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ORIGINAL ARTICLE

Intra-Rater Reliability of Desktop Spirometry in Adults with Type 2 Diabetes Mellitus

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ABSTRACT

Objective: To evaluate the inter-rater reliability of desktop spirometry in adult patients with type 2 diabetes mellitus (T2DM) attending public sector hospital in Panchkula, India.

Methods: Thirty eligible participants with T2DM completed study at government hospital, Panchkula from February 2019 to August 2019. The study was having co-relational design. Pulmonary function test (PFT) was performed twice by each participant through desktop spirometer. T2DM patients aged between 40-64 years with diabetes duration ≥ 1 year were included into the study. Statistical analysis was done using SPSS version 21 and Microsoft excel.

Results: Of 30 participants, the mean age of the participants was 51.537.5 ± years. There were 19 (63.33%) females and 11 (36.7%) males. Mean difference between test-retest came out to be 0.08, 0.035, and -0.93 for Forced Vital Capacity (FVC), Forced expiratory volume in 1st second (FEV_1) and % FEV_1/FVC respectively. The difference was not significant for FEV_1 and % FEV_1/FVC with p-value=0.270 & 0.340 respectively. However, it was significant for FVC with p-value=0.030. Intraclass correlation was 0.959, 0.94, and 0.89 for FVC, FEV_1 and % FEV_1/FVC respectively. Minimal detectable change was 0.3, 0.3, and 8 for FVC, FEV_1, FEV_1/FVC respectively.

Conclusion: This can be concluded from the results that desktop spirometer has good absolute and relative reliability. Therefore, it can be used at the primary health care setting for the evaluation of pulmonary functions of adult patients with T2DM.

Keywords: Pulmonary Functions Test, Reliability, Spirometry, Type 2 Diabetes Mellitus.

INTRODUCTION

Type 2 Diabetes Mellitus (T2DM) has become a global concern in 21st century because of alarming increase in its incidence.[1] As per International Diabetes Federation (IDF) report, India alone houses 77 million people of diabetes mellitus (DM) and 90% cases are of T2DM. DM and its complications have put immense burden over society and nation as Disability Adjusted Life Years (DALYs) due to it has increased by 39.6% in the states of India in past two decades.[2] Complications due to DM have been well documented on major organs of the body like heart, kidneys, eyes, blood vessels, and nerves. Literature has also established the lungs as a target organ among diabetic complications.[3]

Recent meta-analysis confirmed the restrictive type of pulmonary pathology among patients with T2DM.[4] Therefore, screening of pulmonary pathology among diabetics is recommended as a routine practice. It will help in the early detection, prevention and management of pulmonary complications. The screening is usually done through Pulmonary Function Test (PFT). Portable devices for PFT are widely used in today's world of point-of-care testing for fast and precise assessment of pulmonary function.[5] These equipments can be air turbine based, pressure transducer based, or ultrasound based. Accuracy and user-friendliness of turbine based spirometers has been well proved in Literature.[6,7] Extensive western literature have also established the reliability and validity of these spirometers.

RMS Helios-401 is desktop based portable PFT machine which is in huge practice throughout India in primary care centers. It is a computerized, air- turbine based machine, which reflects the pulmonary functions based on the patient's performance on instructions given by the technician. Hence, increasing the chances of error. Therefore, reliability and validity must be established

for this equipment. Reliability is always pre-requisite to validity. Test-re-test reliability determines the consistency of the equipment to give similar results when the test is repeated in the same physical condition and with the same patient between small difference of time point.[8] As per our knowledge, reliability of this equipment is not documented in Indian literature for patients with T2DM. Therefore, the present study was conducted to evaluate the intra-rater reliability of desktop based PFT (RMS Helios-401) among patients with T2DM.

METHODS

This co-relational study was conducted at civil hospital, Panchkula from February 2019 to August 2019. The permission for data collection was taken from the hospital. All the patients were recruited conveniently from medicine out-patient department (OPD) of the hospital, after the confirmed diagnosis of T2DM by the consulting physician.

The patients were evaluated for eligibility on the basis of following inclusion and exclusion criteria: T2DM patients aged between 40-64 years with diabetes duration ≥ 1 year were included into the study. Smokers[9] and those who were suffering from any other cardiopulmonary, musculoskeletal, and neurological problems which could affect study variables[10] were excluded from the study. Pregnant females were also excluded from the study.

The subjects who could not perform PFT as per the quality standards of American Thoracic Society (ATS)[11] as well as those who did not appear for the 2nd test were removed from the study. Informed consent was taken in local language from each participant as per Helsinki declaration, 2013 and Indian Council for Medical Research (ICMR) guidelines 2017. The study has been reported on the basis of Guidelines for Reporting Reliability and Agreement Studies (GRRAS).[12]

One hundred one patients were evaluated for study eligibility. Out of them, 55 (54.46%) were eligible for the study as per set criteria, they were asked to visit the hospital again on specified day for PFT. A reminder call was given to the patients two days prior to the collection of baseline data. Among them, 46 (45.54%) patients reported on the scheduled day to the hospital and gave informed consent for the study. Further 05 patients were unable to perform PFT and 02 patients reported false about the smoking history during initial evaluation. Therefore, these 07 (15.2%) patients were removed from the study. From the remaining 39 patients, only 30 (76.92%) patients reported for the second visit. Therefore, these 30 patients were included in the study.

The demographics and diabetic history was obtained on the brief assessment form. The procedure of the PFT was explained and demonstrated to each participant prior to the performance. All PFT's were performed with RMS Helios- 401 spirometer by a trained technician, with experience of more than 5 years and was blinded with study objectives. All the tests were performed in sitting position without back support. The participants were asked to sit on a chair without arm rest. The sitting posture was also demonstrated for those who were not able to follow correct sitting posture instructions. Nose was clipped during the maneuver. The standard instruction and encouragement was also given as per ATS standardizations.[11] Only those tests were used for analysis which had quality grade of A, B and C[13] and were following all three criterias of acceptability[14] for PFT. Retest was performed after one week with the similar standards.

The outcome measures included for reliability analysis of pulmonary functions were: Forced Vital Capacity (FVC), Forced Expiratory volume during 1st second (FEV_1), and % FEV_1/FVC. The calibration of the machine was checked using 3 litre syringe.[15] It was found in perfect calibration.

Data were analyzed using the SPSS 21 version and Microsoft excel. Paired t-test was used to compare the test-retest values of the variables. Absolute reliability was assessed through intraclass correlation (ICC) and relative reliability was analyzed through standard error of measurement (SEM), and minimal detectable change (MDC).[16] Graphical representation was also plotted through Bland-Altman plot. Kendall's tau correlation and regression analysis was also performed. The normality of the data was evaluated using Shapiro-wilk test. Pulmonary functions were evaluated through FVC, FEV_1 and % FEV_1/FVC. The data were found normal on analysis through Shapiro-wilk test. Therefore, the comparison of test-retest values was done through paired t-test. The p-value ≤0.05 was taken as significant.

RESULTS

Of 30 patients, 19 (63.33%) were females and the mean age of the patients was 51.53±7.5 years. The mean duration of diabetes was 7.57±1.23 years. The mean height and body weight were 1.59±0.10 meters and 66.37±10.62 kilograms respectively. The mean HbA1c was 8.39±1.56. Only 10 (33.33%) patients were on insulin and 26 (86.67%) were on combination of medications to control their hyperglycemia. Only 04 (13.33%) patients

were taking single medicine to control hyperglycemia.

The t-test was found significant for the FVC (p=0.03) and non-significant for FEV_1 (p-value=0.270) and % FEV_1/FVC (p-value=0.340) as seen in table 1. Table 2 shows the intra-rater reliability of pulmonary function among patients with T2DM. It can be seen from the table that ICC ranged from 0.890 to 0.959. Standard error of measurement (SEM) and Minimal detectable change (MDC) were 0.133 to 2.978 and 0.3 to 8 respectively.

Bland-Altman (B-A) plot for FVC, FEV_1, and % FEV_1/FVC respectively are shown in figures 1-3. As seen from the figure 2, there was just one value that crossed the limit of agreement for FEV1. However, for FVC and FEV1/FVC there were few outliers which cross the limit of agreement and heteroscedasticity was also observed for both FVC and FEV1/FVC. Still there is an agreement for most of the measurements for FVC and FEV1/FVC as shown in figure 1 and 3 respectively.

B-A plot for FVC was drawn between percentage difference and mean of two test as the heteroscedasticity was observed in the B-A plot with normal data. Kendall's tau correlation was also found significant (p=0.02) which prove the heteroscedasticity of data. Table 3 represents the bias and limit of agreement for all the variables.

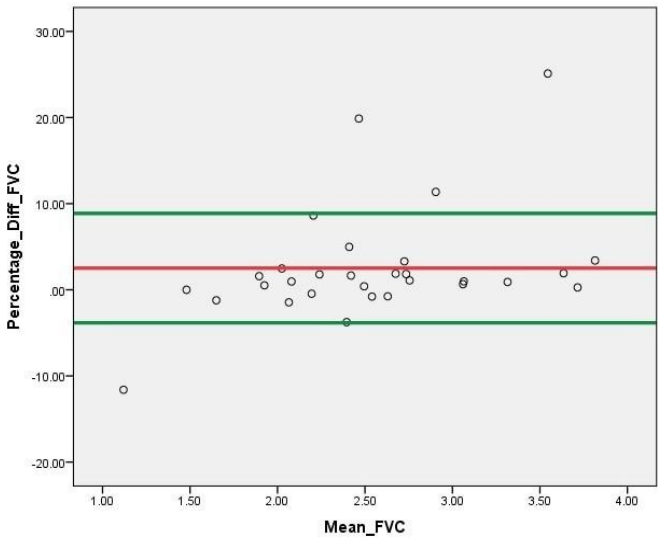

Figure 1: Bland-Altman plot for FVC showing limit of agreement.

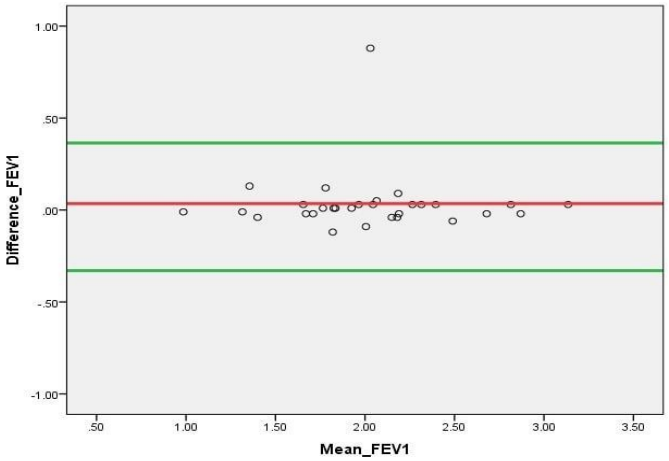

Figure 2: Bland-Altman plot for FEV, showing limit of agreement.

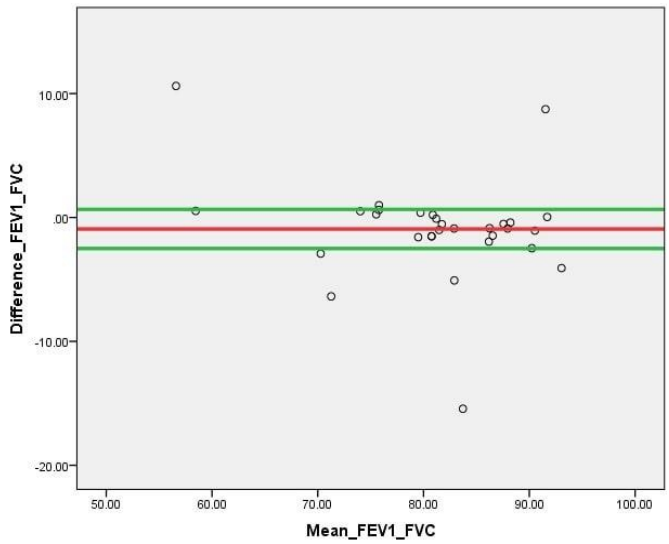

Figure 3: Bland - Altman plot for FEV_1/FVC showing limit of agreement.

DISCUSSION

The deterioration of pulmonary function is an established fact among patients with T2DM. Routine evaluation may detect the pulmonary pathology at early stage. Desktop spirometer can provide point-of-care testing and can make the pulmonary evaluation an easy affair. However, the reliability of the instrument is utmost to get consistent results. Therefore, the present study was done to find the intra-rater reliability of desktop spirometer. The results confirmed the absolute as well as relative reliability of desktop spirometer. In the present study, female participants were more (63%) as compared to males (37%) which can be due to the fact that Indian females are more prone to diabetes because of their poor eating habits, perinatal factors and less physical activity, which directly and indirectly increases the incidence of T2DM.[17] Moreover, exclusion of male patients due to smoking can be the reason of less males in the study, as the prevalence of smoking was observed more among males as compared to females in India.[18]

Excellent absolute reliability was observed from the results, as denoted by values of SEM and MDC. Relative reliability was also eminent as reported by ICC.

Table 1: Comparison of test-retest values of study variables

Variables		*Mean ± SD*	*p-value*
FVC	Test	2.58 ± .69	0.030
	Re-test	2.50 ± .62	
FEV_1	Test	2.04 ± .48	0.270
	Re-test	2.01 ± .49	
% FEV_1/FVC	Test	80.63 ± 8.52	0.340
	Re-test	81.39 ± 9.58	

Abbreviations: -FVC: Forced Vital Capacity; FEV_1: Forced Expiratory volume during 1st second

Table 2: Intra-rater reliability of pulmonary functions

Variable	*Mean difference*	*ICC*	*95% CI*	
			Upper	*Lower*
FVC	.080	0.959	0.917	0.980
FEV_1	.035	0.940	0.878	0.971
% FEV_1/FVC	-.930	0.890	0.783	0.946

Abbreviations: - FVC: Forced Vital Capacity; FEV_1: Forced Expiratory volume during 1st second, ICC: Inter Class Correlation

Table 3: Bias and limit of agreement between test and retest values.

Variable	*Bias*	*Limit of agreement*
FVC*	2.52	-3.84 to 8.88
FEV1	0.03	-0.33 to 0.36
FEV1/FVC	0.93	-2.51 to 0.65

*Data is presented in percentage difference. Abbreviations: -FVC: Forced Vital Capacity; FEV_1: Forced Expiratory volume during 1st second

The 95% CI of the ICC reflects good to excellent reliability of the PFT.[19] The results are in line with recent research for spirokit spirometer. The study concluded the high reliability of spirokit spirometer as SEM %, MDC%, and ICC were 0.12 to 3.39, 0.02 to 3.79, and 0.960 to 0.998 respectively.[20] The findings are also supported by Masa et al for online as well as to conventional PFT among pulmonary patients.[21]

The test for significance came out to be significant for FVC and Bland-Altman plot for FVC also showed heteroscedasticity which means that variability increased with the increase in the value of FVC. The same was reported by Barr et al.[22] But, the variability reported by Barr et al is not within clinical limits. However, the variation, in the present study, was not above the limit of clinical acceptance.[11] Therefore, it supports the reliability of the desktop spirometer in clinical practice. Broader limit of bias for FVC in the present study is also supported by Barr et al for handheld EasyOne) spirometer and Liisto et al for 10 office spirometers.[7,22] Additionally, the test and re-test values of FVC i.e. 2.58 and 2.50 and FEV_1 i.e. 2.04 and 2.01 are lower in present study in comparison to the Barr et al i.e. 3.90 & 3.11 for FVC and FEV_1 respectively. But, the value for % FEV_1/FVC i.e. 81% is normal in present study and greater than Barr et al. This affirms the restrictive pathology of lung among diabetic patients. Therefore, routine pulmonary evaluation should be recommended for these patients for early detection of pulmonary pathology.

The results affirm that RMS (Helios-401) is a reliable tool and can be used in primary health care center for pulmonary function evaluation of patients with T2DM. It is a low-cost equipment which is readily available in Indian market. It can be a cost effective alternate for the laboratory PFT which is neither portable nor easy to perform. Cost and availability of the equipment plays a major role in procurement in developing country like India. Therefore, it is in great use in India. It is the irony of health care system that despite its extensive use, the reliability of this equipment has not been evaluated. This is again directing the important issue of Indian health care system that is "lack of evidence based practice".[23] The present study generate evidence for the reliability of this equipment. Good reliability of the equipment, as established by the present study, consensus its use in clinical as well as research settings. However, future study can be conducted to evaluate its validity so that evidence can be generated to establish its utility in Indian health care system.

There were certain limitations in the current study. First, quality rating was not reported by the machine itself as in some advance machines this may create problem in interpretation for new users. However, this is not a limitation for qualified and experienced user. Secondly, we were able to produce result on the basis of only 30 patients because of limited resources and unavoidable circumstances.

CONCLUSION

Desktop spirometer has good reliability. Therefore, it can be used at the clinical and research settings for the evaluation of pulmonary functions of patients with T2DM. This can also be easily incorporated in the routine evaluation of pulmonary function of these patients at primary heath care centers.

ETHICAL APPROVAL: The study protocol was approved by the Institutional Ethical Committee Guru Jambheshwar University of Science and Technology, Hisar-Haryana (INDIA) (No. PTY/2018-710A, Date: 31/10/2018).

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