Research Article

Impact of Pharmacist Provided Patient Counseling on Quality of Life Inpatients with Asthma in a Tertiary Care Teaching Hospital

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ABSTRACT

Asthma is a chronic inflammatory condition of the airways, affecting millions of people worldwide. The common features of asthma are recurrent episodes of wheezing, breathlessness and chest tightness, associated with widespread narrowing of the airways. Increasing the knowledge of asthma, proper use of drugs and education of patients are the corner stone of the management of asthma. Patient education and counseling will lead to an increased patient confidence in the ability to self-manage of asthma, reduce hospitalization, increase adherence and improve quality of life. The study was carried out to assess the impact of patient counseling on the improvement in quality of life of asthmatic patients. A prospective interventional randomized study carried out for a period of 7 months from August 2012 to March 2013. The patients with asthma who met the study criteria were randomized into test (received counseling along with information leaflet)and control (received the counseling only at the end of the study) groups using chit method. The quality of life of the patients was assessed by using St. George's respiratory questionnaire at the baseline and at final follow up. A total of 73 patients (40 patients in test group and 33 patients in control group) completed the study. A significant differences in SGRQ score was found between the two groups ($p<0.0001$) on the last follow up but not at the baseline ($p>0.05$). Both test (>12) and control (>4) group showed clinical improvement in total SGRQ score. Pharmacist education and counseling has led to clinically and statistically significant improvement in the quality of life of asthmatic patients as compared with the control groups.

Keywords: Patient counseling, quality of life, St. george's respiratory questionnaire asthma, pharmacist

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INTRODUCTION

Asthmais one of the most serious public health problem affecting people of all ages throughout the world. Bronchial asthma is a chronic disorder of the airway that causes the episodes of obstruction, bronchial hyper responsiveness, and airway inflammation that are usually reversible (1).

Chronic disease like asthma has significant effects on patient's health and quality of life. Its effects include reduced quality of life, lost productivity, missed school days, increased health care cost, and the risk of hospitalization and even death.

It was seen as one of the leading cause of morbidity and mortality in rural India (2, 3).

Successful control of asthma relies heavily on patient adherence to prescribed inhaled therapies and the ability of patients to use their inhalers effectively because correct use of inhalation devices is a prerequisite for successful drug management of asthma. However, poor inhaled technique can result in decreases in lung deposition of drug, and increased oropharyngeal deposition with decreased drug efficacy. Adherence to inhaled therapy in asthma is influenced by several factors, including the patient's understanding of the need for therapy, daily dosing frequency and acceptance of the inhaler device. Strategies to monitor, educate and improve adherence are key

components of pharmaceutical care plans, particularly for patients with chronic disease such asasthma (4). Patient education is a solution to increase awareness and for strict adherence to drug schedule. Continuous education of patients with asthma enhances the probability of long-term asthma control and often has essential importance for successful management of all types of asthma. There is a potential of educational assistance of pharmacists who could particularly help in adequate selection and proper usage of asthma medicationS (5).

The conventional clinical parameters of lung function , symptoms and use of reliever medication predict health related quality of life differently depending on the level of asthma, severity and these traditional measures of asthma severity and astma control explain one half of the variance of health related quality of life (6). A major variable relating to HRQoL is perceived stress, and hence stress management might improve their quality of life of patients with asthma[4].The aim of HRQOL is to assess the impact of asthma on the daily functions and emotional well-being. The clinical measures provide information only about the affecting organ but the functional impairment such as physical, emotional and social functions are recognized by the quality of life (2, 6, 7). Few well designed studies have investigated the effect of pharmacist care on asthma patients to date. These studies have shown improvement in peak flow, asthma severity, symptom scores, drug utilization and humanistic outcomes (eg. Quality of life) (8). Also there is increasing evidence that patient education by the assistance of pharmacist could help not only in medication adherence but also in enhancing the probability of long term asthma control and ultimately improving the quality of life (6).

OBJECTIVES:

The main aim of the study was to assess the impact of pharmacist provided patient counseling on quality of life in patients with asthma in a tertiary care teaching hospital by using the St. George Respiratory Questionnaire.

METHODOLOGY

A prospective interventional randomized study carried out over a period of 7months (August 2012- March 2013) at the Out-patient departments of General medicine and chest diseases in Justice K.S Hegde Charitable Hospital.

SUBJECTS: Outpatients with asthma visiting the General medicine and chest department during the study period

INCLUSION CRITERIA:

- Patients of age 18 years and above who are diagnosed to have asthma.
- Patients who are willing to participate in the study.

EXCLUSION CRITERIA:

- Intensive Care Unit patients.
- Acute exacerbation of asthma.
- Chronic Obstructive Pulmonary Disease, Tb (Tuberculosis) and other respiratory diseases or infections.

The instruments used include St. George's Respiratory Questionnaire for quality of Life. It was self-administered questionnaire for measuring impaired health and perceived HRQL in airways disease (COPD and asthma). It consists of 50 (76 weighted) items divided into three domains: 'Symptoms' concerned with the respiratory symptoms, their frequency and severity; 'Activity' concerned with activities that cause or are by breathlessness; 'Impacts' which covers a range of aspects concerned with social functioning and psychological disturbances resulting from airways disease. The Impacts section of the SGRQ contains the questions most closely related to a patient's quality of life (8).A Total score is also calculated which summarizes the impact of the disease on overall health status. Scores are expressed as a percentage of overall impairment. Decrease in score means improvement in quality of life. A score of '100' represents worst possible health status and '0' indicates best possible health status.

STUDY PROCEDURE

The study was approved by Institutional Human Ethical Committee of Nitte University. All the male and female outpatients with or without co-morbidities, diagnosed with asthma in the medicine and

chest department were reviewed by the clinical pharmacist and those who met the study criteria was included in the study after obtaining the informed consent. All the relevant details including medication and lab details of enrolled patients were collected and documented in a suitably designed data collection form. Eligible patients were randomly assigned in to test group and control group so as to prevent bias of inclusion. The patients were asked to pick a chit in which it was written intervention and control group and were categorized accordingly into the groups. In the intervention group apart from the physician care, clinical pharmacist assessed the drug therapy, provided medication counseling and education along with patient information leaflet whereas patients in the control group received the primary care by the physician. The control group patients also received the leaflet at the end of the study. Patients in the intervention group were educated about asthma, The patient counseling was primarily focused on the signs and symptoms of the disease, triggering factors, correct technique of using particular type of inhaler prescribed to the patient, importance of adhering to asthma medications, factors to be considered to avoid the adverse drug reactions, duration of therapy and importance of medication adherence, at what time the drug should be administered, when to take the medication, dose and dosage forms, and given a education aid such as patient information leaflet , with help of dummy inhalers inhalation technique was demonstrated. Information leaflet which contained tips about the disease and other lifestyle modifications to be followed. Permission has been obtained from the author to use the questionnaire for our study in English and local languages. St. George's respiratory questionnaire for Quality of life assessment were administered for both test and control group patients at the base line and last follow up. Patients were reminded about their follow-ups through telephonic conversations after collecting their address and followed at intervals of 2nd and 4th month. The scores between test and control group were compared in order to assess the impact of pharmacist counseling on the improvement of quality of life in patients with asthma.

STATISTICS

The statistical analysis were performed by using SPSS Inc(spss16.0).To assess the significant difference in quality of life scores St. George's Respiratory Questionnaire score between two groups independent ' t' test was used. Significant difference in St. George's Respiratory Questionnaire score within the group before and after patient counseling was also determined by paired't'test. Difference in the proportion of subjects with respect to the demographic characters was assessed by chi square test. Paired sample 't' test was used to assess the difference in (Forced Expiratory Volume) FEV_1 and FVC(Forced Vital Capacity) values between baseline and final month follow up that occurred within the test group.

RESULT

A total of 120 patients (60 patients in test group and 60 patients in the control group) were randomized into intervention and control group by chit method .Only those patients who met the study criteria are recruited in to the study. The total number of study populations who completed the study was found to be 73 and there were 47 patients who lost follow ups. The total number of lost follow ups at the end of the study in both intervention group and control group was found to be 20 and 27 patients respectively. Of the total 73 patients, 40 (54.79%) patients were randomized into test group and 33(45.20%) patients into control group. The average age of patients in test group and control group was found to be 43.85±12.82, 47.3±11.38 years respectively. Of the total 73 patients Budesonide formoterol fumerate inhaler was prescribed in 28 (38.35%) patients[control 13(39.39%),test15 (37.5%)] followed bysalmetrol fluticasone propionate inhaler in 19(26.02%) patients [control 8 (24.24%) test11 (27.5%)], beclomethasone formoterol fumarate combination in 13 (17.80%) patients [control 5 (15.15%), test 8 (20%)], levosalbutamol and ipratropium combination in 12 (16.43%) patients [control 5 (15.15%), test 7 (17.5%)], salbutamol in 4 (5.47%) patients[control

1(3.03%) test3(7.5%)], beclomethazone salbutamol combination in 3(4.1%)patients [control 3(9.09%)test 0], formoterol fluticasone propionate in 2 (2.73%)patients[control 1(3.03%) test 1(2.5%)] was least prescribed. The baseline characteristics have been grouped in to demographic data like age group, sex, total no of patients, no of lost follow up. Clinical variables include life style of patients and co-morbid conditions, and Saint George's Respiratory Questionnaire (SGRQ) scores, type of inhaler prescribed, and mode of therapy is also presented in the table shown in [**Table 1**]. There is no major difference in baseline demographics, clinical variables and Saint George's Respiratory Questionnaire (SGRQ) scores between two groups.

Table 1: Baseline Characteristics of Patients Included in the Study

DEMOGRAPHIC DATA	CONTROL(NO)	PERCENTAGE	TEST(NO)	PERCENTAGE
Total No Of Patients	60	50	60	50
No. Of Lost Follow up	27	45	20	33.33
No Of Patients Completed The Study	33	55	40	66.66
Male	10	30.3	23	57.5
Female	23	69.69	17	42.5
Age In Yrs.				
19-28	2	6.06	5	12.5
29-38	5	15.15	11	27.5
39-48	9	27.27	8	20
49-58	11	33.33	11	27.5
59-68	6	18.18	5	12.5
Mean Age (± Standard Deviation)In Years		47.3±11.38		43.85±12.82
Clinical Variables				
Smoker	0	0	1	2.5
Ex-Smoker	1	3.03	4	10
Family History Of Asthma	5	15.15	4	10
Comorbid Condition	12	36.36	11	27.5
HTN	8	24.24	7	17.5
DM	3	9.09	4	10
Hyperlipidemia	1	3.03	0	0
Allergy	16	48.48	19	47.5
SGRQ SCORE				
Symptoms		53.89±3.56		56.53±7.09
Impacts		49.93±4.08		48.13±6.81
Activity		54.24±4.55		55.25±8.75
Total		52.82±3.03		53.25±5.20
No Of Patients On DPI	19	57.57	25	62.5
No Of Patients On MDI	14	42.42	15	37.5
Single Therapy	0	0	1	2.5
Combination Therapy	32	96.96	36	90
Single Combination Therapy	1	3.03	3	7.5

There was no statistically significant difference (P>0.05) in the baseline quality of life score between the two groups.

Figure 1: Comparison of Base Line SGRQ Score

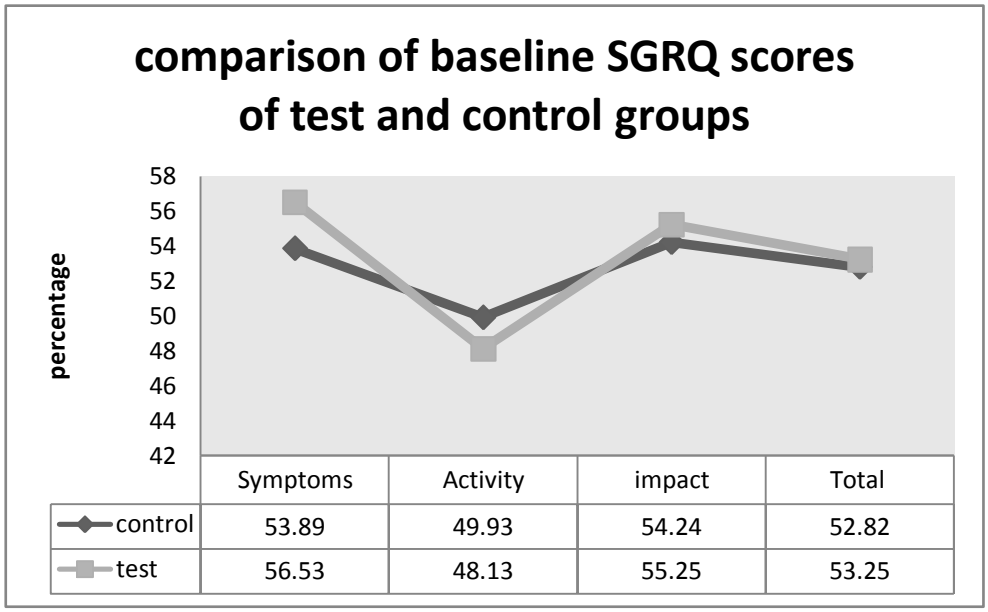
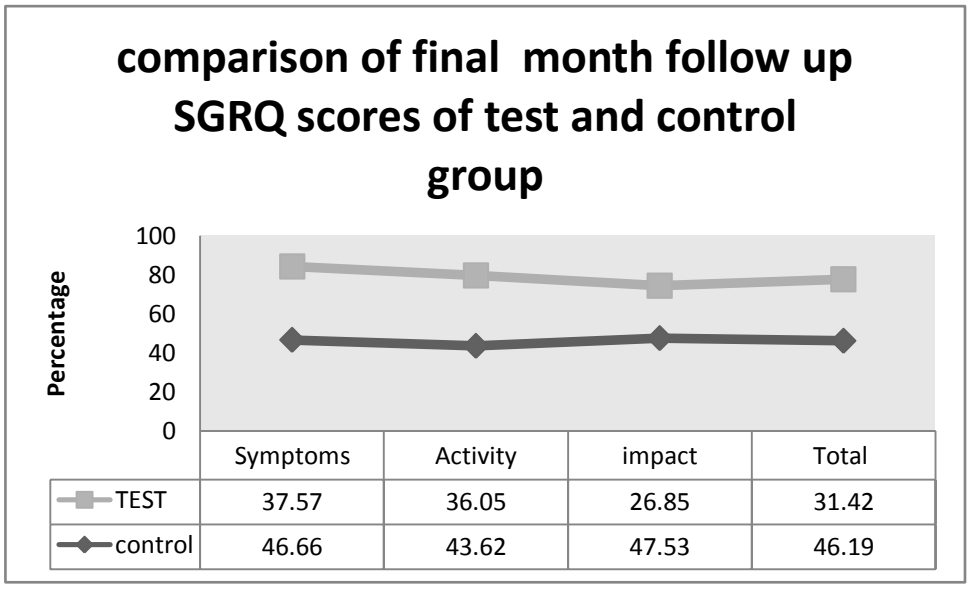


Figure 2: Comparison of Final Month Follow up SGRQ Score of Test and Control Group



A statistically significant differences in score was found between the two groups($p<0.0001$).At the final follow up the test group shows a Saint George's Respiratory Questionnaire (SGRQ) symptom score of 9.1(95% CI=-11.88 to -6.32 SE=1.39) units lower than the control group. The mean score difference is significant ($p<0.0001$).The test group showed a 7.57 unit lower score than control group (95% CI =-10.54 to -4.61, SE= 1.48) .The mean score difference statistically significant ($p<0.0001$).A statistically significant difference of 20.67 unit in the impact section of the Saint George's Respiratory Questionnaire (95% CI= -23.93 to -17.42, SE=1.63) was found between the test and control group. The difference in the mean score was statistically significant ($p<0.0001$),a statistically significant difference of 14.78 units (95% CI= -17.38 to -12.15, SE=1.31) was found. The mean score difference was statistically significant ($p<0.0001$).

Figure 3: Comparison of Baseline and Final Month Follow up SGRQ Score of Test Group

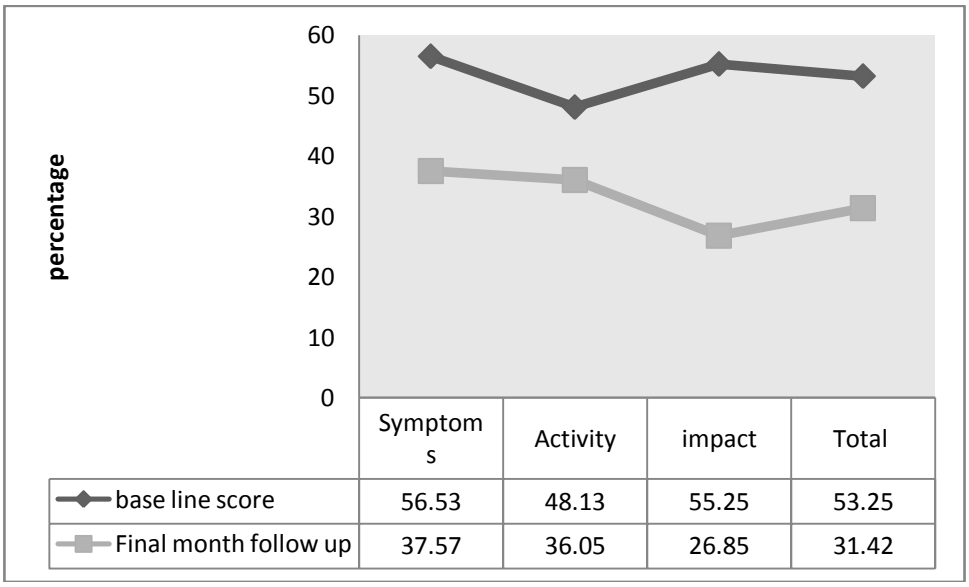
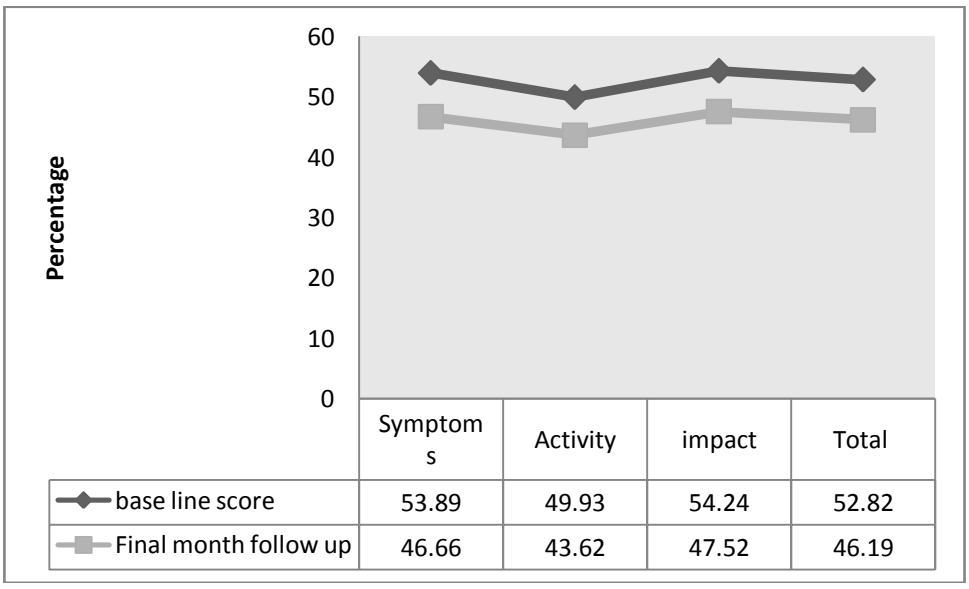


Figure 3: The Asthmatic test group patients had a SGRQ symptom score of 18.96 unit (95 % CI=17.06 to 20.86, SE 0.94 p <0.0001) lower than the baseline .The SGRQ activity score was found to be 12.09 unit (95% CI= 9.77 to 14.40, SE1.14, p<0.0001) lower than the baseline score. The test group patients showed a high statistically significant difference of 28.39 unit (95% CI=25.72 To 31.07, SE 1.32, p<0.0001) lower than the base line impact score. When considering the total SGRQ score a significant difference of 21.82 unit (95 % CI=20.39 to 23.24, SE 0.704, p < 0.0001) was found. The data shows the significant good clinical improvement of symptom score (> 12 unit), activity score (>12), impact score (>12 units).

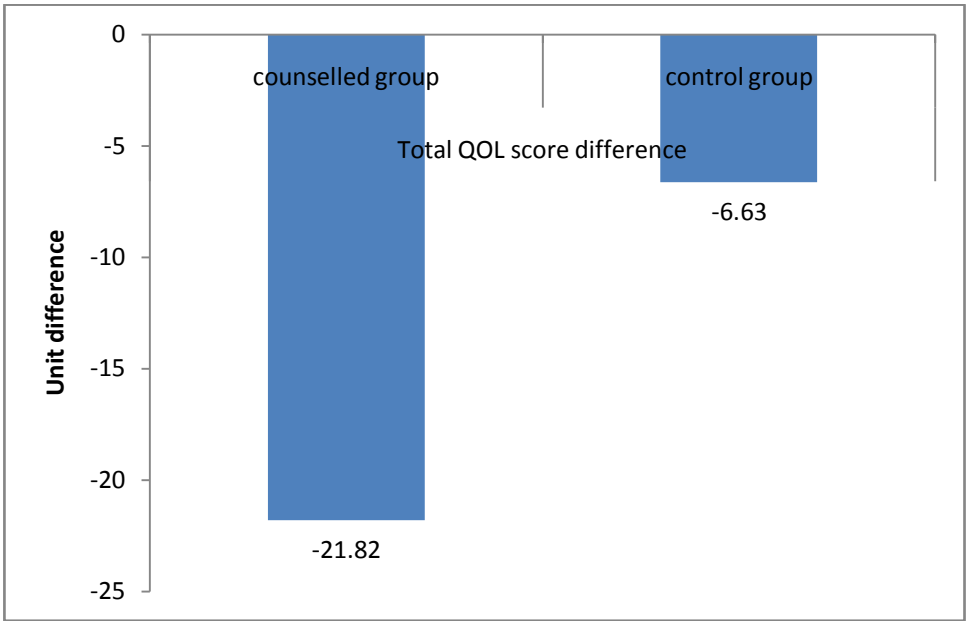
Figure 4: Comparison of Baseline and Final Month Follow up SGRQ Score of Control Group



On comparing the SGRQ score between the baseline and final month follow up of control group demonstrates a significant difference in the mean score. The difference in SGRQ means score within the group was Statistically significant (p<0.0001) .The data exhibits a significant clinical improvement (>4 unit) in the symptom score, activity score and impact score of the control group. When compared with the baseline and final

month follow up score there was a mean difference of 7.22 unit (95% CI=4.85 to 9.59 SE1.16), which implies that there was fall in SGRQ score by 7.22 unit. The variations in the activity score from the baseline is 6.31 unit (95% CI=4.24 to 8.38 SE1.16) for control group. With regard to the impact score 6.72 unit (95% CI= 4 to 9.43 SE 1.33) difference was found. The data shows a significant clinical improvement in the total score, a difference of 6.63 unit (95% CI= 4.41 to 8.85 SE 1.08).

Figure 5: Total Quality of Life Score Difference between the Baseline and Final Month Follow Up



Decrease in 4 units of the total score indicates clinical improvement in the Quality of life. Decrease in 8 units to 12 units indicates good and extreme clinical improvement (2, 14). There was a significant clinical improvement and shows statistical significance ($p<0.0001$) in both the groups. There was a superior improvement in the quality of life score among the test group.

Fig.6: FEV1 Value of Test Group at the Baseline and Last month Follow Up

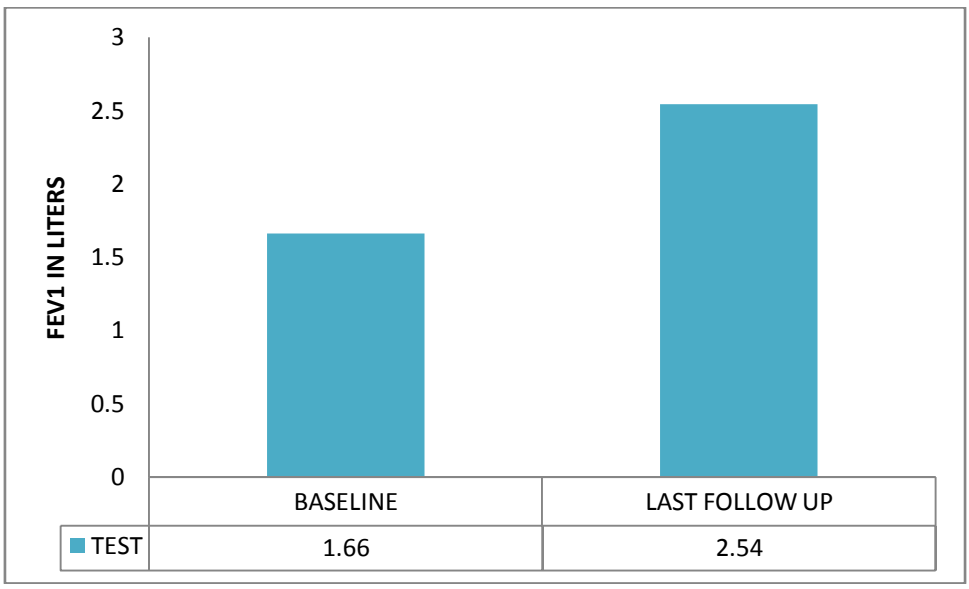
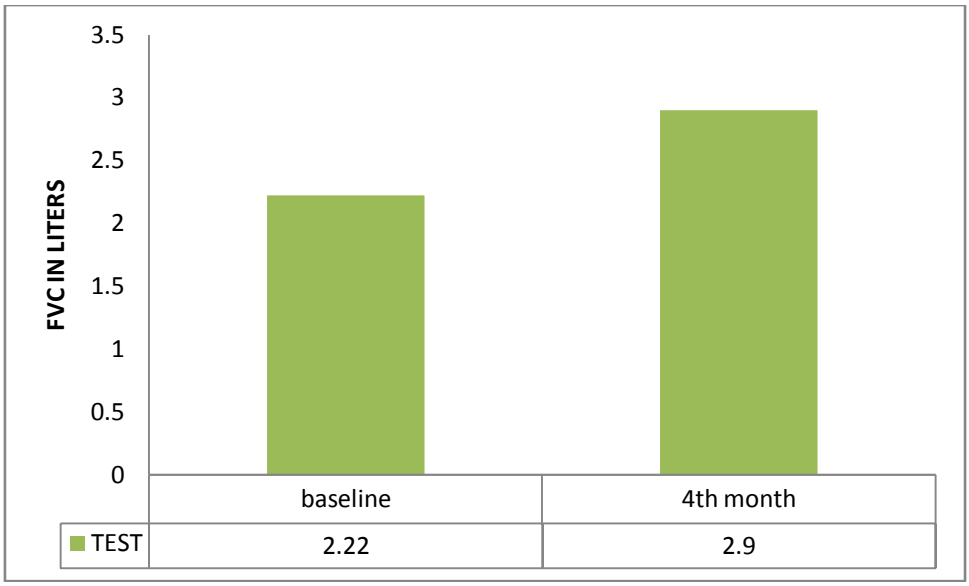


Figure 6 shows the test group shows a significant improvement in FEV1 values over a four month (0.88 unit).p<0.0001

Figure 7: FVC Value of Test Group at the Baseline and Last Month Follow Up



The test group shows a change in FVC (Forced Vital Capacity) values over a four month follow up of 0.68 units. This change was statistically significant p<0.0001.

DISSCUSSION

The study was undertaken to analyze the impact of patient counseling on the quality of life of asthmatic patients. The patient counseling was primarily focused on the signs and symptoms of the disease, triggering factors, inhalation technique of the particular type of inhaler prescribed to the patient, factors to be considered to avoid the adverse effect of inhaled corticosteroids, duration of therapy and importance of medication adherence and right use of inhaler device. For the study purpose, the patients were assessed with Malayalam, Kannada and English version of Saint George's Respiratory Questionnaire (SGRQ instrument). The study result represented the response to this disease specific Quality of life instrument Saint George's Respiratory Questionnaire, which was designed to quantify the impact of airway disease on life and wellbeing of the patients. The study can be compared with the work done by Gallefoss et al (7), who had conducted a research on Quality of life assessment after patient education in asthmatic and COPD patients. Similarly another study on the impact of patient counseling on the Quality of life and pulmonary function of asthmatic patient done by Mohammed saji et al (2).The first published therapeutic trial utilizing the Saint George's Respiratory Questionnaire instrument was performed by P. W. Jones (9), which aided as the baseline for the choice of Saint George's Respiratory Questionnaire (SGRQ instrument) in the study. To understand the effectiveness of patient counseling, the difference in Quality of life score was observed within the group and between the group during the baseline and final month follow-up.

At the baseline, the patient in control group and test group were found to have the similar baseline characters (except there was a difference in proportion of subjects who counseled and who did not with respect of gender at 5% level of significance), clinical variables and SGRQ scores (symptom, activity, impact, total). In context to the Quality of life a decrease in 4 units of total score indicated the clinical improvement. At the baseline there was no statistically significant difference in the SGRQ score of both groups. After the final follow up (fourth month) in both the test and control group a statistically significant difference were found in the

SGRQ(symptom, activity, impact, total score**) (Fig 1, Fig 2).** There was a significant fall in Saint George's Respiratory Questionnaire scores ($p<0.0001$) during the final month follow ups in both the groups showing an improvement in Quality of life. It was observed that the improvement seen with test group was significantly greater than that of control group. The result highlights that the test group patient had less symptom, higher activity and less impact on their quality of life and overall a total improvement in Quality of life during the final month follow up, when compared with control group of patients.

The following set of questions were assessed by the patients

- My cough or breathing is embarrassing in public
- My chest trouble is a nuisance to my family, friends or neighbor's
- I get afraid or panic when I cannot get my breath
- I feel that I am not in control of my chest problem
- My medication does not help me very much
- I get embarrassed using my medication in public

At the baseline follow up, the test group responded with the answer "true", gradually by the final month follow up they began to feel a sense of well-being and that their medication had begun to work. Because of which they responded with the answer "false". This purely reveals the positive effectiveness of the patient counseling. The situation was found to be a contrast in the control group who always responded with the answer true. They felt a sense of discomfort in carrying the reliever medication with them and felt embarrassed using medication in public. The SGRQ measurements of final month follow up confirms the above statements. Among the part of Saint George's Respiratory Questionnaire scores the highest difference was observed for the impact score**[Fig: 2].** These observations were in agreement with results of previous studies (2, 7).The impact section of the Saint George's Respiratory Questionnaire draws together the effects of disease on social functioning and emotional wellbeing of the patients. The impact of asthma on everyday life could be an important factor also when asthma is asymptomatic (13).If patients understand the risks of non-compliance and the benefits of compliance, and believe the treatment is safe, it will increase their motivation and confidence. Thus, it should lead to better compliance with their treatment regimen and improvement in Quality of life.

The control group patients were also found to have statistically significant improvement in the Saint George's Respiratory Questionnaire scores. The unit of Saint George's Respiratory Questionnaire (SGRQ) score difference between baseline and final month follow up in control group was considerably greater than that of the previous studies of similar design, which is possibly due to the number and frequency of clinical assessment together with good accessibility of the physician to their patients.

The asthmatics receiving education showed a mean increase in FEV1and FVC values over a final month follow up and were statistically significant. [**Fig 6, fig 7**]Patient education is considered an important factor regarding inhaler technique in literature (10), and verbal instruction is considered to be more effective than written instruction. Inclusion of a physical demonstration leads to improved inhaler technique. Incorrect use of inhalers is associated with poorer asthma control (11, 12).As all the patients in the study had received counseling about the inhaler technique and in this study written information leaflet and verbal instructions were provided to the patients during the counseling.

CONCLUSION

The study demonstrates the positive impact of clinical pharmacist provided education and counseling in achieving better therapeutic outcomes and improvement in the health related quality of life in patients with asthma. It also strengthens the importance of regular implementation of pharmacist provided patient counseling in disease management program which will help to maintain normal daily activity of asthmatic patients by improving their quality of life.

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