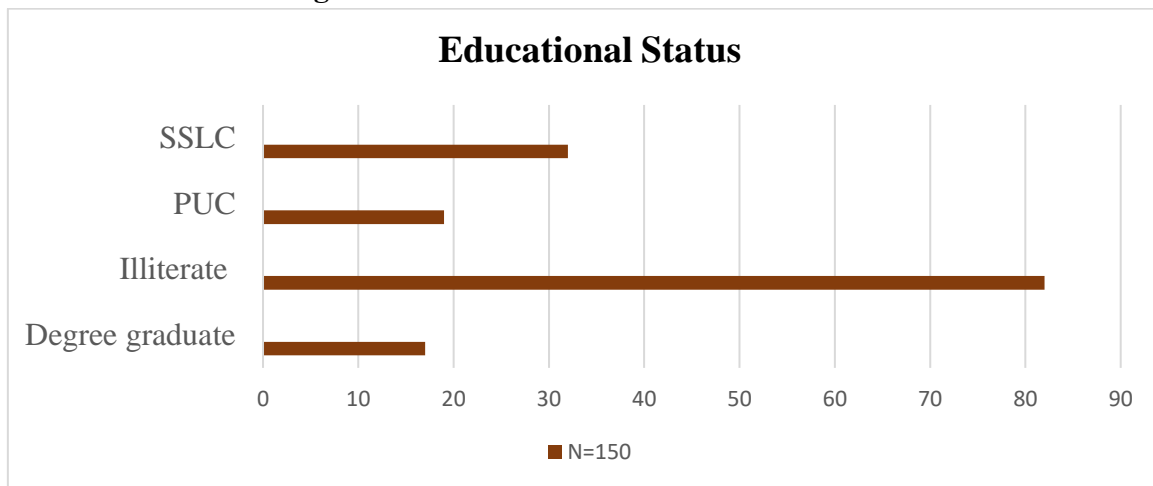
Out of the selected 150 patients, 47 patients belonged to the category others includes Government school/college professors, businessmen and Government staffs, 39 patients were farmers, 32 patients were homemakers, 19 patients were coolies, 9 patients were retired, and 4 patients were watchman. The majority affected with diabetic foot ulcer belonged to others (31.3%) (Table 7; Figure 7)

Table 7: Distribution of Occupational Status

Sl. No	Occupation of the patient	Frequency (N=150)	Percentage (%)
1.	Cooli – Day Labor	19	12.7
2.	Farmer	39	26.0
3.	Homemaker	32	21.3
4.	Retired	9	6.0
5.	Watchman	4	2.7
6.	Others	47	31.3
Total No. of Patients		**150**	

**Figure 7: Distribution of Occupational Status**
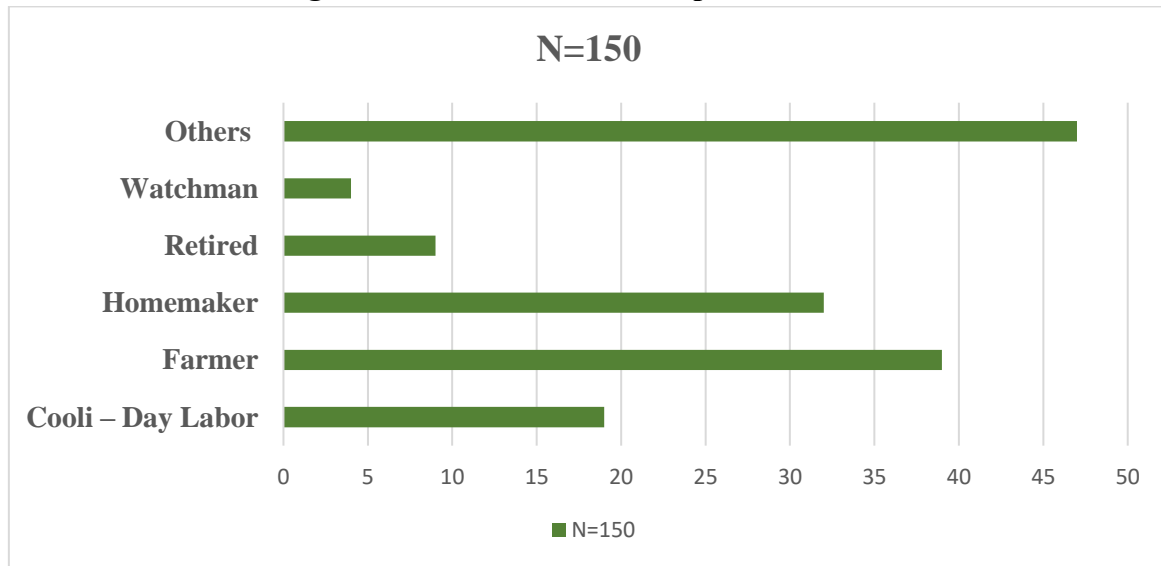
N=150

Out of the 150 patients, 136 patients (90.7%) were diagnosed with Type 2 DM and only 14 patients (9.3) were diagnosed with Type 1 DM (Table 8; Figure 8)

Table 8: Distribution of Diabetes Mellites Types

Sl. No	DM Types	Frequency (N=150)	Percentage (%)
1.	DM Type 1	14	9.3
2.	DM Type 2	136	90.7
Total No. of Patients		**150**	

Figure 8: Distribution of DM Types

N = 150
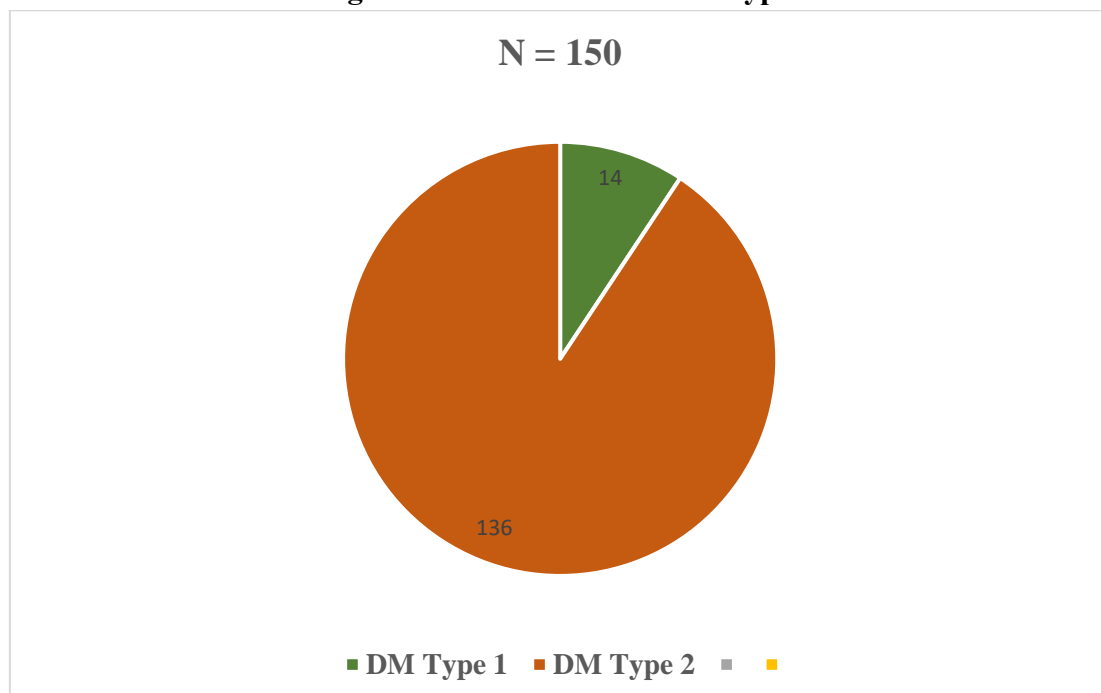
It was observed that most of the patients presented with diabetic foot ulcers had a duration of diabetes mellites between 1-5 years with number of patients 51 (34.0%) and 6-10 years with number of patients 51 (34.0%) (Table 9; Figure 9)

Table 9: Distribution of Diabetes Mellites Duration

Sl. No	DM Duration Distribution	Frequency (N=150)	Percentage (%)
1.	Newly diagnosed	2	1.3
2.	Less than a year	2	1.3
3.	1-5 years	51	34.0
4.	6-10 years	51	34.0
5.	11-15 years	19	12.7
6.	16-20 years	15	10.0
7.	>21 years	10	6.7
Total No. of Patients		**150**	

Figure 9: Distribution of DM Duration
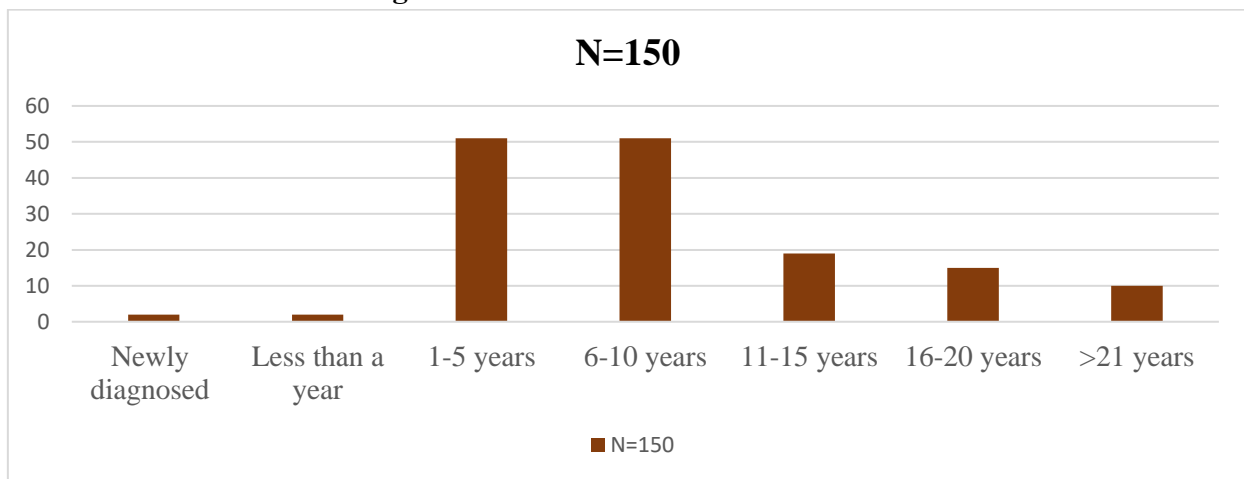
Out of the 150 patients selected, 11 were alcoholic (7.3%), 31 patients (20.6%) were smokers, 16 patients (10.6%) had habit of substance use, 36 patients (24%) were smokers and alcoholic, 6 patients (4%) were alcoholic, smoker, and substance abuser and 50 patients (33.3%) were teetotaller. The majority of the patients presented with diabetic foot ulcers were teetotaller (Table 10; Figure 10).

Table 10: Distribution of Social Status

Sl. No	Social Status Distribution	Frequency (N=150)	Percentage of Patients (%)
1.	Alcoholic	11	7.3
2.	Smoker	31	20.6
3.	Substance Abuse	16	10.6
4.	Alcoholic + Smoker	36	24
5.	Alcoholic + Smoker + Substance Abuse	6	4
6.	Teetotaller	50	33.3

Total No. of Patients	150	

**Figure 10: Distribution of Social Status**
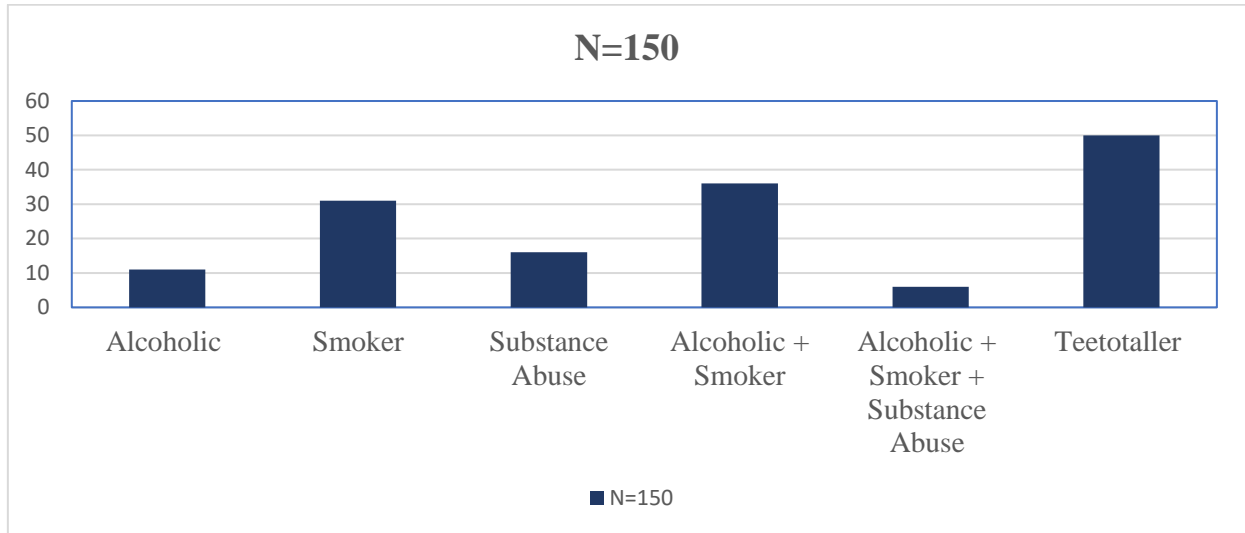
Out of 150 patients, it was observed that 99 patients (66.0%) had family history with DM. The majority of the patients presented with diabetic foot ulcer had family history of DM and were genetically related (Table 11; Figure 11)

Table 11: Distribution of Family History with DM

Sl. No	Family History with DM	Frequency (N=150)	Percentage (%)
1.	Genetically Significant	99	66.0
2.	Nothing Significant	51	34.0
Total No. of Patients	150		

Figure 11: Distribution of Family History with DM
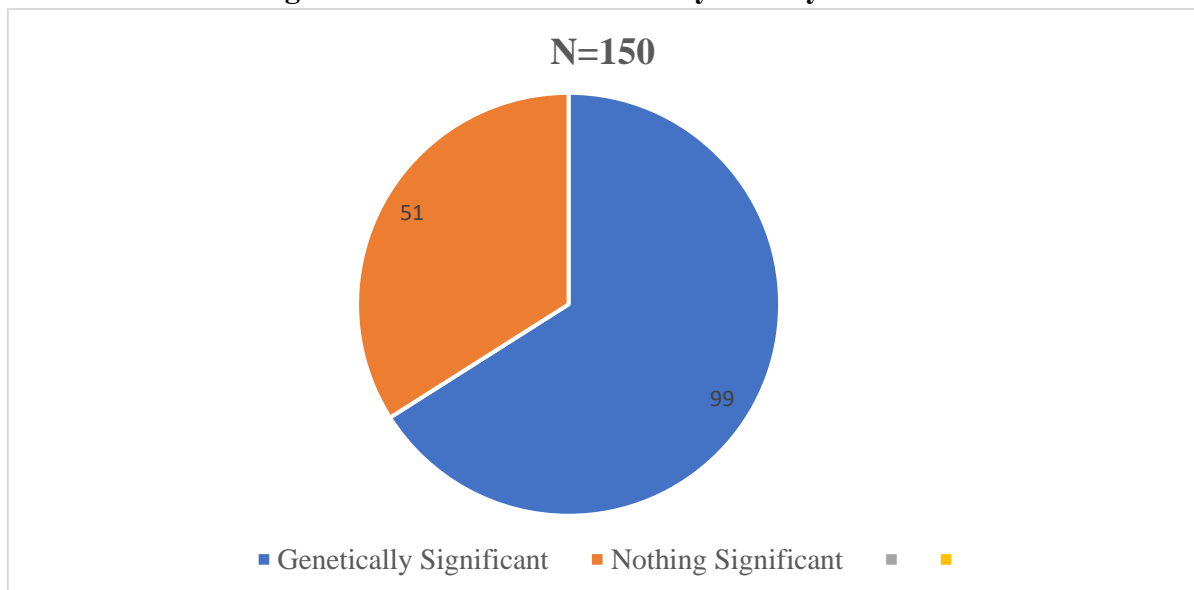
Out of 150 patients, majority of patients were not diagnosed with any co-morbidities (30%) (Table 12; Figure 12).

Table 12: Distribution of Patient's Co-Morbidities

Sl. No	Co-Morbidities	Frequency (N=150)	Percentage (%)
1	Coronary Heart Disease (CHD)	3	2
2	Dyslipidaemia	11	7.3
3	Hypertension (HTN)/High blood pressure	33	22
4	Pulmonary Vascular Disease (PVD)	14	9.3
5	HTN + CHD	7	4.6
6	HTN + PVD	30	20
7	HTN + PVD + Cardiac Disease	2	1.3
8	HTN + PVD +Cardiac Disease + Others	3	2
9	Others	2	1.3
10	Nil	45	30
Total No. of Patients		**150**	

Figure 12: Distribution of Co-Morbidities
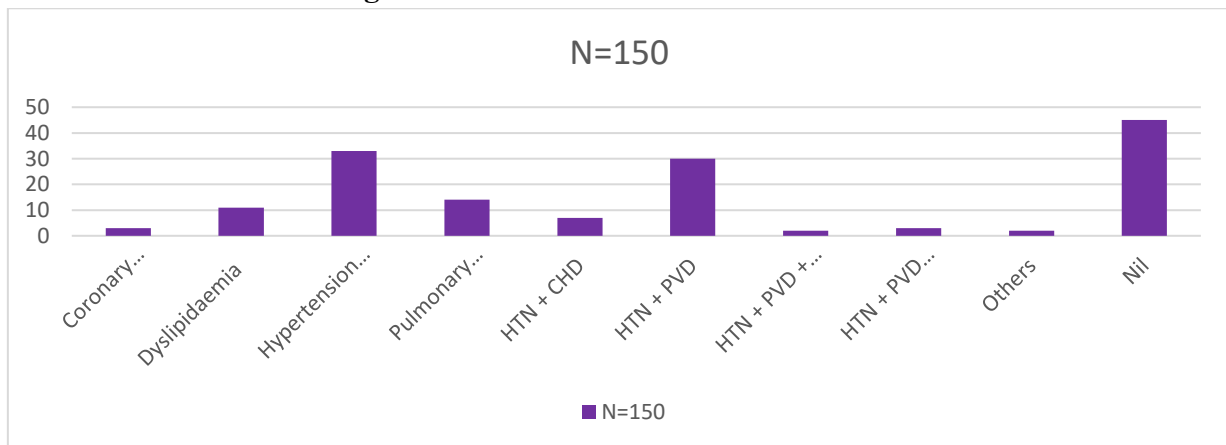
Out of the selected 150 patients, majority of the patients were observed to have neuropathy (67.3%) (Table 13; Figure 13)

Table 13: Distribution of Other Complications of DM

Sl. No	Other complications of DM	Frequency (N=150)	Percentage (%)
1.	Nephropathy	1	0.6
2.	Neuropathy	101	67.3
3.	Neuropathy + Nephropathy	14	9.3
4.	Neuropathy + Retinopathy	23	15.3
5.	Neuropathy + Retinopathy + Nephropathy	5	3.3
6.	Nil	6	4
Total No. of Patients		**150**	

**Figure 13: Distribution of Other complications of DM**
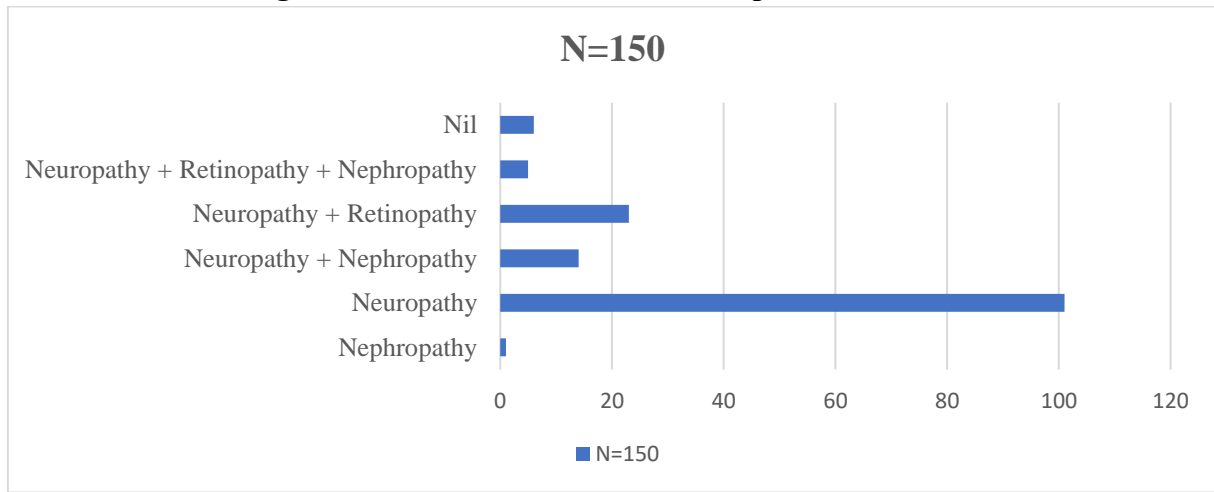
Out of the selected 150 patients, 125 patients (83.3%) of the study participants had fasting blood sugar more than 126mg/dL (Table 14; Figure 14).

Table 14: Distribution of the study participants according to their Fasting Blood Sugar

Sl. No	Fasting Blood Sugar	Frequency (N = 150)	Percentage %
1	101mg/dL - 125mg/dL	25	16.7
2	126mg/dL & above	125	83.3
Total No. of Patients		**150**	

Figure 14: Distribution of the study participants according to their Fasting Blood Sugar
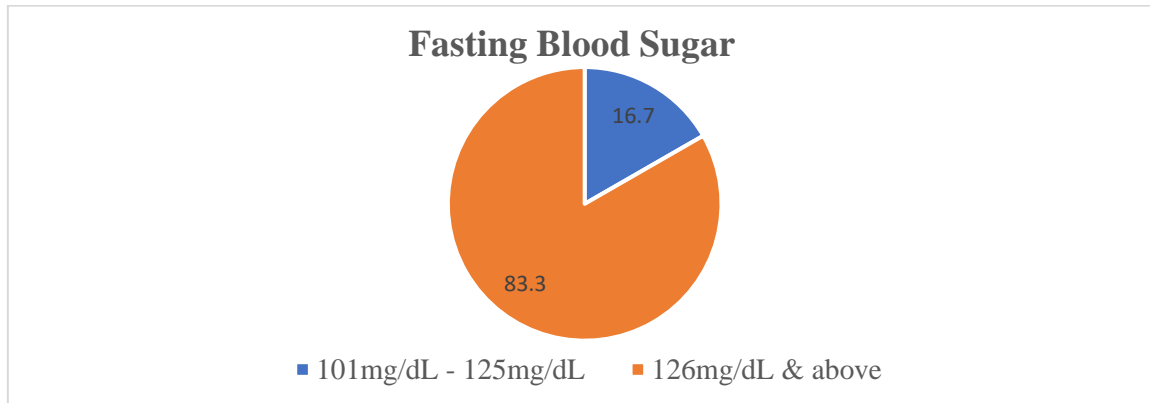
Out of the 150 patients selected, 81 patients (54%) of the study participants had random blood sugar more than 200mg/dL (Table 15; Figure 15)

Table 15: Distribution of the study participants according to their Random Blood Sugar

Sl. No	Random Blood Sugar	Frequency (N = 150)	Percentage %
1	140 - 200mg/dL	69	46.0
2	200mg/dL and above	81	54.0
Total No. of Patients		**150**	

Figure 15: Distribution of the study participants according to their Random Blood sugar
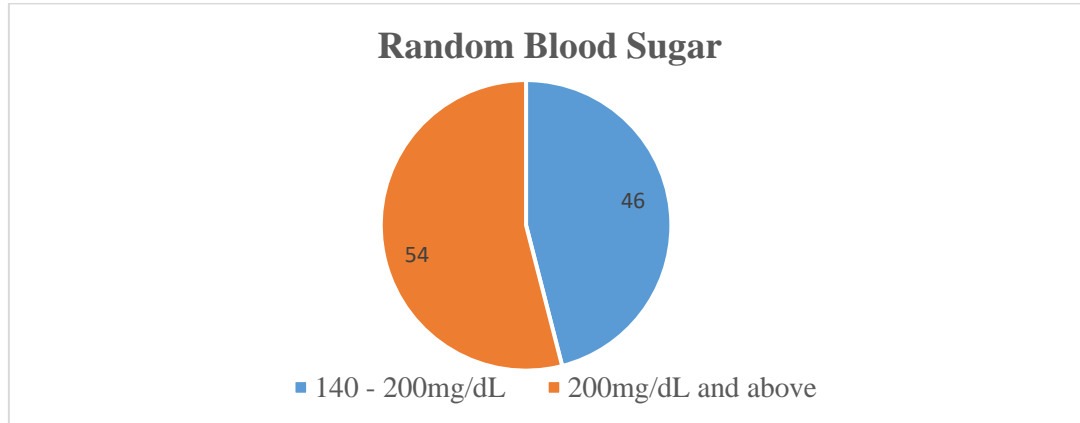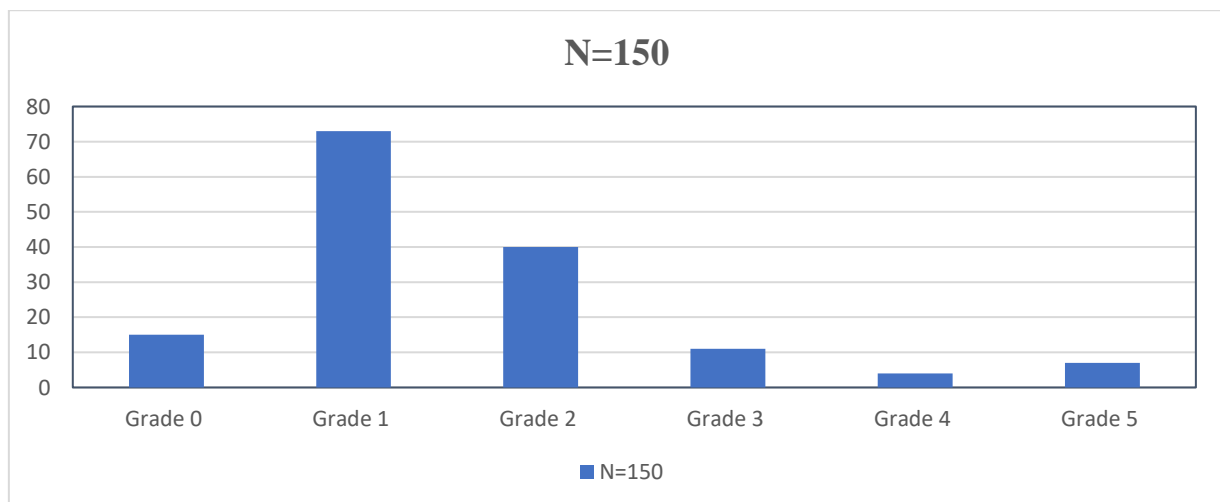

Out of the selected 150 Patients, Majority (48.7%) of the study individuals had Grade 1 Meggitt-Wagner Classification of Foot Ulcers and 26.7% had Grade 2 Meggitt-Wagner Classification of Foot Ulcers (Table 16; Figure 16).

Table 16: Distribution of the study participants according to their Meggitt-Wagner Classification of Foot Ulcers

Meggitt-Wagner Classification of Foot Ulcers	Frequency (N=150)	Percentage %
Grade 0 - Pre- or post-ulcerative lesion completely epithelialized	15	10.0
Grade 1 - Superficial, full-thickness ulcer limited to the dermis, not extending to the subcutis	73	48.7
Grade 2 - Ulcer of the skin extending through the subcutis with exposed tendon or bone and without osteomyelitis or abscess formation	40	26.7
Grade 3 - Deep ulcers with osteomyelitis or abscess formation	11	7.3
Grade 4 - Localized gangrene of the toes or the forefoot	4	2.7
Grade 5 - Foot with extensive gangrene	7	4.7

Figure 16: Distribution of the study participants according to their Meggitt-Wagner Classification of Foot Ulcers

Out of the 150 patients selected, Majority of the patients (45.3%) of the study participants had diabetic foot ulcer for less than a month and 23.3% had diabetic foot ulcer for more than a week (Table 17; Figure 17).

Table 17: Distribution of Diabetic Foot Ulcer Duration

Diabetic Foot Ulcer Duration	Frequency (N=150)	Percentage %
Less than a week	8	5.3
More than a week	35	23.3
Less than a month	68	45.3
More than a month	33	22.0
3 Months and more	6	4.0

**Figure17: Distribution of Diabetic Foot Ulcer Duration**
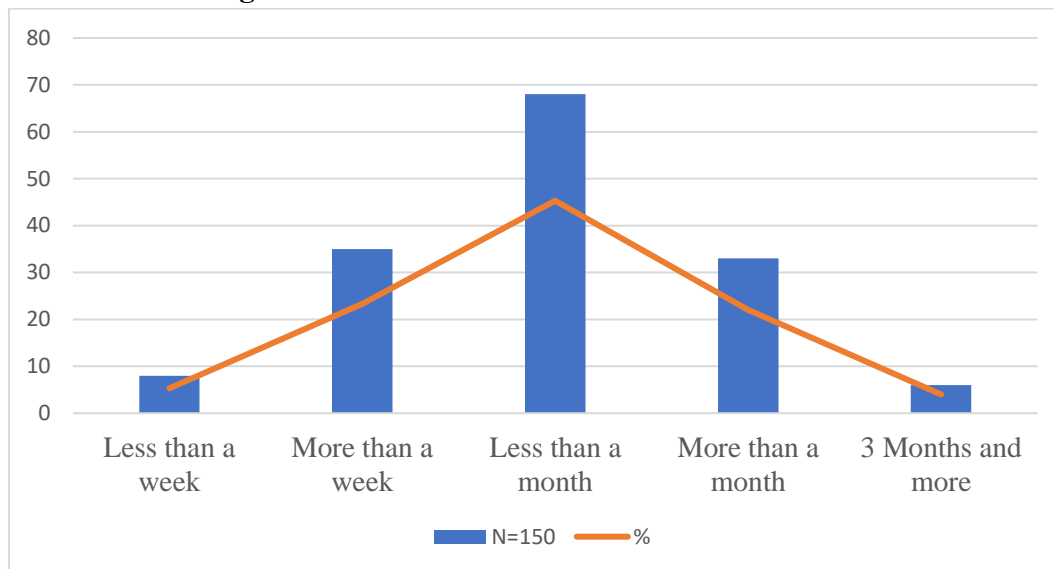
Out of selected 150 patients, 53.3% of patients experienced grade 4 pain and 21.3% of patients experienced grade 2 pain (Table 18; Figure 18).

Table 18: Distribution of Pain Assessment – Wong Baker Faces

| Pain Scale	Frequency (N=150)	Percentage %
0 - No hurt	2	1.3
2 – Hurts a little bit	32	21.3
4 – Hurts little more	80	53.3
6 – Hurts whole lot	19	12.6
8 – Hurts whole lot	14	9.3
10 – Hurts worst	3	2
Total No. of Patients	**150**	

Figure 18: Distribution of Pain Assessment
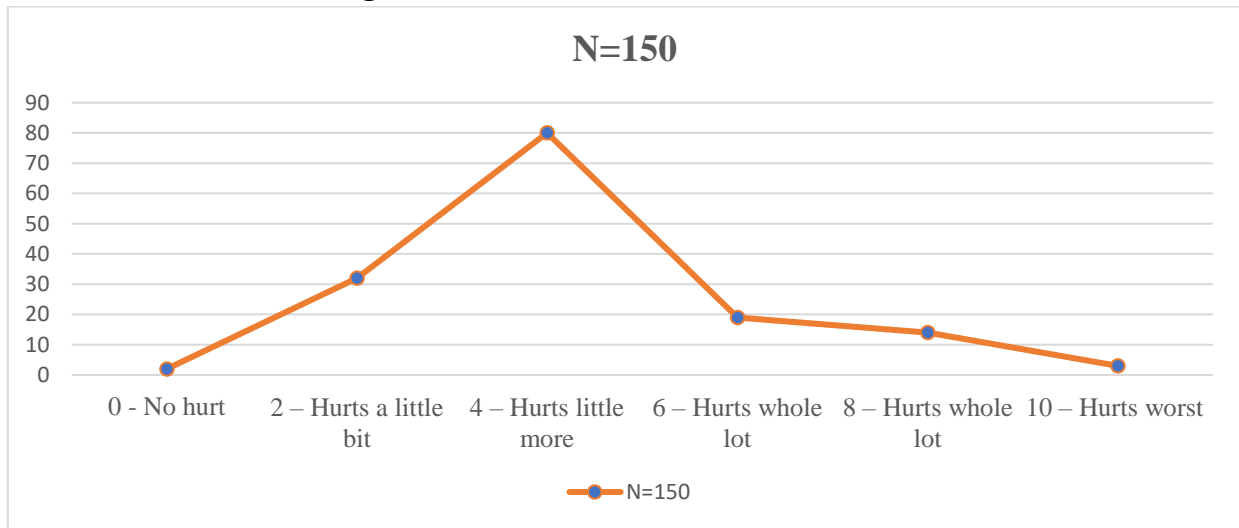
Majority (36%) of the study participants had moderate clinical classification of diabetic foot infection and 29.3% had mild clinical classification of diabetic foot infection (Table 19; Figure 19).

Table 19: Clinical Classification of Diabetic Foot Infection

Clinical Classification of Diabetic Foot Infection	Frequency (N=150)	Percentage %
Not infected	26	17.3
Mild	44	29.3
Moderate	54	36.0
Severe	26	17.3

**Figure 19: Distribution of clinical classification of DFU**
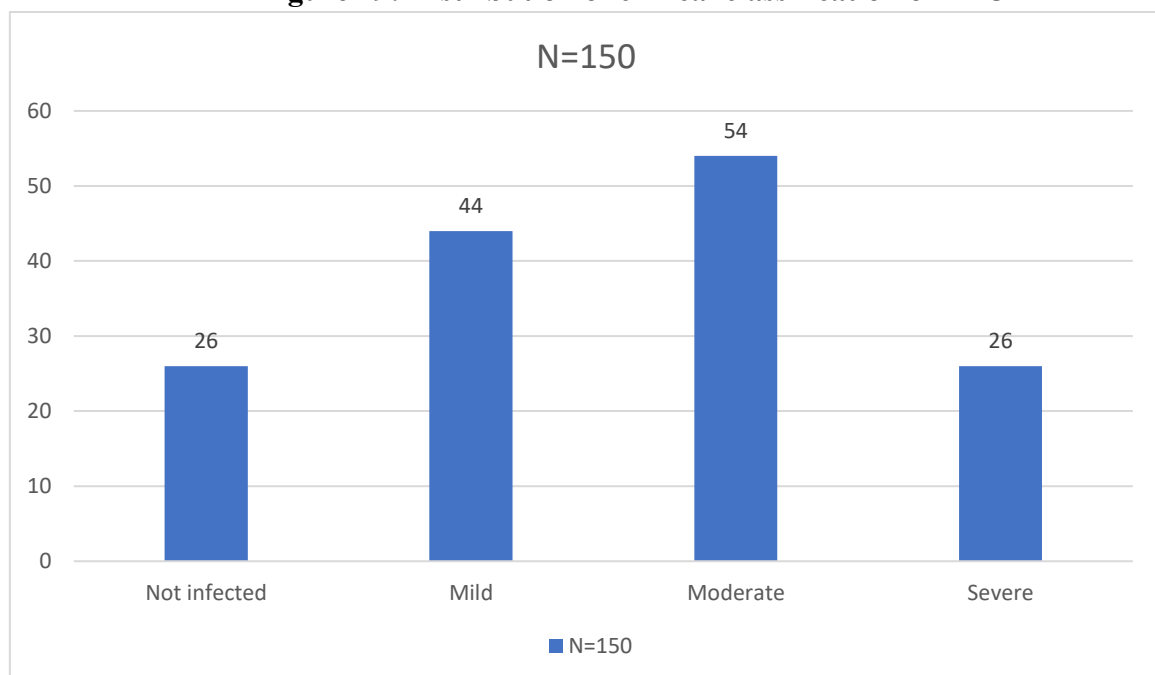
Majority of the organisms isolated from the patients wound were gram positive bacteria of frequency 82 and percentage 54.6% (Table 20; Figure 20).

Table 20: Distribution of Organisms Isolated from the Patient's Wound

Organisms Isolated	Frequency N = 150	Percentage %
Gram Negative Bacteria	32	21.3
Gram Positive Bacteria	82	54.6
Others	10	6.6
Nil	26	17.3
	150	

**Figure 20: Distribution of organisms isolated from the wound**
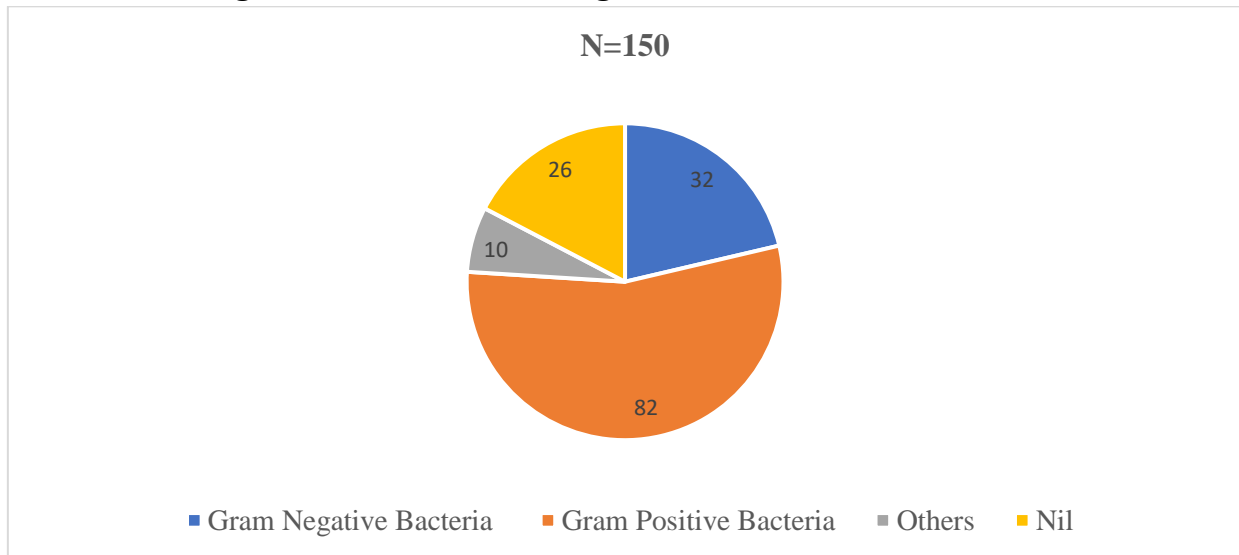
Out of the selected 150 patients, all the patients were given patient education, and their blood sugar levels were controlled (Table 21; Figure 21)

Table 21: Standard of Care

| Standard of care	Frequency (N)	Percentage %
Surgical debridement	141	94.0
Wound-off loading	144	96.0
Glycaemic Control	150	100
Infection control	131	87.3
Amputation	30	20.0
Patient Education	150	100

Figure 21: Distribution of Standard of Care
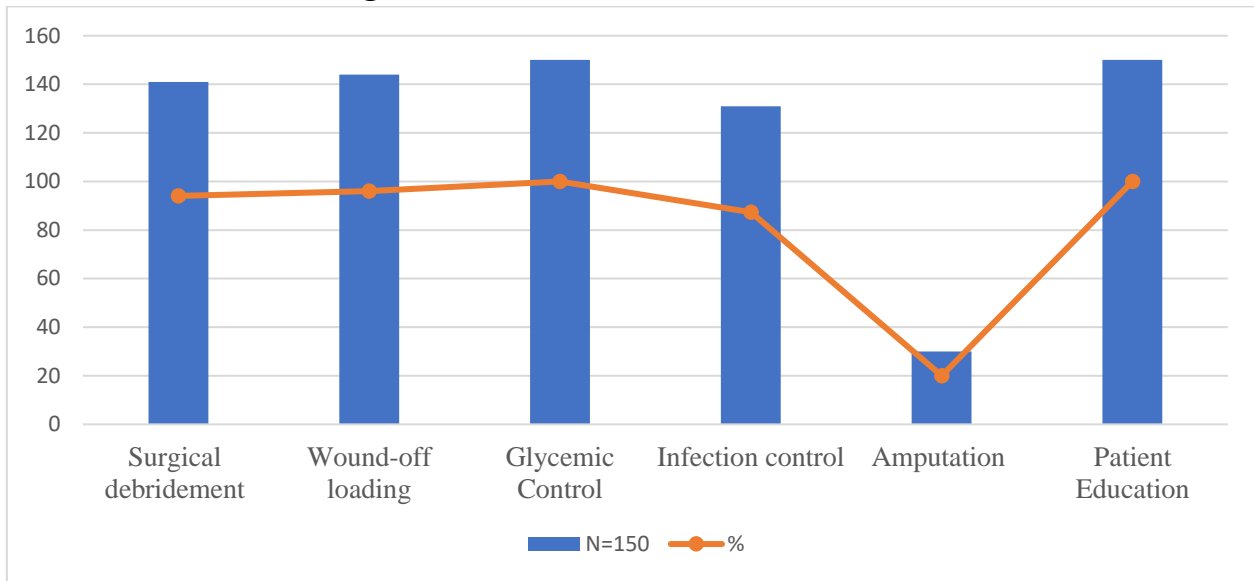
Out of the 150 patients, the majority (141) of patients were prescribed the class of drugs "analgesic", 126 patients were prescribed Insulin, and 124 patients were prescribed Antibiotics/Antimicrobials (Table 22; Figure 22).

Table 22: Class of drugs

Class of Drugs	Frequency (N)	Percentage %
Antibiotics/Antimicrobials	124	82.6
Analgesics	141	94.0
Insulin	126	84.0
Oral Hypoglycaemic drugs	87	58.0
Anti-Hyperglycaemic Drugs	79	52.6
Anti-hypertensive drugs/Antilipidemic	59	39.3
Anti-inflammatory	92	61.3
Vitamins and Nutritional supplements	96	64.0

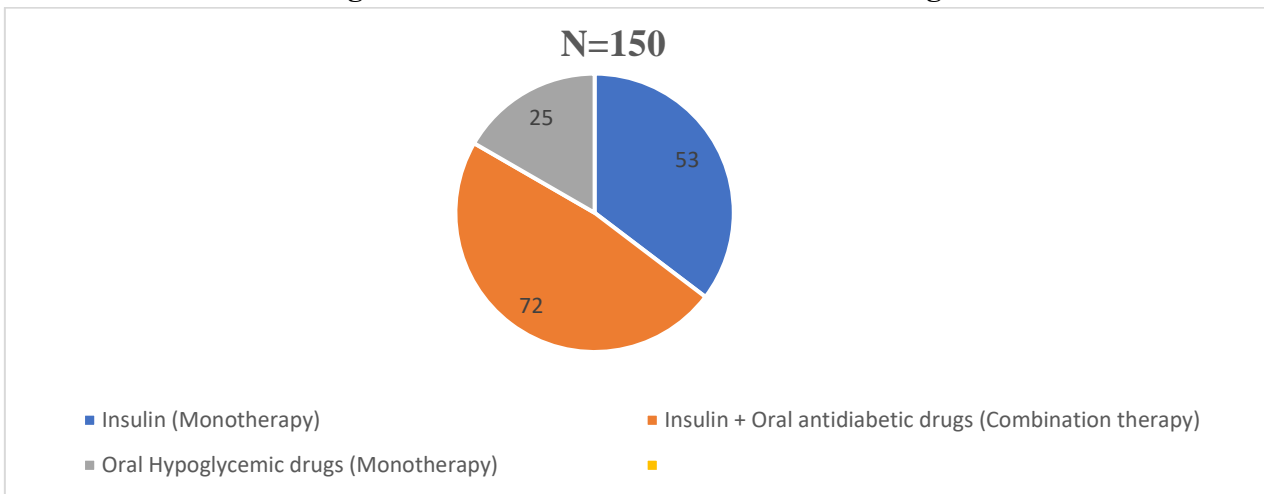**Figure 22: Distribution of class of drugs**
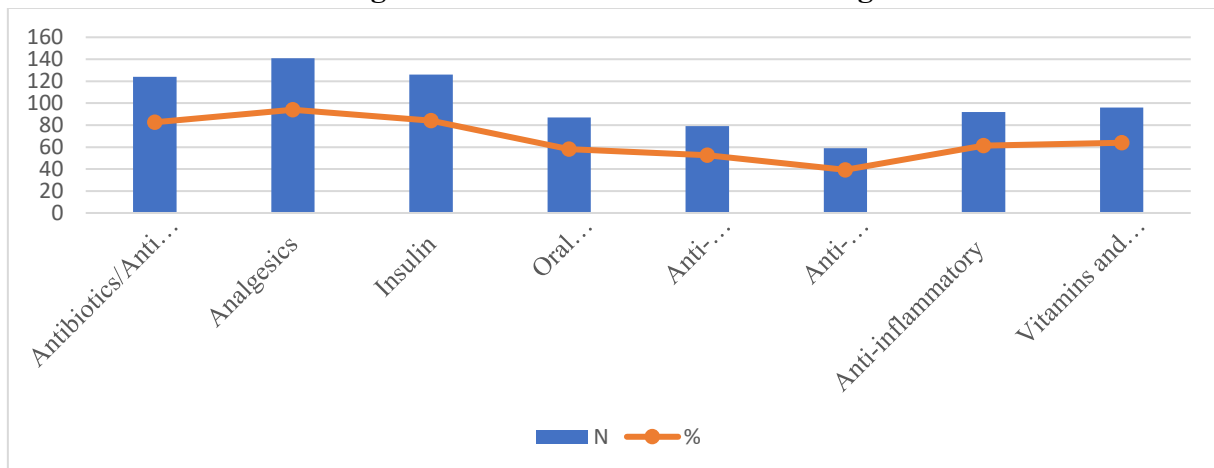
Out of 150 patients, it was observed that the majority (48.0%) of the patients were prescribed with Insulin + Oral antidiabetic drugs (Combination therapy) and 35.3% of patients were prescribed with Insulin (Monotherapy). Least number of patients were prescribed with Oral Hypoglycemic drugs (Monotherapy) (Table 23; Figure 23).

Table 23: Distribution of Anti-Diabetic Drugs

Anti-Diabetic Drugs	Frequency N = 150	Percentage %
Insulin (Monotherapy)	53	35.3
Insulin + Oral antidiabetic drugs (Combination therapy)	72	48.0
Oral Hypoglycaemic drugs (Monotherapy)	25	16.6

Figure 23: Distribution of Anti-Diabetic Drugs

N=150

- Insulin (Monotherapy)
- Insulin + Oral antidiabetic drugs (Combination therapy)
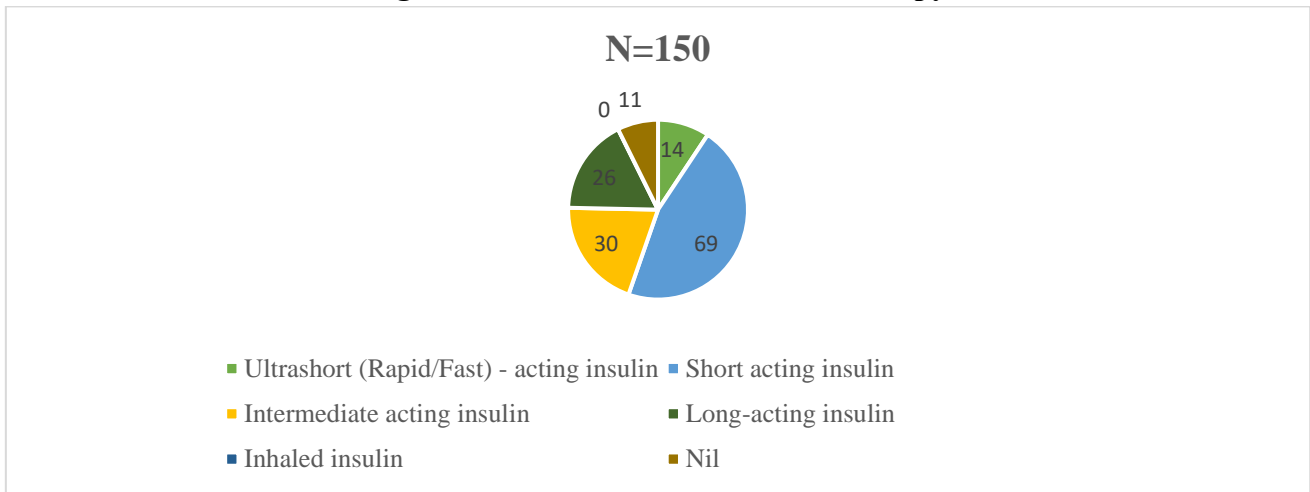- Oral Hypoglycemic drugs (Monotherapy)

Out of 150 patients, it was observed that the majority (46.0%) of the patients were prescribed with Short acting insulin therapy, 20.0 % of patients were prescribed with Intermediate acting Insulin therapy, 17.3 % of patients were prescribed with Long-acting insulin therapy and minority of patients (9.3%) were prescribed with Ultra-short acting insulin (Table 24; Figure 24).

Table 24: Distribution of Insulin Therapy

Insulin Therapy	Frequency (N)	Percentage %
Ultrashort (Rapid/Fast) - acting insulin	14	9.3
Short acting insulin	69	46
Intermediate acting insulin	30	20
Long-acting insulin	26	17.3
Inhaled insulin	0	0
Nil	11	7.3

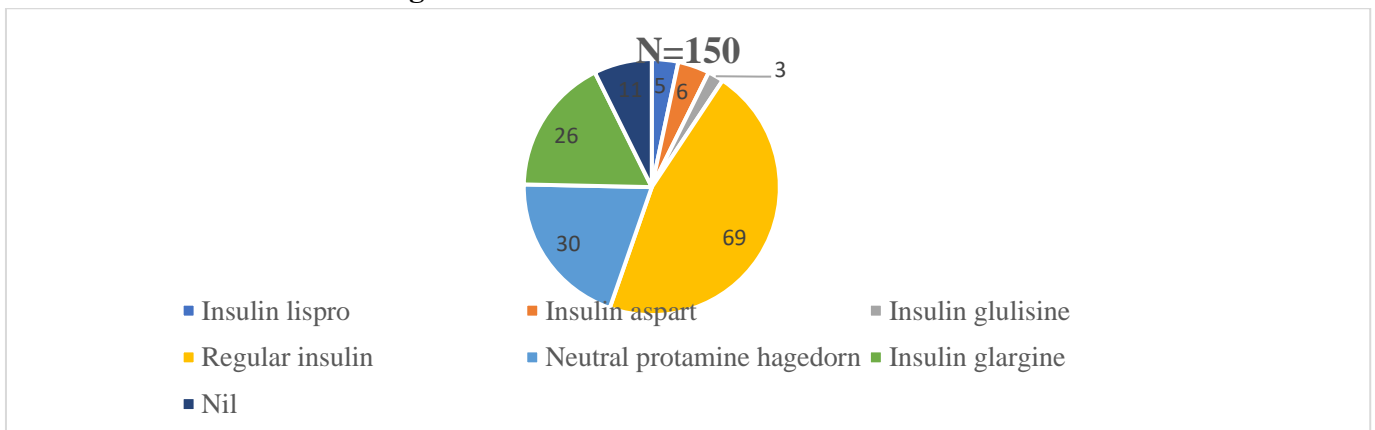**Figure 24: Distribution of Insulin Therapy**

Out of 150 patients, it was observed that the majority (46.0%) of the patients were prescribed with Regular insulin, 20.0 % of patients were prescribed with Neutral protamine Hagedorn, 17.3 % of patients were prescribed with Insulin glargine and minority of patients were prescribed with Insulin lispro, Insulin aspart, Insulin glulisine. (Table 25; Figure 25).

Table 25: Distribution of Insulin Sub Class

Insulin Sub Class	Frequency (N)	Percentage %
Insulin lispro	5	3.3
Insulin aspart	6	4.0
Insulin glulisine	3	2.0
Regular insulin	69	46.0
Neutral protamine Hagedorn	30	20.0
Insulin glargine	26	17.3
Nil	11	7.3

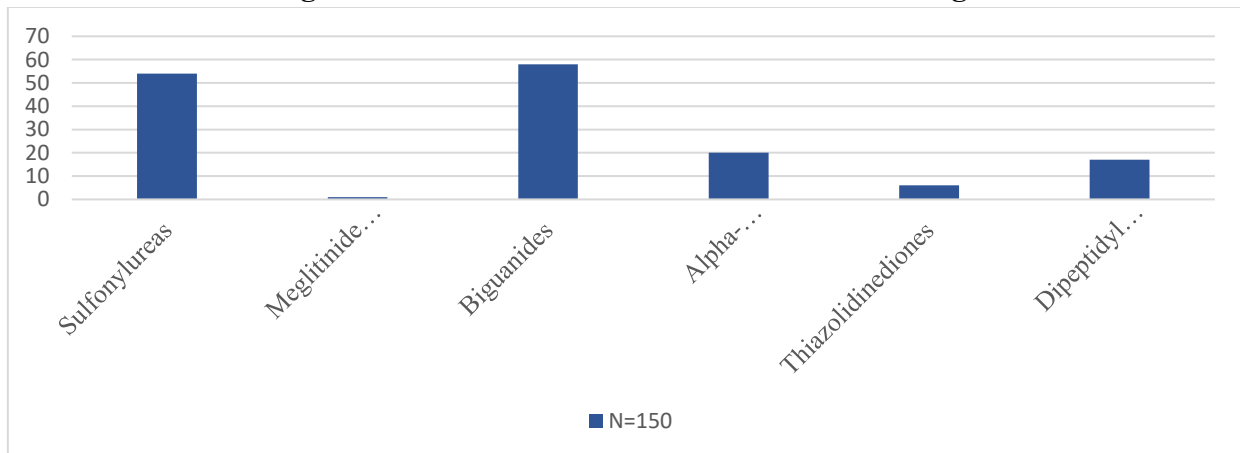**Figure 25: Distribution of Insulin Sub Class**

Out of 150 patients, it was observed that the majority (38.6%) of the patients were prescribed with Biguanides, 36.0 % of patients were prescribed with Sulfonylureas, 13.3 % of patients were prescribed with Alpha- Glucosidase inhibitors and minority of patients were prescribed with Meglitinide analogues (0.6%) and Thiazolidinediones (4.0%). (Table 26; Figure 26).

Table 26: Distribution of Oral Anti-Diabetic Drugs

Oral Anti-Diabetic Drugs	Frequency (N)	Percentage %
Sulfonylureas	54	36.0
Meglitinide analogues	1	0.6
Biguanides	58	38.6
Alpha- Glucosidase inhibitors	20	13.3
Thiazolidinediones	6	4
Dipeptidyl peptidase-4 inhibitors	17	11.3

**Figure 26: Distribution of Oral Anti-Diabetic Drugs**

Out of 150 patients, it was observed that the majority (18.0%) of the patients were prescribed with Sulphonylurea + metformin, 12.6 % of patients were prescribed with Sulphonylurea + alpha glucosidase inhibitors, 10.6 % of patients were prescribed with metformin + vildagliptin/ sitagliptin/ teneligliptin/ linagliptin and Insulin + metformin. Minority of patients were prescribed with Sulphonylurea + pioglitazone (6.0%) (Table 27; Figure 27).

Table 27: Distribution of Combination Therapy

Combination Therapy	Frequency (N)	Percentage %
Sulphonylurea + metformin	27	18.0
Sulphonylurea + pioglitazone	9	6.0
Sulphonylurea + alpha glucosidase inhibitors	19	12.6
metformin + vildagliptin/ sitagliptin/ teneligliptin/ linagliptin	16	10.6
Insulin + metformin	16	10.6

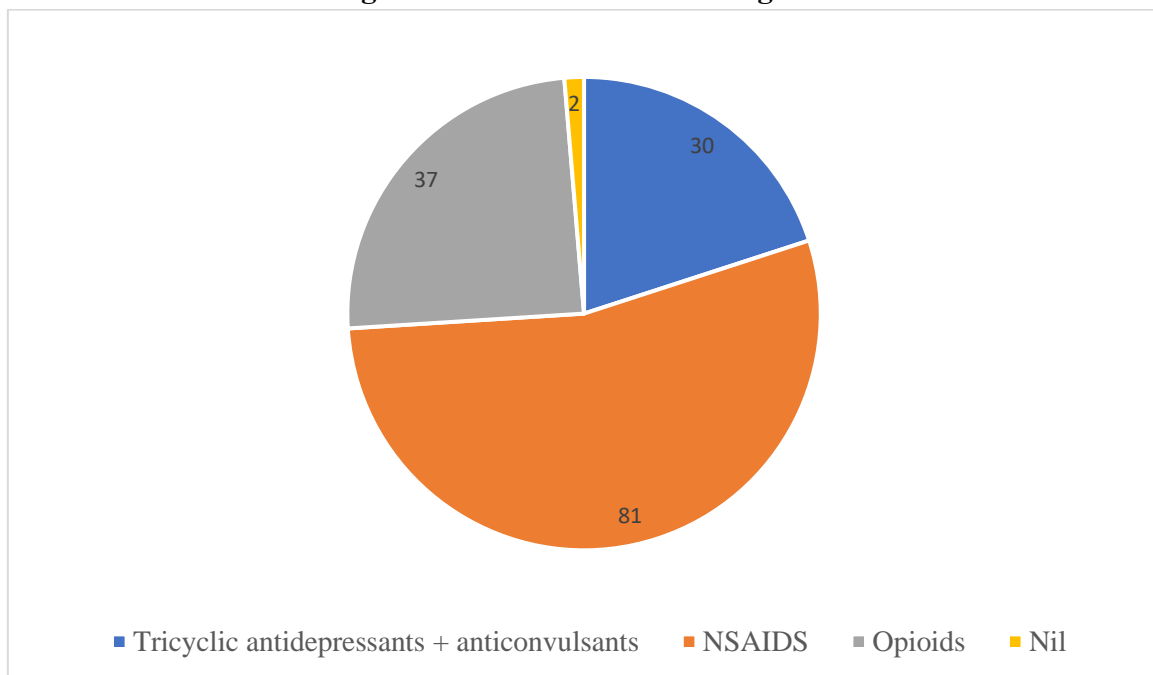**Figure 27: Distribution of combination therapy**
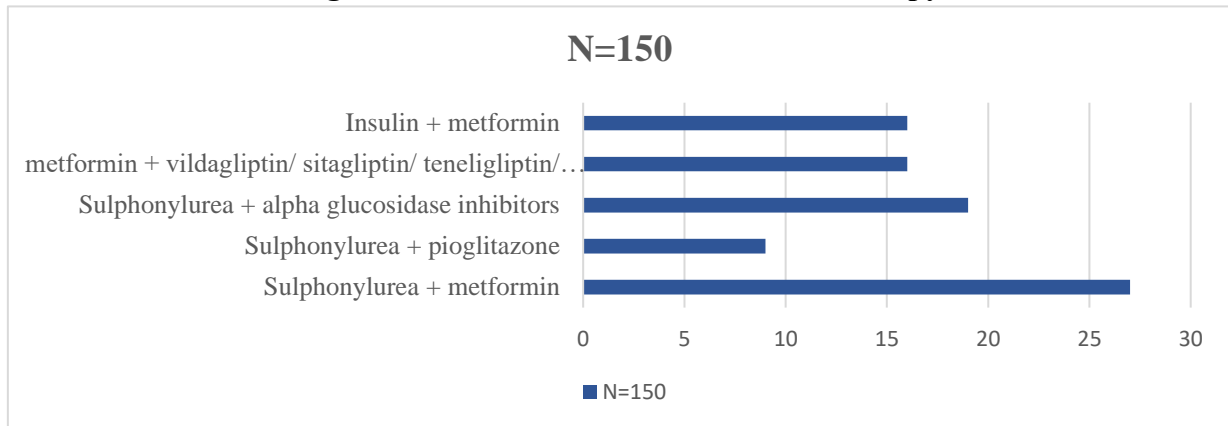
Out of 150 patients, it was observed that the majority (54.0%) of the patients were prescribed with NSAIDS and 24.6 % of patients were prescribed with Opioids, Minority of patients were prescribed with Tricyclic antidepressants + anticonvulsants (20.0%) (Table 28; Figure 28).

Table 28: Distribution of Analgesics

Analgesics	Frequency (N)	Percentage
Tricyclic antidepressants + anticonvulsants	30	20.0
NSAIDS	81	54.0
Opioids	37	24.6
Nil	2	1.3

Figure 28: Distribution of Analgesics

Out of 150 patients, it was observed that the majority (46.0%) of the patients were prescribed with Ceftriaxone, 34.6 % of patients were prescribed with Metronidazole, 34.0% of patients were prescribed with Amoxicillin/Clavulanate. Minority of patients were prescribed with Linezolid (7.3%) and Levofloxacin (2.0%). (Table 29; Figure 29).

Table 29: Distribution of Antibiotics/ Antimicrobials

Antibiotics/ Antimicrobials	Frequency (N)	Percentage %
Dicloxacillin	40	26.6
Cephalexin	0	0
Amoxicillin/Clavulanate	51	34.0
Cefixime/Clavulanate	35	23.3
Cefixime/Ornidazole	0	0
Cefoperazone/Sulbactam	0	0
Ceftazidime/Tazobactam	2	1.3
Ceftriaxone	69	46.0
Ceftriaxone/Sulbactam	0	0
Cefuroxime Axetil	0	0
Ciprofloxacin	30	20.0
Clindamycin	0	0
Cotrimoxazole	0	0
Faropenem	0	0
Levofloxacin	3	2.0
Linezolid	11	7.3
Meropenem	19	12.6
Metronidazole	52	34.6
Nitrofurantoin	21	14.0
Piperacillin/Tazobactam	27	18.0
Vancomycin	50	33.3

Figure 29: Distribution of Antibiotics/ Antimicrobials
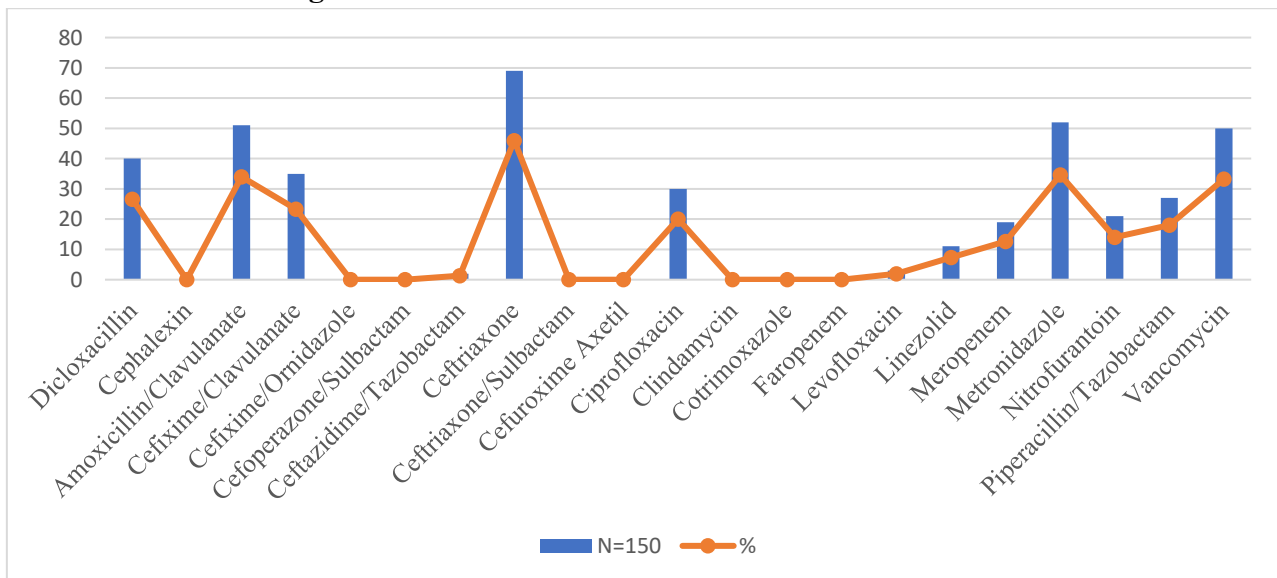
Table 30: Before and after NAFFC total scores after counselling

NAFFC	Mean	Std. Deviation	Std. Error Mean	95% CI		P VALUE
				Lower	Upper	
BEFORE	18.27	5.85	0.430	-24.345	-22.175	**0.001**
AFTER	44.07	4.70	0.346			

The counselling was found to improve the care of diabetic foot as shown from the before and after **NAFFC** scores. This improvement in the **NAFFC** score was found to be statistically significant.

Figure 30: NAFF Score
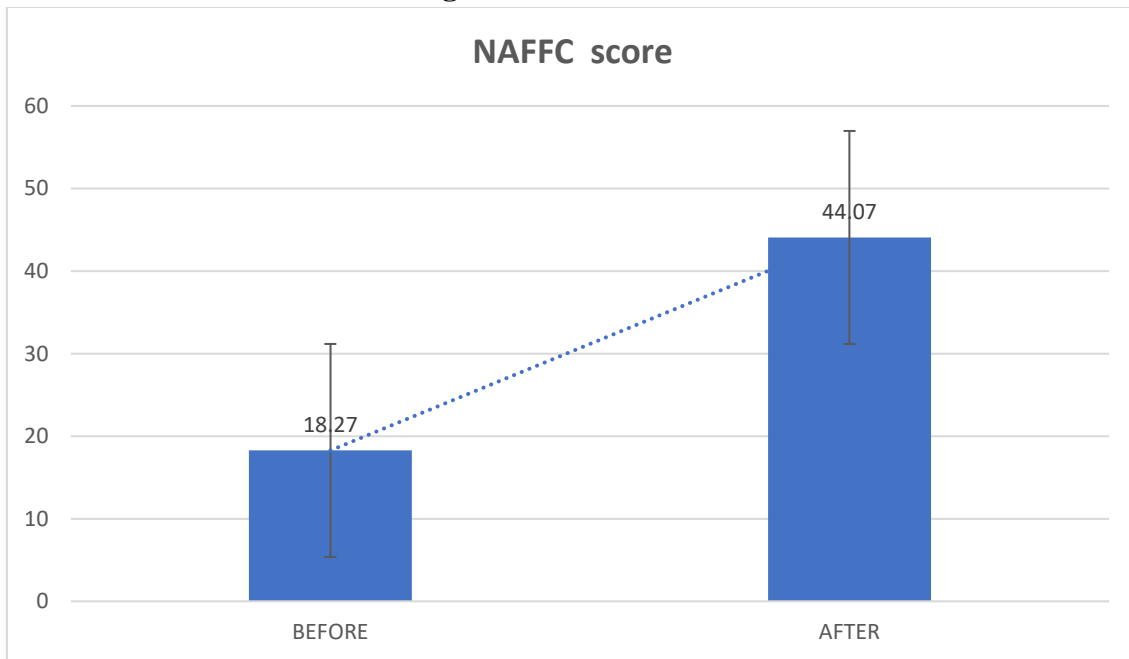
DISCUSSION

A prospective observational study was conducted to study the various modalities of treatment used for Diabetic Foot Ulcer patients and to assess the effect of patient counselling on diabetic foot ulcer patients with standard questionaries.

In this study, majority of the study participants belonged to the age group 61-70 years (30.7%) of age. 22% of the study participants were of the age group between 51-60 years of age. In a study by Alsaleh et al. 43.4% belonged to 50-64 years of age group which was different from this study. In this study, majority (64.7%) of the study participants were males. In a study by Alsaleh et al. [25], Majority i.e., 52.9% were males which was similar to this study. In a study by Heng et al. [26], Majority i.e., 57.6% were males which was similar to this study. In a study by Sekhar et al. [27], Majority i.e., 78.6% were males similar to this study. In this study, majority (54.7%) of the study participants were illiterates. This was in contrast to a study by Alsaleh et al. [25], in which majority i.e., 40% were bachelor's and only 3.4% were illiterates. In this study, majority 90.7% of the study participants had type 2 diabetes mellitus and others had type 1 DM. In a study by Alsaleh et al. [25], 81% had Type 2 DM which was similar to this study. In a study by Sekhar et al. [27],78.6% had Type 2 DM which was similar to this study.

In this study, 34% of the study participants had diabetes in the duration of 1-5 years and 34% had diabetes

in the duration between 6-10 years. Whereas in a study by Alsaleh et al. [25], majority i.e., 48.6% had diabetes for a duration of 10 years and above. In a study by Sekhar et al. [27], mean duration of diabetes was 16.3 ± 7.1 years which was more compared to this study. In this study, 83.3% of the study participants had fasting blood sugar more than 126mg/dL. In this study, 54% of the study participants had random blood sugar more than 200mg/Dl   In this study, majority (48.7%) of the study participants had Grade 1 Meggitt-Wagner Classification of Foot Ulcers and 26.7% had Grade 2 Meggitt-Wagner Classification of Foot Ulcers. In a study by Sekhar et al.[3] majority (60%) had Grade 1 Meggitt-Wagner Classification of Foot Ulcers and 14.3% had Grade 2 Meggitt-Wagner Classification of Foot Ulcers which was similar to this study. In this study, majority (45.3%) of the study participants had diabetic foot ulcer for less than a month and 23.3% had diabetic foot ulcer for more than a week. In this study, majority (36%) of the study participants had moderate clinical classification of diabetic foot infection and 29.3% had mild clinical classification of diabetic foot infection. In this study, all the patients were given patient education, and their blood sugar levels were controlled. The majority (141) of patients were prescribed the class of drugs "analgesic", 126 patients were prescribed Insulin, and 124 patients were prescribed Antibiotics/Antimicrobials. It was observed that the majority (48.0%) of the patients were prescribed with Insulin + Oral antidiabetic drugs (Combination therapy) and 35.3% of patients were prescribed with Insulin (Monotherapy). Least number of patients were prescribed with Oral Hypoglycaemic drugs (Monotherapy). It was observed that the majority (46.0%) of the patients were prescribed with Short acting insulin therapy, 20.0 % of patients were prescribed with Intermediate acting Insulin therapy, 17.3 % of patients were prescribed with Long-acting insulin therapy and minority of patients (9.3%) were prescribed with Ultra-short acting insulin. It was observed that the majority (46.0%) of the patients were prescribed with Regular insulin, 20.0 % of patients were prescribed with Neutral protamine Hagedorn, 17.3 % of patients were prescribed with Insulin glargine and minority of patients were prescribed with Insulin lispro, Insulin aspart, Insulin glulisine. It was observed that the majority (38.6%) of the patients were prescribed with Biguanides, 36.0 % of patients were prescribed with Sulfonylureas, 13.3 % of patients were prescribed with Alpha- Glucosidase inhibitors and minority of patients were prescribed with Meglitinide analogues (0.6%) and Thiazolidinediones (4.0%). It was observed that the majority (18.0%) of the patients were prescribed with Sulphonylurea + metformin, 12.6 % of patients were prescribed with Sulphonylurea + alpha glucosidase inhibitors, 10.6 % of patients were prescribed with metformin + vildagliptin/ sitagliptin/ teneligliptin/ linagliptin and Insulin + metformin. Minority of patients were prescribed with Sulphonylurea + pioglitazone (6.0%). it was observed that the majority (54.0%) of the patients were prescribed with NSAIDS and 24.6 % of patients were prescribed with Opioids, Minority of patients were prescribed with Tricyclic antidepressants + anticonvulsants (20.0%). It was observed that the majority (46.0%) of the patients were prescribed with Ceftriaxone, 34.6 % of patients were prescribed with Metronidazole, 34.0% of patients were prescribed with Amoxicillin/Clavulanate. Minority of patients were prescribed with Linezolid (7.3%) and Levofloxacin (2.0%).

In this study, Nottingham Assessment of Functional Footcare (Revised 2015) was used and an improvement in the total score was found i.e., from 18.27 ± 5.85 before counselling to 44.07 ± 4.70 post counselling which was found to be statistically significant (P<0.001). In a study done by Lincoln et al. [28], which was a randomised controlled trial to assess the effect of education for secondary prevention of foot ulcers in people with diabetes, it was found that the median score in the intervention group was 42.0 compared with 38.7 in the controls (p = 0.03) which was statistically significant similar to this study. In a

study by Malone et al. [29], it was found that education led to a major reduction in ulcer incidence and amputation within 13 months which supports the finding of the present study.

In a study by Alsaleh et al. [25], using the NAFFC it was found that the overall mean score of patients' foot care practice in this study was 55.7 ± 9.2 which was higher compared to this study and it was concluded that knowledge and self-practice of patients with diabetes regarding foot care was rated as good. Patient counselling could improve the NAFFC score among these patients.

In a study by McCabe et al. [30], a randomised study of a diabetic population at high risk, it was reported that the incidence of amputation was lower in the intervention group compared to control group. In a study by Heng et al. [26], intervention group has significant increase in knowledge retention and self-care behaviours score (+5.45) post-study, compared to baseline (P < .001) whereas increase (+1.9, P = .32) was not significant for participants in control group. One interpretation of this finding is that the counselling may promote a individual with a new ulcer to seek expert help as early and that this may lead to an improved result.

In a study by Brand et al. [31], there was a significant improvement in reported foot care behaviour (P < 0.001) after the education session which was similar to this study. In a study by Magbanua et al. [32], patients who received diabetes education training were twice as likely to have a good knowledge score (OR 2.41, 95% CI, 1.09 to 5.32; p=0.03) which supports the finding of the present study. A proper foot care instruction program has been shown to lower the risk of ulceration [33,34].

CONCLUSION

The current study was conducted to study the effect of patient counselling on diabetic foot ulcer patients using NAFFC score. Majority in the study belonged to 61-70 years and were males. Most of them had type 2 DM and grade 1 foot ulcer. In this study, Nottingham Assessment of Functional Footcare (Revised 2015) was used and an improvement in the total score was found i.e., from 18.27+5.85 before counselling to 44.07+4.70 post counselling which was found to be statistically significant (P<0.001). NAFFC score played an important role in the study to assess the functional outcome among diabetics with foot ulcers.

Though there is development of new therapies for the management of diabetic foot ulcers, a high rate of failure ending with amputation still exists. Hence a counselling session to the diabetics with foot ulcers can prevent further complications.

LIMITATION

Although this study was able to meet all the objectives successfully, it comes with its own limitation.

- One of the major limitations includes the financial burden faced by the subjective which made them not compliance to the therapy regimen even after intervention of verbal counselling.
- Sometimes the response obtained from the participants to questions related to diabetic foot ulcer were not entirely true.

The response provided by the caretaker is sometimes found to be not reliable.

SUMMARY

Our study was experimented out on 150 diabetic individuals with foot ulcer. The different pattern of treatment was studied and patient's knowledge and attitude on diabetic foot ulcer were assessed using naff questionnaire. It consists of 25 questions out of which 15 questions were selected to assess the patient. The participants were counselled and educated on diabetic foot ulcer, their symptoms and risks, importa-

nce of taking medications, diet and lifestyle modification to improve the patient's condition.

Out of 150 patients, 2 (1.3%) were in the age group of 21-30 years, 9 patients (6.0%) were in the age group 31-40 years, 29 patients (19.3%) were in the age group 41-50 years, 33 patients (22.0%) were in the age group 51-60 years, 46 patients (30.7%) were in the age group 61-70 years, 26 (17.3%) patients were in the age group 71-80 years and 5 patients (3.3%) were in the age group 81-90 years. The majority of the patients affected were in the age group of 61-70 years. Majority of them were male (64.7%).

In this study, all the patients were given patient education, and their blood sugar levels were controlled. The majority (141) of patients were prescribed the class of drugs "analgesic", 126 patients were prescribed Insulin, and 124 patients were prescribed Antibiotics/Antimicrobials. It was observed that the majority (48.0%) of the patients were prescribed with Insulin + Oral antidiabetic drugs (Combination therapy) and 35.3% of patients were prescribed with Insulin (Monotherapy). Least number of patients were prescribed with Oral Hypoglycaemic drugs (Monotherapy). It was observed that the majority (46.0%) of the patients were prescribed with Short acting insulin therapy, 20.0 % of patients were prescribed with Intermediate acting Insulin therapy, 17.3 % of patients were prescribed with Long-acting insulin therapy and minority of patients (9.3%) were prescribed with Ultra-short acting insulin. It was observed that the majority (46.0%) of the patients were prescribed with Regular insulin, 20.0 % of patients were prescribed with Neutral protamine Hagedorn, 17.3 % of patients were prescribed with Insulin glargine and minority of patients were prescribed with Insulin lispro, Insulin aspart, Insulin glulisine. It was observed that the majority (38.6%) of the patients were prescribed with Biguanides, 36.0 % of patients were prescribed with Sulfonylureas, 13.3 % of patients were prescribed with Alpha- Glucosidase inhibitors and minority of patients were prescribed with Meglitinide analogues (0.6%) and Thiazolidinediones (4.0%). It was observed that the majority (18.0%) of the patients were prescribed with Sulphonylurea + metformin, 12.6 % of patients were prescribed with Sulphonylurea + alpha glucosidase inhibitors, 10.6 % of patients were prescribed with metformin + vildagliptin/ sitagliptin/ teneligliptin/ linagliptin and Insulin + metformin. Minority of patients were prescribed with Sulphonylurea + pioglitazone (6.0%). It was observed that the majority (46.0%) of the patients were prescribed with Ceftriaxone, 34.6 % of patients were prescribed with Metronidazole, 34.0% of patients were prescribed with Amoxicillin/Clavulanate. Minority of patients were prescribed with Linezolid (7.3%) and Levofloxacin (2.0%).

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