

Comparative adherence and quality of life studies to  
measure the impact of a novel patient education program  
for patients with chronic obstructive pulmonary disease

## Synopsis

Máté Oláh

Doctoral School of Pharmaceutical Sciences

Semmelweis University



*Supervisor:* Ágnes Mészáros, PharmD, PhD

*Official reviewers:* Csaba Máthé, MD, PhD

Adrienn Poór, MD, PhD

*Head of the Final Examination Committee:*

Imre Klebovics, PharmD, DSc

*Members of the Final Examination Committee:*

Kornélia Tekes, PharmD, DSc

Márta Péntek, MD, PhD

Budapest,

2020

## 1. Introduction

Chronic health-related conditions such as COPD have an enormous impact on the patient's quality-of-life, and result in increased utilization of health services. Patient education programs improve patients' health awareness and knowledge, symptom management, self-care practices and overall health status thereby reducing the propensity for negative outcomes and associated treatment costs. In recent years, there have been studies looking at the impact of patient education programs on QoL or adherence or both in patients with COPD.

Despite an enormous wealth of information on the effectiveness of patient education in the management of COPD in other parts of the world, there is a noticeable paucity of data from Hungary. Hence, the main goal of our study was to address these shortcomings and our primary objective was to assess the effect of patient education on medication adherence and QoL in COPD patients. We also sought to analyze whether demographic and subgroup parameters influenced adherence and QoL.

## 2. Objectives

The main goal of the dissertation is to provide guidance on the ideal patient education content, validate it in a real-life setting, and to elucidate its effect on patient-related outcomes. In subgroup terms, these are the following:

- (1) to assess the attitudes of two key players (patient, physician) in COPD patient care;
- (2) to conduct *pilot* studies to determine the optimal scenario to *go live* with the education project;
- (3) to investigate the effect of education on quality of life and adherence of COPD patients at different study sites by a different set of validated scales; and to investigate the longitudinal effects of education;
- (4) to propose the ideal conditions of education;
- (5) and to understand the background of adherence in a wider context of pulmonary conditions, including the different setting of cystic fibrosis.<sup>1</sup>

---

<sup>1</sup> In order to ensure brevity, the synopsis will focus on innovative content and original results. You are kindly invited to consult the thesis for further details on this section.

### 3. Methods

#### *3.1. Interview methodology*

We interviewed 20 pulmonologists who are involved in the care of COPD patients; they work in outpatient centers, hospitals and rehabilitation centers. An interview lasted 30 minutes and we examined three clusters of questions (education, patient profile and perceptions, adherence).

The interviews were prepared by a mixed method and recorded in writing. In addition to the semi-structured groups of questions, I tried to allow more space to physicians' views to develop, resulting in an overall shift towards in-depth interviewing methodology. We focused primarily on developing their own thoughts and perceptions, and in each case, we also recorded the specific terms used by the pulmonary therapists.

### *3.2. Study design and considerations*

This non-interventional, multicenter, longitudinal study was conducted between March 2016 and February 2017 at three pulmonology outpatient centers in and around Budapest, Hungary (district 13 and 19 in Budapest and Vác) in n=118 patients. Study subjects were patients visiting the center, having an established diagnosis of COPD by a pulmonologist, and providing an informed consent to participate in the study. Subject recruitment was random in the sense that every tenth patient visiting the center for consultation was invited to participate in the study and if eligible and providing consent, enrolled. In case the tenth patient was ineligible or refused consent, the next patient was invited and so on until a subject was recruited. Study subjects underwent two study visits – one at baseline and the other at follow-up approximately three months later. At baseline, subjects' sociodemographic and medical data was collected, subjects were asked to fill in the adherence, symptom perception, and QoL questionnaires, and patient education was provided. At the follow-up visit, subjects were asked to fill in the same

questionnaires again. Subjects' education level was assessed on a scale of three, ranging from basic to university level. Social status of the subjects as well as their perception on certain outcomes were self-reported.

The study was conducted in accordance with the principles stated in the Declaration of Helsinki (1961) and its subsequent revisions, Good Clinical Practice guidelines, as well as national laws. Prior approval of the study was obtained from the Semmelweis University Regional and Institutional Committee of Science and Research Ethics (241/2015).

### *3.2.1. Inclusion criteria*

Patients who had a diagnosis of COPD and signed a patient consent statement were selected for the study. Patients with the below conditions were excluded from the study:

- (1) barriers to completing the questionnaires (dyslexia, mental retardation, severe psychosis);
- (2) other untreated chronic conditions quality of life (heart failure, pulmonary fibrosis, ischemic heart disease);
- (3) exacerbation within less than 3 months;

(4) acute respiratory disease or tumor at the time of screening.

### *3.2.2. Patient education*

Nurses who had been previously trained to instruct subjects, conducted patient education, based on a fixed content, face-to-face on an individual basis. Subjects were encouraged to ask questions and provided with take-home lessons at the end of the session. By keeping the content same for all study subjects, we ensured uniform patient education, although by answering subjects' questions we also allowed for an individualized approach.

Education provided during personal meetings were reiterated through a short leaflet, which subjects took with them. Information contained in the leaflets was based on that provided by pulmonologists in a previous in-depth interview as well as systematic reviews. The leaflet contained the following key blocks: disease, treatment, and self-management.

### *3.2.3. Assessment questionnaires*

#### *3.2.3.1. Generic measurement tools*

The EuroQoL-5D-5L measures five parameters related to

health: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, each on an ascending scale peaking at 5, supplemented by a visual analogue scale.

#### *3.2.3.2.Disease-specific measurement tools*

The St. George's Respiratory Questionnaire (SGRQ) is a comprehensive scale that measures symptoms, activity, and impact scores.

The COPD Assessment Tool (CAT) is an 8-item questionnaire for assessment of symptoms. Patients rate their symptoms (cough, phlegm, tightness in the chest, etc.) on an ascending scale until five.

#### *3.2.3.3.Adherence algorithm*

The eight-item MMAS-8 has been widely used and recently validated through a meta-analysis for evaluation of adherence.



## 4. Results

### *4.1.Learnings from the interviews*

Interviews describe the following 5 main points that I have observed to develop the education content:

- (1) Fostering smoking cessation is a priority and should be a priority in the program;
- (2) Personal education (lung care, hospital or rehabilitation center) is preferred to education on the phone;
- (3) Content can be repetitive; should include a definition of the disease, symptoms, and information on the use of the drug;
- (4) It is necessary that the patient be familiar with the language of the education, so we have to use simple and easy-to-remember words;
- (5) Elements should be like a “fairy-tale”, like a short story to keep the patient focused and to let them fully internalize content;

## 4.2. Study results

### 4.2.1. Population demographics

The thesis provides an overview of the patient population from the demographic point of view. This has been omitted to ensure brevity.

### 4.2.2. Questionnaire scores

A comparison between baseline and follow-up scores for CAT, MMAS-8, EQ5D and SGRQ scales using the paired samples *t*-test. We noticed an overall increase in adherence with mean ( $\pm$  SD) MMAS-8 total scores increasing from 6.72 ( $\pm$  1.46) at baseline to 7.01 ( $\pm$  1.15) at follow-up ( $t = -2.073$ ;  $P = .040$ ). With respect to severity of COPD symptoms the improvement in CAT scores proved to be non-significant ( $t = -0.441$ ;  $P = .660$ ). There was no significant difference in the QoL (EQ5D;  $t = -0.784$ ;  $P = .435$ ) and general symptoms (SGRQ;  $t = -0.063$ ;  $P = .950$ ) scores between baseline and follow-up.

We also evaluated our data to identify the effects of gender, occupation, and education as inter-subject variables on the change in assessment scores. Due to smaller sizes of subgroups, we investigated only the main

effects while controlling for other independent variables as covariates.

Overall, we could not discern any significant association between gender and occupation on the change in total scores. Besides examining total scores, we looked at the pattern of individual questions of the questionnaires, and we identified a significant difference in two cases. Thus, we discovered that there is a difference between subjects based on their education level on the pattern of MMAS-8 scores by time [TIME(2)  $\times$  MMAS(8)  $\times$  EDUCATION(3)] ( $F = 2.364$ ;  $P = .005$ )., *Post hoc t*-tests showed a significant improvement in MMAS-8 scores in patients with basic education for questions M4 [ $t = -2.485$ ;  $P = .021$ ] and M8 [ $t = -1.766$ ;  $P = .046$ ].

We also observed a statistically significant difference between genders in CAT score patterns [TIME(2)  $\times$  CAT(8)  $\times$  GENDER(2)] ( $F = 3.138$ ,  $P = .005$ ). There was no significant difference in scores for any item on the CAT questionnaire in female subjects. In contrast, on *post hoc* analysis we noticed that in male patients, CAT6 (difficulties in leaving home) scores had increased significantly by the time of follow-up [ $t = -1.543$ ;  $P$

=.049]. On comparing the two groups (male vs. female) by independent sample *t*-test, the significant difference in CAT6 scores in between the genders was found to be only at baseline. This implies that male patients found their symptoms preventing them from leaving their home much less disturbing than female patients ( $t = -2.267$ ;  $P = .025$ ) at baseline, but by the time of follow-up this difference was not detectable ( $t = -0.159$ ;  $P = .312$ ).

## 5. Conclusions

### *5.1. Attitudes and perceptions*

The perception project has managed to meet the objectives that were observed previously. Conclusions to prepare the educational content, based on pulmonologist expert opinion, will be summarized in the following points:

- (1) As for patient profile, the COPD patient is under-socialized, breathless, coughing, smoking. Further implications include plain language, especially by including the words they use.
- (2) Patients should be educated from the basics, since awareness and disease acceptance are missing. Consequently, it is necessary to explain the acronym COPD, laying stress on the chronic component of the disease (e.g. medication cannot be stopped if symptoms are ameliorated); and to make sure about the relationship between smoking and COPD, and to promote smoking cessation.
- (3) The unambiguous symptoms of the disease, such are fatigue, coughing and breathlessness should be associated with it, and the education sessions should

explain how the treatment resolves these symptoms (consistent with the lack of disease coverage). Patients should understand what is the role of each medication (at least if it is a reliever or maintenance therapy), and the supremacy of long-term treatment over the frequent administration of the fast onset relievers.

- (4) Correct dosage, frequency, and proper inhaler use should be the part of everyday life. It should be clear that the lack of adherence is associated with more frequent GP visits and exacerbations, and the latter vastly deteriorates quality of life and long-term survival rates. Consequently, the patients has to know when to contact the doctor and when not to.
- (5) Bidirectional and open communication between patient and healthcare provider, and the question of trust have also appeared in the interviews, which elevate this process to a higher level. Patient engagement and self-management are fostered if the above are created and the patient is willing to take responsibility of their actions and willing to take care of themselves.

Patient interviews vastly reveal the missing concepts, lack of pragmatic knowledge and (non)-adherence data that should be tackled by in our education program. A patient education project was piloted in the community setting, and we will do our best to ensure the scientific support to its continuation. Furthermore, this study has the benefit to envision the three key intervention areas that should be targeted by an education program.

- (1) A relatively small number of COPD patients prefers the pharmacy to get education; however, those who come indeed, are motivated.
- (2) Patients get used to COPD, and they accept “that this comes by age”, “I cannot do this”, though all of them mentioned an activity they still wish to pursue.
- (3) Active listening to patient needs is an effective way to reveal important insight. Namely, asking semi-structured questions; and permitting them to talk about their issues helped us create the guidelines for such content they can benefit. Recording patients’ words and phrases also helps us to put together an easy-to-understand material with catchy content.

### *5.2. Impact of education on quality of life and adherence*

In conclusion, although we did not establish a clear relationship between patient education and QoL, we were successful in demonstrating an association in between patient education and medication adherence. Our research highlights the groups that are receptive to education and parameters that affect adherence in the environment of an outpatient pulmonology center, where the context is fixed, internal consistency of the education ensured, and patients continue with their medications for a period of three months. Patient education results in an improvement in adherence, especially in unique situations such as being away from home. Larger studies will be required to assess the adequacy of current patient counselling strategies and implement newer and improved policies to ensure successful self-management of COPD in Hungary.



### 5.3. Novelties

The *a priori* set research objectives have been met by the PhD research. The below points describe the novelties this work is adding to the body of scientific knowledge:

- (1) It has envisioned The Hungarian COPD patient profile by pulmonology in-depth interviews;
- (2) It has described the perceptions and attitudes of Hungarian pulmonologist related to COPD treatment and adherence;
- (3) It has created a patient centered education content that is tailor-made to the needs of Hungarian patients;
- (4) It has created the major guidelines, along which pulmonologists think that COPD patients can be educated (this provided a fix element to the education project);
- (5) It has initiated a local good practice in the Inczeffy Pharmacy in Göd with a *pilot* community pharmacy project to gather patient insight and information of the implementation of such an educational project in the pharmacy setting;
- (6) It has described attitudes and perceptions related of

Hungarian COPD patients related to COPD treatment and adherence;

- (7) It has performed impact studies in Hungary as a pioneer to demonstrate the impact of COPD patient education of a diverse set of quality of life and adherence questionnaires;
- (8) It has demonstrated significant correlation with total adherence and positive or significant correlation with dimensions of adherence (especially in unique situations such as being away from home, being more treatment-conscious and taking medication at 2 weeks after the medical visit);
- (9) It has provided a peer reviewed overview of challenges of CF treatment, along with an appraisal of adherence of respiratory conditions in a wider context.

## 6. List of publications

### 6.1. Publications relevant to the dissertation

- (1) **Oláh M**, Kresznerits Sz, Gonda X, Perczel-Forintos D, Szabó M, Csánky E, Mészáros Á. (2020) Impact of education on dimensions of adherence in patients with chronic obstructive pulmonary disease. *Acta Poloniae Pharmaceutica* 77: 195-204. **IF<sub>2018</sub>=0.447**
- (2) **Oláh M**, Kresznerits Sz, Perczel-Forintos D, Kun Cs, Csánky E, Mészáros Á. (2020) Egy oktatóprogram fejlesztésének lehetőségei tüdőgyógyász szakorvosok krónikus obstruktív tüdőbetegséggel kapcsolatos megítélése alapján [Aspects of developing an education programme based on pulmonologists' appraisal related to chronic obstructive pulmonary disease]. *Orvosi Hetilap* 161: 95-102. **IF<sub>2018</sub>=0.564**
- (3) **Oláh M**, Inczeffy-Ivicsics K, Mészáros Á. (2019) How to design an education programme for patients with chronic obstructive pulmonary disease? – Learnings from a pilot community pharmacy based project to evaluate patient

- attitudes. *Acta Pharmaceutica Hungarica* 89: 109-115.
- (4) **Oláh M**, Mészáros Á. (2017) Added value of different healthcare professionals, with special regard to pharmacists to COPD therapy experience. *Acta Pharmaceutica Hungarica* 87: 3-4
- (5) Bodnár R, Mészáros Á, **Oláh M**, Ágh T. (2016) Inhaled antibiotics for the treatment of chronic *Pseudomonas aeruginosa* infection in cystic fibrosis patients: challenges to treatment adherence and strategies to improve outcomes. *Patient Preference Adherence*. 10: 183-93. **IF<sub>2016</sub>=1.798**
- (6) Ágh T, Bodnár R, **Oláh M**, Mészáros Á. (2015) Adherence to Inhaled Antibiotics for the Treatment of Chronic *Pseudomonas Aeruginosa* Infection in Patients with Cystic Fibrosis: A Systematic Literature Review. *Value in Health* 18:7 (ISPOR reprint)