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Study on the Economical Way to Offload Diabetic Foot Ulcers: A Prospective Study

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Abstract: ***The rate of limbs lost from diabetes is 28 times greater than those without diabetes. Yet the American Diabetes Association estimates that 85 % of limb loss is preventable. Management of diabetic foot requires a multi system approach that addresses optimal wound care which includes appropriate antibiotic, proper wound cleansing, debridement of any callus and necrotic tissue, focused wound care with application of tissue regenerators and specially off - loading of pressure.***

Keywords: diabetic foot ulcers, offloading pressures over foot

1. Introduction

Diabetic foot ulcers cause substantial morbidity. Prevention and care of diabetic complication of the foot continue to represent a major challenge to the surgeon. Neuropathy, infection, deformity and ischemia are major threats to the diabetic foot and overall functional wellbeing of the diabetic patient. The costs associated with adequately caring for these problems represent a significant impact to the health care system. Diabetes is the leading cause of amputation worldwide. Diabetes constitutes 51% of patients needing lower extremity amputation and more than 54,000 new lower extremity amputations are performed each year.

2. Materials and Methods

1) **Study Area**
   Department of General Surgery, Patna Medical College and Hospital, Patna – 4
2) **Study Population**
   Patients suffering from diabetes mellitus (both type 1 and type 2) with planter foot ulcers attending the Out Patient Department, Emergency Department and also Indoor patients.
3) **Study Period**
   From Jan 2012 to June 2013 – eighteen (18) months.
4) **Sample Size**
   Thirty (30) patients of diabetes mellitus (both type 1 & type 2) with foot ulcers.
5) **Sample Design**
   All consecutive patients attending the General Surgery Out Patient Department, Emergency Department and also the Indoor patients (of the candidate's unit) with diabetic foot ulcers during the period of eighteen (18) months commencing from Jan 2012 willing to participate in the study were enrolled.
6) **Study Design**
   The study design was kept simple. It was a prospective, observational study.
7) **Parameters to be Studied**
   a) ***Parameters of specific objective No. 1:*** A careful history and physical examination, blood glucose estimation and in cases estimation of glycosylated hemoglobin (HbA_1C) for assessment of long term blood glucose status. Assessment of sensory impairment by using Semms-Weinstein monofilament. On presentation of an infected diabetic foot ulcer, deep swabs or a tissue biopsy was taken for microbiological culture and microscopy. Complete hemogram (particularly total leukocytes count, erythrocyte sedimentation rate, hemoglobin level), imaging modalities (like X ray of the affected limb, bone scan, Doppler study of vascular system).
   b) ***Parameters of specific objective No. 2:*** The traditional classification system developed by Wagner for grading diabetic foot ulcers has been used. Diabetic foot infections, divided in to two categories known as non-limb threatening and limb threatening infections are also taken in to consideration.
   c) Parameters of specific objective No. 3:The ulcer outcome was based on:
   - Cultural assessment with baseline macroscopic and microscopic evidence.
   - Eradication / clearance of infection.
   - Need for special rehabilitation measures.
   - Time need for mobilization and return to routine / active life.
   - Need for amputation.
8) **Study Tool:** Different study tools ranging from history taking to application of tissue regenerators and use of pressure relieving measures – all of which contributed to this study.
   a) ***History Taking:*** A careful, thorough and detail history was taken regarding age at onset of diabetes, duration of the disease process, regarding any progress of the ulcer, blood glucose status, detail

history about measures to control hyperglycemic status etc. are noted.

b) ***Clinical Examination:*** It includes various aspect of general survey and brief assessment of allied systemic examination. In local examination of the foot ulcer every characteristics of the ulcer were noted in details. ***On inspection:*** number, site, extent, shape and size are recorded. Margin of the ulcer, whether it is undermined, punched out, sloping, raised and rolled out or everted are noted. Floor of the ulcer (exposed portion) also examined. Any discharge, it's character, amount, smell are also noted. Adjacent area is also examined for any swelling, skin changes, secondary changes or associated venous disease. ***On palpation:*** local temperature and any localized tenderness is present or not is felt. Margin of the ulcer is also palpated for type and any indurations. Movement of the affected limb in particular of the involved joint is noted. Any restriction in the range of mobility needs special attention. Ulcer is measured in all dimensions initially at the time of admission and after intervention in routine follow up.

c) ***Investigations:***

Routine Investigations:

a) Complete haemogram with special reference to hemoglobin level, total leukocyte count, erythrocyte sedimentation rate (ESR) for any underlying infective process.
b) Blood glucose estimation (both fasting and post-prandial) and also estimation of glycosylated hemoglobin (HbA_1C).
c) c) Blood urea and creatinine for assessment of renal function.

Special Investigations

a) Deep swabs has been taken for microbiological culture and microscopy.
b) X-ray of the affected limb to exclude underlying skeletal involvement or any bony deformity. X-rays are necessary to rule out osteomyelitis, gas formation and presence of foreign body.
c) Doppler study of the vascular system: It assesses both anatomical and functional abnormality in the various arterial systems. Significant stenosis is indicated by a peak systolic velocity ratio >2 across the arterial lesion. Waveform analysis can give additional information about the degree of stenosis.
d) Sensation is evaluated using Semms-Weinstein monofilaments.

Wound Care Measures

a) Debridement of the wound is done in a regular manner as it is found to be critically important.
b) Application of tissue regenerator, PDGF, to the wounds for a period of maximum 10 weeks depending on the response.
c) Use of appropriate (as evident from culture and sensitivity) antibiotics suited to that particular wound. Spreading cellulitis, deep sepsis, or osteomyelitis was treated initially with intravenous antibiotics, then oral antibiotic cover for several weeks.
d) Use of used gloves for dressing, as it will act as cushion and hence it acts like offloading device.
e) Use of total contact cast (TCC) for a period ranging from 5-7 weeks and appropriate foot-wear as pressure relieving measures. Appropriate specially designed footwear was made with the help of the Artificial Limb Centre (ALC)

Study Techniques

A predesigned Informed Consent Form (ICF) was given to every patient under the study, explained about it properly and a valid, legal consent was taken from each of them. Subsequently all the data was captured following a predesigned Case Record Form (CRF) and compilation of all the data was done after all CRFs were completed.

Inclusion and Exclusion Criteria

All the patients of diabetes mellitus with planter foot ulcers were included in the study. There were no specific exclusion criteria, but foot ulcers that were caused by conditions other than diabetes mellitus were excluded from this study. The conditions were –

a) Traumatic foot ulcers,
b) Leprotic foot ulcers,
c) Foot ulcers due to peripheral vascular diseases

Specific Objectives of this Study

1) To identify and document the pathophysiological changes (e.g. neuropathy or ischemia) leading to the development of diabetic foot ulcers under study.
2) To make an assessment of the ulcers as appropriate for grading them With Wagner classification and also on the basis of presence of infection.
3) To evaluate the outcome of the ulcers in the baseline grading with "focused wound care" and "pressure relieving measures." Which will require to understand the epidemiology of foot ulcers and to assess the need for amputations.
4) Dressing of the ulcers were done as conventional dressing and to give rest to the part gloves was used as pressure relieving measure which was very economical.

Figure 1: Classic Neuropathic Diabetic Foot Ulcer

Figure 2: Gangrene of Heel

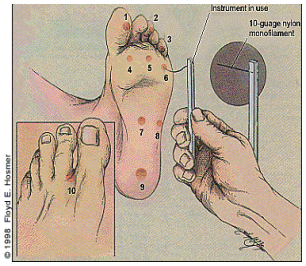


Figure 3: SEMMS-Weinstein Monofilament

Figure 4: 5.07 monofilament is pressed against
The skin until it buckles. This equals to 10gm of linear pressure. If the patient cannot feel
This buckled monofilament, he or she has lost protective sensation

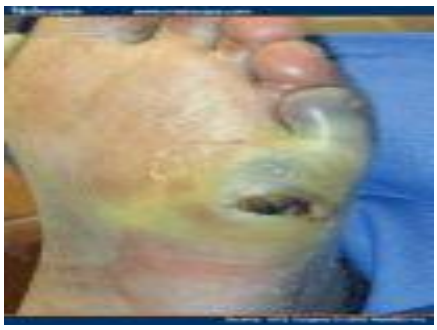


Figure 5: Cyanotic Changes in the Fifth Toe and Livido Reticularis Pattern on the Foot

Figure 6: Ischemic Ulcer. Note The Punched – Out Appearance

3. Discussion

Diabetes mellitus affects every organ system of the body. Foot ulcers are cutaneous erosions characterized by a loss of epithelium that extends into or through the dermis to deeper tissue. They are characterized by an inability to self repair in a timely and orderly manner. Considerable variation is reported in incidence and prevalence of diabetic foot ulcers. The life-time risk for foot ulcers in person with diabetes is estimated at 15%. It has been estimated that every 20 seconds

a) Lower limb is amputated due to complication of diabetes[1]. Amputation may be indicated in the following Circumstances:

☐ Ischaemic rest pain that cannot be managed by analgesia or revascularisation

☐ A life-threatening foot infection that cannot be managed by other measures

☐ A non-healing ulcer that is accompanied by higher burden of disease than would result from amputation. In some cases, for example, complications in a diabetic foot render it functionally useless and a well performed amputation is a better alternative for the patient.

It is reported that Hippocrates, in 400 BC, "Cut away the mortified parts," presumably in patients with gangrene after trauma or vascular occlusion. . Recognising the importance of starting treatment early may allow practitioners to prevent progression to severe and limb-threatening infection and potentially halt the inevitable pathway to amputation[4]. As time has progressed, diagnostic techniques have improved. The disease appears to progress as a function of age, duration of diabetes or both. Neuropathy, infection, deformity and ischemia are major threats to the diabetic foot and the overall functional wellbeing of the diabetic patient. The cost associated with adequately caring for these problems represent a significant impact to the health care system. In my study, I decided to assess the results of the strategy used in avoiding major amputations in patients admitted to our unit with multidisciplinary approach. My study aimed to identify the pathophysiological changes (e.g. neuropathy or ischemia) leading to development of diabetic foot ulcer, to make an assessment of the ulcers as appropriate for grading them with Wagner classification***(Wagner F W Jr. -1979)*** traditionally classified and graded diabetic foot ulcers and it has been widely accepted .The outcome of the ulcers in the baseline grading with "focused wound care" by application of tissue regenerators (PDGF)*as done by* ***Knighton D R et al (1993)*** which has shown that autologous platelet-derived growth factor formula (PDGF) can be important adjunct to healing wounds. Sharp debridement should be carried out by experienced practitioners (eg a specialist podiatrist or nurse) with specialist training[3] . My study was similar to that . The principle aim of DFU management is wound closure[2]. The " pressure relieving measures" by use of gloves dressing to offload planter foot ulcers, *as done* ***by Fisken (1996)***,who suggested that the best policy is to use the safest, simplest and least expensive dressing, which are wet to moist, not wet to dry, saline dressings .My study regarding dressing also matched as above as cost of dressing was only Rs50-80.

Moist wound healing has the potential to address multiple factors that affect wound healing. It involves maintaining a balanced wound environment that is not too moist or too dry. Dressings that can help to manage wound exudate optimally and promote a balanced environment are key to improving outcomes[7].

Deep tissue infection (moderate to severe infection)

b) For treating deep tissue infection (cellulitis, lymphangitis, septic arthritis, fasciitis):

☐ Start patients quickly on broad-spectrum antibiotics, commensurate with the clinical history and according to local protocols where possible[6]

My study matched as above. After initial assessment of glycemic status, the patients under this study were evaluated for any sensory impairment over the wound area. Only six (6) patients had intact sensation as evidenced with 5.07(10-gm) Semms-Weinstein monofilament who observed that sensation can be evaluated using 5.07 (10gm) monofilament as the threshold for protective sensation (i.e. the patient has sufficient sensation to avoid ulceration). Ulcers, however, develop in 10% of patients with sensation at that level. . Patients with a loss of sensation will have decreased awareness of pain and other symptoms of ulceration and infection[5] . My study was similar . Among the studied population twenty (20) patients had non-limb threatening infections and ten (10) patients had limb-threatening infections.

Among the studied group five (5) patients had ischemic ulcers and rest twenty-five (25) patients had no evidence of ischemia.Diabetic patients are 4-times more likely to develop peripheral vascular disease (PVD) with a 5- times greater likelihood of developing critical limb ischemia.

Diabetic foot infections are divided into two categories:

1. Non limb threatening infections are -

a) superficial
b) have minimal cellulitis (< 2 cm)
c) do not involve bone or joint
d) lack ischemia and
e) usually caused by *Staphylococcus aureus*.

These infections are typically treated without hospitalization and often managed on an outpatient basis with oral antibiotics, local wound care and close follow up visits. If the patient is treated as out patient, it is essential to reevaluate the ulcer after 24 to 48 hours because the infection can worsen.

2. Limb threatening infections are -

a) more severe,
b) have > 2 cm of cellulites,
c) involve deeper structure e.g. Bone and joints,
d) may have ischemia and
e) polymicrobial origin.

Representative organisms include aerobic gram positive cocci, gram negative bacilli (E.Coli, Klebsiella and Proteus species and Peptostreptococcus).These serious infections require hospitalization for parenteral antibiotics and surgical debridement. Appropriate antibiotics are no substitute for proper wound care and aggressive surgical drainage and debridement must be carried out promptly. When possible as much of the foot should be preserved to maximize ambulatory function, but all nonviable soft tissue and bone must be removed. Currently, the trend is to perform foot – sparing surgical procedures that are limited to the site of infection instead of traditional amputation sites.

The Biomechanics of the Foot in Diabetes Mellitus

It is important to provide a biomechanical framework on which an understanding of cause, treatment and prevention of foot injury in patients with diabetes . Although peripheral vascular disease has long been implicated in lower limb problems in the diabetic patients, it is now well recognized that the majority of injuries to the foot, principal ulcers, are a consequence of mechanical trauma, not recognized by the patients because of neuropathy. Diabetes related distal symmetric polyneuropathy results in a loss of protective sensation, and subsequently a number of biomechanical risk factors conspire to cause injury.

Most of the skin injuries seen on the feet of patients with diabetic neuropathy occur in the forefoot, with approximately equal distribution on the dorsal and the plantar surfaces. Those on the plantar surface are frequently at sites of high pressure under the foot. Many of the ulcers on the dorsum are at sites of high pressure where the patient's footwear creates a lesion, meaning that the majority of the foot ulcers have, in large part, a biomechanical etiology.

Gait Mechanics

Most foot injuries occur while the patient is walking and are caused by the forces generated during gait. The joint motion in the foot to be quantitatively measured during normal function rather than depending on inferences from a static examination. For example, pattern of dorsiflexion and plantarflexion of the first metatarsophalangeal (MTP) joint during gait, because plantar ulceration of the hallux is a common occurrence in patients with diabetic neuropathy. Dorsiflexion at the first MTP joint is essential during the toe- off phase of gait. When the ability to dorsiflex is mechanically limited, very high pressure must be expected under the hallux during the toe-off, a common finding in patients who ulcerate in this region.

Forces at the Foot

Although the likelihood of high pressure between a region of the foot and the floor can be inferred from an analysis of movement, neither the eye nor the most sophisticated video analysis system can measure these forces and pressures, because it is only the consequences of force that can actually be " seen ". The areas of mechanics in which the forces that cause movement are studied are called "kinetics" whereas the label "kinematics" is applied to studies when the movement per se is measured. The forces that are most frequently measured are the external forces between the foot and either the floor or the footwear. Less frequently, internal forces in tissues or forces between the articulating surfaces of the joints can be measured, estimated or modulated.

Pressure

The harm done by force can be thought as the mechanical input to the foot, yet their magnitude does not necessarily

reflect the risk of injury. Pressure is the critical quantity that determines the harm done by the force. The link between the force and the pressure is ***the area of force application***. Much more damage can be done by a force transmitted through a few plantar prominences than by the same force distributed over a longer area of the plantar surface. Average pressure is calculated by dividing the applied force by the area over which it acts. What is widely called "plantar pressure" in the diabetes literature is known in the mechanical terms as "normal stress"; stress because it is the result of force applied to a defined area and "normal" because it is measured at right angles to the supportive structure

Classification of Diabetic Foot Ulcer

Wagner Classification: Wagner and Meggitt developed a classification system in 1970s at Rancho Los Amigos Hospital in California, which has been known ever since by both names, but most commonly, as the "Wagner classification".The traditional classification system developed by Wagner for grading diabetic foot ulcers has been widely accepted and used. Currently, this system has five grades of lesions, as follows -Grade 0 - Ulcers having intact skin,
Grade 1 - Superficial ulcers with exposed subcutaneous tissue,
Grade 2 - Ulcers have deeper extension,
Grade 3 - Ulcers involves abscess formation or osteomyelitis,
Grade 4 - Partial gangrene of forefoot.
Grade 5 - Extensive gangrene.

Depth - Ischemia Classification

Depth	Grade For Depth	Grade for Ischemia	Ischemia
At risk foot, previous ulcer or neuropathy with deformity that may cause new ulceration.	0	A	Not ischemic
Superficial ulceration, not infected	1	B	Ischemia without gangrene
Deep ulceration exposing tendon or joint (with or without superficial infection)	2	C	Partial (fore foot) Gangrene of Foot
Extensive ulceration with exposed bone and or deep infection (i.e. Osteomyelitis or abscess)	3	D	Complete foot gangrene

Modulating Wound Healing in Diabetes

Wound healing is the process by which tissue responds to an injury. The biologic process is complex and involves chemotaxis, cell replication, production of proteins, neovascularization, maturation and wound remodeling. Growth factors are polypeptides that regulate the growth, differentiation and metabolism of cells and direct the process of tissue repair. Wound healing occurs in three phases: inflammation, fibroplasia and maturation. Such of these phases is controlled by growth factors, polypeptides that initiate cell growth and proliferation and protein production by binding to specific high affinity receptors on cell surface.

Footwear for Injury Prevention

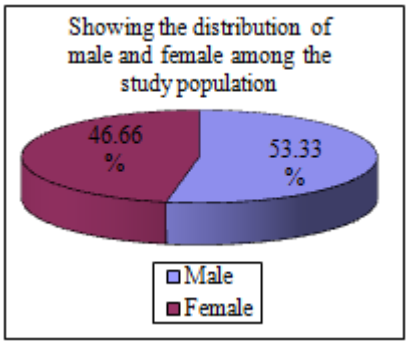
Foot care for the diabetic patient begins with treatment of the first injury. In an ideal situation, however, the possibility of the first foot injury should have been anticipated. Proper care of diabetic foot problems should always include an aggressive programme of injury prevention. All diabetic patients need education on footwear selection and foot infection. With the proper use of appropriate footwear and instruction related to foot care, most diabetic patients can except to avoid a skin wound on their feet.

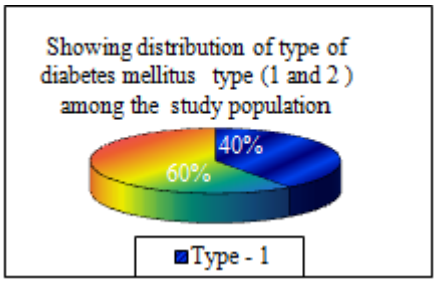
General principles regarding shoe wear for people with diabetes include the following --

a) First, the shoe should match the shape of foot and have enough room for an accommodative insert.
b) Shoe wear with depth comes in a variety of styles and different shapes of toe boxes, but patients who insist on high fashion shoe wear can never have properly fitted shoes that do not exert excessive forces on the foot.
c) The fit of a shoe should be determined by a experienced shoe fitter, such as certified pedorthist, while the patient is standing in the shoe. The shoe should be 1/2 to 5/8 inch longer than the longest toe. Length is only one of the many factors that need to be evaluated to achieve good fit. "Guess-work" can result in permanent damage of the foot.
d) Heel height greater than 2 inches, in particular, shifts the body weight toward the fore foot, particularly on to the first and second metatarsal heads. This shift of body weight increases pressure under the metatarsal heads increasing the risk of foot ulceration. Actual heel height is a vertical measurement from the top of the insole under the metatarsal heads to the top of the insole under the heal.
e) Pressure sensitive shocks are available to help a shoe fitter to objectively evaluate fit. These shocks are coated with wax capsules containing dye that fracture when a certain pressure threshold is exceeded, the dye will stain the sock in areas of high pressure in the shoe as the person walks.

Observation was done under following headings;

- Sex
- Type of diabetes mellitus
- Duration of diabetes mellitus
- FBS/PPBS
- Sensivity
- Limb threatening infections/NLT
- Presence/absence of ischemia
- Treatment with OHA/INSULIN
- Cost of dressings
- Limb salvation





Twelve (12) patients had type 1 diabetes mellitus and eighteen (18) patients had type 2 diabetes mellitus suggesting both the types of diabetes suffer similar foot pathology.

Table 1: Showing the mean duration of diabetes mellitus in year and also diabetic foot ulcer duration in month with standard deviation in study population

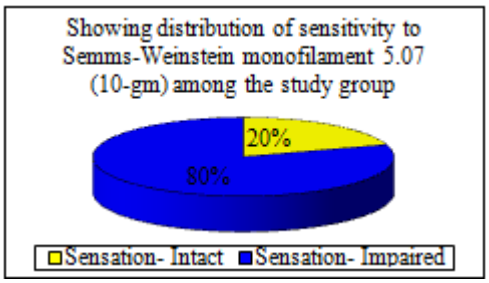
	Mean ± Standard Deviation
DM Duration (Yr)	9.8333 ± 3.630
DFU Duration (Mon)	8.0666 ± 2.7029

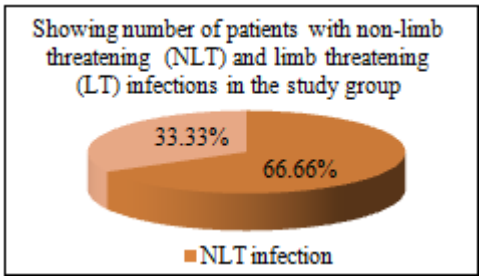
Among the study population, duration of diabetes mellitus varied widely, ranging from four (4) years to long twenty (20) years and foot ulcer duration ranging from four (4) months to twelve (12) months.

Table 2: Showing mean with standard deviation of fasting blood sugar, post prandial blood sugar and glycosylated hemoglobin among the study population

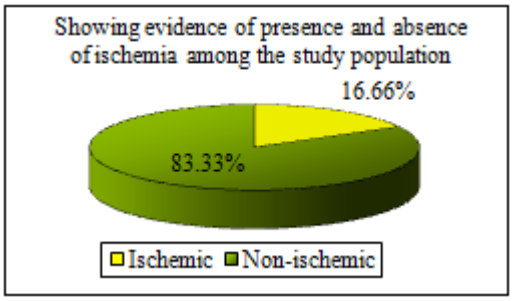
	Mean ± SD
Fasting Blood Sugar (FBS)	119.7000 ± 14.3097
Post Prandial Blood Sugar (PPBS)	213.0330 ± 25.6588
Glycosylated Hemoglobin (HbA_1C)	7.2533 ± 0.5587

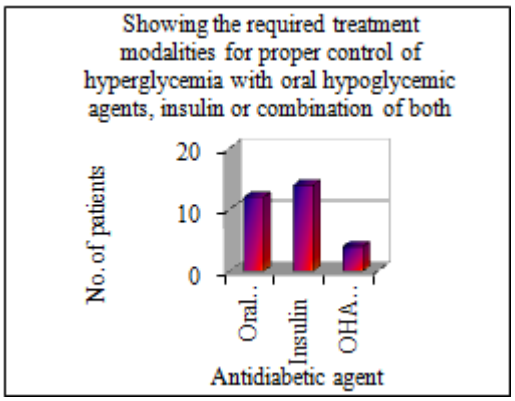
The glycemic status of the study population was observed under three categories. Fasting blood glucose (FBS) were ranging from 86 to 142 mg /dl. Post-prandial blood glucose (PPBS) was ranging from 168 to 266 mg/dl and glycosylated hemoglobin (HbA_1C) values were ranging from 6.2 to 8.2





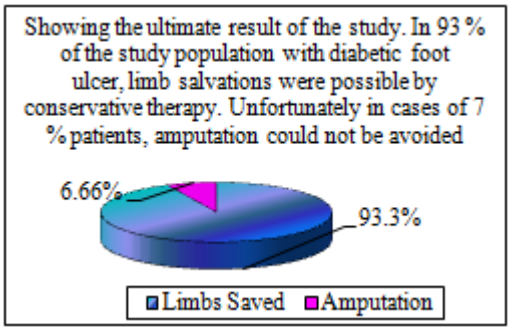
Only 6 pt .had intact sensation Among the studied population twenty (20) patients had non-limb threatening infections and ten (10) patients had limb-threatening infections





(5) patients had ischemic ulcers and patients were treated with OHA and insulin

(25) patients had no evidence of ischemia.



Inspite of all these measures, these two patients ultimately needed amputations *1. left midtarsal amputation, 2. right below knee amputation*.

4. Conclusion

Among the various off-loading methods, pressure off loading methods is economical ,easy to use cost is only Rs.50-Rs.80.Twenty- five (25) patients were given tissue regenerator, PDGF, to the wounds for a maximum duration of ten (10) weeks. Three (3) patients healed remarkably healed during this period without any subsequent intervention. At the end of our interventions, the outcome or post treatment grading as per Wagner classification was as follows: Eighteen (18) patients were converted from grade-2 ulcer to grade-1 ulcer. Among the eight (8) patients of grade-3 ulcer five (5) patients were converted to grade-1 ulcer and three (3) patients were converted to grade-2 ulcer. Two (2) patients, initially suffering from grade-1 ulcer, though remained in the same grading after standard treatment, showed that the residual ulcers healed to some extent.Two (2) patients, one suffering from grade-4 and another suffering from grade-5 ulcer did not show any clinical improvement and remained in the same grade. Hence offloading technique is very useful in diabetic foot ulcers.

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Conflict of interest-none

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