RISK FACTOR DIAGNOSTIC SCORE IN DIABETIC FOOT

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ABSTRACT

INTRODUCTION

Diabetic foot ulcers vary in their clinical presentation and nature of severity and therefore create a challenging problem to the treating surgeon regarding the prediction of the clinical course and the end result of the treatment. Clinical studies have shown that there are certain risk factors for the progression of foot ulcers in diabetics and it may therefore be possible to predict the course of an ulcer foot at presentation itself, thus instituting proper therapy without delay. Spoken otherwise clinical scoring may tell that this particular ulcer is having highest chance of amputation, then one may be able to take an early decision for the same and avoid the septic complications, inconvenience to the patient, long hospital stay and cost of treatments.

AIM OF THE STUDY

Aim of the study is to evaluate the above-mentioned scoring system in predicting the course the diabetic foot ulcers.

MATERIALS AND METHODS

50 patients with Diabetic Foot attending the OPD of Department of Surgery of Government Hospital attached to Calicut Medical College are included in the present study. After thorough history taking and clinical examination, six risk factors like Age, pedal vessels, renal function, neuropathy, radiological findings and ulcers were observed in the patients by giving certain scoring points to each of them. The total number of points scored by the patients at the time of admission or OPD treatment was correlated with the final outcome in these patients, whether leading to amputation or conservative management. All the data was analysed using standard statistical methods.

OBSERVATIONS AND RESULTS

There were 12 females and 38 males with a female to male ratio 1:3.1. All were aged above 30 years. Twenty-four (48%) of them were between 30-60 years and twenty six (52%) were above 60 years**.** 10 patients were treated conservatively with risk score range: 10 to 35. Six had single toe loss with risk score: 25 to 35. Six had multiple toe loss and heel pad loss with risk score: 35 to 45. 11 patients had toe loss with metatarsal nibbling with risk score: 50 to 70. Midtarsal amputation performed in 6 patients with risk score: 55 to 65. Below-knee amputation in 5 patients with score: 70 and 80. 6 patients underwent above-knee amputation with score: 80 and above.

CONCLUSIONS

The clinical scoring system evaluated in this study is useful in predicting the course of diabetic foot ulcers. The scores are directly proportional to the amputation level in the ascending order, from conservative treatment to above-knee amputation. Adjusted R square value of the correlation is 0.880 indicating a predictive value of 88% and the p value is 0 000 conferring statistical significance to the findings.

KEYWORDS

Diabetes, Diabetic foot ulcer, Risk factors, Hyperglycaemia, Type 2 DM, Type 1 DM, complications of DM, Neuropathy and amputation.

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INTRODUCTION: The prevalence rate of Diabetes Mellitus (DM) in India is 1-2% and in persons over the age of 15 years, the overall prevalence rate is 1.73% according to a multicentre study by ICMR.[1] Diabetes mellitus is a clinical syndrome characterised by hyperglycaemia due to absolute or relative deficiency of insulin. Lack of insulin whether absolute or relative affects metabolism of carbohydrate, protein, fat, water & electrolytes leading to a variety of physiological disturbances. The disease is traditionally divided in to type 1 and type 2.[2] Among the long term complications of DM, Diabetic Foot is encountered frequently in surgical practice. Approximately, 10 to 25% of all diabetics develop some foot problems during the course of their illness, ranging from simple calluses to major abscesses and osteomyelitis. It has been stated that decision making in diabetic foot ulcer is often personal, depending merely on the personal view of the treating surgeon.[3] There are certain risk factors for the progression of foot ulcers in diabetics and it may therefore be possible to predict the course of an ulcer foot at presentation itself, thus instituting proper therapy without delay.

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Clinical scoring may predict whether an ulcer is having highest chance of amputation, thus helping the surgeon to take an early decision and avoid the septic complications, inconvenience to the patient, long hospital stay and cost of treatments. One such system designed by the Surgery Department of Sri Ram Chandra Medical College and Research Institute, Chennai includes 6 parameters. It has been claimed that amputation rate is directly proportional to the score. The parameters included were Age of the patient, Pedal Vessels, Renal function, neuropathy, Radiological signs and Status of the Diabetic ulcer. The present study included all these parameters in patients attending the Department of Surgery of our Hospital to assess validity of the risk factors in diabetic foot patients.

AIM OF THE STUDY: Aim of the study is to evaluate the above-mentioned scoring system in predicting the course of the diabetic foot ulcers.

MATERIALS AND METHODS: 50 patients with Diabetic Foot attending the OPD of Department of Surgery of Government Hospital attached to Calicut Medical College were selected and a detailed history and clinical examination was carried out. Patients with the known and suspected risk factors for the development and progression of ulcers were included. They were followed up till the ultimate fate of the ulcer was decided for a period of two years till Nov 2010. At the end of the study, the scores are calculated and relationship between the score and successful treatment in conservative form and amputation are analysed.

The Scoring System: It was designed by the Surgery Department of Sri Ram Chandra Medical College and Research Institute, Chennai which included 6 parameters (Table 1).

Parameters	Points
Age	
<30 years	0
30-60 years	5
>60 years	10
Pedal vessels	
Normal	0
DP or PT absent	10
Both absent	20
Renal function	
Normal	0
Mild depression	5
ESRD	25
Neuropathy	
Category – 1	0
Category – 2	15
Category – 3 or 4	25
X-ray findings	
Normal	0
One finding	5
>one finding	10
Ulcers	
None	0
Wagner 0- 2	5
Wagner 3-5	10

Table 1: Showing the Risk Factors and their Scoring

Inclusion Criteria:

1. Patients of all ages with diabetic foot.
2. Patients either treated as Inpatients or Outpatients.

Exclusion Criteria:

1. Presence of varicose veins in any lower limb.
2. Present or past history of deep vein thrombosis.
3. Presence of Hansen's disease.
4. Immunocompromised states such as AIDS, steroid therapy.
5. Known cases of connective tissue disorders.
6. Neurological illnesses causing immobility of the limbs.

Criteria Definitions: 1. Age: As stated by the patient. 2. DP (dorsalis pedis) and PT (posterior tibial) pulsations: As palpated with fingers. 3. Renal status: Described as normal if no renal disease was present. Mild depression if presence of any one of the following factors like serum creatinine more than 1.5 and presence of albumin in routine urine examination. Clinical diagnosis of CRF in the patient previously end-stage renal disease (ESRD); is defined as previous or present requirement of dialysis for renal support.

NEUROPATHY: Category 1: No loss of sensation, Category 2: Loss of sensation present. Category 3: Loss of sensation with deformity. Category 4: Loss of sensation with ulceration. Loss of sensation is arbitrarily taken in the study as presence of any two among the following: 1. Loss of fine touch sensation. 2. Loss of vibration sense. 3. Loss of position sense. 4. Loss of power. 5. Presence of dryness of feet, an evidence of autonomic neuropathy.

X-RAY FINDINGS: Abnormal findings in x-ray of the foot. The findings to be looked for in a conventional x-ray include the following: 1. Arterial calcifications. 2. Bony deformities and collapsed arches. 3. Charcot's joints. 4. Demineralisation and osteopenia. 5. Oedema of soft tissue. 6. Foreign bodies. 7. Gas in the soft tissue. 8. Evidence of prior surgery or autoamputations. 9. Osteomyelitis. 10. Pathological fractures.

ULCER GRADING: As per Wagner classification.

INTERVENTIONAL CRITERIA: The study did not involve any kind of intervention at any stage of the disease process, in clinical or laboratory investigations or in the treatment offered to the patient. When a suitable patient is admitted in the ward, the risk factors are calculated and the patient receives standard treatment provided in the surgical treatment units and the end result is finally noted. A standard Proforma was used in recording the history and clinical examination of the patient in general and the diabetic foot in particular. All the data was analysed using the standard statistical methods.

OBSERVATIONS: A total number of 50 patients were treated in the department of Surgery was evaluated using the clinical risk factor scoring system and their data were systematically analysed. Scores varied from 0 to 100 and

levels of foot amputation varied from single toe loss to above-knee amputation. The following observations were made, which include certain parameters not related to the aim of the study as well. Twelve (12) out of fifty participants were females (24%). The remaining 76% were Male patients (Fig1). The female to male ratio was 1: 3.1.

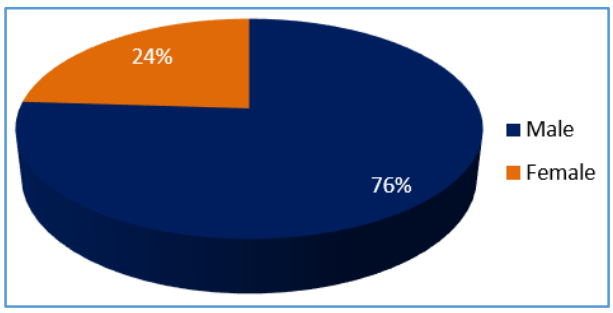


Fig. 1: Showing the Incidence of Diabetic Foot in Males and Females (n=50)

All the patients in the study were aged above 30 years. Twenty-four (48%) of them were between 30-60 years and twenty-six (52%) were above 60 years (Fig. 2).

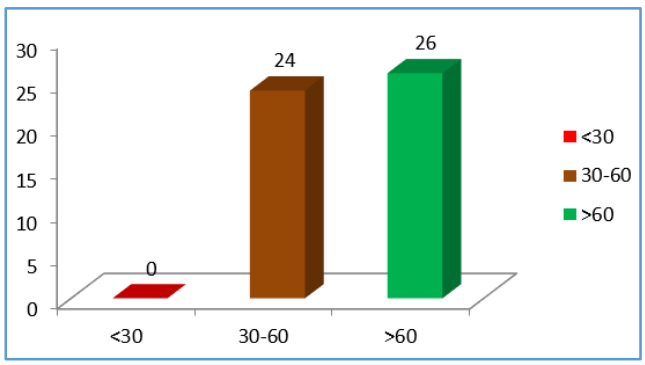


Fig. 2: Showing the Age Incidence of Diabetic Foot (n=50)

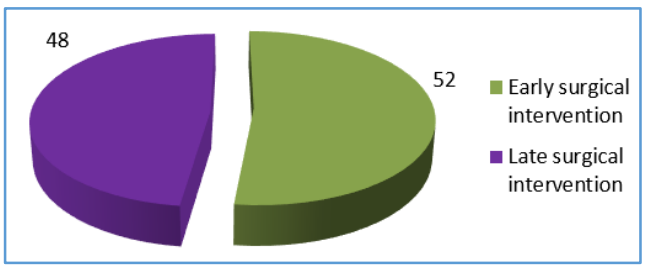
The Chief Observation: The objective of the study being evaluation of the clinical scoring system with respect to its usefulness in predicting the clinical course of diabetic foot ulcers, the following observations were made. Among the 50 patients, 10 belonged to conservative group and their risk score varied from 10 to 35. Six patients had single toe loss and their risk score varied from 25 to 35. Six patients had multiple toe loss and heel pad loss and their risk score varied from 35 to 45. Eleven (11) patients had toe loss with metatarsal nibbling and their risk scoring varied from 50 to 70. Midtarsal amputation was done in 6 patients with risk score varying from 55 to 65. Below-knee amputation was done in 5 patients with scores between 70 and 80. 6 patients underwent above-knee amputation with scores 80 and above (Table 2).

Patient	Total Number	Total scores
1. Conservative group	10	10,10,15,15,15,15,20,20,20,20,35
2. Single toe loss	6	25,25,30,30,30,35
3. Multiple toe loss (heel) pad loss)	6	35,35,40,40,40,45
4. Toe loss with metatarsal nibbling	11	50,50,50,55,55,55,55,55,60,65,70
5. Midtarsal amputation	6	55,60,65,65,65,65
6. Below–knee amputation	5	70,70,75,75,80,80
7. Above-knee amputation	6	80, 80, 80, 85, 85, 90

Table 2: Showing the number of Patients in Different Groups of end results and their Risk Scoring (n=50)

Other Incidental Observations: 1. Score increased from conservative group as level of amputation or toe loss ascended up. 2. Only two patients out of fifty participants answered in the affirmative regarding question whether there were foot problems that can occur in diabetic patients.

26 patients obtained proper surgical intervention for their ulcers early in the course of illness which is arbitrarily taken as within one week. 24 patients were late to get proper intervention, i.e. after one week.



Twelve out of fifty patients revealed renal disease identified by the criteria of protocol (i.e. 24%) (Fig. 3).

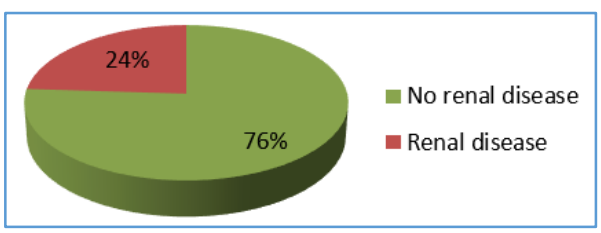


Fig. 3: Showing the Incidence of Renal Disease accompanying the Diabetic Foot (n=50)

The different causes of the initialising ulcer in the study group were identified as follows:

Spontaneous or unknown in 32, Trauma accidental in 10, Nail cutting in 6, Callus in 6, Web space intertrigo in 2, Heel/Sole fissures in 2, Fungal nail infections in 3 (Fig. 4).

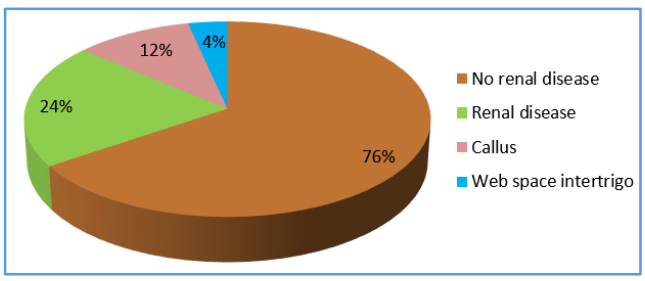


Fig. 4: Showing the Factors of Initialising of the Diabetic foot in the study Group (n=50)

The Duration of diabetes Mellitus varied in the study group as follows: Recent onset (<1 year) in 2 patients, 1 to 10 years in 22 patients (44%), and more than 10 years in 26 patients (52%).

The relationship between duration of diabetes mellitus and amputation level was unpredictable and showed wide variation.

Sl. No.	Surgical Outcome	Number of years with DM	Neuropathy		Regularity of treatment of DM		Surgical intervention	
			CAT-1	CAT-4	Regular	Irregular	Early	Late
1	Conservatively treated	2,3,4,8,8,10,11,14,20,44	9	1	7	3	3	5
2	Single toe loss	6,8,10,10,14	6	0	4	4	3	3
3	Multiple toe loss or loss of heel pad	2,4,7,8,16,20	5	1	2	4	2	4
4	Toe loss with nibbling of Metatarsal	5,8,10,10,10,15,23,24,25,25	0	1	4	5	6	5
5	Midtarsal amputation:	8,10,10,12,16,18	0	6	4	2	3	3
6	Below-knee amputation	5,8,12,16,20,20	0	5	5	1	2	3
7	Above–knee amputation	9,8,8,18,18,20,40	0	6	4	2	3	3

Table 3: Showing the Duration of DM and Surgical Outcome Relationship (n=50)

The relationship between level of amputation and delay in surgical intervention did not show great correlation (Table 3). Relationship between level of amputation and category of neuropathy showed good correlation (Table 3). Relationship between level of amputation and regularity of diabetic treatment was not correlating (Table 3).

DISCUSSION: Diabetes is a leading cause of mortality and morbidity worldwide. It affects 30 million people throughout world with a prevalence of 2-5% in adult population[1]. Diabetes mellitus results in two types of complications[2] like acute complications such as hypoglycaemia, ketoacidosis, nonketotic hyperosmolar coma, lactic acidosis, and acute circulatory failure; long term complications of the disease such as diabetic neuropathy, retinopathy, nephropathy and foot complications. The relationship between diabetic neuropathy and foot ulceration was recognised by Pryce, a British surgeon over a century ago.[3] He stated that it was abundantly evident that the actual cause of the perforating ulcer was peripheral nerve degeneration and that diabetes itself played an active part in the causation of the perforating ulcer.[4] The morbidity in foot disease in Diabetes extracts a considerable toll, not only on health care provision, but especially on patients.[5] Studies have also shown that there is 7% prevalence of active ulceration in foot problems and 3% prevalence of amputation of all or part of foot.[6] At the Indian Institute of Diabetes in Mumbai, more than 10% of all admissions for diabetes are primarily for foot management. More than 70% required surgical intervention and in more than 40% of those interventions, there was a limb or toe amputation. The lack of specialised Chiropody services in India compounds the problems as well. Despite this gloomy picture some glimpses are in the sky and dedicated diabetic foot clinics are being established.[7]

Changes in skeletal system in Diabetic Patients include osteomyelitis secondary to overlying skin necrosis; gas may be seen in soft tissues, Charcot's joints or neuropathic foot, calcification, resorption of terminal tufts of terminal phalanges, localised osteoporosis and subluxations. Pathological changes in diabetic foot result from neuropathy, infection or combination of the two. Although diabetic angiopathy may cause overall ischaemia, autonomic neural impairment results in loss of vasoconstriction in smaller vessels causing hyperaemia and osteoporosis. Chronic hyperglycaemia also causes damage to vasa nervorum of peripheral nerves resulting in glove and stocking anaesthesia of peripheral neuropathy. The foot consequently provides fertile ground for spread of infection to bone from penetrating ulcers and local cellulitis. Because of difficulty in distinguishing the coincidental effects of ischaemia, neuropathy and infection, the blanket term osteopathy is generally used. Radiological diagnosis of acute osteomyelitis on radiographs takes 8-10 days after onset but clue to underlying process may be gained by soft tissue radiograph showing displaced fascial planes and disappearance of fat shadow as a result of oedema fluid osteoporosis is present. In chronic osteomyelitis, plain films typically show ill-defined areas of bone destruction with adjacent areas of remodelling and cortical thickening.[7,8] Pathogenesis of Arteriosclerosis in

Diabetes Mellitus has been reviewed by Cotwell et al, the deposition of lipids, cholesterol, calcium, smooth muscle cells and platelets in plaque are qualitatively same but much greater in quantity in diabetes mellitus. There is often multisegmental involvement, collateral involvement, and involvement of both tibial and peroneal vessels.[7] Charcot's joint is an extreme progression of degenerative osteoarthritis following a loss of proprioceptive or pain sensation.[9] The normal protective reactions are not involved. Relaxation of supportive structures leads to joint instability. Radiologically two forms are known - Atrophic and hypertrophic. Atrophy is seen in upper limb while other form in lower limbs. Spine shows only hypertrophy changes. The underlying disease does not determine which form predominates. Atrophic type is seen as resorption of ends of bone, osteoporosis, no osteophytes or sclerosis, fragmentation or soft tissue debris seen. Hypertrophic arthropathy is also initiated by effusion. Narrowing of joint space, marked bony sclerosis occurs. Fracture and fragmentation of articular surface follow. Periosteal new bone formation may occur. Subluxations and dislocation proceed to destruction, to mal-alignment of articular surface and finally to total disorganisation of joint. Radiographic pattern of deossification common to many diseases are best explained by topographic and anatomic relationships of circulatory system of bone.[10] These patterns of local and regional osteoporosis seem to be a function of a disturbance of nutritional circulatory fields in a particular anatomic site rather than a result of direct effect of disease on cellular activity. Five such patterns are identified based on nutritional circulatory fields associated with Hunters circulus articuli vasculosus. Metaphyseal bands, Metaphyseal cutbacks, epiphyseal sub-articular deossification, combination of these patterns and acute diffuse osteoporosis.[11] Different combinations of these patterns may correlate with combined nutritional circulatory field. One of the particular interests is epimetaphyseal sharpener, which results from combination of Metaphyseal cutback and epiphyseal sub-articular deossification occurring in circumferential manner. This produces a pencil point appearance at the end of a bone or several bones. If the Metaphyseal band deossification is added to Metaphyseal cutback and epiphyseal sub-articular deossification, the appearance of surgical resection may be produced.[12] This pattern is present in many neuropathic joints. Combination patterns are quite frequent. They may occur with Charcot's joints of syphilis, spinal cord injuries, aseptic necrosis, and arthritis mutilans from leprosy, sarcoidosis, Diabetes, psoriasis and rheumatoid arthropathy. Acute diffuse osteoporosis may be seen with burns, frostbite, electroshock, infection, rheumatoid arthritis, shoulder hand syndrome, trauma with or without fracture, Buerger's disease, Raynaud's phenomenon and Diabetes as mottled or spotty osteoporosis may be observed through a large portion of bone or involving many bones of a part. This occurs predominantly in tarsal and carpal bones.[13] Several circulatory fields are involved. Radiographs are characterised by a decreased and mottled density of bone in cortical and cancellous bone.[14] The aetiology of diabetic foot disease is truly multifactorial. Within one individual patient, one factor may predominate and probably account for varying nature of behaviour of foot problems. The risk factors can be classified in terms of pathophysiology of diabetic ulcers in terms of major and minor risk factors as follows: Major: 1. Neuropathy. 2. Vasculopathy. 3. Infections. The Minor factors are: 1. Arch collapse. 2. Microcirculatory abnormality. 3. Glycosylation of skin proteins. 4. Reduced host immunity. 5. Altered blood viscosity and rheological property. 6. Associated renal oedema. 7. Hypertension-induced vessel thickness. 8. Increased weight due to obesity. The changes are gradual and relentless; progressing despite adequate control of sugar but tight control nevertheless slows the process.[15] There are essentially two theories as to the causation of diabetic peripheral neuropathy. One related to metabolic factors and the other associated with microvascular disease. Again, there are two mechanisms by which neuropathy leads to ulcer formation. Extrinsic Neuropathic Ulceration: Here the foot being insensate, patient neglects or is unaware of ongoing trauma. The initial trauma is often trivial but in such situations its progress is unlimited due to lack of care from the patient. At the end point of this insult, an established diabetic foot ulcer results.[16] In a prospective study conducted in the Department of Surgery, Government Medical College Hospital, Kozhikode 50 patients with Diabetic foot were included and their surgical status of the foot examined and proper history was taken and the parameters were entered in a printed Proforma. The ethical committee clearance certificate was obtained from the college authorities prior to the start of the study. Table 2 shows the Surgical Risk Score of the Diabetic foot of these patients. The patients were grouped depending upon their surgical outcome and their risk score was found to vary from 10 to 80. As the table depicted looked cumbersome, it is shown in Fig 5 in a graphic manner. Total score is projected along the Y-axis while graph level of amputation is projected along X-axis. Levels of amputation are numbered as follows: 1. Conservatively treated. 2. Single toe loss. 3. Multiple toe loss or loss of heel pad. 4. Toe loss with nibbling of metatarsal. 5. Midtarsal amputation. 6. Below-knee amputation. 7. Above–knee amputation.

Total score:

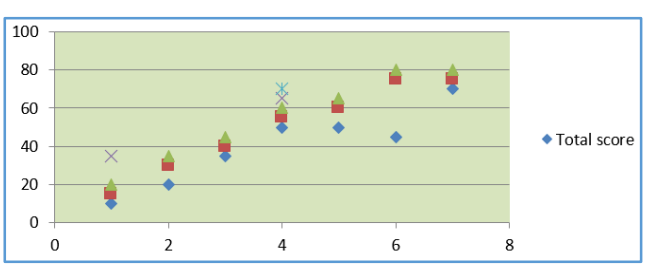


Fig. 5: Showing the Total score versus Surgical Outcome of the Diabetic Foot Patients (n=50)

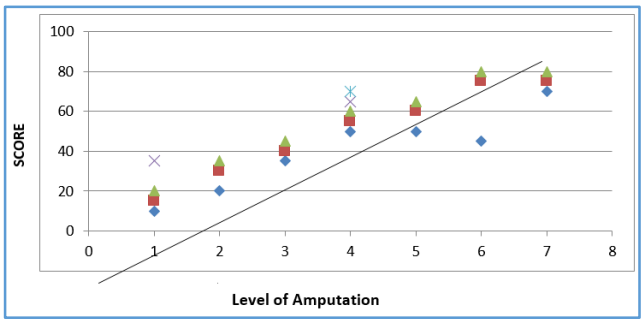


Fig. 6: Showing the Graphic Representation of the Risk score and level of Amputation (n=50)

Level of Amputation:

Model	R	Adjusted R Square
1	.939	.880

ANOVA:

Model		Df	F	P value
1	Regression	.939	359.694	.000

Adjusted R^2 value 0.880 means that the probability of prediction to be correct is 88%. The above-mentioned statistical data attests to the positive correlation of the study between the level of amputation and the total clinical scores. When the score is projected along the Y-axis and level of amputation along the X-axis the resultant graph is a straight line indicating that the clinical score is directly proportional to the level of amputation.

Other Observations: 1. All patients who were studied were above 30 years, 50% of them being above 60 years. 24% of the total patients were females. Considering the small number of the study group and possible selection bias, a significant statistical value may not be attributed to these findings. 2. Commonest cause of ulceration has been identified as unknown trauma or spontaneous cause (64%) followed by accidental trauma (20%). 3. An important finding noticed is the widespread ignorance among the diabetic patients regarding the chance of their foot becoming problematic due to diabetes. Only 2 patients among the 50 (4%) ever knew that they might develop a foot problem before they actually developed it. It is also interesting to note that less than half the number of total patients (52%) received early surgical intervention which is arbitrarily taken as within first week of developing their foot symptom. 4. 24% of patients had renal disease detected by the criteria of the study protocol. This is comparable to the statistics of diabetic literature, providing a simple tool for bedside evaluation of renal status of the patients. 5. An attempt was made in the study analysis to relate various risk factors, some of which are essential components of the scoring system, with respect to various levels of amputation. Most factors did not show an individual correlation probably because of the multifactorial nature of the pathogenesis of diabetic foot ulcers. Anyhow the most consistent relationship was shown to occur between the category of neuropathy and level of amputations. 90% of conservatively treated group and 100% of single toe loss group were in category 1 neuropathy (i.e. no neuropathy) whereas 100% patients who had to undergo an amputation greater than metatarsal nibbling were in category 4. This is obviously in accordance with the statistically proven chief observation because among all others the highest component score was allotted to the category of neuropathy. Time lag between the onset of symptoms and first surgical intervention was found to be almost equally distributed in different groups and duration of diabetes varied greatly in all groups indicating that they are of not much use in predicting the prognosis. Even the regularity of diabetic treatment did not show any prognostic significance. 70% of the conservatively treated group and 67% of the single toe loss group were getting regular treatment for their diabetes compared to similar statistics in the below-knee amputees (83% of whom received regular treatment) and in the above-knee amputees (67% of whom received regular treatment).

Uses of Scoring System: After conducting the study and finding it to be statistically significant, I would like to enlist certain uses of the scoring system in the clinical setup. Clinical practice in diabetic foot ulcers is based more on opinion than scientific facts (Jeffcott, W. J. Diabetic foot ulcers. The Lancet. May 2006; 361-9368 Pp 1545-9). Clinical scoring system is a means to make the decision making scientific using a simple, bedside and easily reproducible tool. Lacking a proper prognostic stratification for the diabetic foot ulcerations, the scoring system may help to compare different group of diabetic feet for various other research purposes. It will also help in predicting the prognosis and in explaining the patients the course of the illness right from the beginning. The prognostic information thus obtained is also useful for instituting proper interventional measures and deciding for early amputation in a patient with a very high score, sparing him from the inconvenience and ill effects of a prolonged and wasteful conservative treatment in that particular setup. This is also useful for identification of at-risk groups.

SUMMARY: A study of 50 cases of diabetic foot ulcers who presented to the Surgery Department of Calicut Medical College was conducted for assessing the validity of the clinical scoring system in predicting the course of diabetic foot ulcers. The patients were assessed for their score using a simple bedside scoring system which comprised of their age, palpability of pedal vessels, renal status, and category of neuropathy, abnormal X-ray findings and grade of foot ulceration. They were followed up until the ultimate fate of their limb is reached, whether complete healing or various levels of amputations. At the end of the study, the data were analysed to find out whether the total scores obtained did show any

relationship to the levels of amputation arranged from distal limb loss to high amputation.

CONCLUSIONS: The clinical scoring system evaluated in this study is useful in predicting the course of diabetic foot ulcers. The scores are directly proportional to the amputation level in the ascending order, from conservative treatment to above-knee amputation. Adjusted R square value of the correlation is 0.880 indicating a predictive value of 88% and the p value is 0.000 conferring statistical significance to the findings.

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