

## STUDY ON THE IMPACT OF PATIENT COUNSELING ON THE QUALITY OF LIFE AND PULMONARY FUNCTION OF ASTHMATIC PATIENT

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### ABSTRACT

This prospective study assessed impact of counseling on quality of life and pulmonary function of asthmatics at a respiratory clinic and community pharmacy. Patients were categorized into counseled and non-counseled (control) by simple block randomization. Quality of life was assessed using St. George's respiratory questionnaire and pulmonary function using spirometer. Assessments were done on the first day and follow-up of 30<sup>th</sup>, 60<sup>th</sup> and 90<sup>th</sup> days.

28 patients were in counseled and 25 in control group. Counseled group showed clinical improvement in total quality of life score from the 30<sup>th</sup> day (> 4 units), and high clinical improvement on the 90<sup>th</sup> day (> 12 units). No clinical improvement in total score of the control was observed. Counseled group showed clinical improvement in pulmonary function (> 5% in forced expiratory volume in one second) on the 30<sup>th</sup> day; the control showed clinical improvement only on the 60<sup>th</sup> day. Clinical pharmacist provided education brought a good practice and compliance in the patients.

**Keywords:** Patient Counseling, Asthma, Quality of Life, Pulmonary Function

### INTRODUCTION

"Asthma is a chronic inflammatory disorder of the airways in which many cells and cellular elements play a role. The chronic inflammation causes an associated increase in airway hyper responsiveness that leads to recurrent episodes of wheezing, breathlessness, chest tightness and coughing, particularly at night or in the early morning. These episodes are usually associated with widespread but variable airflow obstruction that is often reversible either spontaneously or with treatment<sup>1</sup>.

Chronic disease like asthma has significant effects on patient's health and quality of life. The global of asthma is considerable. Its effects include reduced quality of life, lost productivity, missed school days, increased health care cost, and the risk of hospitalization and even death<sup>2</sup>. In year 2002 roughly 14.7 million school days and 11.8 million working days were missed in United States was because of asthma<sup>3</sup>.

Health related quality of life (HRQOL) is recognized as an important health outcome measures in asthma. The aim of HRQOL is to assess the impact of asthma on the daily functions and emotional well being<sup>4</sup>. 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<sup>5</sup>. Patient education is aimed to help the patients to take the actions as needed to control their disease condition. Patient education is a solution to increase awareness and for strict adherence to drug schedule<sup>6,7</sup>.

Studies have been done to compare the different asthmatic drugs on the basis of its effect on the quality of life of the asthmatic patients. But there are not many studies done on the impact of patient counseling and training regarding the disease, management and drugs used on the quality of life and pulmonary function of the asthmatic patients in India. In the Indian scenario it has been seen that medicines bloom up in the market but the patients knowledge regarding its use and regular practice to be done are lagging. Therefore this present study was aimed to assess the impact of patient counseling on the drug use and how far it has got an impact on the quality of life and pulmonary function of asthmatic patients<sup>10</sup>.

### MATERIALS AND METHODS

The study was a prospective study conducted at the Kovai Respiratory Center - a private clinic and Tulasi Pharmacy - a retail pharmacy shop in Coimbatore, Tamil Nadu, India for a period of six months from July 2010 to December 2010.

Male and female patients of age group between 18- 65 years, having moderate to severe asthma and who are able to perform pulmonary function test and all study related tests were included in the study. Pregnant and lactating patients and intolerable adverse drug effects due to medication were excluded from the study. The instruments used include St. George's Respiratory Questionnaire for quality of life and mini spirometer (Clement Clark International) for pulmonary function test. The quality of life questionnaire contains three domains; symptoms, activity and impact scores<sup>8</sup>. Total quality of life scores below 10 are regarded as normal. The pulmonary function test routinely assesses the forced expiratory volume in one second (FEV<sub>1</sub>), peak expiratory flow (PEF) and forced vital capacity (FVC)

The sources data were the patient medical records and patient case history from the clinic and community pharmacy. The study protocol was approved by the Institutional Ethical Committee of JSS College of Pharmacy, Ootacamund, Tamil Nadu, India.

A total of 70 patients who were satisfying the inclusion criteria were enrolled and only 53 patients completed the study. The others were considered as drop outs. Patients were categorized into counseled and non- counseled group (control) by simple block randomization method. Counseling points which was given to the counseled group included various aspects such as the procedures to be followed during the inhalation therapy, self management of acute exacerbations, at what time the drugs should be administered, when to take the medications, and about the dose and dosage form. The control group was only given general information which was given during the dispensing of drug. The counseled group was given a timed education and all education aid such as patient information leaflet, dummy inhalers; visual and pictorial presentations were used. The quality of life and pulmonary function was assessed for all the patients on the first day of the visit that is the baseline. The same was performed on the regular follow-ups that are on the 30<sup>th</sup>, 60<sup>th</sup> and 90<sup>th</sup> days. The adverse drug reaction of the drugs prescribed was monitored on the follow-up days.

### RESULTS

Among the 53 patients who completed the study 28 patients were in the counseled group and 25 patients were in the control group. 30 patients were male and 23 were females. Average age group of the counseled patients was 37.07 ± 13.58 years and 42.76 ± 12.06 years in the case of control group. The patients were mostly prescribed with salmeterol and fluticasone inhalers. The prescribing of formoterol and budesonide inhaler followed in a lesser extent.

Salbutamol inhaler was given as rescue medication. The dose of the inhaler was given as a rescue medication.

### Quality of life

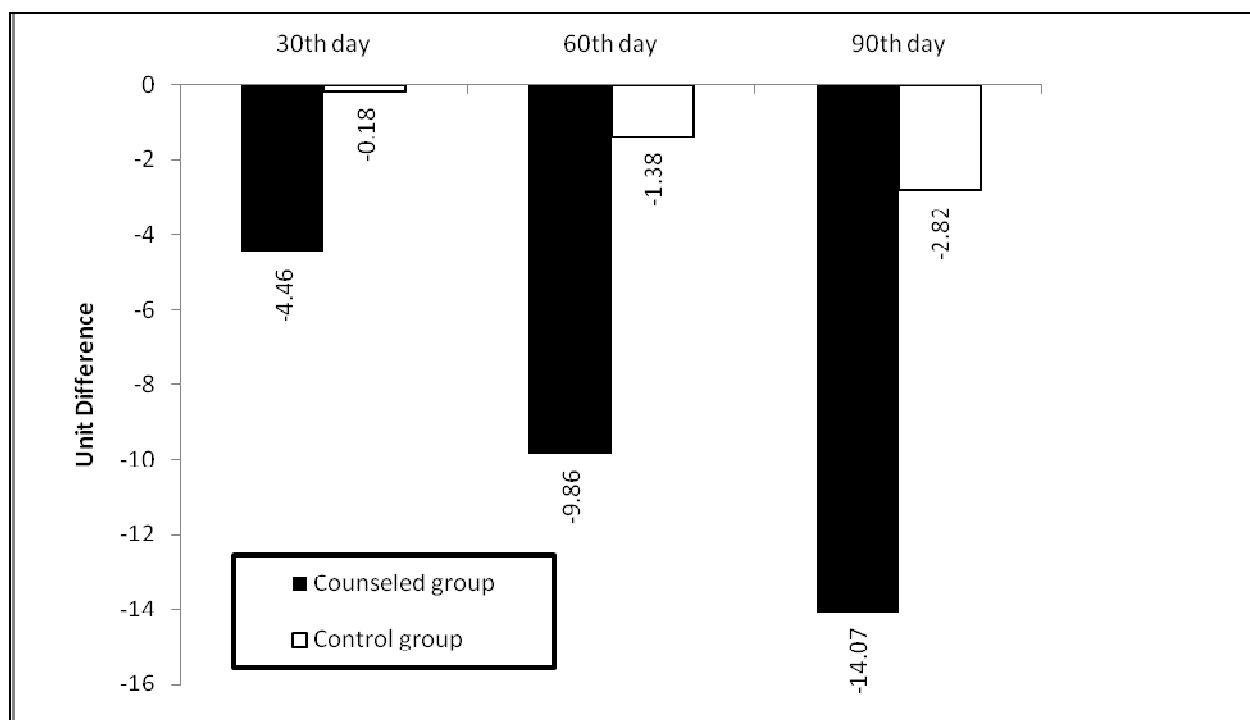
Decrease in 4 units of the total score indicates clinical improvement in the quality of life. Decrease in 8 units to 12 units indicates good and extreme clinical improvement. The counseled group has shown

a clinical improvement (decrease >4 units) and shows a statistical significance on 60<sup>th</sup> and 90<sup>th</sup> days (P value <0.05). The control group did not show any clinical improvement or statistical significance (Table 1 and Fig. 1).

A difference of four units in the scores indicates a slight clinical effect, while a difference of eight or twelve units indicates moderate or very good clinical effects, respectively<sup>9</sup>.

**Table 1: Quality of Life scores of counseled and control group**

Domains	Baseline		30 <sup>th</sup> day		60 <sup>th</sup> day		90 <sup>th</sup> day	
	Counseled	Control	Counseled	Control	Counseled	Control	Counseled	Control
Symptoms Score	50.55	47.09	42.43	44.86	33.67	42.62	28.62	41.3
Activity Score	40.67	44.92	38.02	44.33	33.71	45.77	31.04	45.65
Impact Score	33.65	29.99	28.8	30.77	22.86	29.56	18.62	28.07
Total Score	38.08	38.03	33.62	37.9	28.22	36.7	24.01	35.26



**Fig. 1: Total quality of life score difference**

### Comparison of symptom scores of counseled and non-counseled group

The data shows a significant clinical improvement (>4units) of symptom score in both group except on the 30<sup>th</sup> day of the non-counseled group. And shows a statistical significance on 60<sup>th</sup> and 90<sup>th</sup> day (P value <0.05) but on the baseline and 30<sup>th</sup> day there was no statistical significance

### Comparison of activity scores between counseled and non-counseled group

The data shows a significant clinical improvement (>4units) in counseled group and statistical significance on 60<sup>th</sup> and 90<sup>th</sup> day (P value <0.05) but on the baseline and 30<sup>th</sup> day there was no statistical significance (P value >0.05).

### Comparison of impact scores between counseled and non-counseled group

The data shows a significant clinical improvement (>4units) (Fig. 2). The statistical significance was calculated using unpaired t-test shows a Statistical significance on 60<sup>th</sup> and 90<sup>th</sup> day (P value <0.05)

but on the baseline and 30<sup>th</sup> day there was a Statistical insignificance (P value >0.05).

### Pulmonary function

There was no clinical significance (FEV<sub>1</sub> <200 ml) and statistical significance in the pulmonary function test values of non-counseled group (P value 0.05) shown in Table 2.

But the FEV<sub>1</sub> values have shown a clinical significance during the study in counseled patients shown in Table 3. Only FEV<sub>1</sub> comparison of baseline Vs 90<sup>th</sup> day showed a statistical significance (P value < 0.05). FEV<sub>1</sub> got 5% increased during the follow-ups, which clearly shows the clinical improvement.

### Adverse drug reaction monitoring

ADR's were observed during the entire study period among the study population and necessary follow-ups were performed based on the reported ADR's. The counseled group 3 (10.71%) patients complained of adverse drug reaction while compared with the non-counseled group 2 (8%) patients.

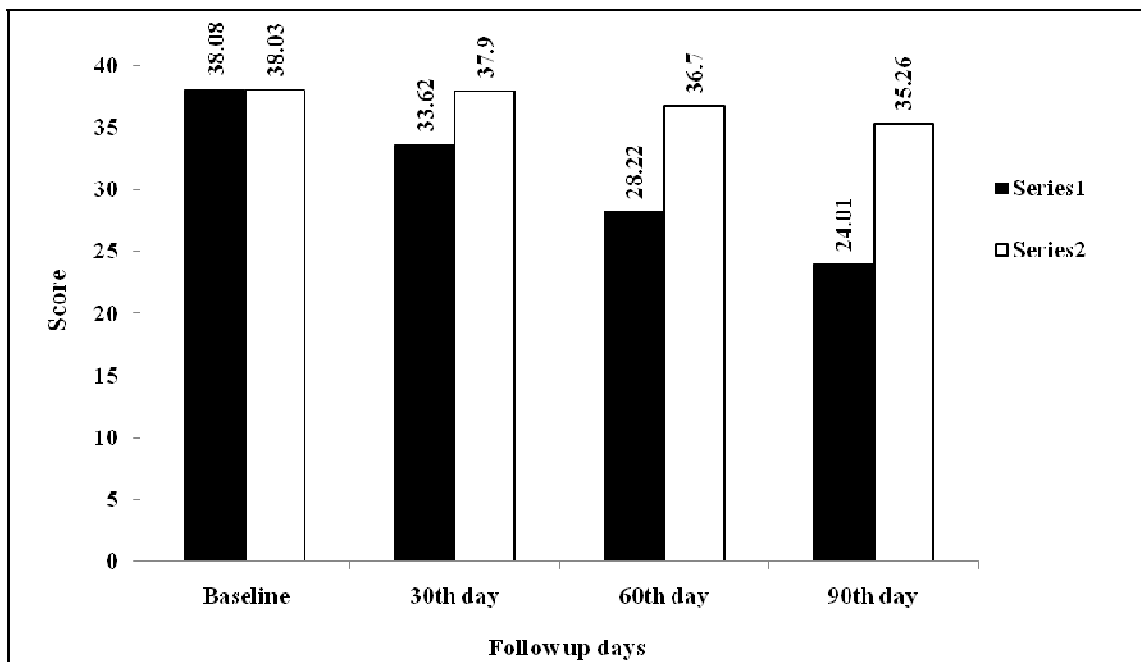


Fig. 2: Total score of Quality of Life

Table 2: Pulmonary function test values of non-counseled group

PFTs	Baseline	30 <sup>th</sup> day	60 <sup>th</sup> day	90 <sup>th</sup> day
FEV <sub>1</sub> (Liters)	1.7	1.77	1.8	1.83
FVC (Liters)	2.27	2.35	2.4	2.42
PEF (Liters/min)	287.4	290.04	301.16	284.34

FEV<sub>1</sub> - Forced expiratory volume in one second; FVC - Forced vital capacity; PEF - Peak expiratory flow

Table 3: Pulmonary function test values of counseled group

PFTs	Baseline	30 <sup>th</sup> day	60 <sup>th</sup> day	90 <sup>th</sup> day
FEV <sub>1</sub> Liters	1.78	2.02	2.16	2.39
FVC Liters	2.31	2.51	2.64	2.84
PEF Liters/min	323.54	346.18	362.93	381.18

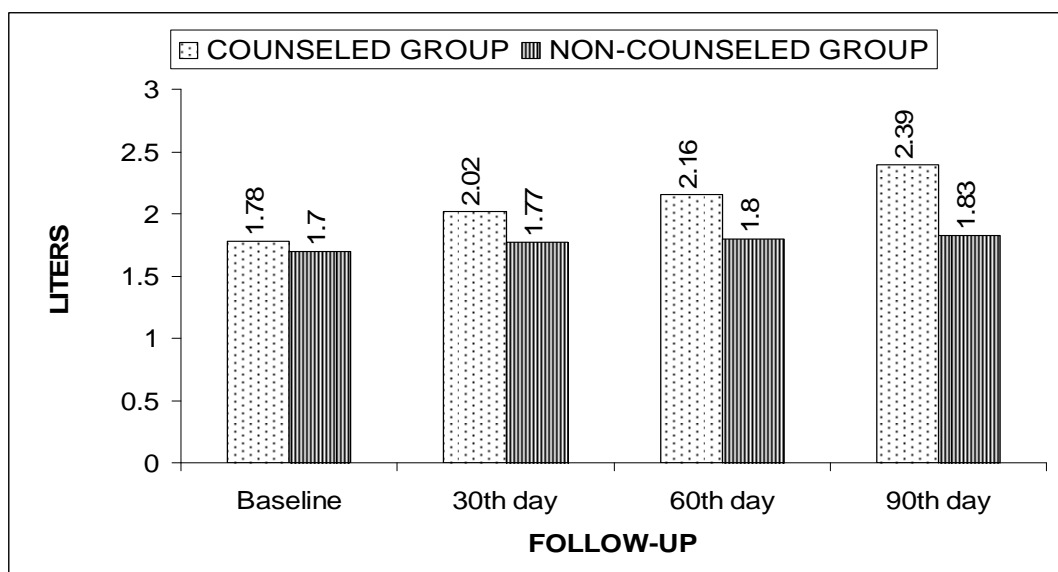


Fig. 3: Comparison of FEV1 values of counseled and non-counseled group

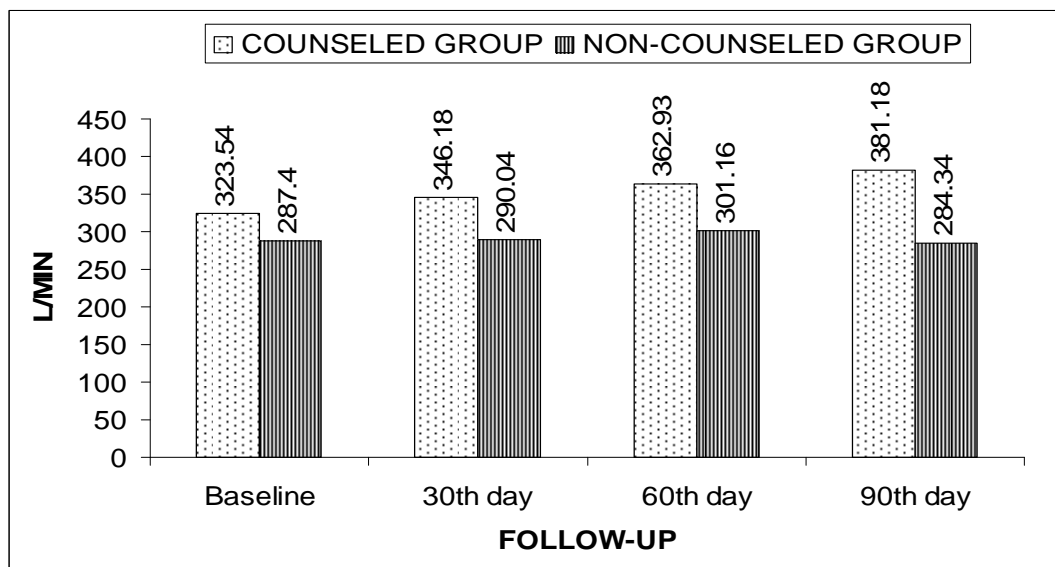


Fig. 4: Comparison of PEF values of counseled and non- counseled group

#### Comparison of FEV<sub>1</sub> values of counseled and non- counseled group

The results show a significant improvement of FEV<sub>1</sub> values (0.48 units) than the non-counseled group shown in Fig. 3. Statistical analysis showed in-significance

#### Comparison of PEF values of counseled and non- counseled group

There was a significant improvement in PEF values describe in Fig. 4. Statistical analysis showed significance.

#### DISCUSSION

The quality of life of the non-counseled and counseled patients were compared for three months and at the end of study period it was assessed that there was a clinical as well as statistical significance seen in case of counseled group at the second and third month follow-ups whereas the non-counseled group didn't show any clinical as well as statistical significance. The present study findings were comparable with the study conducted by Gallefosset al<sup>6</sup> who has done a study on quality of life assessment after the patient education in the asthmatic and the COPD patients.

The forced expiratory volume in one second (FEV<sub>1</sub>) is generally considered as efficacy parameters in asthma clinical trials. The pulmonary function test comparison between the counseled and non-counseled group was done there was no significant improvement in the pulmonary functions for the non-counseled group whereas in the counseled group the improvement was shown at the third follow-up i.e.; at the 90<sup>th</sup> day. These findings were also comparable with the study conducted by Gallefoss et al<sup>9</sup> which concluded that patient education increased the FEV<sub>1</sub> values in the asthmatic patients due to a better practice followed in using the medications.

#### CONCLUSION

The study findings were helpful in determining certain reasons why the patients were not able to get a better outcome from the therapeutic regimen prescribed to them. The main aspects involved are newer drugs in the market which were prescribed to the patient, on which patients did not have enough knowledge on the usage and regular practices to be followed. The patient's knowledge and practice regarding the newer dosage form and its administration procedure were also lagging. Here the clinical pharmacist has used his knowledge and skills about the new drugs and dosage forms to bring about a good practice in the patients. The role of clinical pharmacist in giving the patient counseling and education should continue so as to give a better health care for the patient.

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#### CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

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