Predictive values of risk factors in management of diabetic foot

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Summary:

Background: Outcome of management of patients with diabetic foot is difficult to predict. Assessment of variables in history, examination and investigations were analyzed with outcome of management and whether can be assigned as prognostic factors.

Methods: prospective study of 300 patients with diabetic foot in Baghdad teaching hospital during the period from April 2000 to March 2004 certain criteria was taken in history and examination the

the period from April 2000 to March 2004, certain criteria was taken in history and examination, these were investigated and treated either by conservative procedure or amputation.

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Results: most common age group was 50-59 years (33.3%). The male to female ratio was 2:1. Conservative debridement was performed in (60%) of patients while amputation was employed in (40%), amputation was performed in 604 in patient above 60 years and in(75%) of patients who had diabetic foot lesions for > 2 weeks, and in 90% of smokers for 10 years or more. Amputation was needed in (71%) in those who had history of previous ulceration and 72.5% of patients who had positive history of previous amputation. Amputation was needed in (88%) of those who had their temperature >38 °C. in (91%) of patients who had diabetic foot lesion of Wagner grade>III and 91%, patients with X-ray findings of osteomyelitis.

Conclusions: Highly significant association was found between amputation with following variable, smokers > 10 years, patients with a temperature of > 38 °C, Hypertension > 140/90 mmHg Wagner grade > III, white blood cell count of > 20,000/cc and positive foot X-ray findings. Slight significant association of amputation and the following variables: Age >60 years, duration of foot lesion >2 weeks, history of previous amputation, previous ulceration, negative pedal pulses, deformed feet and patients who had impaired normal vision.

Key words: Diabetic foot, amputation, predictive factors.

Introduction:

Diabetes mellitus is a disorder of carbohydrate metabolism that causes hyperglycemia^{().} Foot complications occur in both forms of diabetes and are related more to the period of time that the illness has been present than to the age of onset ⁽²⁾ Diabetic patients always have suffered from foot ulceration. . Despite progress in the prevention, treatment, and achieving the healing of established ulcers, diabetic foot ulceration remains a considerable challenge^{'3)}. Hitherto, the development of septic foot is the most dreaded complication in diabetic patients ⁽⁴⁾, and the ulceration of the foot is the major precursor leading to amputation('). The pathophysiological changes that contribute to the development of ulceration in diabetic foot patients include the following: structural changes, neuropathic changes abnormal biomechanics, vascular disease, hematological abnormalities and infection(6).

The infection is usually of polymicrobial nature ⁽³⁾, contain both aerobic and anaerobic microorganisms ⁽⁷⁾ In advanced infection or when conservative debridement fails, amputation may be needed to eradicate uncontrollable sepsis⁽⁸⁾

Patients and methods

A consecutive of 300 cases with diabetic foot lesions were managed in Baghdad teaching hospital outpatient department and surgical wards. Assessment of the patients was done regarding their age, sex, duration of their diabetes and its control, duration of their foot lesions, history of smoking, previous ulceration and previous amputation.

Clinical examination was employed to assess patients' temperature, blood pressure, pedal pulses, appearance, mobility and sensation of the foot together with any visual impairment.

According to the severity of presentation, patients were classified according to Wagner's grading of diabetic foot lesions. The patients were investigated by hematological, biochemical and imaging procedures which have included measuring hemoglobin level, WBC count, fasting blood sugar, blood urea and taking an X-ray of the foot ulcer swab and culture sensitivity can not be employed to investigate all of the patients as many of them had already started antibiotics before attending the hospital,. Thus swab culture and sensitivity was excluded from our study. Likewise, Doppler study necessitated very long term appointments in order to be carried out, so it was excluded from this study.

On admission, all patients were started on antibiotic treatment covering both aerobes and anaerobes. Control of diabetes mellitus with soluble insulin was provided together with local

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care of the foot by debridement and adequate drainage. Amputation of one or more toes, excisions of parts of the metatarsal bones, below knee or above knee amputations was

employed whenever needed. Correlation was made between the needed surgical modalities (whether debridement or amputation) and the above mentioned variables in the patients' assessment. Data were collected, statistically analyzed and the results were shown in the form of tables. **Results**

Regarding the age and sex distribution of our patients and their correlation with the modality of treatment, table (1) shows that the highest proportion was found in the (50-59 years) age group (100/300, 33.3%). Male to female ratio 2:1. Conservative debridement was performed in (180/300, 60%) of patients while amputation was employed in (120/300, 40%).

. Concerning the statistical association of the age and sex of the patients with the modality of treatment of diabetic foot, table (2) shows that in patients > 60years, amputation was performed in 72 patients (60%) and debridement in 48 patients (40%), while in patients < 60 years, debridement was done in 132 patients (73%), the remaining 48 patients (27%) ended with amputation. This result was of statistical significance (Odd's ratio = 4).

In regard to the sex of the patient, amputation was performed in (42.5%) of male population, females had amputation in (35%) of them. This result was of no statistical significance (Odd's ratio =1).

In respect to the duration of diabetes mellitus, duration of foot lesion and their association with the type of treatment, table (3) elucidates that in patients who had diabetes mellitus for > 10 years, were treated by (40%) by amputation , (41%) were recorded in less than 10 years diabetic patients giving an Odd's ratio of 1 which is not significant. However, patients who had diabetic foot lesions for _> 2 weeks, (75%) were in need of amputation, In patients of less than 2 weeks duration of chief complaint (16%) were treated by amputative procedures. This result was statistically significant (Odd's ratio = 15).

(91%) had amputation. On the contrary, absence of X-ray evidence of osteomyelitis (10.5%) were treated by amputation. This result was of high statistical significance (Odd's ratio =85).

Age	10005-00) Foregant (0.20		Mode of T		reatment	
group	No.	%	රී	Ŷ	3:2	Debrid	ement	Ampu	tation
(years)						No.	%	No.	%
<40	30	10	12	18	1:1.5	27	90	3	10
40-49	50	16.7	28	22	1.3:1	40	80	10	20
50-59	100	33.3	71	29	2.4:1	65	65	35	35
60-69	75	25	56	19	2.9:1	30	40	45	60
≥70	45	15	35	10	3.5:1	18	40	27	60
Total	300	100	202	98	2:1	180	60	120	40

Table 1: Age and Sex distribution and their correlation with modality of treatment.

Table 2: Statistical correlation between age and sex with the mode of surgical treatment.

Variable		Debrie	dement	Ampı	Odd's		
7411	ant	No.	%	No.	%	Ratio	
Age	≥60	48	40	72	60	- 4	
(years)	<60	132	73	48	27		
Sex	ර්	116	57.5	86	42.5		
Sex	Ŷ	64	65	34	35	1	

Table 3: Relation between duration of diabetes and foot lesions and their association with the type of treatment.

Variable -		Debridement		Атр	Amputation		
		No.	%	No.	%	Ratio	
Duration of *	≥10	79	60%	52	40%		
diabetes mellitus (years)	<10	101	59%	68	41%		
Duration of foot	≥2	31	25%	91	75%	15	
lesion (weeks)**	<2	149	84%	29	16%		

Table (4) shows the correlation between the type of treatment which has been used for control of diabetes and the modality of surgical treatment of diabetic foot lesion. 43% of cases who had NIDDM were in need of amputation while it is recorded in (35%) of cases with IDDM. This result was of no statistical significance (Odd's ratio = 1). In regard to the past surgical and social histories, table (5) clarifies that (90%) of those who smoked for 10 years or more were managed by amputation. On the other hand, in those who smoked for less than 10 years amputation was done in (11%), this result was of high statistical significance (Odd's ratio =72).

Amputation was needed in (71 %) in those who had history of previous ulceration and in (19%) of those with negative history of ulceration. This result was of statistical significance (Odd's ratio = 10).

Implementation of history of previous amputation as a risk factor revealed that (64%) of patients who had positive history were managed by amputation . On the other hand, negative history of previous amputation showed the need of amputation in (27%) of them . This result was of statistical significance (Odd's ratio = 7).Conceming the clinical findings and their association with the surgical modalities table (6) shows that amputation was needed in (88%) of those who had their temperature >_38°C, and in (12.5%) of cases who had their temperature <38°C. This result was of high statistical significance (Odd's ratio=5 1).

Likewise, the association between blood pressure, debridement and amputation carried high statistical significance (Odd's ratio of 42) as amputation was carried out in (86%) of those whom blood pressure > 140/90 mmHg and in (13%) of those with a blood pressure less than 140/90 mmHg. Patients with palpable pedal pulses were in need of amputation in (17%) of them while patients with absent pedal pulses (74%) had amputative procedures. This result was of statistical significance (Odd's ratio=13). Amputation was needed in (41.5%) of patients with intact sanitation . This result was of no statistical significance (Odd's ratio = 1).

The appearance of the foot being normal or deformed had an impact on the type of treatment in that amputation was performed in (71%) of deformed feet and only in (19.7%) of the normally appeared diabetic feet. This result was statistically significant (Odd's ratio=16). Degree of mobility had influenced the treatment modality in that amputation was needed in (73%) of those who had impaired normal mobility and only in (18%) of limbs with normal range mobility. This result was of statistical significance (Odd's ratio= 13). Amputation was employed in (20%) of patients with normal vision and in (70%) of those who had impaired normal vision. This was statistically significant (Odd's ratio=9).

Table 4: Correlation between the type of diabetic treatment and the modality of surgical
treatment of diabetic foot lesion

Variable * -	Debridement		Ampı	Odd's		
	No.	%	No.	%	Ratio	
IDDM	76	65%	41	35%		
NIDDM	104	57%	49	43%	1	

 Table 5: Relation between past surgical and social histories and the modality of surgical treatment of diabetic foot lesion.

Variable		Debri	Debridement		Amputation		
		No.	%	No.	%	Ratio	
History smoking	≥10	11	10%	99	90%	72	
(years) ***	<10	169	89%	21	11%		
History of previous ulceration **	+ve	35	29%	85	71%	10	
	-ve	145	81%	35	19%		
History of previous amputation **	+ve	39	36%	78	64%	7	
	-ve	141	73%	42	27%		

Table 6: Concerning the clinical findings and their association with the surgical mode treatment.

Variah	Variable		dement	Amp	utation	Odd's
		No.	%	No.	%	Ratio
Temperature	≥38	13	12%	96	88%	51
(C ⁰) ***	<38	167	87.5%	24	12.5%	
Blood pressure	≥140/90	15	14%	95	86%	
(mmHg) ***	<140/90	165	87%	25	13%	42
Pedal pulses **	Palpable	148	83%	31	17%	13
	Absent	32	26%	89	74%	
Sensation *	Present	104	61%	66	39%	1
Sensation -	Absent	76	58.5%	54	41.5%	
** **	Normal	146	80.3%	36	19.7%	16
Appearance **	Deformed	34	29%	84	71%	
Mobility **	Normal	148	82%	32	18%	13
Mobility **	Impaired	32	27%	88	73%	
Vision **	Normal	144	80%	37	20%	9
VISION **	Impaired	36	30%	83	70%	9

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Table (7) was edited to verify the distribution of patients according to Wagner's classification of diabetic foot and the incidence of amputation and debridement in each grade. It is shown that the highest proportion of amputation was encountered in grade IV (13/13,100%) and the least in grade I (4/86, 6%). On other hand, debridement was the predominant procedure in grade 1(82/86, 94%) while in grade I non of the patient have underwent debridement.

Table (8) establishes the statistical association between Wagner's grade and the mode of treatment. It is shown that amputation was needed in (91.6%) of patients who had diabetic foot lesion of > grade III and in (11%) in patients whom diabetic foot lesions < grade III. The remaining patients in both groups needed debridement. These results were of high statistical significance (Odd's ratio=84).

In respect to the correlation between certain investigative variables and the modality of surgical treatment, table (9) entails that amputation was done in (42.5%) of patients who had hemoglobin level less than 10 gm/dl and in (39%) of patients with hemoglobin level > 10 gm/dl. The rest of

patients in both groups have their ulcer debrided only. This result is of no statistical significance (Odd's ratio=1).

Regarding WBC count, debridement was carried out in (12%) of patients who had a count $>_20000$ WBC /cc and (86.5%) of patients whom WBC count < 20000/cc. the remaining patients in both groups had amputated procedures. These results were of high statistical significance (Odd's ratio=46).

Considering fasting blood sugar, levels of > 10 mmol/L were associated with amputation rate of (43%). This was less in patients with fasting blood sugar < 10 mmol/L (38%). This was of no statistical significance (Odd's ratio =1).Blood urea levels of > 10 mmol/L estimated an amputation rate of (45%), this decreased to (36.3%) in patients with blood urea level < 10 mmol/L. This result showed no statistical significance.

In regard to X-ray findings of the foot in form of presence or absence of evidence of osteomyelitis, it was found that the majority of patients with X-ray findings of osteomyelitis

Table 7: Distribution of patients according to Wagner's classification of diabetic foot and the incidence of amputation and debridement in each grade.

Wagner's	No. of	Debrid	ement	Amputation		
classification	patients	No.	%	No.	%	
I	86	82	94%	4	6%	
П	99	93	90%	6	10%	
ш	55	6	11%	49	89%	
IV	47	3	6%	44	94%	
V	13		0	13	100%	

Table 8: Statistical association between Wagner's grade and the mode of treatment.

Wagner	Debridement		Amp	Odd's		
wagner	No.	%	No.	%	Ratio	
≥Ш	9	8.4%	98	91.6%	84	
< 111	171	89%	22	11%	04	

Table 9: Correlation between certain investigative variables and the modality of surgical treatment.

Variable		Debri	dement	Атр	itation	Odd's
		No.	%	No.	%	Ratio
Hemoglobin*	≥10g/dl	106	61	67	39	1
memogroun	<10gm/dl	72	57.5	53	42.5	1 -
WBC ***	≥20000/cc	13	12	94	88	
	<20000/cc	167	86.5	26	13.5	46
Fasting blood sugar *	≥10mmol/L	74	57	56	43	
	<10mmol/L	106	62	64	38	.
Blood urea *	≥10mmol/L	72	55	58	45	1 84
	<10mmol/L	109	63.7	62	36.3	1 J
' Foot X-ray changes ***	Evidence of osteomyelitis	10	10	100	91	85
	No evidence of osteomyelitis	170	170	20	10.5	05

Discussion

In this prospective review of a consecutive of 300 cases of diabetic patients presented to the surgi a~ 1 ward in Baghdad teaching hospital during a period of four years, the highest proportion of patients was found in the (50 - 59 years) age group, with a male to female ratio that began with 1:1.5 (table 1) then it was reversed and increased gradually to reach a final ma preponderance of 2:1. This is in accordance with Bentomane A et $al^{(9)}$ who also found that male predominated female in diabetic foot lesions. By comparing these results done in our country Al-Khazraji Z⁽¹⁰⁾: who also found most of the diabetic lesions in the (51-60 years) age group with a male to female ratio of 1.5:1, and studies had done in other countries Walrond ER. and Ramesh $J^{\,(11)}{\rm who}$ found female to male ratio of 1.2:1, one could postulate that the male preponderance in diabetic foot lesions in our country may be attributed to that with increasing age the higher will be the incidence of male population among hard working laborers in our society who are at high risk of the pathophysiological changes in diabetic foot that together with the traumatic factors can lead to diabetic foot ulceration and also may be due to chronic heavy smokers.

Debridement was the cornerstone in the surgical treatment and it achieved healing in (60%) of patients, the rest needed amputative measures. This is in accord with that of Gibbon GWt^{12} and Griffith GD, Wieman $TJ^{(13)}$: who found that adequate cleaning and debridement with dependant drainage are the main stay of treatment of diabetic foot lesions. Higher yields of debridement was achieved with Khammash MR et al⁽¹⁴⁾: who established healing in (84%).

This may be attributed to late presentation of our cases together with poor control of their blood sugar and their health ignorance .

The rate of debridement decreased as the age increased being highest in patients less than 40 years (90%) and lowest in patients > 70 years old (40%). On the contrary, amputative procedures were undertaken in old age more than young age groups (60% versus 10% respectively). This could be explained by that with increasing age the incidence of atherosclerosis and peripheral vascular disease is increased together with the fact that concomitant diabetes mellitus increases the risk and accelerate atherosclerosis. Thus the resultant ischemia will make the presentation of diabetic foot more sever in old age groups and will halt healing of the ulcer, increases the complication and eventually increases the risk of amputation.

Concerning the statistical correlation between age and sex of the patients with the modality of surgical treatment (table 2), it was found that patients >60 years old had 4 times higher risk to have amputation in patients <60 years (odd's ratio=4). While no significant difference was found between males and females regarding the need for amputation (42.5% versus 35% respectively) odd's ratio =1. This result is in agreement with that of Gareth DG and Peter AS (3): who stated that among diabetics it is those who are male and above 60 years old who face the highest risk of amputation. Watt SA et al ⁽¹⁵⁾: who conducted that gender has no implication on fate of the limb in diabetic foot lesions.

In respect to the influence of duration of diabetes mellitus and foot lesion on the surgical management of diabetic foot (table 3), it was found that there is no significant difference regarding the duration of diabetes mellitus (Odd's ratio = 1), while the risk of having amputation among those with foot lesion $>_2$ weeks was 15 times more than those with < 2 weeks lesions (Odd's ratio =15), this result is in accordance with that of Bongala JR ⁽¹⁶⁾: who found that diabetic history as such has no major effect on severity of presentation and does management of diabetic foot lesions however, the longer the history of foot disorders the more severe was the presentation and eventually more radical procedures are needed in the treatment.

Considering the correlation between type of treatment which has been used for control of diabetes mellitus and modality of surgical treatment (table 4), it was found that patients with NIDDM needed amputation more than IDDM patients (43% versus 35% respectively) but this difference remains of no statistical significance (Odd's ratio =1). This result concedes with that of Khammash AR et al (14): who also estimated that there is no significant difference between the two types of diabetes mellitus (NIDDM and IDDM) regarding severity of presentation and modality of treatment. The slightly higher rate of amputation among NIDDM may be attributed to the more insidious onset and poor control of diabetes mellitus by oral hypoglycemic drugs in those patients as compared to IDDM(I7). Regarding the impact of smoking, previous ulceration and previous amputation on the typ of treatment (table 5), it was found that the risk of amputation among those with long history c smokers (> 10 years) is 72 times higher that those with history of < 10 years of smoking. Thi result is in agreement with that of Bongala JR (i6): who also found a high statistical significanc between smoking for long periods and amputation in diabetic foot patients.

To a lesser extent, history of previous amputation and ulceration has influenced the fate c the limb. Patients with previous amputation have 7 times greater chance of having amputatio than non amputated patients, and patients with previous ulceration were at 10 times risk c amputation than those who did not have history of previous ulceration. This result is i accordance with that of Gareth DIG and Peter AS (3): who stated that once one limb ha amputated there is an increased risk that the other limb will also require amputation and thk history of previous ulceration put the limb at higher risk than if the history of previou ulceration was negative.

In respect to the association between the clinical findings with the surgical modality (tabi 6), we have demonstrated highly significant association regarding temperature and bloo pressure with the need of amputation , febrile patients with a temperature of > 38 C° are 5 times more risky for amputation that those with a temperature of $< 38 C^{\circ}$ and hypertensiv patients with a blood pressure of > 140/90 mmHg who represented 36% of our sample had risk of amputation that is 42 times greater than those with a blood pressure of < 140/9 mmHg). This result is in accordance with that of Walrond ER. and Ramesh J(11): who reported rate of 40% of hypertension in diabetic foot patients, Chantelau E et al (18): who reported moi incidence of amputation in diabetic patients with hypertension.

This may be attributed to the breakdown in the regulation of microvascular flow due t decrease in the arterial perfusion pressure; this will result in abnormal vasomotion and uneve distribution of blood flow particularly in nutritive skin capillaries. Consequently, there will b impairment in nutrients supply which is necessary for healing of ulcer. Associated with lock ischemia, this may lead to irreversible tissue damage.

The significant association between temperature and amputation may be related to that hig grade fever reflects a severe underlying inflammatory process including severe infection c deep soft tissues, joints and bones resulting in a rapidly spreading cellulites, fascitis and/or osteomyelitis. Regarding pedal pulses, patients with absent pedal pulses demonstrated an amputation rate of 74%. However, patients with palpable distal pulses were carrying 13 times less risk of amputation as palpable pedal pulses excludes major arterial disease which exacerbate diabetic foot ulcer and increase risk of amputation. This is in accordance with that of Khammash MR et al (14): who recorded an amputation of 67% among patients who had absent pedal pulses. Brodsky JW, Schneider S (19): who found that the presence of pedal pulses can predict good healing after control of infection by debridement and thus less susceptibility of amputation.

In addition, diabetic foot patients with impaired normal vision, deformed feet and impaired mobility carried more risk of amputation (9, 16, 13 times respectively). This is in agreement with Gareth DG and Peter AS (3): who found that impaired vision, deformed feet and impaired mobility put the diabetic foot ulcer at high risk of added complications and increase the risk of amputation.

Conversely, the presence or absence of peripheral neuropathy implied no significant association with the risk of amputation. This result goes with that of Bongala JR et al ⁽¹⁶⁾: who also found that there is no significant association between peripheral neuropathy and amputation in diabetic foot patients This may be related to that peripheral neuropathy plays a role in pathogenesis of diabetic foot ulceration, but once the ulcer is established, peripheral neuropathy impacts no effect on the future fate of ulcer.

Regarding the statistical significance of association between Wagner grade and amputation in (table 8), we have demonstrated a risk of amputation that is 84 times more if Wagner grade >_ III than if it was < III (very high significance). This result is in accordance with that of Mysliwiec J et al ⁽²⁰⁾: who also reported higher incidence of amputation as Wagner grade escalated. This may be explained by the fact that as Wagner grade increases, ischemia will be more and this will make the ulcer of ischemic type and eventually will change the pattern of debridement to amputation.

In respect to the association between certain investigated variables with the modality of surgical treatment and the significance of this association (table 9), we have found high significant association between WBC count and X ray with the needed surgical treatmer (patients with WBC count of > 20.000/cc and X ray evidence of osteomyelitis carried highe risk of amputation than those with WBC count < 20.000/cc and no X ray evidence c osteomyelitis, 46 and 85 times respectively). This result concedes with that of Bongala JR et (16): who also documented the presence of high significant association between leukocytosis an X ray evidence of osteomyelitis with amputated procedures in diabetic foot lesions. Milgrar. JW (21): who found that bone infection in most patients with diabetic foot lesions is associate with vascular impairment. This will prohibit healing of the infected tissues and form a nidus fc the persistence of infection "which will be reflected hematologically by high WBC count" an will end eventually with amputation.of the limb.

Conversely; and inspite of having a slightly higher rate of amputation, patients with raise blood sugar (>_ 1 Ommol/1), high levels of blood urea (> 10 mmol/1) and low hemoglobin level (10gm/dl) showed no statistically significant association with amputation . This result is ii agreement with that of Bongala JR et al (16)

Conclusions:

Foot lesions in diabetic patients are mostly prevalent in the (50-59 years) age group with as overall male to female ratio of 2:1.Debridement was the main used surgical procedure however, the incidence of amputative procedures was escalating as the age of the patier increased. High statistical significance was noted in the correlation between certaii variables and the needed of amputation and these are: history of smoking> 10year: temperature >38C°, blood pressure>140/90, Wagner's grade > III, foot X-ray lesions. Les statistically significant association was concluded with the following variables:Age duration of foot lesion, history of previous amputation history of previous ulceration Visioi impairment, foot deformity, foot mobility . Non significant association was seen betwee the following variables sex of the patient, duration of diabetes mellitus, IDDM versu NIDDM, peripheral neuropathy , hemoglobin level, fasting blood sugar, blood urea.

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