"ASSESSMENT OF SEVERITY OF DIABETIC FOOT ULCERS USING DIABETIC ULCER SEVERITY SCORE IN PATIENTS ADMITTED AT KLES DR. PRABHAKAR KORE HOSPITAL AND MEDICAL RESEARCH CENTRE, BELAGAVI - A ONE YEAR LONGITUDINAL STUDY."

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ENDORSEMENT

This is to certify that the dissertation entitled **"ASSESSMENT OF SEVERITY OF DIABETIC FOOT ULCERS USING DIABETIC ULCER SEVERITY SCORE IN PATIENTS ADMITTED AT KLES DR. PRABHAKAR KORE HOSPITAL AND MEDICAL RESEARCH CENTRE, BELAGAVI - A ONE YEAR LONGITUDINAL STUDY"** is a bonafide research work done by **REG NO. BH0118001.**

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LIST OF ABBREVIATIONS USED:

DM	Diabetes Mellitus
FPG	Fasting Plasma Glucose
OGTT	Oral Glucose Tolerance Test
HbA1c	Glycosylated Haemoglobin
IGT	Impaired Glucose Tolerance
IFG	Impaired Fasting Glucose
S(AD)SAD	Size (Area,Depth), Sepsis, Arteriopathy, Denervation
SINBAD	Size, Ischemia, Neuropathy, Bacterial infection, Area and Depth
DUSS	Diabetic Ulcer Severity Score
PEDIS	Perfusion,Extent of ulcer,Depth, Infection and Sensation
IWGDF	International Working group on Diabetic Foot
IDSA	Infectious Disease Society of America

ABSTRACT

INTRODUCTION:

Diabetes mellitus is a common metabolic disorder, prevalence steadily increasing over the past few decades. The complications associated with it, hence, has also increased. Diabetic foot ulcer is one of the most serious complications, utilizing resources, significantly contributing to the morbidity of the patient. There is hence, a need to correctly identify the severity of the diabetic foot ulcer so as to plan the appropriate management and to help in counselling of such patients.

AIM:

To assess severity in diabetic foot ulcer using diabetic ulcer severity score.

MATERIAL AND METHODOLOGY:

This is a hospital based longitudinal study , conducted on 93 study subjects with diabetic foot ulcers admitted in KLES Dr. Prabhakar Kore Hospital and Medical Research Centre , Belagavi. Diabetic ulcer severity score was calculated for each patient. The score was calculated by adding scores of the respective parameters constituting site of ulcer, number of ulcers, presence/absence of pedal pulsations, presence/ absence of bone involvement. Each patient was followed up for a period of 6 months, or earlier in case of patient undergoing minor/major amputation. After the study was conducted, analysis was done by calculating various percentages of healing /amputation with respect to the score.

RESULTS:

Out of the total 93 study subjects, 74.2% were males. The mean age was calculated to be 59.6 years with maximum number of subjects being in 55-60 years of age group range. Majority of the study subjects were found to have diabetic ulcer severity score of 2 (42%). Out of the total study subjects, 58% had a complete healing, 28% underwent minor amputation whereas 14% underwent major amputation. 100% of the study participants with score 0 had healing of ulcer which decreased to 85% for score 1, 53.8% for score 2 , 6.25% for score 3 and 0% for score 4. This was suggestive of poorer chances of healing as the diabetic ulcer severity score increases.

CONCLUSION:

With the increasing incidence of patients diagnosed with diabetes mellitus, the rate of complications of diabetes has also increased over the past few decades including the risk and occurence of diabetic foot ulcers There is an increasing need for diabetic foot ulcer prognostication systems and universal use of the same. Thus, we recommend the use of diabetic ulcer severity score as a prognostic tool to assess the severity of the diabetic foot which will further enhance communication and counselling of the patient and will help in providing the appropriate treatment to such patients.

KEY WORDS: diabetic foot ulcers, severity, prognostic classification, amputation.

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INTRODUCTION

Diabetes mellitus is so common that India is considered to be the diabetic capital with the prevalence of diabetes being 8.7%(2016) .1,2 This follows that the morbidity associated with diabetes mellitus has also increased over the past few decades.

Diabetic individuals are prone for complications such as diabetic neuropathy and peripheral vascular disorders which are the primary reasons responsible for occurrence of diabetic foot ulcers.

Diabetic foot ulcer is one the most significant, resources utilizing complications which affects the well being of a diabetic patient significantly contributing to the morbidity.6It is one of the major reasons of non traumatic amputations of lower limb.4 Patients with diabetic foot ulcers also require a great deal of rehabilitation further consuming an inevitable amount of the health resources.

There is hence, a need to correctly identify the severity of the disease so that appropriate management can be planned for such patients.

Diabetic foot ulcer classification systems are an important method for evaluating the patients and choosing treatment for them and further, conveying information amongst health executives. There are various classification systems described for anticipating sequelae of diabetic foot ulcer, none of which is universally followed.

Thus, this study is an attempt to evaluate the severity of diabetic foot ulcer using diabetic ulcer severity score (explained by Beckertet al3), and associate it with the outcome which will eventually help in improving the care and counselling of such patients with diabetic foot ulcer.

OBJECTIVES

To assess severity in diabetic foot ulcer using diabeticulcer severity score.

REVIEW OF LITERATURE

Diabetes Mellitus:

Diabetes mellitus refers to a hyperglycemic syndrome resulting from different causes. Broadly, it is classified into type I and type II.

The classification of diabetes also include: late onset diabetes of adult (LADA), maturity onset diabetes of youth (MODY), Ketosis prone diabetes, secondary diabetes which could be as a result of pancreatic disease or chronic excessive corticosteroid use or acromegaly or other rare genetic disorders and lastly rare autoimmune type of diabetes.

Diagnosis of diabetes mellitus [8]

a. A hemoglobin A1c level (HbA1c)
b. A fasting plasma glucose (FPG) > 126 mg/dl
c. An oral glucose tolerance test (OGTT)
d. Symptoms of hyperglycemia and random glucose level of >/= 200 mg/dl

Fasting plasma glucose level	2 hour (75gm) OGTT result		
	<140	140-199	>/=200
<100	Normal	IGT	DM
100-125	IFG	IGT and IFG	DM
>/= 126	DM	DM	DM
HbA1c	<5.7%	5.7-6.4%	>6.5%
	Normal	High risk	DM

IGT : impaired Glucose Tolerance
IFG : Impaired Fasting Glucose

The number of people affected with diabetes mellitus in India was 65 million (2016) compared to 26 million in 1990making India close to being the diabetic capital . The prevalence in 2016 was 8.7% .[2]

ANATOMY OF FOOT:

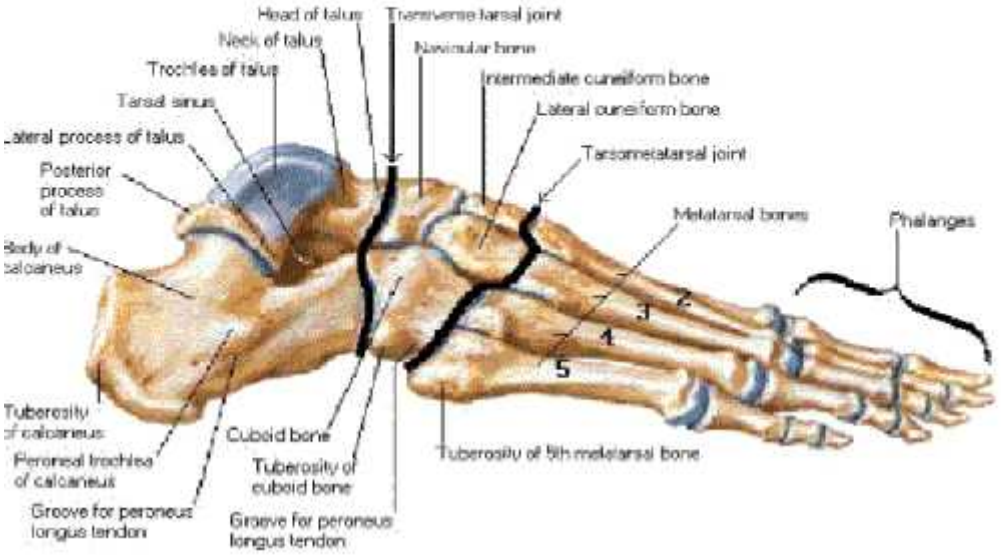
The foot is divided into hindfoot, mid foot and forefoot.

Bones of the foot include:

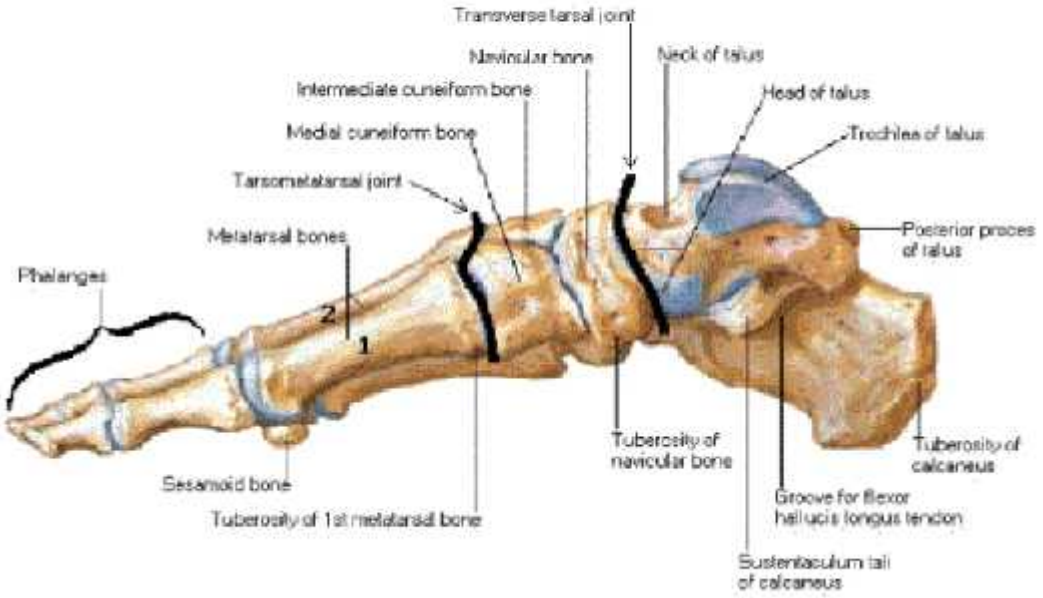
TARSUS:

There are two rows, Talus and calcaneum lie proximally one above the another. The medial cuneiform, intermediate cuneiform, lateral cuneiform and the cuboid, occupy the distal part. Between the proximal and distal rows, the navicular bone is interposed.

Lateral View



Medial View



METATARSUS: Each metatarsalis divided into : base or proximal end ,shaft which is slightly convex dorsally and the head or distal end which is flattened from side to side.

PHALANGES:

Each foot has 14 phalanges: the great toe has two , whereas the rest have three each.As compared to phalanges in hand, they are smaller.

DORSUM OF FOOT : contains superficial fascia and deep fascia , tendons and the intrinsic muscles which is extensor digitorum brevis and extensor hallucis brevis.

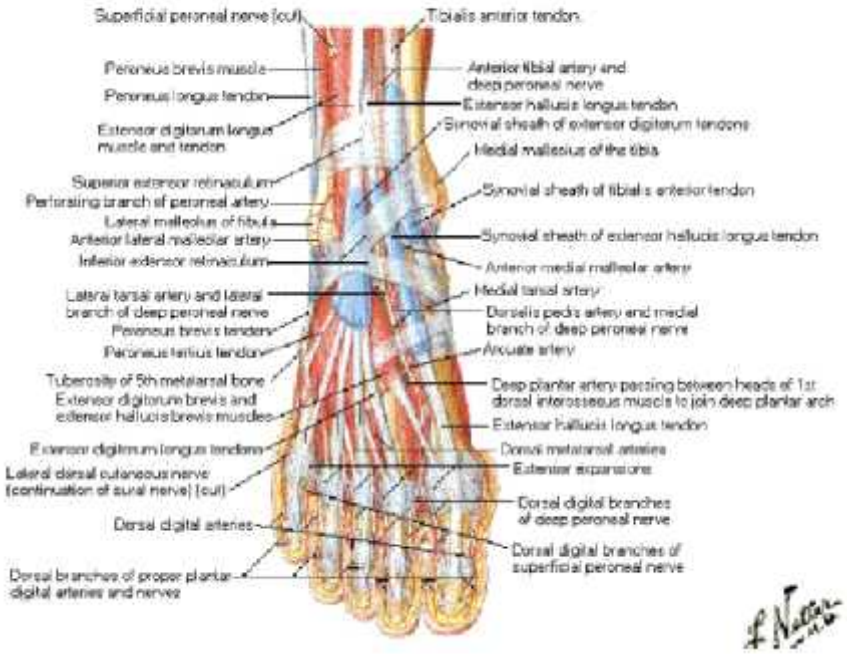
Superficial fascia contains the superficial veins, cutaneous nerves and lymphatics.

Deep fascia is thickened at the ankle to form retinacula which retain the tendons in place

The muscles tendons include that of tibialis anterior ,extensor hallucis longus, extensor digitorum longus, peroneus tertius and extensor digitorum brevis.

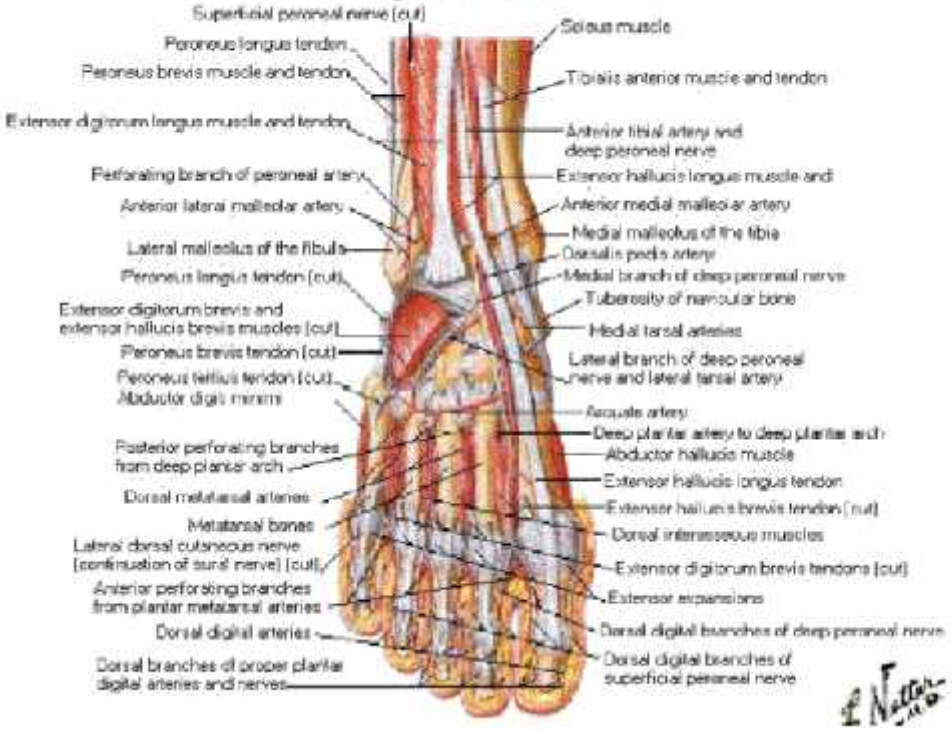
Muscles of Dorsum of Foot

Superficial Dissection



Dorsum of Foot

Deep Dissection



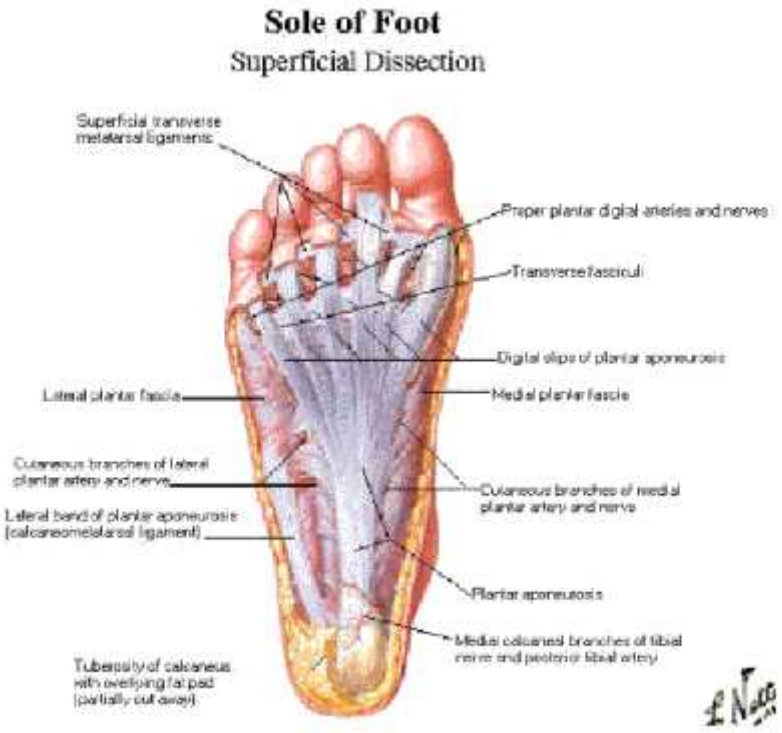
SOLE OF FOOT:

The sole of the foot is comprised of superficial fascia , deep fascia and the muscles which are arranged in four layers with the neurovascular bundles between the first and second layers.

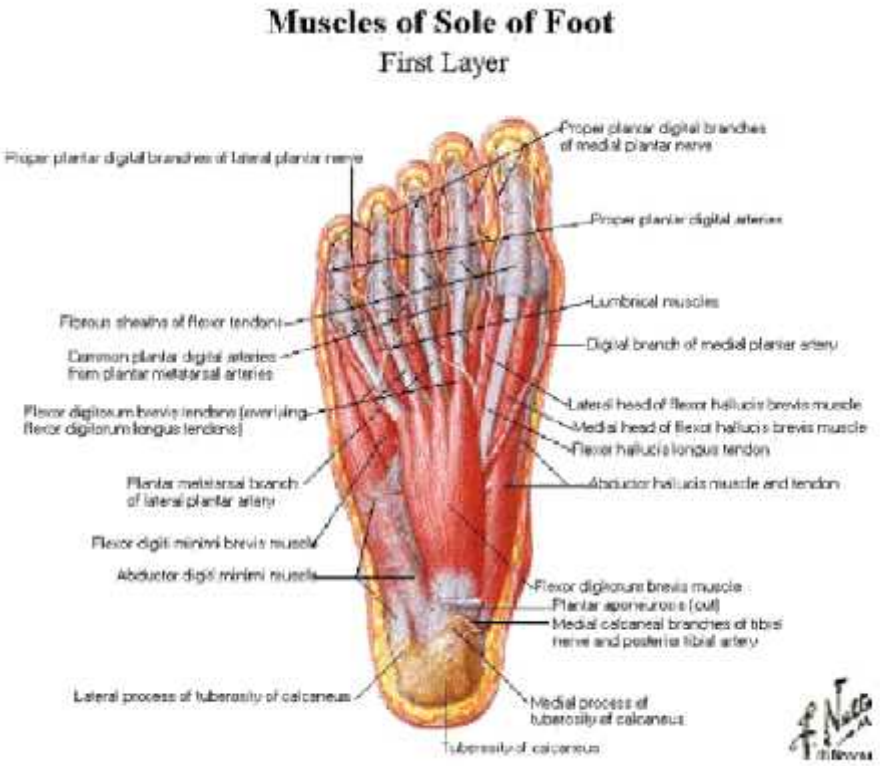
LAYER	MUSCLES/TENDONS
First layer	Flexor digitorum brevis, abductor hallucis and abductor digiti minimi
Second layer	Tendons of flexor digitorum longus and flexor hallucis longus ; flexor digitorum accessorius and lumbrical muscles.
Third layer	Flexor hallucis brevis, flexor digiti minimi brevis and adductor hallucis
Fourth layer	Interosseus muscles, tendons of tibialis posterior and of peroneus longus

BLOOD SUPPLY: The arteries supplying the foot include dorsalis pedis artery which is the continuation of anterior tibial artery. Sole is supplied bylateral and medial plantar arteries .The great saphenous vein lies on the medial side and short saphenous vein on the lateral side.

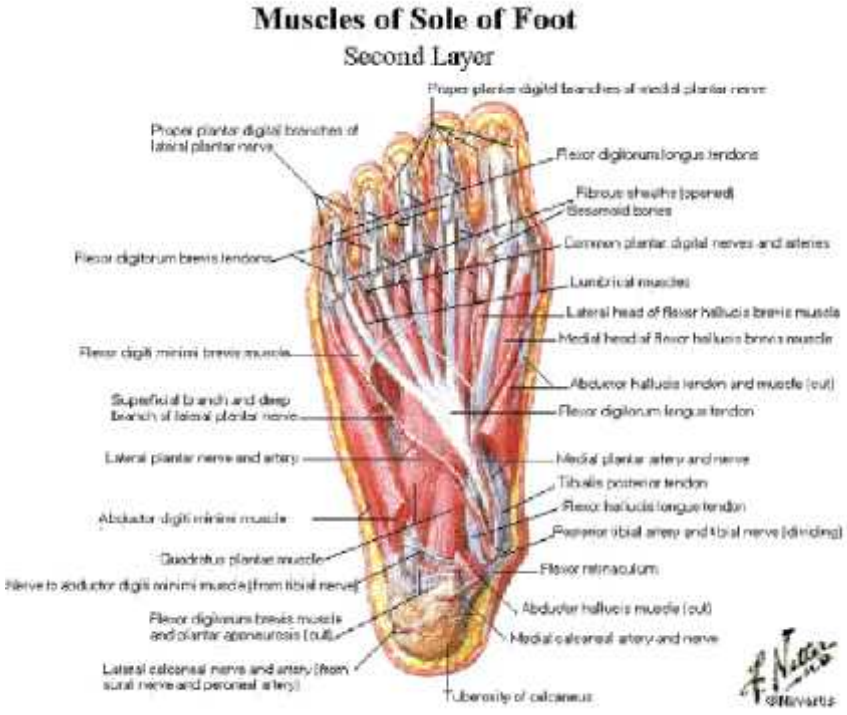
NERVE SUPPLY: The cutaneous nerves of the dorum includes the saphenous nerve, the superficial peroneal nerve (branch of common peroneal nerve) , the sural nerve , the deep peroneal nerve and the digital braches of medial and lateral plantar nerves. The sole is innervated by lateral and medial plantar nerves which are end branches of tibial nerve.


Sole of Foot
Superficial Dissection
Superficial transverse metatarsal ligaments
Proper plantar digital arteries and nerves
Transverse fascículi
Digital slips of plantar aponeurosis
Lateral plantar fascia
Medial plantar fascia
Cutaneous branches of lateral plantar artery and nerve
Cutaneous branches of medial plantar artery and nerve
Lateral band of plantar aponeurosis (calcaneometatarsal ligament)
Plantar aponeurosis
Medial calcaneal branches of tibial nerve and posterior tibial artery
Tuberosity of calcaneus with overlying fat pad (partially cut away)

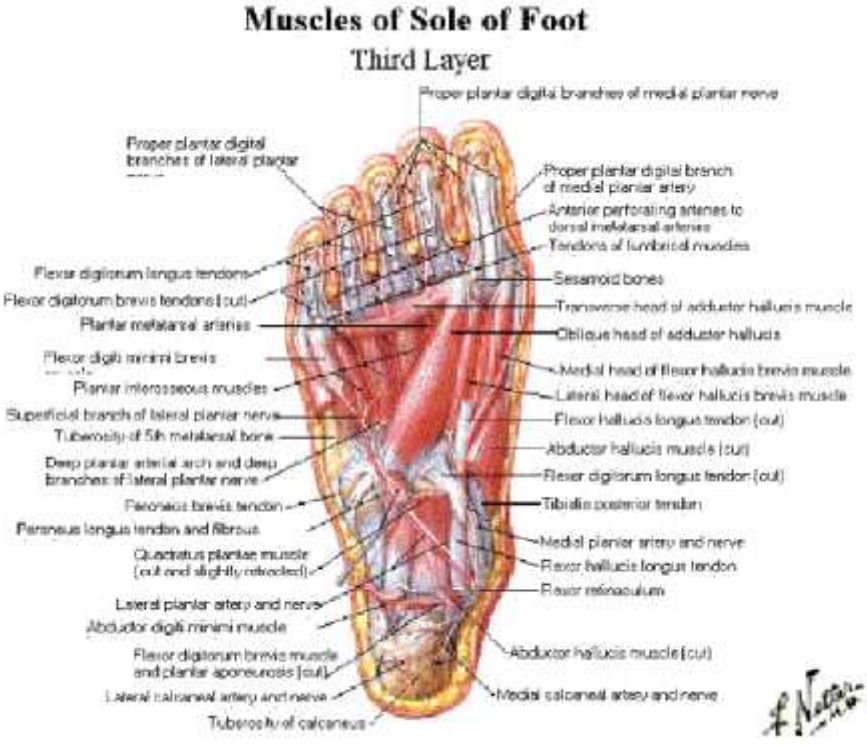
First layer :


Muscles of Sole of Foot
First Layer
Proper plantar digital branches of medial plantar nerve
Proper plantar digital branches of lateral plantar nerve
Proper plantar digital arteries
Lumbrical muscles
Fibrous sheaths of flexor tendons
Digital branch of medial plantar artery
Common plantar digital arteries from plantar metatarsal arteries
Lateral head of flexor hallucis brevis muscle
Flexor digitorum brevis tendons (overlying flexor digitorum longus tendons)
Medial head of flexor hallucis brevis muscle
Flexor hallucis longus tendon
Plantar metatarsal branch of lateral plantar artery
Abductor hallucis muscle and tendon
Flexor digiti minimi brevis muscle
Abductor digiti minimi muscle
Flexor digitorum brevis muscle
Plantar aponeurosis (cut)
Medial calcaneal branches of tibial nerve and posterior tibial artery
Lateral process of tuberosity of calcaneus
Medial process of tuberosity of calcaneus
Tuberosity of calcaneus

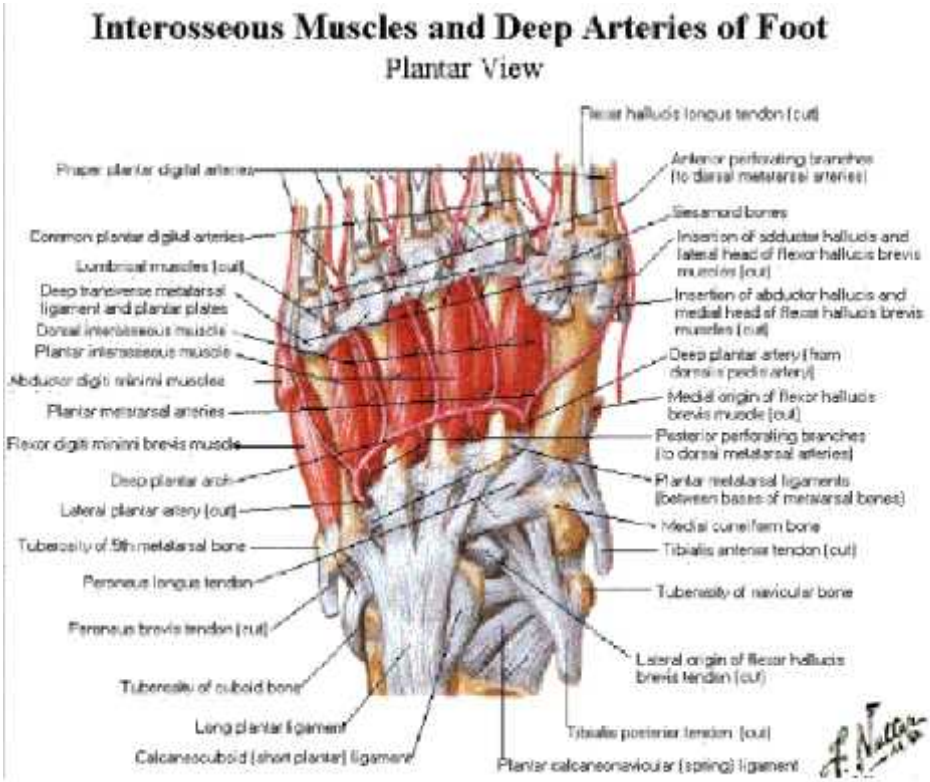
Second layer :



Third layer:



Fourth layer :



DIABETIC FOOT ULCER:

It is defined as “ulceration of the foot (distally from the ankle and including the ankle) associated with neuropathy and different grades of ischemia and infection.”[5]

Diabetic foot per se doesn’t come under a separate classification of ulcers , however , it is a type of non specific ulcer in which ulcer is associated with other diseases such as diabetes mellitus.

It is one of the most significant complication of diabetes and there is a growing need to treat the same.

Aetiology of diabetic foot :

In a patient with diabetes, in case of slight injury to "glucose laden tissue", results in a chronic infection and formation of an ulcer. Secondly, ulceration in a patient with diabetes can be precipitated by ischaemia due to diabetic atherosclerosis. Thirdly, glucose laden tissue is more prone for infection which may result in ulceration. Fourthly, sensory neuropathy which is a well-known complication of diabetes mellitus or peripheral neuritis may also cause ulcer formation due to loss of sensation in foot.[10]

The various sites involved in diabetic foot ulcer include toes and feet, particularly the sole which is the commonest site. Leg can also be affected. Additionally, any other part of the body can be affected.

Nature of diabetic foot ulcer is generally deep and spreading.

CLASSIFICATION OF DIABETIC FOOT ULCERS

There can be either description classification or prognostic stratification classification system.

Diabetic foot ulcer description classification: includes

- *Meggit-Wagner classification [4]:*

Wagner originally described a classification system used at hyperbaric based wound healing centers. This classification was based upon clinical evaluation and did not account for variations in vascular status. It classified ulcers as:

Grade 1	Superficial ulcer : skin and subcutaneous tissue only
Grade 2	Deep ulcer to tendon, muscle, joint capsule or bone
Grade 3	Deep ulcer with abscess, osteomyelitis or tendinitis.
Grade 4	Partial foot gangrene
Grade 5	Whole foot gangrene

-*University of Texas Classification*[17]

This uses a matrix system in which grade and stage are represented horizontally and vertically respectively. The grades of the ulcer are :

0	Pre or post ulcerative site that has healed
1	Superficial wound not involving tendon, capsule or bone
2	Wound penetrating to tendon or capsule
3	Wound penetrating bone or joint

Stage A	Clean wound
Stage B	Non ischemic ,infected wound
Stage C	Ischemic, non infected wound
Stage D	Ischemic, infected wound

-*S(AD)SAD* classification is shorter term used for Size (Area , Depth), Sepsis, Arteriopathy, Denervation.[4]

-*PEDIS* is for perfusion, extent of ulcer, depth, infection and sensation. It was created by International Working Group of Diabetic foot (IWGDF) ; primarily used for research purposes.[19]

-*SINBAD* classification is a reassembly of S(AD)SAD system for Size, Ischaemia , Neuropathy, Bacterial infection, Area and Depth. [25]

-*CHS* classification which came about in 2006, created by Curative Health Services, constitutes of 6 grades which describes abscess, necrotic tissue, depth or osteomyelitis (4,22)

The prognostic stratification classification systems include:

-DEPA: This is a score which is calculated by assessing thebacterial contamination, depth of ulcer,associated aetiology and phase. Each component rates from 1 to 3. There is lower risk of amputation with score less than 6 , moderate risk if score 7-9 and high risk for score between 9 and 12 or with an ulcer with wet gangrene.[13]

***-DUSS*:** This score allocates point of 0 or 1 to each of ulcer site,number, presence or absence of pulses and presence or absence of osteomyelitis ,hence grouping the ulcer from 0 to 4 points.[3] This prognostic scoring system has been studied in our study.

-IDSA- IWGDF: This classification was developed by Infectious Disease Society of America (IDSA) and International Working Group on Diabetic Foot (IWGDF) together and divides the patient's diabetic foot ulcer infection severity into categories.[18]

The prognostic stratification systems predict the severity of the disease which means more the severity, there is an increased chance of amputation. Diabetic foot is a frequent indication for amputation of lower limb due to non traumatic cause.

LOWER LIMB AMPUTATION

Toe amputation (Ray amputation): this is amputation of toe along with the head of the metatarsal. Using a racquet shaped incision, the digit is removed with disarticulation at the metatarso-phalangeal joint. The head of the metatarsal should then be excised using a bone nibbler forceps.

Transmetatarsal amputation: amputation is done through the metatarsal bones.

Transtarsal amputations (Chopart, Lisfranc):These are not recommended in patients with or without vascular damage.

Syme's operation: at the level of ankle joint.

Below knee amputation: In this, the knee joint is preserved .Preserving the knee joint is an added advantage in rehabilitation.

Through knee amputation (disarticulation):This is done in situations when a below knee amputation cannot be done or a non functioning knee. The stump is end bearing here.

Above knee amputation: Here the site of division is taken to be 12 cm approximately from knee joint. The minimum length of stump to fit an above knee prosthesis is 7.5 cm below the insertion of adductor muscle.

Hip disarticulation and hemipelvectomy: Here, the limb is diarticulated at hip joint.

Literature review:

1. The prospective study conducted in Germany in 2006 by Beckert and his colleagues, was the first study which described about the Diabetic Ulcer Severity Score in which "four clinically defined parameters namely palpable pedal pulses,

probing to bone, ulcer location and presence of multiple ulceration were assessed prospectively in 1000 patients". [3]The patients recruited were "followed up for a year or until healing or amputation if earlier".[3] In the study, initially ulcers were graded, the DUSS was calculated using these parameters, which were also shown as independent factors associated with healing.

The results of the study showed "a 93% probability of healing for uncomplicated ulcer (score 0), reducing to 57% for score 4." They also concluded by quoting that "an increase in the DUSS by 1 score point reduced the chance of healing by 35%".

2. A similar study was conducted in Bangalore Medical College, in 2016 by Shashikala CK et al, wherein a total of 100 diabetic patients having diabetic foot ulcers, attending outpatient department or admitted into the hospital were taken into the study. [5] Comparision of score at initial visit was done with the final outcome to validate the prediction of Diabetic Ulcer Severity Score (DUSS). The study showed results that 50% of ulcer with score of 0 and 1 healed by primary intention, 37% of patient underwent grafting procedure, 6.5% underwent minor and 6.5% underwent major amputation and concluded that "the probability of healing with score 0 was 95%, score 1 was 91.6%, 85.7% with score 2, 52% with score 3 and 28.4% with score 4."

3. A study was conducted in Tumkur, Karnataka by Shiva Kumar et al, for vallidating diabetic ulcer severity score with patient outcome clinically. 100 patients were recruited into the study who were prospectively assessed over a period of 2 years which showed 14.25% of people with score 2, 28.57% of people with score 3, 57.14%

of people with score 4 had amputation.[6] According to their study, the probabilty of healing with score 0 was 100%, for score 1 was 84%, score 2 had 19% of healing. Patients with score of 3 and 4 had 0% probabilty of healing according to their study results.

METHODOLOGY

This is a one year hospital based longitudinal study conducted at KLE's Prabhakar Kore hospital and Medical Research Centre, Belagavi.

Study design: Longitudinal study

Study period: January 2019 – December 2019

Study population: Patients admitted with diagnosis of diabetic foot ulcers in KLE's Dr. Prabhakar Kore Hospital, Belagavi.

Calculation of diabetic ulcer severity score:

- Peripheral pulses : absence (score of 1), presence (score of 0), in case of pedal edema/difficulty to palpate pulses : Doppler ultrasound scan bedside : in case flow + : score of 0 , flow absent : score of 1
- X ray foot : bone involved (osteomyelitis)- score of 1, Bone not involved – score of 0
- Site of ulceration : toe (score of 0) , foot ulcer(score of 1)
- Patients with multiple ulcerations (score of 1) , single ulcer (score of 0)

Diabetic Ulcer Severity score will be calculated as addition of the four individual scores

Maximum score:4, Minimum score: 0

Inclusion criteria:

1. Patients diagnosed with diabetes mellitus with ulcer/s over foot.
2. All diabetic foot ulcers irrespective of duration.

Exclusion criteria:

1. Venous ulcers of foot in patients with diabetes mellitus

The eligible patients will be included in the study and the diabetic ulcer severity score of the ulcer will be calculated according to the above mentioned criteria.

Two follow up visits at 3 and 6 months will be taken into account to assess the healing of the ulcer whether it is healed or not or earlier if patient undergoes amputation (at which point the participant will be said to have completed the study).

Healing will be defined as epithelialisation of the ulcer by primary intention or skin grafting. Toe amputation or fore foot amputation will be taken as minor amputation while above or below knee amputation as major.

Sample size:

Prevalence of diabetic ulcers is taken 51.8% as per a study conducted in Karnataka.[6]

$N= 4pq/d^{2,}$ p= 51.8, q= 100-p =48.2, d=10.36 (d is 20% of p)

$N= 4x51.8x48.2/(10.36)^2$

$= 93.05 \sim 93$

STATISTICAL ANALYSIS

The data collected will be entered in Microsoft Excel sheet and analysed using percentages by assessing the percentage of healing/amputation correspondingly.

RESULTS

Table 1: Distribution of study subject according to age

AGE GROUP	NUMBER OF PATIENTS (n)	PERCENTAGE (%)
35-40	5	5.38
40-45	4	4.30
45-50	5	5.38
50-55	12	12.90
55-60	20	21.50
60-65	16	17.20
65-70	12	12.90
70-75	12	12.90
75-80	5	5.38
80-85	1	1.07
85-90	1	1.07
TOTAL (N)	93	100

In the study, a total of 93 study subjects were included of which the maximum percentage were of the age group range of 55-60 years (21.5%). The mean age calculated was 59.6 years.

Youngest patient was 35 years of age and oldest patient was 89 years of age.

Figure 1: Horizontal bar graph representation of age distribution of study subjects.

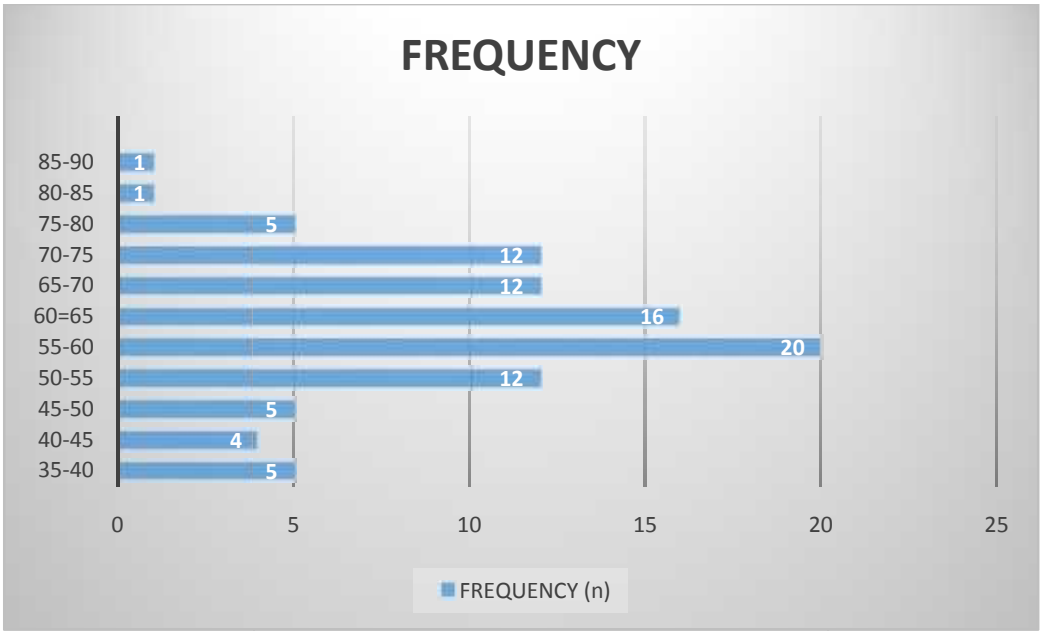


Table 2: Distribution of study subjects according to gender

GENDER	NUMBER (n)	PERCENTAGE (%)
MALE	69	74.2
FEMALE	24	25.8
TOTAL	93	100

Almost three fourth of the study subjects studied were of male gender whereas the rest 25.8% were females.

Figure 2: Depiction of study subjects according to gender

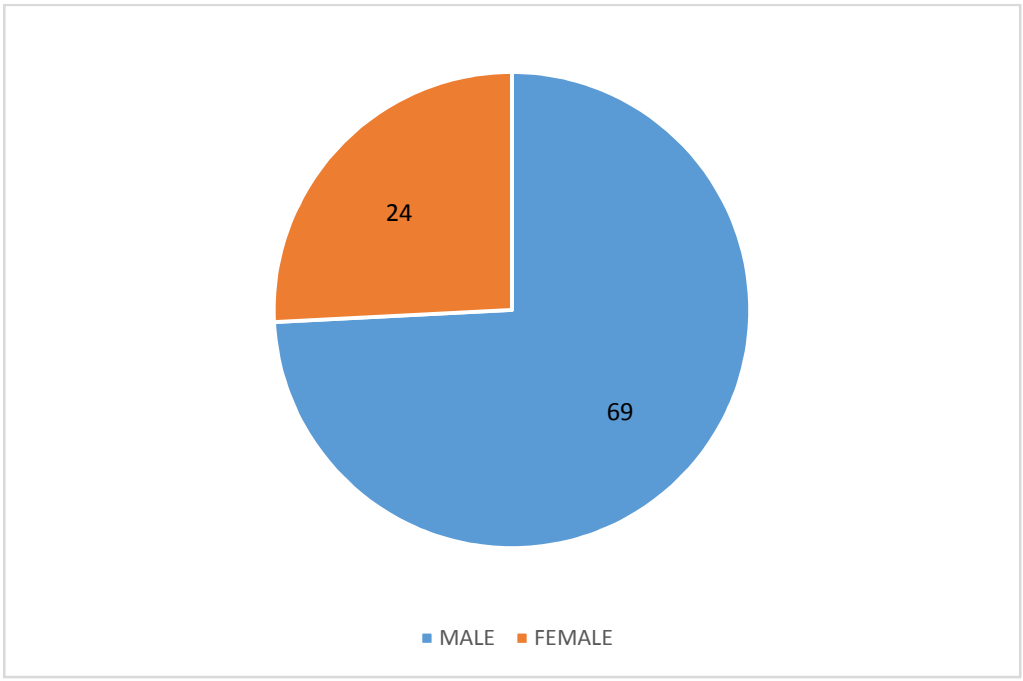


Table 3: Distribution of study subjects according to age and gender

AGE RANGE	MALE	FEMALE
35-40	4	1
40-45	2	2
45-50	2	3
50-55	8	4
55-60	16	4
60-65	14	2
65-70	6	6
70-75	10	2
75-80	5	0
80-85	1	0
85-90	1	0
TOTAL	69	24

Table 4: Distribution of study subjects according to total score (diabetic ulcer severity score)

SCORE	NUMBER (n)	PERCENTAGE (%)
0	9	9.68
1	27	29.03
2	39	41.93
3	16	17.21
4	2	2.15
TOTAL	93	100

42% of the patients included in the study were found to have diabetic ulcer severity score of 2, followed by patients with score 1 (29%), score 3 (17%), score 0 (9.6%) and lastly score 4 (2.15%).

Figure 3: Depiction of study subjects with respect to diabetic ulcer severity score

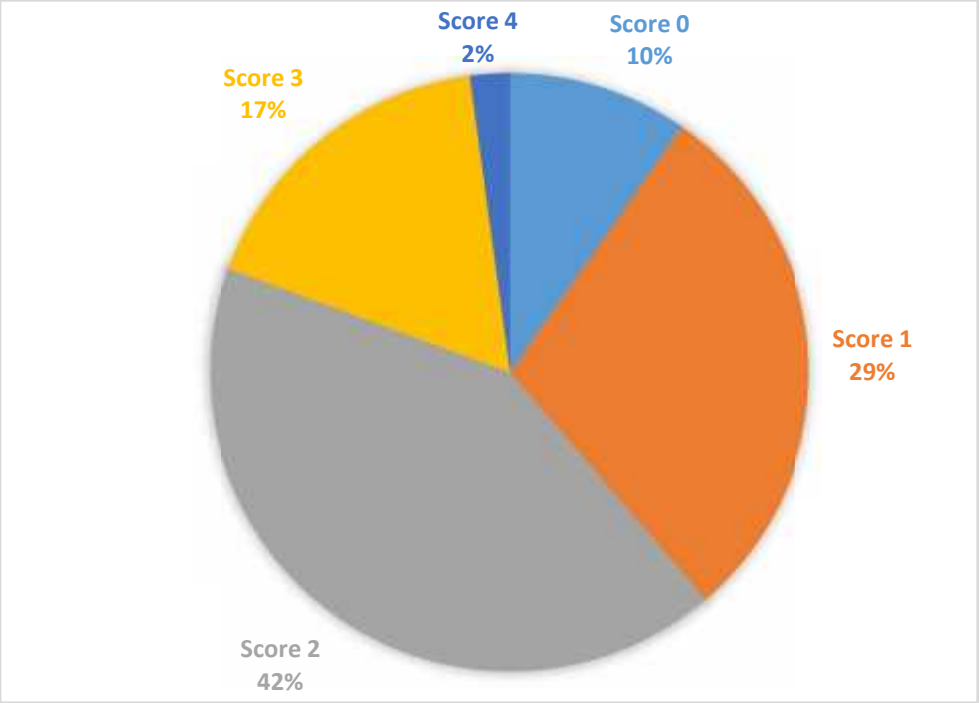


Figure 4: Distribution of study subjects who underwent amputation with respect to duration of diabetes mellitus.

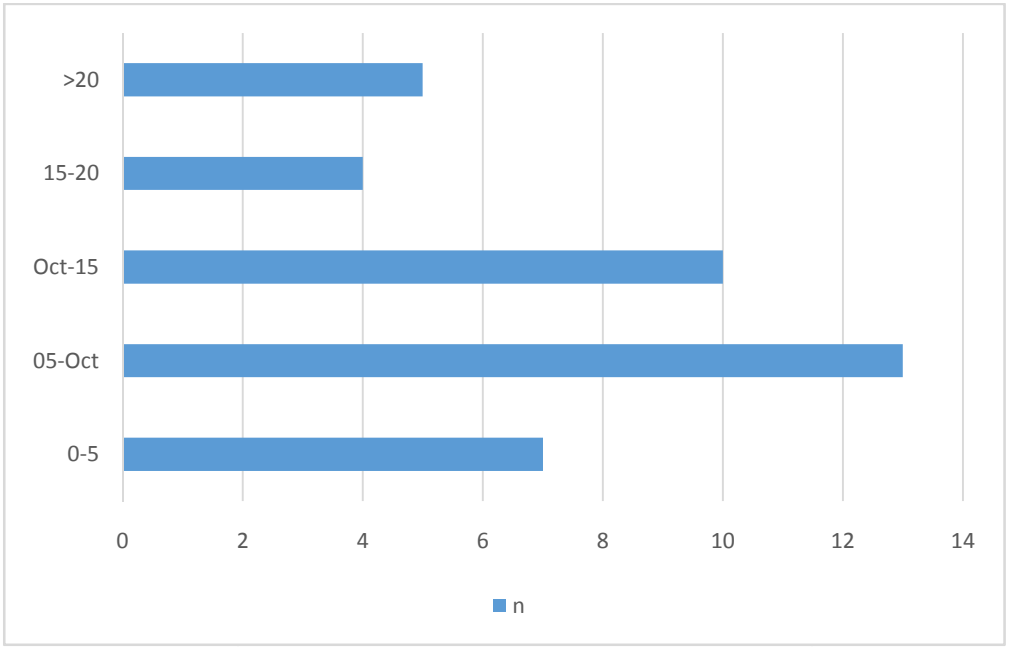
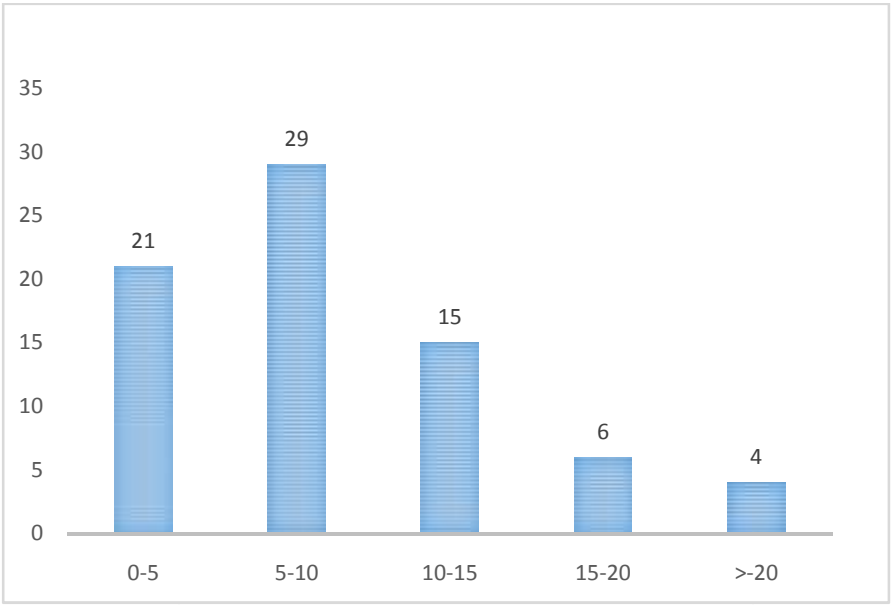
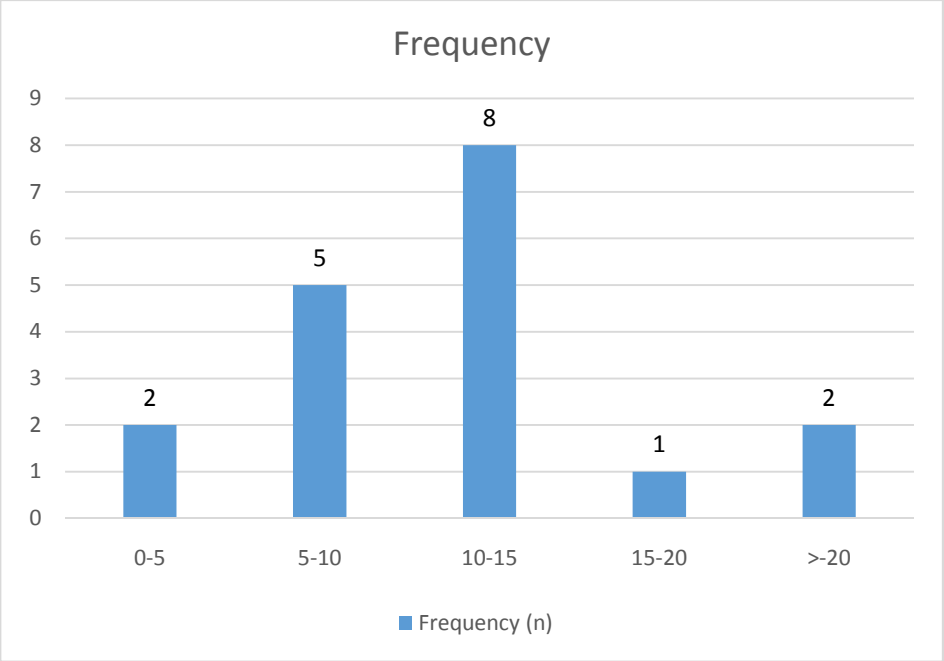


Figure 5: Distribution of study subjects with score 0,1,2 according to duration of diabetes mellitus.



Amongst the patients with Diabetic ulcer severity score of 0 or 1 or 2, 38.6% (n=29) of them had history of diabetes mellitus between 5 to 10 years.

Figure 6: Distribution of study subjects with score 3,4 according to duration of diabetes mellitus.



Amongst the patients with Diabetic ulcer severity score of 3 or 4 , 44.4% (n=8) had duration of diabetes mellitus between 10 to 15 years.

Out of the total study subjects, 58% (n=56) had complete epithelialization of ulcer (healed), 42 % (n=39) had some sort of amputation either minor (28%) or major amputation (14%)

Figure 7: Depiction of study subjects with respect to outcome.

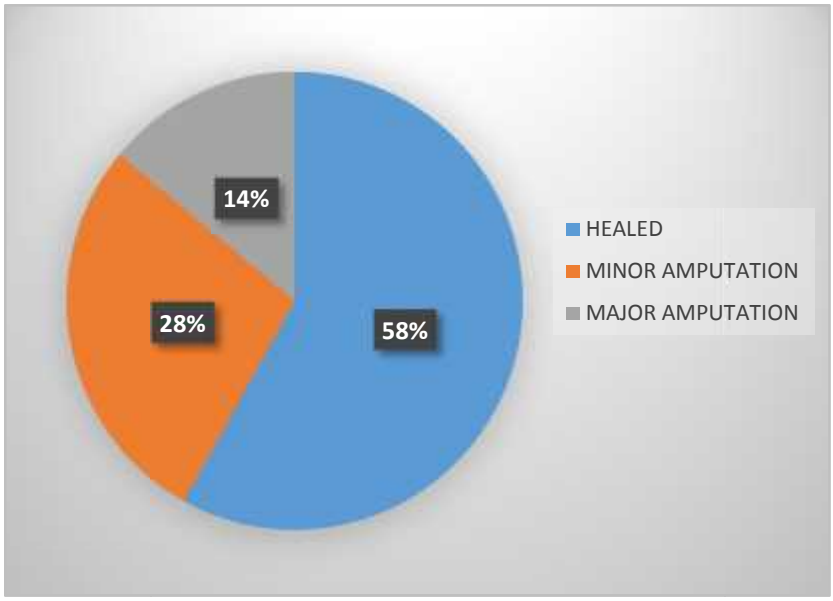


Table 5: Distribution of study subjects with score 0 with respect to outcome.

OUTCOME	NUMBER (n)	PERCENTAGE (%)
HEALED	9	100
MINOR AMPUTATION	0	0
MAJOR AMPUTATION	0	0

100% of the patients with diabetic ulcer severity score of 0, had healing of the diabetic foot.

Figure 8: Depiction of study subjects with score 0 with respect to outcome.

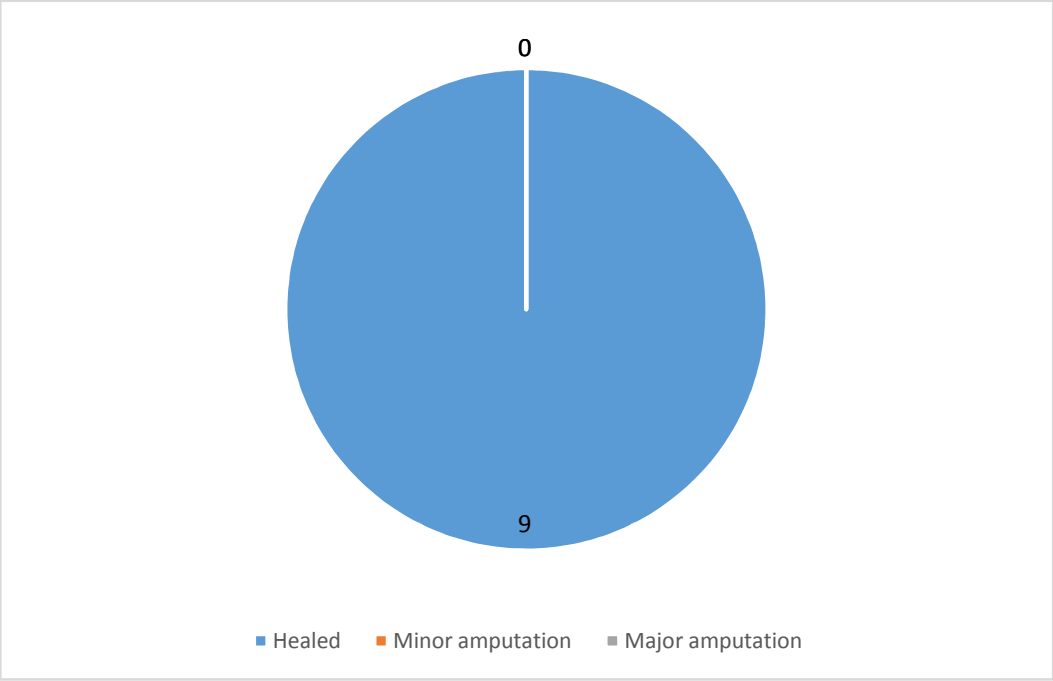


Table 6 : Distribution of study subjects with score 1 with respect to outcome.

OUTCOME	NUMBER (n)	PERCENTAGE (%)
HEALED	23	85
MINOR AMPUTATION	4	15
MAJOR AMPUTATION	0	0

85% of the patients assessed having diabetic ulcer severity score of 1, had healing of the ulcer in the follow up period of 6 months, whereas 15% of them underwent minor amputation.

Figure 9: Depiction of study subjects with score 1 with respect to outcome

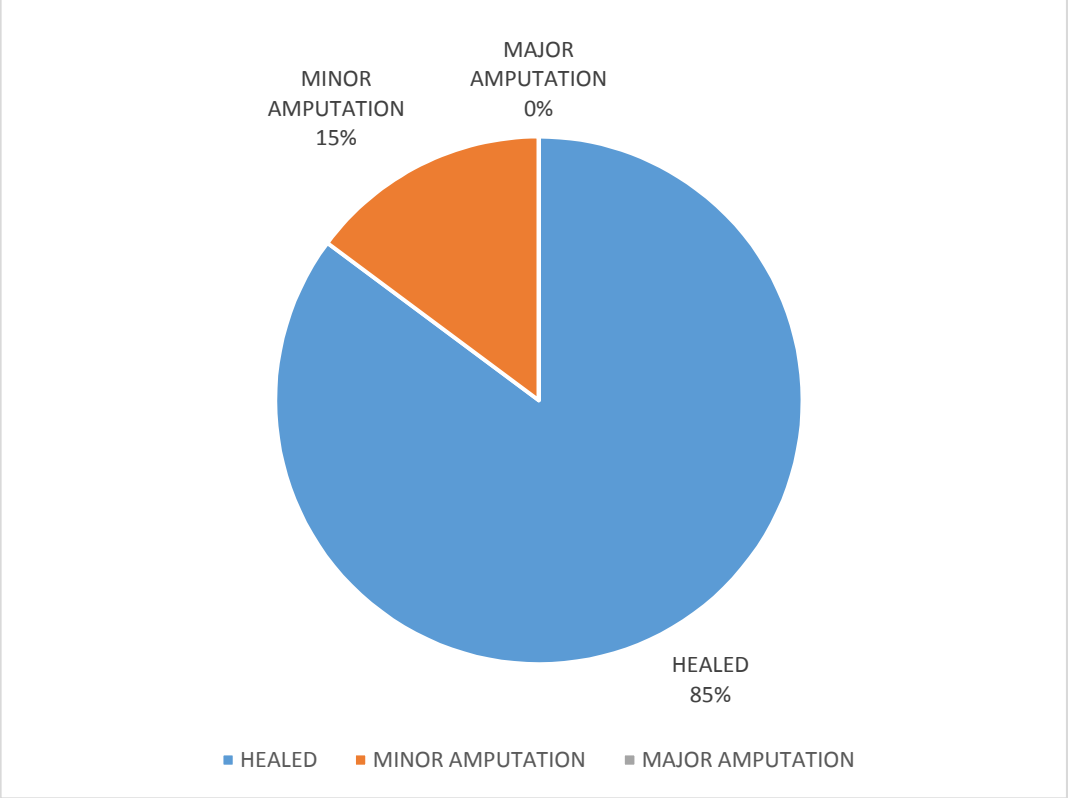


Table 7: Distribution of study subjects with score 2 with respect to outcome.

OUTCOME	NUMBER (n)	PERCENTAGE (%)
HEALED	21	53.8
MINOR AMPUTATION	11	28.2
MAJOR AMPUTATION	7	18

53.8% of the patients assessed with diabetic ulcer severity score of 2 had complete healing of ulcer where as 28% of them underwent minor amputation and 18 % underwent major amputation.

Figure 10: Depictionof study subjects with score 2 with respect to outcome.

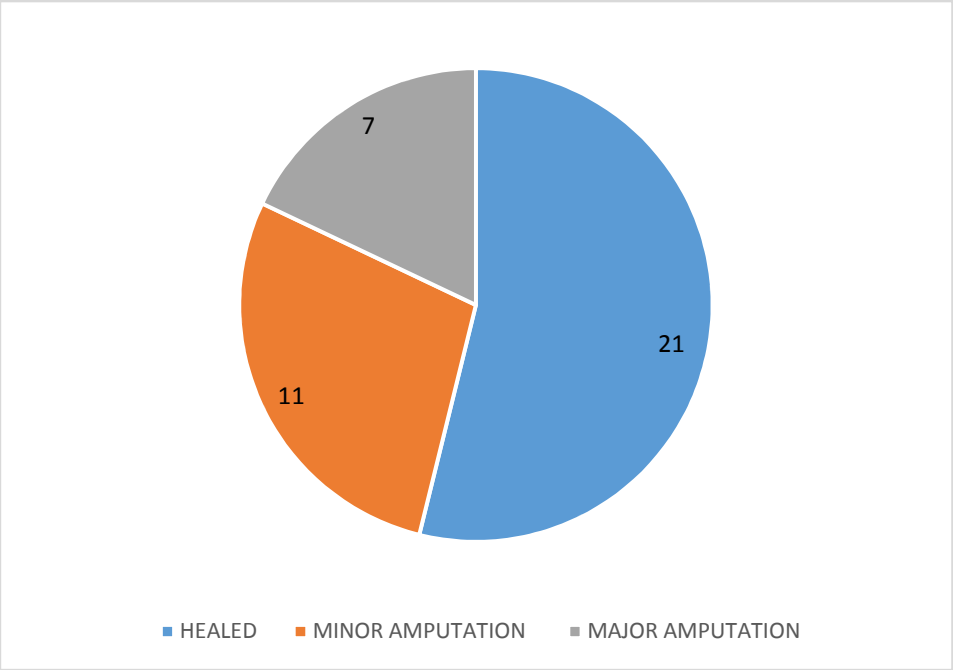


Table 8: Distribution of study subjects with score 3 with respect to outcome

OUTCOME	NUMBER (n)	PERCENTAGE (%)
HEALED	1	6.25
MINOR AMPUTATION	9	56.25
MAJOR AMPUTATION	6	37.5

56.25% of the patients assessed having diabetic ulcer severity score of 3 underwent minor amputation, as compared to 6.25% who had complete healing of ulcer in the follow up period.

Figure 11: Depiction of study subjects with score 3 with respect to outcome

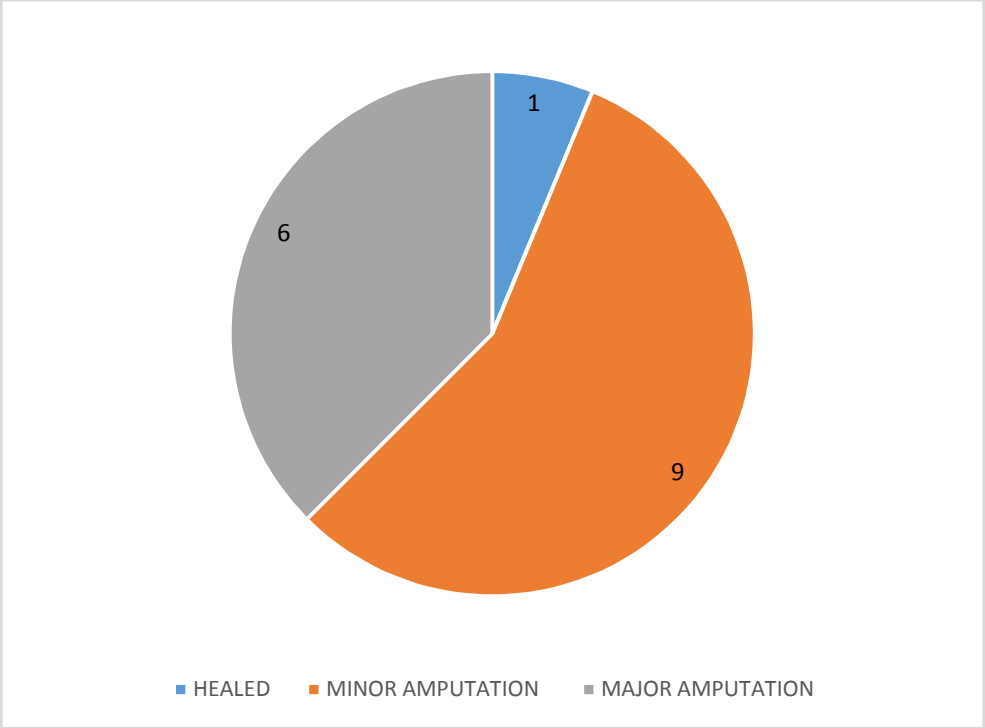


Table 9: Distribution of study subjects with score 4 with respect to outcome

OUTCOME	NUMBER (n)	PERCENTAGE (%)
HEALED	0	0
MINOR AMPUTATION	2	100
MAJOR AMPUTATION	0	0

100% of the patients assessed with diabetic ulcer severity score of 4 underwent amputation.

Figure 12: Distribution of study subjects with score 4 with respect to outcome

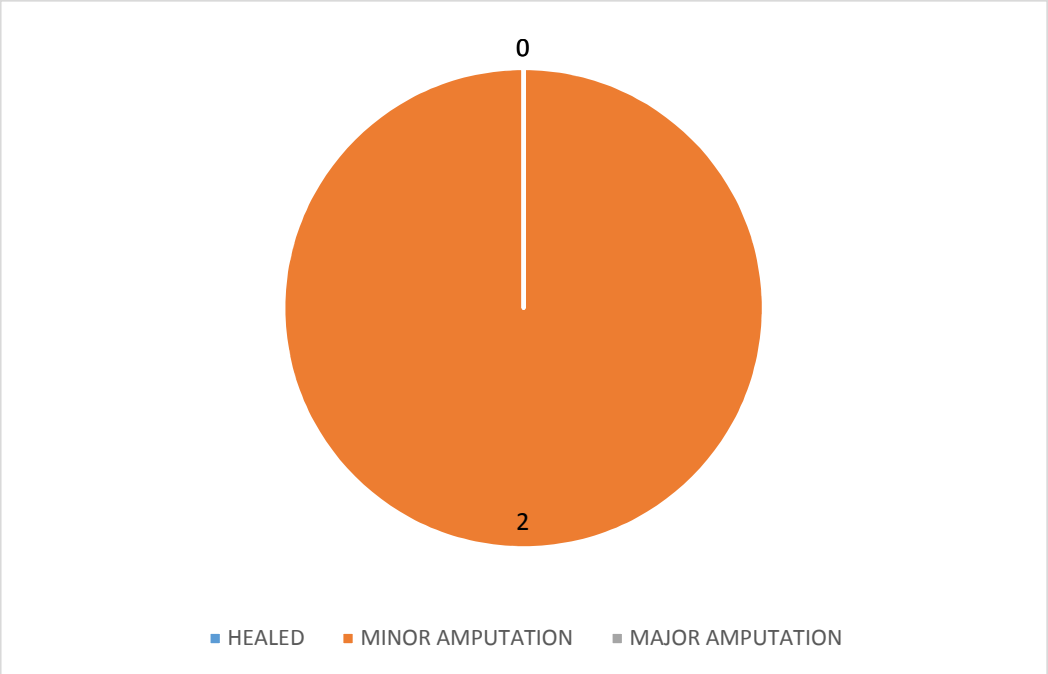


Table 10: Distribution of study subjects with absent pedal pulses with respect to outcome

OUTCOME	NUMBER (n)	PERCENTAGE (%)
HEALED	2	6.4
MINOR AMPUTATION	18	58.1
MAJOR AMPUTATION	11	35.5
TOTAL	31	100

Table 11: Distribution of study subjects with positive bone involvement with respect to outcome

OUTCOME	NUMBER (n)	PERCENTAGE (%)
HEALED	8	30.77
MINOR AMPUTATION	14	53.85
MAJOR AMPUTATION	4	15.38
TOTAL	26	100

DISCUSSION

Diabetic ulcer severity score as a prognostic scoring system for diabetic foot ulcers was first described by Beckert and his colleagues in the year 2006, in Germany.[3] They conducted the study with 1000 participants and concluded that this score is important primarily to improve the communication between health care providers and to facilitate an appropriate treatment with respect to ulcer grading.

A total of 93 patientswere recruited in this study,age ranged from 35-90 years . Most of the patients belonged to the 55-60 years age group, median age being 59.6 years which is comparable to other studies.[3,5]

Almost three fourth of the study population were males (74.2%) as compared to 67.5% in the study conducted by Beckert and his colleagues.

Majority of the patients included in the study were examined to have a diabetic ulcer severity score of 2 (42%) followed by score of 1 (29%).

58% of the total patients included in this study, had probabilty of healing of the ulcer;wherein 100% of the patients with score 0 will have healing of ulcer, decreasing to 85% for score 1 , 53.8% for score 2, 6.25% for score 3 and 0% for score 4. This was in contrast with 93% of healing for score 0 and 57% of healing for score 4 in the study conducted by Beckert and colleagues. The result was however comparable to study conducted by Shashikala and colleagues ,in Bangalore.[5]42% of the patients studied underwent some form of amputation ,with 28% having underwent minor amputation and 14% underwent major amputation.

The majority of the patients who underwent amputation had history of diabetes mellitus diagnosed 5-10 years of presentation (41%), followed by 10-15 years duration (25,6%).

38.6% of patients with score of 0-2 had duration of diabetes in between 5-10 years whereas majority of patients with score 3 or 4 (44.4%) had duration of diabetes mellitus between 10-15 years. This suggests the importance of the duration of the diabetes with respect to the severity of the diabetic foot ulcer.

Among the patients of score 0, none of them underwent any amputation which is comparable to other studies.[5]

Among the patients of score 1, 85% of them had healing whereas 15% underwent amputation, for score 2, 53.8% had healing and 46.2% of them underwent amputation. For score 3 , the percentage of people who had complete healing further decreased to only 6.25% and none of the patients with score 4 had any healing of ulcer and were taken up for amputation.

This shows that the outcome of the disease worsens as score increases and this trend is comparable to other studies previously done.[3,5,6]

The outcome of the patients with absence of pedal pulses was separately studied and it was found that 93.5% of these patients underwent amputation.

This is important to know that as we can infer from the result that having a component of peripheral vascular disease in the patient affects the outcome of the patient. Diabetes mellitus is known to affect the vessels and cause vasculopathy.Similarly, the outcome of the patients having bone involvement in the form of erosion or osteomyelitis as seen on radiographs was noted and compared to the outcome and it was found that 69.23% of such patients underwent amputation.

Thus, this study further reinforces the importance of the finding of osteomyelitis or bone involvement in diabetic foot patients which also eventually affects the outcome.

CONCLUSION

With the increasing incidence of patients diagnosed with diabetes mellitus, the rate of complications of diabetes has also increased over the past few decades including the risk and occurence of diabetic foot ulcers

There is an increasing need for diabetic foot ulcer prognostication systems and universal use of the same. The importance of counselling of diabetic patients about the various complications of diabetic foot and the risk of amputation can not be understated.

Thus, we **recommend** the use of diabetic ulcer severity score as a prognostic tool to assess the severity of the diabetic foot which will further enhance communication and counselling of the patient and will help in providing the appropriate treatment to such patients.

SUMMARY

To summarize, this study included 93 study subjects who met the inclusion criteria. Majority of them (n=69) were of male gender.

The diabetic ulcer severity score as described was calculated for each patient and outcome was noted on follow up.

Majority of the study subjects had a diabetic ulcer severity score of 2.

42% of the total participants underwent major/minor amputation whereas 58% had healing of the diabetic foot ulcer.

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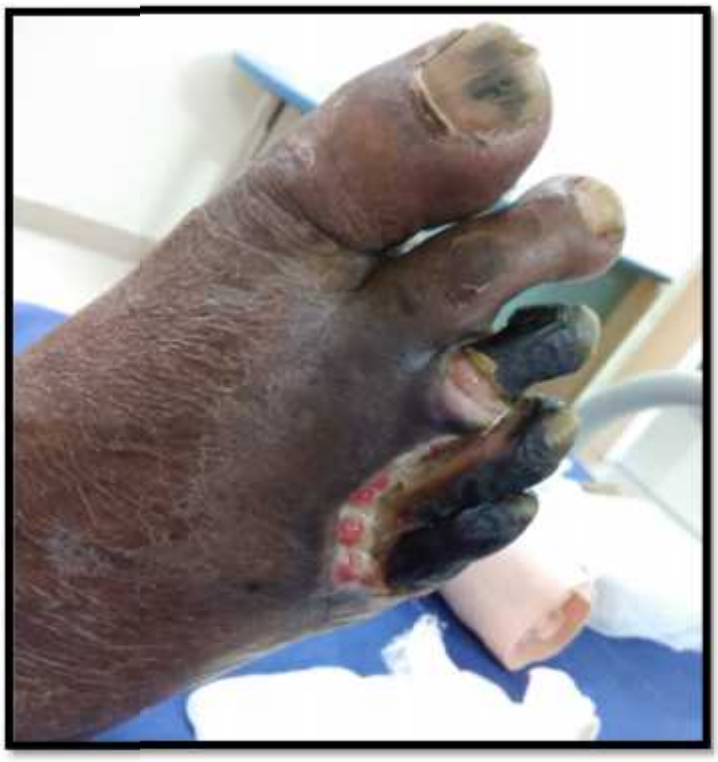
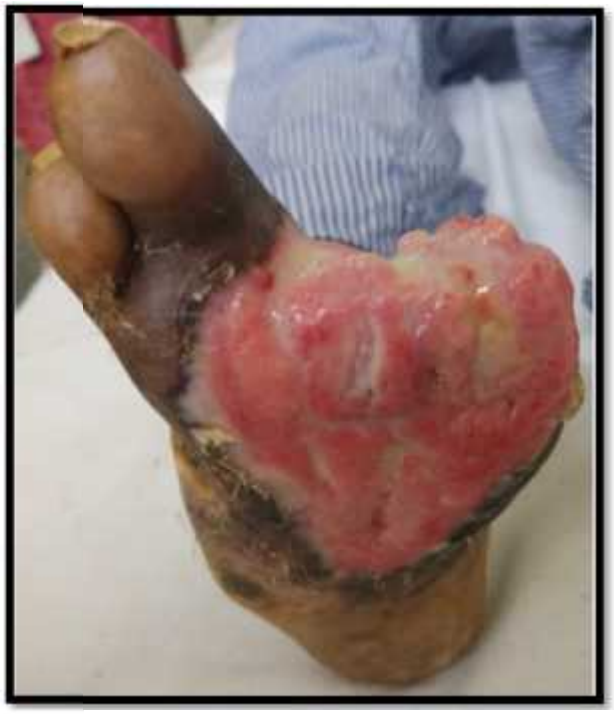
ANNEXURE I. ILLUSTRATIONS

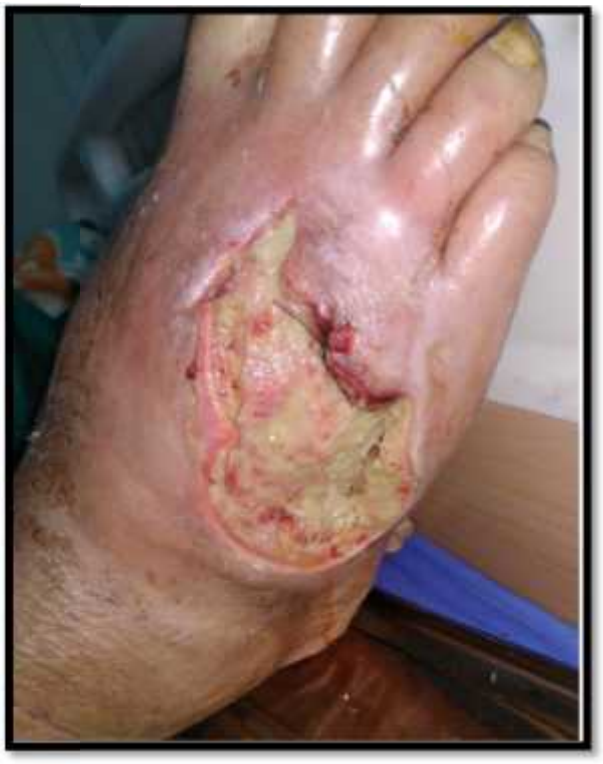
1. DIABETIC FOOT WITH GANGRENE OF TOES



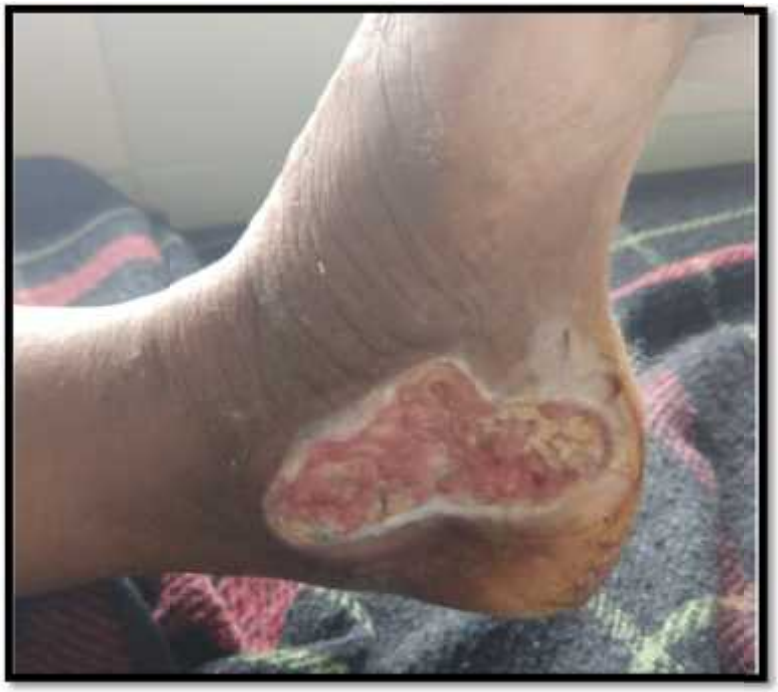
2. DIABETIC FOOT - POST DEBRIDEMENT AND AMPUTATION OF TOES.



3. DIABETIC FOOT - DORSUM OF RIGHT FOOT

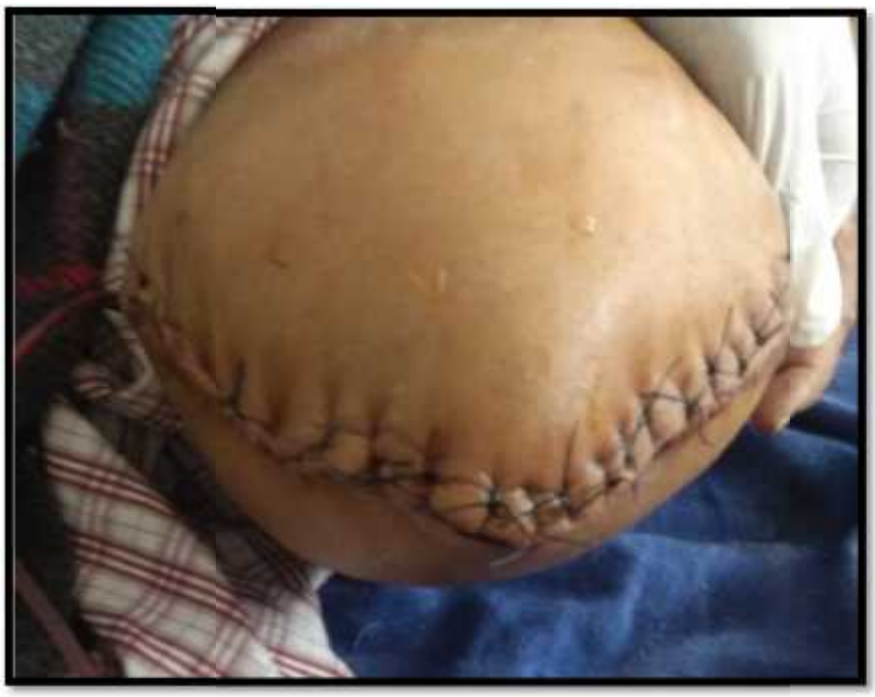


4. **DIABETIC FOOT WITH DIABETIC ULCER SEVERITY SCORE OF 1**



5. HEALED ULCER FOLLOWING SKIN GRAFTING.

6. POST BELOW KNEE AMPUTATION



ANNEXURE II

CONSENT STATEMENT

INFORMED CONSENT

Mr. /Mrs./Dr. _____, you are kindly requested to enroll yourself in a research study tilted, **"ASSESSMENT OF SEVERITY OF DIABETIC FOOT ULCERS USING DIABETIC ULCER SEVERITY SCORE IN PATIENTS ADMITTED AT KLES DR. PRABHAKAR KORE HOSPITAL AND MEDICAL RESEARCH CENTRE, BELAGAVI- A ONE YEAR LONGITUDINAL STUDY ,"**being conducted by REG NO: BH0118001, a post graduate student in M.S. General Surgery and the study will be carried out under the direct supervision and guidance of Dr. _____ , Professor and HOU, Department of General Surgery, Jawaharlal Nehru Medical College, Belgaum.

You have been requested to participate in this as you fit into the laid out criteria for a study 'subject'/ participant.

Your participation in study is voluntary. During the study you will be asked some questions and you are supposed to answer to the best of your knowledge. Your decision whether or not to participate in the study will not affect your treatment in any form during your hospital stay. If you decide to participate you are free to withdraw at any time.

TITLE OF THE STUDY:

"ASSESSMENT OF SEVERITY OF DIABETIC FOOT ULCERS USING DIABETIC ULCER SEVERITY SCORE IN PATIENTS ADMITTED AT

KLES DR. PRABHAKAR KORE HOSPITAL AND MEDICAL RESEARCH CENTRE, BELAGAVI- A ONE YEAR LONGITUDINAL STUDY."

PURPOSE OF THE STUDY:

To assess the severity of diabetic foot ulcers using diabetic ulcer severity score.

PROCEDURES INVOLVED:

If you agree to enroll yourself in my study, you will be interviewed regarding your present, past and family history then you will be clinically examined in detail and investigated accordingly.

The ulcer over the foot will be clinically examined and an x ray foot will be taken. In case, the peripheral pedal pulses are not palpable, a Doppler of the respective lower limb will be carried out. Routine baseline investigations will be carried out which includes complete blood count, serum urea, serum creatinine, FBS/PPBS/ RBS, urine routine and microscopy.

The diabetic ulcer severity score will be calculated according to the respective parameters.

Following this assessment and documentation, you will be called at 3 months and 6 months for assessment of the ulcer and documentation will be done.

RISKS AND BENEFITS:

Risks

No major risks are expected in this study.

Benefits

By assessing the severity of diabetic foot ulcers using diabetic ulcer severity score , the prognosis of the ulcer can be predicted and informed to the patient during the initial course of treatment , hence they are well informed and counseled about their condition and outcome.

No bias will be done to the patients who are not willing to participate in the study from the treatment point of view.

VOLUNTARY PARTICIPATION / WITHDRAWAL FROM THE STUDY:

Taking part in the study is voluntary. You may choose not to enroll yourself in this study and may choose to leave the study anytime in between.

ALTERNATIVES:

Your decision regarding participation in study will not change present or future health care services offered to you at KLES Dr. PrabhakarKore Hospital and Medical Research Centre, Belgaum. You would simply be excluded from the study if you wish to, and all your details shall be kept confidential and you will get the routine line of management.

PRIVACY AND CONFIDENTIALITY:

All data collected or disclosed by you during the course of participation of study, will be kept fully confidential. If however during the course it

becomes necessary for the progress of the course to disclose the identity, it would be done so only after your informed & written consent.

The only people to know that you are a research subject are members of the research team. No information about you will be disclosed to other without your written permission except:

- In emergency to protect your rights AND welfare.
- If required by law.

AUTHORIZATION TO PUBLISH RESULT:

The results of the study may be used to publish an article.When the results of research published or discussed, in a conference, no information will be displayed that would disclose your identity. Any information obtained in connection with this study and that can be identified with you will remain confidential.

FINANCIAL INCENTIVES FOR PARTICIPATION:

No additional costs shall be incurred upon you for the purpose of this study.

It is purely being done with the idea of research and all the cost of study will be borne by the investigator.

QUESTIONS/CONTACT DETAILS:

You shall be free to contact the below mentioned name & addresses anytime during the study period for any clarification or help as you may desire for.

REG NO: BH0118001

Post Graduate Student,

Department of General Surgery,

Jawaharlal Nehru Medical College,

Nehru Nagar, KLE Hospital Road,

Belgaum 590010

Dr. _____

Professor and HOU,

Department of General Surgery,

Jawaharlal Nehru Medical College,

Nehru Nagar, KLE Hospital Road,

Belgaum 590010

In case you need any further information regarding your rights as study participant you may contact:

Dr. ROOPA M BELLAD

Professor of Paediatrics & Chairman,

JNMC Institutional Ethics Committee

on Human Subjects Research,

Jawaharlal Nehru Medical College

Nehru Nagar, KLE Hospital Road

Ph no 0831-2553777

Consent for participation in prospective study

I, Mr/Ms/Mrs. _____ voluntarily agree for the participation as a subject of study. By signing this consent form I am not giving up any of my legal rights, I may withdraw from the study anytime. I am signing the consent form after having read or been read for me in vernacular language, including the risks and the benefits and having all my questions answered.

Subject Name : _____

Signature or the Left Thumb Print of Subject : _____

Date :

Witness Name: _____

Signature:_____ Date :

Investigators Name: _____

Signature:_____ Date :

Place : _____

ತಿಳುವಳಿಕೆಯಸಮ್ಮತಿ

ಶ್ರೀ / ಶ್ರೀಮತಿ / ಡಾ. _____,

ನಿಮಗೆದಯಯಿಂದಒಂದುಸಂಶೋಧನಾಅಧ್ಯಯನದಲ್ಲಿತೊಡಗಿಸಿಕೊಳ್ಳಲುಎನಂತಿಸಲಾಗುತ್ತದ,

ಡಾ. _____ ಎಂ.ಎಸ್ಜನರಲ್ಸರ್ಜರಿಯಲ್ಲಿಸ್ನಾತಕೋತ್ತರವಿದ್ಯಾರ್ಥಿ ಅವರುನಡೆಸಿದಅಧ್ಯಯನದಲ್ಲಿ,

ಡಾ. ಪ್ರಭಾಕರ್ಕೋರೆಹಾಸ್ಪಿಟಲ್ಅಂಡ್ಮೆಡಿಕಲ್ರಿಸರ್ಚ್ಸೆಂಟರ್, ಬೆಳಗಾವಿ-

ಎಒನ್ಇಯರ್ಆಂಗಿಟ್ಯೂಡಿನಲ್ಲ್ಡಿನಲ್ಲಿಸೇರಿಸಿಲಾದರೋಗಿಗಳಲ್ಲಿಡಯಾಬಿಟಿಕ್ಫೂಟ್ಅಲ್ಸರ್ನಡಯಾಬಿಟಿ

ಕ್ಫುಟ್ಅಲ್ಸರ್ತೀವ್ರತೆಯನ್ನುಅಂದಾಜುಮಾಡಲಾಗಿದ. ಎಂ.ಎಸ.

ಜನರಲ್ಸರ್ಜರಿಮತ್ತುಅಧ್ಯಯನವುಬೆಳಗಾವಿನಜವಾಹರಲಾಲ್ನೆಹರೂಮೆಡಿಕಲ್ಕಾಲೇಜ್ನಜನರಲ್ಸರ್ಜರಿಯಇ

ಲಾಖೆಪ್ರೊಫೆಸರ್ಮತ್ತುಎಚ್ಒಯು, _____ ಡಾ.

ಅವರನೇರಮೇಲ್ವಿಚಾರಣೆಮತ್ತುಮಾರ್ಗದರ್ಶನದಲ್ಲಿನಡಸಲಾಗುತ್ತದ.

'ಎಷಯ' /

ಪಾಲ್ಗೊಂಡಿರುವಅಧ್ಯಯನಕ್ಕನೀವುಸಿದ್ಧಪಡಿಸಿದಮಾನದಂಡಕ್ಕಸರಿಹೊಂದುವಂತಇದನ್ನುಭಾಗವಹಿಸಲು

ನಿಮ್ಮನ್ನುಎನಂತಿಸಲಾಗಿದ.

ಅಧ್ಯಯನದಲ್ಲಿನಿಮ್ಮಭಾಗವಹಿಸುವಿಕಸ್ವಯಂಪ್ರೇರಿತವಾಗಿರುತ್ತದ.ಅಧ್ಯಯನದಸಮಯದಲ್ಲಿನಿಮಗಕಲ

ವುಪ್ರಶ್ನೆಗಳನ್ನುಕೇಳಲಾಗುತ್ತದಮತ್ತುನಿಮ್ಮಜ್ಞಾನದಅತ್ಯುತ್ತಮವಾದಉತ್ತರಕ್ಕನೀವುಉತ್ತರಿಸಬೇಕು.ನಿ

ಮ್ಮಆಸ್ಪತ್ರೆಯಲ್ಲಿಉಳಿಯುವಸಮಯದಲ್ಲಯಾವುದೇಚಿಕಿತ್ಸೆಯಲ್ಲನಿಮ್ಮಚಿಕಿತ್ಸೆಯಮೇಲೆಪರಿಣಾಮಬೀರ

ಬಾರದುಎಂಬಅಧ್ಯಯನದಲ್ಲಿಪಾಲ್ಗೊಳ್ಳಬೇಕೆಅಥವಾಬೇಡವೇಎಂಬನಿರ್ಧಾರವನ್ನುನೀವುತೆಗದುಕೊಳ್ಳಬ

ಹುದು.

ನೀವುಭಾಗವಹಿಸಲುನಿರ್ಧರಿಸಿದರನೀವುಯಾವುದೇಸಮಯದಲ್ಲಹಿಂಪಡೆಯಲುಸ್ವತಂತ್ರರಾಗಿರುತ್ತಾರ.

ಅಧ್ಯಯನದಶೀರ್ಷಿಕ:

"ಕಎಲ್ಇಎಸ್ದಾ. ಪ್ರಭಾಕರ್ಕೋರೆಹಾಸ್ಪಟಲ್ಮತ್ತುಮಡಕಲ್ರಿಸರ್ಚ್ಸೆಂಟರ್, ಬಳಗಾವ -

ಎಒನ್ಇಯರ್ಆಂಗಿಟ್ಯೂಡನಲ್ಲ್ಡಿನಲ್ಲಿಸೇರಿಸಲಾದರೋಗಿಗಳಲ್ಲಿಡಯಾಬಿಟಿಕ್ಫುಟ್ಅಲ್ಸರ್ನಡಯಾಬಿಟಿಕ್ಫುಟ್ಅಲ್ಸರ್ತೀವ್ರತೆಯ

ನ್ನುಅಂದಾಜುಮಾಡಲಾಗುತ್ತಿದೆ."

ಅಧ್ಯಯನದಉದ್ದೇಶ:

ಡಯಾಬಿಟಿಕ್ಫುಟ್ತೀವ್ರತೆಯಸ್ಕೋರ್ಅನ್ನುಬಳಸಿಕೊಂಡುಮಧುಮೇಹಕಾಲಿನಹುಣ್ಣುಗಳತೀವ್ರತೆಯನ್ನುನರ್ಣಯಿಸಲು.

ಒಳಗೊಂಡಿರುವವಿಧಾನಗಳು:

ನನ್ನಅಧ್ಯಯನದಲ್ಲಿನಿಮ್ಮನ್ನುತೊಡಗಿಸಿಕೊಳ್ಳಲುನೀವುಒಪ್ಪಿಕೊಂಡರ, ನಮ್ಮಪ್ರಸ್ತುತ,

ಹಿಂದಿನಮತ್ತುಕುಟುಂಬದಇತಿಹಾಸದಬಗ್ಗೆಸಂದರ್ಶಿಸಲಾಗುವುದು,

ನಂತರನೀವುಪ್ರಾಯೋಗಿಕವಾಗಿವಿವರವಾಗಿಪರಿಶೀಲಿಸಲಾಗುವುದುಮತ್ತುಅದಕ್ಕೆತಕ್ಕಂತತನಖಮಾಡಲಾಗುತ್ತದ.

ಪಾದದಮೇಲಹುಣ್ಣುವೈದ್ಯಕೀಯವಾಗಪರೀಕ್ಷಿಸಲ್ಪಡುತ್ತದಮತ್ತುಬಂದುಕ್ಷಕಿರಣವನ್ನುತಗದುಕೂಳ್ಳಲಾಗುತ್ತದ. ಒಂದಒಂದುವೇಳೆ, ಬಾಹ್ಯಪಡಲ್ಬೇಳಿಕಾಳುಗಳುಸ್ಪಷ್ಟವಾಗಲ್ಲ, ಆಯೊಕಳಭಾಗದಅಂಗಾಂಶದಮೋಪ್ಲರ್ಅನ್ನುಕೈಗೊಳ್ಳಲಾಗುತ್ತದ.

ಸಂಪೂರ್ಣರಕ್ತದಎಣಿಕೆ,

ಸೀರಮ್ಯೂರಿಯಾ, ಸೀರಮ್ಕ್ರಿಯಾಟ್ಯನಾ, ಎಚ್ಬಎಸ್ / ಪಿಪಬಬಎಸ್ / ಆರ್ಬಎಸ್,

ಮೂತ್ರವಾಡಿಕೆಯಮತ್ತುಸೂಕ್ಷ್ಮದರ್ಶಕವನ್ನುಒಳಗೊಂಡಿರುವನಿಯತಕ್ರಮದಬಸ್ಸ್ಯಾನ್ ತನಿಖೆಗಳನ್ನುಕೈಗೂಳ್ಳಲಾಗುತ್ತದೆ.

ಆಯಾ ನಿಯತಾಂಕಗಳಪ್ರಕಾರಡಯಾಬಿಟಿಕ್ಅಲ್ಸರ್ತೀವ್ರತೆಯಸ್ಕೋರ್ಅನ್ನುಲೆಕ್ಕಹಾಕಲಾಗುತ್ತದೆ.

ಈಮೌಲ್ಯಮಾಪನಮತ್ತುದಾಖಲಾತಿಯನಂತರ, ಹುಣ್ಣುಮತ್ತುದಾಖಲೆಯಮೌಲ್ಯಮಾಪನಕ್ಕಾಗಿನಿಮ್ಮನ್ನು 3 ತಿಂಗಳಮತ್ತು 6 ತಿಂಗಳುಗಳವರೆಗೆಕರೆಯಲಾಗುವುದು.

ಅಪಾಯಗಳುಮತ್ತುಲಾಭಗಳು :

ಅಪಾಯಗಳು

ಈಅಧ್ಯಯನದಲ್ಲಿಯಾವುದೇಪ್ರಮುಖಅಪಾಯಿಗಳಿಲ್ಲ.

ಲಾಭಗಳು

ಮಧುಮೇಹಹುಣ್ಣುಹುಣ್ಣುಗಳತೀವ್ರತೆಯನ್ನುನಿರ್ಣಯಿಸುವುದರಮೂಲಕಮಧುಮೇಹಹುಣ್ಣುತೀವ್ರತೆಯಸ್ಕೋರ್ಅನ್ನು,

ಆರಂಭಿಕಹಂತದಅವಧಿಯಲ್ಲಿರೋಗಿಗಹುಣ್ಣುಮುನ್ಸೂಚನೆಯನ್ನುಊಹಿಸಬಹುದುಮತ್ತುರೋಗಿಗತಳಿಸಬಹುದು,

ಆದ್ದರಿಂದಅವರಪರಿಸ್ಥಿತಿಮತ್ತುಫಲಿತಾಂಶದಬಗ್ಗೆಅವರುಚಿನ್ನಾಗಿತಿಳಿಸುತ್ತಾರಿಮತ್ತುಸಲಹೆನೀಡುತ್ತಾರೆ.

ಚಿಕಿತ್ಸೆಯದೃಷ್ಟಿಕೋನದಿಂದಪಾಲ್ಗೊಳ್ಳಲುಇಷ್ಟವಿಲ್ಲದರೋಗಿಗಳಿಗೆಯಾವುದೇಪಕ್ಷಪಾತವಿಲ್ಲ.

ಅಧ್ಯಯನದಿಂದಸ್ವಯಂಪ್ರೇರಿತಭಾಗವಹಿಸುವಿಕ / ಹಿಂತಗದುಕೂಳ್ಳುವಿಕ :

ಅಧ್ಯಯನದಲ್ಲಿಪಾಲ್ಗೊಳ್ಳುವುದುಸ್ವಯಂಪ್ರೇರಿತವಾಗಿರುತ್ತದೆ.

ಈಅಧ್ಯಯನದಲ್ಲನಿಮ್ಮನ್ನುಸೇರಿಸಿಕೊಳ್ಳೆದರಲುನೀವುಟೆಯ್ಕಿಮಾಡಿಬಹುದುಮತ್ತುಯಾವುದೇಸಮಯದೆಲ್ಲಯೂವಸಮಯಿದಲ್ಲಾ

ದರೂಅಧ್ಯಯನವನ್ನುಬಡಲುಟಿಯ್ಕಮಾಡಬಹುದು.

ಪರ್ಯಾಯಗಳು :

ಅಧ್ಯಯನದಲ್ಲಪಾಲ್ಗೊಳ್ಳುವಿಕೆಯಬಗ್ಗೆನಮ್ಮನಿರ್ಧಾರವುನಮಗಪ್ರಸ್ತುತಪಡಿಸಿದಅಥವಾಭವಿಷ್ಯದಆರೋಗ್ಯಸೇವಗಳನ್ನುಬದಲಾ

ಯಿಸುವುದೇ, ' ' ಕಎಲಾಇಎಸ್ವಾ. ' ' 'ಪ್ರಭಾಕಕೋರೀಅಸ್ವತ್ರಮತ್ತುವೈದ್ಯಕೀಯಸಂಶೋಧನಾಕೇಂದ್ರ, ಬಳಗಾವಿ.

ನೀವುಬಯಸಿದಲ್ಲಸೇವುಕೇವಲಅಧ್ಯಯನದಿಂದಹೊರಗಿಡಬೇಕು,

ಮತ್ತುನಿಮ್ಮಎಲ್ಲಾವೈದರಗಳನ್ನುಗೌಪ್ಯವಾಗಿಡಬೇಕುಮತ್ತುನೀವುನಿರ್ವಹಣೆಯಿಂಯಿಮತಮಾರ್ಗವನ್ನುಪಡಯುತ್ತೀರ.

ಗೌಪ್ಯತಮತ್ತುಗೋಪ್ಯತ :

ಅಧ್ಯಯನದಪಾಲ್ಗೊಳ್ಳುವಿಕಯಿನಿಮಯದಲ್ಲನೀವುನಿಗ್ರಹಿಸದಅಥವಾಬಹಿರಂಗಪಡಿಸದವಲ್ಲಡೇಟಾವನ್ನುಸಂಪೂರ್ಣವಾಗರಹ

ಸ್ಯವಾಗಿಡಲಾಗುತ್ತದ.ಆದರಸಹಜವಾಗ, ' ' ' ಗುರುತನ್ನುಬಿಹಿರಂಗಪಡಿಸಲುಕೋರ್ಸ್ಗಳಪ್ರಗತಿಗಅತ್ಯವಾದರ,

ನಿಮ್ಮತಿಳುವಳಿಕಯುಳ್ಳಮತ್ತುಲಿಖಿತಸಮ್ಮತಯಿನಂತರಮಾತ್ರಇದನ್ನುಮಾಡಲಾಗುವುದು.

ನೀವುಸಂಶೋಧನಾವಿಷಯವಂದುತಳಿದರುವವಿಕ್ಕಜನರುಸಂಶೋಧನಾತಂಡದಸದಸ್ಯರಾಗಿದ್ದಾರ.

ನಿಮ್ಮಲಿಖಿತಅನುಮತಿಯಿಲ್ಲದನಿಮ್ಮಬಗ್ಗೆಯಾವುದೇಮಾಹಿತಿಯನ್ನುಬಹಿರಂಗಪಡಿಸಲಾಗುವುದಿಲ್ಲ:

- ನಿಮ್ಮಹಕ್ಕುಗಳನ್ನುಮತ್ತುಕಲ್ಯಾಣವನ್ನುರಕ್ಷಿಸಲುತುರ್ತುಸ್ಥಿತಿಯಲ್ಲಿ.
- ಕಾನೂನಿನಿಂದಅಗತ್ಯವಿದ್ದರೆ.

ಫಲಿತಾಂಶಪ್ರಕಟಿಸಲುಅಧಿಕಾರ:

ಲೇಖನವನ್ನುಪ್ರಕಟಿಸಲುಅಧ್ಯಯನದಫಲಿತಾಂಶಗಳನ್ನುಬಳಸಬಹುದು.
ಸಂಶೋಧನೆಯಫಲಿತಾಂಶಗಳನ್ನುಪ್ರಕಟಿಸಿದಾಗಅಥವಾಚರ್ಚಿಸಿದಾಗ, ಒಂದುಸಮ್ಮೇಳನದಲ್ಲಿ,
ನಿಮ್ಮಗುರುತನ್ನುಬಹಿರಂಗಪಡಿಸುವಯಾವುದೇಮಾಹಿತಿಯನ್ನುಪ್ರದರ್ಶಿಸಲಾಗುವುದಿಲ್ಲ.
ಈಅಧ್ಯಯನಕ್ಕೆಸಂಬಂಧಿಸದಯಾವುದೇಮಾಹಿತಮಿತ್ತುನಮ್ಮೊಂದಿಗಿಗುರುತಿಸಿಬಹುದಾದಮಾಹಿತಿಯನ್ನುಗೌಪ್ಯವಾಗಿಉಳಿಯುತ್ತದೆ.

ಪಾಲ್ಗೊಳ್ಳುವಿಕಗಾಗಿಹಣಕಾಸುಪ್ರೋತ್ಸಾಹಧನಗಳು:

ಈಅಧ್ಯಯನದಉದ್ದೇಶಕ್ಕಾಗಿಹಚ್ಚುವಂಪಚ್ಚಗಳುನಮ್ಮಮೇಲಿಲುಂಟಾಗುವುದಿಲ್ಲ.
ಇದುಕೇವಲಸಂಶೋಧನೆಯಪರಿಕಲ್ಪನೆಯೊಂದಿಗೆಮಾಡಲ್ಪಟ್ಟದಿಮೆತ್ತುಅಧ್ಯಯನದಎಲ್ಲಾವಚ್ಚವನ್ನುತನಿಖಾದಾರಿಯಿಹೂರದುತ್ತೆರೆ.

ಪ್ರಶ್ನೆಗಳು / ಸಂಪರ್ಕವಿವರಗಳು:

ನೀವುಬಯಿಸದಂತಯಾವುದೇಸ್ಪಷ್ಟೀಕರಣಅಥವಾಸಹಾಯಿಕ್ಕಾಗಿಅಧ್ಯಯನಅವಧಿಯಸಮಯಿದಲ್ಲಿಯಾವುದೇಸಮಯಿದಲ್ಲಿಸೂ
ಚಿಸಲಾದಹಸರುಮತ್ತುವಳಾಸಗಳನ್ನುಸಂಪರ್ಕಿಸಲುನೀವುಮುಕ್ತರಾಗಿರಬೇಕು.

ಡಾ. _____
ಸ್ನಾತಕೊತ್ತರವಿದ್ಯಾರ್ಥಿ,
ಜನರಲ್ಸರ್ಜರಿಇಲಾಖೆ,
ಜವಾಹರಲಾಲ್ನೆಹರುವೈದ್ಯಕೀಯಕಾಲೇಜು,
ನೆಹರೂನಗರ,ಕ.ಎಲ್.ಇಆಸ್ಪತ್ರೆರಸ್ತೆ,
ಬೆಳಗಾವಿ 590010

ಡಾ. _____
ಪ್ರೊಫೆಸರ್ಮತ್ತುಎಚ್ಒಒಯಿ,
ಜನರಲ್ಸರ್ಜರಿಇಲಾಖೆ,
ಜವಾಹರಲಾಲ್ನೆಹರುವೈದ್ಯಕೀಯಕಾಲೇಜು,
ನೆಹರೂನಗರ,ಕ.ಎಲ್.ಇಆಸ್ಪತ್ರೆರಸ್ತೆ,
ಬೆಳಗಾವಿ 590010

ಒಂದುವೇಳನಮ್ಮಪಾಲುದಾರರುನಮ್ಮಹಕ್ಕುಗಳಬಗ್ಗೆಹಚ್ಚನಮಾಹಿತಬೇಕಾದರೆನೀವುಸಂಪರ್ಕಿಸಬಹುದು:

ಡಾರೂಪಾಎಂಬಲ್ಲಾಡೆ
ಪೀಡಿಯಾಟ್ರಿಕ್ಸ್ತುಅಧ್ಯಕ್ಷಪ್ರೊಫೆಸರ್.
ಜೆಎನ್ಎಂಸಿಇನ್ಸ್ಟ್ಯೂಶನಲ್ಎಥಿಕ್ಸ್ಕಮಿಟಿ
ಮಾನವವಿಷಯಗಳಸಂಶೋಧನೆ,
ಜವಾಹರಲಾಲ್ನೆಹರುವೈದ್ಯಕೀಯಕಾಲೇಜು,
ನೆಹರೂನಗರ,ಕ.ಎಲ್.ಇಆಸ್ಪತ್ರೆರಸ್ತೆ,
ಬೆಳಗಾವಿ 590010
ಮೊಬೈಲ್ -0831-2553777

ನಿರೀಕ್ಷಿತಅಧ್ಯಯನದಭಾಗವಹಿಸುವಿಕೆಗಒಪ್ಪಿಗ

ನಾನು, ಶ್ರೀ / ಶ್ರೀಮತಿ / ಶ್ರೀಮತಿ _____

ಸ್ವಯಂಪ್ರೇರಣೆಯಿಂದಭಾಗವಹಿಸುವಿಕೆಯನ್ನುಅಧ್ಯಯನವಿಷಯವಾಗಿಒಪ್ಪಿಕೊಳ್ಳುತ್ತೇನೆ.
ಈಸಮ್ಮತಿಯನಮೂನೆಯಲ್ಲಿಸಹಿಹಾಕುವಮೂಲಕನನ್ನಯಾವುದೇಕಾನೂನುಹಕ್ಕುಗಳನ್ನುನಾನುಬಿಡುತ್ತಿಲ್ಲ.
ನಾನುಯಾವಸಮಯದಲ್ಲಾದರೂಅಧ್ಯಯನವನ್ನುಹಿಂತೆಗೆದುಕೊಳ್ಳಬಹುದು.
ಓದಿದನಂತರಅಥವಾದೇಶೀಯಭಾಷೆಯಲ್ಲಿನನಗೆಓದಿದನಂತರ,
ಅಪಾಯಗಳುಮತ್ತುಪ್ರಯೋಜನಗಳನ್ನುಒಳಗೊಂಡಂತೆಮತ್ತುನನ್ನಎಲ್ಲಪ್ರಶ್ನೆಗಳಿಗಾಉತ್ತರಿಸಿದನಿಂತರನಾನುಒಪ್ಪಿಗಯನ್ನುಸಹ
ಮಾಡುತ್ತಿದ್ದೇನ .

ವಿಷಯದಹಸರ : _____

ವಿಷಯದಸಹಿಅಥವಾಎಡತಮ್ಮುದ್ರಣ : _____

ದನಾಂಕ :

ವಿಚಾರಿಸಿದವರು : _____

ಸಹಿ: _____ ದನಾಂಕ :

ತನಿಖಾಧಿಕಾರಿಗಳುಹಸರು : _____

ಸಹಿ: _____ ದನಾಂಕ :

ಸ್ಥಳ : _____

माहितीपूर्णसंमती

श्रीमान / श्रीमती / डॉ. _____, आपणासविनम्रपणेविनंतीआहेकीस्वत:
लाशोधअध्यक्षामध्येनामांकितकरा,रुग्णांमध्येमधुमेहअल्सरसेव्हरीटीस्कोअरचावापरकरूनमधुमेहअसलेल्यापा
यांच्याअल्सरचागंभीरपणामूल्यांकनकेएलईएसडॉप्रभाकरकोरेहॉस्पीटलआणिमेडिकलरिसर्चसेंटर, बेलागवी -
एवनइयसेलॉगिट्यूडिनलस्टडीयेथेमान्यआहे . पोस्टग्रेजुएटविद्यार्थीडॉ.यांनीआयोजितकेले
याविषयावरमधुमेहावरीलअल्सरगंभीरतांचावापरकरूनमधुमेहअसलेल्यापायांच्याअल्सरचाआकलन.
एमएसजनरलसर्जरीआणिअभ्यासडॉ. , सामान्यशस्त्रक्रियाविभाग,
जवाहरलालनेहरूमेडिकलकॉलेज, बेळगावयेथीलयांच्याथेटदेखरेखीखालीआणिमार्गदर्शनाखालीकेलेजाईल .
आपण 'विषय' /
सहभागीयाअभ्यासक्रमासाठीनिर्धारितनिकषांनुसारफिटझाल्यासत्यातसहभागीहोण्याचीविनंतीकेलीगेलीआहे .
अभ्यासाततुमचासहभागस्वैच्छिकआहे.
अभ्यासादरम्यानआपल्यालाकाहीप्रश्नविचारलेजातीलआणिआपल्यालाआपल्यासर्वोत्तममाहितीचाउत्तरदेणेआ
वश्यकआहे.
अभ्यासातसहभागीव्हायचेआहेकीनाहीहेआपल्यानिर्णयामुळेआपल्याहॉस्पिटलच्यारुग्णाच्यादरम्यानकोणत्याही
स्वरूपातआपल्याउपचारांवरपरिणामहोणारनाही.
आपणसहभागीहोण्याचेठरविल्यासआपणकोणत्याहीवेळीमागेघेण्यासमोकळेआहात .

अभ्यासाचेशीर्षक:

रुग्णांमध्येमधुमेहअल्सरसेव्हरीटीस्कोअरचावापरकरूनमधुमेहअसलेल्यापायांच्याअल्सरचागंभीरपणामूल्यांकन
केएलएसएसडॉप्रभाकरकोरेहॉस्पिटलआणिमेडिकलरिसर्चसेंटर, बेलागवी -
एवनइयसेलॉगिट्यूडिनलस्टडीयेथेमान्यआहे .

अभ्यासाचाउद्देश

मधुमेहअल्सरतीव्रतास्कोरवापरूनमधुमेहपायअल्सरतीव्रतामूल्यांकनकरण्यासाठी.

प्रक्रियासमाविष्ट

आपणमाझ्याअभ्यासामध्येस्व : लानावनोंदणीकरण्याससहमतअसल्यास, आपल्याविद्यमान, भूतकाळातीलआणिकौटुंबिकइतिहासाबद्दलमुलाखतघेतलीजाईल, त्यानंतरआपल्यालावैद्यकीयदृष्ट्यातपशीलवारपणेतपासणीकेलीजाईलआणित्यानुसारतपासणीकेलीजाईल. पायवरअल्सरवैद्यकीयदृष्ट्यातपासलेजाईलआणिएकएक्सकिरणपाऊलघेतलेजाईल.जरपरिधीयपेडलडाळीयोग्य नसतीलतरसंबंधितनिचराअंगाचेडोप्लरकेलेजाईल.नियमितआधारभूततपासणीकेलीजाईलज्यातसंपूर्णरक्तगण ना, सीरमयूरिया, सीरमक्रिएटिनिन, एफबीएस / पीपीबीएस / आरबीएस, मूत्रनियमितताआणिमायक्रोस्कोपीसमाविष्टआहे.

मधुमेहअल्सरतीव्रतास्कोरसंबंधितपॅरामीटर्सनुसारगणनाकेलीजाईल.यामूल्यांकनआणिदस्तऐवजीकरणानंतर, अल्सरचेमूल्यांकनआणिदस्तऐवजीकरणकेलेजाईलयासाठीआपल्याला 3 महिनेआणि 6 महिनेकॉलकेलेजाईल.

धोकेआणिफायदे

धोके

याअभ्यासातकोणतेहीमोठेधोकेअपेक्षितनाहीत.

फायदे

मधुमेहअल्सरतीव्रतास्कोरवापरूनडायबेटिकपायअल्सरचातीव्रतातपासून, अल्सरचारोगहोण्याचीशक्यतावर्तविलीजाऊशकतेआणिउपचारसुरूवातीच्याकाळातरुग्णालामाहितीदिलीजाऊशक ते, म्हणूनचत्यांनात्यांच्यास्थितीआणिपरिणामांबद्दलचांगलेमाहितीअसतेआणिसल्लादिलाजातो. उपचारांच्यादृष्टीकोनातूनअभ्यासातभागघेण्यासइच्छुकनसलेल्यारुग्णांनाकोणतीहीपूर्वाग्रहकेलीजाणारनाहीत.

अभ्यासातस्वैच्छिकसहभाग / पैसेकाढणे :

अभ्यासातभागघेतस्वैच्छिकआहे.

आपणयाअभ्यासातआपलेनावनभरण्याचेनिवडूशकताआणिकोणत्याहीवेळीअभ्याससोडूशकता.

पर्यायः

अभ्यासातसहभागघेण्यासंबंधीचाआपलानिणेयकेएलईएसडॉप्रभाकरकोरेहॉस्पिटलआणिमेडिकलरिसचेसेंटर, बेलगावीयेथेआपल्यालाप्रदानकेलेल्यावतेमानकिंवाभविष्यातीलआरोग्यसेवांमध्येबदलकरणारनाही. आपणइच्छितअसल्यासआपल्यालाकेवळअभ्यासमधूनवगळण्यातयेईलआणिआपल्यासवेतपशीलांनागोपनीयठेवण्यातयेईलआणिआपल्यालानियमितपणेव्यवस्थापनाचेमागेमिळेल.

गोपनीयताआणिगोपनीयतेची:

अभ्यासाच्यासहभागादरम्यानआपल्याकडूनगोळाकेलेलाकिंवाउघडकेलेलासवेडेटापूणेपणेगोपनीयठेवलाजाईल.ज रअथोतचअथोतचओळखपटवूनदेण्याच्याप्रगतीसाठीआवश्यकअसेलतरतेआपल्यामाहितीआणिलेखीसंमतीनंतर चकेलेजाईल.

आपणसंशोधनविषयआहातहेकेवळलोकांनाचमाहितआहेकीतेसंशोधनकायेसंघाचेसदस्यआहेत. आपल्यालिखितपरवानगीशिवायआपल्याबद्दलकोणतीहीमाहितीइतरांनाउघडकेलीजाणारनाही:

- आपल्याअधिकारांचेआणिकल्याणासाठीचेसंरक्षणकरण्यासाठीआणीबाणीमध्ये.
- कायद्यानुसारआवश्यकअसल्यास.

परिणामप्रकाशितकरण्यासाठीअधिकृतताः

अभ्यासाच्यानिकालांचाउपयोगलेखप्रकाशितकरण्यासाठीकेलाजाऊशकतो. जेव्हाएखाद्यासंशोधनपरिषदेतप्रकाशितकिंवाचचोकेल्याजाततेव्हाकोणतीहीमाहितीप्रदशितकेलीजाणारनाही जीआपलीओळखउघडकरेल. याअभ्यासाशीसंबंधितकोणतीहीमाहितीआणितीआपल्यासहओळखलीजाऊशकतेतीगोपनीयराहील.

भागीदारीसाठीआर्थिकउद्दिष्टेः

याअभ्यासाच्याउद्देशासाठीआपल्यावरकोणतेहीअतिरिक्तखचेकेलेजाणारनाहीत. हेपूणेपणेसंशोधनाचीकल्पनाकरूनकेलेजातआहेआणिसवेखचोचीतपासणीअन्वेषकांद्वारेकेलीजाईल.

प्रश्न / संपर्कतपशील:

आपणइच्छुकअसलेल्याकोणत्याहीस्पष्टीकरणकिंवामदतीसाठीअभ्यासकालावधीदरम्यानकोणत्याहीवेळीखाली नमूदकेलेल्यानावाचाआणिपत्त्यांचासंपर्कसाधण्यासाठीमुक्तअसाल.

डॉ._____

पदव्युत्तरविद्यार्थी,
सामान्यशस्त्रक्रियाविभाग,
जवाहरलालनेहरूमेडिकलकॉलेज,
नेहरूनगर, केएलईहॉस्पिटलरोड,
बेळगाव 590010

डॉ._____

प्राध्यापकआणिएचओयू,
सामान्यशस्त्रक्रियाविभाग,
जवाहरलालनेहरूमेडिकलकॉलेज,
नेहरूनगर, केएलईहॉस्पिटलरोड,
बेळगाव 590010

अभ्याससहभागीम्हणूनआपल्याअधिकारांसंबंधीआपल्यालापुढीलमाहितीचीआवश्यकताअसल्यासआपणयेथेसंपर्कसाधूशकता:

डॉ.रोपाएमबेलद

पेडियाट्रिक्सआणिचेअरमनचेप्राध्यापक,
जेएनएमसीइंस्टिट्यूशनलएथिक्सकमिटी
मानवीविषयसंशोधन,
जवाहरलालनेहरूमेडिकलकॉलेज ,
नेहरूनगर, केएलईहॉस्पिटलरोड,
बेळगाव 590010 - मोबाइल -0831-2553777

संभाव्यअभ्यासातसहभागासाठीसहमती

मी, श्रीमान / श्रीमती / श्रीमती _____
अभ्यासाच्याविषयानुसारसहभागघेण्यासाठीस्वैच्छिकपणेसहमतआहेत.
यासंमतीफॉर्मेवरस्वाक्षरीकरुनमीमाझेकोणतेहीकायदेशीरअधिकारसोडूनदेतनाही,
मीकोणत्याहीवेळीअभ्यासमागेघेऊशकते. मीजोखमीआणिफायदेआणिमाझ्यासवेप्रश्नांचीउत्तरेदेताना,
मलास्थानिकभाषेतवाचल्यानंतरकिंवावाचल्यानंतरसंमतीफॉर्मेवरस्वाक्षरीकरीतआहे .

विषयनाव: _____

स्वाक्षरीकिंवाडावीथंबविषयाचीछपाई: _____

तारीख:

साक्षीदारनाव: _____

स्वाक्षरी: _____ तारीख:

तपासकर्त्याचेनाव: _____

स्वाक्षरी: _____ तारीख:

ठिकाण: _____

सूचितसहमति

श्रीमान / श्रीमती / डॉ _____,

आपसेअनुरोधहैकिआपखुदकोएकशोधअध्ययनमेंनामांकितकरनेकेलिएअनुरोधकरें, "एकस्नातकोत्तर छात्रडॉ। द्वाराआयोजितकिएजारहेकेएलईएसडॉ।प्रभाकरकोरेअस्पतालऔरमेडिकलरिसर्चसेंटर, बेलगावी- एवनइयरलॉन्गिट्यूडिनलस्टडी" मेंआयोजितमरीजोंमेंमधुमेहअल्सरगंभीरतास्कोरकाउपयोगकरकेमधुमेहकेअल्सरगंभीरताकेउपयोगकीमधुमेहके गंभीरताकाआकलन।सुश्रीसामान्यसर्जरीऔरअध्ययनडॉ। , प्रोफेसरऔरएचओयू, जनरलसर्जरीविभाग, जवाहरलालनेहरूमेडिकलकॉलेज, बेलगामकीप्रत्यक्षनिगरानीऔरमार्गदर्शनकेतहतकियाजाएगा।

आपसेइसपरभागलेनेकाअनुरोधकियागयाहैक्योंकिआपएकअध्ययन 'विषय' / प्रतिभागीकेलिएनिर्धारितमानदंडोंमेंफिटबैठतेहैं।

अध्ययनमेंआपकीभागीदारीस्वैच्छिकहै।अध्ययनकेदौरानआपकोकुछप्रश्नपूछेजाएंगेऔरआपकोअपनेसर्वोत्तम ज्ञानकाउत्तरदेनाहोगा।अध्ययनमेंभागलेनेकेलिएयानहीं, आपकानिर्णयआपकेअस्पतालकेठहरनेकेदौरानकिसीभीरूपमेंआपकेइलाजकोप्रभावितनहींकरेगा।यदिआपभागले नेकाफैसलाकरतेहैंतोआपकिसीभीसमयवापसलेनेकेलिएस्वतंत्रहैं।

अध्ययनकाशीर्षक:

"एकस्नातकोत्तरछात्रडॉ।आरुषिमिश्राद्वाराआयोजितकिएजारहेकेएलईएसडॉ।प्रभाकरकोरेअस्पतालऔरमेडिक लरिसर्चसेंटर, बेलगावी- एवनइयरलॉन्गिट्यूडिनलस्टडी"

अध्ययनकाउद्देश्य :

मधुमेहअल्सरगंभीरतास्कोरकाउपयोगकरकेमधुमेहकेपैरअल्सरकीगंभीरताकाआकलनकरनेकेलिए।

शामिलप्रक्रियाएं:

यदिआपअपनेअध्ययनमेंखुदकोनामांकितकरनेकेलिएसहमतहैं, तोआपकेवर्तमान, अतीतऔरपारिवारिकइतिहासकेबारेमेंसाक्षात्कारकियाजाएगा, तोआपकोचिकित्सकीयरूपसेविस्तारसेजांचकीजाएगीऔरतदनुसारजांचकीजाएगी।

पैरपरअल्सरकीचिकित्सकीयजांचकीजाएगीऔरएकएक्सरेपैरलियाजाएगा।यदिपरिधीयपेडलदालेंस्पष्टनहींहैं, तोसंबंधितनिचलेअंगकाएकडॉपलरकियाजाएगा।नियमितआधारभूतजांचकीजाएगीजिसमेंपूर्णरक्तगणना, सीरमयूरिया, सीरमक्रिएटिनिन, एफबीएस / पीपीबीएस / आरबीएस, मूत्ररूटीनऔरमाइक्रोस्कोपीशामिलहै।

मधुमेहअल्सरगंभीरतास्कोरसंबंधितमानकोंकेअनुसारगणनाकीजाएगी।इसमूल्यांकनऔरदस्तावेज़ीकरणकेबाद, आपकोअल्सरकेमूल्यांकनकेलिए 3 महीनेऔर 6 महीनेमेंबुलायाजाएगाऔरदस्तावेज़ीकरणकियाजाएगा।

जोखिमऔरलाभ:

जोखिम

इसअध्ययनमेंकोईबड़ाजोखिमअपेक्षितनहींहै।

लाभ

मधुमेहकेअल्सरगंभीरतास्कोरकाउपयोगकरकेमधुमेहकेपैरअल्सरकीगंभीरताकाआकलनकरके, अल्सरकीपहचानकीभविष्यवाणीकेदौरानरोगीकोभविष्यवाणीऔरसूचितकियाजासकताहै, इसलिएउन्हेंअच्छीतरहसेसूचितकियाजाताहैऔरउनकीस्थितिऔरपरिणामकेबारेमेंसलाहदीजातीहै। उनरोगियोंकोकोईपूर्वाग्रहनहींकियाजाएगाजोउपचारकेदृष्टिकोणसेअध्ययनमेंभागलेनेकेइच्छुकनहींहैं।

अध्ययनसेस्वैच्छिकभागीदारी / निकासी :

अध्ययनमेंभागलेनास्वैच्छिकहै।आपइसअध्ययनमेंखुदकोनामांकितनकरनाचुनसकतेहैंऔरकिसीभीसमयअध्ययनकोछोड़नाचुनसकतेहैं .

विकल्प :

अध्ययनमेंभागीदारीकेबारेमेंआपकानिर्णयकेएलईएसडॉप्रभाकरकोरेअस्पतालऔरमेडिकलरिसर्चसेंटर, बेलगावीमेंआपकोपेशकीगईवर्तमानयाभविष्यकीस्वास्थ्यदेखभालसेवाओंकोनहींबदलेगा।यदिआपचाहें तोआपकोकेवलअध्ययनसेबाहररखाजाएगा, औरआपकेसभीविवरणगोपनीयरखाजाएगाऔरआपकोप्रबंधनकीनियमितरेखामिलजाएगी।

गोपनीयताऔरगोपनीयता :

अध्ययनकीभागीदारीकेदौरानआपकेद्वाराएकत्रयाखुलासाकियागयासभीडेटापूरीतरहसेगोपनीयरखाजाएगा।हालां कि, पाठ्यक्रमकेदौरानपहचानकोप्रकटकरनेकेलिएपाठ्यक्रमकीप्रगतिकेलिएआवश्यकहोजाताहै, तोयहआपकीसूचितऔरलिखितसहमतिकेबादहीकियाजाएगा।

एकमात्रलोगयहजाननाचाहतेहैंकिआपएकशोधविषयहैं, अनुसंधानदलकेसदस्यहैंआपकेबारेमेंकोईजानकारीआपकेलिखितअनुमतिकेबिनाअन्यकोप्रकटनहींकी जाएगी:

- अपनेअधिकारोंऔरकल्याणकीरक्षाकेलिएआपातकालमें
- यदिकानूनद्वाराआवश्यक

परिणामप्रकाशितकरनेकेलिएप्राधिकरण :

अध्ययनकेपरिणामएकलेखप्रकाशितकरनेकेलिएइस्तेमालकियाजासकताहै।जबएकसम्मेलनमेंप्रकाशि तयाचर्चाकेपरिणाम, कोईजानकारीप्रदर्शितनहींकीजाएगीजोआपकीपहचानकाखुलासाकरेगी।इसअध्ययनकेसंबंधमेंप्राप्तको ईभीजानकारीऔरआपकेसाथपहचानाजासकताहैगोपनीयरहेगा।

भागीदारीकेलिएवित्तीयप्रोत्साहन

इसअध्ययनकेप्रयोजनकेलिएआपकेलिएकोईअतिरिक्तलागतनहींहोगी।

यहपूरीतरहसेशोधकेविचारसेकियाजारहाहैऔरअध्ययनकीसभीलागतजांचकर्तादवाराउठाईजाएगी।

प्रश्न / संपर्केविवरण:

आपकिसीभीस्पष्टीकरणयासहायताकेलिएअध्ययनअवधिकेदौरानकिसीभीसमयनीचेउल्लिखितनामऔरपतेसेसं पर्केकरनेकेलिएस्वतंत्रहोंगे।

डॉ _____

स्नातकोत्तरछात्र,

सामान्यसर्जरीविभाग,

जवाहरलालनेहरूमेडिकलकॉलेज ,

नेहरूनगर, केएलईअस्पतालरोड,

बेलगाम 590010

डॉ _____

प्रोफेसरऔरएचओयू,

सामान्यसर्जरीविभाग,

जवाहरलालनेहरूमेडिकलकॉलेज,

नेहरूनगर, केएलईअस्पतालरोड,

बेलगाम 590010

यदिआपकोअध्ययनप्रतिभागीकेरूपमेंअपनेअधिकारोंकेबारेमेंकोईऔरजानकारीचाहिएतोआपसंपर्ककरसकतेहैं:

डॉरूपाएमबेलाद

पेडियाट्रिक्सऔरअध्यक्षकेप्रोफेसर,

जेएनएमसीइंस्टीट्यूशनलएथिक्सकमेटी

मानवविषयअनुसंधानपर,

जवाहरलालनेहरूमेडिकलकॉलेज

नेहरूनगर, केएलईअस्पतालरोड

फोननंबर। 0831-2553777

भावीअध्ययनमेंभागीदारीकेलिएसहमति

मैं, श्रीमान / श्रीमान / श्रीमती _____

स्वेच्छासेअध्ययनकेविषयकेरूपमेंभागीदारीकेलिएसहमतहैं।इससहमतिफॉर्मेपरहस्ताक्षरकरकेमैंअपनेकिसीभीका नूनीअधिकारकोनहींछोड़रहाहूं,

मैंकिसीभीसमयअध्ययनसेवापसआसकताहूं।मैंस्थानीयभाषामेंपढ़नेयापढ़नेकेबादसहमतिफॉर्मेपरहस्ताक्षरकरर हाहूं, जिसमेंजोखिमऔरलाभशामिलहैंऔरमेरेसभीसवालोंकेजवाबदिएगएहैं।

विषयनाम : _____

हस्ताक्षरयाबाएंथंबविषयकाप्रिंट: _____ तारीख :

साक्षीकानाम: _____

हस्ताक्ष _____ तारीख :

जांचकर्ताकानाम: _____

हस्ताक्षर _____तारीख :

जगह : _____

ANNEXURE III. ETHICAL CLEARANCE.

K.L.E. ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Deemed – to- be- University)
Accredited 'A' Grade by NAAC (2nd Cycle) Placed in Category 'A' by MHRD (GoI)
JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)
Website: http//www.jnmc.edu
E-Mail : dome@jnmc.edu
Phone: (+ 91-(0)831 Office : 2472550
Principal: 2471701
Fax No. +91 (0)831 – 2470759

Ref: MDC/DOME/ 33 **Date: 24/11/2018**

To,

REG NO: BH0118001
PG student in Surgery,
J.N.Medical College,
BELAGAVI.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"ASSESSMENT OF SEVERITY OF DIABETIC FOOT ULCERS USING DIABETIC ULCER SEVERITY SCORE IN PATIENTS ADMITTED AT KLES DR. PRABHAKAR KORE HOSPITAL AND MEDICAL RESEARCH CENTRE, BELAGAVI – A ONE YEAR LONGITUDINAL STUDY",** is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

(Dr. Arathi Darshan)
Member Secretary
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

(Dr. Roopa M Bellad)
Chairman,
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

ANNEXURE IV - PROFORMA

The proposed proforma/questionnaire to be used for the data collection for the study titled , **"ASSESSMENT OF SEVERITY OF DIABETIC FOOT ULCERS USING DIABETIC ULCER SEVERITY SCORE IN PATIENTS ADMITTED AT KLES DR. PRABHAKAR KORE HOSPITAL AND MEDICAL RESEARCH CENTRE, BELAGAVI – A ONE YEAR LONGITUDINAL STUDY . "** ,is as follows :

PATIENT DETAILS:

NAME

AGE

SEX

IPD/OPD NO :

ADDRESS /CONTACT DETAILS :

DIABETIC STATUS :

H/O DIABETES SINCE	TREATMENT	DURATION

ULCER DETAIL

MODE OF ONSET

DURATION

ON EXAMINATION OFULCER:

1. NUMBER OF ULCERS
2. SITE
3. SIZE
4. SHAPE

5. EDGE
6. MARGIN
7. FLOOR
8. BASE
9. DISCHARGE
10. PERIPHERAL PULSES
11. SURROUNDING SKIN
12. SLOUGH / NECROTIC TISSUE

PERIPHERAL PULSES

ARTERY	RIGHT	LEFT
DORSALIS PEDIS ARTERY		
ANTERIOR TIBIAL ARTERY		
POSTERIOR TIBIAL ARTERY		
POPLITEAL ARTERY		
FEMORAL ARTERY		

SYSTEMIC EXAMINATION:

CARDIOVASCULAR SYSTEM

RESPIRATORY SYSTEM

CENTRAL NERVOUS SYSTEM

PER ABDOMEN

INVESTIGATIONS:

CBC: HAEMOGLOBIN, TOTAL LEUCOCYTE COUNT , PLATELET COUNT

RBS, FBS, PPBS

SERUM UREA, SERUM CREATININE

HbA1C LEVELS

X RAY FOOT : BONE INVOLVED/ NOT

LOWER LIMB DOPPLER (AS AND WHEN REQUIRED)

CALCULATION OF DIABETIC ULCER SEVERITY SCORE:

TICK THE RESPECTIVE PARAMETER

S. NO	PARAMETER		SCORE
1.	SITE OF ULCER	TOE (SCORE OF 0) / FOOT (SCORE OF 1)	
2.	NUMBER OF ULCERS	SINGLE (SCORE OF 0)/ MULTIPLE (SCORE OF 1)	
3.	PEDAL PULSES	PRESENT (SCORE OF 0) / ABSENT (SCORE OF 1)	
4.	X RAY FOOT – BONE INVOLVEMENT	NO (SCORE OF 0)/ YES (SCORE OF 1)	
	TOTAL SCORE (ADDING THE FOUR INDIVIDUAL SCORES)	-	

DIAGNOSIS: RT /LT DIABETIC FOOT ULCER WITH SCORE OF __/__

FOLLOW UP VISITS:

EARLIER IN CASE OF AMPUTATION (MAJOR/MINOR) (END POINT OF THE STUDY FOR THE RESPECTIVE PARTICIPANT)

AT 3 MONTHS

AT 6 MONTHS

Signature of investigator: _____

Signature of guide: _____

ANNEXURE V - KEY TO MASTERCHART

Sex

- M : Male
- F: Female

Duration of diabetes mellitus:

- 1 : 0-5 years
- 2 : 5-10 years
- 3 : 10-15 years
- 4: 15-20 years
- 5: >20 years

Site of ulcer (score) :

- 0 : toe
- 1 : foot

Number of ulcers (score) :

- 0 : single
- 1 : multiple

Pedal pulses (score) :

- 0 : present
- 1 : absent

X ray foot - bone involvement (score) :

- 0 : no
- -1 : yes (bone involved)

Diabetic ulcer severity score: Adding all 4 scores

Outcome:

- 0 : Healed
- 1 : Minor amputation
- 2 : Major amputation

S.NO	IN PATIENT NUMBER	AGE	SEX	DURATION OF DIABETES MELLITUS	SITE OF ULCER (SCORE)	NUMBER OF ULCERS (SCORE)	PEDAL PULSES (SCORE)	X RAY FOOT (SCORE)	DIABETIC ULCER SEVERITY SCORE	OUTCOME
1	991118	54	M	2	1	0	0	1	2	1
2	925335	51	F	1	1	1	0	0	2	1
3	955960	60	F	1	1	1	0	0	2	1
4	933375	72	M	1	0	0	0	1	1	1
5	935617	53	M	1	1	0	0	0	1	1
6	935690	62	M	1	1	0	0	1	2	2
7	928495	79	M	3	1	1	1	0	3	2
8	936648	54	M	2	1	0	0	1	2	1
9	934428	68	M	3	1	1	1	0	3	2
10	926679	75	M	1	1	0	1	0	2	3
11	928806	58	M	1	1	0	0	0	1	1
12	926410	61	M	2	1	0	0	0	1	1
13	924463	76	M	2	0	0	0	1	1	2
14	911773	58	M	2	1	0	0	1	2	1
15	941560	54	M	2	0	0	0	0	0	1
16	941050	52	M	5	1	1	1	0	3	2
17	941043	56	M	5	1	1	0	0	2	1
18	941689	60	M	1	0	0	0	0	0	1
19	938223	51	M	4	1	0	0	0	1	1
20	940313	53	M	1	1	0	0	1	2	1
21	956437	54	F	1	1	0	0	0	1	1
22	972960	38	M	4	1	1	0	1	3	2
23	956164	63	M	2	0	0	0	0	0	1
24	953927	50	F	1	1	0	0	0	1	2
25	933981	62	M	1	1	0	0	1	2	2
26	953457	58	M	2	0	0	1	1	2	2
27	952188	59	M	2	0	0	1	0	1	2
28	949523	58	M	3	1	1	0	1	3	1
29	952077	72	M	3	1	1	0	0	2	1
30	960555	53	M	2	0	0	0	0	0	1
31	959823	64	M	2	1	1	1	1	4	2
32	963691	67	M	3	1	1	0	0	2	2
33	964494	60	M	4	1	0	0	0	1	1
34	976707	51	F	2	1	0	0	0	1	1
35	971523	58	F	2	1	0	0	0	1	1
36	976043	55	F	3	1	1	1	0	3	3
37	976766	56	M	2	0	0	0	0	0	1
38	976975	77	M	3	1	0	0	1	2	1
39	969075	65	M	1	1	0	1	1	3	2
40	974516	63	M	2	1	0	0	0	1	1
41	974754	68	M	3	1	0	0	0	1	1
42	926266	38	M	1	1	1	0	0	2	1
43	924364	42	M	1	1	0	0	0	1	1
44	992464	72	F	2	1	0	0	0	1	1
45	985433	73	F	2	1	0	1	1	3	2
46	992463	59	M	1	0	0	1	1	2	2
47	992040	65	F	1	1	1	0	0	2	1
48	992205	41	F	2	1	0	1	1	3	3
49	991862	62	F	1	1	0	0	0	1	1
50	989233	48	F	5	1	0	0	1	2	3
51	925824	71	M	1	1	0	1	1	3	3
52	929525	35	M	1	0	0	0	0	0	1
53	929543	65	F	4	1	0	0	0	1	1
54	928884	59	M	2	1	0	1	1	3	2
55	920358	64	M	3	1	1	1	1	4	2
56	927383	89	M	2	1	0	0	0	1	1
57	929109	57	M	3	1	1	0	0	2	1
58	927819	48	M	3	1	0	1	0	2	1
59	926875	80	M	5	1	0	1	0	2	3

S.NO	IN PATIENT NUMBER	AGE	SEX	DURATION OF DIABETES MELLITUS	SITE OF ULCER (SCORE)	NUMBER OF ULCERS (SCORE)	PEDAL PULSES (SCORE)	X RAY FOOT (SCORE)	DIABETIC ULCER SEVERITY SCORE	OUTCOME
62	963229	68	F	3	1	1	1	0	3	3
63	965098	57	M	2	1	0	1	0	2	1
64	982975	38	M	1	0	0	0	0	0	1
65	983662	60	M	3	1	0	1	0	2	3
66	981952	55	M	2	1	0	0	0	1	1
67	983214	69	M	3	1	1	0	0	2	1
68	985382	72	M	4	1	0	1	0	2	3
69	983256	41	F	2	1	0	1	0	2	3
70	983158	78	M	3	0	1	1	0	2	2
71	981293	55	M	2	1	0	0	0	1	1
72	981726	57	M	2	1	1	0	0	2	1
73	981439	70	M	4	1	0	1	0	2	2
74	981791	68	F	3	0	1	0	1	2	2
75	982702	45	F	2	0	1	0	1	2	2
76	982953	61	M	3	1	0	0	1	2	1
77	967813	55	F	3	1	1	1	0	3	2
78	968414	71	M	5	1	0	1	0	2	3
79	965464	70	M	3	1	0	0	0	1	1
80	960633	65	M	3	1	1	0	0	2	1
81	967034	60	M	2	1	1	0	0	2	1
82	966530	45	F	2	1	0	1	0	2	2
83	963439	70	M	4	1	0	0	0	1	2
84	982044	65	F	2	0	1	0	0	1	1
85	968767	61	M	1	0	0	0	0	0	1
86	967318	65	F	2	1	0	0	0	1	1
87	968750	44	M	2	1	1	0	0	2	1
88	969025	57	F	3	1	0	0	0	1	1
89	969375	56	M	3	1	0	1	1	3	2
90	970010	35	F	1	1	1	0	0	2	1
91	970014	45	M	2	0	1	1	0	2	2
92	969511	56	M	2	1	0	0	0	1	1
93	971599	61	M	3	0	0	0	0	0	1