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A cross-sectional study of paper grip test as an additional test for early-stage screening of the feet in patients with diabetes

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Abstract---Introduction: Studies have shown that foot deformities such as claw foot, hammer toes can occur due to paralysis of intrinsic muscles of the feet which in turn pose a high risk for foot ulcerations, gait disturbances and falls alongside decreased sensations of the foot. Current guidelines for the screening of diabetic foot involves testing for sensations of the foot by the Semmes Weinstein Monofilament (SWM) test but testing for intrinsic muscle weakness is not done routinely. Based on available literature, onset of structural changes of the foot occurs earlier than loss of sensations hence this study was undertaken to identify intrinsic muscle weakness of the feet using a simple, test called Paper Grip test (PGT) in diabetics with normal sensations of the feet. Methodology: An analytical cross-sectional study was conducted in JSS Hospital from November 2018 to September 2020 involving diabetic patients visiting Medicine OPD and admitted patients meeting inclusion criteria of this study. Necessary

ethical clearance from the institutional ethics committee of JSS medical college was obtained. Functional status of intrinsic muscles of the foot was tested by PGT and the sensations of the sole of the foot was assessed by SWM. Results: 335 diabetics (Mean age was 56.5 years, 93.7% had type II DM and 47.8% were females) met the inclusion criteria and were examined for the intrinsic muscle function and foot sensations as defined in the protocol by two observers and it showed that 131(57.7%) study participants had normal foot sensations but hallux muscle weakness. Multivariate regression analysis showed that age and duration of diabetes were associated with impaired hallux muscle function. Conclusion: The data from this study shows that there could be an added advantage of PGT while examining the feet of diabetic patients as an inexpensive tool to identify weakness of intrinsic muscles of the feet to establish preventive measures to reduce incidence of diabetic foot ulcers and other diabetes related complications of the feet.

Keywords---Paper Grip test, Semmes – Weinstein Monofilament, Foot sensations, intrinsic muscle weakness

Introduction

Diabetes Mellitus is the most frequent disease encountered in clinical practice. The metabolic dysregulation associated with diabetes causes secondary symptomatic complications which amount to a significant effect on the quality of life of these patients. Ulceration, infection, or destruction of foot are present in 6% of patients with diabetes.^[1] The development of diabetic foot is a multifactorial process that has been associated with diabetic neuropathy, minor foot trauma, and foot deformities. It has been estimated that about 80% of non-traumatic amputations are secondary to diabetes.^[2] Studies have shown that foot deformities such as claw foot, hammer toes can occur due to paralysis of intrinsic muscles of the foot which in turn pose a high risk for foot ulcerations, gait disturbances and falls.

In a study conducted by Srinivasan H in patients with leprosy an additional risk of ulceration by a factor of 10-12 in anesthetic feet with intrinsic muscle weakness was identified.^[3] The combination of anesthesia and intrinsic muscle weakness was found in 85% of all ulcers in patients with leprosy.^{[3][4]} In a recent study published, diabetics with neuropathy were found to have small intrinsic muscle volumes and thick plantar aponeuroses. The postulated mechanism of these changes was non enzymatic glycation and mechanical loading in diabetes.^[5] It had been identified that in early stage of intrinsic muscle weakness patient education and special footwear can help prevent deformities and ulcerations.

Accelerated loss of muscle mass and strength was recorded in individuals with diabetes and was found to be greater with longer duration of diabetes or higher HbA_{1c} and is attenuated by use of insulin sensitizers. ^[6-8] Studies in diabetics revealed that impaired muscle function in diabetes facilitates the impaired gait and slower walking speed ^[6]. There is limited data available in assessing intrinsic

muscle weakness of the foot in diabetics, therefore keeping the therapeutic implications of early detection of muscle weakness in preventing diabetic foot, we have undertaken this study to assess the use of a paper grip test (PGT) described first by W.J Theuvenet and P.W Roche from the Anandban Leprosy hospital, The leprosy mission, Nepal in 1990^[9] in addition to assessment of sensations of sole of the foot to identify patients with diabetes at high risk of foot problems.

Objectives:

1. To investigate the frequency of patients with diabetes presenting with intrinsic muscle weakness of the hallux but with normal sensations of the sole of the foot.
2. To co-relate the performance of PGT in relation to
 - Age
 - Sex
 - HbA1c levels
 - Duration and type of diabetes
 - BMI.

Materials and Methods

Our study was designed to be an analytical cross-sectional study conducted over a period of 18 months at a tertiary care center in Mysore, Karnataka. Diabetic patients attending the Medicine OPD and inpatient diabetics admitted in the Medicine wards at JSS Hospital, Mysore meeting the inclusion criteria were recruited for the study.

Assuming the percentage of patients with Diabetes mellitus presenting with intrinsic muscle weakness but with normal sensibility of foot as 32.3% based on values from the reference study with a precision of 5% and with a confidence interval of 95%, a sample size of 335 patients was calculated for the study.

Summary statistics were done by means of proportions for categorical/binary variables and mean, median, Standard deviation, Inter Quartile Range (IQR) for continuous variables. Inferential statistics were done by using chi square test, one way ANOVA, kappa statistics, McNemar test and logistic regression. All the statistical methods were done using SPSS 21.0 version for windows. $P < 0.05$ was considered statistically significant.

a) Inclusion Criteria:

Patients aged 18 and above who are diagnosed with Type 1 or Type 2 Diabetes Mellitus

b) Exclusion criteria:

- Patients with diseases of the central nervous system
- Amputations of feet
- Deformities or large infections of the feet
- Ulceration grade 4-5 on the feet
- Known neuropathies unrelated to diabetes mellitus.

- Myopathies
- Radiculopathies of L4- S2

Data from patients was collected in a structured proforma.

- Age
- Gender
- Clinical/Personal/Family history
- Provisional diagnosis
- Type of diabetes Mellitus
- Duration of diabetes
- Height and weight of the patient to calculate BMI.
- HbA1c value

Qualified patients underwent the following tests done by two examiners.

The Paper Grip Test (PGT):

The paper grip test was conducted in the same way as described by Win et al. in 2002.^[9] The participants were asked to sit up straight with hips, knees, and ankles in 90 degrees of flexion. The examiner ensured that the participants stayed in the same position through the test, looked at his or her feet and keep his/her heels on the floor during the test. A slip of paper of 250-300g/m² with a size of 86/54mm was placed under the phalanges of the hallux, just distal to the MTP joints. The examiner pulled the paper away with gradually increasing power in a horizontal direction, while the participants offered resistance. In all examinations a smooth underground was used.

The PGT was performed up-to three times on both the feet when the patient was not able to grip the paper. The PGT was considered positive/abnormal when it was possible to easily pull the paper away all three times. The test was considered negative/normal when the patient was able to grip the paper at least one out of three times.



Fig 1: Method of examination – Paper grip Test

Semmes- Weinstein Monofilament test (SWM Test)

Sensibility of the foot sole was tested by means of SWM. It was conducted using a 5.07/10g monofilament applied to a non-callused site on three areas.

- The first meta-tarsal head- Medial Plantar Nerve
- The fifth meta-tarsal head- Lateral plantar nerve
- The heel pad- Calcaneal branch of the tibial nerve

This test was performed up to three times on both feet.

The SWM was considered positive/ abnormal when the patient does not feel the monofilament on two or more regions. The SWM was considered negative/normal when the patient feels the monofilament on at least 2/3 regions.



Fig 2: Method of examination – Semmes Weinstein Monofilament Test

Results

Among 335 subjects, the mean age was found to be 56.5 years ($SD \pm 13.5$). The minimum age was found to be 18 and the maximum age was 88 years. 175 (52.2%) were male and 160 (47.8%) were found to be female. It was found that 21 (6.3%) of them were diagnosed with type I diabetes and 314 (93.7%) of them had type II diabetes. The study participants were grouped according to the BMI scale for Asian population and a mean BMI of 25.02 ($SD \pm 3.36$) was recorded. The study participants were divided into three groups depending upon their glycemic control measured using HbA1c. 77 participants (23.0%) had good glycemic control ($HbA1c < 7.0$), 71 participants (21.2%) of them had moderate glycemic control ($HbA1c 7-8$) and 187 participants (55.8%) were found to have poor glycemic control ($HbA1c > 8.0$). Out of 335 patients 133 (39.7%) participants were found to have a positive Semmes Weinstein monofilament (SWM) test and 202 (60.3%) were found to have a negative result. (As shown in table 1)

Table 1: Distribution of participants based on Semmes – Weinstein monofilament test

		Count	%
SWM test	Negative	202	60.3%
	Positive	133	39.7%
	Total	335	100.0%

Comparison of PGT and SWM test (as shown in table 2)

- In the study 131(57.7%) study participants were found to have a positive paper grip test (PGT) and a negative SWM test which was statistically significant with a p value of <0.001 but with poor agreeability (kappa value 0.065) .
- 96(42.3%) of the participants had anesthetic feet and weakness of intrinsic muscles of the hallux.
- 37 (34.3%) of the participants had anesthetic feet with normal function of the intrinsic muscles of the hallux.
- 71(65.7%) of the participants had normal sensibility and normal function of intrinsic muscles of the hallux

Table 2: Semmes – Weinstein Monofilament Test v/s Paper grip test

		SMF test					
		Positive		Negative		Total	
		Count	%	Count	%	Count	%
PGT	Positive	96	42.3%	131	57.7%	227	100.0%
	Negative	37	34.3%	71	65.7%	108	100.0%
	Total	133	39.7%	202	60.3%	335	100.0%

McNemar test $p < 0.001$

Kappa= 0.065 (poor)

PGT- 227/335= 67.76%

SMF test – 133/335=39.7%

Additional yield is 28%.

Demographics of study participants influencing the Paper grip test were duration of diabetes and age (shown in Figure 3 and 4 respectively) in both univariate and multivariate analysis. Other factors such as Sex, Glycemic control, type, and BMI s were not statistically relevant (Table 5)

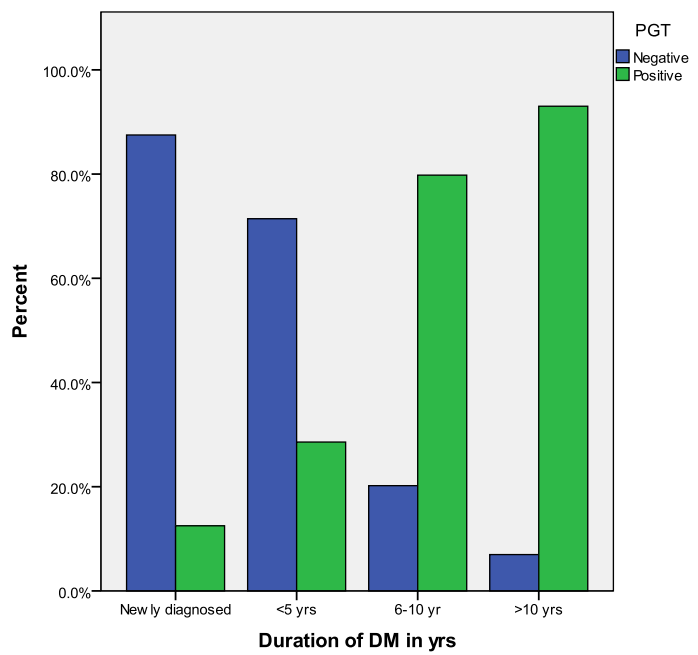


Figure 3: Co-relation between duration of diabetes and paper grip test

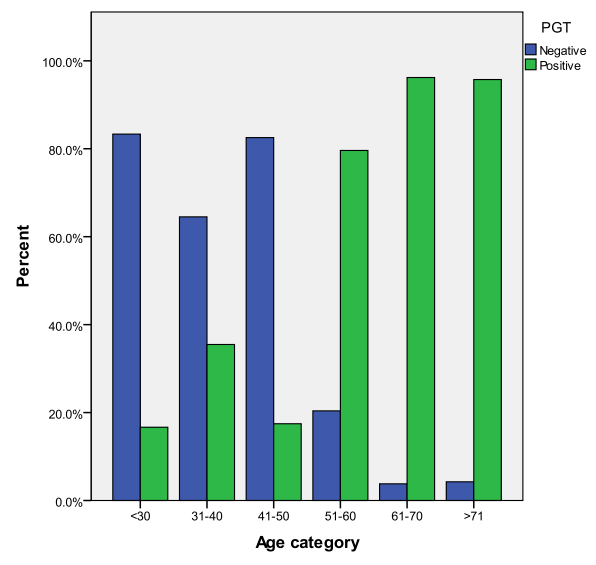


Figure 4: Co-relation between age and paper Grip test

Table 5: Regression for DM neuropathy as detected by Paper Grip test

Variables in the Equation

	B	S.E.	Wald	df	p	OR	95% C.I.for OR	
							Lower	Upper
Age category (Ref <30)			53.853	5	.000			
31-40	2.690	1.290	4.353	1	.037	14.736	1.177	184.503
41-50	2.081	1.480	1.976	1	.160	8.014	.440	145.892
51-60	5.037	1.498	11.307	1	.001	154.078	8.177	2903.374
61-70	6.901	1.609	18.388	1	.000	993.483	42.390	23283.794
>71	6.053	1.678	13.008	1	.000	425.474	15.859	11415.102
SEX (female as ref)	-1.098	.432	6.459	1	.011	.334	.143	.778
Type of DM	-.573	1.192	.231	1	.631	.564	.055	5.833
Duration of DM (ref new DM)			41.414	3	.000			
<5 yrs	1.104	.928	1.416	1	.234	3.017	.489	18.602
6-10 yr	3.432	.957	12.863	1	.000	30.951	4.743	201.972
>10 yrs	4.365	1.007	18.793	1	.000	78.653	10.931	565.967
Glycemic control (ref good control)			9.423	2	.009			
Moderate control (7-8)	-.382	.651	.345	1	.557	.682	.190	2.445
Poor control (>8)	1.166	.567	4.227	1	.040	3.209	1.056	9.752
BMI (<23 ref)			2.233	3	.525			
23-25	-.581	.520	1.247	1	.264	.559	.202	1.551
25-30	.008	.549	.000	1	.989	1.008	.343	2.957
>30	-.803	.905	.787	1	.375	.448	.076	2.641
Constant	-5.327	1.369	15.149	1	.000	.005		

a. Variable(s) entered on step 1: age_category, SEX, type of DM, Duration of DM, Glycemic control, BMI.

B=Beta test, S.E: Standard error of regression, Wald: Wald test, df: Degree of freedom, OR: Odds Ratio, CI:Confidence interval

Discussion

The use of the PGT as a screening test for diabetic foot

Our study showed that out of 335 participants, 131(57.7%) of them showed normal sensations of the foot but weakness of the intrinsic muscles of the hallux as tested by the SWM test and the PGT, respectively. It was also found that 96(42.3%) of the participants had anesthetic feet and abnormal Paper grip test. While 37(34.3%) participants had anesthetic feet but no weakness of intrinsic muscles of the hallux. These values were statistically significant ($p < 0.0001$) and the agreeability between the two tests for identifying peripheral neuropathy was poor (Kappa = 0.065). The above figures show that a significant proportion of the study participants that is 57.7% of them have intrinsic muscle weakness before loss of sensations of the foot. 42.3% of the participants were found to have loss of foot sensations as well as intrinsic muscle weakness.

In comparison to a similar study done by R.Mahieu et al ^[10] comparing the SWM test and the PGT in 266 diabetic patients showed that 54 participants (20%) had abnormal PGT but normal sensations of the foot. Our study is comparable to the above studies with respect to statistically significant number of participants who presented with intrinsic muscle weakness of the hallux but normal foot sensations, we noticed that we had a significantly higher number of participants with a positive PGT. The possible explanations could be that our study also included patients with peripheral vascular disease and the smoking status of the patients was not evaluated. This study did not address the lifestyle factors such as use of footwear, occupational conditions affecting the foot muscles which could have played a significant role in affecting the structure of the feet and in turn intrinsic muscle function. This could also be explained by the relatively low sensitivity of the 10g monofilament used. It is open for argument if lower than 10g force is necessary to bend the monofilament for assessing sensibility of the sole of the feet. Larger studies including demographics such as occupation, lifestyle, racial characters are necessary to understand the changes occurring in feet completely.

Outcome of PGT with respect to variables such as age, gender, duration of diabetes and glycemic control

In our study we also observed the outcome of PGT and SWM test in relation to variables such as age, gender, glycemic control, BMI, type, and duration of diabetes. With respect to PGT, age and duration of diabetes were found to be of statistical significance ($p < 0.0001$) to determine the outcome of the test result. PGT was positive in 95.7% of study participants who were above the age of 71 years, 96.2% of participants between 61-70 years and 79.6% of study participants between 51 and 60 years of age which suggests weakness of intrinsic muscles of the hallux as age progresses. These results are comparable with those of R. Mahieu^[10] et.al. In their study the outcome of PGT was found to be influenced by increasing age and the female gender. This can be explained by the loss of skeletal muscle mass caused by ageing which was outlined by Lexell J in his article about human ageing and its effect on muscle mass and fiber type composition.^[11]

In our study there were 129 patients who had diabetes for more than 10 years, 120 of them had a positive paper grip test. In a study conducted by Kumar et al in 2015 [12], it was proven that there are foot changes in diabetic population when compared to normal population in the form of loss of intrinsic muscle volume and loss of thickness of plantar aponeurosis which can cause a high risk of ulcers and injuries secondary to gait disturbances in these individuals. In a study done by Park SW et al, it was observed that there was an accelerated loss of skeletal muscle mass in diabetic patients and it was found to be higher in those with higher HbA1c values and those with longer duration of diabetes.[6][7] In a study done by Kalyani et al it was found that duration of diabetes was associated with decreased lower quadriceps strength in older individuals.[13] The data from this study can be extrapolated with respect to intrinsic muscles of the foot. Much larger studies are necessary to identify duration of diabetes as an independent risk factor for intrinsic muscle weakness of the foot. There was no significant impact of gender, BMI, glycemic control, and type of diabetes on the outcome of PGT in our study.

Limitations:

- The lack of gold standard methods to compare the paper grip test and sensibility testing by Semmes Weinstein monofilament testing is a limitation in our study. Another limitation was the possibility of false positive PGTs due to insufficient force exerted by participants, misunderstanding of the test procedure and weakness of the muscles. The exclusion of diabetic patients with foot deformities could have led to an underestimation of the number of patients with intrinsic muscle weakness.
- The number of participants with Type I Diabetes was not significant in our study hence the outcome of PGT based on type of diabetes could not be compared effectively.
- The influence of different surfaces, the direction and rate of force and area where force was applied were not standardized which was a major limitation of the study. Further studies testing and standardizing paper grip test are warranted.

Conclusion

- In this study intrinsic muscle weakness of the hallux was present as identified by a positive PGT even though sensations of the feet were normal as evidenced by a negative SWM test.
- Participants with older age and longer duration of diabetes are more likely to have intrinsic muscle weakness of the hallux.

The results imply that there is a possibility of identifying 'feet at risk' by using PGT as an additional test for screening of foot in diabetic patients and interventions such as counselling, appropriate footwear, reconstructive surgery can be possible before foot deformities and ulcerations manifest.

Statements**Consent:**

Study Approval Statement: A clearance was obtained from the Institutional Ethics Committee of JSS Medical college, JSS Academy of Higher education and Research.

Consent to participate: A valid written consent was obtained from the attendants of the study subjects after explaining in detail regarding the nature of the study and the tests that will be conducted.

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Conflict of Interest:

The authors declare no conflict of interest.

Contribution of authors:

Dr. Manvitha Nadella and Dr. Varsha.T – Design of study, acquisition of data, analysis and interpretation of data, drafting the article, literature search, clinical studies, manuscript editing.

Dr. Manthappa.M , Dr. B.J SubhashChandra – Concept and design of the study, definition of intellectual content, revising the article critically for important intellectual content, manuscript review, final approval of the version to be published.

The manuscript has been read and approved by all the authors and the requirements for authorship have been met and each author believes that the manuscript represents honest work.

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