

## PROGNOSTIC INDICES OF DIABETIC FOOT DISEASE

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### ABSTRACT

Forty six diabetic feet in 38 patients were studied using a predetermined protocol of clinical and management indices. There were 24 males and 14 females giving a male:female ratio of 1.7:1. The ages ranged from 26 years to 74 years with a mean age of 52.8 years.

The venous filling time, Meggit-Wagner grading status, associated medical condition, eye signs, duration and type of diabetes mellitus were found to correlate with prognosis. Aggressive antibiotic treatment following aerobic and anaerobic culture, radical serial debridement, and frequent dressings after hypertonic saline soaks of the limbs resulted in healing of 31 out of 46 feet (67.4%) at a mean healing time of 2.4 months. Eight limbs had major amputation giving amputation rates of 17.4%. We recorded six mortalities out of the 38 patients (15.8%).

We conclude that diligent clinical assessment, prompt and aggressive antibiotic treatment, radical sequential debridement, and meticulous attention to wound dressing in a multidisciplinary setting would reduce rate of amputation and mortality in diabetic foot diseases. Where limb salvage is not possible, above knee amputation is the best option.

### Key Words

Diabetic foot, amputation, debridement, limb salvage

### INTRODUCTION

Diabetic foot disease is a major surgical problem in our environment<sup>1</sup>. In Naaeder's series on lower limb amputation in Ghana, diabetic foot disease was the leading cause, while in Jos and Ogbomoso diabetic foot gangrene was the second commonest indication for amputation<sup>2,3,4</sup>. In our environment, late

presentation of the patients, often with septicaemia increases the mortality arising from diabetic foot disease<sup>5,6</sup>. Most hospitals lack facilities for accurate assessment of the vascular status of the diabetic feet. This has made management decision difficult and dictated by the need to urgently save life. It has been observed that quite a number of amputations were carried out on salvageable limbs<sup>3</sup>.

While limb salvage procedures and microsurgical technique abound in advanced countries, it still remains a rarity in most hospitals in developing countries. Furthermore, the microbial flora of diabetic foot disease tends to vary from place to place<sup>7</sup>.

Criteria for management decisions are often empirical. It is to determine the prognostic indices and outline objective factors to be considered in management of diabetic foot disease that this prospective multidisciplinary study was undertaken.

### PATIENTS AND METHODS

Consecutive diabetic patients with foot lesions presenting in Jos University Teaching Hospital over a 1½ year period – between July 1997 and December 1998 were enrolled in a prospective study. Clinical assessment was carried out on admission in accordance with a prepared study protocol to include age, sex, type and duration of Diabetes Mellitus, details of foot lesions, trophic changes, signs and symptoms of Macro and Micro – vascular disease.

The precipitating cause of the foot lesions and patients' previous knowledge of diabetic foot care was ascertained.

The clinical examination included the venous filling time which was done by elevating the limbs until collapse of the superficial veins is noted. Thereafter the limb was made dependent and time taken for refill

ascertained. Dorsalis pedi pulse as well as posterior tibial, popliteal and femoral pulses were assessed. Ankle blood pressure measurement was not done. The ophthalmic study was carried out by the physician for evidence of cataract or retinal changes. Wound swabs for both aerobic and anaerobic cultures were done for all the patients. Anterior-posterior and lateral views of plan x-rays of the foot were obtained when indicated. All the patients had routine ward urinalysis, fasting blood sugar and serum urea and electrolyte checks.

Non-diabetics with chronic foot ulcers and diabetics whose ulcers were caused by significant trauma were not included in this study.

All the foot lesions were graded from 0 to 5 according to the classification of Megitt and Wagner (Wagners' Grading). Diabetic control was carried out by the medical team. All foot lesions (from Wagners Grade 1) had initial debridement and subsequently hypertonic saline emersion and wound dressing using hydrogen peroxide and Eusol.

For the purposes of this study, debridement refers to removal of all necrotic and infected tissue including amputation of gangrenous toes and removal of phalanges and metatarsals involved in chronic osteomyelitis. Patients were routinely placed on Ampiclox, Gentamycin and Metronidazole pending the outcome of culture and sensitivity results.

Healing was said to have occurred when there was closure of the entire wound and limbs said to have been salvaged if patient can wear shoes irrespective of loss of toes.

## RESULTS

During the study period, 38 patients with a male:female ratio of 1.7:1.0 presented with 46 diabetic foot lesions. Eight patients had bilateral foot lesions. The right foot was involved in 28 cases while the left was involved in 18. the ages of the patients ranged from 26 to 74 years with a mean age of 52.8 years. The peak age incidence of 44.7% occurred in the 6<sup>th</sup> decade of

life followed by 23.7% in the 5<sup>th</sup> decade. The age distribution is shown in Table I.

## DURATION AND TYPE OF DIABETES MELLITUS/FOOT LESIONS

The duration of Diabetes Mellitus in the study population ranged from 4 months to 24 years with a mean duration of 10.6 years. Four patients were not certain of the duration of their disease. (Table II shows the duration of diabetes mellitus). Of the 38 patients, 5 had Type 1 diabetes (Insulin Dependent Diabetes Mellitus) and 33 had Type 2 Diabetes (Non-Insulin Dependent Diabetes Mellitus) giving a Type 1:Type 2 ratio of 1:6.6. 52.6% of the patients presented within one month of developing the foot lesion, while 34.2% presented in the 2<sup>nd</sup> month. The rest presented at intervals ranging from 3 to 6 months. 57.9% of the patients were admitted with septicaemia.

The diabetic foot ulcers were found in 52 sites. Of these, the hallux and dorsum of the foot were found to be the most frequent sites in 23.1% of cases each. These were followed by ulcers or gangrene involving entire forefoot in 15.4% and whole foot and leg in 11.5%. The heel, the digits and the lateral aspect of the sole of the foot were involved in 7.7% of cases each. Multiple ulcers were found in 6 patients. Table III shows the sites of the foot lesions.

Thirty five out of the forty six foot lesions (76.1%) started as "spontaneous" blisters while 13% were caused by trivial trauma to the foot. 3 patients (6.5%) had burns of the foot, one of these was a self-inflicted scald when the patient attempted to warm his foot during cold season. In 2 patients, the lesions started as spontaneous gangrene.

Thirteen of the diabetic feet had no trophic changes. Associated predisposing findings were calluses in 27 cases, caring in 17 and fissures in 22 cases. 28 patients or 73.7% showed signs of peripheral neuropathy. Of the 8 patients who had major amputation, 5 had peripheral neuropathy.

### **VENOUS FILLING TIME**

The venous filling time is shown in Table IV. The mean venous filling time for the right lower limb was 20.9 seconds and that of the left 19.0 seconds. The salvaged limbs had a lower mean venous filling time of 16.8 seconds for the right and 16.4 seconds for the left. The filling time for the amputated limbs ranged from 28-35 seconds with a mean of 32.9 seconds. Of the 6 mortalities recorded, the venous filling time for five of them ranged from 28-35 seconds with a mean of 30.2 seconds. One patient who had a filling time of 10 seconds, had bilateral disease and septicaemia. The mean venous filling time was significantly higher in amputated and mortality cases than in patients with salvaged limb ( $P = < 0.05$ ).

### **MEGITT – WAGNER GRADING OF THE FOOT LESIONS**

The grading of the foot lesions is shown in Table V. 30.4% of the cases came with advanced foot lesions (grades 4 and 5), 37% had grade 2 and 26.1% had grade 3 diseases. Of the 8 patients who had major amputations, there was even distribution of grades 4 and 5 lesions. However, of the mortality cases, 66.7% had grade 4 and 5 stages, 16.7% had grade 3 diseases and one case (16.7%) had bilateral involvement (grades 3 and 2).

### **EYE SIGNS**

Retinopathy was observed in 18 of the 38 patients (47.4%). Of these, 15 patients had background retinopathy grade II and 3 had proliferative retinopathy. Nine patients showed no evidence of retinopathy while in 9 patients, the retina was not visualized. Cataract with consequent blindness was found in 12 patients; 7 of these were bilateral.

### **CULTURAL CHARACTERISTICS OF AETIOLOGICAL AGENTS**

Fifty four positive cultures were obtained in 34 patients as shown in Table IV. There were 44 aerobic

organisms, 8 anaerobic organisms and one fungal growth. One of the anaerobic cultures grew marginally species which is a microaerophilic organism. *Staphylococcus aureus* was found to be the most frequent aetiological agent, followed closely by coliform organisms and then anaerobes. Unusual organisms causing wound infection like flavobacterium species and acinobacter species were isolated in one case each. Mixed flora was obtained in 15 patients.

### **SENSITIVITY PATTERN OF ISOLATED ORGANISMS**

Third generation cephalosporins were found to be the most sensitive antibiotics in 17.1% of cases followed by perfloxacin in 9.8%. Of the others gentamycin, augmentin and clindamycin were effective in 8.5% each. The latter was found sensitive for both aerobic and anaerobic organisms. Other agents that showed sensitivity were Erythromycin, Tetracycline, Azithromycine and Colistine sulfate. Table VII shows antibiotic sensitivity pattern of isolates. Metronidazole was found sensitive in only 2.4%.

### **MODALITIES OF TREATMENT OFFERED**

Details of modalities of treatment offered is shown in Table VIII. Thirteen patients had multiple debridement while 17 had single debridement. One patient was offered protective ambulatory plaster cast. Below knee and above knee amputations were carried out in two and eight patients respectively.

Duration of hospital stay for healed cases ranged from 1 month to 5 months with a mean of 2.4 months. Ten and seven patients had healing time of two and three months respectively while six patients each had healing time of one and four months. Two patients had healing time of 5 months.

Observed severity indices for the mortality cases is summarized in Table IX. All the mortality cases had septicaemia at presentation while two of them had associated cardiac failure. Eye signs were present in all the six cases, while the Wagner grading of the

foot lesions were 3 and above. The various filling time for all the mortality cases was above 28 seconds except one that had a venous filling time of 10 seconds with bilateral foot lesions.

**Table I: Age distribution of patients with diabetic foot disease**

Age of patients	Frequency	%
0-20	0	0.0
21-30	2	5.3
31-40	4	10.5
41-50	9	23.7
51-60	17	44.7
61-70	4	10.5
71-80	2	5.3
<b>Total</b>	<b>38</b>	<b>100.0</b>

**Table II: Duration of Diabetes Mellitus**

Time	Number	%
Less than one year	4	10.5
0-5 years	4	10.5
6-10 years	6	15.8
11-15 years	14	36.8
16-20 years	3	7.9
21-25 years	3	7.9
Uncertain	4	10.5
<b>Total</b>	<b>38</b>	<b>100.0</b>

**Table III: Sites of diabetic foot lesions**

Sites	Number	%
Dorsum of foot	12	23.1
Big toe	12	23.1
Entire forefoot	8	15.4
Whole foot and leg	6	11.5
Heel	4	7.7
Digits only	4	7.7
Lateral part of sole of foot	4	7.7
Medial malleolus	1	1.9
Pressure area of metatarsals	1	1.9
<b>Total</b>	<b>52</b>	<b>100.0</b>

**Table IV: Venous Filling time**

Time (Second)	Right	Left
6-10	4	4
11-15	13	13
16-20	7	7
21-25	1	7
26-30	8	3
31-35	5	2
<b>Total</b>	<b>38</b>	<b>36</b>

**Table V: Meggitt Wagner Grading**

Grade	Frequency	%
0	0	0.0
1	3	6.5
2	17	37.0
3	12	26.1
4	8	17.4
5	6	13.0
<b>Total</b>	<b>46</b>	<b>100.0</b>

**Table VI: Cultural characteristics of aetiological agents**

S/NO.	Organism	Frequency	%
1.	Staph. Aureus	17	31.5
2.	Proteus species	9	16.7
3.	Pseudomonas deriginosa	6	11.1
4.	Klebsiella species	5	9.3
5.	* Peptococcus	4	7.4
6.	* Clostridium perfringes	3	5.6
7.	E. Coli	3	5.6
8.	** Candida species	2	3.7
9.	Strep. Viridans	1	1.9
10.	Flavobacterium species	1	1.9
11.	Acinobacter species	1	1.9
12.	*** Marginella species	1	1.9
13.	* B. fragilis	1	1.9
	No growth	4	
	<b>Total Positive</b>	<b>54</b>	<b>100.0</b>

Mixed growth in 15 patients

\* Anaerobic organism

\*\* Fungus

\*\*\* Micro-aerophilic organism

**Table VII: Antibiotic Sensitivity pattern of isolated organisms**

S/NO.	Organism	Freq uency	%
1.	Third generation cephalosporins	14	17.1
2.	Pefloxacin	8	9.8
3.	Gentamycin	7	8.5
4.	Augmentin	7	8.5
5.	Clindamycin	7	8.5
6.	Erythromycine	6	7.3
7.	Colistine	5	6.1
8.	Azithromycine	5	6.1
9.	Tetracycline	4	4.9
10.	Sultamicillin	3	3.7

11.	Nalidixic acid	3	3.7	18.	Nitrofurantoin	1	1.2
12.	Chloramphenicol	3	3.7	19.	Unacine	1	1.2
13.	Metronidazole	2	2.4	20.	Ofloxacin	1	1.2
14.	Ciprofloxacin	1	1.2	21.	Streptomycin	1	1.2
15.	Carbenicillin	1	1.2	<b>Total</b>		<b>82</b>	<b>100.0</b>
16.	Cotrimoxazole	1	1.2				
17.	Ampicillin	1	1.2				

**Table VIII: Modalities of treatments offered**

S/NO.	Type of treatment	Agent/specific procedure	Frequency	No. of patients
1	Wound dressing	Hydrogen peroxide	Daily	4
		And Eusol	Twice daily	26
		Venegar 1:6 dilution	Twice daily	2
		Flavin dressing	Twice daily	1
		Debridement	Single	17
2	Operative treatment	Multiple		13
		Incision and drainage		1
		Toe amputations		2
		Metatarsectomy		1
		Rotational flap closure		1
		Below knee amputation		2
3	Other ancillary treatment	Above knee amputation		8
		Protective ambulatory plaster cast		1

**Table IX: Severity indices for mortality cases**

Mortality Cases	Venous time (sec)	filling	Wagner grading	Septicaemia	Below knee amputation	Eye signs
Case 1	35		4 → 5			Bilateral cataract
Case 2	30		3			Bilateral cataract
Case 3	28		4	Cardiac failure	-	Grade II Retinopathy
Case 4	30		5	Severe DM	-	Bilateral cataract
Case 5	10		2 and 3 (bilateral)	Septicaemia	-	Blind cataract
Case 6	28		4 (bilateral)	Septicaemia + cardiac failure		Grade II Retinopathy

## DISCUSSION

Even though numerous classifications of diabetic foot disease, aimed at assisting management decisions abound, e.g. Megitt – Wagner classification, the San Antonio Union of Texas Wound Classification, Diabetic foot severity score, Macfarlane and Jeffcoat system etc, the practicability of their clinical use in our environment is doubtful<sup>8,9</sup>. The simple clinical prognostic parameters investigated in this study are aimed at establishing precise criteria for decision taking in diabetic foot disease.

The mean duration of 10.6 years of diabetes mellitus prior to development of foot disease in predominantly non-insulin dependent diabetics is in consonance with other observed characteristics of the disease<sup>10,11</sup>. In addition, 36 patients out of 38 are above 40 years of age. Prolonged venous filling time of more than 30 seconds is a bad prognostic index of the disease. This simple clinical assessment correlated significantly ( $P < 0.005$ ) with mortality and amputated cases. The only mortality case that had low (10 seconds) venous filling time had bilateral disease and

septicaemia. In addition, this series recorded mortalities and limb loses among patients with associated medical complications and relatively high Meggit-Wagner grading ( $\geq 4$ ) of the foot lesions. This would suggest a more careful assessment of the patient in the presence of these complications. Cataract and blindness found in 12 patients and retinopathy in 18 contribute to the Aetiology of the foot disease<sup>10,12</sup>. In addition, eye signs were present in all mortality cases. This may indicate a grave prognostic sign in conjunction with other manifestations.

Thus, anaerobic organisms were isolated (8 out of 54 positive cultures); even then only 2.4% sensitivity to metronidazole was recorded. This would call to question the practice of routine inclusion of this drug in early treatment of diabetic foot disease prior to culture and sensitivity. Aggressive debridement which were often multiple (13 patients) coupled with dressing with desloughing agents after hypertonic saline immersion of the limbs was found useful in healed cases<sup>1,3,5,8</sup>.

Reamputation at a higher level was indicated in two patients that had earlier below knee amputation. When conservative management fails and there is indication for major amputation, a much more proximal level would reduce morbidity. Moreso, patients with diabetic foot disease requiring surgery are anaesthetic risks. From this series, we propose that initial meticulous clinical assessment of the patients using simple prognostic variables would be of immense help in making objective management judgment. In addition, aggressive sequential debridement and repetitive dressing is recommended.

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