Original Article

Pharmaceutical care for asthma patients: A Developing Country's Experience

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ABSTRACT

\textbf{Objective:} This study aims at the outcome of providing pharmaceutical care service for asthma patients through an active partnership between clinical pharmacist and patients, for an optimal pharmacotherapy and a better quality of life (QoL).

\textbf{Methods:} In this controlled clinical trial, which was conducted for 8 months (2009) in the Institute of Pulmonary Medicine and Research Centre of a 550-bedded multispeciality tertiary care teaching hospital in India, all patients diagnosed with asthma at least 6 months before getting enrolled in this study were included (\(n = 66\)). Patients were divided into the intervention group who received pharmaceutical care through asthma education, medication counselling, instructions on lifestyle modifications, asthma care diary, etc., and the control group who were not provided any pharmaceutical care. Asthma control in the two groups was assessed using Asthma Control Test (ACT) at regular intervals. QoL in both groups was assessed at regular intervals using standardized Asthma Quality of Life Questionnaire (AQLQ).

\textbf{Findings:} The mean AQLQ scores for the intervention group at the baseline were increased to significantly higher amounts in the final visit indicating overall, activity, symptoms, emotional, and environmental domains, respectively (\(P < 0.05\)). The mean ACT scores for intervention group at baseline were also increased in statistically significant amounts in the final visit for all the five ACT questions (\(P < 0.05\)).

\textbf{Conclusion:} Our pharmaceutical care program showed a positive impact in improving patient's asthma-related QoL, lung function, and asthma control. By providing structured pharmaceutical care, clinical pharmacists can help asthma patients to achieve desired health outcomes.

\textbf{Keywords:} Asthma; pharmaceutical care; quality of life

INTRODUCTION

Asthma is a chronic respiratory disorder that affects 1–18% of the world’s population\textsuperscript{[1]} and is a major cause of chronic morbidity and economic burden worldwide.\textsuperscript{[2]} According to the National Institute of Health (NIH) Expert Panel report “Asthma is now defined as a chronic inflammatory disorder of the airways in which many cells and cellular elements play a role, in particular, mast cells, eosinophils, T lymphocytes, neutrophils, and epithelial cells”.\textsuperscript{[3]} In susceptible individuals, this inflammation causes recurrent episodes of wheezing, breathlessness, chest tightness, and coughing, particularly at night or in the morning. These episodes are usually associated with widespread but variable airflow obstruction that is often reversible either spontaneously or with treatment. Minimizing impairment and risk is the goal of therapy for all levels of asthma severity. The attainment of asthma control correlates with improved quality of life (QoL) and reduced health care use.\textsuperscript{[4]} Pharmaceutical care is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient’s QoL. Some
medical practitioners fail to ask and/or document longitudinally the basic set of clinical information required to assess whether asthma is under con. This consequently leads to inconsistency and variability in clinical decision making and practice. Pharmaceutical care is an essential factor for the control and management of asthma. Several studies conducted proved that pharmaceutical care provided by a pharmacist is an important part in the asthma management. Use of drugs in asthma patients is also a matter of self-regulation and self-management. This study aims at the outcome of providing pharmaceutical care for asthma patients through an active partnership between clinical pharmacist and patients, for achieving a good control of asthma with symptom monitoring, optimal pharmacotherapy, and control of confounding factors.

METHODS

In this prospective, controlled clinical trial, which was conducted for 8 months (2009) in the Institute of Pulmonary Medicine and Research Centre of a 550-bedded multispecialty tertiary care teaching hospital in India, all patients diagnosed with asthma at least 6 months before getting enrolled in this study were included. A questionnaire for the assessment of the patient's perception about the asthma, medications, and inhalation therapy was prepared according to the Indian Council of Medical Research asthma questionnaire. This questionnaire was tested for face validity and reliability using current and standard methods.

The Asthma Quality of Life Questionnaire (AQLQ) was used both in English as well as Tamil version for India. The Standardized AQLQ was selected for the work and it consists of 32 questions with a 7-point scale of responses for each (e.g., 1 = totally limited to 7 = not at all limited). The questions were grouped into four domains which was based on the symptoms (all generic), activity limitations, emotional function, and environmental stimuli. Domain consisted of 12, 11, 5, and 4 questions, respectively. A quick test which provided a numerical score to assess asthma control was prepared and the questions were made according to the NIH 2007 asthma guidelines. Asthma Control Test (ACT) is a 5-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 3 months from May 2009 to August 2009. Clinical pharmacist recruited 22 medically diagnosed asthma patients according to the selection criteria 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 peak expiratory flow rate (PEFR) value, QoL scores, and asthma control scores. Intervention group received pharmaceutical care (asthma care diary, education, and counseling) till the end of the study, while the control group patients were not offered any intervention. The interviews for the measurement of QoL were 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 29 th day from the baseline. The patients were asked to complete asthma control test questionnaire and the responses are on a 5-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. Clinical pharmacist followed the patient’s progress with follow-up visits and phone calls and patient’s progress was noted.

For AQLQ questionnaire, the mean score per question for each of the four domains was calculated, and the overall score was derived from the mean score of all questions. For all ACT questions, mean score per question was also calculated. 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.

RESULTS

Baseline characteristics of the control and intervention (case) group patients are shown in Table 1.

Baseline study

In the baseline study, 22 cases were analyzed, of which 73% were male. Some of the patients had a history of smoking, taking at least one packet of cigarette daily.
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18% of the patients were found to be asthmatic in their early ages and the remaining 82% of them during their adulthood. In overall patients, 64% of them have asthma (or) recurrence of asthma episodes for more than 10 years and for the remaining 36% it was found to be less than 10 years. Asthma was found to have a seasonal variation in most of the subjects. For 82% of patients, the asthma attack mainly occurs during the winter season and for 36% at night. Routine work was found to be disturbed for 80% of patients. For about 50% of patients, sleep pattern was found to be disturbed. Overall, 60% of patients wanted to know about their lifestyle modifications, 90% of them about their medications, and majority of them wanted to know about the management of an emergency attack.

**Asthma quality of life and asthma control assessment**
Baseline and final visit outcome measures among intervention patients and control patients are shown in Table 2. Here, a total of 66 patients were enrolled.

The participants were divided into control and intervention (cases) groups. 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 9.48 ± 8.1 and 7.45 ± 5.4, respectively [Table 1].

**Asthma control test scores**
Asthma control test consists of five questions with a 5-point scale of responses for each. Questions are about the frequency of asthma, shortness of breath, symptoms, medication, and rating of asthma. Control is the parameter assessed in patients receiving treatment. The mean value for the score of all the five asthma control test questions for the intervention group was higher than the control group in the final visit \( (P<0.05, \text{Figure } 1 \text{ and Table } 2) \).

| Sl. No. | Characteristic | Intervention (mean ± SD) | Control (mean ± SD) | \( P^* \) |
|---------|----------------|--------------------------|---------------------|----------|
|         | ACT 1          | Intervention group        | 2.09 ± 0.77         | 4.12 ± 0.74 | <0.05    |
|         |                | Control group             | 2.51 ± 1.12         | 3.66 ± 0.85 | <0.05    |
|         | ACT 2          | Intervention group        | 2.18 ± 0.85         | 3.88 ± 0.55 | <0.05    |
|         |                | Control group             | 2.39 ± 0.93         | 3.36 ± 0.74 | <0.05    |
|         | ACT 3          | Intervention group        | 2.21 ± 0.82         | 4.21 ± 0.60 | <0.05    |
|         |                | Control group             | 2.51 ± 0.66         | 3.75 ± 0.43 | <0.05    |
|         | ACT 4          | Intervention group        | 2.64 ± 1.06         | 4.64 ± 0.55 | <0.05    |
|         |                | Control group             | 2.57 ± 0.90         | 4.27 ± 0.57 | <0.05    |
|         | ACT 5          | Intervention group        | 2.18 ± 0.68         | 4.15 ± 0.57 | <0.05    |
|         |                | Control group             | 2.51 ± 0.79         | 3.66 ± 0.47 | <0.05    |
|         | AQLQ (S) scores| AQLQ 1                   | 2.93 ± 0.83         | 5.66 ± 0.58 | <0.05    |
|         |                | Intervention group        | 2.93 ± 0.83         | 5.66 ± 0.58 | <0.05    |
|         |                | Control group             | 3.08 ± 0.76         | 4.60 ± 0.53 | <0.05    |
|         | AQLQ 2         | Intervention group        | 2.79 ± 0.89         | 5.63 ± 0.54 | <0.05    |
|         |                | Control group             | 3.23 ± 0.72         | 4.64 ± 0.49 | <0.05    |
|         | AQLQ 3         | Intervention group        | 2.81 ± 0.99         | 5.67 ± 0.54 | <0.05    |
|         |                | Control group             | 2.79 ± 0.82         | 4.48 ± 0.63 | <0.05    |
|         | AQLQ 4         | Intervention group        | 3.53 ± 0.88         | 6.00 ± 0.53 | <0.05    |
|         |                | Control group             | 3.55 ± 0.86         | 5.10 ± 0.51 | <0.05    |
|         | AQLQ 5         | Intervention group        | 2.73 ± 1.48         | 5.61 ± 0.73 | <0.05    |
|         |                | Control group             | 2.47 ± 1.21         | 4.15 ± 0.83 | <0.05    |

\*Paired t-test between the two groups in their final visit. *Significant \((P < 0.05)\), ACT: Asthma control test, AQLQ: Asthma quality of life questionnaire
Asthma quality of life scores
The Standardized AQLQ (S) consists of 32 questions with a 7-point scale of responses for each (e.g., 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 ($P<0.05$, Table 2).

Peak expiratory flow rate values
In the intervention group, the mean 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 ($P<0.05$, Figure 2).

**DISCUSSION**
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 result of the study demonstrated that the intervention group which was provided with pharmaceutical care had an improvement in mean score values of the domains of asthma QoL measurement. A study conducted by Abdelhamid et al[17] on pharmaceutical care services for patients with asthma showed that the intervention group showed a significant greater improvement in the score for assessing the inhalation technique ($P < 0.001$), patient's knowledge about asthma ($P < 0.001$), and its drug therapy ($P = 0.01$) compared with control.
There was also a significant increase in the PEFR values at the final visits, in the intervention group, whereas only a slight increase was seen in the control group.

Their asthma control improvement is also supported by the mean values of ACT, which was found to be higher in the intervention group compared with that of the control group. Pereira et al in a study on QoL in asthma\textsuperscript{[18]} showed that the ACT scores were statistically correlated with the QoL ($r = -0.72; P < 0.01$), symptoms improvement ($r = -0.78; P < 0.01$) and better physical activity ($r = -0.67; P < 0.01$); which may means that better asthma control scores may translates to better QoL. Another study by Ko et al\textsuperscript{[19]} demonstrated that the measurement of ACT is useful for assessing asthma control, prediction of exacerbation, and changes in treatment decisions.

In this study the lung function of the intervention group were 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. Two studies on self-management of asthma by Mancuso et al\textsuperscript{[20,21]} revealed that the intervention patients had more improvement in AQLQ scores after 5 months, and the AQLQ scores improved significantly from 4.1 to a mean of 5.1 ($P < 0.001$). In their patients the clinical asthma status measured with the AQLQ showed more knowledge ($P = 0.005$), more positive attitude ($P = 0.02$), and more self-efficacy ($P = 0.01$) were associated with better AQLQ scores.

Similar study by Mehuys et al\textsuperscript{[22]} demonstrated the effectiveness of pharmacist intervention for asthma control improvement. They found that pragmatic community pharmacy-based programs can significantly improve therapeutic outcomes in adult asthma patients. Santos et al\textsuperscript{[23]} in their study on pharmaceutical care for patients with persistent asthma have reported that counseling provided by the pharmacist to the patient was important to assist in the implementation of the appropriate inhalation technique.

It seems that providing pharmaceutical care has an important role in the management of asthma and such studies taken up by the clinical pharmacists can help the healthcare professionals to improve patient’s QoL and in turn the patient health care.

The aim of the asthma management is to gain and maintain control of the disease. Clinical Pharmacists are recommended to get involved in developing clinical management plans and Asthma Action Plans for asthma patients, reviewing and educating on inhaler technique and undertaking regular reviews. The pharmaceutical care program provided in this study showed a positive impact in improving patient’s asthma-related QoL, lung function, and asthma control. The interventions by the clinical pharmacists resulted in improvements in asthma control, adherence to preventer medication, QoL, and asthma knowledge. This study has demonstrated a better outcome on QoL and lung function for the control of asthma by the intervention of clinical pharmacists and it seems that by providing well-structured patient-oriented pharmaceutical care, pharmacists can help asthma patients in achieving desired health outcomes.

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AUTHORS’ CONTRIBUTION

All authors contributed the idea of research, design of study, data analysis and manuscript preparation.

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