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RESEARCH ARTICLE

Efficacy of an education session by pharmacists for patients with asthma: A randomised controlled trial

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Abstract

Background: Asthma education interventions are provided by pharmacists in many developed countries, although it is still a matter of concern in developing countries. This study aimed to evaluate the effectiveness of pharmacist education sessions on asthma patients. **Methods:** A three-month single-blinded randomised control trial was conducted to evaluate the impact of pharmacist education sessions on asthma patients. The 60-minute pharmacist sessions provided education to patients about asthma management. The primary outcome of the study was to measure the change in the score of the asthma control questionnaire (ACQ). **Results:** The 82 participants who completed the study were grouped into two groups. A clinically significant improvement of $p>0.5$ in the ACQ score was found in the symptoms and environment domains in the intervention group. A significant difference in the ACQ score was also found between the two groups ($p=<0.05$) after 1 and 2 months of intervention. The proportion of patients with controlled asthma increased from 26 (63.4%) to 31 (75.6%) after the second follow-up in the intervention group. Furthermore, a significant increase ($p=0.043$) in the AQLQ score was noticed from 4.834 at baseline to 5.433 after the intervention. **Conclusion:** This study concluded that short-time pharmacist education sessions could improve patients asthma status and quality of life.

Introduction

Asthma cases are a growing concern worldwide and have become a substantial burden for healthcare systems (World Health Organization, 2008). Asthma is an inflammatory condition of the airways that results in difficulty breathing, chest tightness, wheezing, production of sputum, and dry cough (Lemière et al., 2004). In asthma patients, response to the stimulus is increased and barricades the airways that can be treated with appropriate therapy or can be reversed spontaneously (Masoli *et al.,* 2004). Many factors are known to increase the risk of developing asthma. Among these, the most dominants are a family history of asthma, allergic conditions, exposure to stimulating antigens that can trigger asthma-like house dust mites, and the smoke of tobacco or chemicals (National Heart Lung and Blood Institute, 2011). Guidelines are available to treat this condition with the appropriate therapy of asthma drugs and proper asthma. Factors that can affect asthma therapy include the routes of drug administration, using the devices for inhalers, and patient compliance with treatment (Bryant *et al.,* 2013).

The concept of self-management is the key to countering chronic conditions. One of the main issues in chronic disease self-management is the patient's responsibility and understanding of how to counteract and monitor their condition. For chronic conditions such as asthma, knowledge of associated inflammation, the onset of symptoms, risk factors for triggering the disease, and appropriate use of medications can help improve self-management and adherence to treatment. However, understanding asthma may not directly affect disease management but may compel the individual to adapt to the chronic disease (De Vries & Petermann, 2008). Many studies have shown that asthma knowledge was associated with better control, adherence, and quality of life (Huang, 2007; Hermosa *et al.,* 2010; Mancuso, Sayles & Allegrante, 2010). Therefore, improving knowledge about the disease is a pivotal step to perceiving better results in the long term. Proper education, patient counselling, fundamentals of asthma care programmes, and asthma management guidelines are developed to deepen patient understanding and improve asthma and health-related outcomes (Myers, 2008).

Asthma prevalence is increasing worldwide in developed and developing countries despite proper medications for asthma management being available everywhere. Respiratory disease conditions are responsible for 17.4% of deaths around the globe. In 2020, the World Health Organisation reported that more than 339 million people had asthma. Most asthma-related deaths are in low- and middle-income countries, with the WHO reporting 417,918 deaths due to asthma at the global level. Proper therapy and effective management of the disease could save many lives (World Health Organization, 2020a, 2020b).

This study is the first literature-based survey in Indonesia that uncovers the implication of pharmacists' educational intervention on self-management and its effect on asthma patients, their behaviours, understanding of asthma, asthma control, and treatment adherence. Studies showed that treatment compliance and the proper use of asthma medications play a significant role in chronic illness management. Hence, the pharmacist specialist plays a vital role in medication therapy management. Asthma can be controlled by the active involvement of the patient in self-management, which includes assessing the function of the lungs, monitoring the symptoms, following therapy plans, and consulting doctors regularly about their conditions (Gibson *et al.,* 2003). Therefore, this randomised controlled study aimed to assess the effectiveness of pharmacist educational sessions on asthma patients in Indonesia. It was thus hypothesised that patients in the intervention group had better asthma control as measured by decreased Asthma Control Questionnaire (ACQ) scores after three months of follow-up.

Methods

Study setting

The study participants were recruited from the outpatient department of pulmonology at Universitas Airlangga teaching hospital.

Ethical approval

Ethical approval was obtained from the human research ethics committee of Universitas Airlangga teaching hospital. Apart from that, written informed consent was provided by all the participants at the time of recruitment.

Study design

The current study is a retrospective, single-blinded, randomised controlled trial (Thai Clinical Trials Registry # TCTR20171219001). The protocol of the study has been published elsewhere (Zairina *et al.,* 2018). The total duration of the study was three months. A sample of 82 patients were recruited, and 41 participants were allocated to each group. Both the intervention and the control group were followed up for three months, and outcomes were compared with baseline after the 1, 2, and 3 months.

Inclusion and exclusion criteria

This study included asthma patients aged 18 or older who had used asthma medication in the past 12 months and could communicate in Indonesian. Those unable to explain the lung's activity through a spirometer were excluded from the study.

Participants recruitment and sample size

Asthma patients were identified by doctors upon visiting the outpatient department of pulmonology at Universitas Airlangga teaching hospital. The research assistants approached the participants and screened them based on the study inclusion and exclusion criteria. Those who met the inclusion criteria and showed interest in participating were selected; they provided a written informed consent form to the hospital. The contact numbers were obtained from participants for further communication. The total number of participants recruited was 82. The participants were distributed on a 1:1 basis, and 41 participants were allocated to each of the intervention and control groups.

Group allocation

The allocation was done using the sealed opaque envelope technique, where random numbers were generated using a random allocation software programme (Kim & Shin, 2014) by an external researcher not involved in the study. Only the external researcher knew the numbers allocated, and the numbers were allocated by the researcher to the intervention and control group.

Control: Usual care group

Participants in the control group received the usual care provided by the health professionals in the department of pulmonology of Universitas Airlangga teaching hospital, which included monthly visits depending on the condition of the patients.

Intervention: Education group

Before delivering the interventions or educational sessions, the pharmacist included in the study received training to become a certified asthma educator (EZ). The intervention included a one-on-one education session delivered by the pharmacist to the patient regarding the following matters: (1) asthma medication that has been used; (2) how to use asthma medication devices correctly; (3) asthma symptoms and how to prevent exacerbation of asthma; and (4) how to manage asthma triggers and environmental control measures.

A video was shown to the patients regarding the proper use of medications. A booklet was also provided to the intervention group about the use of asthma medications and how to avoid asthma triggers.

Consistent with the Global Initiative for Asthma guidelines action plan, a written asthma action plan was translated into the Indonesian language and used in asthma patients based on the information at baseline. The education session provided information about the correct use and time of medication information, recognising the worsened condition of asthma and what to do, and information regarding the plans for acute asthmatic attacks.

Outcome measures

In the current study, the primary outcome was the change in asthma conditions measured with Juniper's Asthma Controlled Questionnaire (ACQ) (Juniper *et al.,* 1999b). The secondary outcomes of the study were the changes in Juniper's Asthma Quality of Life Questionnaire (Juniper *et al.,* 1999a) and Adherence to Refills and Medications Scales (ARMS) scores.

Data collection and follow-up

ACQ, AQLQ, and ARMS scores were collected at baseline and at one, two, and three months to compare between baseline and follow-ups. The same form was used for data collection in both the control and intervention groups. The data measured at each follow-up were recorded for specific groups of patients.

Data analysis

The results of the current study were analysed using SPSS version 25. Descriptive statistics were used to calculate the frequencies of participant characteristics in each group. The baseline characteristics of both groups were compared using the Mann U Whitney, independent sample t-test, chi-square, and Fisher exact test where applicable. Descriptive statistics were used to calculate the mean ACQ score in different domains and the increase or decrease in the number of patients with controlled asthma in both groups at baseline and follow-up. The mean ACQ score of the respondents in both groups at baseline and follow-up was analysed using a one-way ANOVA. A pairwise comparison of ACQ scores for both groups was also performed. The Wilcoxon test was used to find out a significant difference in the means score of AQLQ in both groups after the intervention compared with the mean score at baseline.

Results

A total of 82 participants participated in the study and were divided into two groups of 41 participants each. Of the total sample, 23 were male and 59 female. The mean age was 51.29 ± SD 12.38 in the intervention group and 51.93 ± 12.586 in the control group. Most participants (n=80; 97.56%) were from Surabaya. The majority of participants in both groups were housewives, 19(46.3%) and 21(51.12%), respectively. The intervention group included 38(92.7%) smoker participants compared to 35(85.4%) in the control group. Table I displays the baseline characteristics of the participants.

Table II illustrates the score of all ACQ domains. An improvement of $p>0.5$ in the ACQ score was found in the symptoms and environment domains in the intervention group after follow-up. There was also a progressive improvement in other domains of ACQ in the intervention group.

Table I: Baseline characteristics of the respondents by interventions and control group (n=82)

Patient characteristics	Intervention group	Control group	*p*-value
Gender			
Male	10 (24.4%)	13 (31.7%)	0.461
Female	31 (75.5%)	28 (68.3%)	
Age - mean SD	51.29 (12.238)	51. 93 (12.586)	0.818
City			
Surabaya	41 (100%)	39 (95.1%)	0.494
Other	0	2 (4. 9%)	
Occupation			
PNS – Government employees	1 (2.4%)	2 (4. 9%)	
Private	15 (36.6%)	11 (26.8%)	
Self-employed	4 (9.8%)	5 (12.2%)	0. 917
Housewokers	19 (46.3%)	21 (51.2%)	
Others	2 (4.9%)	2 (4.9%)	
Education			
Incomplete elementary	2 (4.9%	1 (2.4%)	
Elementary	4 (9.8%)	9 (22%)	
Junior high school	4 (9.8%)	6 (14.6%)	
Education senior high school	16 39%)	11 26.8%)	0.348
Diploma	5 (12.2%)	1 (2.4%)	
Bachelor's degree	9 (22%)	11 (26.8%)	
Master's degree	1 (2.4%)	2 (4. 9%)	
Smoking			
Yes	38 (92.7%)	35 (85.4%)	0.482
No	3 (7.3%)	6 (14.6%)	
BPJS – National Health Insurance			
Yes	40 (97.6%)	41 (100%)	> 0.05
No	1 (2.4%)	0 (0%)	
Change asthma med in last week			
Yes	35 (85.4%)	40 (97.6%)	0.109
No	6 (14.6%)	1 (2.4%)	
Last visit at heath care facilities			
A week ago	11 (27.5%)	7 (17.1%)	
2 weeks ago	0 (0%)	3 (7.3%)	0.111
3 weeks ago	0 (0%)	2 (4.9%)	
A month ago	29 (72.5%)	29 (70.7%)	
Monthly income (IDR)			
3.000.000	28 (68.3%	29 (76.3%)	
3.000.000 – 6.000.0000	13 (31.7%)	7 (18.4%)	0.157
6.000.000 – 12.000.000	0 (0%)	2 (5.3%)	

The ACQ scores in the intervention and control group at baseline were (1.476 ± 1.08) and (1.798 ± 1.34), respectively. The scores after the first follow-up decreased to 1.267 ± 1.04 in the intervention group, which was lower compared to the control group (1.817 ± 1.36). Significant differences in ACQ scores were found between the groups after the first and the second follow-up (p = 0.044) and (p = 0.027), respectively. After the last follow-up, the ACQ score in the intervention group was lower than in the control group, but no significant difference was found (p = 1.171). The comparison of ACQ scores between both groups can be seen in Table III.

Table II: ACQ score of all domains in both groups from baseline to follow-up

ACQ	Groups	Baseline, Mean ± SD	Follow-up 1, Mean ± SD	Follow-up 2, Mean ± SD	Follow-up 3, Mean ± SD
Symptoms	Intervention group	2.00 ± 1.949	1.85 ± 1.797	1.39 ± 1.656	1.27 ± 1.533[a]
	Control group	1.56 ± 2.001	2.00 ± 2.110	1.61 ± 2.072	1.78 ± 2.139
Emotions	Intervention group	1.15 ± 1.315	1.54 ± 1.325	1.07 ± 1.034	1.10 ± 1.319
	Control group	1.68 ± 1.781	1.90 ± 1.729	1.71 ± 1.750	1.71 ± 1.927
Activities	Intervention group	1.20 ± 1.487	1.12 ± 1.520	0.98 ± 1.193	1.05 ± 1.465
	Control group	1.41 ± 1.549	1.63 ± 1.593	1.49 ± 1.551	1.51 ± 1.690
Environment	Intervention group	2.17 ± 1.395	1.83 ± 1.283	1.61 ± 1.339	1.59 ± 1.303[a]
	Control group	1.73 ± 1.467	2.17 ± 1.611	1.95 ± 1.717	1.95 ± 1.802
Generic health status					
Physical	Intervention group	1.17 ± 1.358	1.34 ± 1.442	1.29 ± 1.250	1.10 ±1.497
	Control group	1.54 ± 1.776	2.05 ± 2.024	1.83 ± 2.084	1.68 ± 2.138
Mental	Intervention group	1.10 ± 0.917	1.20 ± 1.167	0.88 ± 0.822	0.83 ± 0.874
	Control group	1.15 ± 1.108	1.27 ±1.073	1.10 ± 1.091	1.15 ± 1.315
Other Symptoms	Intervention group	2.51 ±2.111	1.93 ± 2.054	2.12 ± 1.900	2.40 ± 2.171
	Control group	2.93 ± 2.317	2.78 ± 2.351	2.99 ± 2.359	2.88 ± 2.400

[a] Improvement in ACQ score (>0.5) after follow-up; ACQ = Asthma controlled questionnaire

Table III: Comparison of ACQ between the intervention and the control group

	ACQ score (mean ± SD) Intervention group	ACQ score (mean ± SD) Control group	Mean difference (95% CI)	*p*-value
Baseline	1.476 ± 1.08	1.798 ± 1.34	-0.322 (-0.859 - 0.216)	0.238
Follow up 1	1.267 ± 1.04	1.817 ± 1.36	-0.550 (-1.084 - 0.016)	0.044
Follow up 2	1.240 ± 0.96	1.825 ± 1.35	-0.585 (-1.101 - -0.069)	0.027
Follow up 3	1.391 ± 1.17	1.776 ± 1.34	-0.385 (-0.940 – 0.17)	0.171

ACQ = Asthma controlled questionnaire; SD = standard deviation; CI = confidence interval

Table IV shows that the number of patients with well-controlled asthma increased in the intervention group compared to the control group. Asthma control was significantly different ($p<0.05$) in both groups after the first and second follow-ups. The proportion of patients with controlled asthma increased from 26 (63.4%) to 31 (75.6%) after the second follow-up in the intervention group, while the numbers deviated slightly in the usual care group. However, after the third follow-up, no significant difference was noticed in the number of patients regarding asthma control in the intervention group compared with the numbers at baseline.

Table IV: Proportion of patients with well-controlled and not well-controlled asthma based on ACQ

	Well-controlled Asthma (ACQ score ≥ 1.5)	Not well controlled asthma (ACQ score <1.5)	*p*-value
Baseline			
Intervention group	26 (63.4%)	15(36.6%)	0.120
Control group	19 (46.3%)	22 (53.7%)	
Follow up 1			
Intervention group	29 (70.7%)	12 (29.3%)	0.043
Control group	20 (48.8%)	21 (51.2%)	
Follow up 2			
Intervention group	31 (75.6%)	10 (24.4%)	0.022
Control group	21 (51.2%)	20 (48.8%)	
Follow up 3			
Intervention group	27 (65.9%)	14 (34.1%)	0.260
Control group	22 (53.7%)	19 (46.3%)	

ACQ = Asthma controlled questionnaire

Table V explains the results of the secondary outcome, i.e., the change in AQLQ scores. The results showed a significant increase in the AQLQ score from baseline to follow-up in intervention groups, while no significant difference was found in the usual care group.

Table V: Difference in AQLQ scores between baseline and follow-up

	Mean ± SD	*p*-value
Intervention group		
AQLQ score baseline	4.834 ± 1.209	0.005
AQLQ score after intervention	5.433 ± 1.474	
Control group		
AQLQ score baseline	4.955 ± 1.178	0.230
AQLQ score after intervention	5.086 ± 1.339	

AQLQ = Asthma quality of life questionnaire; SD = standard deviation

The other secondary outcome was a change in ARMS score, lung function, asthma-related health visits, days off from work due to asthma, and oral corticosteroid use. No significant or progressive change was found in the ARMS score in both the intervention or control groups. There was a slight but not significant improvement in the lung functions of the patients in the intervention group compared to the control group. Other secondary outcomes, such as asthma-related health visits, days off from work due to asthma, and the use of corticosteroids in both groups, had no significant change or improvement, and hence the results are not presented in the study.

Discussion

This study has demonstrated that pharmacist interventions can lead to controlled asthma. As asthma is managed, the patient quality of life is also improved. This study is the first in Indonesia to provide insights into the role of pharmacists in improving patient asthma and increasing quality of life. The results showed a significant improvement in asthma patients in intervention groups after the follow-up as compared to the control group. These results are consistent with previous findings indicating that a pharmacist with basic training in asthma care can deliver a simple educational programme resulting in improvements in asthma (Dolovich et al., 2007; Berry *et al.,* 2011).

The results show that the pharmacist intervention in three months improved asthma control in patients allocated in the intervention group compared to those receiving the usual care. The overall results of our study are consistent with some previous findings stating that pharmacist interventions increase the asthma-controlled number in intervention groups. The ACQ score of patients was decreased in follow-ups compared to the baseline in the intervention group. A decrease of 0.5 on the scale in domains of symptoms and environment of the ACQ score indicated clinical improvement of asthma (Juniper *et al.,* 2005), while the score of other domains also showed a slight deviation from the baseline in the intervention group consistent with the prior research (García-Cárdenas *et al.,* 2013).

An improvement in the mean score of ACQ was also found in the intervention group, in line with previous studies (Smith *et al.,* 2007; Mehuys *et al.,* 2008; Armour *et al.,* 2013; García-Cárdenas *et al.,* 2013; Lim *et al.,* 2014). Another study also showed that after the intervention, the ACQ scores of all participants were significantly improved (p <0.05) (Zanghelini & Carvalho, 2013). The current study also recorded that the number of patients having well-controlled asthma increased in the intervention group compared to a slight improvement in the usual care group. These results are in agreement with previous findings, where the number of asthma patients significantly increased by 30.1% after six months of intervention (García-Cárdenas *et al.,* 2013). One study assessed asthma control through a symptom/activity tool and the ACQ. It recorded an increase in patients classified as having well-controlled asthma and a mean decrease in the ACQ scores, similar to our results (Armour *et al.,* 2013). A systematic review of clinical trials on asthma patients concluded that the ACQ score was improved after interventions (Bateman et al., 2015). Other randomised controlled studies also showed an increase in the overall percentage of asthma-controlled patients after the interventions (Mehuys *et al.,* 2008; García-Cárdenas *et al.,* 2013; McDonald *et al.,* 2020; Freitas et al., 2021).

The secondary outcome of our study was a change in Juniper's Asthma Quality of Life Questionnaire score. A significant increase in the AQLQ score was found after the intervention, consistent with previous findings (Turner *et al.,* 2011; Rondinel *et al.,* 2015; Özbey *et al.,* 2020). A study in New Zealand also showed a notable improvement in patient quality of life after pharmacist interventions (Kheir, Emmerton & Shaw, 2001). Other secondary outcomes important for asthma management were also improved, such as medication adherence and lung function, in the intervention group compared to usual care (Närhi *et al.,* 2000; Barbanel, Eldridge & Griffiths, 2003; Emmerton, Shaw & Kheir, 2003; Bunting & Cranor, 2006).

Generally, asthma patients accept the symptoms related to their disease and are ready to acquire every challenge to control asthma (Umoh *et al.,* 2013). However, it is the responsibility of healthcare providers to help patients manage asthma and live a productive life (Alpaydin *et al.,* 2012). Patients with poorly controlled asthma should be

targeted for medication compliance and medication-taking techniques, especially the use of inhalers (Westerik *et al.,* 2016).

In this study, the pharmacist's educational intervention could significantly improve ACQ scores, increase the number of patients with controlled asthma, and improve patient quality of life. The role of the pharmacist in asthma management is growing with time (Benavides, Rodriguez & Maniscalco-Feichtl, 2009). The visits of asthma patients to healthcare providers are also necessary to keep the disease under control and show adherence to therapy (Ngahane *et al.,* 2016), which can be improved through shared decision-making strategies between patients and pharmacists in chronic conditions (Wilson *et al.,* 2010).

Limitations

This study has some limitations. Firstly, only patients using asthma medication for the past 12 months and patients from a single health setting were included in the study; therefore, the sample may not be generalised to the entire asthma population. Secondly, significant differences in ACQ scores were observed after the first and the second follow-up; thus, a future investigation on a large number of patients with a prolonged period of interventions is suggested. The current study did not find any significant improvement in the secondary outcomes, such as adherence, lung functions, asthma-related visits, and day-off from work due to asthma, so future RCT studies evaluating these outcomes are recommended. Finally, as the patient outcomes were obtained after a 3-month intervention, the feasibility of the current results on prolonged interventions cannot be poised.

Conclusion

In conclusion, asthma portrays a global problem, and public health initiatives are essential to encourage asthma education for patients and healthcare professionals. The study focused on the leading outcomes of asthma management and revealed that the designed short-term intervention could help the patients improve their disease, increase the number of controlled asthma patients, and have a better quality of life. Apart from the intervention, additional approaches would be required to identify the principal asthma-related issues for future implementation in healthcare settings.

Conflict of Interest

The authors declare no conflict of interest.

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