DIABETIC FOOT ULCER IT'S COMPLICATION AND MANAGEMENT A MEDICAL COLLEGE BASED DESCRIPTIVE STUDY IN ODISHA, AN EASTERN STATE OF INDIA

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Abstract:

Aim: Aim of this study was to prepare a profile of diabetic foot ulcer (DFU) complications and its management and to assess the outcome of the surgical interventions.

Materials and methods: A prospective study was carried out in 60 patients with DFU during the period of January 2009 to October 2010 to categorize them based on Meggit Wagner system; find out the complications, management, below knee amputation rate and Mortality rate.

Results: Majority of the patients (30%, n=18) presented with Wegner grade 3 DFU. Only 3 patients (5%) presented with grade 0 DFU. Split Skin Grafting was the most frequently done intervention, comprising 29% of the time. Below knee amputation was required in 10% of cases and mortality rate 12%.

Conclusion: Lack of awareness about Diabetes mellitus and its lower limb complications, poor compliance to the treatment, poorly controlled blood sugar levels, delay in diagnosis, late presentation to the tertiary care center are all factors which led to occurrence DFU at an age earlier than that seen in other studies.

Keywords: diabetic foot ulcer; complications; management

Introduction:

The world health organization defines diabetic foot as the lower limb of a diabetic patient that has the potential risk of pathologic consequences, including infection, ulceration, and/or destruction of deep tissues associated with neurologic abnormalities, various degrees of peripheral vascular disease, and/or metabolic complications of diabetes. The world is facing a major epidemic of diabetes. About 194 million people worldwide or 5.1% in the age group 20-79 were estimated to have diabetes in 2003.[1] This estimate is expected to increase to some 333 million or 6.3% of the adult population by 2025.[1] India is the world capital of known diabetes. There are currently more than 30 million people living with diabetes in India. There is also an increasing number of young people and children with type 2 diabetes, especially among ethnic minority groups. This increase in diabetes is mainly attributed to modernization or westernization of the world's societies.[2] In the United States diabetes is expected to increase by 60% over the next 22 years, while in Europe diabetes is expected to increase by 16%. Diabetes is expected to increase in Australia by 59%, in South America by 88% and in Africa, Middle East, and Asia by a tremendous 98%.[3] Foot ulcers develop in about 15% of

patients with diabetes and foot disorders are leading cause of hospitalization for patients with diabetes.[4-6] The lifetime risk of a person with diabetes developing a foot ulcer could be as high as 25%.[7] Up to 70% of all leg amputations in the United States are performed on people with diabetes,[8] and approximately 85%.of lower limb amputations in patients with diabetes are preceded by foot ulceration,[5] highlighting the importance of prevention and appropriate management of foot lesions. Worldwide, a lower limb is lost every 30 seconds as a consequence of diabetes.[9] Among persons with diabetes, 15% develop foot ulcers during their lifetime. Their risk of lower extremity amputation (LEA) increases by a factor of 8 once an ulcer develops. There is a mortality rate of 36% at 2 years following transtibial amputation[10] for diabetic foot ulcer. In fact, every year approximately 5% of diabetics develop foot ulcers and 1% requires amputation. Diabetic peripheral neuropathy, present in 60% of diabetic persons and 80% of diabetic persons with foot ulcers, confers the greatest risk of foot ulceration; microvascular disease and suboptimal glycemic control contribute. Even after successful management resulting in ulcer healing, the recurrence rate is 66% and the amputation rate rises to 12%. Half of all non traumatic amputations are the result of diabetic foot complications, and the 5-year risk of needing a contralateral amputation is 50%.[11] Diabetes occurs in 3-6% of Americans. Of these, 10% have type 1 diabetes and are usually diagnosed when they are younger than 40 years. Among middle-aged adults, the prevalence of diabetes is about 10% (of these, 90% have type 2 diabetes). Diabetic neuropathy tends to occur about 10 years after the onset of diabetes, and, therefore, diabetic foot deformity and ulceration occurs sometime thereafter. Charcot foot (neuropathic osteoarthropathy) is most commonly observed in diabetes mellitus, affecting about 2% of diabetic persons.

Materials and methods

Aim of this study was to prepare a profile of diabetic foot ulcer complications and its management and to assess the outcome of the surgical interventions. The objectives were to find out all the cases of Diabetic foot ulcer (DFU), to take a detailed history and do a standard clinical examination and do necessary investigations, categorize them into six grades from 0 to 5 based on Meggit Wagner classification system, find out the complications of DFU in each case, study the different types of management of DFU in those cases and to find out below knee amputation rate and

Mortality rate. All the cases of diabetic foot ulcer that were treated in MKCG Medical College, Berhampur during the period of January 2009 to October 2010 were taken as the study population and a descriptive study was carried out in 60 consecutive cases with DFU. Patients with diabetic foot ulcer having other diseases causing ulcer in the foot and those cases which could not be followed up for a minimum period of 6 weeks were excluded from this study. Written informed consents were obtained from the patients and they were evaluated and a follow up was done at 6 weeks to note the recurrence. All the details of the patient, their examination findings, diagnosis and investigation reports were maintained as per the proforma. Foot ulcers were categorized into six grades from 0 to 5 based on Meggit Wagner classification system as follows.

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.

A semi structured questionnaire was developed to record the medical history, examination details and investigation reports. A pilot study was carried out on 5 subjects and we found that Transcutaneous oxygen tension, ABPI and Doppler study could not be carried out in all patients because of the lack of facility and poor financial back up of patients, and those parameters were omitted from the proforma. Neuropathy was assessed by 128 hz tuning fork and 10 gm monofilament. Absent pulsations of dorsalis pedis, posterior tibial, poplitial or femoral vessels was considered to be sign of ischaemia. In cases with bilateral involvement, the foot with higher grade was studied. Septic shock is defined by a fall in systolic BP below 90 mm of Hg along with any two or more of the following: pulse rate >90/min, respiratory rate >20/min, body temperature >38°C or <36°C, Neutrophil count <4000 or >14000 per cubic milliliter. Ketosis; if the urine ketone bodies were positive. Hyperosmolar state is defined by a plasma osmolality >310 mmol/L. Osmolality was calculated using the equation:

$$Posm(mOsm/L)=2 \times serum\ [Na^+(mmol/L)+K^+(mmol/L)]+glucose\ (mg/dL)\ /\ 18+BUN\ (mg/dL)\ /\ 2.8.$$ Serum

sodium concentration below 110 mmol/L was defined as hyponatremia.

Data collection was done using the proforma and the study variables recorded. The study parameters were age, sex and occupation of the patient, duration of symptoms, duration of diabetes mellitus, type of treatment, compliance to treatment, Wegner grade of the DFU, haemoglobin percentage at the time of admission, number of units of blood transfused, complications of DFU, pus culture, modality of management, duration of hospital stay and recurrence of DFU at 6 weeks after completion of treatment. Age at the time of diagnosis of diabetes mellitus, smoking, alcoholism, awareness of complications, peripheral neuropathy, peripheral vascular disease, pulse rate, systolic and diastolic BP in mm of Hg, respiratory rate, RBS, serum osmolality, axillary temperature in degree Celsius, serum Sodium in mmol/L were also recorded during admission. The data was collected and analyzed using descriptive statistics.

Results

In the 60 DFU patients studied 42(70%) were males and 18(30%) were females. Male to female ratio is 2.33:1. The age of patients ranged from 20 to 80 years. Mean age was 54.57 years and SD was 13 years. Majority of patients (54%) were in the age group 51 to 70 years. Majority of male patients were in the age group of 51 to 60 years. Majority of female patients were in the age group of 61 to 70 years(graph 1). 75% (n=45) of patients were above 40 years of age, while 25% (n=15) were 40 years and below at the time of diagnosis of Diabetes mellitus.

Only 8 patients (13.33%) presented to the tertiary care centre within 5 days of onset of symptoms. Only 20 patients (34%) presented within 30 days of onset of symptoms, whereas majority of patients (66%) presented after one month of symptom onset. 83% (n=50) of cases were known cases of diabetes.17% (n=10) were newly diagnosed and they presented with DFU as the initial symptom. In majority of patients (48%, n=24) diabetes was diagnosed within 5 years only (graph 2). Mean duration of diabetes was 5.975 years and SD 5.265 years.
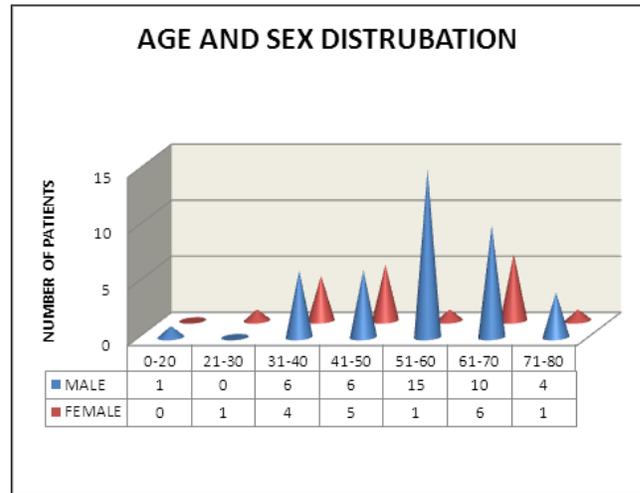

Graph 1 : age and sex distribution

Only 20 patients (40%) were taking drugs regularly, while 30 patients (60%) were on irregular treatment. 24 patients (48%) were taking subcutaneous insulin and 25 patients (50%) oral hypo glycaemic drugs (OHAs) and 1 patient (2%) was not taking any treatment 22% of the patients were dependants, 29% were doing either office job, teaching or business, 22% were housewives, 20% were carpenters or other moderate physical activity workers. Only 7% were manual labourers or agricultural workers. Only 18% (n=11) of patients were aware of lower limb complications of diabetes where as 82% (n=49) were unaware of it. 18 patients (30%) were smokers and 15% (n=9) were alcoholics. Neuropathy was present in 38 patients (63%) and peripheral vascular disease in 21 patients (35%). The mean RBS was 278.25mg/dI, SD was 88.26mg/dl. 82% of patients were having RBS more than 200 mg/dl, that means with uncontrolled diabetes mellitus.15% of patients (n=9) were having Hb 6 gm/dl and below; another 15% (n=9) between 6.1 and 7.9 gm/dl. Majority of patients (70%, n=42) were having Hb of 8 gm/dl or more. Mean Haemoglobin was 9.11 gm/dl and SD is 2.14 gm/dl. Blood transfusion was given to 52% (n=31) patients, among whom 23% (n=7) received 1 unit, 29% (n=9) received 2 units, 23% (n=7) received 3 units, 19% (n=6) received 4 units, 3% (n=1) received 5 units and 3% (n=1) received 6 units.

Out of 60 pus samples collected 3 samples (5%) were sterile; 13 samples (22%) showed poly microbial flora and 44 samples (73%) showed mono microbial flora. Out of the 68 isolated and cultured organisms 61 (90%) were bacteriae and 7 (10%) fungi. 62% of isolates in grade 5 DFU were poly microbial and none of the samples were sterile. 80% of the isolates in grade 4 were mono microbial and 30%

were poly microbial and 7% were sterile. 28% (n=17) pseudomonas aeruginosa, 25% (n=15) staphylococcus aereus, 18% (n=11) E-coli, 11% (n=7) proteus, 6% (n=4) enterococcus fecalis, 5% (n=3) klebsiellapneumoniae, 5% (n=3) acinetobacter, 2% (n=1) citrobacter were the isolated bacteriae in the pus culture. Pseudomonas was isolated in 28% of the samples and staphylococcus in 25% of the samples. Poly microbial flora is seen more in grade 5 compared to other grades. Out of the 7 fungal isolates Candida was present 4 times and Aspergillus 2 times and Fusarium once. Poly microbial flora is seen more in grade 5 compared to grade 4. P value is 0.0147.
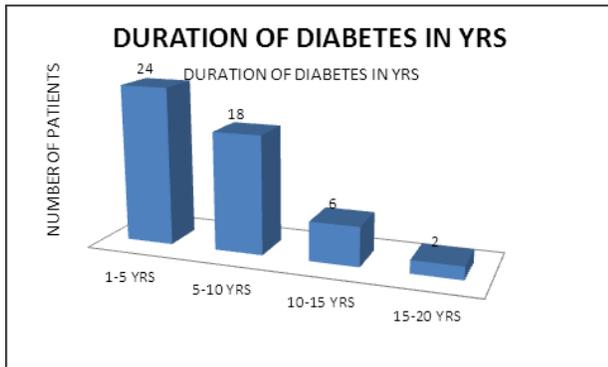
Graph 2: duration of diabetes in years

Out of the 60 cases 5% (n=3) were Wagner grade 0, 10% (n=6) were grade-1, 17% (n=10) were grade-2, 30% (n=18) were grade-3, 25% (n=15) grade-4, 13% (n=8) grade¬-5.Majority of the patients (30%, n=18) presented with Wegner grade 3 DFU. Only 3 patients (5%) presented with grade 0 DFU. Out of the 60 cases 38.33% (n=23) presented with various complications; 35% (n=8) had septic shock, 4% (n=1) had serum hyperosmolarity, 13% (n=3) had ketosis, 26% (n=6) had both septic shock and hyperosmolarity, 9% (n=2) had septic shock and ketosis, 13% (n=3) had Hyponatremia. Septic shock (70%) was the most commonly encountered complication being present in 35% cases alone and along with other complications in another 35% cases.
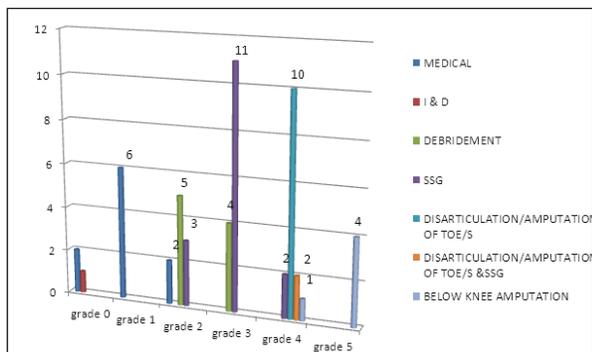
Graph 3: management of diabetic foot ulcer in different grades

Out of the 53 patients who survived 19% (n=10) were treated by medical means, 2% (n=1) by incision and drainage, 17% (n=9) by debridement, 29% (n=16) by debridement and split skin graft, 19% (n=10) by disarticulation / amputation of toe/s, 4% (n=2) by disarticulation/ amputation of toe/s and split skin graft, 10% (n=5) by below knee amputation. SSG (29%) was the most frequently done intervention for the management of DFU. In grade 0 and 1 DFU, medical management alone was successful in 88.9% of cases (graph 3). Amputation was required in 89.5% of cases of grade 4 & 5 DFU. Below knee Amputation rate is high in grade 5 compared to grade 4 DFU. P value is 0.0164. 51% of the patients had to stay in the hospital for more than 20 days. Out of the 53 patients who were treated successfully; 7 patients had recurrence at 6 weeks follow up. Of the 7 patients who died; septic shock was present in 1 patient, septic   shock and hyperosmolar state in 3 patients, septic shock and ketosis in 2 patients and hyponatremia in 1 patient.

Discussion

Average age of DFU in our study was 2.5 years less than Ektabansaletal's [12] Study (table 1). In our study more female patients were present as the male to female ratio is 2.33 only. In our study majority of patients had duration of diabetes of less than 5 years. Awareness to lower limb complications were very less in our study subjects compared to Ektabansaletal's study. Majority of patients were non compliant to the treatment and revealed poor glycemic control. In the present study neuropathy was more and PVD was less prevalent. Gram positive to gram negative ratio is almost same in both studies. Pseudomonas was the predominant isolate in both studies but showing higher percentage in present study. Out of the 60 patients, 12% (n=7) mortality was observed in our Study. The remaining 53 patients who were treated successfully; 7 patients had recurrence at 6 weeks follow up. Poly microbial flora was seen more in grade 5 compared to grade 4 (p-value is 0.0147). Amputation rate is high in grade 5 compared to grade 4 (p-value is 0.0164).

DFU is a disease seen exclusively in diabetic patients and it develops usually in the 6th and 7th decades of life. It usually develops at 5 to 10 years duration of Diabetes mellitus. The main predisposing factors were peripheral neuropathy and PVD. Other contributory risk factors include obesity, sedentary life style, smoking, and

alcoholism. Slight male predominance was observed. Lack of awareness about Diabetes mellitus and its lower limb complications, poor compliance to treatment, delay in diagnosis, late presentation to the tertiary care centre are all factors which led to occurrence DFU at a younger age than that was observed in other studies. DFU is a poly microbial infection and its poly microbial nature is more evident in higher grades 4 & 5. Majority of isolates were gram negative. Pseudomonas was the most common organism isolated and Staphylococcus was the most common gram positive isolate. Non pathogenic fungi cause opportunistic infection in Diabetic foot patients. Candida was the most commonly isolated fungus. DFU is associated with systemic complications such as septic shock, diabetic ketoacidosis, hyperglycemic hyperosmolar state and hyponatremia which can be life threatening if not recognized and treated promptly. Debridement and SSG were the most frequently performed surgical intervention for DFU. The disease is a financial burden to the patient as the average hospital stay is 25 days. DFU carries 33% amputation rate and 12% mortality.

Parameter	Present Study	EktaBansalEtal Study
Average age in years	54.57	57.05
Male to female ratio	2.33	3.68
Duration of diabetes (D o d)<5 years	48%	25.24
D o d 5-10 years	36%	26.21
D o d >10 years	16%	48.54
Smoking	30%	20.39
Alcoholism	15%	36.89
No awareness of lower limb complications	82%	77%
Non-compliant to treatment of diabetes	60%	37.11%
Neuropathy	63%	57.28%
PVD	35%	75.73%
Poor glycemic control >200mg/dL	82%	67%
Gram positive	25%	24%
Gram negative	75%	76%
Pseudomonas	28%	21.67%
Staphylococcus	25%	18.88%
E-coli	18%	18.18%

Table 1 : comparison between present study and EktaBansaletal's[12] study

References

1. International Diabetes Federation. Diabetes Atlas. Available at http://www.eaqtlas.idf.orq/Prevalence/AlI diabetes. Accessed May 17, 2006.

2. Wild S. Roglic G, Green A. Sicree R, King H. Global prevalence of diabetes: estimates for the year 2000 and projections for 2030. Diabetes Care. 2004:27 (5) 1047-1053.

3. Centers for Disease Control and Prevention National Diabetes Fact Sheet 2005 Available at: http://www.edc.qov/diabetes/pubs/estimates05.htm#prev. Accessed May 17, 2006.

4. Mayfield JA, Reiber GE, Sanders LJ. Janisse D, Pogach LM, Preventive foot care in people with diabetes. Diabetes Care. 1998:21 (12):2161-2177.

5. Palumbo PJ. Melton LJ III. Peripheral vascular disease and diabetes. In: Diabetes in America: Diabetes Data complete 1984. Washington. DC-. Government Printing Office. 1985, XV-I-XV-21.

6. Consensus Development Conference on Diabetic Foot Wound Care. 7-8 April 1999. Boston. Massachusetts. American Diabetes Association Diabetes Care. 1999-2298):1354-1360.

7. Singh N. Armstrong DG Lipsky BA. Preventing foot ulcers in patients with diabetes. JAMA. 2005:293(2):217-228.

8. Reiber GE, Ledous WR. Epidemiology of diabetic foot ulcers and amputations evidence for prevention. In Williams R. Herman W. Kinmonth Al. Wareham NJ. Eds. The evidence Base for Diabetes Care. Hoboken NJ: J Wiley & Sons-2002.-642-665.

9. International Diabetes Federation. Time to act. Diabetes and foot care. Brussels, Belgium: International Diabetes Federations -2005.

10. Michael S Pinzur, MD: In: Diabetic Foot, Available at http://emedicirie.medscape.com/article/1234396-overview. Accessed 20 October 2010.

11. Richard M Stillman, MD, FAGS. Diabetic Ulcers-Updated: Jun 7, 2010 Available at http://emedicine.medscape.com/article/460282-overview. Accessed 20 october 2010.

12. Bansal E, Garg A, Bhatia S, Attri AK, Chander J. Spectrum of microbial flora in diabetic foot ulcers. Indian J PatholMicrobiol 2008;51:204-8