Print ISSN: 2321-6379
Online ISSN: 2321-595X
DOI: 10.17354/ijss/2016/638

Original Article

Analyzing Predictive Factors for Major Lower Extremity Amputations in Diabetic Foot Infection: A Prospective Study

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Abstract

Introduction: Diabetic foot is a common entity in developing nations. Amputation due to diabetic foot infection adds up burden to an individual as well as to the economy of the country. Moreover, there are no separate criteria/scoring for detecting early unsalvageable limb.

Materials and Methods: This is a prospective observational study which was carried out in 120 patients who were admitted with diabetic foot infections in Government Rajaji Hospital, Madurai for a period of 18-month and they were observed for gangrene, pulse status, ankle-brachial index (ABI), infection patterns, osteomyelitis, hemoglobin (Hb), total white blood cells (WBC) count, erythrocyte sedimentation rate (ESR), C-reactive protein (CRP), Lipid profile Lipoprotein (LDL), and cardiac status at the time of admission. A scoring system was devised using these parameters.

Results: Out of these parameters - gangrene, pulse status, infection, osteomyelitis, and ABI were found to be major contributory factors and Hb, duration of diabetes, total WBC count, CRP, cardiac status, ESR, and lipid profile were found to be minor contributory/predictive factors. In this scoring system, patients with score 13 and below were managed by conservative procedures, those with 14-17 went for minor amputation and scores 18 and above went for major amputation.

Conclusion: Using our scoring system, we can separate the patient who is more likely to go for amputations as early as possible and provide them an early apt intervention to save his/her limb.

Key words: Amputation, Diabetes, Diabetic foot, Predictive factors, Scoring

INTRODUCTION

India with approximately 42 million cases is ranked on top of the list of 10 nations massively affected with diabetes.[1,2] Among diabetes related complications, ulceration of foot is the most common one, affecting about 15% of diabetic patients in their lifetime.[2] This can be attributed to several day to day social and cultural practices. Among those barefoot walking, inadequate facilities for diabetes care, poor hygiene, illiteracy, and poor socioeconomic conditions are important which lead to ulceration.[3] Limb amputation has a significant impact on an individual, not only by affecting the physical status but also leads to increasing dependency, loss of income and expenses of treating foot ulcers if patients require admission in a hospital.[4] Sporadic qualitative research suggests that diabetic foot ulceration (DFUs) has a significant social impact with patients reporting stigma, isolation from society, loss of basic social role, and unemployment.[5]

Foot ulceration is absolutely preventable and by simple interventions one can reduce amputations up to 80%. Good hemoglobin (Hb) status, adequate control of blood pressure, and prompt lipid levels are well established crucial elements in the reduction of risk related to complications of diabetes.[6,7] Regular evaluation and early treatment are the most effective mechanisms to prevent the devastating diabetic foot complications. Unfortunately, the majority of

Access this article online

IJSS
www.ijss-sn.com

Month of Submission : 10-2016
Month of Peer Review : 11-2016
Month of Acceptance : 11-2016
Month of Publishing : 12-2016

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patients admitted in the health-care center for DFUs receive an inadequate lower extremity evaluation.[8] Although, there is an obvious increase in diabetic foot care awareness, there are tremendous gaps in routine foot evaluations. To achieve such aims, early detection of the foot at risk should be afforded a high clinical priority. Our interest in identifying the prevalence of risk factors aroused mainly due to the fact that the number of cases attending to our hospital with DFUs has increased tremendously during the last 3-4 years. To our knowledge, this is probably the first report wherein a hospital-based survey from India was conducted to evaluate the role of risk factors involved in DFUs to devise a scoring system.

MATERIALS AND METHODS

This study was conducted in the Department of General Surgery, Government Rajaji Hospital, Madurai. It was conducted after seeking prior approval from the Ethical Committee of the institute. Prior written consent was obtained from every recruited patient.

In total, 403 diabetic patients attending the hospital were examined and 120 were diagnosed to have diabetic foot infections in the span of 18 months.

Diabetes was diagnosed following the criteria of the World Health Organization of a fasting venous plasma glucose >7.0 mmol/L or a 2 h postprandial venous plasma glucose level of >11.1 mmol/L using the glucose oxidase method.[9] Patients were interviewed using a pretested structured questionnaire to document clinical history namely family/social history, age, sex, routine habits (smoking, tobacco chewing, and alcohol intake), duration of diabetes and diabetic foot, treatment, and causes of foot ulcer. Patients were critically asked to provide details related to the duration of the DFUs and possible causative factors if they were able to sense the presence of the foot ulcer before its actual appearance.

A complete clinical examination was performed on the foot to identify any presence of gangrene, involvement of bone, cellulitis, pulse status, and ankle-brachial index (ABI).

Complete biochemical investigations such as Hb%, total white blood cells (WBC) count, erythrocyte sedimentation rate (ESR), C-reactive protein (CRP), lipid profile (LDL), and renal function tests were performed.

X-ray of concerned local part, bacteriological tissue culture, and echocardiogram were also taken.

Using these data and clinical analysis, a scoring system was formulated (Table 1).

RESULTS

Total number of patients - 120
Conservatively managed - 76
Major amputations - 35

- Amputation at transtibial level (below knee amputation) or higher.

Minor amputations - 9

- Toe disarticulation
- Ray amputation
- Midtarsal amputation
- Tarso-metatarso amputation.

Age distribution of 120 cases was studied. Out of which, youngest patient was 35 years old and eldest patient was 75 years old. Highest number of cases was found in the age group of 61-70 (Table 2). By age distribution, patients with younger age tend to have aggressive disease.

Out of 120 patients, 96 were male and 24 were female (Table 3). Males are more commonly affected in diabetic foot infections and amputation rates are also higher compared to females.

100% of patients with complete gangrene went for amputation (Table 4).

100% of patients with absent pulse went for amputations. In case of weak pulse, out of 48 patients, 9 went for minor amputation (Table 5).

In case of ABI, patients with critical limb (i.e., <0.3) were 100% unsalvageable (Table 6).

In case of bony involvement, i.e., osteomyelitis, out of 30 patients with osteomyelitis, 17 went for amputation, 9 went for minor amputation; in comparison with nonosteomyelitic limb out of 90 patients 18 alone went for amputation (Table 7). Infections tend to be more severe in case of polymicrobes. Out of 35 amputations, 34 are infected with polymicrobes (Table 8). In all those 35 amputations, amputees had resistant organisms invariably (Table 9).

With regards to duration of diabetes, out of 35 patients, 30 were having diabetes for more than 5 years and within a year of diagnosis of diabetes no one was going for amputation (Table 10).

Out of 35 patients, who went for amputation, 25 patients were with Hb <8 g/DL (Table 11). Patients with total WBC count more than 15000 cells/cumm, 22 patients went for amputation. And with count 10000 cells/cumm to 15000 cells/cumm, 13 patients went for amputation (Table 12).

Table 1: Scoring system

Madurai medical (MM) scoring system for analyzing major contributing factors for lower limb amputations in diabetic foot infections			
	0	1	2
Presence of gangrene	Nil	Minimal color change	(+)(+) Complete gangrene
Pulse status of concerned part	(+) (+)	(+)	(−)
ABI	0.9-1.1	0.9-0.3	<0.3
Bony involvement	Nil		Osteomyelitis (+)
Infections	Nil	Monomicrobial	Polymicrobial
Duration of diabetes	<1 year	1-5 yr	More than 5 years
Antibiotic sensitivity	No resistance		Resistant to any drug
HB%	>12 g	8-12 g	<8 g
TC	<10000 cells/cumm	10000-15000 cells/cumm	>15000 cells/cumm
ESR	<20 mm/h	20-100 mm/h	>100 mm/h
CRP	<0-10 mg/l	10-15 mg/l	>15 mg/L
LDL	<100 mg/dl	100-189 mg/dl	>190 mg/dl
Cardiac status	Normal ECHO study	LVEF<50%	LV thrombus; EF<40%

LVEF: Left ventricular ejection fraction, ABI: Ankle-brachial index, ESR: Erythrocyte sedimentation rate, CRP: C-reactive protein, TC: Total count, Hb: Hemoglobin, LDL: Lipid profile

Table 2: Age distribution

Age	Conservative	Amputation	Minor
<50	9	14	0
51-60	17	12	3
61-70	39	7	4
>70	11	2	2

Table 3: Sex distribution

Sex	Conservative	Amputation	Minor
Male	62	27	7
Female	14	8	2

Table 4: Presence of gangrene

Presence of gangrene	Conservative	Amputation	Minor
Nil	41	0	0
Minimal color change	35	0	9
(+)(+) Complete gangrene	0	35	0

Table 5: Pulse status of concerned part

Pulse status of concerned part	Conservative	Amputation	Minor
(+)(+)	37	0	0
(+)	39	0	9
(-)	0	35	0

Table 6: ABI

ABI	Conservative	Amputation	Minor
0.9-1.1 (38)	38	0	0
0.9-0.3 (47)	38	0	9
<0.3 (35)	0	35	0

ABI: Ankle-brachial index

Out of 35 amputations, 32 patients had high levels of CRP, i.e., more than 10 mg/L (Table 13). In case of ESR <20 mm/h, all those patients were managed conservatively while patients with ESR>100 mm/h went for amputation invariably (Table 14).

Lipid profile plays an important role in influencing diabetic foot amputation. Out of the total 35 amputees, 10 had LDL level <100 mg/dl whereas 25 had >100 mg/dl (Table 15). Cardiac status of the patient was evaluated by left ventricular ejection fraction (LVEF). In almost 60% of amputated patients, the LVEF is <50% (Table 16).

Scoring System Observed from Above Study (Table 17)

Scores 13 or below went for debridement alone.
Scores 14-17 went for minor amputation.
Scores 18 and above went for major amputation.

DISCUSSION

In our study, among those amputees, patient with age <50 years - 40% went for amputation, 51-60 - 34.3% went for amputation, 61-70 - 20% went for amputation, and >70 - 5.7% went for amputation. Young people tend to have more aggressive disease. Patients with presence of gangrene, absent local pulse, critical ABI went for major amputations, whereas patients with pregangrenous change, weak local pulse there is increased chances of minor amputation. Persistent infection may occur due to underlying osteomyelitis.[10] In case of bony involvement, i.e., patients with features of osteomyelitis 56.6% went for major amputation and 30% went for minor amputation. A diabetic patient with neuropathy is more prone for repetitive trauma and infection.[11] Polymicrobes are invariably common in amputees and accounts for about 97.1%. Moreover, they are resistant to at least one drug. Among amputees, 85.7% of patients have diabetes >5 years.

Table 7: Bony involvement

Bony involvement	Conservative	Amputation	Minor
Nil	72	18	0
Osteomyelitis (+)	4	17	9

Table 8: Infections

Infections	Amputation
Nil	0
Monomicrobial	1
Polymicrobial	34

Table 9: Antibiotic sensitivity

Antibiotic sensitivity	Amputation
No resistance	0
Resistant to any drug	35

Table 10: Duration of diabetes

Duration of diabetes (year)	Amputation
<1	0
1-5	5
More than 5	30

Table 11: Hemoglobin

Hb%	Amputation
>8 g	10
<8 g	25

Hb: Hemoglobin

Table 12: Total WBC count

TC (cells/cumm)	Amputation
<10000	0
10000-15000	13
>15000	22

WBC: White blood cells, TC: Total count

Hb level plays an important role since it is responsible for the cellular oxygen supply.[12] Hence, amputation tendency increases with fall in Hb% levels due to reduced oxygen supply. Total WBC count reflects the wound infection rate and it increases in infection.[13] In our study, amputation rate increases with increase in total count (TC). Among those 35 amputations, 62.8% of patients had TC >15000 cells/cumm.

CRP provides a direct index of acute inflammatory process[13] and 91.4% of total amputees had elevated CRP levels.

ESR denotes an indirect measure of acute phase response.[13] Out of 35 amputees, 17.2% had elevated ESR >100 mm/h and 82.8% had elevated ESR levels but <100 mm/h.

Table 13: C-reactive protein

CRP	Amputation
<0-10 mg/dl	3
>10 mg/dl	32

CRP: C-reactive protein

Table 14: ESR

ESR	Amputation
<20 mm/h (8 patients)	0
20-100 mm/h (106 patients)	29
>100 mm/h (6 patients)	6

ESR: Erythrocyte sedimentation rate

Table 15: LDL

LDL	Amputation
<100 mg/dl (80 patients)	10 (29%)
>100 mg/dl (40 patients)	25 (71%)

LDL: Lipid profile

Table 16: Cardiac status

Cardiac status	Conservative	Amputation	Minor
Normal ECHO study	65	11	4
LVEF<50%	11	24	5

ECHO: Echocardiogram, LVEF: Left ventricular ejection fraction

Table 17: Conclusion

Score	Surgical management
13 and below	Debridement alone
14-17	Minor amputation
18 and above	Nonsalvageable

Dyslipidemia is a risk factor for peripheral arterial disease.[14] High LDL is a major risk factor for atherosclerosis[15] and peripheral arterial disease. Among those amputation, 71.4% of patients had elevated LDL levels. A decrease in ejection fraction compromises cardiac function and may lead to cardiac failure,[16] which aggravates ischemic changes.[11] In almost 60% of amputated patients, LVEF is <50%.

From the above study, the following factors are considered as major contributory/predictive factors for amputation in diabetic foot patients - presence of gangrene, pulse status of concerned part, ABI, presence of osteomyelitis, and soft tissue infections. The minor contributory/predictive factors for amputation in diabetic foot patients are as follows - hemoglobin status, total WBC count, ESR, CRP, lipid profile (LDL), duration of diabetes, and cardiac status.

CONCLUSION

Diabetic foot infection should be treated aggressively to prevent morbidity and mortality of the patient. Our study concluded about the major and minor predictive/ contributory factors for amputation. Moreover, we also devised a scoring system to predict the early unsalvageable limb so as to attain the best possible outcome for the patient, i.e., a stable limb with intact sensation that can engage in everyday activities.

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How to cite this article: Chitra S, Mary CF, Sathiyaseelan. Analyzing Predictive Factors for Major Lower Extremity Amputations in Diabetic Foot Infection: A Prospective Study. Int J Sci Stud 2016;4(9):168-172.

Source of Support: Nil, **Conflict of Interest:** None declared.