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IMPACT OF A PHARMACIST-LED EDUCATIONAL INTERVENTION ON QUALITY OF LIFE AMONG PATIENTS WITH ASTHMA

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ABSTRACT

Objectives: Asthma is a chronic disease resulting in reduced quality of life (QoL) of most affected individuals. Training in asthma-related knowledge, inhaler skills, medicine usage, and the prevention of adverse drug events is demonstrated to improve asthma patients' QoL. Therefore, the research was conducted to evaluate the effectiveness of education intervention undertaken by pharmacists on QoL of patients with asthma.

Methods: We conducted a clinical randomized controlled trial among asthmatic outpatients aged 18 years or older in the Department of Screening Respiratory Function, University Medical Center, Ho Chi Minh City, Vietnam. Patients were randomized into an intervention group (IG) and a non-IG (NIG). The clinical pharmacists' intervention program included training in asthma-related knowledge, inhaler technique, recognition, prevention of adverse drug events, and lifestyle adjustment. Participant screening was conducted using the telephone on a monthly basis. QoL was measured using the Vietnamese Version of the Mini Asthma QoL Questionnaire (MiniAQLQ). The main outcome was the difference in QoL scores between IG and NIG after 3 months follow-up.

Results: After 3 months, the number of patients with asthma in the IG and in the NIG was 173 and 96, respectively. QoL mean scores in the IG patients were significantly higher than those in their NIG counterparts (1.79±1.01 vs. 1.06±0.93, respectively, p<0.001). Pharmacist-based interventions overall QoL scores (multivariate-adjusted regression coefficient =0.362; p<0.001).

Conclusions: Clinical pharmacist-led counseling can improve asthmatic patients' QoL.

Keywords: Quality of life, Clinical pharmacist-led intervention, Mini Asthma Quality of life Questionnaire, Randomized controlled trial, Asthmatic education.

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INTRODUCTION

The worldwide prevalence of asthma has increased rapidly [1]. Growing attention has been drawn to Asia, including Vietnam where the prevalence of asthmatic adults was reported to range from 2.5% to 5.0% [2]. Patients with asthma can suffer from critical health problems such as reduced quality of life (QoL) and increased risk of death [3-5]. Of those approaches to improve QoL among asthma patients, pharmacistled educational interventions in collaboration with physicians (e.g., face-to-face or email counseling providing information of asthma, medication management, and lifestyle changes) have been demonstrated to be applicable to improve safety, effectiveness of treatment outcomes, and QoL of patients with long-term medical condition [6,7], such as asthma [8-10]. However, those approaches are not widely implemented across the health-care system in Vietnam. Therefore, this study aimed to evaluate whether asthma patients gain health benefits from pharmacistled educational interventions involving face-to-face and telephone counseling in a hospital in Vietnam.

METHODS

Setting and study participants

We conducted a randomized controlled clinical trial of outpatients who were diagnosed with asthma (International Classification of Diseases 10:J45), aged ≥18 years visiting Department of Respiratory Function Screening (DRFS), University Medical Center, from October 15, 2016, to February 15, 2017. Participants were excluded if (1) personal information or contact addresses were incomplete; (2) Mini–Mental State Examination (MMSE) scores were <17; (3) baseline mini asthma qol questionnaire (MiniAQLQ) scores were \geq 6; and (4) patients were diagnosed with chronic obstructive pulmonary disease (COPD) or (5) illiterate.

Baseline examination

Baseline characteristics were collected for all participants. Demographic data included age, gender, and education level. For baseline examination, participants were asked to wear light clothing and no shoes before measuring body height and weight. Body mass index (BMI) is defined as the weight (kg) divided by the square of height (m). Obese patients were those with BMI ≥25 kg/m² and overweight patients were those with BMI range from 23 kg/m² to 25 kg/m² according to international obesity taskforce classification [11]. Data on asthma at baseline included asthma severity (based on GINA 2016 classification) [12], having any comorbidities, having asthma-related comorbidities (including gastroesophageal reflux disease [GERD], allergic rhinitis, and allergic condition), and mistake in inhaler technique (defined as "Yes" if a participant had at least one incorrect step of inhaler usage and "No" if all steps were correct; the technique instructions followed GINA 2016) [12].

QoL assessment

We used a validated Vietnamese version of the MiniAQLQ to calculate QoL scores for all patients [13]. The MiniAQLQ questionnaire includes 15 questions classified into four main domains: Symptom (questions 1, 4, 6, 8, and 10), activity (questions 12, 13, 14, and 15), environment (questions 2, 7, and 11), and emotion (questions 3, 5, and 9). Each question is given a score ranging from 1 to 7. A higher score denotes

a higher QoL; an increase in the total score indicates an improvement in QoL [14]. Every patient would complete two surveys about QoL, one at the beginning of the study and one at the end of follow-up for about 10 min each time.

Intervention program

Eligible patients were randomly allocated into the IG or the control group (CG) using a list composed by Excel corresponding with their registered order at DRFS. Both groups were interviewed about their inhaler techniques and QoL at baseline during a face-to-face meeting and at the end of the study by mobile phone call. Patients in the CG only received usual care from health-care providers and were not aware of the ongoing intervention, whereas those in the IG were additionally consulted by clinical pharmacists repeatedly. At the end of the patients' first visit to the outpatient department, the clinical pharmacist educated the IG on medication self-management. Patients were shown diseaserelated knowledge, how to use inhalers correctly, how to prevent or handle the common adverse drug effects, and some advice on lifestyle changes. The content of the educational session was based on guidelines from the Global Initiative for Asthma 2016 (GINA 2016) [12]. Next, every month, clinical pharmacists made a mobile phone call to ensure IG patients had followed the instructions correctly. At the end of the follow-up, the researchers reassessed QoL scores in both groups. For ethnicity purposes, CG patients were also given a short counseling period on disease and proper drug use after the survey finished. The research process is shown in Fig. 1.

Outcomes

The main outcome was the differences in QoL score changes from baseline after the 3-month intervention between the IG and the CG.

Sample size

The required sample size for each group was calculated using the following formula:

$$n = \frac{2C}{ES^2} = \frac{2C}{(\frac{\mu_1 - \mu_2}{s_1})^2}$$

where C=7.85 (α =0.05, reliability 95%, β =0.2, and power=0.8). According to Bereznicki *et al.* [15], each group should have a minimum size of 90 participants. To account for the loss of follow-up, we recruited at least 110 patients for each group.

Statistical analysis

Descriptive data were presented as mean and Standard deviation if normally distributed or median and IOR if skewed. Differences between two groups were evaluated using Chi-square tests for percentages or t-test for mean values. The association between intervention program and QoL was assessed using multivariate regression analysis, adjusted for potential confounders including baseline age (18-60; ≥60 years of age), gender (male; female), overweight/obesity (yes; no), asthma severity grade (from 1 to 5), education level (primary/secondary/ high school level; college/university/postgrad-level), having any comorbidities (yes; no), having GERD/allergic rhinitis/Allergic (yes; no), improper inhaler technique (yes; no), and baseline MiniAQLQ scores. Results were presented as per-protocol analysis for the remaining sample after 3-month follow-up. We also considered an intention-totreat (ITT) analysis with baseline characteristics of all participants at randomization. In case a patient was lost to follow-up, we assumed that the QoL at the 3-month interval was unchanged. Statistical analyses were performed using the Statistical Package for the Social Sciences Program, version 20.0. The level of statistical significance was specified at p<0.05.

Ethics approval

Informed consent was obtained from all study participants. The protocol was approved by the Institutional Review Board of University



Fig. 1: Flowchart of the research process

Medical Center, Ho Chi Minh City, Vietnam. All procedures in this study followed the ethical standards of the institutional and/or national research committee and all amendments or comparable ethical standards, including the 1964 Helsinki declaration.

RESULTS

A number of 575 patients were eligible to enter the study. Participants were excluded if they refused to take part in the study (n=75), had asthma – COPD overlap syndrome (ACOS) (n=42), had missing baseline information (n=24), were inaccessible to phone (n=10), had MMSE scores <17 (n=22), or baseline MiniAQLQ score \geq 6 (n=40). The resulting sample left a total of 362 patients for randomization (181 in IG and 181 in CG). After the 3-month follow-up, 269 patients remained in the study (Fig. 1). Results are presented as per protocol analysis on the remaining participants.

Patient characteristics

All characteristics at baseline for all patients in IG and CG are summarized in Table 1. Most patients were in the middle age (85.5% [IG] vs. 87.5% [CG]). The majority was female (61.8% [IG] vs. 66.7% [CG]) and having education level lower than college (63% [IG] vs. 67.8% [CG]). The allergic rhinitis was the most prevalent comorbidity (75.8% [IG] vs. 69.7% [CG]). A substantially high number of patients had at least one error in inhaler techniques (91.9% [IG] vs. 91.5% [CG]).

Assessment of QoL

Baseline MiniAQLQ scores are presented in Table 2. Except for the environment, the scores for the other three domains and overall score between the two groups were not statistically different (p>0.05).

After 3 months, the overall QoL scores in the IG were significantly higher than those in the CG (6.10 ± 0.84 vs. 5.50 ± 0.98 , p<0.001). A statistically significant difference in changes of scores from baseline was also observed in patients receiving pharmacist-led intervention compared with those in the CG (overall changes of score 1.79 ± 1.01 vs. 1.06 ± 0.93 , p<0.05).

In a multivariate linear regression model, the significance was still held after adjusting for confounding factors including age, sex, education level, obesity, comorbidities, and baseline inappropriate inhaler technique (p<0.001) (Table 3).

To investigate whether or not the large loss to – follow-up proportion (>20%) affected our findings, we performed two analyses. In the first one, referred as ITT analysis, results of multivariate regression analysis in all patients at randomization (n=342) showed that intervention program was associated with a positive change in QoL (β =0.474; 95% Confidence interval: 0.830 ÷ 1.214; p<0.001) (Supplemental Table 1). In the second analysis, we assessed if there were any differences in the baseline characteristics between remaining CG patients and loss to follow-up CG patients after 3 months. No, statistically differences in baseline demographic features or MiniAQLQ scores were detected (Supplemental Table 2).

DISCUSSION

The current study showed that a pharmacist-led educational intervention improved QoL in patients with asthma after a short period (3 months). The MiniAQLQ scores and its changes (Δ) in the IG were significantly higher than those in CG (p<0.001). Furthermore, the results of the multivariate regression analysis confirmed the major

Table 1: Baseline characteristics of participants (n=269)

Characteristics	Overall (%)	Group	Group	
		IG (n=173)(%)	CG (n=96) (%)	•
Female	65.8	61.8	66.7	0.342
Mean age	42.02±14.95	40.92±15.49	43.27±13.36	0.161
18-60	85.1	85.5	87.5	0.656
≥60	14.9	14.5	12.5	
BMI (kg/m^2)	22.32±2.69	22.09±2.58	22.95±3.04	0.034
Over-weight/obesity	37.7	37	46.9	0.114
Education level				
Primary/secondary/high school	66.1	63	67.8	0.257
University/college/postgraduate	33.9	37	32.2	
Asthma severity (GINA 2016)	3.18±0.93	3.16±0.85	3.10±0.99	0.938
Comorbidities				
Yes	86	87	85.4	0.730
GERD	29.9	36.6	29.2	0.235
Allergic rhinitis/sinusitis	71.5	75.8	69.7	0.294
Allergy	31.9	30.8	35.4	0.440
Inappropriate inhaler technique	91.4	91.9	91.5	0.906

Mean age, body mass index, and asthma were compared between the two groups using the t-test. Rates of gender, age groups, overweight/obesity patients, education level, comorbidities, and inappropriate inhaler technique were compared using the Chi-square test. BMI: Body mass index, GERD: Gastroesophageal reflux disease

Characteristics	Baseline QoL scores		After 3 months QoL scores			Changes of QoL scores (Δ score*)			
	IG	CG	p-value	IG	CG	p-value	IG	CG	p-value
MiniAQLQ score	4.31±0.89	4.45±0.92	0.170	6.10±0.84	5.50±0.98	< 0.001	1.79±1.01	1.06±0.93	< 0.001
Symptom score	4.00±1.16	4.21±1.23	0.109	6.31±0.74	5.51±1.20	< 0.001	2.31±1.29	1.30±1.27	< 0.001
Activity score	5.29±1.12	5.07±1.30	0.265	6.36±0.74	5.64±1.10	< 0.001	1.07 ± 1.15	0.58±1.06	0.001
Environment score	3.99±1.44	4.42±1.45	0.010	5.54±1.54	5.39±1.56	0.241	1.55 ± 1.27	0.97±1.39	0.002
Emotion score	3.86±1.37	4.05±1.21	0.232	5.98±1.19	5.43±1.34	< 0.001	2.12±1.56	1.38±1.34	0.001
*A score=score after 3 months – baseline score									

Mean MiniAQLQ score, Symptom score, Activity score, Environment score, Emotion score, and the changes of MiniAQLQ score and all other domains of IG and CG were compared using the t-test. QoL: Quality of Life, MiniAQLQ: Mini Asthma QoL Questionnaire

Factor	tor Beta 9		95% CI		
		Upper	Lower		
Intervention (yes)	0.362	0.514	0.924	< 0.001	
Baseline QoLscore	0.415	0.330	0.545	< 0.001	
Age	0.016	-0.008	0.006	0.776	
Gender (Male)	-0.047	-0.297	0.112	0.375	
Education level (University/College/Postgrad)	0.046	-0.136	0.316	0.433	
Allergic rhinitis/sinusitis (yes)	0.060	-0.192	0.447	0.432	
GERD (yes)	-0.072	-0.382	0.092	0.228	
Allergy (yes)	0.222	0.224	0.673	< 0.001	
Having any comorbidity (yes)	-0.006	-0.445	0.411	0.938	
Asthma severity	0.213	0.113	0.337	< 0.001	
Over weight/Obesity (yes)	0.035	-0.136	0.271	0.513	
Baseline inappropriate inhaler technique	0.065	-0.129	0.569	0.218	

Table 3: Effect of an intervention p	program on total QoL scores after 3-month follow-up)
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GERD: Gastroesophageal reflux disease, CI: Confidence interval

contribution of the intervention factor in increasing QoL scores despite the apparent role of the patient's allergy situation and asthma severity.

Our findings are consistent with four previous studies in which interventions were direct educational programs, face-to-face meetings with patients, or only providing instructions through email and information package [15-18]. In these studies, the QoL scores in the IG were significantly higher than those in the CG. In contrast, two other studies reported different findings from our study [19,20]. Although these studies were unable to demonstrate the effect of education-based interventions, several positive findings were recorded. For instance, Wang *et al.* indicated that symptom scores in the IG significantly increased after 6-month follow-up [19]; Petkova showed that QoL scores in the IG increased while those in the CG decreased after 4 months [20].

Besides the disparity in some demographic characteristics, our distinction from the previous studies was the higher frequency of patient-pharmacist contact and intervention approach. Particularly, the interval between consultations was every 2 and 3 months or longer period of 6 months or 12 months in studies by Plaza et al., Armour et al., and Wang et al. [16,17,19], whereas in the studies by Bereznicki et al. [15] and Shanmugam et al. [18], there was only one consultation at the beginning of the study. However, in the current study, clinical pharmacists communicated with patients at the start of the study and repeatedly at every month. In general, communication between healthcare providers and patients in consultations is the keystone to improve the effectiveness of therapy [10,21,22]. Good pharmacist-patient communication or consultation can help to increase asthma control, belief in pharmacotherapy, inhaler-usage [22-24]. Therefore, repeated consultation for patients with asthma may optimize their inhaler usage skills and consequently, increase the patient's QoL [23].

Another strength of our study is a combination of face-to-face and mobile phone counseling. Despite lacking previous supporting research for the benefit of this combination in improving asthmatic patients' QoL, each type of these approaches has been positively demonstrated to facilitate patients' treatment [8-10,25-29] Particularly, face-to-face consultations may raise patients' awareness of asthma and enhance their proper use of inhalers [8-10,25]. In some studies, counseling and patient monitoring through phone were shown to be feasible for not only following up a large number of patients but also supporting patients in asthma control and medicine usage [26-29]. Moreover, most of our patients visited the hospital from distant provinces; thus, the mobile phone was an available option to contact patients for consultation when they were back home. That is why it was reasonable for us to combine two methods in the educational program of which purpose is to improve the patient's QoL.

Last but not least, our study provided evidence to support the key role of pharmacists in improving issues among patients with asthma. Together with physicians, pharmacists could monitor the treatment process; provide useful advice on medicine usage and lifestyle changes to asthmatic patients [30-31]. This perception and our result may give more evidence for strengthening Vietnam's clinical pharmacy system, which is still lacking facilities and standard clinical pharmacists [32].

Limitation

Our study had some limitations. First, the percentage of loss to follow-up after 3-months was above 20% in the CG. However, the baseline characteristics between patients lost to follow-up and the remaining participants after 3 months were not statistically different, and the ITT analysis showed similar results with per protocol analysis (Supplemental Table 1 and 2). Second, the duration of follow-up was not long enough to verify the permanent effects of the intervention. Finally, the study was also designed as an open trial, which could reduce reliability due to the interference of objective elements (such as viewpoints of interviewers or dishonesty of patients). Therefore, a longer blinded trial may be necessary to overcome this issue.

CONCLUSION

The pharmacist-led educational intervention integrating face-to-face consultation and mobile phone counseling was demonstrated to increase QoL of asthmatic patients. It may be necessary to standardize these programs as routine health care to improve the quality of treatment.

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AUTHORS'CONTRIBUTIONS

Quynh Thi Huong Bui, Khoi Xuan Pham, Tien Hoang Tran, Ho Nhu Nguyen, and Lan Thi Tuyet Le conceived and designed the study. Khoi Xuan Pham, Tien Hoang Tran, and Quynh Thi Huong Bui performed the study. Quynh Thi Huong Buiand Khoi Xuan Pham analyzed the data. Quynh Thi Huong Bui, Khoi Xuan Pham wrote the paper. Quynh Thi Huong Bui, Ho Nhu Nguyen, and Lan Thi Tuyet Le revised the manuscript for important intellectual content. All authors read and approved the final manuscript.

CONFLICTS OF INTEREST

All authors approved the manuscript and this submission. The authors reported no conflicts of interest and no funding was received for this work.

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SUPPLEMENTAL TABLES

Supplemental Table 1: Effect of an intervention program on total QoL scores after 3-month follow-up with ITT analysis (n=342)

Factor	Beta	95% CI	p-value	
		Upper	Lower	
Intervention (yes)	0.474	0.830	1.214	< 0.001
Baseline QoL score	0.416	0.401	0.613	< 0.001
Age	0.016	-0.006	0.008	0.743
Gender (Male)	0.015	-0.167	0.235	0.741
Education level	0.057	-0.090	0.346	0.249
(University/College/Postgrad)				
Allergic rhinitis/sinusitis (yes)	0.106	-0.053	0.556	0.105
GERD (ves)	0.013	-0.202	0.262	0.799
Allergy (yes)	0.211	0.267	0.703	< 0.001
Comorbidities (yes)	-0.078	-0.638	0.169	0.253
Asthma severity	0.084	-0.006	0.199	0.066
Over weight/Obesity (yes)	0.081	-0.020	0.377	0.077
Baseline inappropriate inhaler	0.073	-0.054	0.599	0.101
technique				

GERD: Gastroesophageal reflux disease, CI: Confidence interval

Supplemental Table 2: Baseline characteristics of patients lost to follow-up and remaining after 3 months in the CG (n=161)

Characteristics	Overall (n=161) (%)	Group		p-value
		Loss to follow-up CG (n=65) (%)	3 rd month remaining CG (n=96) (%)	
Female	69.6	73.8	66.7	0.331
Mean Age	43.36±14.33	43.48±15.74	43.27±13.37	0.935
18-60	83.9	78.5	87.5	0.126
≥60	16.1	21.5	12.5	
BMI (kg/m ²)	22.64±2.80	22.17±2.34	22.95±3.04	0.155
Over-weight/Obesity	40.4	30.8	46.9	0.05
Education level				
Primary/secondary/High	68.3	69.2	67.7	0.839
school				
University/College/Postgrad	31.7	30.8	32.3	
Asthma severity (GINA 2016)	3.18±1.01	3.29±1.02	3.10±0.99	0.262
Comorbidities				
Yes	81.1	74.1	85.4	0.094
GERD	26	24.1	27.1	0.687
Allergic rhinitis/sinusitis	65.7	59.3	69.7	0.204
Allergy	34.2	32.3	35.4	0.683
Inappropriate inhaler	91.1	90.5	91.5	0.827
technique				
Baseline QoL scores	4.43±0.89	4.40±0.85	4.45±0.92	0.588

Mean age, body mass index, and asthma were compared between the two groups using the t-test. Rates of gender, age groups, overweight/obesity patients, education level, comorbidities, and inappropriate inhaler technique were compared using the Chi-square test. BMI: Body mass index, GERD: Gastroesophageal reflux disease