



Research article

Study on prevalence of asthma and impact of pharmaceutical care in a clinical setting

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Abstract

Aim: Improvement in Asthma Control, Peak Expiratory Flow Rate (PEFR) and Asthma related Quality of Life Scores (AQLQ'S). **Objectives:** To document all the asthma cases admitted in the study department. To ascertain the knowledge of the patients regarding their disease and the therapy. To provide pharmaceutical care pertaining to disease and use of inhalational devices to the study group, which is to be compared with the control group. To analyse the impact of pharmaceutical care on quality of life in patients with asthma. **Selection criteria:** **Inclusion:** The patients diagnosed with asthma at least 6 months before enrolling in this study. Those patients having no infectious diseases. Patients above 12 years **Exclusion:** Those who are unable or unwilling to participate in the asthma education program. Pregnant and lactating women. **Method:** A baseline study was conducted for one month to assess the patients' perception about asthma, their medications, and the inhalation therapy using a questionnaire prepared. Patients were also divided into an intervention and control group. Intervention group received pharmaceutical care through asthma education, medication counselling, instructions on life style modifications, etc. whereas the control group patients were not provided any pharmaceutical care till the end of the study. Asthma control in the two groups was assessed using ACT at regular intervals. Asthma related Quality of Life of patients in both the groups was assessed at regular intervals using AQLQ'S. **Results:** The intervention group patients showed an improvement in AQLQ'S baseline study indicating overall, activity, symptoms, emotional and environmental domains respectively. The mean AQLQ'S for the control group patients at the baseline increased by the final visit indicating overall, activity, symptoms, emotional and environmental domains respectively. The p value between the two groups at initial and final visit showed a significant difference (<0.05). The mean value of all the five asthma control test questions for the intervention group was higher than the control group in the final visit. The mean ACT scores for study group at baseline was found to be increased in the final visit for all the five ACT questions respectively. The mean ACT scores for the control group at the baseline were low and at the final visit it was high for each question. The p value between the two groups at two visits showed a significant difference (< 0.05). In the intervention group, the mean Peak Expiratory Flow Rate (PEFR) improved from 282.48±95.40 at baseline to 336.24±88.11 L/min at the final visit whereas for the control patients the value at baseline was 264.93±93.3 and at the final it was about 268.54±85.1. **Conclusion:** The pharmaceutical care program showed a positive impact in improving patient's asthma related Quality of Life, lung function and asthma control. By providing structured pharmaceutical care, pharmacists can help asthma patients to achieve desired health outcomes.

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1. Introduction

Asthma is a significant public health issue worldwide [1]. Asthma has been known since antiquity, yet it is a disease that still defies precise definition. The word asthma is of Greek origin and means "panting". More than 200 years ago, Hippocrates used the word asthma to describe

episode of shortness of breath; however, the first detailed clinical description of asthmatic patient was made by Aretaeus in the second century [2-4].

Pharmaceutical care

Asthma is a major cause of chronic morbidity and economic burden worldwide [5]. The mission of the

pharmacist is to provide pharmaceutical care [6]. Pharmaceutical care is an essential factor for the control and management of asthma.

Pharmaceutical care is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's Quality of Life. These outcomes are (i) cure of a disease; (ii) elimination or reduction of a patient's symptomatology; (iii) arresting or slowing of a disease process; or (iv) preventing a disease or symptomatology [7]. The principal elements of pharmaceutical care are that it is medication related; it is the care that is directly provided to the patient; it is provided to produce definite outcomes; these outcomes are intended to improve the patient's Quality of Life; and the provider accepts personal responsibility for the outcomes [6]. ASHP believes that pharmaceutical care is fundamental to the profession's purpose of helping people make the best use of medications. It is a unifying concept that transcends all types of patients and all categories of pharmacists and pharmacy organizations. Pharmaceutical care is applicable and achievable by pharmacists in all practice settings. The provision of pharmaceutical care is not limited to pharmacists in inpatient, outpatient, or community settings, nor to pharmacists with certain degrees, specialty certifications, residencies, or other credentials. It is not limited to those in academic or teaching settings. Pharmaceutical care is not a matter of formal credentials or place of work. Rather, it is a matter of a direct personal, professional, responsible relationship with a patient to ensure that the patient's use of medication is optimal and leads to improvements in the patient's Quality of Life [6].

Medication Related: Pharmaceutical care involves not only medication therapy (the actual provision of medication) but also decisions about medication use for individual patients. As appropriate, this includes decisions not to use medication therapy as well as judgments about medication selection, dosages, routes and methods of administration, medication therapy monitoring, and the provision of medication-related information and counselling to individual patients.

Care: The pharmacist contributes unique knowledge and skills to ensure optimal outcomes from the use of medications.

Outcome: It is the goal of pharmaceutical care to improve an individual patient's quality of life through achievement of definite (predefined), medication-related therapeutic outcomes.

Quality of Life: A complete assessment of a patient's quality of life should include both objective and subjective (e.g., the patient's own) assessments. Patients should be involved, in an informed way, in establishing Quality-of-Life goals for their therapies.

Responsibility: In pharmaceutical care, the direct

relationship between an individual pharmacist and an individual patient is that of a professional covenant in which the patient's safety and wellbeing are entrusted to the pharmacist, who commits to honoring that trust through competent professional actions that are in the patient's best interest. As an accountable member of the health-care team, the pharmacist must document the care provided. The pharmacist is personally accountable for patient outcomes (the quality of care) that ensue from the pharmacist's actions and decisions. In the provision of pharmaceutical care, professional communication about the patient's needs between responsible pharmacists in each area of practice is essential. ASHP believes that the development of recognized methods of practicing pharmaceutical care that will enhance such communication is an important priority for the profession. Pharmaceutical care can be conceived as both a purpose for pharmacy practice and a purpose of medication use processes. That is, a fundamental professional reason that pharmacists engage in pharmacy practice should be to deliver pharmaceutical care. Furthermore, the medication use systems that pharmacists (and others) operate should be designed to support and enable the delivery of pharmaceutical care by individual pharmacists. ASHP believes that, in organized health-care settings, pharmaceutical care can be most successfully provided when it is a part of the pharmacy department's central mission and when management activity is focused on facilitating the provision of pharmaceutical care by individual pharmacists. This approach, in which empowered frontline staffs provide direct care to individual patients and are supported by managers, other pharmacists, and support systems, is new for many pharmacists and managers. The aspects of asthma care falls within four elements of Good Pharmacy Practice in WHO's document on GPP [8].

i.e.

1. Health promotion and ill – health prevention.
2. Supply, use of prescribed medicines and other health care products.
3. Self care.
4. Influencing prescribing and medicine use.

These can be achieved by applying the following three levels:

1. Technical advice giving:

To provide systematic drug information on asthma medicines; Systematic counselling on correct use of inhalers and inhaler devices and other devices; Consistent performance by the staff; Documentation of the care services.

2. Outcome oriented patient counselling:

The provision of pharmaceutical care for asthma patients by systematic identification and assessment of drug related problems; choosing and implementing the best solution in co-operation with the patient; ensuring the individual patient's understanding of the use and effect of the medication; a regular follow up on patients and

responding to new problems (if any); the asthma patients (and caregivers) are educated on the purpose and technique of self monitoring (peak flow measuring and diary keeping).

3. Therapeutic Outcomes Monitoring (TOM):

TOM is: continuous quality improvement of drug therapy for the individual patient; a systematic, structured, ongoing, documented process; individualized patient care - holistic and outcome oriented.

Patient Counselling

Patient counselling is a systematic, structured, ongoing, documented process and is a main part of pharmaceutical care. It mainly focus on the patient's quality of life. It is a shared responsibility with the patient and the prescriber for the patient's outcome of drug therapy.

Assessment of drug therapy and compliance check

This is to identify possible drug related problems by assessing the patient's medication record. Patient education in self monitoring (peak flow measuring and diary keeping) education of the patient (and caregivers) includes: How and when to use peak flow meter; How to record the measurements in a diary; How to interpret the measurements; How to respond to change. Drug therapy is an essential element in managing asthma. It is well accepted that patients may experience problems of uncontrolled asthma due to inappropriate therapy and also due to poor compliance, lack of understanding of their condition and the importance of regular preventive drug therapy. However, studies on asthma patient's drug use have shown that the process of medication use is very complex and problems cannot be characterized as solely non-compliance or knowledge gaps. Use of drugs in asthma patients is also a matter of self regulation and self management. Thus through an active partnership between pharmacist and patients, most patients can achieve good control of their asthma with symptom monitoring, optimal pharmacotherapy, and control of confounding factors.

2. Materials and methods

Study site:

The institute of Pulmonary Medicine and Research Centre of a 750 bedded multi-specialty tertiary care teaching hospital, Coimbatore.

Study period:

6 months, from December 2014-June 2015

Study design:

Prospective, Control (versus) intervention

Selection criteria:

Inclusion: The patients diagnosed with asthma at least 6 months before getting enrolled in this study.

: Those patients having no infectious diseases.

: Patients above 12 years

Exclusion: Those who are unable or unwilling to participate in the asthma education Program

: Pregnant and lactating women

Method:

Permission to carry out the study was obtained from the hospital authorities and concerned department head of the study hospital after submitting the study protocol. Patients were enrolled according to the inclusion and exclusion criteria of the study. Patients were briefed on the project through Patient Information form and there after obtained consent form signed from them. A questionnaire for the assessment of Patient's perception about the asthma, medications and inhalation therapy was prepared according to the ICMR asthma questionnaire. The Asthma Quality of Life Questionnaire which was used in many studies reported and found to be more valid was chosen for the study. The Standardized Asthma Quality of Life Questionnaire AQLQ(S) was selected for the work and it consists of 32 questions with a 7 point scale of responses for each (eg: 1-totally limited to 7-not at all limited). The questions were grouped into four domains which are based on symptoms (all generic), activity limitations, emotional function and environmental stimuli. Each domain consists of 12, 11, 5 and 4 questions respectively. A quick test which provides a numerical score to assess asthma control was prepared and the questions were made according to National Institutes of Health (NIH) 2007 asthma guidelines. Asthma Control Test (ACT) is a five point scale questionnaire consisting of five questions. A patient education leaflet was designed and printed both in English and Tamil for educating the patient on the proper usage of inhalers and was given to the patients in the baseline study.

An asthma care diary was designed and printed both in English and Tamil to educate the patient about their asthma and its management. Only the intervention group patients were provided with asthma care diary which consists of mainly pictorial representation of asthma, an information leaflet for patients, small briefing on asthma, Pictorial representation of the five steps in asthma management, how to use peak flow meter, Inhalation techniques for selected inhalation devices, asthma management plan and asthma symptoms log sheet.

The baseline study using the prepared questionnaire was carried out for 2 months from December 2014 to February 2015. Pharmacist recruited 22 medically diagnosed asthma patients according to the selection criteria for the study. All data concerning patient demographics, asthma history were collected by customized data entry forms which were specially developed for the study.

66 patients were enrolled for the complete study. The patients were randomly divided into two groups, Intervention group and control group. Personal interviews were conducted with all the patients. Outcome measures included PEF Value, Quality of Life Scores and Asthma Control Scores. Intervention group received pharmaceutical care (education and counseling) till the end of the study, while the control group patients were not offered any intervention during the study period.

The interviews for the measurement of QoL were been

conducted at three different timings i.e., first was at the baseline, second was at the 15th day from baseline and third was at 29th day from the baseline. Two interviews were conducted for the measurement of asthma control, one at the baseline and other at the 29th day from the baseline. The patients were asked to complete asthma control test questionnaire and the responses are on a five point scale. At the time of interviews the QoL questions and asthma control test were administered to the patients of both groups. The control group did not receive any input. Pharmacist followed the patient’s progress with follow up visits and phone calls and patient’s progress was noted. Attempts were also made to have all participants repeat the completion of the AQLQ(S) during the final interview.

Statistical analysis

For the AQLQ the mean score per question was calculated for each of the four domains, and the overall score derived from the mean of all questions. For all ACT questions also mean score per question was calculated. SD was calculated from the raw data. Mean changes from baseline were analyzed overall and for the four domains of AQLQ and also for the ACT questions. P value <0.05 was considered statistically significant.

3. Result

This research study “Study on prevalence of asthma and impact of pharmaceutical care in a clinical setting” was carried out for a period of 6 months in a 750 bedded multispecialty hospital in the department of Pulmonology where Asthma Research Centre is situated. Baseline Study: A baseline study on the Assessment of Patient’s Perception about Asthma, Medications and

Inhalation therapy was first carried out during the study period from December 2014 to June 2015. 22 participants consisting of 16 male and 6 female patients were enrolled for the study and they were assessed using a questionnaire. Asthma QoL and Asthma Control Assessment: A total of 66 patients were enrolled. The participants were divided into control and intervention (study) group. The control group consists of 33 patients with 12 male and 21 female patients. The intervention group consists of 33 patients with 20 male and 13 female patients. The control group had a mean age of 41.24 ± 16.1 years and the intervention group had a mean of 46.9 ± 16.7 years. The mean duration for asthma for the intervention and the control was 9.4 ± 8.1 and 7.45 ± 5.4 respectively. **Asthma control test results:** Asthma control test consists of five questions with a 5 point scale of responses for each. Questions are about frequency of asthma, shortness of breath, symptoms, medication and rating of asthma. Control is the parameter assessed in patients receiving treatment. Good control is the goal of asthma management whatever the disease severity. The mean value of all the five asthma control test questions for the intervention group was higher than the control group in the final visit. The Mean ACT scores for study group at baseline was found to be 2.09 ± 0.77, 2.18 ± 0.85, 2.21 ± 0.82, 2.64 ± 1.06, 2.18 ± 0.68 and it increased to 4.12 ± 0.74, 3.88 ± 0.55, 4.21 ± 0.60, 4.64 ± 0.55, 4.15 ± 0.57 in the final visit for all the five ACT questions respectively. The mean ACT scores for the control group at the baseline were 2.51 ± 1.12, 2.39 ± 0.93, 2.51 ± 0.66, 2.57 ± 0.90, 2.51 ± 0.79 and at the final visit it was 3.66 ± 0.85, 3.36 ± 0.74, 3.75 ± 0.43, 4.27 ± 0.57 and 3.66 ± 0.47 for each questions. The p value between the two groups at final showed a significant difference.

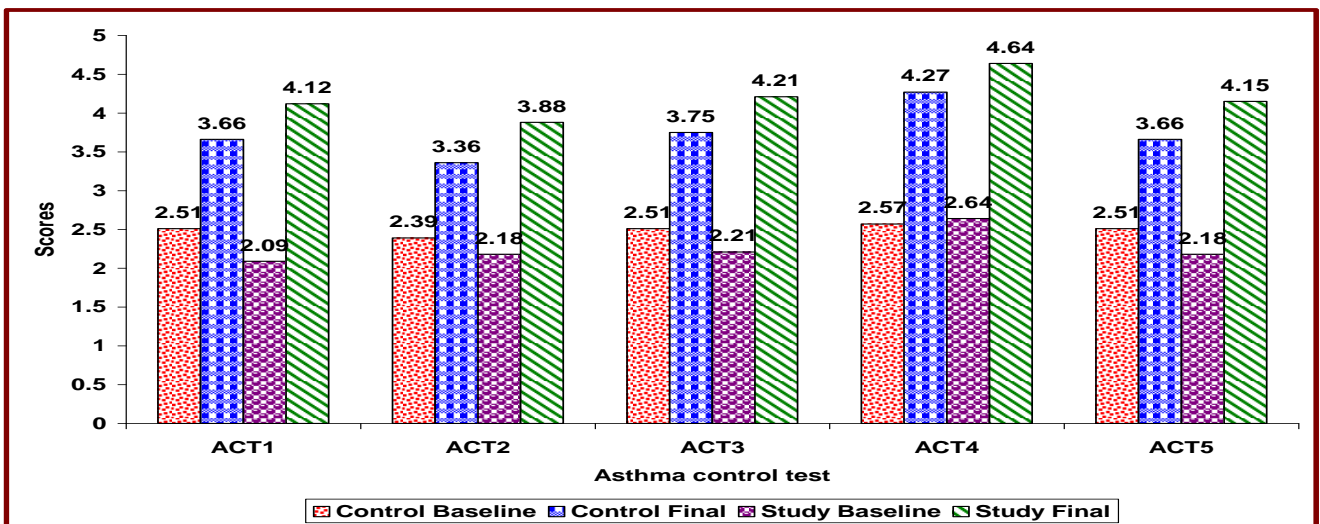


Figure no.1: ACT scores for the control group (n = 33) and study group (n = 33) at the baseline and final interview

Table no.1: Baseline and final visit outcome measures among intervention patients (n= 33) and control patients (n = 33) Asthma control test (act) scores

S. N	Characteristic	Baseline Score	Final Score	Paired t test p* < 0.05
		Mean ± SD	Mean ± SD	
1	ACT 1			< 0.05
	Intervention group	2.09 ± 0.77	4.12 ± 0.74	
	Control group	2.51 ± 1.12	3.66 ± 0.85	
2	ACT 2			< 0.05
	Intervention group	2.18 ± 0.85	3.88 ± 0.55	
	Control group	2.39 ± 0.93	3.36 ± 0.74	
3	ACT 3			< 0.05
	Intervention group	2.21 ± 0.82	4.21 ± 0.60	
	Control group	2.51 ± 0.66	3.75 ± 0.43	
4	ACT 4			< 0.05
	Intervention group	2.64 ± 1.06	4.64 ± 0.55	
	Control group	2.57 ± 0.90	4.27 ± 0.57	
5	ACT 5			< 0.05
	Intervention group	2.18 ± 0.68	4.15 ± 0.57	
	Control group	2.51 ± 0.79	3.66 ± 0.47	

Quality of life results:

The Standardized Asthma Quality of Life Questionnaire AQLQ(S) consists of 32 questions with a 7 point scale of responses for each(eg: 1-totally limited to 7-not at all limited). The questions were grouped into four domains which are based on symptoms (all generic), activity limitations, emotional function and environmental stimuli. Each domain consists of 12, 11, 5 and 4 questions respectively. The intervention group patients showed improvement in the mean AQLQ score. The reported AQLQ score the baseline were 2.93 ± 0.83, 2.79 ± 0.89, 2.81 ± 0.99, 3.53 ± 0.88, 2.73 ± 1.48 to 5.66 ± 0.58, 5.63 ± 0.54, 5.67 ± 0.54, 6.00 ± 0.53, 5.61 ± 0.73 indicating overall, activity, symptoms, emotional and environmental domains respectively. The mean AQLQ scores for the control group patients at the baseline were 3.08 ± 0.76, 3.23 ± 0.70, 2.79 ± 0.82, 3.55 ± 0.86, 2.47 ± 1.21 to 4.6 ± 0.53, 4.64 ± 0.49, 4.48 ± 0.63, 5.10 ± 0.51, 4.15 ± 0.83 indicating overall, activity, symptoms, emotional and environmental domains respectively.

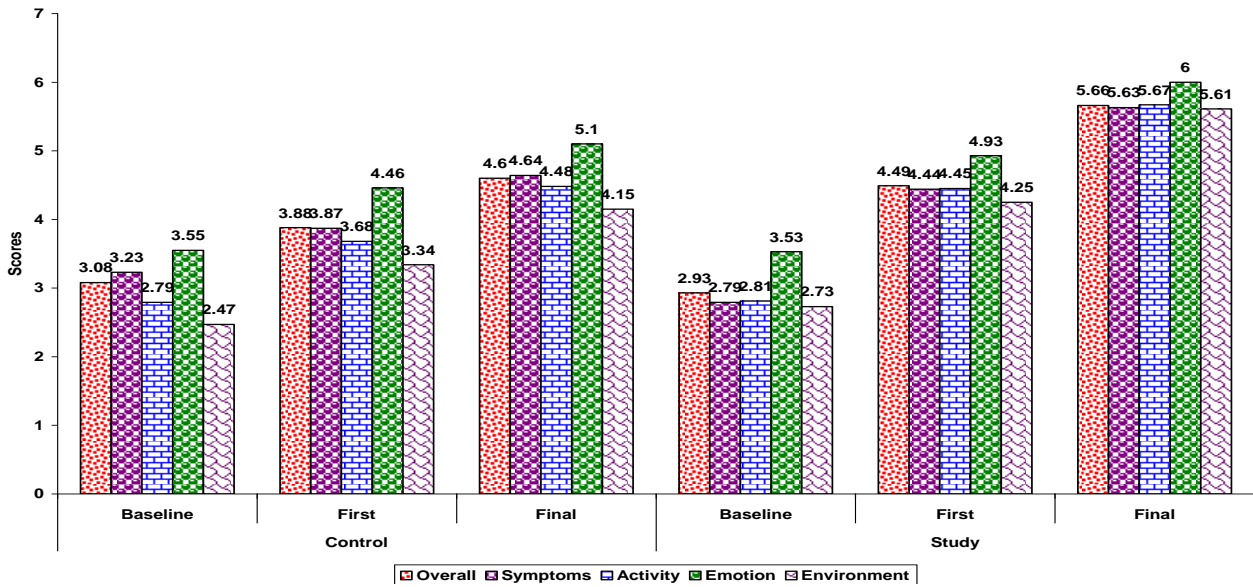


Figure no. 2: AQLQ scores for the study group (n= 33) and control group (n= 33) at three interviews

Table no.2: Standardized asthma quality of life questionnaire [AQLQ(S)] scores (n= 33)

S . N	Characteristic	Baseline Score Mean ± SD	Final Score Mean ± SD	P*
1	Intervention group	2.93 ± 0.83	5.66 ± 0.58	< 0.05
	Control group	3.08 ± 0.76	4.60 ± 0.53	
2	Intervention group	2.79 ± 0.89	5.63 ± 0.54	< 0.05
	Control group	3.23 ± 0.72	4.64 ± 0.49	
3	Intervention group	2.81 ± 0.99	5.67 ± 0.54	< 0.05
	Control group	2.79 ± 0.82	4.48 ± 0.63	
4	Intervention group	3.53 ± 0.88	6.00 ± 0.53	< 0.05
	Control group	3.55 ± 0.86	5.10 ± 0.51	
5	Intervention group	2.73 ± 1.48	5.61 ± 0.73	< 0.05
	Control group	2.47 ± 1.21	4.15 ± 0.83	

Paired t test between the two groups in their final visit. P*Significant (p< 0.05). Peak expiratory flow rate results: In the intervention group, the mean PEFr improved from 282.48 ± 95.4 at baseline to 336.24 ± 88.11 L/Min at the final visit where as for the control patients the value at baseline was 264.93 ± 0.93 and at the final it was about 268.54 ± 85.14.

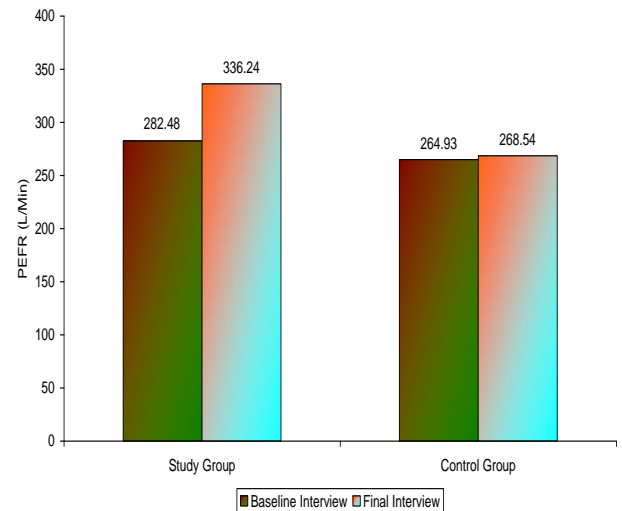


Figure no.3: PEFr(l/min) reported by intervention(n=33) and control group(n= 33) at baseline and final visits

Table no.3: Peak expiratory flow rate (PEFR) l/min (n = 33)

S N	Characteristic	Baseline Score Mean ± SD	Final Score Mean ± SD	P*
1	Intervention group	282.48 ± 95.4	336.24 ± 88.11	< 0.05
	Control group	264 ± 0.93	268 ± 85.14	

3. Discussion

The study evaluated the impact of Pharmaceutical Care on the Quality of Life in asthma patients. Asthma is a common chronic inflammatory condition of the lung airways whose cause is incompletely understood. Asthma is associated with an enormous social, psychological and economic burden in patients. Thus it affects the quality of life of patients. Asthma cannot be cured, but it can be controlled with proper asthma management. Studies have demonstrated the importance and benefit in outcome of patient counseling, support and production of written self medication plans that allows the patients to adjust their medication when necessary. Self management of asthma is reported to reduce its incidence and improve patient's Quality Of Life (QoL). The baseline study performed to assess the patients showed that most of them do not have a proper understanding of the symptoms and severity of asthma. The study revealed the unawareness of patients about their triggering factors. Most of them were non compliant with their treatment regimens. They were also unaware about the management of an emergency attack. Several studies proved the positive impact of pharmaceutical care on the quality of life in asthma patients. Mehuys E *et al* (2008) demonstrated the effectiveness of pharmacist intervention for asthma control improvement. They investigated whether pharmacist interventions, focused on appropriate use of asthma medication and tailor- made to the patient's current asthma control, would improve asthma control in adult patients. They found that pragmatic community pharmacy - based programmes can significantly improve therapeutic outcomes in adult asthma patients.

Paul B *et al* (2009) studied the effect of a minimal pharmacy intervention on the improvement of adherence to asthma guidelines. Adherence was evaluated by studying prescriptions with asthma. They concluded that the assistance of pharmacists in adherence to paediatric asthma guidelines is beneficial and pharmacists should be involved actively in the case of children with asthma.

Armour C *et al* (2007) through his Pharmacy Asthma Care Program (PACP) reported that the community pharmacist delivered asthma care programme based on national guidelines improves asthma control by improved clinical and humanistic outcomes. The intervention resulted in improved adherence to preventer medication, QoL and perceived control of asthma questionnaires

The result of the study demonstrated that the intervention group which was provided with pharmaceutical care reported an improvement in mean score values of the domains of asthma QoL measurement. Their asthma control improvement is also supported by the mean values of ACT. Their lung function is also improved when they are compared with the control group. The four domains of AQLQ indicated significant improvement in the intervention group than the control group. Thus the

pharmaceutical care has a crucial role in the management of asthma and such studies taken up by the Clinical Pharmacists can help the healthcare professionals to improve patient's Quality of Life and return the patient healthcare.

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Abbreviations

AAP	:	Asthma Action Plan
ACQ	:	Asthma Control Questionnaire
ACT	:	Asthma Control Test
AQLQ	:	Asthma Quality of Life Questionnaire
AQLQ(S)	:	Standardized version of Asthma Quality of Life Questionnaire
ASHP	:	American Society for Health System Pharmacists
ASME	:	Asthma Self Management Education
DPI	:	Dry Powder Inhaler
ED	:	Emergency Department
EPR-3	:	Expert Panel Report 3
FEV ₁	:	Forced Expiratory Volume in One Second
FVC	:	Forced Vital Capacity
GINA	:	Global Initiative for Asthma
GPP	:	Good Pharmacy Practice
HRQoL	:	Health Related Quality of Life
ICMR	:	Indian Council of Medical Research
ICS	:	Inhaled Corticosteroids
IgE	:	Immunoglobulin E
IL5	:	Interleukin 5
LABA	:	Long Acting Beta Agonist
MDI	:	Metered Dose Inhaler
NHLBI	:	National Heart Lung and Blood Institute
NIH	:	National Institute of Health
p value	:	Observed Significance Level
PACP	:	Pharmacist Asthma Care Program
PC	:	Pharmaceutical Care
PEF	:	Peak Expiratory Flow
PEFR	:	Peak Expiratory Flow Rate
PFT	:	Pulmonary Function Test
QoL	:	Quality of Life
RAMS	:	Rural Asthma Management Services
SABA	:	Short Acting Beta Agonist
SD	:	Standard Deviation
WHO	:	World Health Organization