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Original Research Article

Effectiveness of Pedocycle on Pulmonary and Functional Capacity Parameters with Quality of Life in Chronic Obstructive Pulmonary Disease

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ABSTRACT

Aim: The study was conducted to analyse the effect of pedocycle on pulmonary parameters, dyspnea, functional capacity and quality of life in chronic obstructive pulmonary disease.
Methods: This experimental study was conducted on 30 subjects with referred Chronic obstructive pulmonary disease (COPD) at IAMR Institute, Ghaziabad. The subjects were randomly allocated to three groups; one control group (stationary cycle SC group) and two experimental groups (pedocycle in sitting (PS) and pedocycle in lying (PL)). Subjects received four weeks of aerobic training with stationary cycle and pedocycle in sitting and lying position respectively along with conventional therapy of pulmonary rehabilitation. Pre and Post intervention assessment included: pulmonary function test (PFT) for pulmonary parameters, mMRC grading for dyspnea, six-minute cycle test for functional capacity and St. George's Respiratory Questionnaire for COPD for quality of life. Data were analysed using descriptive statistics, paired t-test and ANOVA.
Result: On evaluation, there was no significant between-groups difference in pre to post interventions for pulmonary parameters, dyspnea, functional capacity and quality of life after four weeks. However, significant with-in-group difference was seen in all the outcome variables.
Conclusion: The result of the study indicates that the aerobic training with pedocycle can be an adjunct to stationary cycle in pulmonary rehabilitation for COPD patients.

Key Words: chronic obstructive pulmonary disease; dyspnea; functional capacity; pedocycle; pulmonary rehabilitation; quality of life.

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is one of the major health concerns and leading non -communicable cause of mortality worldwide, as well as in India. According to WHO, currently it is the sixth leading cause of mortality in the world and is predicted to attain third position by 2030.[1] The prevalence of COPD is high in the middle-aged males due to increased frequency of smoking amongst them. The Global Burden of Disease for India reported that there is increase in the prevalence of COPD from 3.3% in 1990 to 4.4% in 2016.[2]

COPD patients presents with symptoms of chronic cough, sputum production, dyspnea, history of exposure to risk factors and family history of COPD. The associated risk factors identified such as smoking, occupational exposure, biomass combustion products, environmental pollution, stress, anxiety and mosquito coil.[3]

Classically, COPD has been considered as a pulmonary condition that affect lungs but there are several systemic manifestations also associated with it. These are exercise intolerance, peripheral muscle dysfunction, unintentional weight loss, an increased risk of cardiovascular disease, osteoporosis, anxiety and depression. Prevalence of systemic consequences increases with increased severity of airflow obstruction and that results in impaired functional capacity, worsening dyspnea, reduced health-related quality of life and increased mortality.[4]

Peripheral muscle dysfunction, the most significant systemic manifestation is caused by both systemic inflammation and physical inactivity. Quadriceps muscle dysfunction occurs even at early stages in approximately one third of the patients with COPD.[5] In lower limb musculature various cellular and molecular events takes place which mediate the effect of etiological factors leading to changes in its phenotype and function. Conversion of slow-twitch fibres to fast -twitch fibres has markedly seen in vastus lateralis muscle in advanced COPD patients. The fast- twitch are smaller in size and muscle mass hence contributing to muscle weakness. Peripheral muscle dysfunction is also associated with adverse pathophysiological changes, namely early lactic acidemia with reduced oxidative capacity and stresses, decrease in muscle fibre volume, altered capillarization and impaired muscle regeneration. Impaired muscle regeneration is related to lower proportion of central nuclei and decreased maximal telomere length that has been correlated with reduced cross-sectional area of the muscle.

Potential mechanism for muscle wasting includes excessive reactive oxygen species production and altered amino-acid metabolism.[6] These alterations build up higher concentration of lactic acid for any given task that stimulate ventilation, provoking hyperinflation and increasing burden of ventilation. The limitation in activity promotes social isolation and sedentary lifestyle, associated with high-risk anxiety and depression. This limitation leads to further inactivity because of fear of dyspnea, hence further physical deconditioning through a vicious cycle.

Various studies had characterized peripheral muscle dysfunction as an extra pulmonary manifestation and concluded it as prime predictor of muscle atrophy and decreased muscular strength and endurance leading to early muscle fatigue, reduced ability to execute physical activity, impaired quality of life and difficulty in survival.[7] Dyspnea, exercise intolerance and decreased quality of life are the chief complaints in COPD patients.[8] Patient refrain from their work and become isolated as a consequences of exercise intolerance. Poor exercise had been shown to contribute to early morality. Sarah Bernard et al demonstrated the relationship between FEV_1 and the functional status of COPD patients.[9]

Pulmonary rehabilitation (PR) is a principal element in clinical management of exercise intolerance, dyspnea, muscle fatigue, psychological distresses, prolonged hospital stay and for reduced quality of life. It aims to reverse the systemic manifestation along with the associated fear and anxiety, thereby improving patient's day-to day life. The American College of Physicians demonstrated that PR is beneficial for exercise-limited patients with ($FEV_1 \geq 50\%$ of predicted) and symptomatic severe COPD ($FEV_1 > 50\%$ of predicted).[10]

Presently aerobic training is considered as a cornerstone component of pulmonary rehabilitation in treating COPD patients.[11] Aerobic training conclusively resulted in improvement of exercise intolerance, dyspnea, leg fatigue and health related quality of life in patients with COPD. Patients with all degree of severity of chronic air flow limitation, including severe reduction in FEV_1, get benefits from aerobic training. Training keeps cardiopulmonary system healthy and improves overall fitness, maintains good posture and stability. Thus, improves daily activities such as walking, washing, gardening etc. and increases independence by reversing the cycle of inactivity.[12] It considerably improve the endurance and strength of respiratory muscles, decrease lung resistance, increase lung elasticity and alveolar expansion by improving the pulmonary capacities and volume.[13]

Lower-limb aerobic training consistently improves exercise tolerance in COPD patients. Studies had demonstrated that pedalling rate is widely accepted as an important factor that affects cycling performance. Increase in muscle activity of Gluteus maximus, vastus Medialis semimembranosus, Gastrocnemius and Soleus had experienced as the pedalling rate increases from 40 to 100 revolutions per minute.[14]

Although as aerobic training for improving endurance, treadmill and cycling is recommended but in India patients with lower socioeconomic status can't afford expensive treatment and prefers home based exercise intervention. Prescribed drugs, hospitalizations in acute exacerbations and emergency department visits cost a lot and contributes as an economic burden. Development of home-based models is one of the actions undertaken to improve access and delivery of PR services for suitable patients, due to the problems of cost and accessibility faced by hospital in the present scenario.[15]

A study by N.R. Bhatt et al suggested that early aerobic activity with the help of pedal exerciser results in reduction of respiratory morbidity postoperatively most likely by improving in the pulmonary function.[16] Pedocycle, a foot pedal exerciser is a portable stationary bike, which allows the patient to perform aerobic activity anywhere while sitting comfortably in a chair. It can be an important and necessary solution in pandemic like COVID-19 pandemic, where outpatient programs were advised to suspend their activities.

The study aimed to analyse the effectiveness of pedocycle on pulmonary functions, functional capacity, dyspnea status and quality of life measured with pulmonary function test, six- Minute cycle test, dyspnea scoring and SGRQ-C scoring. And also, to analyse the effect of pedocycle in sitting and position.

METHODOLOGY

Study design and Sampling method:

This was an experimental study with convenient Sampling conducted at IAMR (Institute of Applied Medicine and Research) Ghaziabad on moderate and severe COPD referred by chest physician. The duration of the study was nine months. The inclusion criteria were both male and female patients aged from 40 to 60 years with moderate (50% $\leq$ FEV_1 <80% predicted) and severe (30% $\leq$ FEV_1 <50% predicted) COPD and no participation in pulmonary rehabilitation in the previous 6 months.[17] Subjects were excluded if having any significant disease other than COPD that might interfere with the exercise testing and place the patient at undue risk of exercise training, on supplement oxygen therapy for long duration or benefited with any kind of ventilator, having an exacerbation history within three months and having any amputation, prosthesis, crutches and other leg disorders/ deformities that hampers with testing and training.

Method:

Patients were screened according to inclusion and exclusion criteria. They received verbal explanation of the purpose, risk, benefits and procedure of the study and provided with informed consent. 10 patients each were allocated randomly into three group; Control group (Stationary cycle SC) and Experimental groups (pedocycle in sitting PS group & pedocycle in lying PL group) respectively. Randomization was done via computer generated method. They were oriented to the study and data collection procedure at the time of consent.

Protocol:

Each session began with a warm-up period of five minutes. The aerobic training program consisted of stationary cycle in control group and pedocycle in sitting and lying position in two experimental groups respectively. The aerobic training time started at ten minutes and this interval was increased up to a maximum of 20 minutes. Progression in duration had changed according to the subjective feeling of effort. This is followed by a cool-down session of 10 minutes.

Measurements:

Baseline evaluation of pulmonary function test, dyspnea scoring, functional capacity and quality of life was done. Pulmonary function testing was done and values for FEV_1, FVC and ratio of FEV_1 and FVC was recorded. Dyspnea was assessed on mMRC Grading. Functional capacity was measured using six-minute cycle test (6MCT). Quality of life was assessed using St. George's Respiratory Questionnaire for COPD (SGRQ-C). Exercise training was given as per the intervention designed for all the three groups. All 3 Groups received supervised sessions for four weeks. Total duration of the training was 40-45 minutes which was progressed every week till fourth week. After completing four weeks of training post outcomes variables were measured and documented.

Data analysis:

All the response from the filled Performa's will be recorded and analysed on statistical package for social science (SPSS) software 23.0 version. The variables will be recorded as Mean ± Standard Deviation. Paired t-test was done to determine changes in pre- to post-intervention. One way ANOVA was used to compare the outcome variables between the groups. Hypothesis was tested at significant value of $p<0.05$.

RESULT

A total number of 42 subjects with moderate and severe COPD has been enrolled in the study as per the inclusion and exclusion criteria, of which 30 complete the post assessment and were included in the analysis. All the 30 subjects were divided in the three equal groups i.e., Group SC (stationary cycle), Group PS (pedocycle in sitting), Group PL (pedocycle in lying) with the Conventional Physiotherapy Treatment Protocol.

Table 1: - Demographic details of study population in the Groups

	Stationary Cycle (SC) Group (N=10)	Pedocycle in sitting (PS) Group (N=10)	Pedocycle in lying (PL) Group (N=10)	F - value	p-value
Age (Years) Range	49.7±6.46	48.2±4.37	49.7±5.12	0.256	0.776
Male	8	7	7	-	-
Female	2	3	3	-	-
Moderate COPD	6	7	6	-	-
Severe COPD	4	3	4	-	-

Demographic details in table 1 for study population shows:

- The mean age value of the SC group was 49.7 years (range 40-60 years) in population taken of 80% male (n=8) and 20% female (n=2)
- The mean age value of the PS group was 48.2 years (range40-55 years) in population taken of 70% male (n=7) and 30% female (n=3).
- The mean age value of the PL group was 49.7 years (range42-57years) in population taken of 70% male (n=7) and 30% female (n=3).

Within Group Analysis

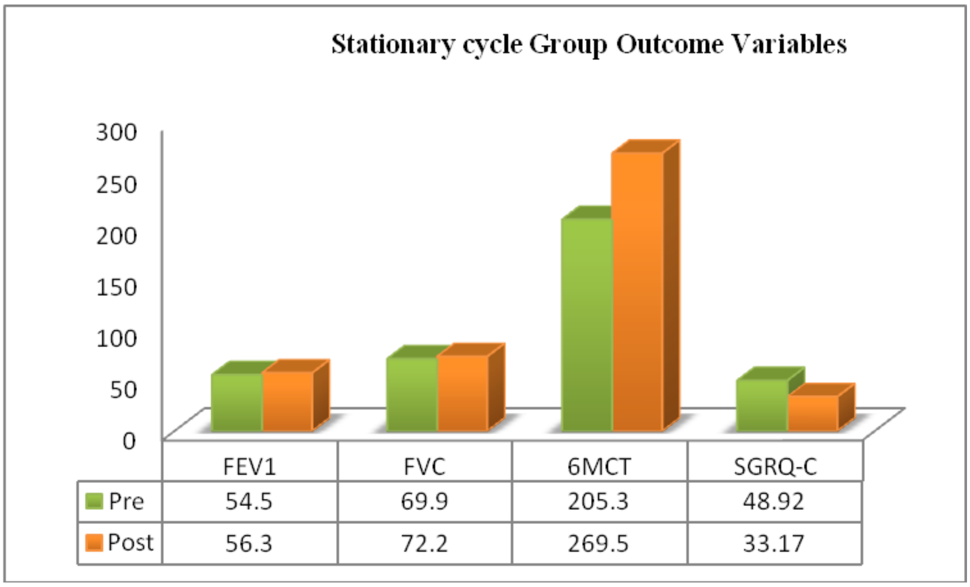
Table 2 showing Descriptive pre and post intervention statistical analysis of pulmonary parameters, dyspnea score, functional capacity and quality of life in Stationary Cycle Group.

Outcomes	Stationary Bicycle (SC) group		t-value	p-value
	Pre	Post		
FEV_1/FVC	0.61±0.05	0.62±0.05	-2.05	0.070
FEV_1	54.50±14.29	56.30±13.36	-2.42	0.038*
FVC	69.90±9.64	72.20±8.80	-5.12	0.001*
Dyspnea	2.10±0.73	1.82±0.63	1.96	0.081
6MCT	205.30±20.82	269.50±29.22	-18.10	0.000*
SGRQ-C total score	48.92±19.58	33.17±15.18	8.13	0.000*

**p-value less than 0.05 (p<0.05).*

Within group analysis in Table 2 shows:

- There is significant improvement for FEV_1 with p-value = 0.038 and for FVC with p-value= 0.001 in stationary cycle group.
- The change in the mean and standard deviation of dyspnea from 2.1±0.73 to1.82±0.63 does not show any significant improvement with p-value =0.081.
- The change in the mean and standard deviation of functional capacity from 205.30±20.82 to 269.50±29.22 shows a significant improvement with p-value=0.000.
- The change in the mean and standard deviation of SGRQ total score from 48.9 ±19.6 to 33.17±15.18 shows a significant improvement with p-value=0.000.



Graph 1: showing the pre and post intervention graphical representation of pulmonary parameters, dyspnea score, functional capacity and quality of life in Stationary Cycle Group.

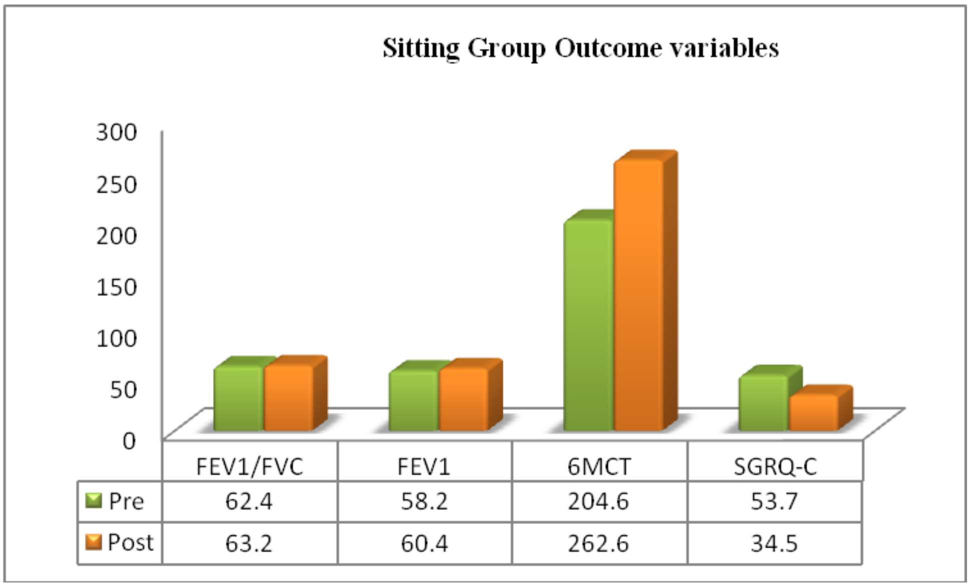
Table 3: showing Descriptive pre and post intervention statistical analysis of pulmonary parameters, dyspnea score, functional capacity and quality of life in pedocycle in sitting Group.

Outcomes	Pedocycle in sitting (PS) Group		t-value	p-value
	Pre	Post		
FEV_1/FVC	0.62±0.05	0.63±0.05	-4.00	0.003*
FEV_1	58.20±11.65	60.40±11.72	-4.71	0.001*
FVC	74.70±8.99	75.90±8.47	-1.80	0.104
Dyspnea	2.30±0.94	1.70±0.82	2.44	0.037*
6MCT	204.60±21.61	262.6±31.64	-15.76	0.000*
SGRQ-C total score	53.70±13.08	34.50±12.36	19.02	0.000*

**p-value less than 0.05 (p<0.05).*

Within group analysis of Table 3 shows:

- There is significant improvement in pulmonary parameter for FEV_1/FVC with p-value=0.003 and FEV_1 with p-value = 0.001 in pedocycle in sitting group.
- The change in the mean and standard deviation of dyspnea from 2.30±0.94 to 1.70±0.82 shows a significant improvement with p-value =0.037.
- The change in the mean and standard deviation of functional capacity from to 204.60±21.61 to 262.6±31.64 shows a significant improvement with p-value=0.000.
- The change in the mean and standard deviation of SGRQ total score from to 53.70±13.08 to 34.50±12.36 shows a significant improvement with p-value=0.000.



Graph 2: showing the pre and post intervention graphical representation of pulmonary parameters, dyspnea score, functional capacity and quality of life in pedocycle in sitting Group.

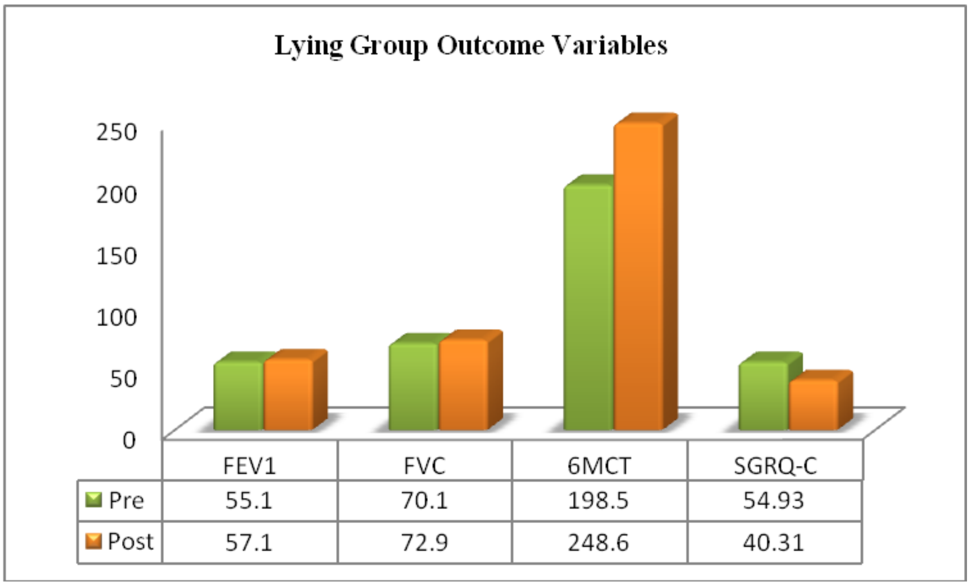
Table 4 showing Descriptive pre and post intervention statistical analysis of pulmonary parameters, dyspnea score, functional capacity and quality of life in pedocycle in lying Group.

Outcomes	Pedocycle in lying (PL) Group		t-value	P -value
	Pre	Post		
FEV_1/FVC	0.60±0.04	0.60±0.04	-1.07	0.309
FEV_1	55.10±13.11	57.10±13.45	-4.04	0.003*
FVC	70.10±10.29	72.90±9.07	-3.77	0.004*
Dyspnea	2.17±0.83	1.90±0.87	2.44	0.037*
6MCT	198.5±27.04	248.6±37.27	-11.13	0.000*
SGRQ-C total score	54.93±18.55	40.31±15.79	7.86	0.000*

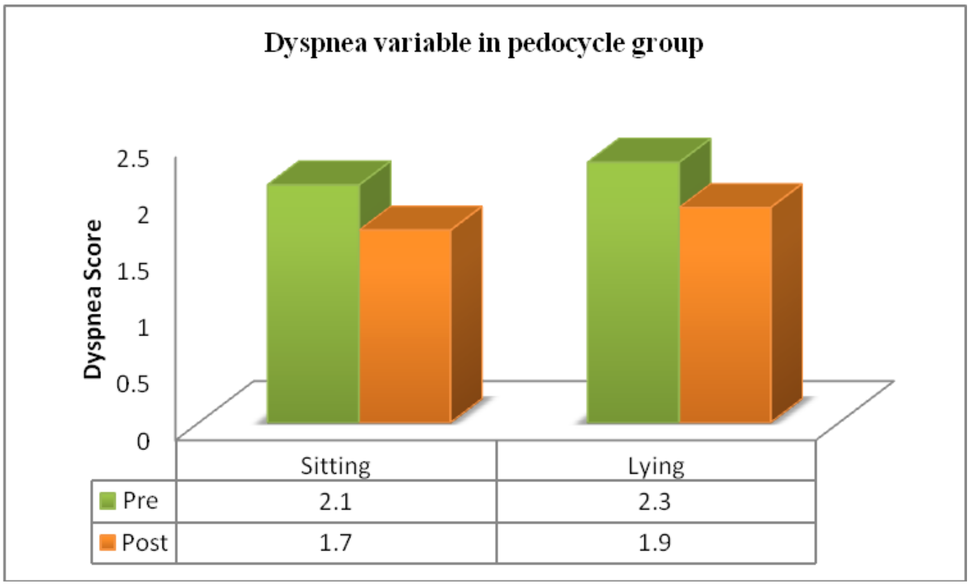
**p-value less than 0.05 (p<0.05).*

Within group analysis of Table 4 shows:

- There is significant improvement in pulmonary parameter for FEV_1 with p-value=0.003 and FVC with p-value = 0.004 in pedocycle in lying group.
- The change in the mean and standard deviation of dyspnea from 2.17±0.83 to 1.90±0.87 shows a significant improvement with p-value =0.037.
- The change in the mean and standard deviation of functional capacity from 198.5±27.04 to 248.6±37.27 shows a significant improvement with p-value=0.000.
- The change in the mean and standard deviation of SGRQ total score from 54.93±18.55 to 40.31±15.79 shows a significant improvement with p-value=0.000.



Graph 3: showing the pre and post intervention graphical representation of pulmonary parameters, dyspnea score, functional capacity and quality of life in pedocycle in lying Group.



Graph 4: showing the pre and post intervention graphical representation of dyspnea score in pedocycle in sitting and lying Group.

Between the Group Analysis

Table 5 showing Intragroup analysis of SC Group, PS Group and PL Group.

	Stationary cycle (SC) Group		Pedocycle in sitting (PS) Group		Pedocycle in lying (PL) Group		F-value	p- value
	Pre	post	pre	post	pre	post		
FEV_1/FVC	0.61±0.05	0.62±0.05	0.62±0.05	0.63±0.05	0.60±0.04	0.60±0.04	0.486	0.62
FEV_1	54.50±14.29	56.30±13.36	58.20±11.65	60.40±11.72	55.10±13.11	57.10±13.45	0.118	0.88
FVC	69.90±9.64	72.20±8.80	74.70±8.99	75.90±8.47	70.10±10.29	72.90±9.07	1.686	0.20
Dyspnea	2.10±0.73	1.82±0.63	2.30±0.94	1.70±0.82	2.17±0.83	1.90±0.87	0.130	0.87
6MCT	205.30±20.82	269.50±29.22	204.60±21.61	262.6±31.64	198.5±27.04	248.6±37.27	3.233	0.05
SGRQ-C total score	48.92±19.58	33.17±15.18	53.70±13.08	34.50±12.36	54.93±18.55	40.31±15.79	2.084	0.14

Intragroup analysis in table 5 shows:

There is no significant improvement in pulmonary parameters with FEV_1/FVC (p-value=0.62), FEV_1 (p-value=0.88), FVC (p-value=0.20), dyspnea score (p-value=0.87), 6MCT (p-value=0.05) and SGRQ-C total score (p-value=0.14).

DISCUSSION

The main objective of the study was to analyse the effectiveness of pedocycle in improving pulmonary functions, dyspnea status, functional capacity and quality of life in moderate and severe COPD patients. The secondary objective was to analyse the effect of pedocycle in sitting and lying position on pulmonary functions, dyspnea status, functional capacity and quality of life. The main findings of the study revealed no significant difference in pulmonary functions, dyspnea, functional capacity and quality of life in patients with COPD using pedocycle as aerobic training compared with control after for four weeks. This study also did not find any significant difference for pedocycle in sitting and lying position.

The study results are similar to the study by Naglaa Bakry et al who found no statistically significant difference in physiological parameters between the control group and the respiratory training group but there was a statistically significant improvement of both FVC and FEV_1 parameters within the respiratory training group.[18] Another study by Zoe J McKeough et al also found no significant difference in the total score of the SGRQ between groups following the intervention.[19]

However, this study had shown with-in-group significant improvement in all the variables within the group analysis after four weeks of training. There is significant improvement in FEV_1 and FVC in stationary cycle group with p-value (<0.05). The pedocycle in sitting group showed significant improvement for FEV_1/FVC and FEV_1 and pedocycle in lying group showed significant improvement for FEV_1 and FVC with p-value (<0.05) respectively. The study results are supported by studies done by Nirupal et al and Pandergast et al that lower extremity exercise tends to improve respiratory function in short duration.[20] The improvement occurs mainly due to lower limb aerobic training effect on the respiratory mechanics and also because of large muscle mass of lower limb musculature, as the larger muscle mass requires more oxygen consumption, this improves pulmonary capacities and volumes. Morris and Sheppard studied that emphysema is characterized by destruction of alveolar extracellular matrix leading to enlargement of airspaces and decrease in alveolar-capillary exchange area. Exercise protocol resulted in decrease in lung hyperinflation, number of apoptotic cells, rupture of alveolar walls and collagen deposition.[21] Another study by Maysa Alves et al had demonstrated that aerobic training attenuated lung emphysema and inflammatory responses in COPD subjects.[22] The study had shown that aerobic exercise reduces both pulmonary and systemic manifestations by inhibitory effect of aerobic exercises on cellular infiltrate and proinflammatory cytokines level, thus improves pulmonary capacities and volumes. In a study by Richard Casaburi, a substantial improvement in exercise tolerance had been shown. They suggested that exercise training reduces the ventilatory requirement in severe COPD patients. They also found a small, but significant, increase in FEV_1 after exercise training.[23]

Study by Merrill Landers et al supports our assertion of the possible underlying physiologic mechanisms that may be responsible for position-related pulmonary changes in the stationary cycle group that had shown no significant improvement in FEV_1/FVC.[24] In subjects with stationary cycle group, thoracic flexion with concomitant lower cervical extension causes a shortening of the accessory inspiratory muscles such as scalene sternocleidomastoid, pectoralis major, pectoralis minor, which serve to expand the thorax by elevating the ribs leading to decrease in intercoastal spaces and subsequent decrease in lung volumes. While, the erect and back supported posture while doing pedocycle in sitting enhance the mechanics of thoracic spine and ribs. Thus, increase the caudal excursion of diaphragm. Study by Zoe J Mckeough suggested that when the arm is kept in elevated position then the rib cage is expanded by the passive stretch of pectoralis major and major and active contraction of serratus anterior, thus contributing to ventilatory constraint.[19]

In SC group where the subjects did exercise with stationary cycle. The upper extremity and pectoralis are engaged, so full chest expansion was not possible. While the patients who did pedocycle in sitting and lying position, the upper extremity musculature was relaxed so they can work more effectively and efficiently as a ventilatory muscle, hence explain the improvement in parameters within these two groups as well.

Patients with COPD had altered breathing pattern and experiences dyspnea particularly when they exercise or perform activities of daily livings. In our study, there was with-in-group significant improvement in dyspnea index in group doing pedocycle in sitting and lying position with p-value (<0.05). The exercise intervention changes the breathing pattern and improve the endurance that contributes increase in ventilation and lung functions of these patients. Studies had shown that increase aerobic capacities with exercise leads to decline in lactate production hence improves dyspnea. Jacome and Marques et al demonstrated a perceived clinical improvement in dyspnea in moderate to severe COPD patients. Exercise training has a potential to reverse the restriction experienced in performing activities of daily living because of dyspnea.[25] However, reduction in dyspnea from 2.1±0.73 to 1.82±0.63 on mMRC grading was measured in stationary cycle group but did not reach statistical significance. This can be explained by lack of difference in FEV_1/FVC within in the group.

This study showed with-in-group significant improvement in functional capacity with p-value (<0.05) in all the three groups. The base line value of 6MCT in stationary cycle group has changed from 205.30±20.82 to 269.50±29.22, in pedocycle in sitting from to 204.60±21.61 to 262.6±31.64 and in pedocycle in lying from 198.5±27.04 to 248.6±37.27. Although, the COPD patients performing pedocycle in lying position felt difficulty in lying. The progression was slow but as they participated, they were able to maintain the posture and are able to perform aerobic training. The improvement in exercise capacity after aerobic training program may be due to reconditioning of the peripheral skeletal muscle dysfunction and exercise intolerance in COPD patients, improved ventilatory muscle function and desensitization to dyspnea. Study by Porszasz and associates demonstrated that physical training of patients with severe COPD reduces the degree of hyperinflation at a given level of exercise and, consequently, improves exercise tolerance.[26]

This study also showed significant with-in-group improvement in quality of life measured as SGRQ-C score with p-value (<0.05). The baseline value of SGRQ total score in stationary cycle group has changed from 48.9±19.6 to 33.17±15.18, in pedocycle in sitting group from 53.70± 13.08 to 34.50±12.36 and in pedocycle in lying from 54.93±18.55 to 40.31±15.79.

Pulmonary rehabilitation is still under development in India. Due to unawareness of available resources, high cost of rehabilitation and long-term rehabilitation protocol required, the COPD patients has to rely upon home-based treatment protocols. This would help the patients to practice the rehabilitation for long term at home. The present study provides us with portable and cost-effective aerobic training tool.

Strength

In Indian population patients from middle to lower socioeconomic status who can't afford or come to the hospital for pulmonary rehabilitation regularly, can use pedocycle as a home-based aerobic training tool.

Future Research

Future research with larger study population and follow up period should be selected for generalization of the results as we had investigated the pulmonary functions, functional capacity and quality of life immediately after four weeks of pulmonary rehabilitation, so it is not clear that how long the improvement will last. Also, the present study didn't demonstrate any significant effect of pedocycle on variables such as VO_2 max and ABG analysis. Thus, future research is needed to evaluate the effect of pedocycle on these physiological variables.

CONCLUSION

In conclusion this study suggested that for aerobic training, pedocycle should be considered as an adjunct to stationary cycle as exercise component of pulmonary rehabilitation. These findings will be able to provide a compact, portable and cost-effective exercise intervention of pulmonary rehabilitation tool to improve exercise tolerance and functional capacity in COPD patients.

Limitations

Some of the limitations of this study include:

The exercise training protocol conducted in this study had two sessions per week which lasted for four weeks. The frequency of sessions and total duration protocol is shorter when compared with other studies. Longer sessions and duration of intervention are required for patients with COPD to assess the long-term effects of aerobic training intervention through the pedocycle.

Also, the study had a limited small sample size in respective groups. Thus, further study with large sample size may be required to relate with the parameters to get the best outcomes for patients with COPD.

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Ethical clearance

As per the Ref. No. IAMR/22/4033 Institute of Applied Medicine and Research given the ethical clearance for the research. There is no funding and conflict of interest.

Conflict of Interest: There is no conflict of interest.

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