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General Surgery

SCORING SYSTEM FOR ASSESSING RISK OF AMPUTATION IN PATIENT'S WITH DIABETIC FOOT

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ABSTRACT Diabetic foot problems are common throughout the world, resulting in major economic consequences for the patients, their families, and society. Our aim is "To formulate a risk scoring system that can predict the risk of amputation in a patient with an infected diabetic foot". Previously published studies aimed at identifying independent risk factors for lower-extremity amputation in patients with a DFI have noted an association with older age, the presence of fever, elevated acute-phase reactants, higher HbA1c levels, and renal insufficiency. In the current study, we have identified that Age, Duration of diabetes, History of amputations, Ulcer depth, Ankle-brachial index, Severity of infection, and Peripheral neuropathy, Peripheral arterial diseases are significantly associated with Lower Extremity amputation. Peripheral vascular disease and infection were the most powerful predictors, as 65% of patients who underwent amputations in our study belonged to Rutherford grade 3 and grade 4. We developed a New Risk score for predicting amputation in diabetic patients with an infected foot ulcer, which can be readily used in daily clinical practice without the necessity of extensive lab investigations. Patients with a score of >16.5 are at increased risk of lower extremity amputation. 66.6% of our follow up cases who underwent reamputations belonged to the group with a score of >16.5. Risk of amputation increases as the score increases.

KEYWORDS :

INTRODUCTION:

Diabetic foot defined by the World Health Organization (WHO) as "The foot of a Diabetic patient that has the potential risk of pathologic consequences, including infection, ulceration, and destruction of deep tissues associated with neurologic abnormalities, various degrees of peripheral vascular diseases and or metabolic complications of diabetes in lower limb" [(1)].

India is slowly progressing at a pace in the present world with the largest number of diabetic patients and is being anticipated to be the "diabetes capital of the world." According to the Diabetes Atlas 2013 published by the International Diabetes Federation, the number of people with diabetes in India currently is 65.1 million, which is expected to rise to 142.7 million by 2035[(2)].

After a major amputation, 50% of subjects will need to have the contralateral extremity amputated within two years. People with diabetic foot ulcers have a 40% greater 10-year death rate than people with diabetes alone. [(3)] Although recent population-based data for Diabetic Foot Ulcer (DFU) is not readily available, and approximately about 45,000 legs are amputated each year in India [(4-6)] Diabetes cost a whopping USD 548 billion in health expenditure globally in 2013. In a report published by Gupta S (2012), an average Indian would spend approximately 1960 USD to complete the neuron-ischemic foot. [(5)]

MATERIALS AND METHODS:

Study area: Department of general surgery, Katuri medical college.
Study population: Both OPD and IPD Patients who have come to Katuri medical college & hospital for the management of Diabetic Foot Infection.
Study Design: Prospective observational study.
Sample size: 150
The sample size was determined by using the effect sizes from the previously published studies [(5)] and with the help of following formula [(7,8,9)]:

$$n = z2\frac{pq}{(me)}2$$

p = 0.25 (Approximate estimate of incidence of amputation among the cases presented with diabetic foot related complications having relatively higher risk Factors).
q = 0.75, Z = 1.96, me = 0.070
z = score at 95% confidence interval = 1.96.
me = 0.070 (margin of error).
Thus, according to this formula, the minimum sample size required is 147; we have conducted a study on 150 population.
Sampling Technique: Convenience sampling.
Time frame: 18 months (December1st,2018, to June 1st, 2020).

INCLUSION CRITERIA:

1)Patients above 18 years of age with a primary diagnosis of DM and presenting with a foot ulcer, infection.
2) All the patients with diabetic foot who underwent amputation in the past
and presenting with diabetic ulcer of the opposite foot or same foot.

EXCLUSION CRITERIA:

1) All the foot ulcers caused by peripheral vascular disease not associated
with DM.
2) All the traumatic amputations.
3) Patients admitted for diabetic foot infection but not willing to participate in
the study.
4) Patients less than 18 years of age.

DATA COLLECTION:

1) Patient's case file
2) Investigation reports
3) Patient information sheets and informed consent forms.

MATERIALS:

Sphygmomanometer, 10g monofilament, hand-held Doppler.

METHODOLOGY:

The study includes 150 subjects who were previously diagnosed with Diabetes by a physician and now presented with diabetic foot ulcer infection to katuri medical college & hospital.

All the eligible subjects for inclusion criteria were included in the study after their consent for participation in this research. Exclusion criteria include subjects who were lost to follow up, subjects who expired after taking part in the study within 18 months, subjects with

psychiatric illness that prevented informed consent, subjects under 18 years of age, and all subjects diagnosed with non-diabetic amputations were excluded. A total of 203 patients presented with infected diabetic foot ulcer to our hospital, of which 29 refused to participate in the study, 3 were psychiatric patients who were unable to give consent to participate in the present study, seven patients expired within the follow-up period, and 14 patients lost to follow up.

STATISTICAL METHODS:

The data on categorical variables are presented as n (% of cases). The statistical significance of the difference of categorical variables across two study groups (Amputation Required Group and Amputation Not Required Group) is tested using the Chi-Square test or Fisher's exact probability test. The optimal discriminating threshold cut-off of the Total risk score for predicting amputation incidence is determined using Receiver operating characteristics (ROC) curve analysis. The diagnostic efficacy indices such as sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy are calculated and 95% CI for accuracy measures. P-values less than 0.05 are statistically significant. All the hypotheses are formulated using two-tailed alternatives against each null hypothesis. The entire data was statistically analysed using Statistical Package for Social Sciences for MS Windows.

RESULTS:

1) Distribution of cases studied and amputations according to the levels of total risk score (n=150): 81.8% of cases who underwent amputation had a score >16. As the score increased, the amputation risk increased, with 100% of cases who scored >25 underwent amputation.

2) Distribution of cases studied according to levels of total risk score amputation cases(n=44): A maximum number of amputations were identified in the group with a Risk score ranging from 20-24, with 34% of 44 cases.

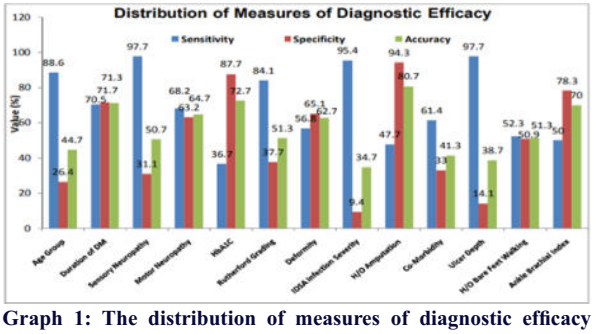
3) Distribution of incidence of amputation according to age group (n =150): The maximum number of patients were found to be in the age group of 50- 65 years, of which 28% underwent amputations. But the incidence rate of amputations was high in the age group of >65 years, which was 54%.

4) Distribution of incidence of amputation according to the duration of diabetes (n =150): The longer the duration of diabetes greater is the risk of amputation.71.4% of patients with > 20 years of duration of diabetes underwent amputations compared to 14.6% in the group with <10yrs.

5) Distribution of incidence of amputation according to grades of Sensory neuropathy (n =150): Subjects with sensory neuropathy involving ≥3 sites have a higher risk of amputations as compared to the subjects with no neuropathy. 68.1 % of the patients with grade 2 neuropathy (i.e., ≥3 sites) underwent amputations compared to 2.9 % in the group without neuropathy.

6) Distribution of incidence of amputation according to Motor neuropathy (n =150): 43.5% of patients with sensory neuropathy underwent amputations. 82.7% of patients without sensory neuropathy did not require amputations.

DIAGNOSTIC EFFICACY:

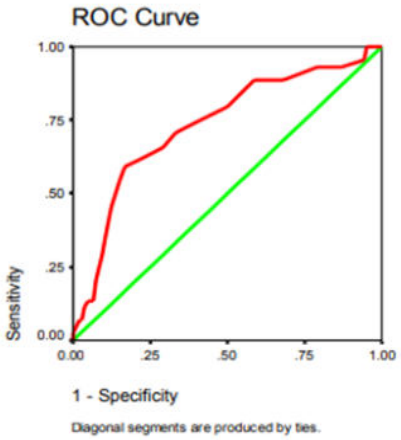


Graph 1: The distribution of measures of diagnostic efficacy [Sensitivity, Specificity, PPV, NPV, and Accuracy] of various risk factors studied for predicting the incidence of amputation (n= 150).

Interpretation:

History of amputation, HbA1c, Ankle-brachial index, and duration of diabetes showed high accuracy in predicting lower extremity amputations in an infected diabetic ulcer patient.

Receiver Operating Characteristics (ROC) curve for Total Risk Score including 13 risk factors.



Graph 2: ROC Curve for Total Risk Score as a predictor for Amputation – ROC Analysis (n=150).

Variables in the model		Odds Ratio (OR)	95% CI of OR	P-value
Age Group	<50 years	1.0	--	--
	>50years	1.77	0.86 – 2.36	0.103^{NS}
Duration of DM	<10 years	1.0	--	--
	>10 years	3.84	1.88 – 5.32	0.001***
Sensory Neuropathy	Grade 0	1.0	--	--
	Grade>0	1.63	0.89 – 3.13	0.098^{NS}
Motor Neuropathy	Grade 0	1.0	--	--
	Grade>0	1.83	0.90 – 2.46	0.229^{NS}
HbA1C	≤7%	1.0	--	--
	>7%	5.84	3.03 – 7.49	0.001***
Rutherford Grading	Grade 0	1.0	--	--
	Grade>0	3.48	2.06 – 5.23	0.002**
Deformity	Absent	1.0	--	--
	Yes	1.41	0.83 – 2.32	0.343^{NS}
IDSA Infection Severity	Grade 1	1.0	--	--
	Grade>1	1.56	0.91 – 2.03	0.239^{NS}
H/O Amputation	Absent	1.0	--	--
	Yes	1.53	0.91 – 1.96	0.314^{NS}
Co-Morbidity	Absent	1.0	--	--
	Yes	1.61	0.83 – 2.56	0.199^{NS}
Ulcer depth	Grade 1	1.0	--	--
	Grade>1	1.56	0.83 – 2.06	0.144^{NS}
H/O bare feet walking	Absent	1.00	--	--
	Yes	1.45	0.84 – 1.94	0.203^{NS}
Ankle brachial index	0.91 – 1.29	1.0	--	--
	≤0.9 OR ≥1.30	2.47	1.23 – 3.98	0.038*

Table 1- Significance Of Variables. P-value <0.05 Is Statistically Significant.

Interpretation:

Duration of DM, HbA1c, Rutherford grading, and ankle-brachial index are the significant and independent determinants of Amputation (P-value <0.005 for all).

DISCUSSION:

Previously published studies aimed at identifying independent risk factors for lower-extremity amputation in patients with a DFI have noted an association with older age [10] the presence of fever, elevated acute-phase reactants, higher HbA1c levels [11], and renal insufficiency. In the current study, we have identified that Age, Duration of diabetes, History of amputations, Ulcer depth, Ankle-brachial index, Severity of infection, and Peripheral neuropathy, Peripheral arterial diseases are significantly associated with Lower Extremity amputation. Peripheral vascular disease and infection were the most powerful predictors, as 65% of patients who underwent amputations in our study belonged to Rutherford grade 3 and grade 4.

Lipsky et al. described that the severity of infection is an independent risk factor for diabetic foot amputation. The risk of amputation increases with the severity of the infection [12]. The same was reflected in our study, with the highest incidence rate of 44.7% of amputations belonged to IDSA grade 4.

Adler AI et al. demonstrated a direct association between hyperglycaemia (as measured by HbA1c) and lower extremity amputation, according to which the risk of amputation raises 1.26 times for each percentage point increase in the HbA1c [13]

Our study results show a significant association between HbA1c and Lower extremity amputation, with the maximum number of

amputations identified in patients with HbA1c ≥9.5.

In the present study,77.8% of patients who had a history of lower extremity amputation due to diabetes underwent amputations [13]. Several studies demonstrated the ulcer's depth as an independent risk factor for lower extremity amputations in a diabetic patient. Some studied the correlation of positive probe to bone test with the incidence of major LEA [14]. 68.1% of patients who underwent amputations had sensory neuropathy in ≥3 sites. There was a significant correlation between motor neuropathy and lower extremity amputation in our study [15]. Also, Age and Duration of diabetes were found to be significantly correlated with the incidence of Lower extremity amputation [16]. Using the specificity and sensitivity of our 13 risk factors, we constructed a ROC curve according to which our new Risk score had a high prognostic accuracy based on the area under the curve of 0.733, which was higher than the International Working Group on the Diabetic Foot (IWGDF) system which was 0.67 [14].Of the 13 risk factors, two risk factors were found to be significantly not associated with lower extremity amputation; hence we excluded them. Remaining 11 risk factors that had a significant correlation with diabetic foot amputation were used to construct another ROC curve, which had a higher prognostic accuracy than the previous area under the curve of 0.903. The Resultant ROC curve yielded a cut-off score of 16.5 A total of 9 patients required re amputation and 26 patients who were our previous amputee subjects required re debridement within a period of 18 months. All the patients who underwent reamputation had a score of >16.5.

CONCLUSION:

1. We developed a New Risk score for predicting amputation in diabetic patients with an infected foot ulcer, which can be readily used in daily clinical practice without the necessity of extensive lab investigations.
2. Patients with a score of >16.5 are at increased risk of lower extremity amputation.
3. 66.6% of our follow up cases who underwent re amputations belonged to the group with a score of >16.5.
4. Risk of amputation increases as the score increases.
5. Of the several risk factors, we studied the duration of diabetes, HbA1c, Peripheral Vascular Disease, and the Ankle Brachial Index were found to be independent risk factors.
6. According to our study, HbA1c is independent risk factor with the highest accuracy in predicting lower extremity amputation in a patient with an infected diabetic foot ulcer.
7. Since the study was conducted in a single institution, further cohorts are required to validate our results.

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