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Title: Can patients with COPD assimilate disease-specific information during an acute exacerbation? Results of a pilot randomized controlled trial.

Short title/running head: Brief education program post-AECOPD

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ABBREVIATION LIST

AECOPD – Acute Exacerbations of Chronic Obstructive Pulmonary Disease

BCKQ - Bristol COPD Knowledge Questionnaire

COPD - Chronic Obstructive Pulmonary Disease

LINQ - The Lung Information Needs Questionnaire

RCT - Randomized controlled trial

ABSTRACT

Background: The study aimed to determine the feasibility and effectiveness of an introductory disease-specific education program delivered during an acute exacerbation of chronic obstructive pulmonary disease (AECOPD) on objective measures of disease-specific knowledge.

Methods: Patients admitted to a community hospital with an AECOPD were randomly assigned to a control group (standard care) or intervention group (standard care + brief education). The intervention group received two 30-minute education sessions in hospital or at home within two weeks of hospital admission. Feasibility measures included the number of eligible patients, compliance with the sessions and number of follow-up measures completed. Disease specific knowledge and information needs were measured using the Bristol COPD Knowledge Questionnaire (BCKQ) and the Lung Information Needs Questionnaire (LINQ) respectively before and after the intervention period.

Results: Thirty-one patients (72±10 yrs) with an AECOPD participated in the study. Of 102 approached patients, 75 consented to screening (73.5%) and 67 (66%) were eligible for the study. Thirty-four patients declined participation. All intervention patients (n=15) completed the education sessions and follow up measures. Three patients (control group) did not complete the follow-up measures. The mean change and standard deviation (SD) for the BCKQ in the intervention and control groups were 8 ± 5.14 and 3.4± 4.9 respectively (p=0.02). No difference between groups was found for the LINQ (p=0.8).

Conclusions: A brief education program delivered at the time of hospitalization for an AECOPD was feasible for a subset of patients, resulted in improved disease-specific knowledge and may be a bridge to more active approaches.

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INTRODUCTION

Acute exacerbations of chronic obstructive pulmonary disease (AECOPD) are one of the most common reasons for emergency hospital admission[1] and are associated with high rates of re-hospitalization[2,3] and consequently responsible for a substantial healthcare burden.[4] As such, there is strong interest in any intervention that might reduce subsequent acute episodes. Professional respiratory guidelines strongly suggest that patient self-management be improved by providing simple education together with an action plan that includes responsibilities for ongoing care and advice on recognizing and managing future AECOPD.[5-7] Despite these recommendations, structured COPD-specific education is rarely offered within the acute care hospital setting and its impact is unclear. Moreover, there is limited information on whether in the peri-hospitalization period, patients with COPD are able to assimilate information regarding their disease.

Disease-specific education is an essential component of self-management.[8] In patients with stable COPD, disease-specific self-management has been shown to reduce all-cause hospitalization and all-cause emergency visits for a period of 2 years.[9] Brief education programs during hospitalization have been successful in improving the management of acute asthma and insulin-dependent diabetes.[10,11] A randomized controlled trial (RCT) of an education-self management program in adults admitted to hospital with acute asthma reported a reduction in post-discharge morbidity and readmission.[11] In insulin-dependent diabetes, a structured inpatient education program improved glycemic control and disease knowledge.[10]

In primary care, two hours of education regarding COPD increased objective measures of disease-specific knowledge assessed 1 month following the educational intervention.[12] However the impact of an education intervention during or immediately after hospitalization for an AECOPD has not been reported. While it is conceivable that during the peri-exacerbation period patients with COPD may be too dyspneic or too anxious to retain healthcare information,[13,14] being admitted to hospital might present an

opportunity for healthcare professionals to deliver an intervention that might reduce subsequent acute episodes. Patients may be more motivated to change their behaviour at a time of perceived vulnerability and may engage in an intervention that aims to improve their health. For example, smoking cessation programs initiated during hospitalization do promote smoking cessation.[15] The aim of this study was to determine the feasibility and effectiveness of an introductory disease-specific education program delivered during or shortly after an AECOPD on objective measures of disease-specific knowledge.

METHODS

Study design

A pilot RCT was performed and followed the CONSORT guidelines. Patients were randomized to a control group (usual care) or an intervention group (disease-specific education) using a computer-generated random number sequence. The randomization sequence was stratified according to the Modified Medical Research Council dyspnea scale[16] to minimize any potential confounding effect that severity of symptoms and functional limitations might have on patients' ability to participate in an intervention delivered when they are acutely unwell. The healthcare professionals were unaware of the group allocation. However, given that this study was carried out in the patient's room it cannot be guaranteed that no contamination occurred. The timeline of the study is presented in Figure 1. Ethics approval was obtained from the Research Ethics Board at Humber River Hospital (#2014-014-M).

Study population

Consecutive patients admitted with an AECOPD to the Humber River Hospital (Toronto, Ontario, Canada) were approached by a research staff over a period of 15 months (February 2015 and April 2016). The Humber River Hospital has two sites with a total of 260 medical beds and with 460 admissions per annum for exacerbations of COPD. Inclusion criterion was a medically confirmed diagnosis of an AECOPD as the main reason for admission. Exclusion criteria were: 1) admitted to hospital with lung

diseases other than COPD, 2) formal COPD education in the previous 6 months (e.g. as part of pulmonary rehabilitation), 3) any diagnosed cognitive impairment or perceived communication impairment that might prevent an effective understanding of the study or educational interaction, 4) repeat AECOPD admission if previously enrolled in the study.

Intervention Group

The intervention group received two, one-on-one 30-minute education sessions, provided by a physiotherapist with expertise in COPD. The first education session occurred within 7 days of hospital admission and took place either at the hospital (patients' room) or at home following their discharge. The second education session was offered within two weeks of admission (Figure 1). The following topics were addressed: (i) normal lung function, (ii) how COPD affects the lungs, (iii) symptoms and aggravating factors, (iv) importance of smoking cessation, (v) strategies for smoking cessation, (vi) respiratory medications and how to use them, (vii) identification of symptoms of an acute exacerbation, (viii) the role of pulmonary rehabilitation and (ix) the importance of maintaining an active lifestyle. The information was delivered using a written teaching manual that was adapted from the educational program used by Hill et al[12] which itself had been developed from the *Living Well with COPD* program.[17] The manual used minimal medical jargon and included many illustrations. After completion of the second education session, participants were given the manual for use at home.

Control group

Individuals allocated to the control group received usual care which included pharmacologic treatment and oxygen therapy as required. Whereas those in the control group may have received some disease specific education consistent with being attended by healthcare professionals, there was no access to any formal education program or certified respiratory educators at the study site. At the end of the study period, patients that were assigned to this group were provided with the above booklet.

Outcome measures

Feasibility measures

Program feasibility was reflected by: the number of eligible patients enrolled, timing of intervention sessions, baseline and follow-up measures as initially targeted, location of the intervention and follow-up sessions, compliance with the sessions and follow-up rates.

Knowledge and information needs

Disease-specific knowledge and information needs were measured using the Bristol COPD Knowledge Questionnaire (BCKQ)[18] and the Lung Information Needs Questionnaire (LINQ)[19] respectively. The BCKQ is a self-administered instrument that takes approximately 20 minutes to complete and includes 13 domains: (i) disease pathophysiology, (ii) risk factors, (iii) symptoms, (iv) causes of dyspnea, (v) sputum clearance, (vi) exacerbations, (vii) exercise, (viii) smoking, (ix) vaccinations, (x) bronchodilators, (xi) antibiotics, (xii) oral steroid therapy, and (xiii) inhaled steroid therapy. Each domain consists of five statements that the subject needs to identify as "true", "false", or "don't know". Correct answers are either "true" or "false" responses. The BCKQ is a valid, reliable and responsive questionnaire[18], scored at between 24 and 65 points, with no mark for an incorrect or "don't know" response.

The LINQ is a valid and reliable 6-minute self-administered questionnaire that measures the overall information needs of patients with COPD.[19] It includes questions about disease knowledge, medicines, self-management, exercise and diet and measures two types of information needs: (i) the patient communicates a need for information and (ii) the patient indicates a behaviour that is considered "incorrect" and may compromise self-management. The minimum score is zero and the maximum is 25, with higher scores indicating greater information needs.

The baseline BCKQ and LINQ were administered to the intervention and control groups immediately prior to randomization with follow-up testing scheduled at four weeks after randomization (which for intervention patients was two weeks after the last education session).

Descriptive Measures

At baseline, age, height, weight, sex, level of education and symptom severity (measured by the Modified Medical Research Council scale[16] were collected. Data on forced expiratory volume in one second (FEV_1) in percentage predicted and the ratio FEV_1/Functional Vital Capacity from the last 6 months were retrieved from the patients' charts. Number of comorbidities, duration of COPD diagnosis, previous AECOPD, emergency visits, hospitalizations were also collected.

Patient Satisfaction and Willingness to Participate in Pulmonary Rehabilitation

We assessed patient satisfaction from a short study specific questionnaire asking follow-up patients in the intervention group whether they would recommend the education program and how it might be improved. We also asked if they were willing to participate in a pulmonary rehabilitation program.

Sample size calculation and data analysis

Calculations indicated that a sample size of 30 participants (15 in each group) was required to detect a between-group difference of 8.3 points on the BCKQ using an unpaired *t*-test (80% power, alpha = 0.05). A difference 8.3 points was chosen as this difference had previously been demonstrated between patients with COPD who received and who did not receive education in a primary care setting.[12] The minimum clinically important difference for the BCKQ is not known.

Analyses were performed using the R programming language version 3.2.2. Differences in descriptive measures were examined using unpaired *t*-test for continuous variables and Fisher's exact test for

dichotomous variables. Between-group differences in the BCKQ and LINQ were examined using unpaired *t*-test respectively. P-values of less than 0.05 were considered significant.

RESULTS

A total of 102 patients were approached to participate in the study of whom thirty-one patients were randomized to either intervention (n=15) or control (n = 16) groups (Figure 2). All patients assigned to the intervention group completed the study. Of the 16 patients allocated to the control group, three withdrew before completing the study (two patients declined the follow-up visit for unknown reasons and one declined from the emergency room on the day of the follow up). The characteristics of the patients who completed the study are described in Table 1. No statistically between-group differences were noted in either the baseline characteristics (Table 1) or in the baseline data of the BCKQ and LINQ ($p = 0.76$ and $p = 0.70$ respectively).

Attendance and feasibility of the intervention

Out of the 102 patients approached, 75 (73.5%) consented to screening, 67 (66%) were eligible to participate in the study and 34 declined participation (Figure 2). Data regarding timing and compliance of the intervention sessions, baseline and follow-up measures are presented in Table 2. Twenty-nine (94%) out of the 31 included patients completed the baseline measures in hospital while two (6%) completed them at home after hospital discharge. Eleven of the 15 (73%) first education sessions were completed in hospital while 4 (27%) were completed after hospital discharge at patients' home. Seven of the 15 (47%) second education sessions were completed in hospital and 8 (53%) were completed at home. Twenty-two (71%) patients completed the follow-up measures at home and six (19%) completed the follow-up measures at the hospital during re-admission. Three patients (10%) out of the 16 randomized to the control group did not complete the follow-up measures.

Disease-specific knowledge and information needs

Compared with the changes observed in the control group (mean change 3.4 ± 4.9), the magnitude of change in the intervention group was greater for the BCKQ (mean change 8 ± 5.14) (p= 0.018) (Figure 3). The proportion of correct responses for each domain of the BCKQ is presented in Table 3. There was no between-group difference in information needs as measured by the LINQ (mean change: -1.6 ± 2.3 (control group) vs. -2.4 ± 2.7 (intervention group); p = 0.41) (Figure 3).

Patient satisfaction with the education program

When asked, 14/15 patients indicated that the program should be delivered to every patient admitted with an AECOPD, 13/15 patients indicated that nothing was required to improve the program with one suggesting decreasing the session time and one suggesting that we increase the number of questions.

DISCUSSION

A brief education program using minimal resources provided to patients hospitalized with an AECOPD proved to be feasible for a subset of patients and improved patient knowledge about their disease as measured by the BCKQ. These improvements in disease-specific knowledge indicate that patients were able to assimilate information about COPD during the peri-hospitalization period.

The delivery of the intervention was shown to be feasible, however, of the 102 patients approached for screening, 75 consented to screening, 8 were not eligible and 34 declined participation after screening. Although this has implications for the reach of this intervention, one third of those approached agreed to participate and those in the intervention group benefited, suggesting that it is still a worthwhile intervention for patients hospitalized with an AECOPD.

Another finding in support of study feasibility is the absence of drop outs. In the intervention group patients valued the education sessions, as confirmed by our satisfaction survey, and built rapport with the physiotherapist who delivered the intervention, making them more likely to complete the final measures. Only two dropouts occurred in the control group, who had signed consent and had

completed the baseline assessment. These observations are encouraging of a larger study evaluating an educational intervention post exacerbation.

Many of the patients who had consented to being screened (34/75) declined participation on medical grounds such as co-morbidities or repeat exacerbations, or social grounds such feeling that there was "too much going on," or because they had already received notification of hospital discharge and did not want to participate in a research study. This suggests that flexibility in terms of timing of delivery of the intervention, such as it being available on follow-up may enable more patients to participate.

The observation of an 8-point improvement in disease-specific knowledge is in keeping with the findings by Hill and colleagues[12] who noted a mean change of 8.3 points in patients who received a similar education program in a primary care setting. The change itself is relatively modest suggesting more frequent sessions might result in greater improvements. For example, White and colleagues[18] reported a mean change of 18.3 points in the intervention group in the BCKQ following an 8-week educational intervention as part of a pulmonary rehabilitation program. In contrast, in a self-management intervention delivered post-AECOPD that included a 176-page workbook, the mean change in BCKQ scores was 2.79 at 6 weeks and 3.21 at 6 months post-intervention.[20] Various factors make it difficult to compare the impact of educational interventions, especially when they are delivered as part of a broader combination of self-management intervention which includes self-assessment, goal setting and action plans rather than only disease-specific education. Alternatively, the modest improvements noted in some studies may be related to the patients' level of literacy.[21-24] Although our booklet used simple language, 53.3% of the patients in the intervention group had not completed high school and may have found the content difficult. Literacy carries a stigma and therefore patients may not have identified a lack of understanding of the material provided.[22,23] Eighty-seven percent (n=13) of the patients reported that nothing was required to improve the program. Although the intervention group included a higher proportion of patients with a low level of education, the increase in BCKQ

suggests that the intervention adequately targeted patients who may have had low health literacy. A larger sample of subjects would enable examination of the correlation between BCKQ improvement and level of education.

The greatest changes in knowledge in the intervention group were seen in the questions pertaining to the use of oral steroid medication which at baseline presented with the lowest scores in both groups. This highlights the need for an improved understanding of prescribed medications which may be of pharmacologic benefit in preventing and controlling exacerbations.[25]

The majority of the questions in the LINQ ask whether or not a doctor or nurse has explained a specific question to the patient. Since a physiotherapist delivered the program, had the wording been altered to include physiotherapists or a more general term for healthcare professionals, we may have seen a change in these results. Alternatively, if patients in the intervention group did still have needs for information at the end of the study, it may indicate that two sessions of 30 minutes were not sufficient to attend patients' learning needs. Other possibilities include that the knowledge items improved in the BCKQ did not fully meet the information needs of patients or that the study was underpowered to detect changes in the LINQ as the sample size calculation was based on the BCKQ.

Exacerbations have negative effects on physical[26-28] and mental function[26,29] in addition to the high cost of hospitalization.[2,3] Despite evidence that pulmonary rehabilitation post-AECOPD has a beneficial effect on function as well as a reduction in re-hospitalization,[30] referral rates are low and many patients decline enrollment.[31] In our cohort, when asked about pulmonary rehabilitation, 13/15 patients in the intervention group indicated that it was "too soon" to consider. There is good evidence that self-management education can influence exacerbation frequency but the designs and definitions of self-management remain heterogeneous and the programs usually last for several weeks.[32] Therefore, a brief education intervention may be part of a bridge to more active approaches, to be delivered when the patients have had greater recovery from the impact of the AECOPD.

Limitations of this study include the small sample size and absence of longer term follow-up. We were not able to evaluate the relationship between increased knowledge and changes in behaviour and are mindful of several other components such as motivation, self-efficacy and patient activation contribute to changes in behaviour. However, the between-group differences after only two 30-minute sessions support further investigation into the efficacy of disease specific education post-AECOPD. Another limitation was that the education sessions were offered as a research study, at a time when patients may not have felt receptive to enrolling. A clinical program offered at several locations, such as hospital, home or at the time of first follow-up with choices of delivery such as face-to-face or electronically might have attracted higher enrollment.

CONCLUSION

A brief education program delivered at the time of hospitalization for an AECOPD was feasible for a subset of patients and resulted in improved disease-specific knowledge. Early education may be a bridge to more active approaches and could provide an important contribution to self-management interventions post-AECOPD.

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Role of each author:

Dr. Tania Janaudis-Ferreira has made direct and substantial contribution to this work by participating in conceiving and designing the study; analyzing and interpreting the data; writing the manuscript and approving the final version of the manuscript.

Mrs. Jocelyn Carr has made direct and substantial contribution to this work by participating in collecting the data; analyzing and interpreting the data; providing critical revisions that are important for the intellectual content and approving the final version of the manuscript.

Dr. Samantha L. Harrison has made direct and substantial contribution to this work by participating in conceiving and designing the study; interpreting the data; providing critical revisions that are important for the intellectual content and approving the final version of the manuscript.

Dr. Andrea Gershon has made direct and substantial contribution to this work by participating in conceiving and designing the study; interpreting the data; providing critical revisions that are important for the intellectual content and approving the final version of the manuscript.

Mrs. Siobhan Milner has made direct and substantial contribution to this work by participating in interpreting the data; assisting with drafting the manuscript, providing critical revisions that are important for the intellectual content and approving the final version of the manuscript.

Dr. Sean Carr has made direct and substantial contribution to this work by participating in conceiving and designing the study; assisting with patient recruitment, interpreting the data; providing critical revisions that are important for the intellectual content and approving the final version of the manuscript.

Dr. David Fishbein has made direct and substantial contribution to this work by participating in conceiving and designing the study; assisting with patient recruitment, interpreting the data; providing critical revisions that are important for the intellectual content and approving the final version of the manuscript.

Dr. Roger Goldstein has made direct and substantial contribution to this work by participating in conceiving and designing the study; interpreting the data; assisting with drafting the manuscript, providing critical revisions that are important for the intellectual content and approving the final version of the manuscript.

Guarantor: Dr. Tania Janaudis-Ferreira has had full access to all of the data in the study and takes full responsibility for the integrity of all of the data and the accuracy of the data analysis, including and especially any adverse effects.

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FIGURE LEGENDS

Fig 1. Timeline of the study

Fig 2. Flowchart of the study

Fig 3. Results of the BCKQ and LINQ

Table 1. Characteristics of patients with COPD who completed the study.

Characteristics	Intervention Group (n = 15)	Control Group (n = 13)
Age (years)	71 ± 11	74 ± 10
Gender (M/F)	8M/7F	4M/9F
FEV_1 (% pred)*	45.25 ± 7.36	34.7 ± 23.8
FEV_1/FVC*	0.45 ± 0.09	0.46 ± 0.09
MRC	4 ± 0.8	4 ± 0.8
Pack years	52.4 ± 32	39.7 ± 11
Non-smoker	67%	85%
Time since COPD diagnosis (years)	5.36 ± 3.5	7.31 ± 7.9
Previous Exacerbations **No exacerbation :** **1-5 :** **>5 :**	 n = 1 (7%) n = 8 (53%) n = 6 (40%)	 n = 1 (8%) n = 6 (46%) n = 6 (46%)
COPD-ER visits in the last three years **No ER visits :** **1-5 :** **>5 :**	 n = 3 (20%) n = 11 (73%) n = 1 (7%)	 n = 3 (23%) n = 8 (62%) n = 2 (15%)
COPD hospitalization in the last three years **No hospitalization :** **1-5 :** **>5 :**	 n = 4 (27%) n = 11 (73%) n = 0 (0%)	 n = 3 (23%) n = 9 (69%) n = 1 (8%)
Number of comorbidities	6.27 ± 2.9	6.38 ± 1.98
LOS (days)	8.4 ± 5.50	5.9 ± 4.86
Level of Education	53.3 % did not complete high school 33.3 % completed high school 13.3 % completed college/university	31% did not complete high school 54% completed high school 15% completed college/university

Data are presented as mean ± SD unless otherwise stated.

Table 2. Feasibility measures

Feasibility variables	Intervention Group (N=15)	Control Group (n=16)*
Baseline measures completed	15 (100%)	16 (100%)
Follow-up measures completed	15 (100%)	13 (81%)
Both education sessions completed	15 (100%)	Not applicable
Time to baseline measures from admission (days)	4.33 ± 4.45	3.94 ± 3.77
Number of baseline measures completed within target (7 days of admission)	12 (80%)	15 (94%)
Time to first education session from admission (days)	7.2 ± 4.87	Not applicable
Number of first education sessions within target of 7 days of admission	9 (60%)	Not applicable
Time to second education session from admission (days)	9.6 ± 5.35	Not applicable
Number of second education sessions within target (14 days of admission)	12 (80%)	Not applicable
Time to follow-up measures from admission (days)	30.07 ± 4.91	30.58 ± 4.44
Number of follow-up measures within target (28 days of admission)	7 (47%)	5 (42%)

*Sixteen patients were randomized to control group and completed the baseline measures and 13 completed follow-up measures.

Table 3. The proportion of correct answers in each domain of the BCKQ per group at baseline and after the intervention period

	Intervention Group (n=15)			Control Group (n=13)		
BCKQ-Domain	Percentage of correct responses (Baseline)	Percentage of correct responses (Post)	Mean difference (%)	Percentage of correct responses (Baseline)	Percentage of correct responses (Post)	Mean difference (%)
Disease Pathophysiology	**47%**	**52%**	**5%**	**40%**	**43%**	**3%**
Risk Factors	76%	79%	3%	65%	78%	13%
Symptoms	**60%**	**72%**	**12%**	**55%**	**62%**	**7%**
Causes of Dyspnea	48%	60%	12%	49%	48%	-1%
Sputum Clearance	**61%**	**69%**	**8%**	**69%**	**65%**	**-4%**
Exacerbations	61%	72%	11%	51%	51%	0%
Exercise	**52%**	**68%**	**16%**	**62%**	**66%**	**4%**
Smoking	64%	61%	-3%	60%	69%	9%
Vaccinations	**53%**	**65%**	**12%**	**65%**	**69%**	**4%**
Bronchodilators	43%	57%	14%	49%	58%	9%
Antibiotics	**43%**	**51%**	**8%**	**49%**	**51%**	**2%**
Oral Steroid Therapy	35%	68%	33%	26%	40%	14%
Inhaled Steroid Therapy	**11%**	**57%**	**46%**	**26%**	**35%**	**9%**

Total possible number of correct responses per domain is 5. In the intervention group, since n= 15, the total number of possible correct answers is 75. In the control group, since n = 13, the total number of possible correct answers is 65.