Predictive validity of Amit Jain's screening tool in estimating the risk of complications in diabetic foot — a retrospective cohort study


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Aim: The aim of this study was to assess the new Amit Jain's linear foot test (LFT) screening tool (scored) in estimating the risk of developing complications in the foot in diabetes. **Method and materials:** All patients who were seen at Amit Jain's Institute of Diabetic Foot and Wound Care at Brindhavvan Areion Hospital, Bengaluru, India, were included in this study. The study period was from January 15, 2019 to July 15, 2019 and patients were followed until June 15, 2020. Statistical analysis was done using SPSS 25 and *P* value of less than 0.05 was considered significant. The study was approved by ethics committee. **Results:** Fifty-two patients were included in the study: 63.5% were males. Only 10 patients (19.23%) had diabetes of more than 20 years' duration. Around 84.6% had underlying neuropathy and 21.2% had non-palpable pulses. Jain's LFT screening tool was used to estimate the risk of developing complications in diabetic foot; 53.8% of the patients had a score of 2 and 71.2% belonged to high-risk category. Within the high-risk group, 27% of the patients developed complications within 1 year. The sensitivity of this score was 100% and area under curve was 0.704 showing that this scoring system is clinically useful. **Conclusion:** The new Amit Jain's scoring system for the LFT screening tool shows a good sensitivity and area under curve. Patients in the high-risk category are at significant risk of developing complications in the foot within 1 year and they should be followed up periodically. This new scoring to the screening tool increases the utility of the Amit Jain's triple assessment and opens further prospects for research of the tool.

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It is estimated that by 2045, there will be 628 million people living with diabetes (Abdisaa et al, 2020). Diabetes and its complications are growing rapidly globally, and the increase is higher in Asian and African countries, leading to huge burden on healthcare system (Rowley et al, 2017; Wang et al, 2018). One serious complication of diabetes is diabetic foot ulceration, which leads to an increase in morbidity and mortality, thereby decreasing the quality of life, especially after amputation (Abdisaa et al, 2020). Prior to ulceration, the feet of people with diabetes often have underlying problems, such as neuropathy, ischaemia or deformities.

Trauma to the insensate foot often leads to entry of bacteria (Zubair, 2020). Furthermore, loss of sensation leads to higher pressure areas on plantar aspects leading to callus formation and ulceration, which could lead to amputation (Mishra, 2017).

It is well known that 15% of patients with diabetes are likely to develop ulcers in the foot during their lifetime with 5% of people with diabetes developing foot ulcers annually and more than half of these foot ulcers going on to become infected (Alonso-Fernandex et al, 2014; Jain and Gopal, 2020). As many as 7–20% of these will result in some form of lower-limb amputation (Alonso-Fernandex et al, 2014).

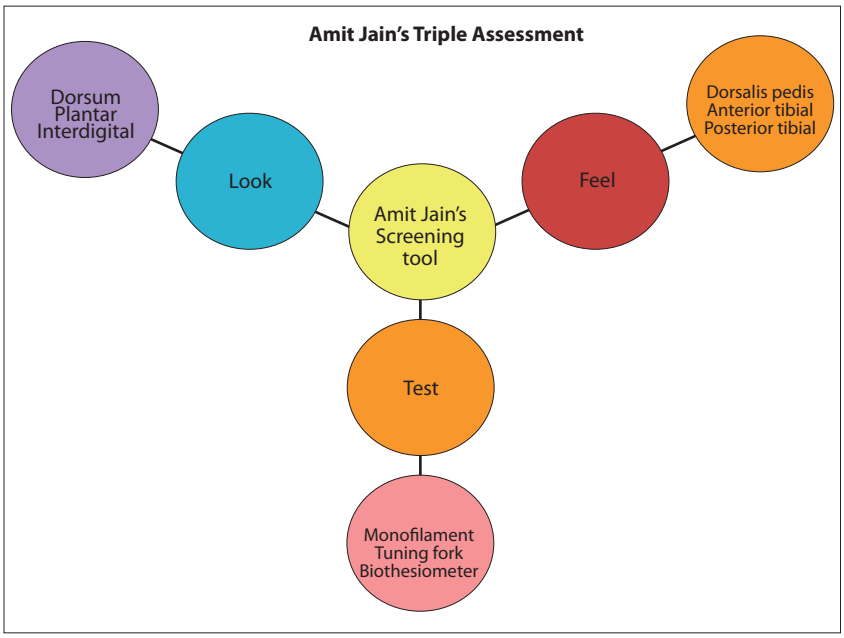

Figure 1 (above). Amit Jain's screening tool for diabetic foot.

Figure 2 (right). Dorsum of the foot — Look component.

Figure 3 (right). Palpation of dorsalis pedis artery — Feel component.

In a recent study from India (Jain and Santosh, 2020), around 40% of diabetic foot patients presenting to hospital will require an amputation. The problem does not end here. These patients are prone for readmissions, recurrence of problem or re-amputations (Galea et al, 2009; Ang et al, 2013; Choi et al, 2014). It is well known that ulcer recurrence is high within 1 year after healing (Gale et al, 2009; Khalifa, 2018).

Foot amputations in people with diabetes can be prevented by identifying high-risk groups and this can be achieved through screening (Nanwani et al, 2019; Abdisaa et al, 2020; Jain and Gopal, 2020). Despite knowing that 75–80% of diabetic foot complications and amputations can be prevented by screening and education, there are many studies that show screening is omitted by some healthcare professionals (Jain and Gopal, 2020). A hospital-based study from Karachi, Pakistan, by Kumar et al (2016) showed that only 13.5% of the feet of people with diabetes were screened.

Various novel methods of foot evaluations/screening/campaign have been developed over years and they include comprehensive foot examination, 3-minute foot examination, Inlow's 60-second screening tool, simplified 60-second foot screen (Boulton, 2008; Sibbald et al, 2012, Kunhe et al, 2013; Miller et al, 2014; Stang et al, 2014; Jain, 2017).

Each of the diabetic screening tools has its own merits. The comprehensive foot examination and 3-minute foot exam are not screening methods, but are detailed foot evaluation methods and often require charts to remember. Inlow's 60-second screening tool and simplified 60-second foot screen also requires a chart to remember the parameters and often can take longer if performed by non-specialists and other healthcare professionals.

A new screening tool, known as Amit Jain's triple assessment for diabetic foot, was proposed by the authors recently *[Figure 1]*. It is also known as 'Amit Jain's 10–20 second screening tool/Linear foot test' (Santosh and Jain, 2018; Jain et al, 2018; Jain, 2020; Jain and Gopal, 2020). This screening tool can be easily performed by any healthcare professionals, including family physicians who are primary care givers. This screening tool has three components namely the Look, the Feel and the Test component.

The Look component aims to identify infection/ulcer and pre-ulcerative lesion like callus. The areas of the foot that needs to be seen are the dorsum *[Figure 2]*, interdigital/

Figure 4. Monofilament testing — Test component.

Figure 5. Common sites on foot for neuropathy testing.

web space and the plantar surface. The Feel component aims to assess the blood supply to the foot. One can palpate the dorsalis pedis/anterior tibial artery *[Figure 3]* and the posterior tibial artery. The Test component aims to assess the sensation of the foot addressing the neuropathic diabetic foot (Jain et al, 2018; Jain et al, 2019). One can use commonly suggested instruments like Semmes monofilament *[Figure 4]*, Tuning fork, vibratip and biothesiometer (Jain et al 2019). The monofilament test determines the touch sensation of the foot, whereas the tuning fork or the biothesiometer assesses the vibration sensation. One is advised to check at least three to four sites on the foot *[Figure 5]* and the commonly tested sites are the pulp of great toe, first and the fifth MTP region of the foot (Jain et al, 2019). A study by Santosh et al (2018) on the Amit Jain's screening tool revealed that only 7.7% of the feet of people with diabetes were screened, while just 6.2% were inspected, 1.5% pulses were checked and none of the patients had sensation assessed (Santosh et al, 2018).

Later, scores *[Table 1]* were added to each component of this new screening tool (Jain, 2020). This new Amit Jain's scoring system has a maximum score of 3. Patients with a score of 0 or 1 belong to low-risk categories, whereas those scoring 2 and 3 are in high-risk categories *[Figure 6]*. This study aimed to determine the predictive validity of this new Amit Jain's scoring system for diabetic foot screening.

Methods and materials

All patients who were seen or screened at Amit Jain's Institute for Diabetic Foot and Wound Care at Brindhavvan Areion hospital, Bengaluru, India, from January 15 to July 15, 2019 were included in this study and were followed until June 2020 (at the same centre) to determine whether or not there was an occurrence of new complications. Outpatient records, operation theatre register and emergency room records were reviewed. All the patients who underwent surgery from January to July 2019 were included in the study. Patients who operated elsewhere during the above period or were not followed up were not included. The study was approved by Institutional ethics committee (RRMCH-IEC/22/2020-21).

Demographic data collected included age, sex, diabetes duration, presence of comorbidities like hypertension, chronic kidney disease and ischaemic heart disease were collected from case notes, admission sheets, operation register and discharge summaries. The adequacy of foot circulation was checked clinically by palpating the pulses. Only in cases where foot oedema prevented pulses from being palpated was a handheld Doppler or duplex ultrasound used. The presence of neuropathy was determined with 10 g monofilament, vibratip or Biothesiometer. The authors usually use a combination of monofilament and vibratip and, in some cases, Biothesiometer. Patients were subsequently scored. All patients with scores of 0 and 1 were deemed low risk (Group A), while patients scoring 2 and 3 were considered high risk (Group B).

Statistical analysis

Both descriptive and inferential statistics were measured in this study. Descriptive statistics are reported using mean and SD for the

Table 1. Amit Jain's scoring system for the LFT screening tool.

Parameters	Description		Score
Look	Any infection/ulcer or pre-ulcer causing pathology-like callus	No	0
		Yes	1
Feel	Pulses of foot – palpable or not	Yes	0
		No	1
Test	Sensation of the foot – present or not	Yes	0
		No	1
The maximum score is 3			

Figure 6. Risk categorisation of the new Amit Jain's scoring system.

normally distributed continuous variables, for the variables that are not normally distributed were median with 25th and 75th percentiles. Categorical variables were reported as number and percentage. Student t test (two tailed) has been used to find the significance of study parameters on continuous scale between two groups (Inter group analysis) on metric parameters. The Chi-square/Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups. Logistic regression analysis was performed to find the factors associated with the high-risk category. Adjusted odds ratio and 95% confidence interval was reported. The discriminative power of the prediction of score was assessed by calculating the area under the receiver operating characteristic (ROC) curves (AUC). Sensitivity, specificity, positive predictive and negative predictive values were reported. A *P* value less than 0.05 was considered statistically significant. All the analyses were performed using SPSS version 25.0 (IBM Corp-2017).

Results

A total of 52 patients were included in this pilot study. The mean age was 60.43 ± 11.27 years. Males accounted for the majority of the cases (63.5%). A total of 19.23% of patients had diabetes mellitus of more than 20 years' duration *[Table 2]*. No statistical significant difference in age, gender or duration of diabetes mellitus was found between the groups.

Comorbidities, such as hypertension, ischaemic heart disease or chronic kidney disease were present in 63.5% of the sample. Hypertension was common and seen in 53.8%, chronic kidney disease was seen in

Table 2. Patient demographics.				
Variables	Number (*n*=52)		Total (percentage)	*P* value
	Group A (low risk)	Group B (high risk)		
Age (years)	60.73 ± 10.14	60.38 ± 11.96		0.184
Gender				
- Male	8 (53.5%)	25 (67.6%)	33 (63.5%)	0.334
- Female	7 (46.7%)	12 (32.4%)	19 (36.5%)	
Duration of diabetes mellitus (years)	13.8 ± 7.37	15.32 ± 7.98		0.852
<10 years	6 (40%)	12 (32.4%)	18 (34.62%)	0.756
11–20 years	7 (46.7%)	17 (45.9%)	24 (46.15%)	
>20 years	2 (13.3%)	8 (21.6%)	10 (19.23%)	

3.8% and 21.2% of patients had ischaemic heart disease. Using the three components, 71.2% of the patients had some lesions (Look component), 21.2% of patients did not have palpable pulses (Feel component) and 84.6% had underlying neuropathy (Test component) *[Table 3]*. The majority of the patients were in high-risk category (71.2%). A total of 53.8% of the patients had 2 as the highest score. Ten patients (19.2%) *[Table 4]* presented with some complications within the follow-up year. Four patients presented with ulceration, two with calluses, two with abscess, one wet gangrene and one with cellulitis. The authors compared the variables with diabetes duration as it is well known that diabetes of a long duration can result in neuropathy, as well as peripheral vascular disease.

No association was seen between risk categories, complications, the Look component and the Test component with duration of diabetes duration *[Table 5]*, although significant association was noted between the Feel component (palpable pulses) and diabetes duration (*P*=0.041). Only 18.2% of patients who had pulses absent had diabetes of less than 10 years' duration, whereas 45.5% of patients whose pulses were not palpable had diabetes of more than 20 years. Logistic regression analysis revealed that comorbidity presence was the only significant factor associated with the high-risk category. The presence of any comorbidity was 4.3 times [AOR = 4.3, 95% C.I. (1.01, 19.1)] more likely to be in the high-risk category as compared to patients with no comorbidity adjusted for age, gender and duration of diabetes.

Table 6 shows the sensitivity, specificity, positive predictive (PPV) and negative predictive values (NPV). None of the patients in the low-risk category developed complications whereas 10 patients (27%) in high-risk category developed complications within a year (*P*=0.046, significant). Based on the ROC curve analysis *[Figure 7]*, the Amit Jain's LFT score achieved AUC of 0.704. The

Table 3. Patient screening variables.		
Screening variables	Number of patients (total=52)	Percentage (%)
Look		
0	15	28.8
1	37	71.2
Feel		
0	41	78.8
1	11	21.2
Test		
0	8	15.4
1	44	84.6

Table 4. Patient variables.		
Variables	Number of patients (total=52)	Percentage (%)
Total scores		
Score 0	7	13.5
Score 1	8	15.4
Score 2	28	53.8
Score 3	9	17.3
Group		
Low-risk category	15	28.8
High-risk category	37	71.2
Complications within 1 year		
Yes	10	19.2
No	42	80.8

Table 5. Different patient variables with diabetes duration.				
Variables	**Diabetes duration**			***P* value**
	<10 years	**10–20 years**	**>20 years**	
Look				
0	5 (33.3)	6 (40)	4 (26.7)	0.674
1	13 (35.1)	18 (48.6)	6 (16.2)	
Feel				
0	16 (39)	20 (48.8)	5 (12.2)	0.041
1	2 (18.2)	4 (36.4)	5 (45.5)	
Test				
0	4 (50)	3 (37.5)	1 (12.5)	0.600
1	14 (31.8)	21 (47.7)	9 (20.5)	
Complications within 1 year				
Yes	2 (20)	5 (50)	3 (30)	0.461
No	16 (38.1)	19 (45.2)	7 (16.7)	
Risk category				
Low-risk	6 (40)	7 (46.7)	2 (13.3)	0.756
High-risk	12 (32.4)	17 (45.9)	8 (21.6)	

Table 6. Sensitivity, specificity, positive predictive (PPV) and negative predictive (NPV) values.							
Risk category	**Complications within 1 year**			***P* value**	**Sensitivity**	**Specificity**	**PPV**	**NPV**
	Yes	No	Total	0.046	100%	36%	27%	100%
Low-risk	0 (0)	15 (100)	15 (100)					
High-risk	10 (27)	27 (73)	37 (100)					

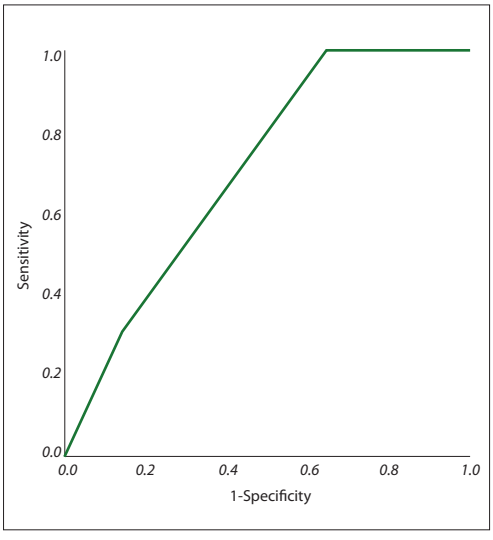

Figure 7. Receiver operating characteristic (ROC) curve for Amit Jain's LFT scoring.

predictive validity of the Amit Jain's LFT screening score shows that a score of 2 (AUC of the ROC was 0.704) and above can predict the complications within a year (*P*=0.047) and is clinically very useful. People in these category should be taught to take care of their feet to avoid the complications.

Discussion

No risk screening tool is effective if it is not done. The ease of using a tool makes it more likely to be used. The assessment of diabetic limbs should include an assessment of skin injury (for example, callus, ulceration), perfusion (pulses) and neuropathy. Early screening allows for education of the patient on how to avoid injury to the feet and how to inspect the foot daily. The tool tested in this study was easy to use and score. It also predicted the risk of complications of the diabetic foot accurately. In this study, we noticed that 27% of patients who were in the high-risk category [AJ score 2 and 3], developed some form of foot complications within 1 year. These complications collectively studied by us ranged from an ulcer to development of abscess, cellulitis, necrotising fasciitis, etc.

The recurrent problems will add huge financial burden to already financially squeezed patients with a diabetic foot/feet and the situation is worse if patient is uninsured and is in developing and underdeveloped countries. It is recommended by the authors that individuals in the high-risk category should be followed at least quarterly to semi-annually and those in the low-risk category should be followed semi-annually to annually in an attempt to reduce

diabetic foot complications.

The limitation of this study is that the sample size was small. Further, the authors did not study patients lost to follow-up.

Conclusion

The Amit Jain's LFT screening tool is a new simple screening tool for diabetic foot that addresses the triopathy efficiently and is quick to complete with minimum resources. The patients can be effectively categorised into the low-risk group and high-risk group. This new scoring system for screening has good predictive ability with sensitivity of 100%. Further studies are needed on this new LFT scoring system for diabetic foot screening. WINT

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