Prediction of amputation in diabetic foot ulcers

using SVS WIfI scoring system

A dissertation submitted in partial fulfilment of M.S General Surgery Branch I Examination of the Tamil Nadu Dr. M.G.R University, Chennai to be held in 2020

CERTIFICATE

This is to certify that the dissertation titled “Prediction of amputation in diabetic foot ulcers using SVS-WIfI scoring system” is a bonafide work of Dr. Ashwin Prem Solomon.P, carried out under our guidance towards partial fulfilment of M.S General Surgery Branch I Examination of the Tamil Nadu Dr. M.G.R University, Chennai to be held in 2020.

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ABSTRACT

Background:

Foot ulcers and their complications are an important cause of morbidity and mortality in patients with Diabetes. About 80% of patients undergoing non-traumatic lower limb amputations have Diabetes. In patients with diabetes, limb threat is part of a broad disease spectrum. Perfusion is only one determinant of outcome. Wound extent, infection also greatly impact the threat to a limb. WIfi scoring system has been validated in diabetic foot ulcers in the West.

Aim:

To predict the risk of amputation in diabetic foot ulcers using WIfI scoring system.

Objectives:

- To study the predictive role of WIfI staging system in diabetic foot ulcers undergoing amputation.
- To study the association between individual components of WIfI staging system and outcome of diabetic foot ulcers
- To study the association between glycemic control and outcome of diabetic foot ulcers.

Materials and Method:

The subjects were patients with diabetic foot ulcers presenting to General surgery, Vascular Surgery or Diabetic foot clinic in Christian Medical College, Vellore. WIfI

scoring of the diabetic ulcer was done after obtaining informed consent from the patient at the time of presentation. Patients were followed up at 6 months and outcome was noted.

Results:

A total of 163 patients were recruited in this study. 60 belonged to group 1 comprising of WIfI stages 1-3 and 103 belonged to group 2 comprising of WIfI stage 4. Among the 163 patients, 113(69.3%) patients underwent amputations (minor and major). 50(30.7%) of them had major amputations (level proximal to the ankle).
In patients with WIfI stage 4, 90.9% [93/103] underwent amputations within six months of recruitment. 45.6% of them underwent major amputation. Major amputation in group 1 patients [WIfI stages 1-3] was 5%.
70% who underwent major amputations had HbA1C values of > 6.4 mmol/L..

Conclusions:

WIfI scoring system was predictive of major amputations in patients with diabetic foot ulcers within six months of recruitment. Poor glycaemic control was associated with worse outcome.

INTRODUCTION

Diabetes mellitus is rapidly gaining the status of an epidemic in India with about 65 million people diagnosed with the disease. Complications related to the disease are deterrent to the quality of life.

Foot ulcers and their complications are an important cause of morbidity and mortality in patients with Diabetes. About 50% of patients undergoing non-traumatic lower limb amputations have Diabetes. Diabetic foot ulcers lead to loss of mobility affecting patients ability to perform simple, everyday tasks and to participate in leisure activities. These patients have a high mortality following amputation, ranging from 39% to 80% at 5 years.

Due to demographic shifts over the last 40 years, especially a dramatic rise in the incidence of diabetes mellitus and rapidly expanding techniques of revascularization, it has become increasingly difficult to perform meaningful outcomes analysis for patients with threatened limbs using the existing classification systems. Critical limb ischemia was used to delineate a subgroup of patients with a threatened lower extremity needing amputation primarily because of chronic ischemia. Older wound classification systems like Fontaine and Rutherford Systems have been used to classify risk of amputation and likelihood of benefit from revascularization by subcategorizing patients into two groups:

ischemic rest pain and tissue loss. Perfusion is only one determinant of outcome; wound extent and the presence and severity of infection also greatly impact the threat to a limb.

Therefore, the Society for Vascular Surgery Lower Extremity Guidelines Committee undertook the task of creating a new classification of the threatened lower extremity that reflects these important considerations and termed this new framework, the Society for Vascular Surgery Lower Extremity Threatened Limb Classification System. Risk stratification is based on three major factors that impact amputation risk and clinical management: Wound, Ischemia, and foot Infection (WIfI). The implementation of this classification system is intended to permit more meaningful analysis of outcomes for various forms of therapy in this challenging, but heterogeneous population.

The SVS WIfI classification system is a first step towards re-examining the evaluation and treatment of patients with a spectrum of lower extremity ulcer. It is intended to be an interactive process with the goal of more precisely stratifying patients according to their initial disease burden.

AIM

To predict the risk of amputation in patients with diabetic foot ulcers using SVS WIfI scoring system

OBJECTIVES

Primary objective

- To study the role of SVS WIfI scoring system in predicting amputations in patients with diabetic foot ulcers.

Secondary objectives

- To study the association between individual components of WIfI staging system and outcome of diabetic foot ulcers

- To study the association between glycaemic control and outcome of diabetic foot ulcers.

LITERATURE REVIEW

Introduction to diabetes mellitus dates back to 1500BC when it was mentioned as ‘too great emptying of the urine’. It was later described by Indian physicians as honey urine as they noticed ants attracted to patient’s urine. The term ‘Diabetes’ has its origin from the Greek meaning ‘to pass through’ and was first used in 250BC. Diabetes as a disease was mentioned in various ancient literature across the world. Although diabetes have been described since antiquity, the disease and its pathogenesis was understood only in 1900s leading to discovery of insulin and its relation to pathogenesis of diabetes mellitus by Charles Best and Frederick Banting in 1920.

Figure 1: Charles H.Bent and Frederick Banting in 1924

Incidence of diabetes mellitus has increased over the last four decades. Lack of exercise, change of dietary habits and abundance of food has been attributed as the cause. India topped the world in 2000 with the highest number of diabetics [31.7 million]. China [20.8 million] and United States of America [17.7 million] followed at second and third place respectively.(1) Diabetes mellitus is predicted to double from 2000 to 2030 with a maximum increase in India, according to Wild et al.(2)

Diabetes mellitus is characterised by hyperglycaemia caused due to the defects in insulin secretion, action or both. Type1 diabetes indicates diabetes mellitus as a result of defect in insulin secretion while type2 diabetes mellitus is characterised by insulin resistance and relative insulin deficiency.

Pathophysiology of Diabetes related complications

Micro vessels comprises of arterioles, capillaries and venules and form the basic functional unit of cardiovascular system. Micro vessels are responsible for maintaining blood pressure and nutrient delivery while macro vessels supply blood to the organs.(3) Microcirculation plays a vital role in controlling vascular permeability and myogenic responses responsible for change in blood flow depending on local metabolic needs.

Alteration in micro vascular function in diabetics may arise even before overt hyperglycaemia.(3) Diabetes mellitus increases the thickness of capillary basement membrane in arterioles [retina, myocardium, skin, glomeruli] leading to diabetic micro angiopathy. This thickening eventually leads to hypertension, tissue hypoxia and delayed wound healing. Micro angiopathy leading to neovascularisation in vasovasorum plays an important role in macro vascular atherosclerosis.

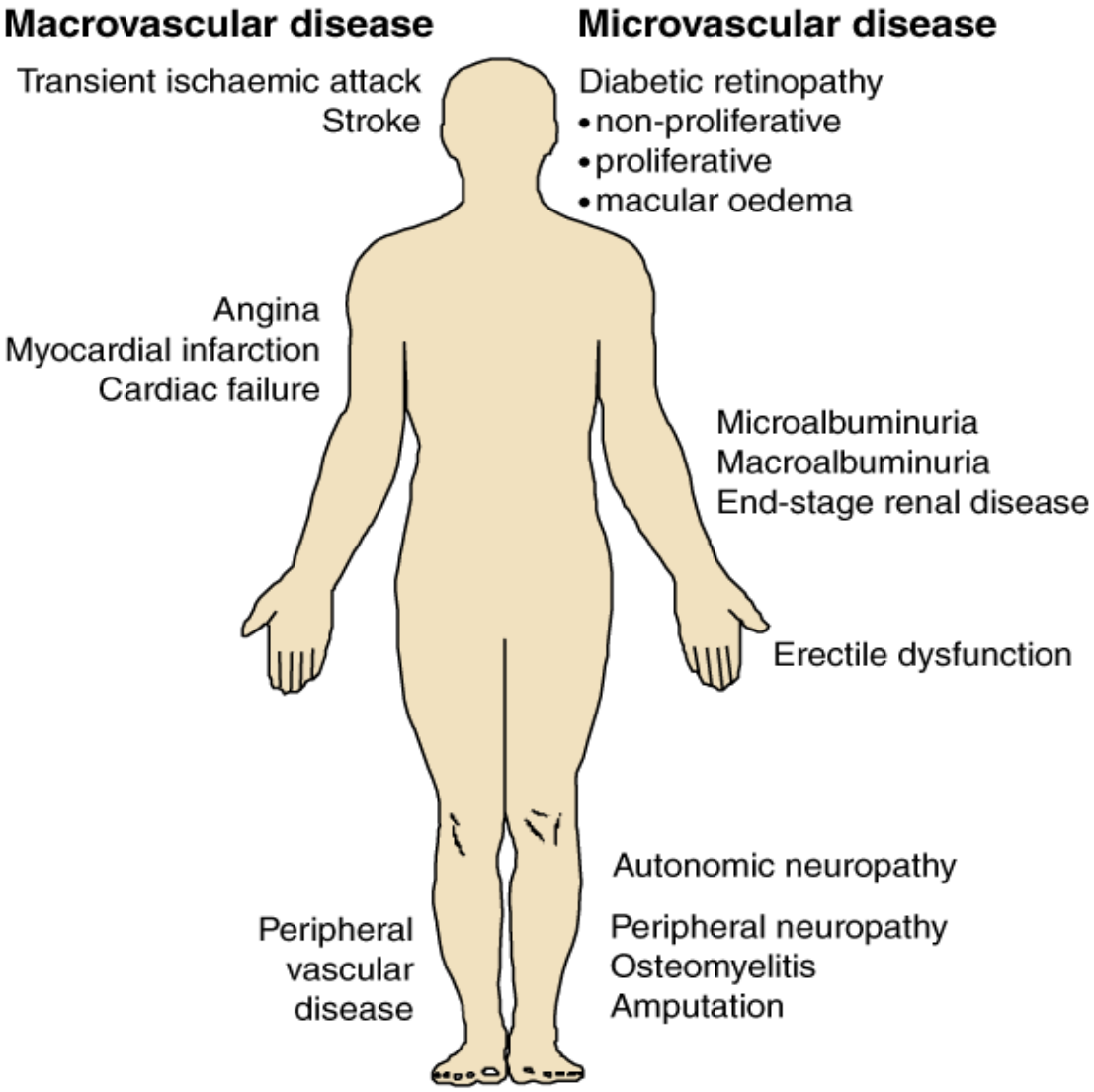


Figure 2: Common micro and macro vascular complications of diabetes mellitus affecting quality of life

Diabetic foot ulcers

Approximately 15% of diabetics develop foot ulcers and ulcers are a leading cause of hospital admission in these patients. Lower limb ulcers and complications are an important cause of morbidity in patients with Diabetes. About 50% of patients undergoing nontraumatic amputations have Diabetes,(4) 85% of lower limb amputations in diabetics are preceded by ulceration. Thus prevention and timely management of foot ulcers are of paramount importance.

Peripheral vascular disease is another important cause of ulceration and delayed wound healing. Callus formation, oedema and deformity also contribute. Two thirds of the patients with diabetic foot ulcers have the triad of deformity, trauma and neuropathy. Ischemia, oedema and callus formation are the other factors causing ulceration. Infection is rarely implicated in the aetiology of foot ulcers(5). However the foot ulcers are susceptible to infection once ulceration occurs.

Diabetic Neuropathy

Neuropathy caused by diabetes mellitus leads to both autonomic and peripheral dysfunction, affecting almost 50% of the diabetic population. Duration and magnitude of hyperglycaemia is directly related to the development of diabetic neuropathy. (3) Prevalence of diabetic neuropathy in India is as high as 29.2% in the north Indian

population. (3) Mechanisms of enhanced oxidative stress, injury from activated glycation products and hyperglycaemia induced polyol pathway were implicated in the pathogenesis of mechanism of injury to peripheral nerves due to hyperglycaemia. The incidence of cardiac events and peripheral vascular disease is higher in diabetic patients with neuropathy than those without neuropathy. (6)

Autonomic neuropathy results in dry skin and warm feet. Peripheral neuropathy leads to loss of pain sensation which is an important protective mechanism preventing trauma.

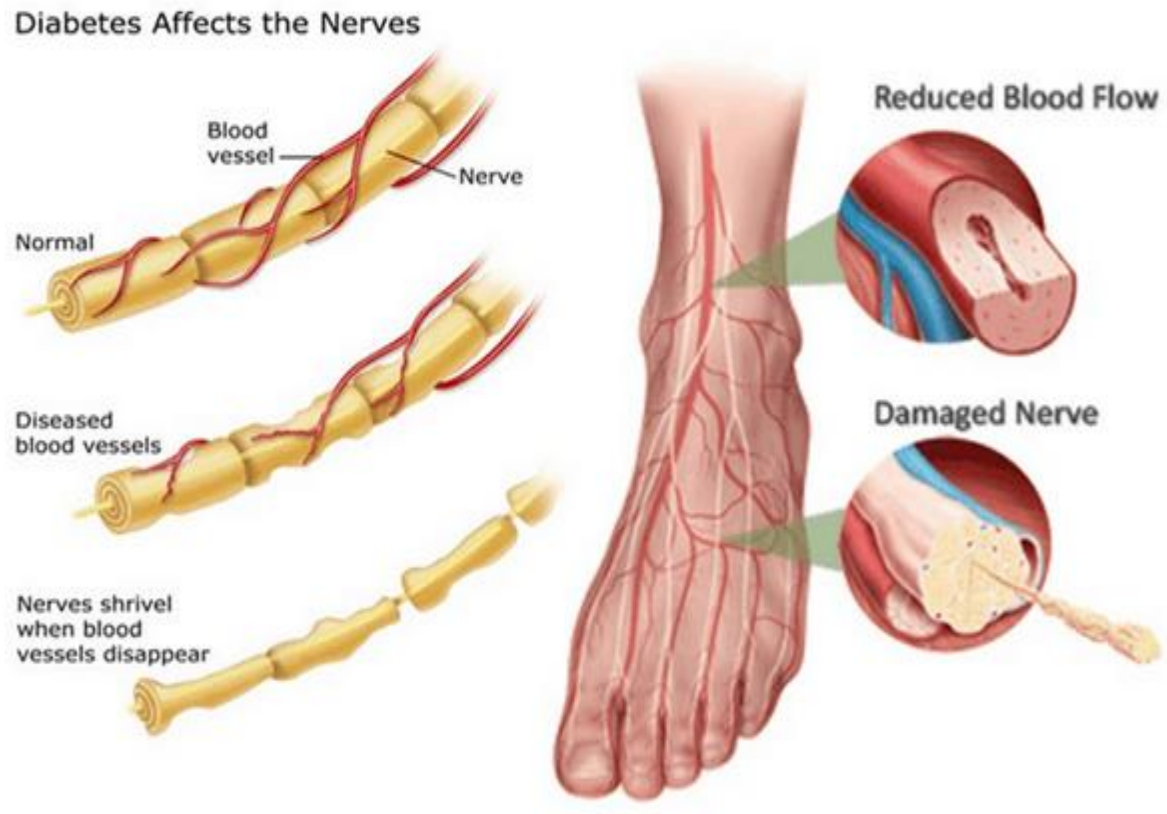


Figure 3: Mechanism of neuropathy in diabetes due to reduced blood flow

Trauma

Repeated micro trauma in patients with insensate foot due to diabetic neuropathy is considered a risk factor for ulcer development. Diabetic patients with neuropathy have higher plantar pressures due to the deformity associated with the same. Stress fractures usually have atypical presentation in diabetics with neuropathy, typical features such as pain is usually not evident. Patients present with foot oedema which leads to decreased incidence of detection of fractures.(7) Such micro trauma with associated pathological bone remodelling seen in diabetic patients result in deformities which acts as a risk factor for diabetic foot ulcers.

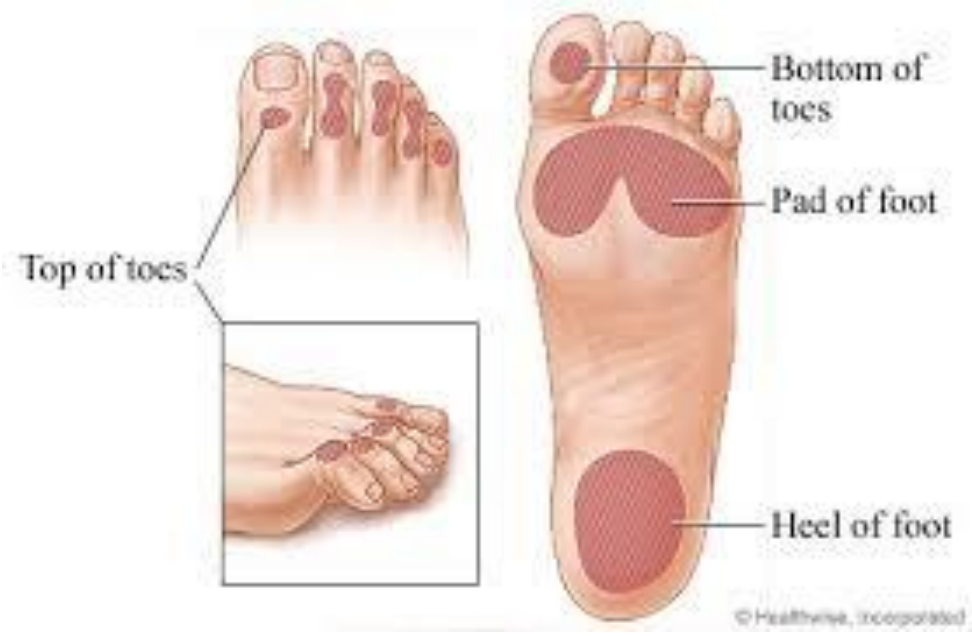


Figure 4: Areas of the foot more prone to diabetic foot ulcers due to increased pressure

Deformity

Deformity is part of the triad responsible for development of diabetic foot ulcers. Motor neuropathy causing intrinsic foot muscle atrophy and in turn causing muscle imbalance is commonly believed to be the cause of diabetic foot deformities. Acroosteolysis denotes gradual progressive resorption of the distal phalanges in the feet. Exact pathogenesis is uncertain, however severe sensory neuropathy and micro vascular ischemia were attributed to be the cause in diabetics.(7)

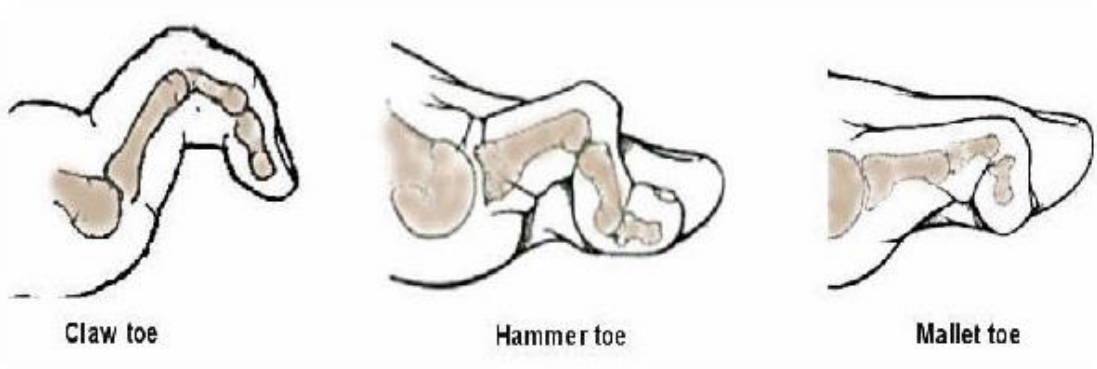


Figure 5: Deformities of toe in diabetes mellitus

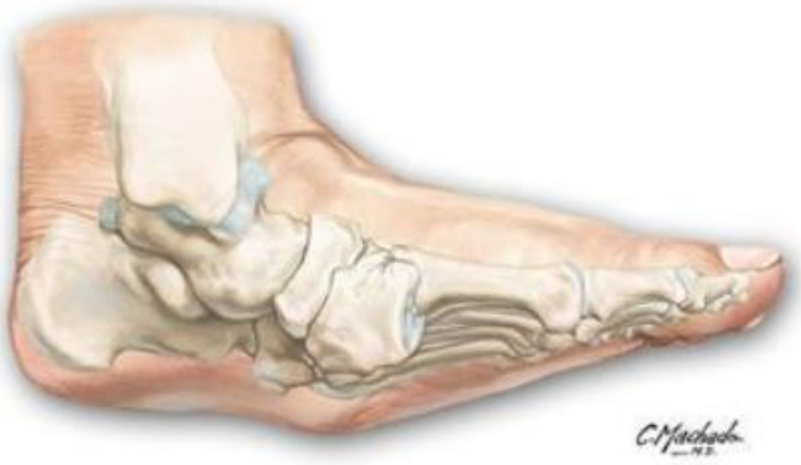


Figure 6: Charcotts arthropathy

Management of diabetic foot ulcers:

Ulcer management includes infection control, healing measures and identification of the cause and eradicating them.

Evaluation:

Ulcer evaluation is critical and should be aimed at directing management. Size, depth, location and appearance of the ulcer is important in evaluation and helps in mapping the progress of the treatment.(5) Deep abscesses, critical ischemia, presence of osteomyelitis and cellulitis extending 2cm radially from the ulcer margins are indicators of limb threatening infections.

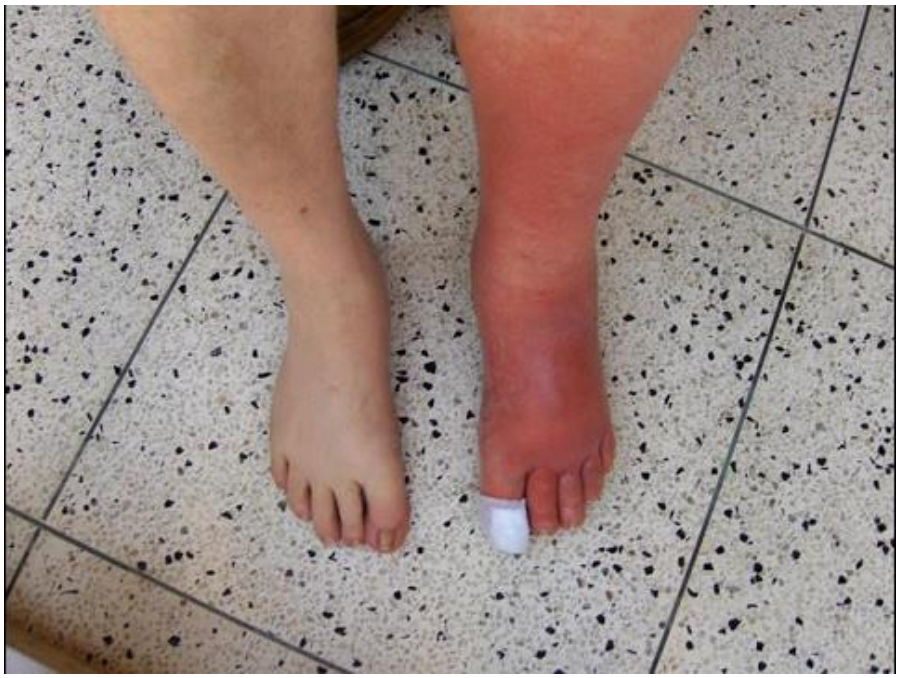


Figure 7: Cellulitis associated with diabetic foot ulcer indicative of on-going infection

Culture swabs from the ulcer, if infected and radiographic evaluation of the limb by x-ray, in deep ulcers is critical in planning the management. Almost all ulcers are contaminated in view of their chronic nature. Hence pus culture swabs from non-infected wounds is usually not recommended.(5)

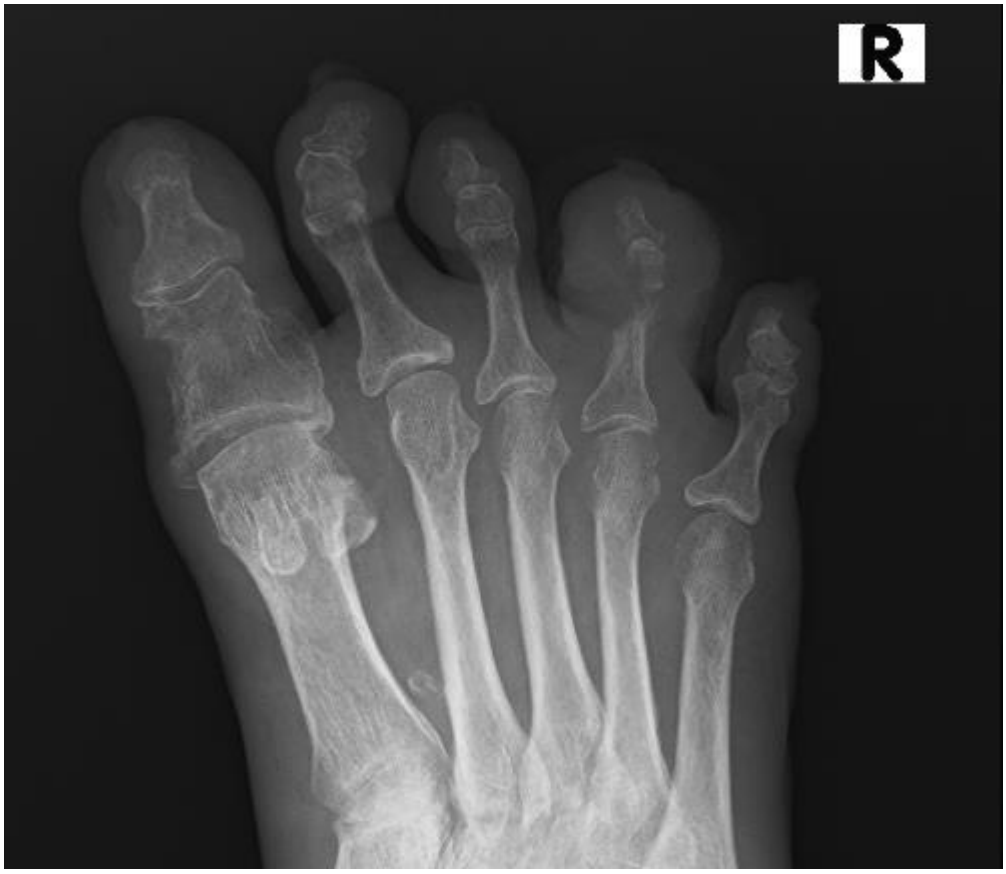


Figure 8: Osteomyelitis of fourth toe phalanges, need for amputation for wound healing

Vascular status of the limb is indicative of the prognosis of the foot ulcer. Poor vascularity affects by decreased wound healing and progression of infection. Presence of popliteal and both pedal pulses is a reliable clinical indicator of the arterial perfusion of the foot. If pulses are absent, non-invasive Doppler studies can be used to

augment the evaluation of the vascularity of the limb. In cases with significant suspicion of ischemia, vascular surgeon opinion and intervention may be of benefit.(5)

Logical approach to the treatment of the diabetic foot ulcers is facilitated by classification of ulceration. Several wound grading systems have been created and were used. Wagner ulcer classification system is the most widely accepted wound classification system. Wagner classification system is based on the depth of ulceration.

Wagner Ulcer Classification System

Grade	*Lesion*
0	No open lesions; may have deformity or cellulitis
1	Superficial diabetic ulcer (partial or full thickness)
2	Ulcer extension to ligament, tendon, joint capsule, or deep fascia without abscess or osteomyelitis
3	Deep ulcer with abscess, osteomyelitis, or joint sepsis
4	Gangrene localized to portion of forefoot or heel
5	Extensive gangrenous involvement of the entire foot

Figure 9: Wagners ulcer classification system

Assessment of vascularity of lower limb:

As discussed previously, presence of ischemia in combination with diabetic foot ulcer alters the outcome drastically. Hence assessment of vascularity in the affected limb is essential in evaluating and investigating diabetic foot ulcer. Various

methods of assessment of vascularity have been introduced: plethysmography, Doppler studies and contrast angiogram. Clinical evaluation along with blood pressure studies has made assessment of vascularity of a limb easier. Few of the blood pressure studies used to quantify ischemia is described below:

- **Ankle brachial Pressure Index**:

Ankle brachial pressure index, abbreviated as ABPI, was described as early as 1950's by Winsor. Blood pressure is measured in all four limbs. ABPI for a particular lower limb is calculated by ankle pressure of the limb by the higher of two brachial systolic blood pressures. Normal ABPI value is between 0.9 and 1.3.(8) ABPI is a primary clinical diagnostic test for peripheral arterial disease. ABPI has high specificity and sensitivity, however such high accuracy cannot be achieved in elderly patients.(8) Elderly patients, patients with renal disease or diabetes have arteries which are calcified and are poorly compressible. This leads to poor sensitivity in such cases.

In symptomatic cases, a single ABPI measurement may not be diagnostic. In that setting, the patient is asked to perform moderate physical exercise and ABPI is measured immediately after the same. Decrease in post exercise ABPI value indicates severe form of peripheral arterial disease. Limitations of ABPI measurement are location of arterial occlusion or stenosis is difficult to predict.

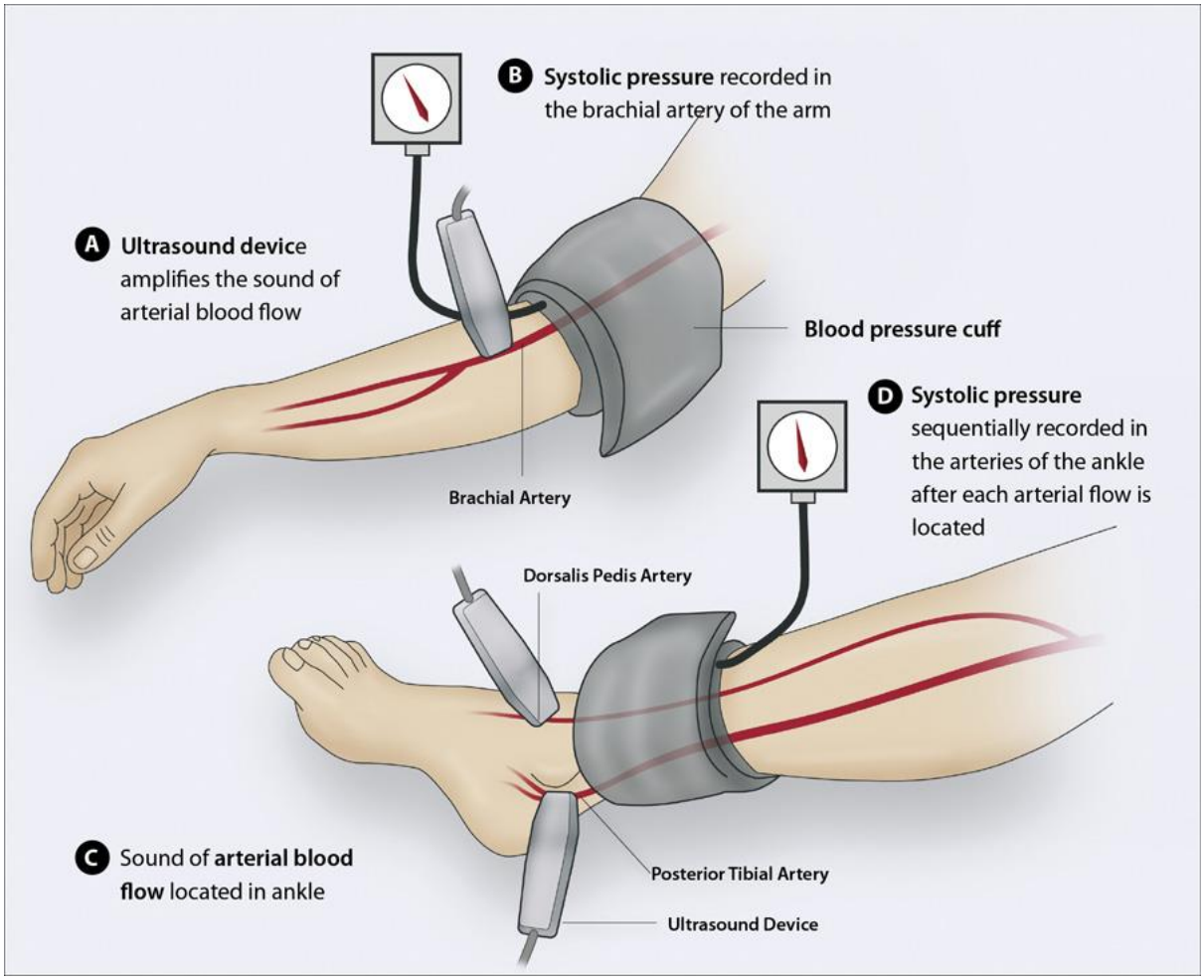


Figure 10: Pictorial depiction of calculating ankle brachial pressure index

- **Toe pressure:**

Toe pressure is usually used as an adjunct to ABPI while screening for peripheral arterial disease. It is beneficial in measuring vascularity in patients with medial arterial calcification.(9) Resting systolic toe pressure is a useful measure of small arterial function in the periphery and is considered a good predictor of wound healing.

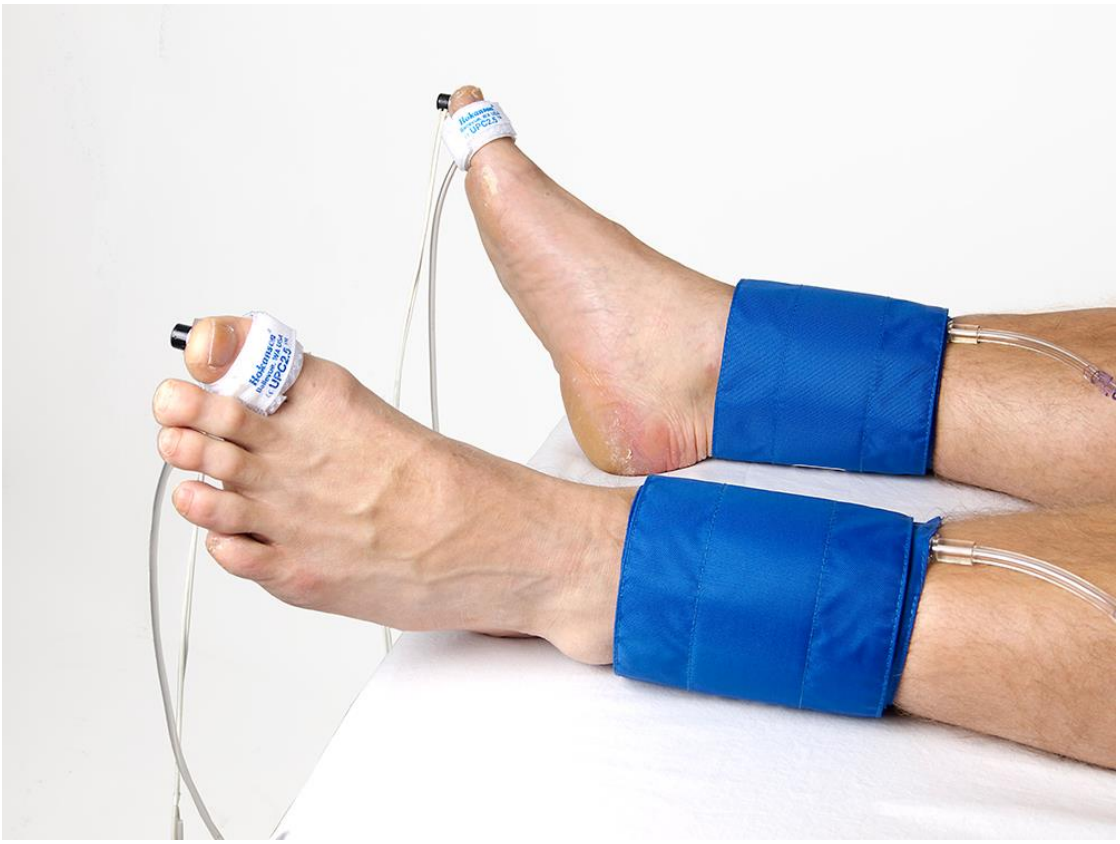


Figure 11: Toe pressure used as a adjunct to ABPI in diabetics

Toe systolic pressure is divided by the brachial pressure to calculate the toe brachial index [TBI].(8) TBI is considered superior to ABPI in patients with medial arterial classification, where usually ABPI is abnormally high [ABPI > 1.3].Toe brachial index of 0.7 is considered normal.(10) TBI is considered to be highly sensitive [90-100%] than specific [65-100%].(10) Measurement of TBI is considered technically more difficult and may require Doppler flow meter and plethysmography. This can limit its use in some clinical setting.

- **Transcutaneous oxygen pressure [TcPO2]:**

Transcutaneous oxymetry is used for assessment of cutaneous ischemia in lower limbs and thus assess advanced stage of arteriopathy. It is considered as a good predictor of wound healing when pressure > 30mmHg. Healing process maybe hindered and may have an unfavourable course if pressure <10mmHg.

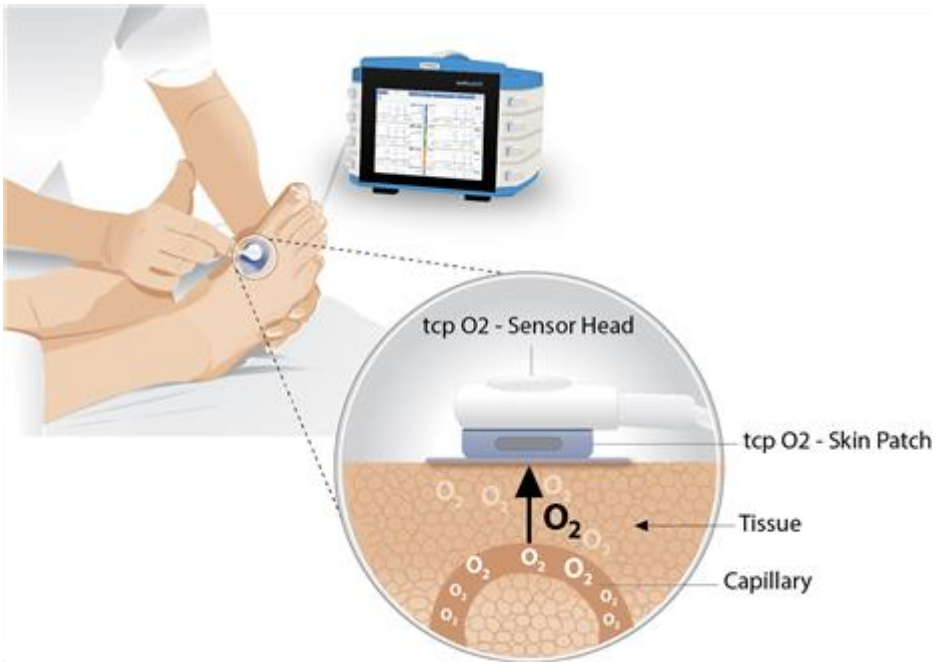


Figure 12: TcPO2 measurement used for assessing cutaneous ischemia

It is also useful in determining level of amputations if planned for an ischemic limb and in improvement of vascularity of a limb after a revascularisation procedure.

Treatment:

- Obtaining wound closure is the primary goal in treatment of diabetic foot ulcers. Severity of the ulcer, presence of infection and vascularity of the limb determines the management of the ulcer. In patients with numerous comorbidities, a multidisciplinary approach is needed for effective management.

- Relieving pressure over ulcerated areas by avoiding ill-fitting footwear, using offloading footwear play an important role in the management of diabetic foot ulcers. Wheelchairs and crutches can be used in providing total offloading if indicated. Total contact casting is considered the optimal method of offloading for neuropathic ulcers, however considerable experience and weekly change of casting and inspection of ulcer is indicated in optimal use of the total contact casting.

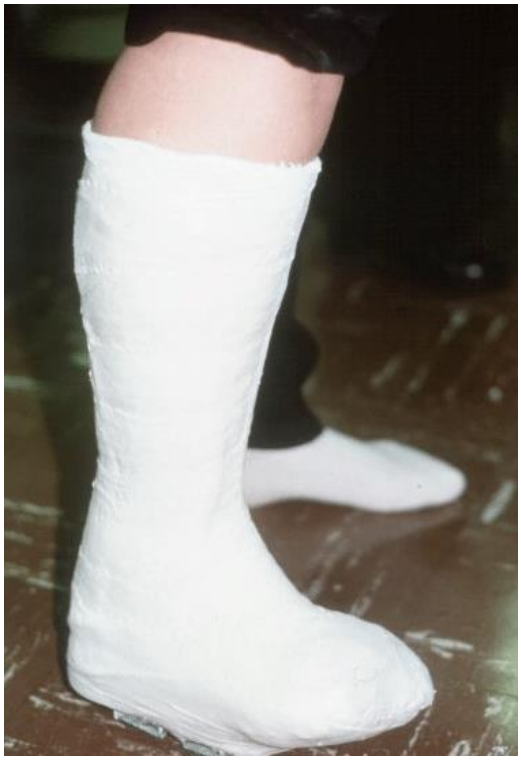


Figure 13: Total contact casting

- Another modality involved in the treatment of diabetic foot ulcers is debridement. Frequent interval debridement of all callus, fibrotic tissue and necrosis forms mainstay of prevention and control of infection in diabetic foot ulcers. Debriding unhealthy tissue with sharp dissection till visualizing adequate healthy bleeding helps in visualization of deep abscesses or sinuses and to quantify the accurate extent of the ulcer.

- Dressings play a role in ulcer care by constantly removing slough and necrotic tissue from the ulcer. Numerous topical ointments and gels were promoted for ulcer care. However, no topical medications proved to be more efficacious than

saline wet to dry dressings. Moist, warm environment protected from external contamination is the principle of dressing the diabetic foot ulcers.

- Wound cover is under studies. Topical genetically engineered gels or ointments for promotion of granulation such as platelet derived growth factor have little evidence for use in neuropathic ulcers. (5) Skin grafting, bioengineered skin is new mode of skin cover which act by providing growth factors. Human dermis stimulates granulation by providing extra cellular matrix components through the dermal elements which contain active human fibroblasts.

- Regardless of other treatment methods, ischemia, if present should be addressed for achieving a successful outcome. Ischemia should be evaluated for when despite adequate management, ulcer does not show progressive healing. Vascular surgeon intervention if needed, is to be sought for adequate wound healing.

- Antibiotics are used if there are signs of wound infection. Antibiotic coverage is tailored based on the culture sensitivity of the microorganism and clinical response. Surgical debridement, drainage and foot amputations are adjuncts to antibiotic coverage in infected diabetic foot ulcers. Hospitalization and prompt surgical drainage is indicated in patients with deep infection with gangrene, cellulitis, abscess or osteomyelitis.

Prevention:

Prevention is better than cure. Prevention of diabetic foot ulcers by adequate use of a multidisciplinary team committed to limb salvage is of higher beneficial value. Involvement of a diabetologist, podiatrist, physical therapist in patient education and frequent follow up plays a major role in prevention of diabetic foot ulcers. Improved rates of wound healing and reduction in number of lower limb amputation have been reported in centres with instituted teams for this purpose.

- Instruction on proper footwear, daily inspection, foot hygiene and necessity of prompt treatment of new lesions are part of the patient education.

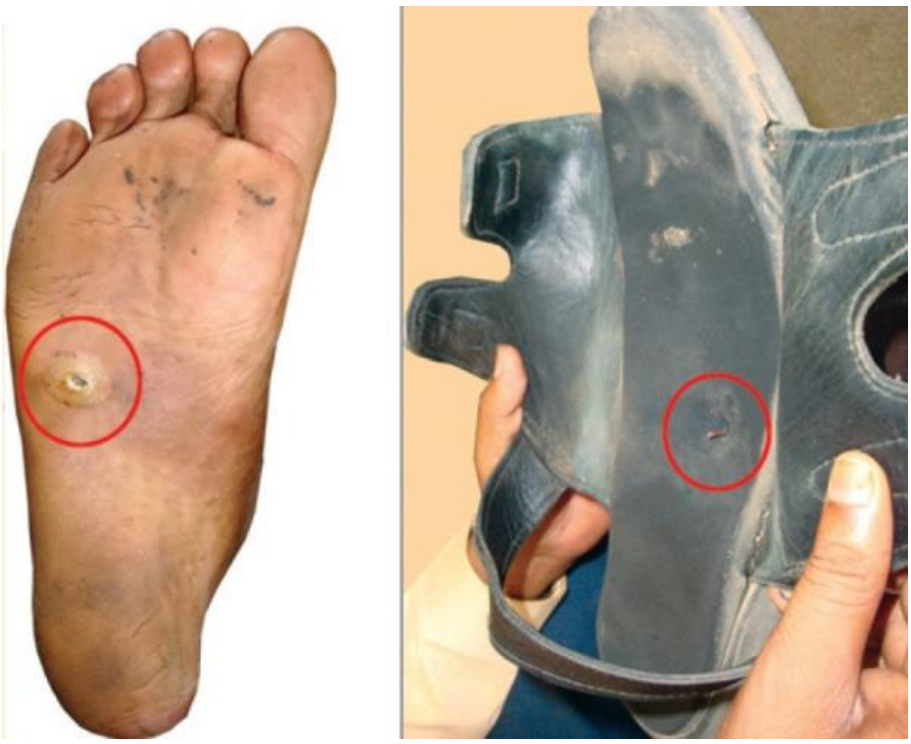


Figure 14: Improper footwear causing trauma to the foot

- Regular foot care examinations and frequent debridement of calluses and ingrown toe nails play a role in providing opportunity to reinforce self are behaviors and help in detecting new lesions and impending foot problems.

- Therapeutic footwear in patients with deformities to prevent ulceration can be issued based on pressure mapping and appropriate designing. Elective procedures as in Achilles tendon lengthening, hammertoe repair and metatarsal osteotomies can be performed to prevent ulceration. Such procedures can be successfully performed in patients with neuropathic limb under local anesthesia.

- In ischemic limb with deformities, working in unison with a vascular surgeon and planning reconstructive procedures after establishing vascularity by revascularization procedures is associated with higher success rates.(5)

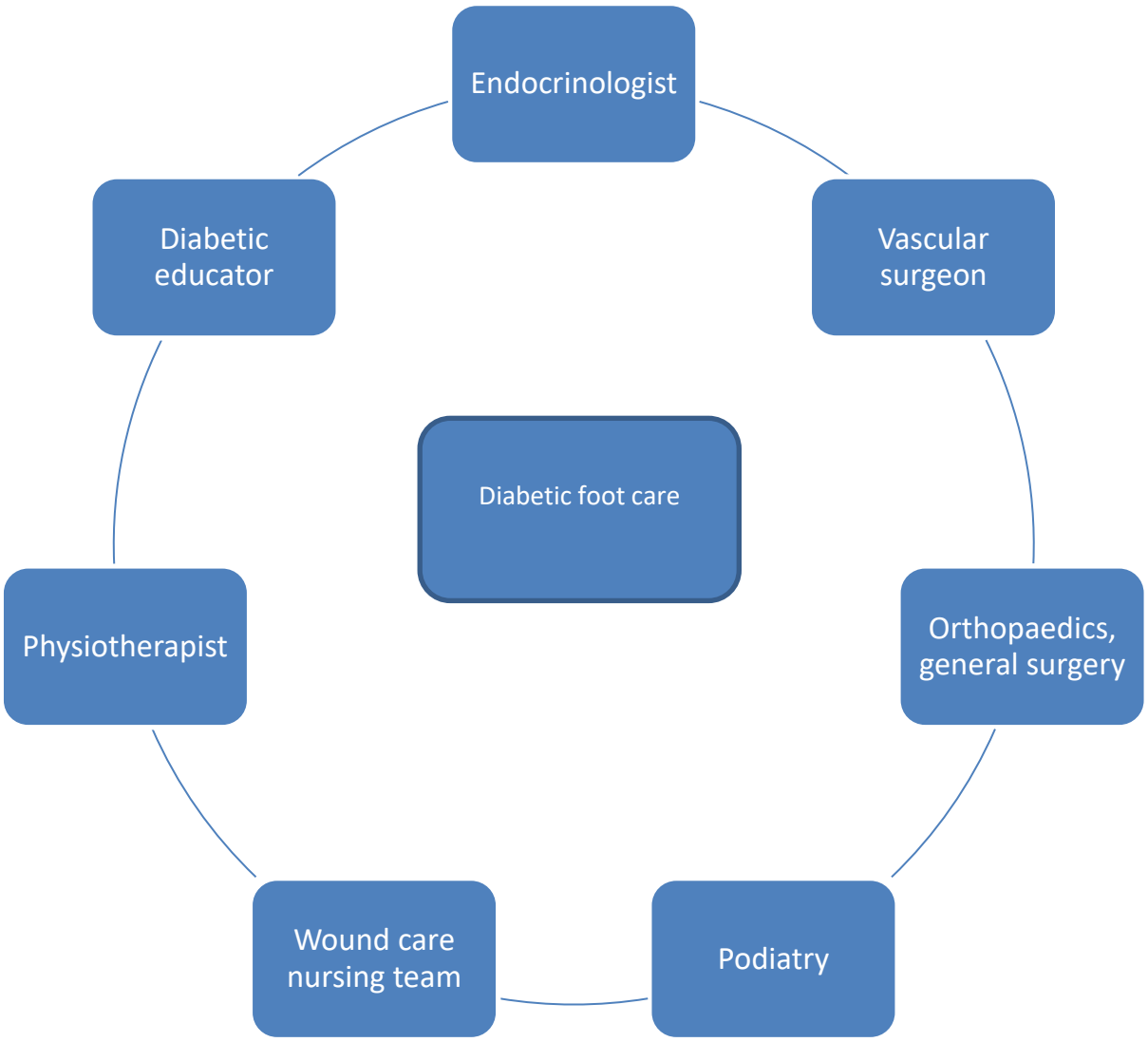


Figure 15: Multidisciplinary team in diabetic foot care

Diabetic foot ulcers – Scoring systems:

Various scoring systems have been used in classification of diabetic foot ulcers. As mentioned above, Wagners system is one of the simplest and hence commonest scoring system used in grading the severity of diabetic foot ulcers. Few of the established scoring systems are discussed here along with named scoring systems used to categorise vascularity of a limb:

Wagners classification:

Wagners system of wound classification was first proposed by Meggitt [1976] and was popularized by Wagner. It is a linear grading system and is simple for clinical application. Hence it gained popularity. It included features such as wound location, depth and presence of gangrene. Presence of neuropathy, infection and ischemia in diabetic foot ulcers were not weighted in this classification.(11) Ischemia is included only in the final two grades and there was no classification of severity of ischemia.

University of Texas [UT] scoring system:

This system included grading of Ischemia and infection with each level of ulcer depth, thus producing 16 square matrix. However wound size was not accounted for in the scoring. In comparison with the Wagner score, University of Texas scoring is found superior in predicting wound healing time rather predicting amputations.(12)

However, this scoring system does not comprehend on peripheral vascular disease. The severity of ischemia is not included, though the presence or absence included.

University of Texas Diabetic Wound Classification System				
Stage	**Grade**			
	0	**I**	**II**	**III**
A (no infection or ischemia)	Pre- or post-ulcerative lesion completely epithelialized	Superficial wound not involving tendon, capsule, or bone	Wound penetrating to tendon or capsule	Wound penetrating to bone or joint
B	Infection	Infection	Infection	Infection
C	Ischemia	Ischemia	Ischemia	Ischemia
D	Infection and ischemia	Infection and ischemia	Infection and ischemia	Infection and ischemia

Figure 16: University of Texas Diabetic wound classification system

S[AD]SAD score:

S[AD]SAD scoring system was derived by Macfarlane and Jeffcoate in 1999 by modifying an earlier scoring system. This system includes extent of the ulcer [area, depth], arteriopathy, sepsis and denervation.

Simplified version of this scoring system is called SINBAD modification of the S[AD]SAD system and is considered one of the most validated scoring system.

THE S(AD) SAD CLASSIFICATION SYSTEM					
Grade	Area	Depth	Sepsis	Arteriopathy	Denervation
0	Skin intact	Skin intact	No infection	Pedal pulses palpable	Pinprick sensation/ VPT normal
1	<10mm^2	Skin and subcutaneous tissues	Superficial: slough or exudate	Diminution of both pulses or absence of one	Reduced or absent pinprick sensation VPT raised
2	10–30mm^2	Tendon, joint capsule, perisoteum	Cellulitis	Absence of both pedal pulses	Neuropathy dominant: palpable pedal pulses
3	>30mm^2	Bone and/or joint spaces	Osteomyelitis	Gangrene	Charcot foot

Figure 17: S[AD]SAD classification system

PEDIS scoring system:

PEDIS scoring system is based on the same variables as S[AD]SAD scoring system and was developed by the International Working Group on Diabetic Foot [IWGDF] in 2004. PEDIS stands for Perfusion, Extent, Depth, Infection and Sensation. Thus it includes area of the ulcer, presence of infection, neuropathy and presence or absence of wound ischemia. However, this scoring system does not categorise ischemic rest pain or gangrene and severity of infection.

Grade	Perfusion	Extent	Depth	Infection	Sensation	Score
1	No PAD	Skin intact	Skin intact	None	No loss	0
2	PAD, No CLI	<1 cm^2	Superficial	Surface	Loss	1
3	CLI	1–3 cm^2	Fascia, muscle, tendon	Abscess, fasciitis, septic arthritis		2
4		>3 cm^2	Bone or joint	SIRS		3

PAD, peripheral arterial disease; CLI, critical limb ischemia.

Figure 18: PEDIS scoring system

Diabetic ulcer severity score:

Diabetic ulcer severity score was formed in 2006 and includes four clinical parameters. Location of the ulcer, presence of multiple ulceration, presence of pulses and probing to bone were includes as dichotomous variables. Thought he score includes ulcer location as a part of the scoring system, there was no grading of presence or absence of ischemia.

DUSS scoring system

Variables	Score 0	Score 1
Palpable Pedal pulses	Presence	Absence
Probing to bone	No	Yes
Ulcer site	Toes	Foot
Ulcer number	Single	Multiple

Figure 19: Diabetic ulcer severity scoring system

Local pathology of the individual ulcers are the main focus of the majority of the scoring system mentioned above. Presence of multiple ulcers in different locations on a diabetic foot is not accounted for. In few of the scoring systems, presence of ischemia and infection was included, However, grading of ischemia and severity of the infection were not explored.(11) There is a need for a score which will be able to predict the long term outcome by clinical assessment alone without the need for investigative equipment.(11)

Fontaine classification system:

Fontaine classification system was introduced by the European society of cardiovascular surgery in 1954. Fontaine classification system was used to grade the vascularity of limbs based on clinical symptoms such as claudication, presence of gangrene or rest pain. It was used mainly for categorising patients for research purpose and was not used for planning further management in patient care.

Grade	Symptoms
Stage I	Asymptomatic, incomplete blood vessel obstruction
Stage II	Mild claudication pain in limb
Stage IIA	Claudication at a distance > 200 m
Stage IIB	Claudication at a distance < 200 m
Stage III	Rest pain, mostly in the feet
Stage IV	Necrosis and/or gangrene of the limb

Figure 20: Fontaine classification system for ischemic limb

Rutherford classification system:

Rutherford classification of peripheral vascular disease was adapted in 1986 and was revised in 1997 by Rutherford. Rutherford delineates ischaemic limb into acute and chronic based on clinical symptoms, Doppler studies, pulse volume recordings and Ankle brachial indices [ABPI]. Thus, with addition of objective non-invasive data, Rutherford classification system is similar to Fontaine's classification.

Rutherford's classification system classifies ischemic limb into viable, threatened and nonviable limb.

Grade	Category	Clinical description	Objective criteria
0	0	Asymptomatic-no hemodynamically significant occlusive disease	Normal treadmill or reactive hyperemia test
	1	Mild claudication	Completes treadmill exercise; AP after exercise > 50 mmHg but at least 20 mmHg lower than resting value
I	2	Moderate claudication	Between categories 1 and 3
	3	Severe claudication	Cannot complete standard treadmill exercise, and AP after exercise < 50 mm Hg
II	4	Ischemic rest pain	Resting AP < 40 mmHg, flat or barely pulsatile ankle or metatarsal PVR; TP < 30 mm Hg
III	5	Minor tissue loss non-healing ulcer, focal gangrene with diffuse pedal ischemia	Resting AP < 60 mm Hg, ankle or metatarsal PVR flat or barely pulsatile; TP < 40 mm Hg
	6	Major tissue loss-extending above TM level, functional foot no longer salvageable	Same as category 5

AP: ankle pressure; PVR: pulse volume recording; TM: transmetatarsal; TP: toe pressure.

Figure 21: Rutherfords classification of limb ischemia

Problems in devising systems of classification:(13)

- Development of foot ulcers and failure to heal of different foot ulcers has multifactorial reasons.
- There may be presence of multiple ulcers or different lesions in the same foot. In such cases, outcome of one ulcer may be dependent upon the outcome of another.
- There is difficulty in predicting which of the different etiological factors played a predominant role in a particular patient with foot ulcer.
- Difficulty in reproducing the presence, extent or severity of the different factors such as neuropathy, infection or Ischemia.

- People’s practices change over time and there may be recurrent ulceration or faster healing based on the change in lifestyle.

Need for newer comprehensive scoring system:

There were multiple scoring systems described to categorise diabetic foot ulcers and thus predict outcomes. However the pathogenesis of diabetic foot ulcers are complex and thus a scoring system which addresses all components of the pathogenesis was not available. Ischemia, infection and characteristics of the ulcer are the three factors responsible for the progression of the foot ulcers. Severity of each component has different effect on the outcome depending on the severity of the other components.

It is difficult to predict which of the factors play predominant role in pathogenesis of a specific ulcer. For example, a smaller ulcer with underlying osteomyelitis has poor healing and higher risk of amputation when compared to larger superficial ulcer with no bone involvement or infection. An superficial ulcer in a limb with decreased vascularity has poor healing compared to a deep ulcer in limb with good vascularity. Thus outcomes of a diabetic foot ulcer depend on the combination of the three factors described with one playing a more prominent role than the other in the causative process.

The earlier classification systems were based on the ulcer characteristics. Factors like presence of infection and Ischemia were not taken into account which grading the ulcer. Hence though they were of use in clinical setting to grade the foot ulcers, they were not able to predict the wound healing time or amputation risk. Later classification systems used critical limb Ischemia as the major determinant factor in predicting salvageable nature of the diabetic foot ulcer. Wound healing, however, does not depend solely on the degree of Ischemia, but also on the presence and severity of infection and extent and depth of the wound. Existing Ischemia scoring system fails to categorise the other components such as tissue loss, presence and severity of infection.(14)

Arterial anatomy and limb perfusion are key factors in predicting risk of amputation. However ulcer recurrence and amputation also depends on the presence of neuropathy. Classification systems published till date are of limited use in decision making as they focus on specific aspects of the lower extremity. Most diabetic foot ulcer classification has ischemia included as mere presence or absence with no grading of severity. Description of gangrene and tissue loss is not includes in most of the diabetic foot ulcer grading system. Thus most of the grading systems of diabetic foot ulcer do not provide adequate patient baseline stratification to enable comparison of outcomes in different patient subgroups, different centres and revascularisation procedures. (14)

Presence of infection along with systemic response and local signs of inflammation plays a major role in prediction of amputations. The infectious Disease society of America clinical classification system [IDSA] strongly correlates with amputation risk and works well for infection component of diabetic foot ulcers. However the classification system does not address perfusion status or wound characteristics.

Clinical description	Infectious Diseases Society of America
Wound without purulence or any manifestations of inflammation	Uninfected
≥2 Manifestations of inflammation (purulence or erythema, pain, tenderness, warmth, or induration); any cellulitis or erythema extends ≤2 cm around ulcer, and infection is limited to skin or superficial subcutaneous tissues; no local complications or systemic illness	Mild
Infection in a patient who is systemically well and metabolically stable but has ≥2 cm; lymphangitis; spread beneath fascia; deep tissue abscess; gangrene; muscle, tendon, joint, or bone involvement	Moderate
Infection in a patient with systemic toxicity or metabolic instability (e.g., fever, chills, tachycardia, hypotension, confusion, vomiting, leukocytosis, acidosis, hyperglycemia, or azotemia)	Severe

Figure 22: Infectious Diseases society of America classification system

A more comprehensive system is required for grading and predicting outcome in view of improved understanding of the causative factor and pathogenesis of the disease. Mere presence or absence of Ischemia no longer applies as a classification of ischemic limb. It has been understood that limb ischemia does not have clear cut-off points. Presence and extent of infection and extent of the wound play a role in progression of diabetic foot ulcers. Need for revascularisation and debridement in order to preserve the limb and prevent amputation depends on grading of infection, ischemia and extent of the wound.

Society of vascular surgery scoring system:

In the intention to create a classification system for diabetic foot ulcer analogous in comprehension to the TNM staging of cancers, society of Vascular surgery developed a lower extremity threatened limb classification system, a risk stratification grading based on Wound, Ischemia and Foot infection [WIfI]. This grading system was based on merging multiple other systems which focuses on diabetic foot ulcers and ischaemic limbs. SVS – WIfI scoring system has three components.

Wound grades:

In the wound component of the SVS-WIfI scoring system, diabetic foot ulcers are graded from 0 to 3 based on severity, depth, size and anticipated difficulty in wound healing. A patient with no wound is graded 0, thus indicating this scoring can be used to grade patients with pure Ischemia changes too. Presence and extent of gangrene is also included in the wound component of this scoring system.

Foot ulcer with minor tissue loss which can be salvaged with a single digit amputation is graded as grade 1. A more extensive ulcer which may require multiple digits amputations or involvement of forefoot which may require transmetatarsal amputation to salvage the limb is graded as grade 2. Extensive tissue involvement requiring any amputation above the level of transtarsal/transmetatarsal level as involvement of hind foot [full thickness heel ulcer or ulcer requiring flap cover after

debridement] is graded as grade 3. Extensive gangrene during presentation that may prevent the chance of salvaging a functional foot is excluded from the grading system.

W: Wound/clinical category
SVS grades for rest pain and wounds/tissue loss (ulcers and gangrene):
0 (ischemic rest pain, ischemia grade 3; no ulcer) 1 (mild) 2 (moderate) 3 (severe)

Grade	*Ulcer*	*Gangrene*
0	No ulcer	No gangrene
Clinical description: ischemic rest pain (requires typical symptoms + ischemia grade 3); no wound.		
1	Small, shallow ulcer(s) on distal leg or foot; no exposed bone, unless limited to distal phalanx	No gangrene
Clinical description: minor tissue loss. Salvageable with simple digital amputation (1 or 2 digits) or skin coverage.		
2	Deeper ulcer with exposed bone, joint or tendon; generally not involving the heel; shallow heel ulcer, without calcaneal involvement	Gangrenous changes limited to digits
Clinical description: major tissue loss salvageable with multiple (≥3) digital amputations or standard TMA ± skin coverage.		
3	Extensive, deep ulcer involving forefoot and/or midfoot; deep, full thickness heel ulcer ± calcaneal involvement	Extensive gangrene involving forefoot and /or midfoot; full thickness heel necrosis ± calcaneal involvement
Clinical description: extensive tissue loss salvageable only with a complex foot reconstruction or nontraditional TMA (Chopart or Lisfranc); flap coverage or complex wound management needed for large soft tissue defect		

TMA, Transmetatarsal amputation.

Figure 23: Wound grades in WIfI scoring system

Ischemia grades:

In the Ischemia component of the WIfI scoring system, ABPI [Ankle Brachial Pressure Index] is used to assess the vascularity of the limb. If ABPI values are incompressible or unreliable, Toe pressure or transcutaneous oximetry [TcPO2] values are used to grade the lower limb. In the elderly, later measurements are preferred as ABPI values are usually unreliable in view of medical calcinosis causing incompressible blood vessels.

In the other classification systems, ABPI values above 0.8 are considered to be associated with low risk of amputation. In such patient, wound extent and presence of

infection are considered as the determinants of amputation risk. ABPI values less than 0.8 are characterised as limbs with decreased vascularity and are advised revascularisation procedures if indicated and feasible.

In WIfI scoring system, ABPI values above 0.8 is graded as grade 0. ABPI values less than 0.4 are graded as grade 3. Rest of the grading based on ABPI and toe pressure values are as given below.

I: Ischemia
Hemodynamics/perfusion: Measure TP or $TcPO_2$ if ABI incompressible (>1.3)
SVS grades 0 (none), 1 (mild), 2 (moderate), and 3 (severe).

Grade	*ABI*	*Ankle systolic pressure*	*TP, $TcPO_2$*
0	≥0.80	>100 mm Hg	≥60 mm Hg
1	0.6-0.79	70-100 mm Hg	40-59 mm Hg
2	0.4-0.59	50-70 mm Hg	30-39 mm Hg
3	≤0.39	<50 mm Hg	<30 mm Hg

ABI, Ankle-brachial index; *PVR*, pulse volume recording; *SPP*, skin perfusion pressure; *TP*, toe pressure; *$TcPO_2$*, transcutaneous oximetry.
Patients with diabetes should have TP measurements. If arterial calcification precludes reliable ABI or TP measurements, ischemia should be documented by $TcPO_2$, SPP, or PVR. If TP and ABI measurements result in different grades, TP will be the primary determinant of ischemia grade.
Flat or minimally pulsatile forefoot PVR = grade 3.

Figure 24: Ischemia grades in WIfI scoring system

Infection grades:

Many classification systems have ignored the presence and severity of infection and its threat to limb with foot ulcers. Increase in severity of infection increases the risk of amputation. In the present of peripheral vascular disease, infection dramatically increases risk. Presence of infection increases the need for increased blood supply by increasing the metabolic enzyme and can cause small vessel thrombosis by producing angiotoxic enzymes. IDSA system of classification of infection in ulcers is adapted

into the SVS-WIfI classification system as there was no particular mention about infection in the other frequently used classification systems.

fI: foot Infection:
SVS grades 0 (none), 1 (mild), 2 (moderate), and 3 (severe: limb and/or life-threatening)
SVS adaptation of Infectious Diseases Society of America (*IDSA*) and International Working Group on the Diabetic Foot (IWGDF) perfusion, extent/size, depth/tissue loss, infection, sensation (*PEDIS*) classifications of diabetic foot infection

Clinical manifestation of infection	*SVS*	*IDSA/PEDIS infection severity*
No symptoms or signs of infection	0	Uninfected
Infection present, as defined by the presence of at least 2 of the following items: • Local swelling or induration • Erythema >0.5 to ≤2 cm around the ulcer • Local tenderness or pain • Local warmth • Purulent discharge (thick, opaque to white, or sanguineous secretion)	1	Mild
Local infection involving only the skin and the subcutaneous tissue (without involvement of deeper tissues and without systemic signs as described below). Exclude other causes of an inflammatory response of the skin (eg, trauma, gout, acute Charcot neuro-osteoarthropathy, fracture, thrombosis, venous stasis)		
Local infection (as described above) with erythema >2 cm, or involving structures deeper than skin and subcutaneous tissues (eg, abscess, osteomyelitis, septic arthritis, fasciitis), and No systemic inflammatory response signs (as described below)	2	Moderate
Local infection (as described above) with the signs of SIRS, as manifested by two or more of the following: • Temperature >38° or <36°C • Heart rate >90 beats/min • Respiratory rate >20 breaths/min or $PaCO_2$ <32 mm Hg • White blood cell count >12,000 or <4000 cu/mm or 10% immature (band) forms	3	Severe[a]

$PACO_2$, Partial pressure of arterial carbon dioxide; *SIRS*, systemic inflammatory response syndrome.
[a]Ischemia may complicate and increase the severity of any infection. Systemic infection may sometimes manifest with other clinical findings, such as hypotension, confusion, vomiting, or evidence of metabolic disturbances, such as acidosis, severe hyperglycemia, new-onset azotemia.

Figure 25: Foot infection grades in WIfI scoring system with correlation to IDSA system

Following conditions are excluded from the target patient population for clinical application of SVS-WIfI scoring system

- Patients with acute limb Ischemia.

- Patients with pure venous ulcers,
- Patients with acute ‘trash’ foot
- Patients with acute trauma/mangled extremity
- Patients with acute Ischemia due to emboli
- Patients with wounds related to non-atherosclerotic conditions such as collagen vascular disease, neoplasm, vasculitis and radiation.

Predictive role of SVS-WIfI scoring system:

When a diabetic foot ulcer is scored based on SVS-WIfI scoring system, the ulcer is assigned a score each for wound characteristics, Ischemia and infection factors which invariably produces 64 theoretically possible clinical combinations. Thus to grade the severity by comparing all three components, the society of Vascular surgery Lower extremity guidelines committee and experts in the field of limb Ischemia carried out a Delphi consensus.

Delphi consensus:

Delphi method is an interactive forecasting method, initially developed for business forecasting and relies on the opinion and decisions taken by a panel of experts. It is based on the principle that decisions taken by a structured group of individuals expertise in a field are more accurate than decisions taken by a unstructured group. Different panel of experts are expected to answer questionnaires in two or more rounds. After each rounds, the questionnaire and the decisions are

discussed and argued upon where they provide reasons for their judgements. Then the experts are allowed to revise their earlier answers based on the answers given by the other experts in the previous round. It is believed that by repeating the process of discussion and argument about the decisions made and a chance of re-answering or recoding, the range of answers will decrease and it will converge to the correct answer or decision. In SVS-WIfI scoring system development, a similar Delphi consensus method was used to risk stratify the diabetic foot ulcers into various grades.

Prediction of risk of amputation:

As per the method explained above, each of the 64 theoretical patient combinations were assigned a limb threat clinical stage by the members of the Delphi consensus group. Based on the decision, the risk of amputation was staged as very low, low, moderate and high and numbered as 1-4 respectively. Table given below shows the one year risk of amputation for each of the 64 theoretical patient combinations when treated with medical therapy alone.

	Ischemia -0				Ischemia -1				Ischemia - 2				Ischemia -3			
W-0	1	1	2	3	1	2	3	4	2	2	3	4	2	3	3	4
W-1	1	1	2	3	1	2	3	4	2	3	4	4	3	3	4	4
W-2	2	2	3	4	3	3	4	4	3	4	4	4	4	4	4	4
W-3	3	3	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	Fi-0	Fi-1	Fi-2	Fi-3	Fi-0	Fi-1	Fi-2	Fi-3	Fi-0	Fi-1	Fi-2	Fi-3	Fi-0	Fi-1	Fi-2	Fi-3

Figure 26: Estimated risk of amputation at 1 year

W – Wound grade

Fi – Foot infection grade

Stage 1 – very low risk of amputation

Stage 2 – low risk of amputation

Stage 3 – moderate risk of amputation

Stage 4 – high risk of amputation

Prediction of benefit/requirement of revascularisation procedure:

SVS-WIfI scoring is devised with the intention of using the scoring system to predict benefit from revascularisation alongside limb salvage. As mentioned below, benefit from revascularisation is almost minimal in the 16 combinations involving Ischemia as 0 [ABPI>0.8]. Assuming infection is under control, Delphi consensus performed over the theoretical combination for benefit/requirement of revascularisation procedure is as mentioned in the table below.

	Ischemia -0				Ischemia -1				Ischemia – 2				Ischemia -3			
W-0	1	1	1	1	1	2	2	3	2	2	3	3	3	4	4	4
W-1	1	1	1	1	2	3	3	3	3	4	4	4	4	4	4	4
W-2	1	1	1	1	3	3	4	4	4	4	4	4	4	4	4	4
W-3	1	1	1	1	3	3	3	4	4	4	4	4	4	4	4	4
	Fi-0	Fi-1	Fi-2	Fi-3	Fi-0	Fi-1	Fi-2	Fi-3	Fi-0	Fi-1	Fi-2	Fi-3	Fi-0	Fi-1	Fi-2	Fi-3

Figure 27: Estimate likelihood of requirement /benefit from revascularisation procedure

W- wound grade

Fi – Foot infection grade

Stage 1 – Revascularisation procedure not indicated.

Stage 2- low benefit from revascularisation

Stage 3 – moderate benefit from revascularisation

Stage 4 – high benefit from revascularisation

Interpretation of staging by Delphi consensus:

- Increased risk of amputation as there in increase in wound grade [correlates with PEDIS,UT and other wound classification systems]
- Infection and Ischemia are synergistic. Infected wound in combination with peripheral vascular disease has higher risk of amputation.
- Regardless of other factors, Higher grade of infection [3] is poses moderate to high risk of amputation [correlated with IDSA guidelines]

SVS-WIfI scoring system is devised to stratify patients with diabetic foot ulcers based on spectrum of various factors. The application of SVS- WIfI scoring is aimed at stratifying patients according to their initial disease burden, similar to TNM staging for cancers, not to dictate therapy. It is devised to improve clinical trials design. Appropriate stratification of patients by this scoring system will yield a better platform to assess and test the impact of latest therapies in various randomised clinical trials.

WIFI scoring system is not devised to perform as a standalone clinical decision making tool. In selecting the best therapy, patient risk factors and comorbidities also play a major role. Moreover, attention should be directed towards redefining outcomes. Amputation free survival and limb salvage are not the only criteria for success of treatment.

Justification of study:

Over multiple diabetic foot ulcer classification system, SVS-WIfI scoring system has the advantage of being comprehensive and includes grading of all three major components of pathogenesis of diabetic foot ulcers. This scoring system has been studied in multiple centres across the world and has been found to be a good predicting tool for predicting wound healing, need for revascularisation procedures and amputations. There are no prediction models validated in our population.

The aim of this study is to study the predictive role of SVS –WIfI scoring system in predicting amputations in patients with diabetic foot ulcer in Indian population presenting to a tertiary centre. Henceforth, this scoring system can be used in patients at presentation to grade them and plan management by amputation if indicated.

METHODOLOGY

Dates of data collection

January 2018 – December 2018

Follow-up till June 2019

Study Methodology

This study was approved by the Institutional Review Board and Ethics committee of Christian Medical College, Vellore.

Patients with diabetic foot ulcers admitted under department of General surgery and Vascular surgery for management in ward and patients visiting diabetic foot clinic in Endocrinology OPD were recruited in this study. Information booklets were provided to the patient and they were consented after explaining the intention of the study and their role in the study. The patients who consented for this study underwent evaluation by SVS-WIfI scoring system and their standard laboratory investigations were noted. Clinical proforma form was filled and appropriate WIfI score for the patient was calculated. Patients were grouped according to their WIfI score into group 1 [stages 1-3] and group 2 [stage 4].

Patients were followed up after six months from recruitment either through telephone or OPD chart analysis and outcomes noted. Data was then analysed to compare outcomes between the two groups.

Key criteria

Inclusion Criteria:

- Patients with diabetic foot ulcers presenting to the diabetic foot clinic, General surgery or Vascular surgery in CMC

Exclusion criteria:

- Vulnerable age groups [Age <15,>70], pregnant women
- Stump ulcers
- Patients who did not consent

Sample size

Single Proportion - Absolute Precision	Positive Predictive Value for stage IV	Negative Predictive value for stages I-III
Expected Positive Predictive Value	0.4	0.9
Precision (%)	10	10
Desired confidence level (1- alpha) %	95	95
Required sample size	92	35

The Positive predictive value (PPV) that has been reported for Stage IV was about 40%.(15,16) In order to estimate this with the precision of 10%, with 95% Confidence interval, the sample size needed is 92 subjects. Incorporating 10% drop out we would like to study about 100 subjects who are positive to the scoring system (stage IV) to estimate the PPV of the scoring system.

However, the Negative predictive value (NPV) for Stages I-III was expected to be about 90%. The scoring system would suggest Stages I-III as negative. In order to estimate this NPV with the precision of 10%, we need to study 35 subjects who are negative to the scoring system. Incorporating drop out we decided to study about 50 subjects.

Method of selection

All patients with diabetic foot ulcers admitted under department of General surgery and vascular surgery and patients on follow up with diabetic foot care clinic in Department of Endocrinology were included in the study.

Consent administration

Patients were provided with information booklet and were consented by the primary investigator during the time of recruitment and initial scoring after explaining the intention of the study and their role.

Staging

Diabetic patients with foot ulcers were recruited from general surgery and vascular surgery wards and patients presenting in diabetic foot care OP clinic in Endocrinology department. Wound was examined and depth of the wound and presence and extent of gangrene was noted. Ischemia component of the lower limb was scored from the ABPI values and Toe pressure values. Foot infection component of the score was calculated from clinical assessment of presence of local signs of inflammation and presence of systemic signs of infection. WIfI score, thus calculated was used to group patients into group 1 and 2. Stages 1-3 were grouped under group 1 and stage 4 was considered group 2. Sample size calculation was performed as

mentioned above. 60 patients were recruited under group 1 and 103 patients recruited under group 4.

Routine blood investigations were noted. Glycaemic control was assessed by HbA1c values done within three months from recruitment.

Follow up

Patients were followed up through telephone or by analysing outpatient follow up charts at six months from recruitment. Patients outpatient charts were analysed for follow up if patient was regular on follow up. In case of defaulters to outpatient follow up, patients were contacted through telephone and mail and outcome noted.

Primary outcome

Amputation within six months from time of recruitment.

Secondary outcomes

1. Association between the individual components of WIfI staging system and outcome of diabetic foot ulcers studied.
2. Association between glycemic control and outcome of diabetic foot ulcers studied.

Statistical analysis

Analysis of the primary outcome

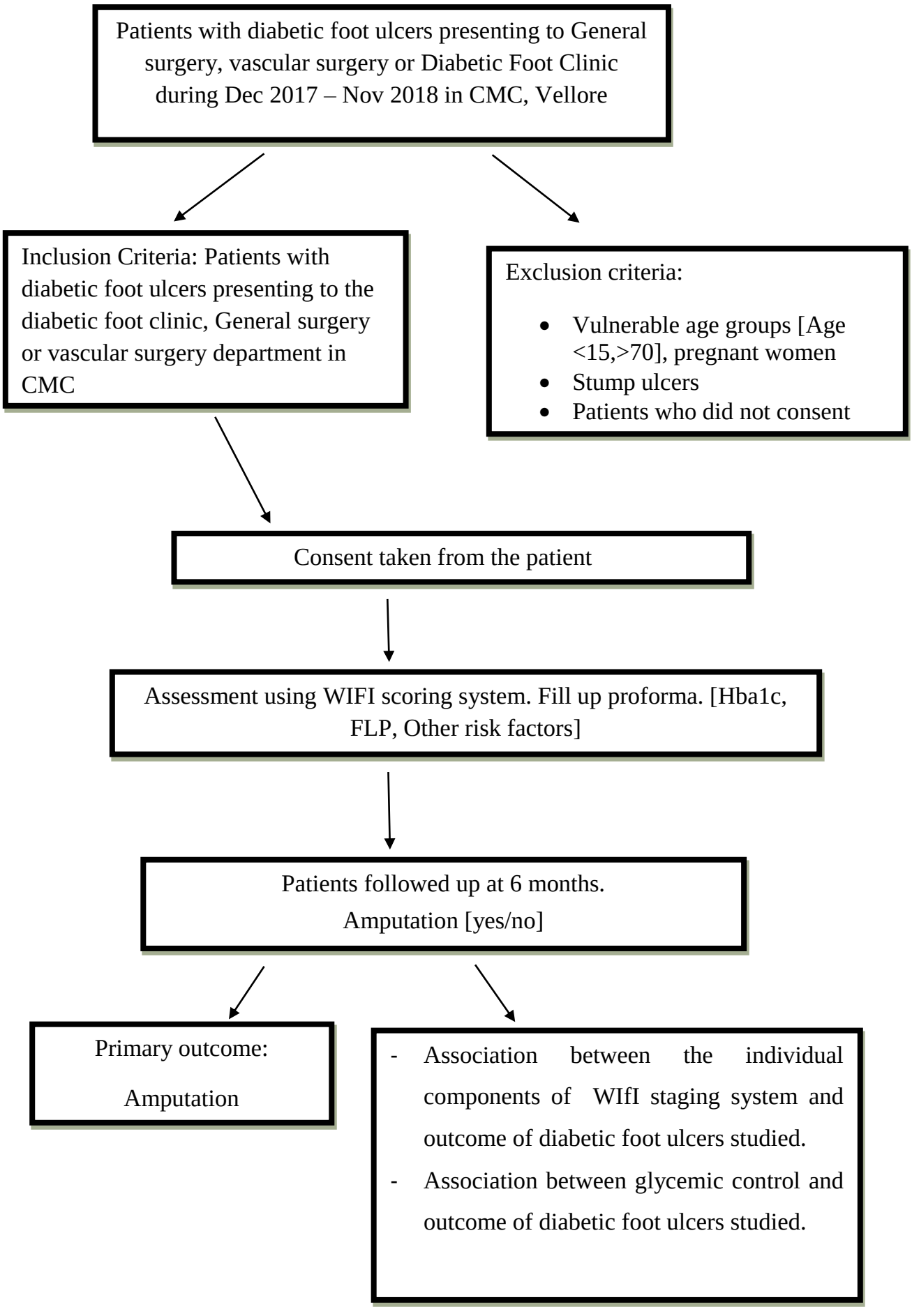
Patients recruited were divided into group 1 and 2 based on WIfI score as mentioned above and were followed up at 6 months after recruitment. Amputation was noted as primary outcome. Data was analysed to compare both the groups by 2x2 tables.

Analysis of the secondary outcomes

Data analysis between incidences of amputation in different subgroups of WIfI component was done by 2x2 table. Relationship between glycaemic control and incidence of amputation was analysed using 2x2 tables.

Brief algorithm of the study is as given below:

Algorithm of the study



RESULTS

The total number of cases enrolled in this study was 163. Among 163, 60 were grouped as group 1 [Stages 1-3] and remaining 103 were under group 2 [Stage 4]. AS mentioned in the methodology earlier, patients were followed up for 6 months and outcome was noted.

Table 1: Number of patients in each group

	Total, n=163
Group 1 [stages 1-3]	60
Group 2	103

Age distribution:

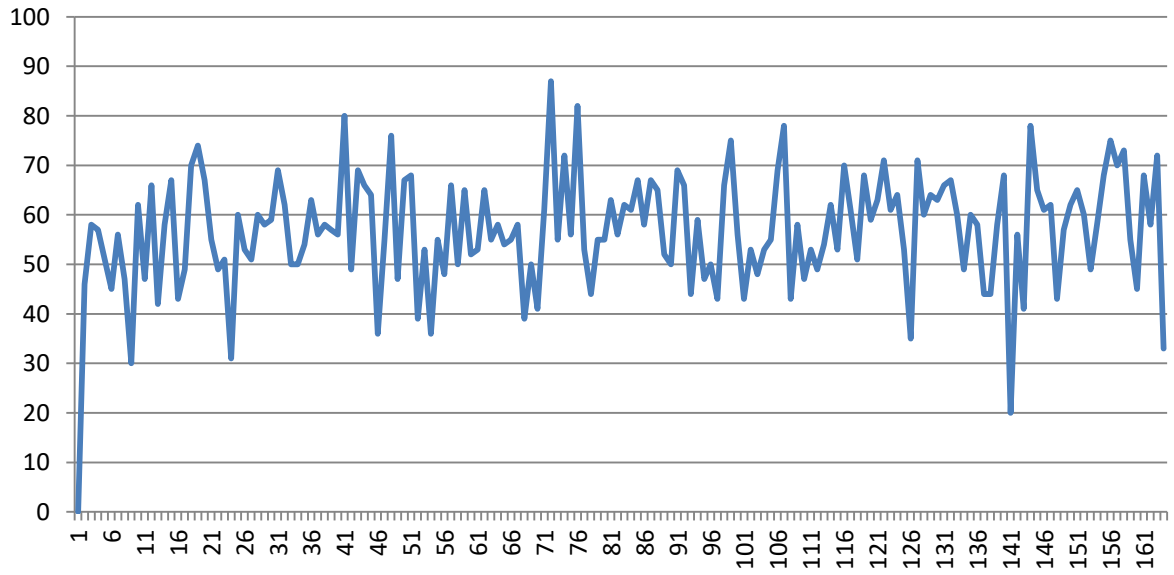


Figure 28: Age distribution of all patients

The mean age of the cases was 57 years. The youngest patient being 20 years old and the oldest patient was 87 years old.

In group 1,

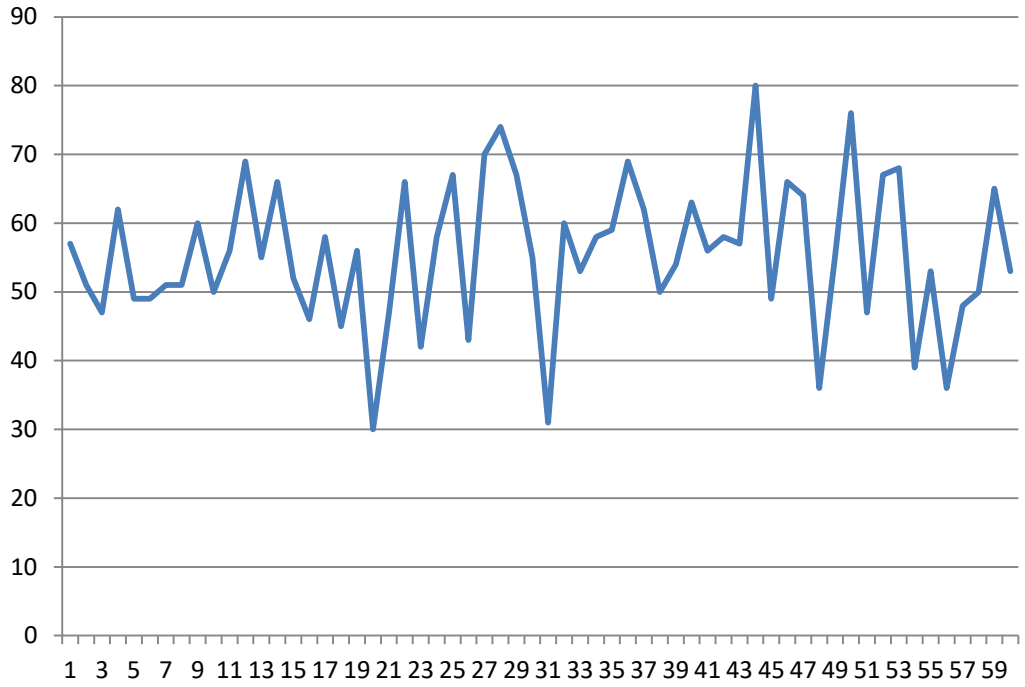


Figure 29: Age distribution of patients in group 1

The mean age of the cases was 55.51 years. The youngest patient was 30 years old and the oldest patient was 80 years old.

In group 2, The mean age of the cases was 57.97 years. The youngest patient was 20 years old and the oldest patient was 87 years old.

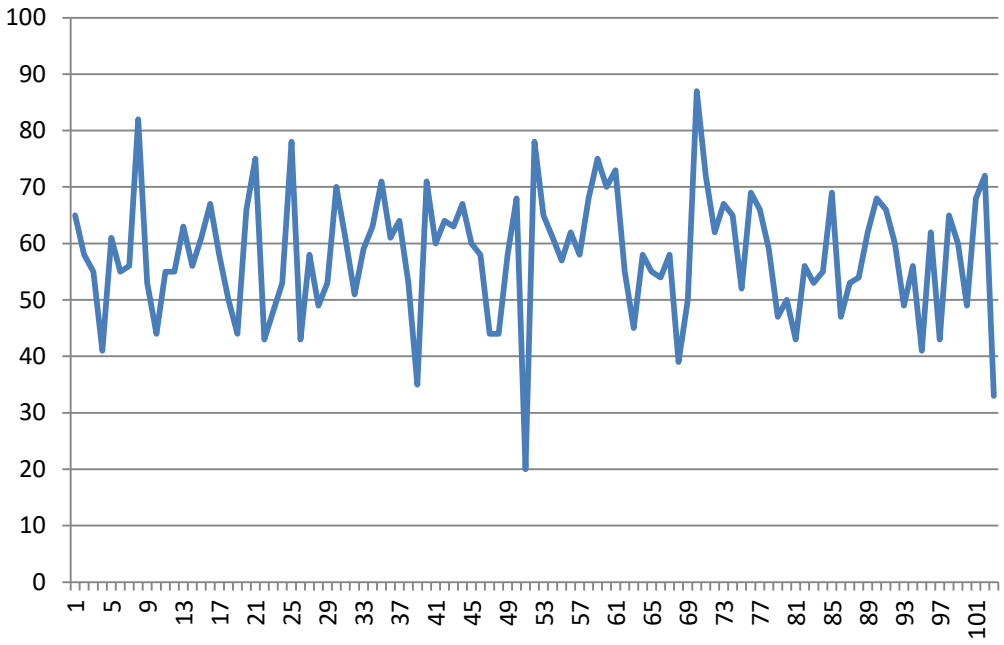


Figure 30: Age distribution of patients in group 2

Gender distribution:

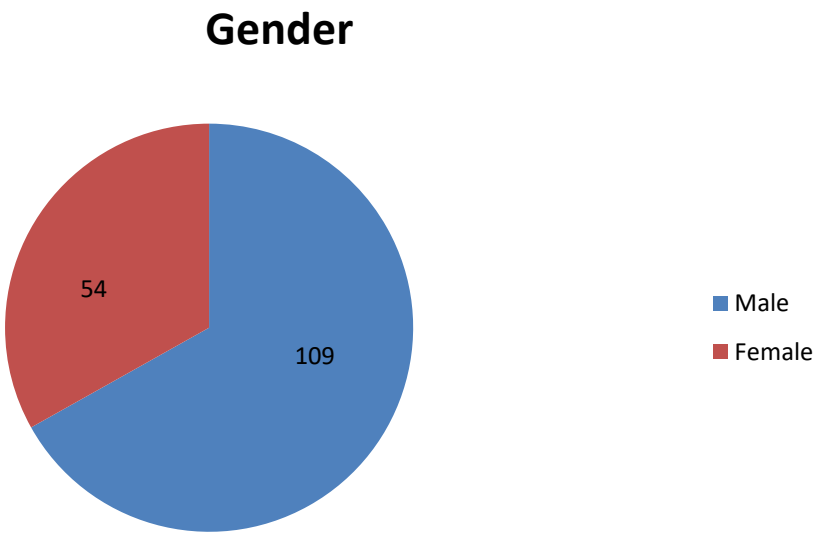


Figure 31: Gender distribution of all recruited patients

There were 109 male patients and 54 female patients recruited in this study making a 66.87% of male patients.

In group 1,

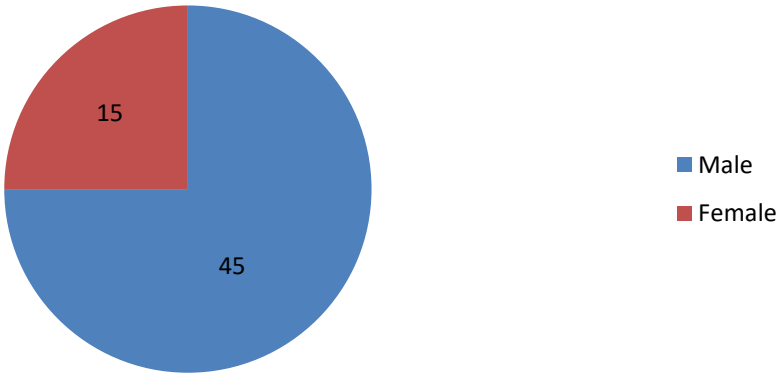


Figure 32: Gender distribution of patients in group 1

There were 45 male patients and 15 female patients making a 75% of male patients.

In group 2,

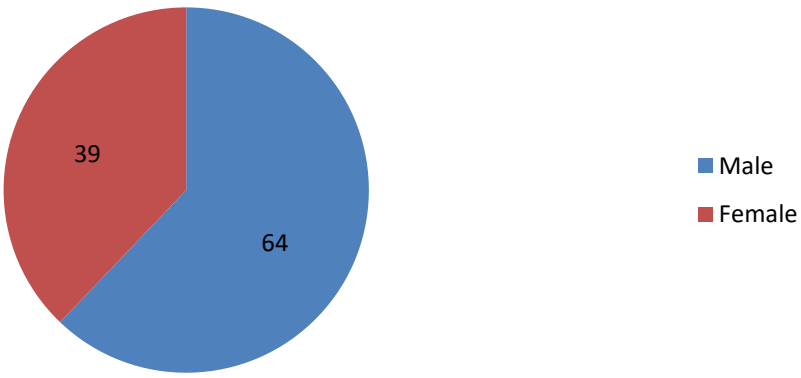


Figure 33: Gender distribution of patients in group 2

There were 64 male patients and 39 female patients adding to a 62.13% of male patients.

Primary outcome:

Considering incidence of amputation as the primary outcome, patients were followed up at 6 months after recruitment. Amputations including ray amputation and transmetatarsal/transtarsal amputations were considered as minor amputations. Any amputation above the level of transtarsal level is considered as major amputation.

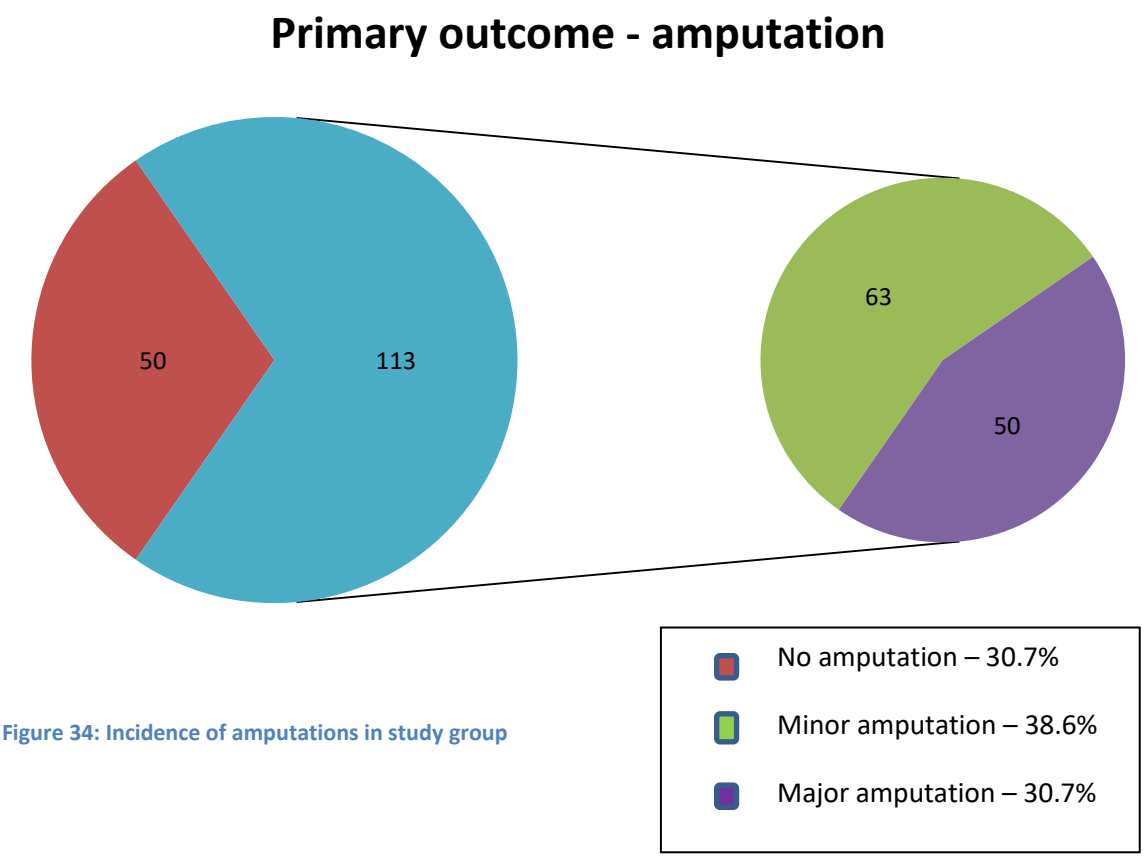


Figure 34: Incidence of amputations in study group

The outcome in both groups are as mentioned below.

Among 163 recruited patients, 113 had undergone amputations in both groups. Among 113 amputations, 63 had minor amputations and 50 had major amputations.

In group 1 [stages 1-3],

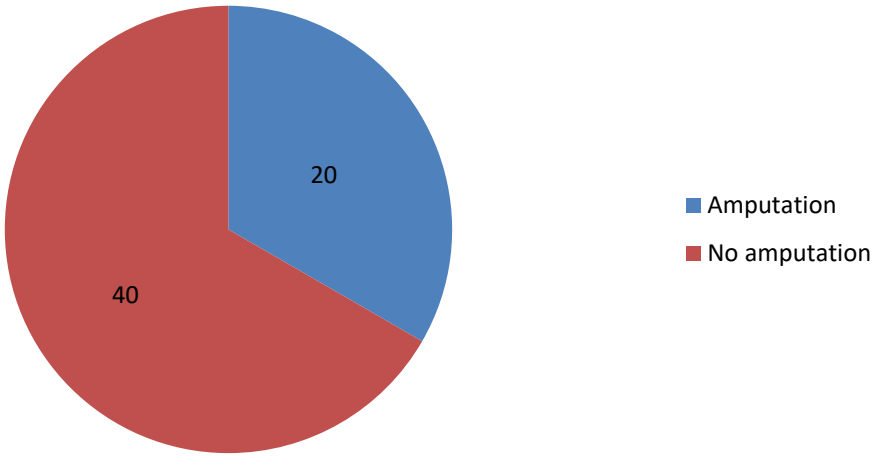


Figure 35: Primary outcome in patients in group 1

33.3% of patients belonging to group 1 underwent any form of amputations, whereas 66.7% did not undergo amputations within 6 months from recruitment. Further categorisation of amputation into major and minor yielded the following results.

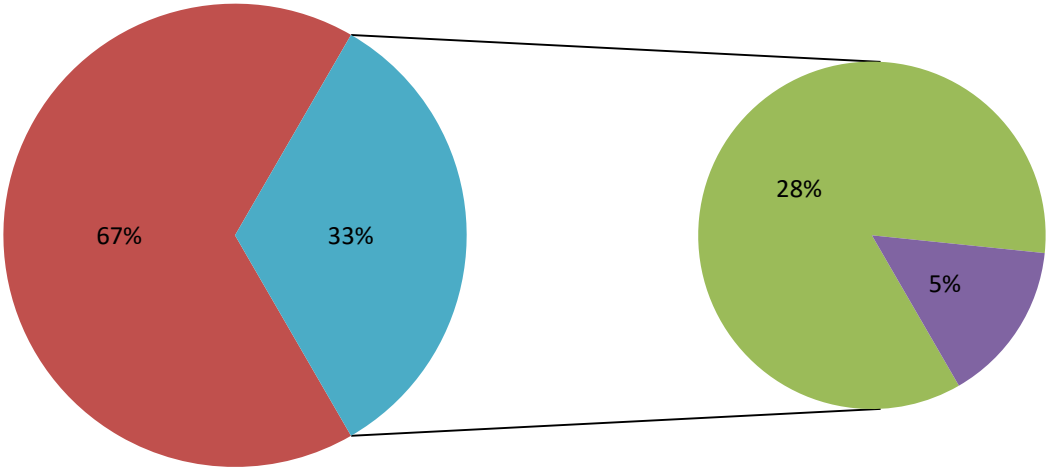


Figure 36: Primary outcomes broken into minor and major amputations in patients in group 1

28% of patients in group 1 had undergone minor amputations, whereas 5% of patients in group 1 underwent major amputations.

In group 2, comprising of patients scored as stage 4,

90.3% of the patients had undergone amputations either minor or major. Remaining 9.7% had no amputation.

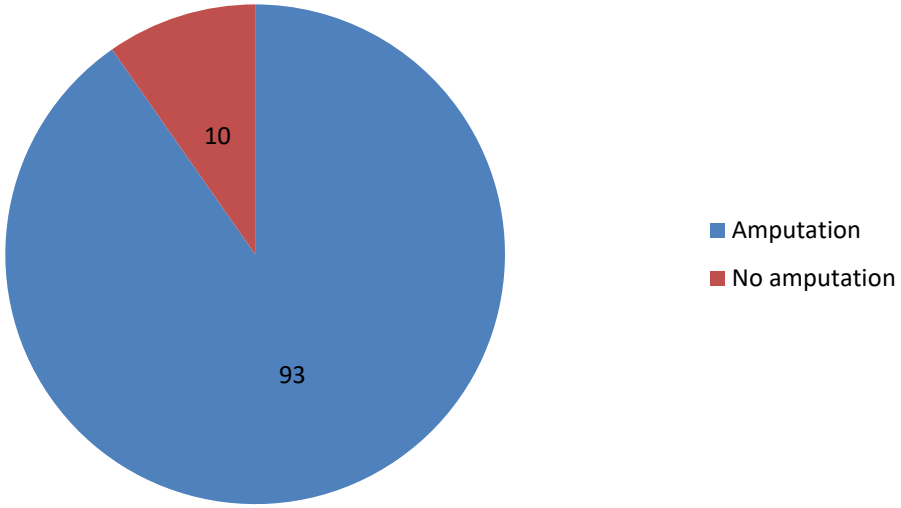


Figure 37: Primary outcome in patients in group 2

Further categorisation of the amputation into minor and major category revealed the following results.

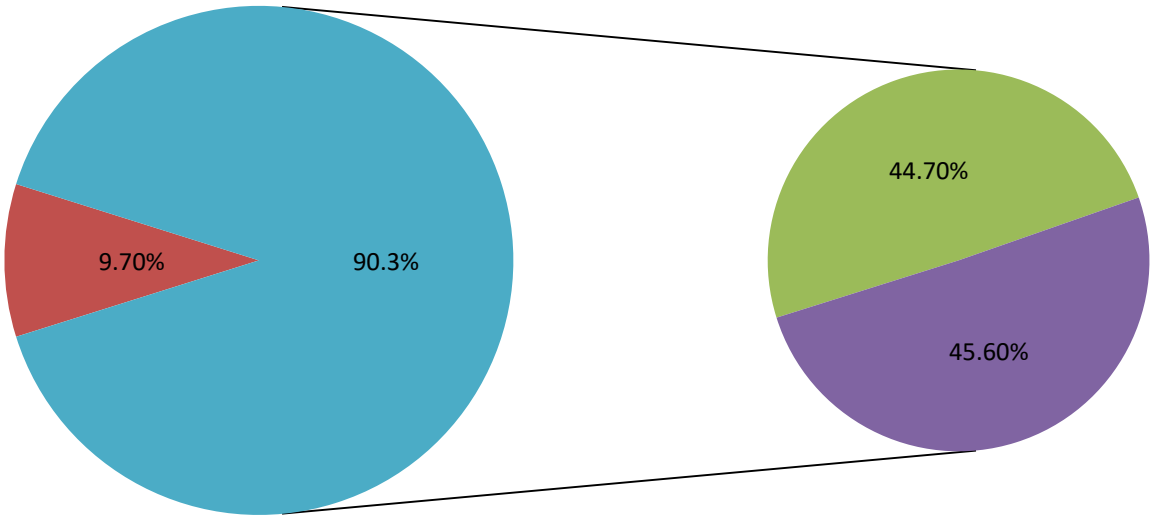
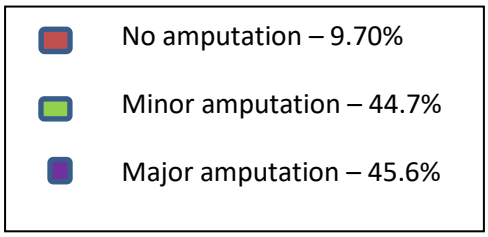


Figure 38: Primary outcome broken into minor and major amputation in patients in group 2



Stage wise division of outcomes:

Among patients in group 1, the breakup of stages is as given below:

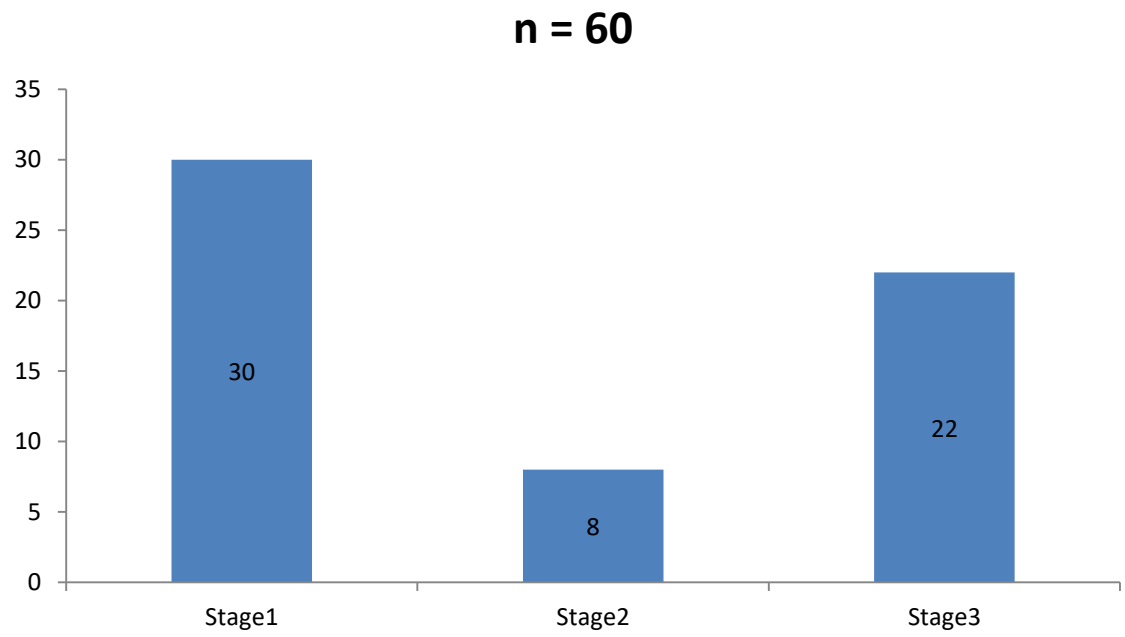


Figure 39: Breakdown of stages 1-3 in group 1

50% of the patients belonged to stage 1, 13.3% belonged to stage 2 and 36.7% belonged to stage 3.

Among patients in stage 1, 3 out of 30 patients had undergone amputations. All 3 of them underwent major amputation within 6 months. This indicates lower amputation rates in early stage of diabetic foot ulcer.

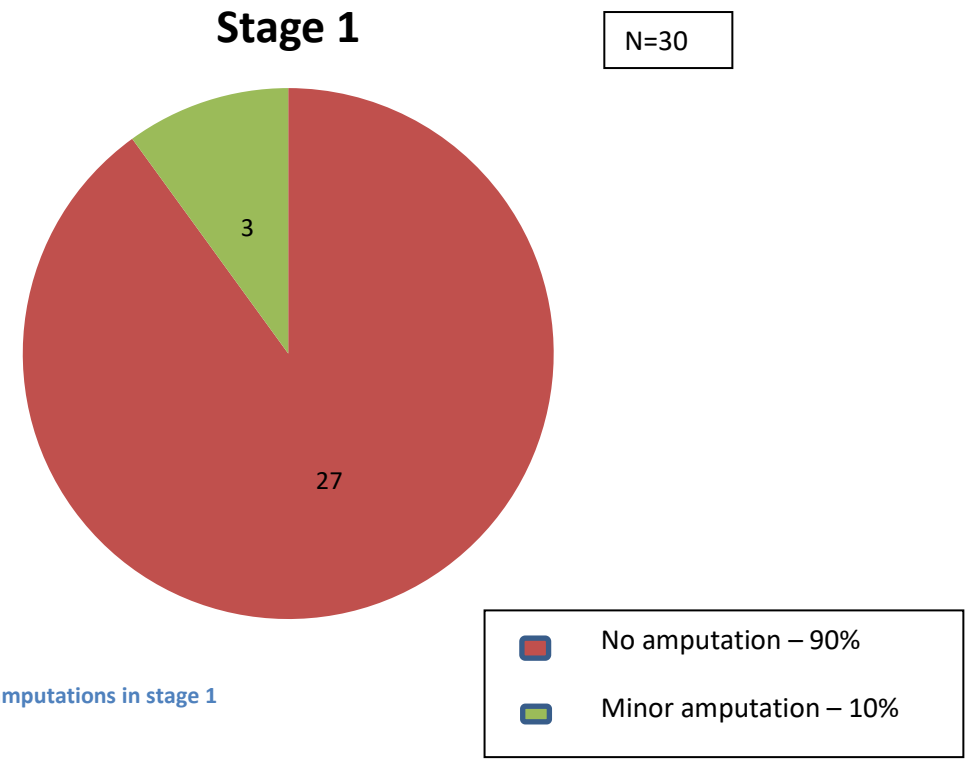


Figure 40: Minor and major amputations in stage 1

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Among patients in stage 2,

25% of the patients had no amputations. 62.5% of the patients had minor amputation and 12.5% had major amputations. Total number of patients staged as stage 2 was 8.

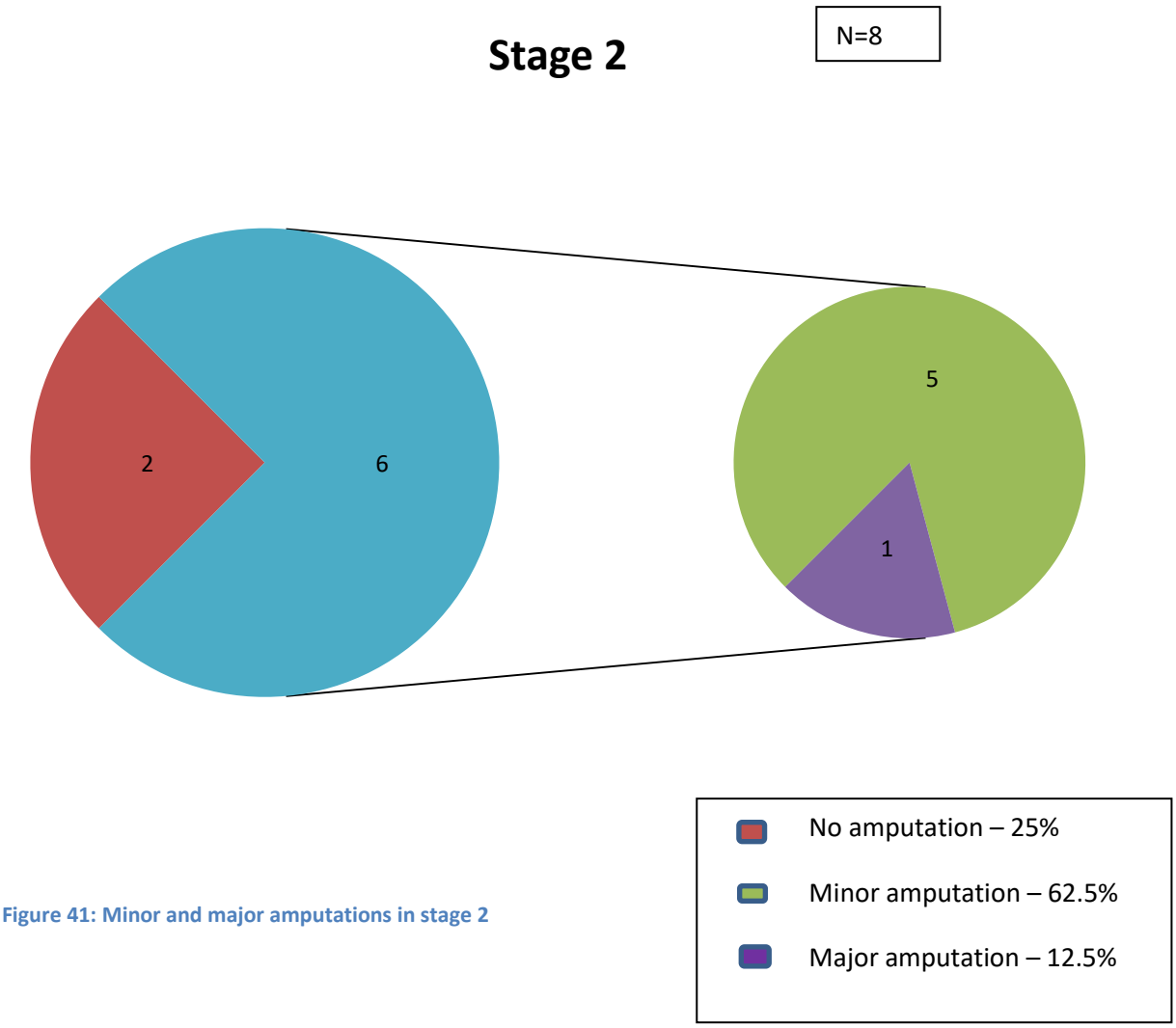

Figure 41: Minor and major amputations in stage 2

Among patients in stage 3,

In stage 3, 50% of the patients had undergone amputations within 6 months from recruitment. However, incidence of major amputation was as low as 9.1%

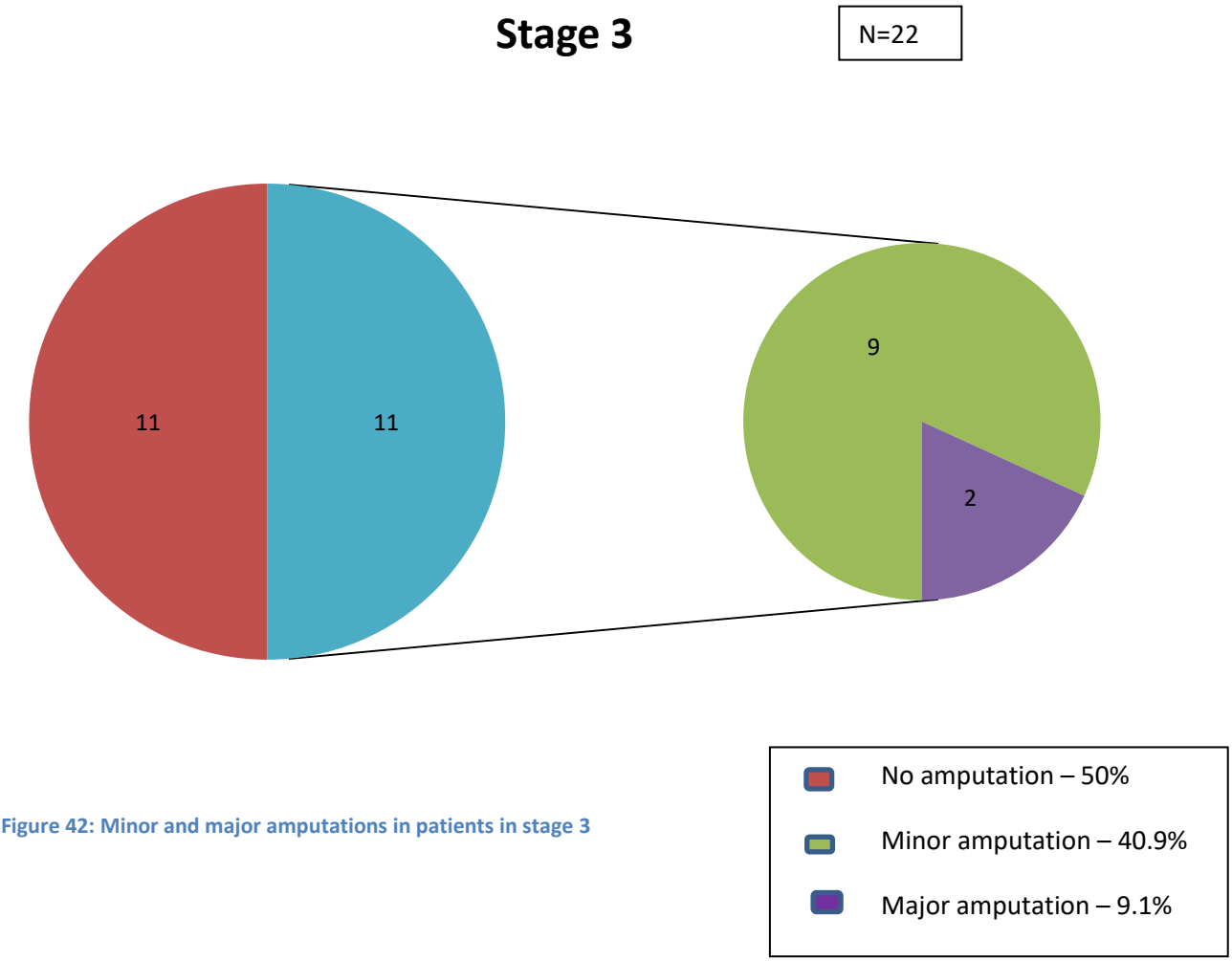

Figure 42: Minor and major amputations in patients in stage 3

.

Results of patients in stage 4, grouped separately as group 2 is already described above.

Sugar control and amputation risk::

HbA1c values done three months within time of recruitment into the study is noted down for documentation of sugar control. 16 out of 163 patients had no HBA1c values done. 132 patients had HbA1C values above 6.4 indicative of poor glycaemic control.

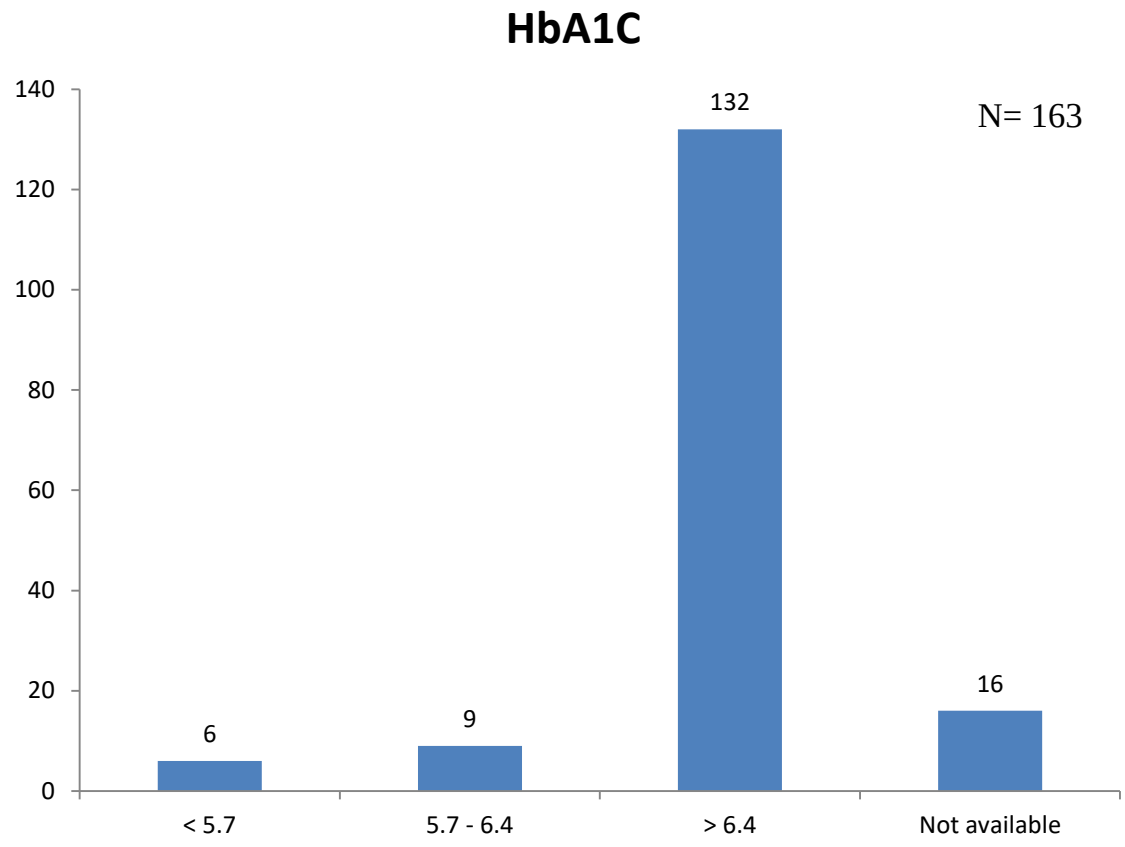

Figure 43: HbA1C trend among the study group

A total of 113 patients had undergone amputations during the study period. 14 out of the 113 patients who had amputations had no HbA1c values. 89 out of 113 patients [78.7%] who had amputations had HbA1C values above 6.4 indicating poor glycaemic control.

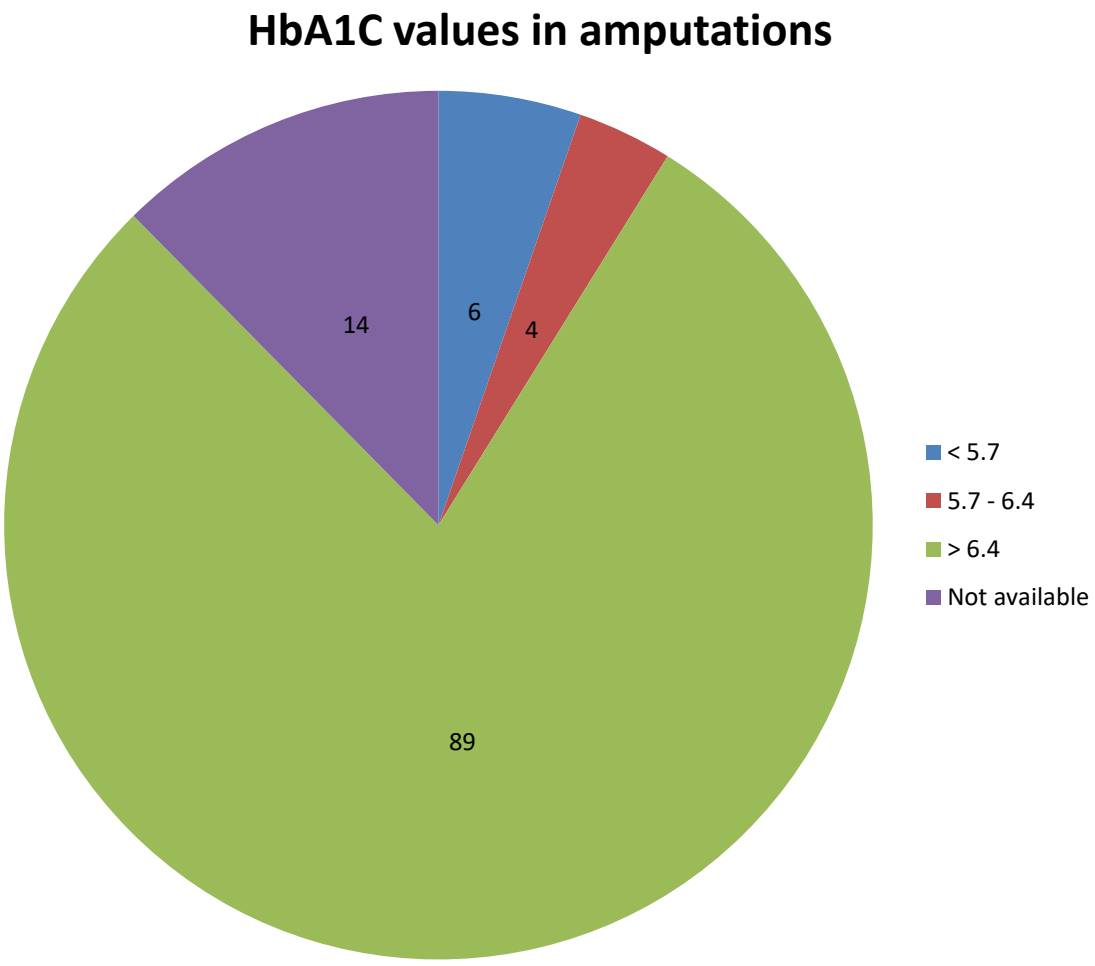

Figure 44: HbA1C values in patients who underwent amputations

Out of 51 patients who had major amputations, 8 patients had no HbA1C values. 36 patients [70.6%] had HbA1c value more than 6.4, indicative of poor glycaemic control.

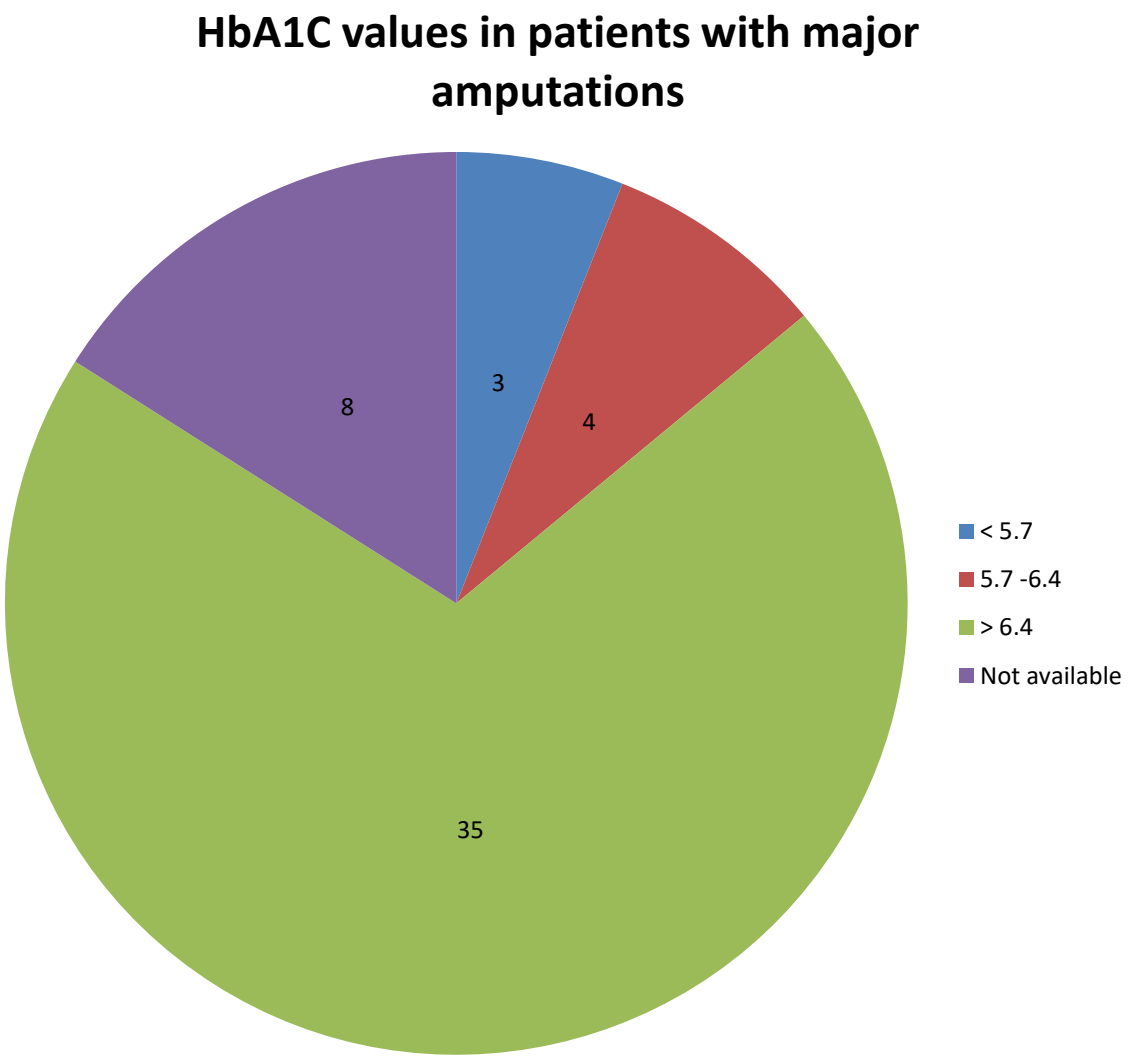

Figure 45: Glycemic control in patients who underwent major amputations

Individual components of WIfI scoring system and amputation risk:

Another secondary objective studied was comparison of individual component leading to predict which component caused more risk for amputation. Patient data was analysed into separate categories: wound, ischemia and foot infection.

Wound grade:

Among 163 patients involved in the study, 55 patients had wound grading of 1, 97 patients had wound grading of 2 and 11 patients had wound grading of 3.

	Wound 0	Wound 1	Wound 2	Wound 3
No amputation	0	35	15	0
Minor amputation	0	14	48	1
Major amputation	0	6 [10.9%]	34 [35.05%]	10 [90.9%]
Total [n=163]	0	55	97	11

Figure 46: Incidence of amputation in different grading of wound characteristics

There was no patients scored wound 0 as patients with foot ulcers were only included in the study. Among wound graded 3, 100% of the patients had undergone amputations, out of which 90.9% were major amputations. In wound category 2, 84.5 % of patients had undergone amputations, out of which 35.05% of them were major amputations. Among category 1, 36.36 % of patients had undergone amputations and

10.9% of those were major amputations. This correlates with the higher incidence of amputation in higher grades of final WIfI staging.

Ischemia grade:

Among 163 patients involved in the study, 111 patients had ischemia grading of 0, 30 patients had ischemia grading of 1, 6 patients had ischemia grading of 2 and 16 patients had ischemia grading of 3.

	Ischemia 0	Ischemia 1	Ischemia 2	Ischemia 3
No amputation	44	5	1	0
Minor amputation	42	14	1	6
Major amputation	25[22.5%]	11[36.7%]	4[66.7%]	10[62.5%]
Total [n=163]	111	30	6	16

Figure 47: Incidence of amputation in different ischemia grading

There was higher number of patients with vascularity of lower extremity within normal limits [Ischemia 0 -111patients]. Among ischemia graded 0, 60% of the patients had undergone amputations, out of which 22.5% of patients had undergone major amputations which is not correlating with the final outcomes as expected. All patients graded grade 3 had undergone amputations, out of which 62.5% of them had major amputations. Ischemia grade 2 had higher incidence of major amputations [66.7%], however total number of patients within the group was small.

Foot Infection grade:

Among 163 patients involved in the study, 15 patients had infection grading of 0, 27 patients had infection grading of 1, 20 patients had infection grading of 2 and 101 patients had infection grading of 3.

	Infection 0	Infection 1	Infection 2	Infection 3
No amputation	14	16	4	16
Minor amputation	1	6	12	44
Major amputation	0	5 [18.5%]	4 [20%]	41 [40.6%]
Total [n=163]	15	27	20	101

Figure 48: Incidence of amputation in different foot infection grades

One out of 15 patients belonging to infection grade 0 underwent minor amputation. Among 27 patients graded infection 1, 40.7% had undergone amputations, out of which 18.5% had major amputations. Among 20 patients graded infection 2, 80% had undergone amputations, out of which 20% had major amputations. Among 101 patients graded infection 3, 84.15% had undergone amputations, out of which 40.6% had major amputations. Thus incidence of amputations, major or minor increased with increasing severity of foot infection.

Sensitivity and specificity of WIfI scoring system in predicting amputation:

Sensitivity and sensitivity were calculated by using 2x2 table as given below:

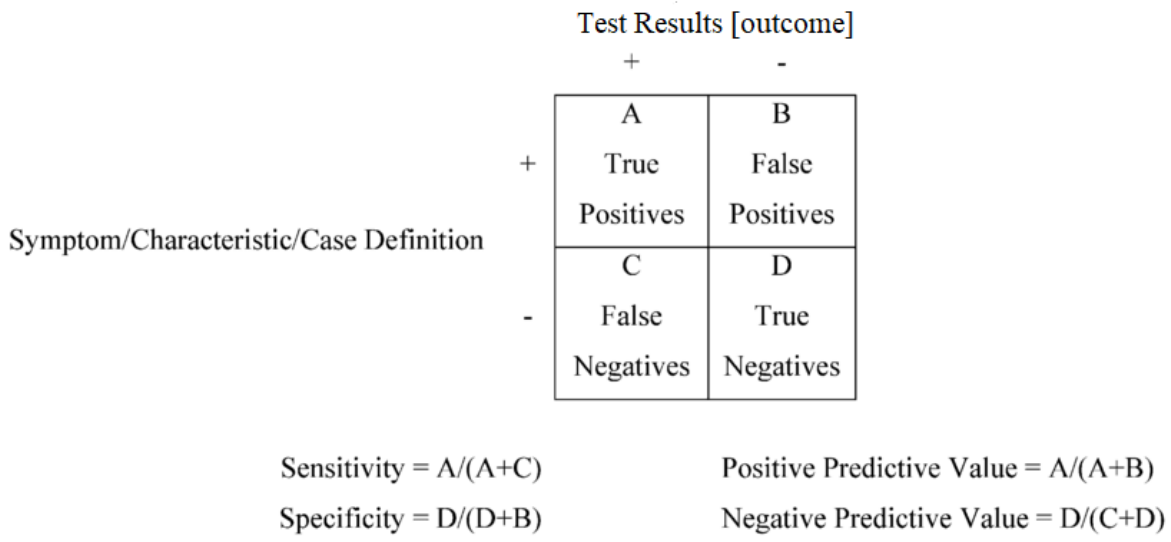

Figure 49: Model to calculate to sensitivity and specificity by 2x2 table

Sensitivity = True positive / [True positive + False negative]

Specificity = True negative / [False positive + True negative]

Positive predictive value = True positive / [True positive + False positive]

Negative predictive value = True negative / [False negative + True negative]

Applying the same to the data available from the study, sensitivity, specificity, positive predictive value and negative predictive value of the WIfI scoring system was calculated for both amputations and major amputations.

Considering amputation as the final outcome:

	Amputation	No amputation
Group 1 [Stage 4]	93	10
Group 2 [Stages 1-3]	20	60

Figure 50: Number of amputations in group 1 and 2

Sensitivity = 93 / [93+20] = 82.3

Specificity = 40 / [10+40] = 80

Positive predictive value = 93 / [93+10] = 90.29

Negative predictive value = 40 / [20+40] = 66.6

Sensitivity and specificity of WIfI scoring system in predicting major amputations:

Considering major amputation as the final outcome

	Major amputation [yes]	Major amputation [no]
Group 1 [Stage 4]	50	63
Group 2 [Stages 1-3]	3	57

Figure 51: Number of major amputation in group 1 and 2

Sensitivity = 50 / [50+3] = 94.84

Specificity = 53 / [63+57] = 44.2

Positive predictive value = 50 / [50+63] = 44.24

Negative predictive value = 57 / [3+57] = 95

Multivariate Analysis:

Multivariate analysis of the data did not yield statistically significant values.

	Odds ratio	Std. Error	z	P > z	95% confidence interval	
Hypertension [Yes]	0.8622024	1.140402	-0.11	0.911	0.0645294	11.52021
Wound 1	1.758683	5.520791	0.18	0.857	0.0037422	826.5079
Wound 2	3.152077	6.795308	0.53	0.594	0.046085	215.5924
Dyslipidemia [Yes]	0.3100236	0.5535309	-0.66	0.512	0.0093674	1.26055
Ischemia 1	0.6390978	1.110542	-0.26	0.797	0.021206	19.2609
Ischemia 2	0.1760378	0.3667458	-0.83	0.404	0.0029667	10.44586
Ischemia 3	0.4279211	1.037636	-0.35	0.726	0.0036927	49.58882
Foot infection 1	1.174672	3.314287	0.06	0.954	0.0046589	296.1732
Foot infection 2	1.222069	3.172448	0.08	0.938	0.0075406	198.0546
Foot infection 3	0.127037	6.153106	0.26	0.794	0.0073352	616.7892
Group 1-3	0.6179787	2.011904	-0.15	0.882	0.0010466	364.8904
Operative intervention [Yes]	0.5808957	0.8636146	-0.37	0.715	0.0315225	10.70471

Figure 52: Multivariate analysis of individual risk factors

DISCUSSION

Diabetic foot ulcers, as mentioned are one of the common complications of diabetes mellitus and its related micro and macro-vascular effects. With multiple

We undertook this study to validate the SVS-WIfI scoring developed by the society of vascular surgery in order to establish a scoring system which included all three major factors that would predict amputations, namely infection, ischemia and characteristics of the ulcer. Studies have suggested that SVS-WIfI scoring has good amputation prediction effects and wound healing time prediction. In this study, we were evaluating the amputation prediction accuracy of WIfI scoring system.

163 patients were recruited from endocrinology Diabetic foot clinic, general surgery and vascular surgery outpatient department and inpatient wards. Among the 163 patients recruited, 60 were grouped into group 1 as they were staged as stages 1-3 based on the SVS-WIfI scoring system. Remaining 103 patients were grouped as group 2, they were staged as stage 4 based on the SVS-WIfI scoring system at time of recruitment.

Most of the patients recruited in the study were men [66.87%] with the mean age of 57 years. There were 75% men in group 1 and 62.13% men in group 2. This was found to be similar to the published literature.

The primary objective of the study was to study the predictive ability of the SVS-WIfI scoring system in predicting amputation in patients with diabetic foot ulcers. Patients were followed up six months after recruitment and outcomes noted. Among 163 recruited patients, 113 had undergone amputations with both groups considered together. 50 out of 113 patients who had amputations had amputations at the level proximal to ankle [major amputations] which comprises 48.54% of all patients who underwent amputations and 30.7% of all patients included in the study.

In group 1 comprising of patients staged 1-3, 40 out of 60 patients had no amputations. 20 out of 60 [33.33%] patients underwent amputations at different levels. 17 out of 20 patients underwent minor amputations and 3 patients in group 1 underwent major amputations. Therefore 5% of patients belonging to group 1 underwent major amputations which is comparable to the results in literature.

In group 2 comprising of patients staged 4, 93 out of 103 patients [90.9%] had amputations within six months from recruitment which is in correlation to the results described in literature. Among 93 patients, 46 patients [44.7%] underwent minor

amputations while 47 patients [45.6%] underwent major amputations. Hence 45.6% of patients staged stage 4 underwent major amputations within six months of recruitment. The literature states approximately 90% major amputations in stage 4 patients within one year. Hence shorter follow up period may be considered as the reason for decrease in incidence of major amputations in stage 4 patients.

Breakdown of incidence of amputations in individual stages of group 1 denotes increase in incidence of amputations in patients with increasing stage. Among 30 patients under stage 1, 3 patients underwent amputations at a level distal to the ankle. None of them underwent major amputations.

Among 8 patients under stage 2, 6 patients underwent amputations and one of them [12.5%] underwent major amputation.

Among 22 patients in stage 3, 50% of them underwent amputations and 2 out of 11 underwent major amputations within six months from recruitment. 9 out of 22 patients underwent minor amputations.

Stage 4 results were reflected as group 2 results. Thus there is an increase in incidence of major amputations with increasing stages according to SVS-WIfI scoring system.

On breakdown of WIfI scoring system into individual components, increase in incidence of amputations was noted in increasing severity of wound characteristics, ischemia and foot infection. There was no patients scored wound 0 as patients with foot ulcers were only included in the study. Among wound graded 3, 100% of the patients had undergone amputations, out of which 90.9% were major amputations.

There was higher number of patients with vascularity of lower extremity within normal limits [Ischemia 0 -111patients]. All patients graded grade 3 ischemia had undergone amputations, out of which 62.5% of them had major amputations.

Foot infection grading indicated increase in incidence of amputation in both grades 2 and 3. Among 20 patients graded infection 2, 80% had undergone amputations, out of which 20% had major amputations. Among 101 patients graded infection 3, 84.15% had undergone amputations, out of which 40.6% had major amputations. This may be indicative of emergency amputations done for source control of sepsis.

Another secondary outcome studied was the relationship between incidence of amputations and glycaemic control reflected by HbA1C values done during the time of recruitment. Among 163 patients recruited for the study, 14 patients did not have

recent HbA1C values done. Among the 50 patients who had undergone major amputations,35 patients [70%] had HbA1C values of > 6.4 mmol/l.

Positive predictive value of stage 4 for amputations and major amputations is calculated to be 0.9 and 0.44 respectively. Negative predictive value of stages 1-3 for amputations and major amputations is 0.66 and 0.95 respectively. This is in accordance with the literature when considered for major amputations as shown below:

Table 2: Comparing the results with that from literature

	Positive predictive value for stage IV	Negative predictive value for stages I - III
Literature(14,15)	0.4	0.9
Calculated from the study	0.44	0.95

Thus SVS WIfI scoring system proves to be a good predictor of major amputations in patients with diabetic foot ulcers. However grading of the foot ulcer based on this system have not been checked for planning management of the same.

LIMITATIONS

- SVS WIfI scoring was initially designed to predict major amputations at 1 year of follow up. However, in view of limited time limit for follow up in this current study, the follow up period was limited to six months.

- Wound healing could not be assessed in this study as telephonic follow up was also accepted. Mere incidence of amputation was documented as outcome. Ulcers were assessed during the time of recruitment. However they were not assessed during follow up. Wound review after six monthly follow up can denoted wound healing by decrease in the WIfI scoring.

- HbA1C values were not regularly done for all the patients. Thus there was higher number of patients with no assessment of glycemic control. Good glycemic control is beneficial by favoring wound healing and decreases incidence of infections.

- Equal number of patients in different grading of the scoring system would represent a better distribution of study population and could have been useful in comparison of data.

- Transcutaneous oxymetry of the lower limb is indicative of the severity of cutaneous ischemia and is superior in detecting small arteriopathy. Ischemia status of the limb was assessed using ABPI values. If discrepancies seen, toe pressure was calculated and was used for grading severity of ischemia. A single criterion could have been used to prevent variability in data collection.

- Variations in treatment plan made by endocrinology department and general surgery department in the form of choice of antibiotics and need for investigations and interventions may have resulted in discrepancies in outcomes. However decision for amputation resided with the surgical department.

CONCLUSIONS OF THE STUDY

1. The SVS WIfI scoring system was predictive of major amputations in patients with diabetic foot ulcers within six months of recruitment.
2. Poor glycemic control was associated with worse outcome.

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ANNEXURES

1. IRB approval letter
2. Fund approval letter
3. Clinical research form
4. Patient information sheet [English provided]
5. Consent form [English provided]
6. Data sheet [excel]
7. Values in data sheet explained

IRB APPROVAL LETTER

OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA

Dr. B.J. Prashantham, M.A., M.A., Dr. Min (Clinical)
Director, Christian Counseling Center,
Chairperson, Ethics Committee.

Dr. Anna Benjamin Pulimood, M.B.B.S., MD., Ph.D.,
Chairperson, Research Committee & Principal

Dr. Biju George, M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

October 17, 2017.

Dr. Ashwin Prem Solomon,
Junior Resident,
Department of Surgery,
Christian Medical College,
Vellore – 632 002.

Sub: **Fluid Research Grant NEW PROPOSAL:**
Prediction of amputation in diabetic foot ulcers using SVS WIFi scoring system.
Dr. Ashwin Prem Solomon.P, Employment Number: 29635, Junior Resident, Surgery, DR. Sukria Nayak, Employment Number: 30005, Dr. Sunil Agarwal, General Surgery IV office, Dr. Albert Abhinay Kota, Employment number: 28763, Dr.L.Jeyaseelan, Biostatistics.

Ref: IRB Min. No. 10894 dated 03.10.2017

Dear Dr. Ashwin Prem Solomon,

The Institutional Review Board (**Blue**, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project titled "Prediction of amputation in diabetic foot ulcers using SVS WIFi scoring system" on October 03rd 2017. I am quoting below the minutes of the meeting.

The Committee raises the following queries:

1. How will the follow up occur – is it over telephone
2. How will the scoring be done
3. Decision to amputate may vary between physicians – how will you ensure that these influences do not affect the study
4. Is there a standard protocol for antibiotic use
5. Information sheet should start with "you are invited to participate"
6. Tamil version has may spelling mistakes – please recheck and correct it

Drs Ashwin Prem Solomon and Albert Abhinay Kota were present during the presentation of the proposal and satisfactorily responded to the queries raised by the Members. After discussion, it was resolved to **ACCEPT the proposal after receiving the suggested modifications and answers to the queries.**

Ethics Committee Blue, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002
Tel: 0416 – 2284294, 2284202 Fax: 0416 – 2262788, 2284481 E-mail: research@cmcvellore.ac.in

Dr. B.J. Prashantham, M.A., M.A., Dr. Min (Clinical)
Director, Christian Counseling Center,
Chairperson, Ethics Committee.

Dr. Anna Benjamin Pulimood, M.B.B.S., MD., Ph.D.,
Chairperson, Research Committee & Principal

Dr. Biju George, M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

Note: 1. Kindly HIGHLIGHT the modifications in the revised proposal.
2. Keep a covering letter and point out the answer to the queries.
3. Reply to the queries should be submitted within 3 months duration the time of the thesis/ protocol presentation, if not the thesis/protocol has to be resubmitted to the IRB.
4. The checklist has to be sent along with the answers to queries.

Email the details to research@cmcvellore.ac.in and send a hard copy through internal dispatch to Dr. Biju George, Addl. Vice-Principal (Research), Principal's Office, CMC.

Yours sincerely,

Dr. Biju George
Secretary (Ethics Committee)
Institutional Review Board.

Dr. BIJU GEORGE
MBBS., MD., DM.
SECRETARY - (ETHICS COMMITTEE)
Institutional Review Board,
Christian Medical College, Vellore - 632 002.

Cc: Dr Sukria Nayak, Department of Surgery - 4, CMC, Vellore.

IRB Min. No. 10894 dated 03.10.2017

Ethics Committee Blue, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002
Tel: 0416 – 2284294, 2284202 Fax: 0416 – 2262788, 2284481 E-mail: research@cmcvellore.ac.in

OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA

Dr. B.J. Prashantham, M.A., M.A., Dr. Min (Clinical)
Director, Christian Counseling Center,
Chairperson, Ethics Committee.

Dr. Anna Benjamin Pulimood, M.B.B.S., MD., Ph.D.,
Chairperson, Research Committee & Principal

Dr. Biju George, M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

November 23, 2017

Dr. Ashwin Prem Solomon.P,
Jr. Resident,
Department of General Surgery - 4,
Christian Medical College,
Vellore – 632 002.

Sub: **Fluid Research Grant NEW PROPOSAL:**
Prediction of amputation in diabetic foot ulcers using SVS WIFi scoring system. Dr. Ashwin Prem Solomon.P, Employment Number: 29635, Junior Resident, Surgery, DR. Sukria Nayak, Employment Number: 30005, Dr. Sunil Agarwal, General Surgery IV office, Dr. Albert Abhinay Kota, Employment number: 28763, Dr.L.Jeyaseelan, Biostatistics.

Ref: IRB Min. No. 10894 [OBSERVE] dated 03.10.2017

Dear Dr. Ashwin Prem Solomon.P,

I enclose the following documents:-

1. Institutional Review Board approval 2. Agreement

Could you please sign the agreement and send it to Dr. Biju George, Addl. Vice Principal (Research), so that the grant money can be released.

With best wishes,

Dr. Biju George
Secretary (Ethics Committee)
Institutional Review Board

Dr. BIJU GEORGE
MBBS., MD., DM.
SECRETARY - (ETHICS COMMITTEE)
Institutional Review Board,
Christian Medical College, Vellore - 632 002.

Cc: DR. Sukria Nayak, Dept. of General Surgery - 4, CMC, Vellore

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Ref: IRB Min. No. 10894 [OBSERVE] dated 03.10.2017

Dear Dr. Ashwin Prem Solomon.P,

The Institutional Review Board **(Blue**, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project titled "Prediction of amputation in diabetic foot ulcers using SVS WIFi scoring system" on October 03rd 2017.

The Committee reviewed the following documents:

1. IRB application format
2. Information Sheet and Informed Consent Form (English, Tamil, Telugu and Bengali)
3. Proforma
4. Cvs of Drs. Ashwin Prem Solomon.P, Albert Abhinay Kota, Sukria Nayak, L.Jeyaseelan, Sunil Agarwal,
5. No. of documents 1- 4.

The following Institutional Review Board (Blue, Research & Ethics Committee) members were present at the meeting held on October 03rd 2017 in the C K Job Hall, Paul Brand Building, Christian Medical College, Vellore 632 004.

2 of 4

Dr. B.J. Prashantham, M.A., M.A., Dr. Min (Clinical)
Director, Christian Counseling Center,
Chairperson, Ethics Committee.

Dr. Anna Benjamin Pulimood, M.B.B.S., MD., Ph.D.,
Chairperson, Research Committee & Principal

Dr. Biju George, M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

Name	Qualification	Designation	Affiliation
Dr. Biju George	MBBS, MD, DM	Professor, Haematology, Research), Additional Vice Principal , Deputy Chairperson (Research Committee), Member Secretary (Ethics Committee), IRB, CMC, Vellore	Internal, Clinician
Dr. B. J. Prashantham	MA(Counseling Psychology), MA (Theology), Dr. Min (Clinical Counselling)	Chairperson, Ethics Committee, IRB. Director, Christian Counseling Centre, Vellore	External, Social Scientist
Dr. Ratna Prabha	MBBS, MD (Pharma)	Associate Professor, Clinical Pharmacology, CMC, Vellore	Internal, Pharmacologist
Dr. Thomas V Paul	MBBS, MD, DNB, PhD	Professor, Endocrinology, CMC, Vellore	Internal, Clinician
Dr. Sowmya Sathyendra	MBBS, MD (Gen. Medicine)	Professor, Medicine III, CMC, Vellore	Internal, Clinician
Dr. Visalakshi. J	MPH, PhD	Lecturer, Biostatistics, CMC, Vellore	Internal, Statistician
Mr. C. Sampath	BSc, BL	Advocate, Vellore	External, Legal Expert
Dr. Sathish Kumar	MBBS, MD, DCH	Professor, Child Health, CMC, Vellore	Internal, Clinician
Mrs. Emily Daniel	MSc Nursing	Professor, Medical Surgical Nursing, CMC, Vellore	Internal, Nurse
Dr. Ajith Sivadasan	MD, DM	Professor, Neurological Sciences, CMC, Vellore	Internal, Clinician
Dr. Balamugesh	MBBS, MD(Int Med), DM, FCCP (USA)	Professor, Pulmonary Medicine, CMC, Vellore	Internal, Clinician

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Dr. Biju George, M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

Mrs. Pattabiraman	BSc, DSSA	Social Worker, Vellore	External, Lay Person
Dr. John Antony Jude Prakash	MBBS, MD	Professor, Clinical Microbiology, CMC, Vellore.	Internal, Clinician.

We approve the project to be conducted as presented.

Kindly provide the total number of patients enrolled in your study and the total number of Withdrawals for the study entitled: "Prediction of amputation in diabetic foot ulcers using SVS WIFi scoring system" on a monthly basis. Please send copies of this to the Research Office (research@cmcvellore.ac.in).

Fluid Grant Allocation:

A sum of 1,00,000/- INR (Rupees One Lakh Only) will be granted for 2 years. 50,000/- INR (Rupees Fifty Thousand only) will be granted for 12 months as an 1st Installment. The rest of the 50,000/- INR (Rupees Fifty thousand only) each will be released at the end of the first year as 2 nd Installment

Yours sincerely,

Dr. Biju George
Secretary (Ethics Committee)
Institutional Review Board

Dr. BIJU GEORGE
MBBS., MD., DM.
SECRETARY - (ETHICS COMMITTEE)
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CLINICAL RESEARCH FORM

CASE NO: ____

Christian Medical College, Vellore

Department of General Surgery

Prediction of amputation in diabetic foot ulcers using SVS WIFi scoring system. - Proforma

Name : **Date:**

Age : **Sex:** **Hospital No:**

BMI : **Phone No:**

Diabetic since : **Smoking:**

Other comorbidities :

SCORING:

Wound - Measurements: Hba1c :

Depth : Fasting lipid profile :

Infection- Local signs:

HR: RR:

Temp: TC/DC:

Ischaemia- ABPI:

Toe pressure:

TcPO2:

W	I	FI
STAGE		

FOLLOW UP:

Month:

Amputation : **YES / NO**

Operative intervention : YES / NO ; If YES,

_____

INFORMATION SHEET

Christian Medical College, Vellore

Department of General Surgery

Prediction of amputation in diabetic foot ulcers using SVS WIFi scoring system.

Information sheet

You are invited to take part in this study titled 'Prediction of amputation in diabetic foot ulcers using SVS WIFi scoring system'

If you take part what will you have to do?

If you agree to participate in this study, your base line data will be collected.

All the other treatments that you are already on will be continued and your regular treatment will not be changed during this study. Your laboratory results will be looked at and recorded.

After consenting for the study, you will receive phone calls from us at 6 months and we will ask certain questions. No additional procedures or blood tests will be conducted routinely for this study.

If at any time you experience any problems, you can report this to the doctor.

Can you withdraw from this study after it starts?

Your participation in this study is entirely voluntary and you are also free to decide to withdraw permission to participate in this study. If you do so, this will not affect your usual treatment at this hospital in any way.

What will happen if you develop any study related injury?

We do not expect any injury to happen to you because of taking part in this study.

Will you have to pay anything extra to take part in the study?

You will not incur any extra charges for taking part in this study

Any other treatment that you usually take will continue but the usual arrangements that you have with the hospital will decide how much you pay for this.

What happens after the study is over?

Outcome of your disease will not be affected by the study that you are a part of. However the conclusions drawn from this study will be useful to manage similar patients in future.

Will your personal details be kept confidential?

The results of this study may be published in a medical journal but you will not be identified by name in any publication or presentation of results. However, your medical notes may be reviewed by people associated with the study, without your additional permission, should you decide to participate in this study.

There will be approximately 150 participants enrolled for the study. You are urged to communicate the health condition to the best of your knowledge

If you have any further questions, please ask

Dr. Ashwin Prem Solomon.P, M.B.B.S.,

PG Registrar,

Department of General Surgery,

Christian Medical College Hospital,

Vellore, Tamilnadu

INFORMED CONSENT FORM

Christian Medical College, Vellore

Department of General Surgery

Prediction of amputation in diabetic foot ulcers using SVS WIFi scoring system.

Informed consent form

Informed consent form to participate in a research study

Study Title : Prediction of amputation in diabetic foot ulcers using SVS WIFi scoring system.

Study Number: _____

Subject's Name: _____

Date of Birth / Age: _____

(Subject)

(i) I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions. [ ]

(ii) I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. [ ]

(iii) I understand that the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from

the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. [ ]

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). [ ]

(v) I agree to take part in the above study. [ ]

Signature (or Thumb impression) of the Subject/Legally Acceptable

Date: _____/_____/_____

Signatory's Name: _____

Signature of the Investigator: _____

Date: _____/_____/_____

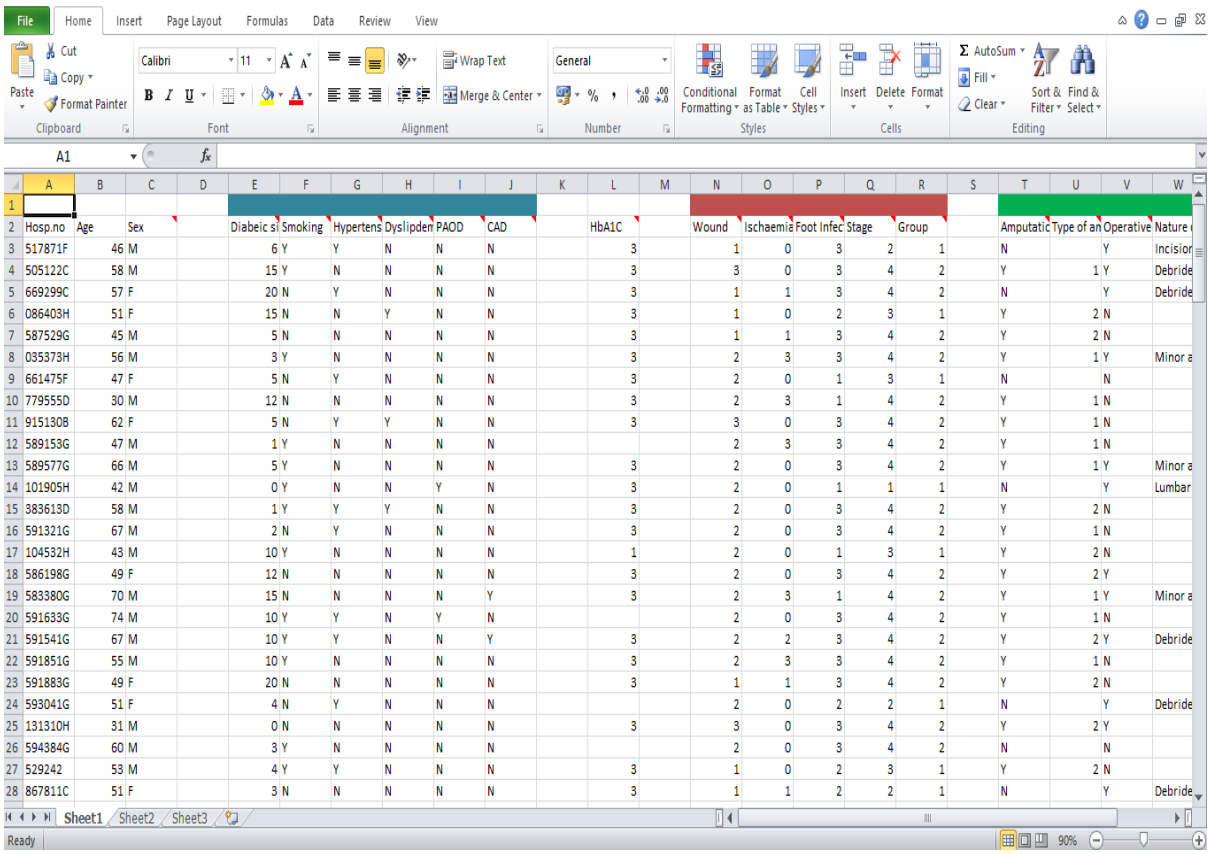
Study Investigator's Name: _____

Signature or thumb impression of the Witness: _____

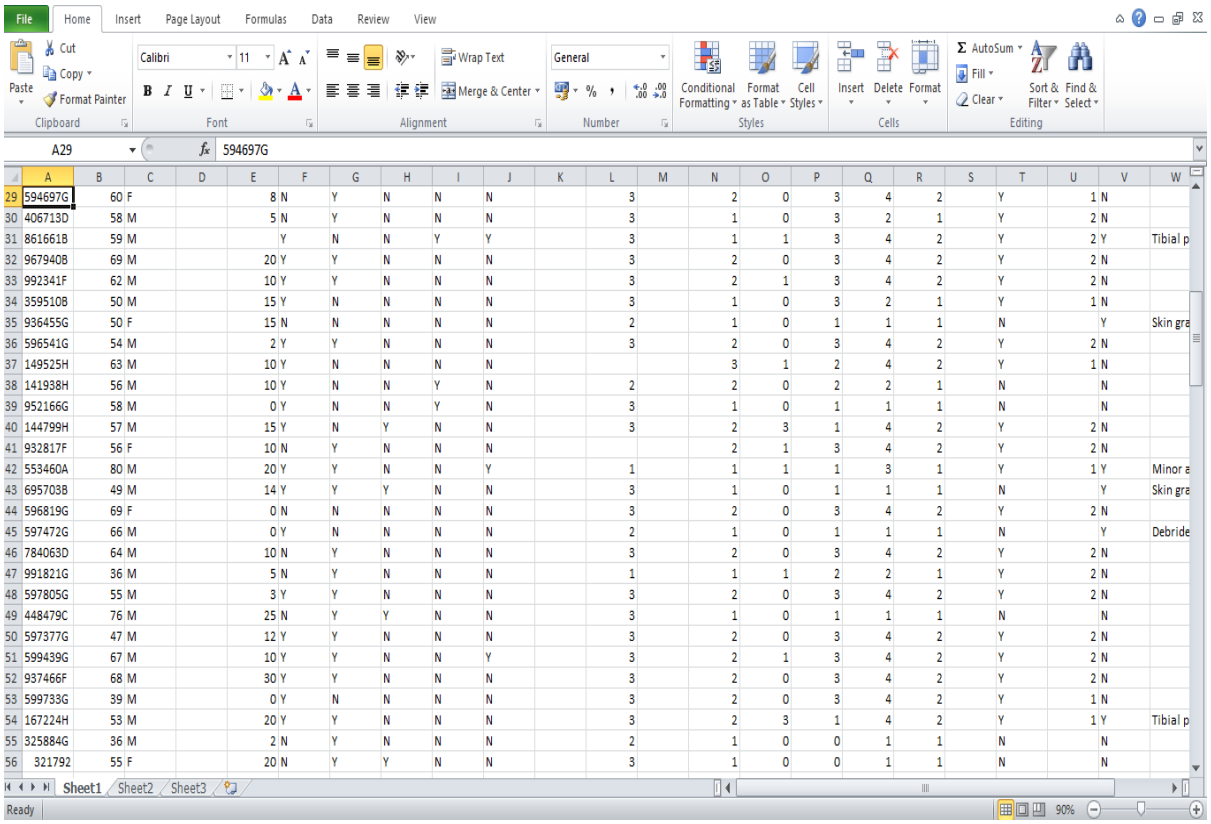
Date: _____/_____/_____

Name & Address of the Witness:

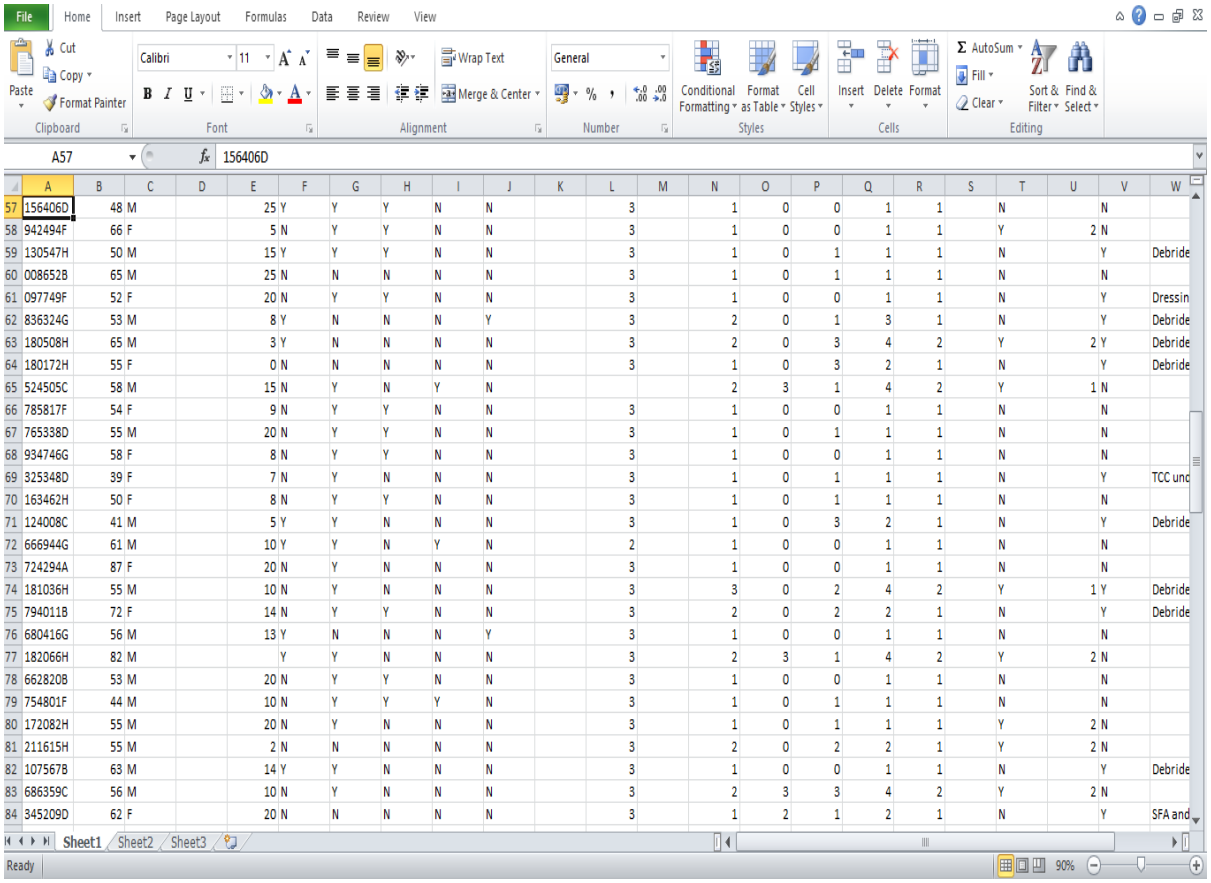
STUDY DATA



Hosp.no	Age	Sex	Diabetic s	Smoking	Hypertens	Dyslipden	PAOD	CAD	HbA1C	Wound	Ischaemia	Foot Infec	Stage	Group	Amputatic	Type of an	Operative	Nature
517871F	46	M	6	Y	Y	N	N	N	3	1	0	3	2	1	N		Y	Incisior
505122C	58	M	15	Y	N	N	N	N	3	3	0	3	4	2	Y	1	Y	Debride
669299C	57	F	20	N	Y	N	N	N	3	1	1	3	4	2	N		Y	Debride
086403H	51	F	15	N	N	Y	N	N	3	1	0	2	3	1	Y	2	N	
587529G	45	M	5	N	N	N	N	N	3	1	1	3	4	2	Y	2	N	
035373H	56	M	3	Y	N	N	N	N	3	2	3	3	4	2	Y	1	Y	Minor a
661475F	47	F	5	N	Y	N	N	N	3	2	0	1	3	1	N		N	
779555D	30	M	12	N	N	N	N	N	3	2	3	1	4	2	Y	1	N	
915130B	62	F	5	N	Y	Y	N	N	3	3	0	3	4	2	Y	1	N	
589153G	47	M	1	Y	N	N	N	N		2	3	3	4	2	Y	1	N	
589577G	66	M	5	Y	N	N	N	N	3	2	0	3	4	2	Y	1	Y	Minor a
101905H	42	M	0	Y	N	N	Y	N	3	2	0	1	1	1	N		Y	Lumbar
383613D	58	M	1	Y	Y	Y	N	N	3	2	0	3	4	2	Y	2	N	
591321G	67	M	2	N	Y	N	N	N	3	2	0	3	4	2	Y	1	N	
104532H	43	M	10	Y	N	N	N	N	1	2	0	1	3	1	Y	2	N	
586198G	49	F	12	N	N	N	N	N	3	2	0	3	4	2	Y	2	Y	
583380G	70	M	15	N	N	N	N	Y	3	2	3	1	4	2	Y	1	Y	Minor a
591633G	74	M	10	Y	Y	N	Y	N		2	0	3	4	2	Y	1	N	
591541G	67	M	10	Y	Y	N	N	Y	3	2	2	3	4	2	Y	2	Y	Debride
591851G	55	M	10	Y	N	N	N	N	3	2	3	3	4	2	Y	1	N	
591883G	49	F	20	N	N	N	N	N	3	1	1	3	4	2	Y	2	N	
593041G	51	F	4	N	Y	N	N	N		2	0	2	2	1	N		Y	Debride
131310H	31	M	0	N	N	N	N	N	3	3	0	3	4	2	Y	2	Y	
594384G	60	M	3	Y	N	N	N	N		2	0	3	4	2	N		N	
529242	53	M	4	Y	Y	N	N	N	3	1	0	2	3	1	Y	2	N	
867811C	51	F	3	N	N	N	N	N	3	1	1	2	2	1	N		Y	Debride



Hosp.no	Age	Sex	Diabetic s	Smoking	Hypertens	Dyslipden	PAOD	CAD	HbA1C	Wound	Ischaemia	Foot Infec	Stage	Group	Amputatic	Type of an	Operative	Nature
594697G	60	F	8	N	Y	N	N	N	3	2	0	3	4	2	Y	1	N	
406713D	58	M	5	N	Y	N	N	N	3	1	0	3	2	1	Y	2	N	
861661B	59	M		Y	N	N	Y	Y	3	1	1	3	4	2	Y	2	Y	Tibial p
967940B	69	M	20	Y	Y	N	N	N	3	2	0	3	4	2	Y	2	N	
992341F	62	M	10	Y	Y	N	N	N	3	2	1	3	4	2	Y	2	N	
359510B	50	M	15	Y	N	N	N	N	3	1	0	3	2	1	Y	1	N	
936455G	50	F	15	N	N	N	N	N	2	1	0	1	1	1	N		Y	Skin gra
596541G	54	M	2	Y	Y	N	N	N	3	2	0	3	4	2	Y	2	N	
149525H	63	M	10	Y	N	N	N	N		3	1	2	4	2	Y	1	N	
141938H	56	M	10	Y	N	N	Y	N	2	2	0	2	2	1	N		N	
952166G	58	M	0	Y	N	N	Y	N	3	1	0	1	1	1	N		N	
144799H	57	M	15	Y	N	Y	N	N	3	2	3	1	4	2	Y	2	N	
932817F	56	F	10	N	Y	N	N	N		2	1	3	4	2	Y	2	N	
553460A	80	M	20	Y	Y	N	N	Y	1	1	1	1	3	1	Y	1	Y	Minor a
695703B	49	M	14	Y	Y	Y	N	N	3	1	0	1	1	1	N		Y	Skin gra
596819G	69	F	0	N	N	N	N	N	3	2	0	3	4	2	Y	2	N	
597472G	66	M	0	Y	N	N	N	N	2	1	0	1	1	1	N		Y	Debride
784063D	64	M	10	N	Y	N	N	N	3	2	0	3	4	2	Y	2	N	
991821G	36	M	5	N	Y	N	N	N	1	1	1	2	2	1	Y	2	N	
597805G	55	M	3	Y	Y	N	N	N	3	2	0	3	4	2	Y	2	N	
448479C	76	M	25	N	Y	Y	N	N	3	1	0	1	1	1	N		N	
597377G	47	M	12	Y	Y	N	N	N	3	2	0	3	4	2	Y	2	N	
599439G	67	M	10	Y	Y	N	N	Y	3	2	1	3	4	2	Y	2	N	
937466F	68	M	30	Y	Y	N	N	N	3	2	0	3	4	2	Y	2	N	
599733G	39	M	0	Y	N	N	N	N	3	2	0	3	4	2	Y	1	N	
167224H	53	M	20	Y	Y	N	N	N	3	2	3	1	4	2	Y	1	Y	Tibial p
325884G	36	M	2	N	Y	N	N	N	2	1	0	0	1	1	N		N	
321792	55	F	20	N	Y	Y	N	N	3	1	0	0	1	1	N		N	



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58	942494F	66	F		5	N	Y	Y	N	N		3		1	0	0	1	1		Y	2	N	
59	130547H	50	M		15	Y	Y	Y	N	N		3		1	0	1	1	1		N		Y	Debride
60	008652B	65	M		25	N	N	N	N	N		3		1	0	1	1	1		N		N	
61	097749F	52	F		20	N	Y	Y	N	N		3		1	0	0	1	1		N		Y	Dressin
62	836324G	53	M		8	Y	N	N	N	Y		3		2	0	1	3	1		N		Y	Debride
63	180508H	65	M		3	Y	N	N	N	N		3		2	0	3	4	2		Y	2	Y	Debride
64	180172H	55	F		0	N	N	N	N	N		3		1	0	3	2	1		N		Y	Debride
65	524505C	58	M		15	N	Y	N	Y	N				2	3	1	4	2		Y	1	N	
66	785817F	54	F		9	N	Y	Y	N	N		3		1	0	0	1	1		N		N	
67	765338D	55	M		20	N	Y	Y	N	N		3		1	0	1	1	1		N		N	
68	934746G	58	F		8	N	Y	Y	N	N		3		1	0	0	1	1		N		N	
69	325348D	39	F		7	N	Y	N	N	N		3		1	0	1	1	1		N		Y	TCC unc
70	163462H	50	F		8	N	Y	Y	N	N		3		1	0	1	1	1		N		N	
71	124008C	41	M		5	Y	Y	N	N	N		3		1	0	3	2	1		N		Y	Debride
72	666944G	61	M		10	Y	Y	N	Y	N		2		1	0	0	1	1		N		N	
73	724294A	87	F		20	N	Y	N	N	N		3		1	0	0	1	1		N		N	
74	181036H	55	M		10	N	Y	N	N	N		3		3	0	2	4	2		Y	1	Y	Debride
75	794011B	72	F		14	N	Y	Y	N	N		3		2	0	2	2	1		N		Y	Debride
76	680416G	56	M		13	Y	N	N	N	Y		3		1	0	0	1	1		N		N	
77	182066H	82	M			Y	Y	N	N	N		3		2	3	1	4	2		Y	2	N	
78	662820B	53	M		20	N	Y	Y	N	N		3		1	0	0	1	1		N		N	
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82	107567B	63	M		14	Y	Y	N	N	N		3		1	0	0	1	1		N		Y	Debride
83	686359C	56	M		10	N	Y	N	N	N		3		2	3	3	4	2		Y	2	N	
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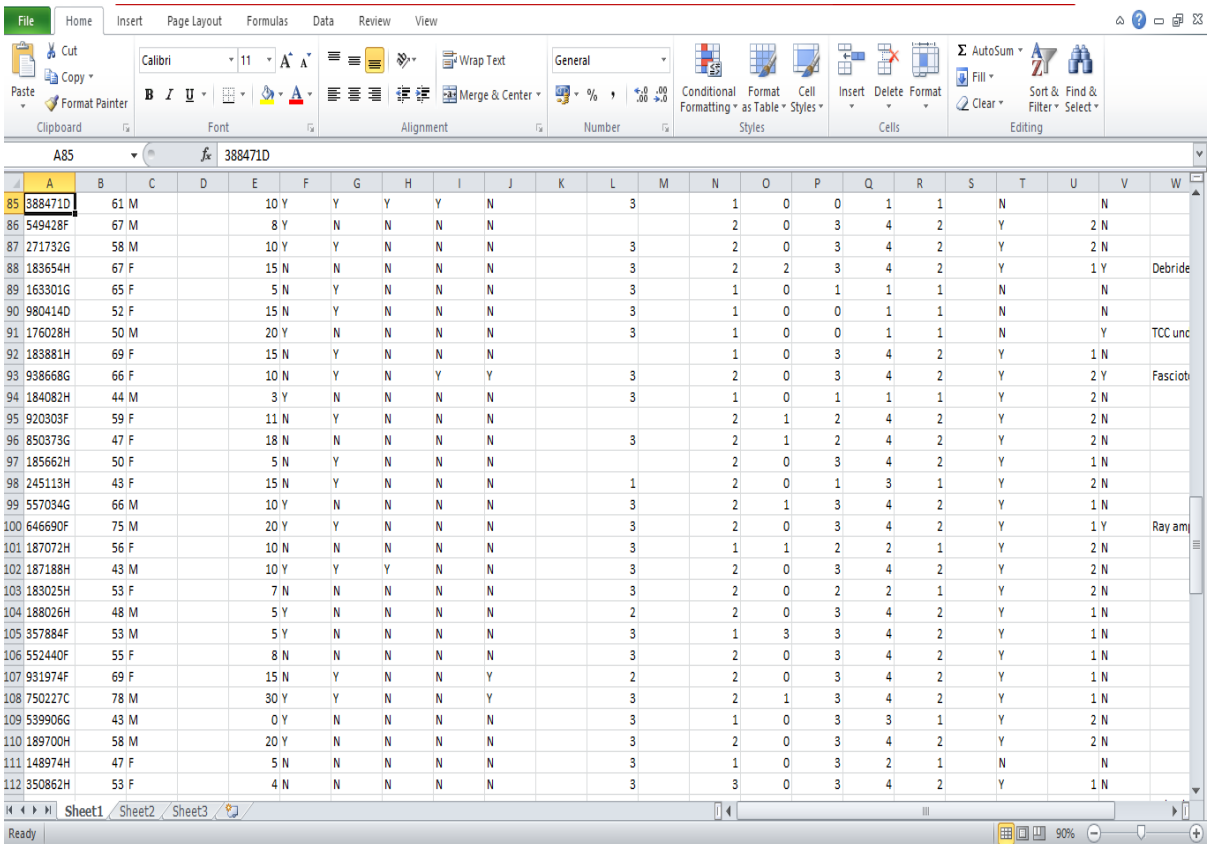

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	U	V	W
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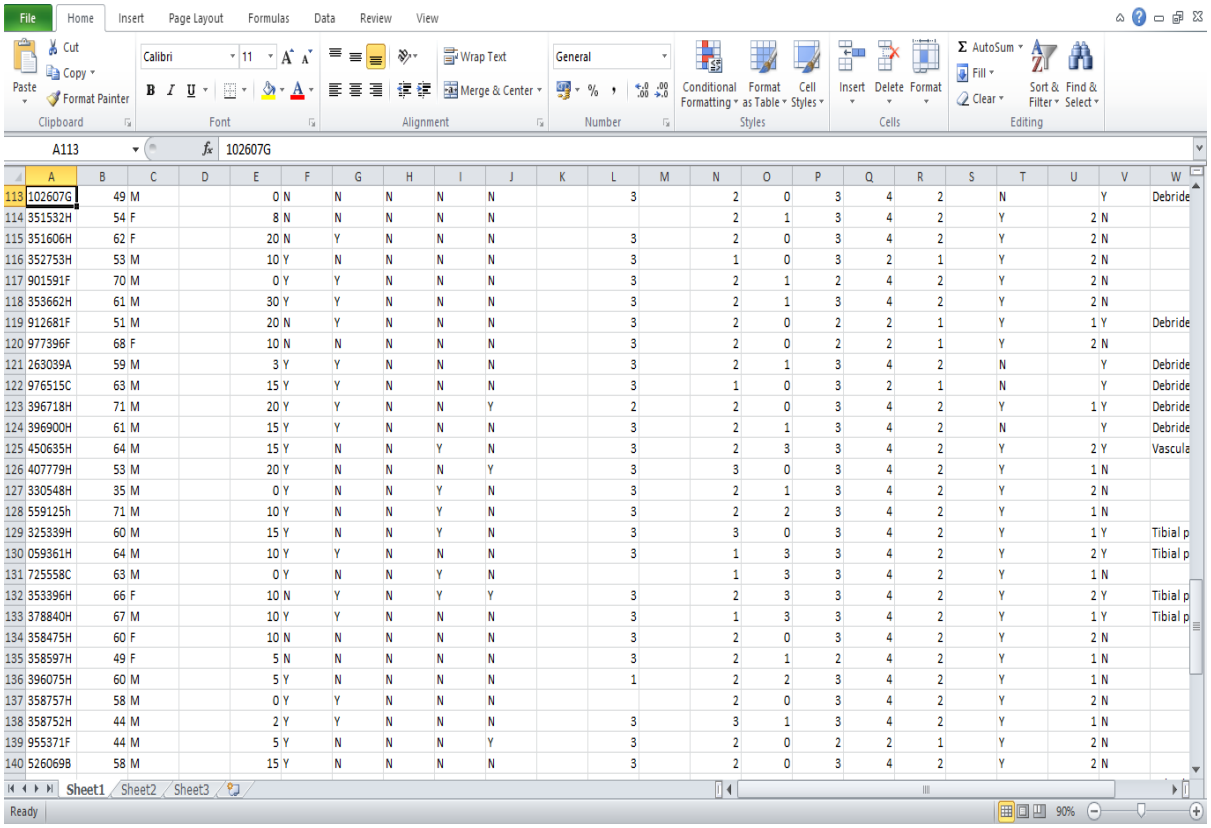

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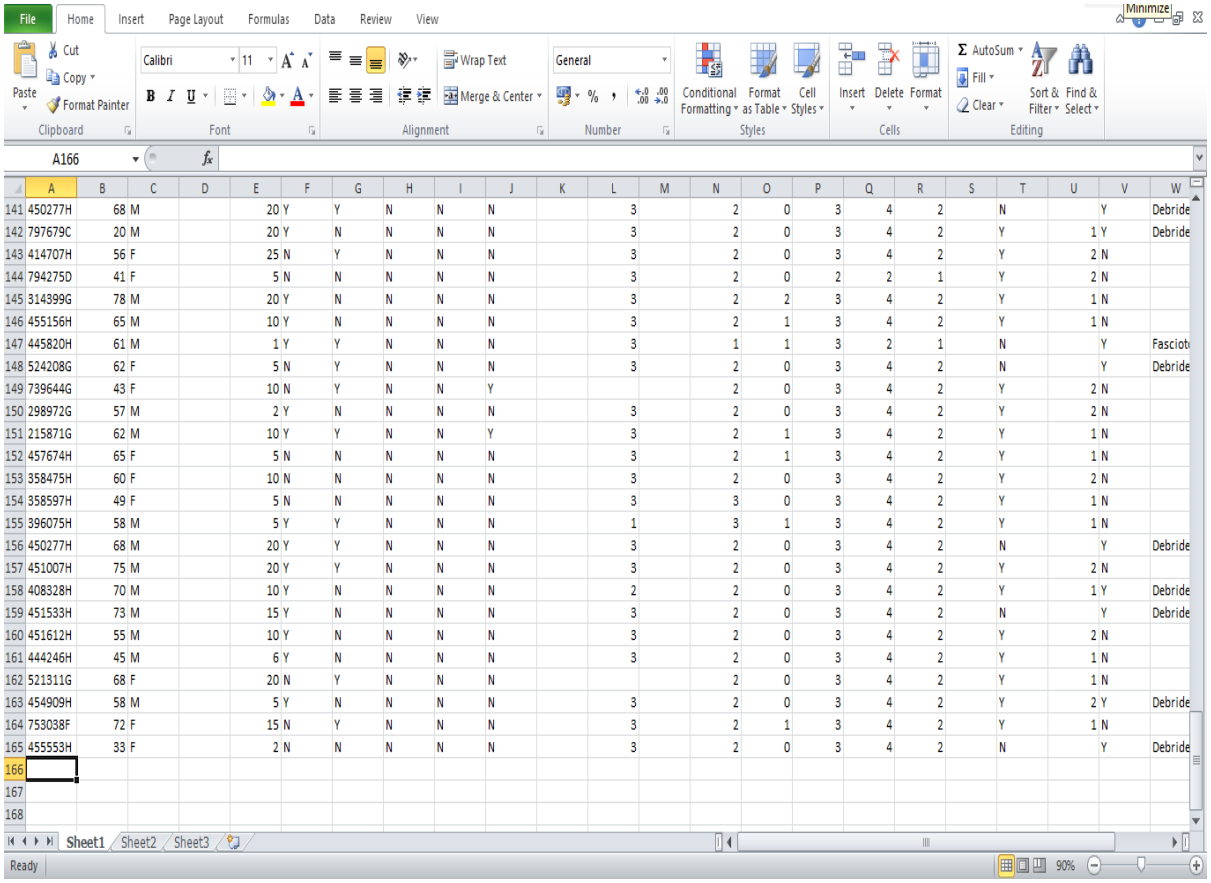

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166																							
167																							
168																							

VALUES IN DATA SHEET EXPLAINED

Gender:

M – Male

F – Female

Smoking history, hypertension,PAOD,CAD

Y – Present

N – Absent

HbA1C:

Blank – value not available

1 – < 5.7 mmol/L

2 – 5.7 – 6.4 mmol/L

3 – > 6.4 mmol/L

Wound, ischemia, foot infection, stage:

Value as in WIfI scoring system

Group:

1 – Stages 1-3

2 – Stage 4

Amputaion:

Y – Yes

N – No

Type of amputation:

1 – Major amputation

2 – Minor amputation

Operative intervention performed:[other than amputation]

Y – Yes

N – No

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