

Efficacy of Inhalational Devices Utilization and Quality of Life in Mild to Severe Asthma

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Abstract: Introduction: Asthma is an extensive term which refers the disorders of respiratory system that commonly leads to episodic difficulty in breathing. It is a chronic disease whose symptoms are well known and still the management is quite difficult. Effectiveness of the inhalational devices as well as the quality of life of asthmatic patients were determined through the current study. Aim: To evaluate the efficacy of inhalational devices in asthmatic patients and their quality of life. Objective: To study the effectiveness of different types of inhalational devices in asthmatic patient, to observe the quality of life using questionnaire and spirometer and to educate the use of inhaler devices. Methodology: A randomized interventional study was conducted with the selected asthma patients over a period of 6 months in the Department of Respiratory Medicine, Pariyaram Medical College, Kannur, Kerala. The severities of the patients were estimated using the spirometer. Results: A total of 75 patients had completed the study, 22 (29%) were male and 53 (71%) were female and majority of the patients were non-smokers (84%), followed by smokers (12%) and ex-smokers (4%). The FEV₁ baseline value of MDI was found to be 1.88 L and at the end of 60th day follow up, the patient had shown 0.9 L improvement in lung function compared to other two devices. The patients who received inhalational devices after counseling showed clinical improvement in symptom score on the 15th day, the further follow-up days showed very good clinical significance. Conclusion: Appropriate education regarding the use of MDI is helpful in improving the pulmonary function and HRQoL of the patients. It reveals that patients using MDI shows more effectiveness than other inhalational devices after providing adequate counseling. We conclude that proper education on the usage of MDI can clinically and statistically improve the quality of life of moderate to severe asthmatic patients.

Keywords: Efficacy, Inhalational devices, Quality of life, Asthma

1. Introduction

Asthma the most common chronic disease is the one which leads to hospital admissions recurrently or else the presentation to local health centers (LHC).(1) It is an extensive term which refers the disorders of respiratory system that commonly leads to episodic difficulty in breathing.(2) It is an inflammatory condition of airways characterized with limited airway and punctuated by acute symptoms which finally leads to hyper responsiveness of airways.(3)

The Expert Panel Report 3 (EPR-3) of National Institute of Health (NIH), Guidelines for Diagnosis and Management of Asthma, defines asthma as a “chronic inflammatory disorder of airways in which many cells and cellular elements play a role, in particular, mast cells, eosinophils, T-lymphocytes, neutrophils and epithelial cells. The inflammation of airways causes recurrent episodes of wheezing, breathlessness, chest tightness and cough, particularly at night and in early morning. The inflammation also causes an increase in existing bronchial hyper-responsiveness to a variety of stimuli.(4) Asthma as a word comes from the Greek verb “azein” which exist with a meaning of to pant, to exhale with open mouth or sharp breath. The renowned textbook Corpus Hippocraticum written by Hippocrates is the earliest text that mentioned asthma as a medical term. (5)

India has an estimate of around 12 million people suffering from asthma. It states that among the Indian population around 15 % adults and 5 % to 7 % children are diagnosed

with asthma. Among these 60 % are referred to the pulmonologist and the rest 40 % are diagnosed and treated at periphery level.(6) A recent review of 15 epidemiological studies showed that the mean prevalence of asthma among children was 7.24 %.(7) In the year 2016, among Indian population, 73.27 lakh people in urban areas 277.49 lakh in rural areas were choked up with chronic asthma.(8) Around 14 % of world’s children and 8.6 % of young adults were experienced with asthma symptoms. Global prevalence rate of doctor diagnosed asthma were 4.3 % where as that of clinical or treated asthma and wheezing in adults were 4.5 % and 8.6 % respectively. The prevalence rate of asthma varies from a high of 21 % for Australia to a low of 0.2 % for China. Additional 100 million cases of asthma are expected globally by the year 2025.(9)

The major advantage of Aerosol delivery of drugs for asthma management is being site-specific and thus enhancing the therapeutic ratio. More rapid inhalation can be acquired through the inhalation of short-acting beta2-agonist. New devices for delivering topically active medication has been emerged followed by the international ban on the production and use of chlorofluorocarbons. The present study mainly deals with the Metered Dose Inhaler (MDI), Dry Powder Inhaler (DPI) and Metered Dose Inhaler with Spacer Device.(10)

As an index for evaluating health care services or outcomes, the HRQoL is as important as life expectancy. These instruments can be classified into generic and disease-specific instruments. There are numerous disease-specific

instruments that can be used for patients with asthma, such as Juniper *et al.*'s Asthma Quality of Life Questionnaire (AQLQ), the Living with Asthma Questionnaire (LWAQ), the St. George's Respiratory Questionnaire (SGRQ), and Marks *et al.*'s Asthma Quality of Life Questionnaire (AQLQ).

The characteristics of each instrument should be considered in the selection of specific HRQoL questionnaires for clinical research. Generally, the HRQoL is more disturbed in patients with severe asthma, and has been considered to be an important end-point in randomized controlled trials that involve asthma patients.(11) Asthma is a chronic disease whose symptoms are well known and still the management is quite difficult. Improper inhaler usage is often the Achilles heel in the management of patients with respiratory disorders. We aimed to determine the effectiveness of inhaler use, as well as to assess the quality of life after imparting appropriate education over a period of time.

2. Aim and Objectives

The aim of the study was to evaluate the efficacy of inhalational devices in asthmatic patients and their quality of life. The objective of the study include

- To study the effectiveness of different types of inhalational devices in asthmatic patient.
- To observe the quality of life using questionnaire and spirometer.
- To educate the use of inhaler devices.

3. Literature Review

Federico Lavorini *et.al* (2007)(12) suggested that DPIs are common among patients with asthma and COPD, and that poor inhalation technique has detrimental consequences for clinical efficacy. Several studies by PiyushArora *et.al* (2014)(13), HashemRahmati *et.al* (2014)(14) and AvijithGanguly *et.al* (2014)(3) had shown that majority of patients using inhalation devices made errors while using the device.

Studies by Basheer Y Khassawneh *et.al* (2008)(15) and Geerth .N. Rootmensen *et.al* (2010)(16) states that correct inhalation technique was followed with prefilled DPI and had a lower rate of incorrect handling, when compared with the MDI. According to Federico Lavorini *et.al* (2007)(12) improvement in asthma management could be achieved by new DPIs that are easy to use correctly and are forgiving of poor inhalation technique, thus ensuring more successful drug delivery.

4. Methodology

The study was conducted in the Outpatient Department of Respiratory Medicine, Academy of Medical Sciences, Pariyaram, a tertiary care hospital of Kannur district for a period of 6 months from December 2017 to June 2018 with the following criterias.

Inclusion: All patients with mild to severe asthma aged between 18 to 70 and who are able to perform spirometry.

Exclusion: Patients with COPD, TB, heart diseases and any other significant diseases who had voluntarily withdrawn from the study including pregnant women and lactating mothers and those who are hospitalized.

The following study was conducted as a randomized interventional study with the selected asthma patients who were able to give the written informed consent. Spirometry of each patient was performed along with demographic data collection to identify the severity. The patients are subjected to follow up with 15th, 30th, 45th and 60th day duration for evaluating the effectiveness of inhalational devices. FEV₁ % predicted of the patients were recorded from baseline to 15th, 30th, 45th and 60th days follow up using spirometer. Health related quality of life were assessed from baseline to four follow up using SGRQ. Patients are educated regarding the appropriate utilization of inhalational devices at the beginning of the study.

5. Result

A total of 91 patients were screened for the study. Among them 16 were dropouts and 75 patients had completed the study successfully. The details of patient's status in study are shown in table 1.

Table 1: Patient enrollment during study

Sl.No	Process	No.of patients
1	Screened	91
2	Study completed	75
3	Dropout &Withdrawal	16

Table 2: Demographic data

S. No	Demographic	Characteristics	No.of patients	Percentage %
1	Gender	Male	22	29%
		Female	53	71%
2	Age	<25 years	7	9%
		25-55 years	21	28%
		>55 years	47	63%
3	Education status	Literate	47	63%
		Illiterate	28	37%
4	Occupational status	Student	6	8%
		Office	15	20%
		Daily wages	14	19%
		Unemployed	40	53%
5	Number of years of asthma disorder	<5 years	65	87%
		5-10years	7	9%
		>10 years	3	4%
6	Smoking status	Smoker	9	12%
		Ex-smoker	3	4%
		Non smoker	63	84%

5.1 Severity of the patients

The severities of the patients were estimated using the spirometer. The patients were categorized into mild, moderate and severe according to NAEPP/EPR 2 by assessing their FEV₁% predicted.

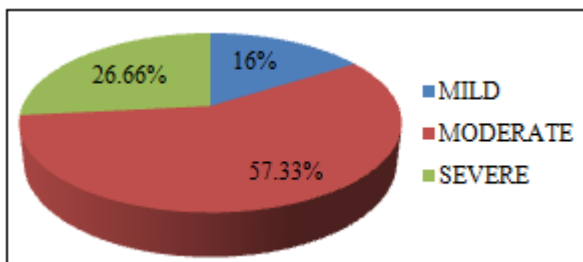


Figure 1: Severity categorization of study patients

5.2 Pulmonary Function assessment during the study

1) Baseline variable estimation:

On the first visit, the pulmonary function and quality of life of the enrolled patients were assessed using spirometry and Saint George’s Respiratory Questionnaire respectively. The severities of the patients were estimated using spirometry. The patients were categorized into mild, moderate and severe patients. Fig: 3 represent the patient categorized based on the severity.

2) Pulmonary function

The major pulmonary function parameter assessed during the study was the forced expiratory volume in one second (FEV₁). The follow up FEV₁ were compared to observe the significant difference with the baseline.

3) Follow-up assessments

The enrolled 75 patients were assessed for their FEV₁ % predicted and quality of life during their follow-up visits i.e., 15th, 30th, 45th and 60th days from the baseline visits.

a) Change in FEV₁ for prescribed inhalational devices

All the prescribed inhalational drugs had shown clinical improvements with different inhalational devices. Table No.3 and Fig: 2 represent the changes noted in FEV₁ for prescribed inhalational devices. The patient prescribed with MDI had shown better improvement after counseling when compared with DPI and MDI and thus they are clinically and statistically significant. The FEV₁ baseline value of MDI was found to be 1.88 L and at the end of 60th day follow up, the patient had shown 0.9 L improvement in lung function compared to other two devices.

Table 3: Change in FEV₁ for prescribed inhalational devices

Treatment group	Baseline	15 th day	30 th day	45 th day	60 th day
DPI	1.45	1.56	1.67	1.81	1.95
MDI	1.88	1.98	2.08	2.48	2.78
MDI with spacer	1.46	1.57	1.78	1.98	2.26

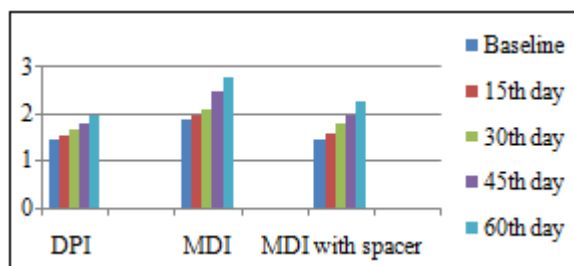


Figure 2: Change in FEV₁ for prescribed inhalational devices

b) Quality of Life Assessment during the study

The symptom score was assessed during the baseline and follow-up. The patients who received inhalational devices after counseling showed clinical improvement in symptom score on the 15th day, the further follow-up days showed very good clinical significance as shown Fig:3

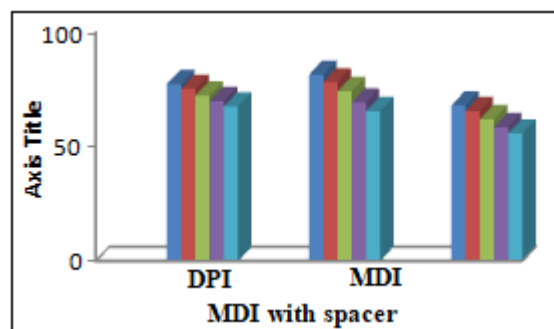


Figure 3: Changes in SGRQ for prescribed inhalational devices

6. Conclusion

The study findings were helpful in determining the effectiveness of inhalational devices in asthmatic patients. Appropriate education regarding the use of MDI is helpful in improving the pulmonary function and HRQoL of the patients. It reveals that patients using MDI shows more effectiveness than other inhalational devices after providing adequate counselling. Most commonly prescribed inhalational device among the study population was DPI compared to others. We conclude that proper education on the usage of MDI can clinically and statistically improve the quality of life of moderate to severe asthmatic patients.

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