RESEARCH ARTICLE

Evaluation of Effect of Inhaled Corticosteroid (ICS) on Spirometric Parameters of COPD Patients

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Abstract

Introduction: Chronic Obstructive Pulmonary Disease (COPD) is currently the fourth leading cause of death in the world but is projected to be the 3rd leading cause of death by 2020. More than 3 million people died of COPD in 2012 accounting for 6% of all deaths globally. COPD represent an important public health challenge that is both preventable and treatable. COPD is a major cause of chronic morbidity and mortality throughout the world; many people suffer from this disease for years, and die prematurely from it or its complications. Afghanistan is also one of those countries in which the mortality rate of COPD has gradually increased, therefore this problem needs prompt attention and is more essential to focus on.

Objective: This study aimed to determine and evaluate the effect of inhaled corticosteroid (ICS) on Spirometric parameters of COPD patients and association between inhaled corticosteroid (ICS) and changes of spirometric parameters of various age groups, gender and smokers in OPD patients of COPD of Khost province of Afghanistan.

Material and Methods: It is prospective observational research, on 100 COPD patients in Khost province from 2019/3/22 to 2019/8/24. Spirometric parameters of all 100 patients under study (research) after diagnosis of COPD before treatment such as FVC, FEV1 and PEFR by (ME1 2AZ) model spirometer manufactured by (VYair) Company in (2005), diagnosed and recorded in computer special format, then inhaled corticosteroids therapy prescribed for three months and prescriptions are copied. After three months of treatment, the spirometric parameters of all 100 patients under study (research) were re-diagnosed and recorded using this model spirometer. The pre-treatment and post-treatment recorded spirometric parameters processing, comparison and evaluation results have been identified by IBM SPSS-25 version.

Results: The study was conducted over a five month period from March 2019 to August 2019 in 100 COPD patients in Khost province. Initially the effects of ICS on spirometric parameters were evaluated in all COPD patients and it was proved that ICS has a positive impact on all three spirometric parameters of all age groups, The average FEV1 before ICS is 67.13 ∓3,79 and after ICS is 74.69 ∓3,70 the positive improvement between the average is 7.56%. Average FVC before ICS is 74.37 ∓4,33 and after ICS is 81.71 ∓ 4,41, improvement between average is 7.34%. Average PEFR before ICS is 67.15 ∓ 7,46 and after ICS 83.53 ∓ 7,39, improvement between average is 16.38%. The progression between the average is seen in all parameters, but the effect on PEFR (16.38%) is more pronounced than in FEV1 and FVC and in all three parameters $P < 0.05$(see table-1). The effects of ICS on all three spirometric parameters in different age groups of total COPD patients showed that ICS affects all age groups, but the age group VI (70-79Y) has an average of 67.43 FEV1 before ICS and 75.86 after ICS, with a positive improvement between the average of 8.43%.The FVC average before ICS is 74.63 and after ICS is 83.23, the improvement between the average is 8.60%. The average PEFR before ICS is 64.96 and after ICS is 82.60, the improvement between the average is 17.63%. The effect of ICS is most pronounced on all three spirometric parameters of this age category. The second row has a significant effect on the group VII (80-90Y) and the third row has a significant effect on the group V (60-69Y). The effect of ICS gradually decreases from the first group I (22-29Y), this meaning that ICS is more effective in older age groups than in younger age groups (see table-2). Research on gender, tobacco use, and middle age in all COPD patients showed that the Khost province's COPD prevalence was 23 (23%) in males and 77 (77%) in females. COPD is more prevalent in female (77%) than in male. Also, smoking does not significantly affect the prevalence of COPD, as the total percentage of smokers is 9 (9%) and the average age of patients with COPD is 61.05 years (see Table 3).

Conclusion: Overall, the findings indicated that ICS has a positive impact on spirometric parameters of all age groups of COPD patients, but ICS has significant effect on PEFR parameter. ICS also has a positive impact on spirometric parameters of all age groups of COPD patients, but ICS have a significant effect on spirometric parameters of VI-(70-79Y) and V-(60-69Y) age groups and ICS effect in young age groups gradually decreased. Moreover prevalence of COPD at Khost province is significantly increased in female. Smoking has not significant effect on prevalence of COPD. Mean age if COPD patients elderly at Khost province.

Keywords: COPD, FVC, ICS, Khost, PEFR, Spirometry, Spirometric parameters- FEV1.

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Introduction

Chronic Obstructive Pulmonary Disease (COPD) is currently the fourth leading cause of death in the world but is projected to be the 3rd leading cause of death by 2020. More than 3 million people died of COPD in 2012 accounting for 6% of all deaths globally. COPD represent an important public health challenge that is both preventable and treatable. COPD is a major cause of chronic morbidity and mortality throughout the world; many people suffer from this disease for years, and die prematurely from it or its complications. Globally, the COPD burden is projected to increase in coming decades because of continued exposure to COPD risk factors and aging of the population.[1]

COPD is presented mainly by bronchitis and emphysema in various combinations, often with asthmatic complications. Development of cor pulmonale and/or upper respiratory infections may exacerbate the clinical outcome in chronic course of the disease.[2] The study aimed to explore the association between inhaled corticosteroid (ICS) and changes of spirometric parameters of disease severity in COPD patients to identify evaluation of effect of inhaled corticosteroid (ICS) on age group of COPD patients.

Spirometry (measuring of breath) is the most common of the pulmonary function tests (PFTs). It measures lung function, specifically the amount (volume) and/or speed (flow) of air that can be inhaled and exhaled. Spirometry is helpful in assessing breathing patterns that identify conditions such as asthma, pulmonary fibrosis, cystic fibrosis, and COPD. It is also helpful as part of a system of health surveillance, in which breathing patterns are measured over time. Spirometry generates pneumotachographs, which are charts that plot the volume and flow of air coming in and out of the lungs from one inhalation and one exhalation.

The most common parameters measured in spirometry are Vital capacity (VC), Forced Vital Capacity (FVC), Forced Expiratory Volume (FEV) at timed intervals of 0.5, 1.0 (FEV1), 2.0, and 3.0 seconds, forced expiratory flow 25–75% (FEF 25–75) and maximal voluntary ventilation (MVV), also known as Maximum breathing capacity.[3] Other tests may be performed in certain situations.

Results are usually given in both raw data (litres, litres per second) and percent predicted—the test result as a percent of the "predicted values" for the patients of similar characteristics (height, age, sex, and sometimes race and weight).[4] The interpretation of the results can vary depending on the physician and the source of the predicted values. Generally speaking, results nearest to 100% predicted are the most normal, and results over 80% are often considered normal. Multiple publications of predicted values have been published and may be calculated based on age, sex, weight and ethnicity.[5] However, review by a doctor is necessary for accurate diagnosis of any individual situation.

A bronchodilator is also given in certain circumstances and a pre/post treatment graph for comparison is done to assess the effectiveness of the bronchodilator. See the example printout.

Forced vital capacity (FVC) is the volume of air that can forcibly be blown out after full inspiration, measured in liters. FVC is the most basic maneuver in spirometry tests.[6]

FEV1 is the volume of air that can forcibly be blown out in first 1 second, after full inspiration. Average values for FEV1 in healthy people depend mainly on sex and age, according to the diagram. Values of between 80% and 120% of the average value are considered normal.[7] Predicted normal values for FEV1 can be calculated and depend on age, sex, height, mass and ethnicity as well as the research study that they are based on.

FEV1/FVC is the ratio of FEV1 to FVC. In healthy adults this should be approximately 70–80% (declining with age).[8] In obstructive diseases (asthma, COPD, chronic bronchitis, emphysema) FEV1 is diminished because of increased airway resistance to expiratory flow; the FVC may be decreased as well, due to the premature closure of airway in expiration, just not in the same proportion as FEV1 (for instance, both FEV1 and FVC are reduced, but the former is more affected because of the increased airway resistance).[9] This generates a reduced value (<70%, often ~45%). In restrictive diseases (such as pulmonary fibrosis) the FEV1 and FVC are both reduced proportionally and the value may be normal or even increased as a result of decreased lung compliance.[10]

A derived value of FEV1 is FEV1% predicted (FEV1%), which is defined as FEV1 of the patient divided by the average FEV1 in the population for any person of the same age, height, gender, and race. Peak expiratory flow (PEF) is the maximal flow (or speed) achieved during the maximally forced expiration initiated at full inspiration, measured in liters per minute or in liters per second.[11]

Based on the GOLD criteria, COPD was considered very severe if FEVI/FVC < 0.7 and FEV1 < 30% predicted or FEV1 < 50% predicted with respiratory failure or signs of right heart failure; severe if 30 ≤ FEV ≤ 50%; moderate if 50 ≤ FEV ≤ 80%, and mild (GOLD I) if the FEV 1 /FVC ratio was < 70 and FEV 1 ≥ 80% of the predicted value. Otherwise they were considered to have no lung disease (Normal) or GOLD stage 0 if they reported respiratory symptoms.[12]

Objective

This study aimed to determine and evaluate the effect of inhaled corticosteroid (ICS) on Spirometric parameters of COPD patients and association between inhaled corticosteroid (ICS) and changes of spirometric parameters of various age groups, gender and smokers in OPD patients of COPD of Khost province of Afghanistan.

Material and Methods

It is prospective observational research on 100 COPD patients in Khost province from 2019/3/22 to 2019/8/24. Spirometric parameters of all 100 patients under study (research) after diagnosis of COPD before treatment such as FVC, FEV1 and PEFR by (ME1 2AZ) model spirometer manufactured

by (VYair) Company in (2005), diagnosed and recorded in computer special format, then inhaled corticosteroids therapy prescribed for three months and prescriptions are copied. After three months of treatment, the spirometric parameters of all 100 patients under study (research) were re-diagnosed and recorded using this model spirometer. The pre-treatment and post-treatment recorded spirometric parameters processing, comparison, and evaluation results have been identified by IBM SPSS-25 version.

Results

The study was conducted on 100 patients with COPD, including 23 males and 77 females (mean age: 61.05 ± 14.83; range: 19-90 years). The spirometric parameters of the patients are described in the following tables.

The study was conducted over a five month period from March 2019 to August 2019 in 100 COPD patients in Khost province. Initially the effects of ICS on spirometric parameters were evaluated in all COPD patients and it was proved that ICS has a positive impact on all three spirometric parameters of all age groups, The average FEV1 before ICS is 67.13 ∓3,79 and after ICS is 74.69 ∓3,70 the positive improvement between the average is 7.56%. Average FVC before ICS is 74.37 ∓4,33 and after ICS is 81.71 ∓ 4,41, improvement between average is 7.34%. Average PEFR before ICS is 67.15 ∓ 7,46 and after ICS 83.53 ∓ 7,39, improvement between average is 16.38%.The progression between the average is seen in all parameters, but the effect on PEFR (16.38%) is more pronounced than in FEV1 and FVC and in all three parameters $p < 0.05$ (Table 1). The effects of ICS on all three spirometric parameters in different age groups of total COPD patients showed that ICS affects all age groups, but the age VI- (70-79Y) group has an average of 67.43 FEV1 before ICS and 75.86 after ICS, with a positive improvement between the average of 8.43%.The FVC average before ICS is 74.63 and after ICS is 83.23, the improvement between the average is 8.60%. The average PEFR before ICS is 64.96 and after ICS is 82.60, the improvement between the average is 17.63%. The effect of ICS is most pronounced on all three spirometric parameters of this age category. The second row has a significant effect on the VII- (80-90Y) group and the third row has a significant effect on the group V (60-69Y). The effect of ICS gradually decreased in ascending order from more advanced age groups to age group I (22-29Y), which means ICS is more effective in older age groups than in younger age groups (See Table 2). Research on gender, tobacco use, and middle age in all COPD patients showed that the Khost province's COPD prevalence was 23 (23%) in males and 77 (77%) in females. COPD is more prevalent in female (77%) than in male. Also, smoking does not significantly affect the prevalence of COPD, as the total percentage of smokers is 9 (9%) and the average age of patients with COPD is 61.05 years (See Table 3).

Discussion

This prospective observational study is conducted during five months on 100 COPD patients that were OPD in Khost province of Afghanistan. According to the GOLD Pocket guide to COPD diagnosis, management and prevention 2020, COPD is currently the fourth leading cause of death in the world but is projected to be the 3rd leading cause of death by 2020. More than 3 million people died of COPD in 2012, accounting for 6% of all deaths globally. COPD represent an important public health challenge that is both preventable and treatable. COPD is a major cause of chronic morbidity and mortality throughout the world; many people suffer from this disease for years, and die prematurely from it or its complications. Globally, the COPD burden is projected to increase in coming decades because of continued exposure to COPD risk factors and aging of the population. Moreover, direct measurement of the pulmonary function (spirometry) and analysis are indicated for COPD's clinical management.[5,12]

This study's basic aims were to declare and evaluate the effect of inhaled corticosteroid (ICS) on spirometric parameters of COPD patients and association between inhaled corticosteroid (ICS) and changes of spirometric parameters of various age groups, gender and smokers in OPD patients.[13]

Our study results declared that ICS has a positive impact on spirometric parameters of all age groups of COPD patients, e.g. FEV1 before ICS [100(67.13)], after ICS [100(74.69)] the improvement is 7.56%, FVC before ICS [100(74.37)], after ICS [100(81.71)] the improvement is 7.34%, PEFR before ICS [100(67.15)], after ICS [100(83.53)] the improvement is 16.38%. The effect of ICS was more pronounced on PEFR parameter.[14]

ICS also has a positive impact on spirometric parameters of all age groups of COPD patients, e.g. FEV1 before ICS in group age I-(22-29Y) was [6 (71.16)], after ICS [6(76.16)] the improvement is 5%, FVC before ICS in age group I-(22-29Y) was [6 (73.16)], after ICS [6(78.16)] the improvement is 5%, PEFR before ICS in age group I-(22-29Y) was [6 (72.66)], after ICS [6(88.83)] the improvement is 16.17%.

Table 1: Descriptive statistics of spirometric parameters in total COPD patients.

Spirometric Parameters	*No. of patients*	*Min*	*Max*	*Mean*	*Std. deviation*	*Improvement*	*P. Value*
FEV1-% (Before steroid Inhaler)	100	56	79	67.13	3.79	7.56%	P0.05
FEV1-% (After 3 months of steroid Inhaler)		65	87	74.69	3.70		
FVC-% (Before steroid Inhaler)	"	67	87	74.37	4.33	7.34%	P0.05
FVC-% (After 3 months of steroid Inhaler)		73	95	81.71	4.41		
PEFR-% (Before steroid Inhaler)	"	52	84	67.15	7.46	16.38%	P0.05
PEFR-% (After 3 months of steroid Inhaler)		59	99	83.53	7.39		

Table 2: Descriptive statistics of ICS effect on spirometric parameters in various age groups of total COPD patients.

Spirometric Parameters	*Age groups*	*N = of patients*	*Gender*		*Min*	*Max.*	*Mean*	*Improvement*
			M	*F*				
FEV1-% (Before steroid Inhaler)	I-(22-29Y)	6	0	6	66	74	71.16	5%
FEV1-% (After 3 months of steroid Inhaler)					70	80	76.16	
FVC-% (Before steroid Inhaler)					67	77	73.16	5%
FVC-% (After 3 months of steroid Inhaler)					74	82	78.16	
PEFR-% (Before steroid Inhaler)					69	76	72.66	16.17%
PEFR-% (After 3 months of steroid Inhaler)					78	92	88.83	
FEV1-% (Before steroid Inhaler)	II-(30-39Y)	4	0	4	62	70	66.75	5.75%
FEV1-% (After 3 months of steroid Inhaler)					68	77	72.50	
FVC-% (Before steroid Inhaler)					73	75	73.75	5.75%
FVC-% (After 3 months of steroid Inhaler)					78	81	79.50	
PEFR-% (Before steroid Inhaler)					57	76	67.75	15.5%
PEFR-% (After 3 months of steroid Inhaler)					70	95	83.25	
FEV1-% (Before steroid Inhaler)	III-(40-49Y)	5	2	3	56	69	65.77	7%
FEV1-% (After 3 months of steroid Inhaler)					65	77	72.40	
FVC-% (Before steroid Inhaler)					69	75	71.8	7.4%
FVC-% (After 3 months of steroid Inhaler)					75	81	79.2	
PEFR-% (Before steroid Inhaler)					59	80	67.8	13%
PEFR-% (After 3 months of steroid Inhaler)					72	97	80.8	
FEV1-% (Before steroid Inhaler)	IV-(50-59Y)	14	5	9	62	79	68.14	7.14%
FEV1-% (After 3 months of steroid Inhaler)					67	87	75.28	
FVC-% (Before steroid Inhaler)					67	85	74.50	6.85%
FVC-% (After 3 months of steroid Inhaler)					75	90	81.35	
PEFR-% (Before steroid Inhaler)					52	78	65.71	17.57%
PEFR-% (After 3 months of steroid Inhaler)					59	99	83.28	
FEV1-% (Before steroid Inhaler)	V-(60-69Y)	33	8	25	57	72	65.90	7.10%
FEV1-% (After 3 months of steroid Inhaler)					68	78	73.00	
FVC-% (Before steroid Inhaler)					68	93	75.09	7%
FVC-% (After 3 months of steroid Inhaler)					73	91	82.09	
PEFR-% (Before steroid Inhaler)					53	84	67.51	15.97%
PEFR-% (After 3 months of steroid Inhaler)					64	98	83.48	
FEV1-% (Before steroid Inhaler)	VI-(70-79Y)	30	5	25	61	76	67.43	8.43%
FEV1-% (After 3 months of steroid Inhaler)					69	81	75.86	
FVC-% (Before steroid Inhaler)					67	86	74.63	8.60%
FVC-% (After 3 months of steroid Inhaler)					74	95	83.23	
PEFR-% (Before steroid Inhaler)					56	80	64.96	17.63%
PEFR-% (After 3 months of steroid Inhaler)					72	95	82.60	
FEV1-% (Before steroid Inhaler)	VII-(80-90Y)	8	3	5	65	71	67.50	8.37%
FEV1-% (After 3 months of steroid Inhaler)					75	77	75.87	
FVC-% (Before steroid Inhaler)					69	77	72.50	8.37%
FVC-% (After 3 months of steroid Inhaler)					75	86	80.87	
PEFR-% (Before steroid Inhaler)					59	79	71.50	12.25%
PEFR-% (After 3 months of steroid Inhaler)					72	93	83.75	
Total	7- groups	100	23	77				

Table 3: Descriptive statistics of all COPD patients, according to gender, smokers and age range.

	Gender		*Male (23)*		*Female (77)*			
N = of patients	*M%*	*F%*	*Smoker%*	*Non%*	*Smoker%*	*Non%*	*Age range*	*Mean age*
100	23(23)	77(77)	8(34.78)	15(65.22)	1(1.29)	76(98.71)	19-90 years	61.05 ± 14.83
Total	100(100%)		23(100%)		77(100%)			

FEV1 before ICS of II-(30-39Y) age group [4 (66.75)], after ICS [4(72.50)] the improvement is 5.75%, FVC before ICS in age group II-(30-39Y) was [4 (66.75)], after ICS [4(72.50)] the improvement is 5.75%, PEFR before ICS in age group II-(30-39Y) was [4 (67.75)], after ICS [4(83.25)] the improvement is 15.5%.

FEV1 before ICS of age group III-(40-49Y) was [5 (65.77)], after ICS [5(72.40)] the improvement is 7%, FVC before ICS of age group III-(40-49Y) was [5 (71.8)], after ICS [5(79.2)] the improvement is 7.4%, PEFR before ICS of III-(40-49Y) age group [5 (67.8)], after ICS [5 (80.8)] the improvement is 13%.

FEV1 before ICS of age group IV-(50-59Y) was [14 (68.14)], after ICS [14(75.28)] the improvement is 7.14%, FVC before ICS in age group IV-(50-59Y) was [14 (74.50)], after ICS [14(81.35)] the improvement is 6.85%, PEFR before ICS of age group IV-(50-59Y) was [14 (65.71)], after ICS [14 (83.28)] the improvement is 17.57%.

FEV1 before ICS of age group V-(60-69Y) was [33 (65.90)], after ICS [33 (73.00)] the improvement is 7.10%, FVC before ICS in age group V-(60-69Y) was [33 (75.09)], after ICS [33 (82.09)] the improvement is 7%, PEFR before ICS of age group V-(60-69Y) was [33 (67.51)], after ICS [33 (83.48)] the improvement is 15.97%.

FEV1 before ICS in age group VI-(70-79Y) was [30 (67.43)], after ICS [30 (75.86)] the improvement is 8.43%, FVC before ICS of age group VI-(70-79Y) was [30 (74.63)], after ICS [30 (83.23)] the improvement is 8.60%, PEFR before ICS of age group VI-(70-79Y) was [30 (64.96)], after ICS [30 (82.60)] the improvement is 17.63%.

FEV1 before ICS of VII-(80-90Y) age group [8 (67.50)], after ICS [8 (75.87)] the improvement is 8.37%, FVC before ICS of VII-(80-90Y) age group [8 (72.50)], after ICS [8 (80.87)] the improvement is 8.37%, PEFR before ICS in age group VII-(80-90Y) was [8 (71.50)], after ICS [8 (83.75)] the improvement is 12.25%, but the comparative results indicated that ICS has significant effect on spirometric parameters in age groups VI-(70-79Y) and V-(60-69Y). The ICS effect in young age groups gradually decreased.

Prevalence according to gender of COPD patients, male [23 (23%)], female [77(77%)] indicated that prevalence of COPD is significantly increased in female [77 (77%)]. Smoking [9(9%)] has no significant effect on prevalence of COPD. Mean age (61.05 ± 14.83) of COPD patients is elderly.

In Iran one study has been conducted on Spirometry Findings Following Treatment with Oral and Inhalant Corticosteroids in Mild to Moderate Asthma Exacerbation in Children, study estimated that there was no significant difference between pulmonary function tests before and after treatment between groups. Children receiving oral prednisolone had significantly more improvement in Peak expiratory flow (PEF) ($p=0.01$). There was significant improvement in all respiratory parameters after treatment in both groups ($p < 0.05$), but PEF had no significant change after treatment in inhaled Budesonide group ($p = 0.63$). [10]

Recent meta-analysis confirmed that among 194 eligible studies, summary prevalence was 9.23% (95% credible interval [CrI]: 8.16%-10.36%) in men and 6.16% (95% CrI: 5.41%-6.95%) in women. Gender prevalence varied widely by the World Health Organization Global Burden of Disease sub-regions, with the highest female prevalence found in North America (8.07% vs 7.30%) and in participants in urban settings (13.03% vs 8.34%). Meta-regression indicated that in age ≥40 and bronchodilator testing contributed most significantly to heterogeneity of prevalence estimates across studies.[3]

About using smoking rates, another study estimate that 15.3 million people who are > 40 years of age in the United States have COPD. The prevalence estimate, based on spirometric definitions for COPD in the same age group using the Third National Health and Nutrition Examination Survey (NHANES III), is 17.1 million people. NHANES III and other US national health-care surveys further suggest that only between 2.4 and 7 million people actually have COPD diagnosed; thus, the proportion of COPD that is currently being diagnosed in the United States is between 14% and 46% of all cases. Using smoking rates and our model, which was developed and validated for the United States, we calculated the prevalence of COPD for Germany (2.7 million people), the United Kingdom (3.0 million people), Spain (1.5 million people), Italy (2.6 million people), and France (2.6 million people) in those people > 45 years of age.[15]

Conclusion

Overall, the findings indicated that ICS has a positive impact on spirometric parameters of all age groups of COPD patients, but ICS has significant effect on PEFR parameter. ICS also has a positive impact on spirometric parameters of all age groups of COPD patients, but ICS have significant effect on spirometric parameters in age groups VI-(70-79Y) and V-(60-69Y) with least effective in young age groups. Moreover prevalence of COPD at Khost province is significantly increased in female. Smoking has no significant effect on prevalence of COPD. The mean age of 61.05 ± 14.83 years were detected having COPD in Khost province.

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