Original article

Efficacy of six minute walk test in improving exercise tolerance in South Indian Patients with Idiopathic Pulmonary Fibrosis

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Abstract

Introduction: The six minute walk test (6MWT) is a practical and reliable measure of exercise tolerance that is widely used to assess the functional status of the patients with a variety of cardiac and pulmonary diseases, including heart failure, pulmonary hypertension, and Chronic Obstructive Pulmonary Disease (COPD). **Objective**: To evaluate the reliability validity and responsiveness of the six minute walk test and to measure the minimal clinically important difference (MCID) in South Indian IPF patients. **Methods**: The study population consisted of 30 patients diagnosed as IPF. Six minute walk test distance and other parameters were measured at baseline and at 18 week interval using a standard protocol. Correlation coefficients were used to evaluate the association between six minute walk distance and measures of dyspnea using Borg Scale rate of perceived exertion and Quality of Life questionnaire using St George Respiratory Questionnaire. The distribution based method was used to quantify the MCID. **Results**: The relationship between 6MWD with dyspnea and St George Respiratory Questionnaire showed good reliability (coefficient = 0.69 $p<0.05$). There was strong correlation between increase in 6MWD and decrease in Borg Scale of rate of perceived exertion and also decreased St George Respiratory Questionnaire indicating improvement in quality of life. The calculated MCID was 15 m. The decline in 6MWD indicated the prognosis of the disease. **Conclusions**: The six minute walk test is a clinically helpful measure of status of the disease and the prognosis in South Indian patients with IPF.

Keywords: Idiopathic pulmonary fibrosis, interstitial lung disease, minimal clinically important difference, six minute walk test.

Introduction

Idiopathic pulmonary fibrosis (IPF) is a progressive life-threatening, interstitial lung disease of unknown etiology.[1] It is one of the most important disabling disorders of the lung and it is being increasingly recognised in India.[2] There is a progressive deterioration in lung function gradually limiting routine physical activity. Idiopathic pulmonary fibrosis is the most common idiopathic pneumonia with a median survival of only 2-5 years after diagnosis.[3]

The six minute walk test (6MWT) is a practical and reliable measure of exercise tolerance that is used to assess the functional status of patients with many cardiac and pulmonary diseases, including heart failure, pulmonary hypertension, and chronic obstructive pulmonary disease (COPD).[4-7] However, studies assessing the efficacy of the six minute walk test in south Indian patients with Idiopathic Pulmonary fibrosis have been limited.[8] There

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were limited or no studies estimating the minimal clinically important difference (MCID) for the six minute walk patients in Idiopathic pulmonary fibrosis in South Indian population. The MCID is the smallest difference in the domain of interest which patients perceive as beneficial and which would mandate in the absence of troublesome side effects and excessive cost, a change in the patient's management.[9]

There is paucity of data establishing effectiveness of six minute walk test in patients with Idiopathic pulmonary fibrosis in India as well as South India. In the present study we evaluated the effectiveness of six minute walk test in improving exercise tolerance and quality of life in Idiopathic pulmonary fibrosis patients.

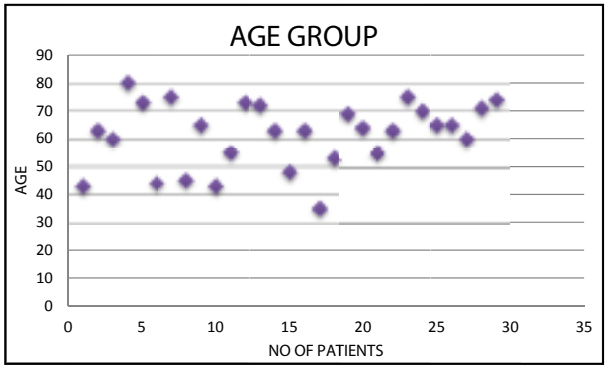

Figure 1: Age group

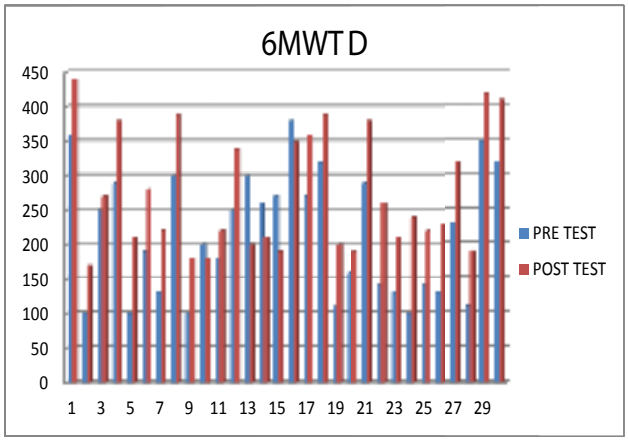

Figure 2: Six minute walk distance in metres

Methods

Study Population

The study population consisted of 30 patients diagnosed as Idiopathic Pulmonary Fibrosis according to the American Thoracic Society Criteria,[10-11] FVC greater than or equal to 55% of predicted, Diffusing capacity of carbon monoxide (DL_{co}) greater than or equal to 35% of predicted .Patients with comorbidites such as musculoskeletal disorders affecting lower limb such as Osteoarthritis, Rheumatoid arthritis and collagen disorders were excluded.

Study protocol

The 6MWT was performed at the baseline and at 18 weeks intervals. The test was performed indoors on a flat, straight corridor with a hard non-slippery surface. An oxygen titration procedure was performed at the baseline to evaluate a flow rate for patients who need supplemental oxygen. Before each 6MWT, patients were required to have resting oxygen saturation as measured by finger pulse oximetry of at least 85% after 5 minutes of breathing room air. Patients were instructed to walk at their own pace and allowed to take rest periods during walking. The test was stopped if the patient experienced any chest pain, dyspnoea, leg cramps, excessive sweating, or had desaturation below 85%. Assessments of dyspnoea using rate of perceived exertion, 6MWT distance in metres, health related quality of life using St.George's Respiratory Questionnaire were also done at the baseline and at 18 weeks intervals.[12] The St George's Respiratory Questionnaire consists of three respiratory specific domains: a.Symptom, b.Activity, c. Impacts. Each domain of the questionnaire ranges from 0-100 with an advancing score indicating worsening HRQOL.[13]

Statistical Analyses

Statistical analyses were done using SPSS 17. Wilcoxon Signed rank test was used to measure the reliability of Borg Scale of Rate of Perceived Exertion and St George Respiratory Questionnaire between the baseline and at 18 weeks. The reliability of the Six Minute walk distance was measured using paired' test between baseline and at 18 weeks. Criterion validity was assessed based on the relationships between six minute walk test and measures of physiologic status such as dyspnoea, St George Respiratory Questionnaire using Spearman correlation coefficients. All deaths during the 18 week period were included in the analysis. The distribution based method was used to estimate the minimally clinical important difference (MCID).

The distribution methods include the standard error of measurement (SEM).

Table 1: Baseline characteristics

Characteristic	Value
Age (years) Mean (SD)	62 (11)
Gender n (%) Male Female	 20(66%) 10 (34%)
6MWT Distance in mMean (SD)	215.3 (90.58)
FVC,% predicted - Mean (SD)	67.9 (7.9)
DL_{co} ,% predictedMean(SD)	44.1(5.9)
SGRQ ScoreMean(SD)	31.66(35.5)

6MWT = 6-minute walk test; DLco= carbon monoxide diffusion capacity; SGRQ = St George Respiratory Questionnaire

Table 2: Correlation between 6mwt distance and other measures

Variable	N	Coefficient*	P value
Borg Scale	30	0.847	0.05
SGRQ scores	30	0.747	0.05

6MWT = 6-minute walk test; capacity; SGRQ = St George Respiratory Questionnaire
*- Pearson correlation coefficient

Table 3: Estimation of the minimal clinically important difference in 6 MWT in patients with pulmonary interstitial fibrosis

	Mean	SD	Correlation	SEM
6MWT distance, m	275	87.3	0.612	15

Definition of abbreviation: 6MWT = 6-minute walk test; capacity; SEM- standard error of measurement
*- Pearson correlation coefficient

Results

Patient characteristics

A total of 30 patients were selected based on the inclusion criteria. There were no drop outs during the 18 weeks period. However, some patients were readmitted for acute exacerbations and then they continued the study. Mean (± SD) age at the entry of the study was 62 (±11) years and 80% of the study subjects were male. The mean (±SD) value for 6MWD at baseline and at 18 weeks was 216 (± 90) m and 275 (± 88) respectively. There were significant variations between the study subjects in terms of dyspnoea, six minute walk distance and SGRQ scores.

Reliability

The 6MWT had good reliability in patients with Idiopathic pulmonary fibrosis. The intraclass Pearson's correlation coefficient for six minute walk distance between baseline and at 18 weeks was 0.6125($P < 0.05$). The patient experienced good sense of relief from the activities that required tolerance due to the improvement in six minute walk distance.

Validity

The strong associations between the sub maximal intensity activities such as six minute walk test and measures of rate of perceived exertion (Borg Scale) and St George Respiratory questionnaire were in the desired direction. The Spearman's Correlation Coefficient between six minute walk test and Borg Scale was 0.87 which was statistically significant at $p<0.05$.The correlation coefficient between six minute walk test and St George Respiratory Questionnaire was 0.69 which was statistically significant at $p<0.05$.

Responsiveness

Correlations between changes in six minute walk test distance and changes in Borg Scale of rate of perceived exertion and quality of life were in the desired direction. There was a strong positive correlation between six minute walk test distance and Borg Scale of rate of perceived exertion and St George Respiratory Questionnaire scores. The six minute walk test distance values between baseline and at 18 weeks period values were prognostic over the subsequent 1 year period. The risk of death was more for patients with a decline in six minute walk test distance greater than 50 m according to DuBois *et al.*[13] In our study the risk of death was more for patients with a decline in six minute walk test distance greater than 30 m.

Minimal clinically important difference

The calculated SEM for the six minute walk test and the corresponding MCID was 15 m (95% CI).The MCID was minimal as compared to other MCIDs published in various articles. The effect size could not be measured since it was a single group quasi experimental design.

Discussion

The six minute walk test is a broadly used technique of quantifying exercise tolerance in various pulmonary disease patients. From the clinical point of view, the six minute walk test is pragmatic and has

more safety. It requires only limited equipments and less training as compared to other Cardiopulmonary Exercise Testing. It is well appreciated and tolerated because the six minute walks test is self paced and resembles activities of daily living (ADL).

Based on the above advantages, the six minute walk test is a valuable assessment tool to evaluate the exercise tolerance and functional status in Idiopathic pulmonary fibrosis. Eaton *et al* found high correlations between six minute walk test distance and Vo_2 max on maximal exercise testing and predicted DL_{co} in idiopathic interstitial pneumonia.[14] Caminati and coworkers postulated moderate correlations between six minute walk test distance and percent predicted FVC and percent predicted DLco (r = 0.40 and 0.42 respectively) in a retrospective analysis of 44 patients with IPF.[15] Both the researches had not shown the predictors of mortality.

In our study, we examined the reliability, validity and responsiveness of the six minute walk test and projected the MCID in small samples who performed according to the study protocol. Compared to previous studies as conducted in western countries, the distance walked during the six minute walk test was well reproducible, representing good reliability but the sample size was small. The relationship between 18 week changes in six minute walk distance and the risk of 1 year mortality was good and said to be greatly responsiveness. The risk of death was more for patients with a decline in six minute walk test distance greater than 30 m. This is an extremely important measure of prognosis for IPF patients.

The minimal clinically important differences for our patients were 15 m and it was less as compared to Roland et al studies and Redelmeier at al studies in COPD.[16] The results were as close to 29 m reorted by Holland *et al*.[17] Till date there was no published data for MCID for six minute walk test in South Indian IPF patients and so we could not compare the data. However, the patient experienced a sense of well being after 18 weeks and it was evident in quality of life scores and improvement in six minute walk distance. There are some limitations in our study such as there was no control group and the sample size was small.

Conclusion

The six minute walk test is consistent, suitable measure of exercise tolerance in IPF patients. A MCID of 15 m is less but much appreciable since there are no related studies representing Indian as well as south Indian IPF patients. The six minute walk test is a clinically helpful measure of status of the disease and the mortality.

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