Effectiveness of discharge-coordinator intervention in patients with chronic obstructive pulmonary disease: study protocol of a randomized controlled clinical trial

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Summary

Background: Chronic obstructive pulmonary disease (COPD) follows a slowly progressive natural course that can be accelerated by acute exacerbations, which frequently trigger admissions to hospital. Specific healthcare professional profiles such as that of discharge coordinator have been successful in reducing numbers of hospitalizations and need for medical care in patients with various chronic diseases, but data for COPD are sparse and inconclusive. This study was conceived to test whether coordinated discharge and post-discharge care could reduce re-hospitalizations and use of resources in patients with COPD.

Methods/Design: This ongoing single-center randomized controlled clinical trial, which began in November 2009, is enrolling COPD patients in Global Initiative for Chronic Obstructive Lung Disease (GOLD) stages II–IV, hospitalized because of acute exacerbation. Patients are randomized in a 1:1 fashion to the intervention group, which has care organized by a discharge coordinator, and a control group receiving the usual care. The primary endpoint of the study is the number of patients hospitalized because of worsening of COPD. Data are collected at baseline, at the time of hospital discharge, and at the following time-points after discharge: 48 hours, 7–10 days, 30 days, 90 days, and 180 days.

Discussion: In COPD patients requiring hospital admission, coordinated discharge appears a feasible option for improving patient and healthcare system-related outcomes. This study will provide evidence on the effectiveness of a discharge coordinator in patients hospitalized because of acute exacerbation of COPD and may give relevant guidance for implementation in clinical practice.

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Background

Chronic diseases are the leading cause of morbidity and mortality in Europe, and research suggests that they will impose an even larger burden in the future. Among such diseases, chronic obstructive pulmonary disease (COPD) contributes significantly to disability and high death rates in the adult population and should therefore represent a major public health concern. In addition to the considerable health burden, COPD also incurs substantial social and economic costs. COPD follows a slowly progressive natural course that can be accelerated by acute exacerbations, which frequently trigger admissions to hospital. This sets the stage...
for a downward spiral where patients are experiencing breakdowns in care during multiple transitions from hospital to home. Such a patient journey also impairs the already reduced health-related quality of life and translates to about 1% of available healthcare resources. Effective management strategies to prevent patient deterioration are therefore essential and represent one of the key areas of research. With lack of any clear survival benefit, pharmacological interventions primarily serve to control symptoms and only a modest additional benefit from ongoing or planned studies is expected in future years.

Non-pharmacological interventions focusing on tailored care and management are much less investigated, despite that they are likely to have considerable potential in patients with COPD. To date, various strategies and interventions for managing acute exacerbation of COPD have been studied. Exacerbation prevention programs and immediate (hospital at home) or early-assisted hospital discharge schemes are applicable to patients with stable disease or with mild-to-moderate worsening of COPD and have shown reduction of healthcare utilization. Patients with more severe deterioration have considerably increased demand for care during hospitalization and at discharge. When in hospital, patients may be more receptive to non-pharmacological interventions, and ample opportunity exists for inclusion of patients and caregivers in management planning and implementation. Specific healthcare professional profiles such as that of discharge coordinator have been successful in reducing re-hospitalizations and need for medical care in other chronic diseases.

In COPD, the information on coordinated discharge appears positive, but the intensity, design and setting of the intervention to obtain maximum clinical benefit is not clearly defined. This study was conceived to test whether coordinated discharge and post-discharge care could reduce re-hospitalizations and use of resources in patients with COPD.

Methods/Design

Study design

This is an ongoing single-center randomized controlled clinical trial to assess the effectiveness of discharge-coordinator intervention in comparison with usual care in patients with COPD. Figure 1 summarizes the study design.

Study participants and setting

The study, which began in November 2009, is being conducted at the University Clinic of Pulmonary and Allergic Diseases Golnik, Slovenia. Patients with suspected acute exacerbation of COPD are screened on admission and informed about the details of the study. After explanation of any concerns and questions that they might have, signed informed consent is collected from each patient. During hospitalization, visits by a discharge coordinator are scheduled according to the patients' problems and homecare needs. At 48 hours after hospital discharge, a discharge coordinator contacts the patient by phone to check the process of adjustment to the home environment and to inquire about any additional needs. Thereafter, phone contacts are scheduled according to the patients' needs, and 7-10 days after hospital discharge a discharge coordinator makes a home visit.

The activities of the discharge coordinator are discussed with the attending physician and nurse as appropriate and have the following objectives:

1. to ensure patient education about COPD and self-care in order that the patient has sufficient knowledge and skill to manage their disease,
2. to include the patient's relatives and caregivers in the education and disease management process,
3. to communicate the discharge planning with the patient in order to stimulate active participation of the patient and their relatives/caregivers,
4. to assess the patient's home-care needs for effective self-care when back in the home environment,
5. to make contact with the community care/home-care nurse, general practitioner, social care worker, physiotherapist, and other providers of home services as appropriate, and

Fig. 1. Study flow-chart.

if they die during hospitalization, or if they are unable to follow the study protocol.

Randomization of patients, using Random Allocation Software Version 1.0, 2004, was performed by a person unrelated to the study. Study personnel have been given consecutively numbered sealed envelopes and patients are assigned to intervention or the control group according to their sequence of entrance.

Intervention

In the intervention group, a discharge coordinator contacts hospitalized patients the day after allocation to the group. During hospitalization, visits by a discharge coordinator are scheduled according to patients' problems and homecare needs. At 48 hours after hospital discharge, a discharge coordinator contacts the patient by phone to check the process of adjustment to the home environment and to inquire about any additional needs. Thereafter, phone contacts are scheduled according to the patients' needs, and 7-10 days after hospital discharge a discharge coordinator makes a home visit.

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Table 1
Summary of key inclusion and exclusion criteria

<table>
<thead>
<tr>
<th>Key inclusion criteria</th>
<th>Key exclusion criteria</th>
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<tbody>
<tr>
<td>Age &gt;35 years</td>
<td>Diagnosis of cognitive impairment</td>
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<tr>
<td>Acute exacerbation of COPD stage II–IV</td>
<td>Unstable or terminal disease other than COPD</td>
</tr>
<tr>
<td>Residence in the geographical area linked to the study hospital</td>
<td>Withdrawal of written informed consent before discharge</td>
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<tr>
<td>Ability to communicate by phone</td>
<td>Inability to deal with phone contact</td>
</tr>
<tr>
<td>Written informed consent given</td>
<td>Death during hospitalization</td>
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</tbody>
</table>

COPD: Chronic obstructive pulmonary disease.

(6) to provide continuity of care and care coordination across different levels of healthcare.

Patients in the control group have their disease managed by the attending physician, primary care physician, and/or pneumologist in accordance with established clinical practice. In both groups, patients are followed for 180 days.

Data collection and study variables
Data are collected at baseline, at the time of hospital discharge, and then at 48 hours, 7–10 days, 30 days, 90 days, and 180 days after hospital discharge. Patients are contacted by phone at 48 hours, 30 days, and 90 days, and are visited at home at 7–10 days and 180 days after hospital discharge.

Healthcare utilization and healthcare costs
Healthcare utilization is assessed at 7–10 days, 30 days, 90 days, and 180 days after hospital discharge. Patients and/or their caregivers are asked about all contacts with the healthcare system. The information obtained is verified against medical documentation. Ambulatory visits at primary and secondary level are screened for acute exacerbations of COPD. Hospital records are screened for ambulatory visits and hospitalizations.

Healthcare costs per patient in the two groups will be estimated using the current rates for healthcare utilization as provided by the insurance companies.

Mortality
Mortality is assessed at 7–10 days, 30 days, 90 days, and 180 days after hospital discharge. If study personnel fail to contact a patient at a scheduled time-point, relatives and/or caregivers are asked about the vital status. Mortality data are verified with the Central Population Registry.

Health-related quality of life
Health-related quality of life is assessed using a standardized self-completed questionnaire (St. George’s Respiratory Questionnaire) for measuring impaired health and perceived well-being in patients with mild-to-severe airway obstruction disease. Data are collected at 7–10 days, 30 days, 90 days, and 180 days after hospital discharge.

Dyspnea
Patients’ level of dyspnea is assessed at the time of hospital discharge, and at 48 hours, 7–10 days, 30 days, 90 days, and 180 days after hospital discharge, using the modified Medical Research Council dyspnea scale. This is a simple, standardized, self-administered 5-point scale that quantifies the effect of breathlessness on daily activities and thus measures perceived respiratory disability.17

Care dependency level
The level of dependency of patients is assessed at 48 hours after hospital discharge using the Care Dependency Scale, which can be used as a tool for case-finding and assessment of needs in the first stage of the nursing process. The scale indicates the level of care needed to help the patient regain some of their self-care abilities.18

Depression
For assessment of the presence and degree of depressive symptomatology, the Center for Epidemiologic Studies Depression Scale is used at 7–10 days and 180 days after hospital discharge. This instrument is a freely available and widely used 20-item self-report scale with emphasis on assessment of depressed mood during the previous week.19

Sociodemographic characteristics
Data are collected at baseline using a questionnaire developed specifically for the purpose of this study. We collect information on age, sex, educational level, marital status, job situation, and living conditions.

Clinical characteristics, investigations and measurements
Medical records are reviewed for information on COPD onset and severity, smoking status, body weight, height, waist circumference, and concomitant illness. Body mass index is calculated (body weight in kg/square of body height in m).

During hospitalization patients undergo blood pressure measurement, chest X-ray, pulmonary function testing, electrocardiogram, echocardiography, body composition assessment with bioimpedance, and exercise capacity testing.

For laboratory investigations, blood is collected on admission, at hospital discharge, and at 7–10 days and 180 days after discharge.

Pharmacological treatment, including exact dosing and application, is obtained from medical records and at all contacts with the patient.

Study endpoints
The primary endpoint of the study is the number of patients hospitalized because of worsening of COPD. Hospitalization is defined as an unplanned overnight stay in hospital (different dates for admission and discharge) because of acute worsening of COPD. Key secondary endpoints are the time to hospitalization due to COPD worsening, all-cause mortality, acute exacerbations of COPD, days alive and out of hospital, health-related quality of life, and healthcare costs.
Endpoints are assessed at regular study contacts by a study nurse blinded to patient allocation. In addition, endpoints are determined from review of medical records in the electronic database, by contacting the patients and/or their relatives, and by inquiry about vital status at the Central Population Registry.

**Statistical considerations**

**Sample size**
A review of the literature has shown a 40% short-term hospitalization rate in patients admitted because of COPD exacerbation. We assume that our study intervention will reduce the hospitalization rate by 15%, thus 306 patients would be required for detection of a difference between the groups at a two-sided significance level of 0.05 and with 80% power. However, if a 20% follow-up loss rate is expected, the necessary sample size is 184 patients per group or a total of 368 patients. Hospital statistics at the University Clinic of Respiratory and Allergic Diseases Golnik indicate that we expect to enroll four patients per week.

**Statistical analysis**
The primary endpoint will be analyzed according to study group allocation using the intention-to-treat principle, and ignoring potential interventions in the control group during follow-up. Time-to-event data will be analyzed using Kaplan-Meier plots, and log-rank tests will be used to compare different management strategies. A Cox model of proportional hazards will be built for a multivariate analysis. Results will be presented as hazard ratios with corresponding 95% confidence intervals. Descriptive statistics will include median values with interquartile range, mean value ± standard deviation, and absolute numbers and proportions as appropriate. To evaluate the differences between variables, the Student’s t-test, chi-squared test, Mann Whitney U-test, and paired t-test will be used. For the multivariate analysis, linear and logistic regression models will be built. Results will be presented as odds ratios and 95% confidence intervals.

The software package SPSS 17.0 (Statistical Package for Social Sciences Inc., Chicago, IL, USA) will be used for data collection and all calculations. For all tests, a p-value ≤ 0.05 (two-sided) will be considered statistically significant.

**Ethical considerations**
Participation in the study is voluntary and confidentiality of the study participants will be protected. Written informed consent will be provided by all patients prior to any study-related procedures. The study protocol was approved by the National Medical Ethics Committee of the Republic of Slovenia in 2009.

**Current status of the study**
Enrollment of patients began in November 2009. As of January 2011, 203 patients have been enrolled. The estimated date for study completion is November 2011.

**Discussion**
Studies on disease management in COPD are rare and there is no gold standard for discharge coordination and management in the outpatient setting. Further, patient populations, the type and duration of intervention, and the settings have been importantly different between studies, thus no general advice for clinical practice can be given. As a consequence of the lack of evidence, the GOLD guidelines are nonspecific and additional research in the field is urgently needed.

Chronic diseases can rarely be cured and at present our goal remains the optimal control and stability of disease. COPD shares typical features with other diseases of its kind. Patients are frequently older, with several concomitant illnesses, in need of social and medical care, and with insufficient social support. In such a frail population, COPD has a significant impact on a patient’s health-related quality of life and outcome. Deterioration caused by acute exacerbation is the most common respiratory condition dealt with in emergency departments and often requires hospital admission. Many episodes could be prevented provided that patients were capable of managing the disease within the limits of their performance and ability. Most COPD patients have considerable potential to improve their knowledge, skills, and self-care management strategies. As in other chronic conditions, assessment of a patient’s situation and inclusion of the patient in the decision-making process can decrease the burden of morbidity and improve outcome.

Exposure to the healthcare system, particularly hospitalization, drives the increasing cost of COPD management. Several strategies focusing on tailored care have been tested in COPD exacerbations. These include an exacerbation prevention program and immediate or early/assisted hospital discharge schemes, although the latter are applicable only to patients with less severe deterioration. It is well accepted that patients with the highest demands and highest risk of repeated hospitalization are those with advanced disease and those in need of hospital care. Such patients would also benefit most from specific interventions but evidence from properly designed and conducted trials is sparse and inconclusive.

Transitional care has been defined as a set of actions designed to ensure the coordination and continuity of healthcare as patients transfer between different locations or different levels of care in the same location. Potential solutions for improving the quality of transitional care must be found. In patients requiring hospital admission, coordinated discharge appears a feasible option for improving patient and healthcare system-related outcomes. The discharge process is a key element in the healthcare continuum. Discharge coordination and support for COPD patients is an important issue in minimizing the impact of the acute episode and preventing future relapses. During hospitalization, a thorough evaluation of the patient’s knowledge of the disease and ability to perform self-care activities, together with inclusion of caregivers, should be mandatory. Importantly, when experiencing potentially life threatening situations, uncontrolled dyspnea, and reduced physical performance, patients may be more receptive to management planning and active involvement. Patients should be educated about skills and measures to increase their confidence about decision making once COPD deterioration is anticipated or even present. The discharge coordinator has sufficient time and resources to make the transition from hospital to home easier and more patient-friendly. This provides a unique opportunity to
coordinate between secondary and primary care, involving other services to make disease management for patients and/or caregivers easier and feasible.

The significant potential for improving COPD management through coordinated discharge in patients admitted with COPD exacerbation is based on experience with other diseases. To determine the modality, extent, intensity, and applicability to COPD clinical practice, appropriate studies are necessary. Interest in the field has been stimulated by previous and ongoing research, and the results of our own and other ongoing trials should provide relevant guidance for implementation in clinical practice.

**Conflict of interest statement**

The authors declare that they have no competing interest.

**Authors’ contributions**

JF, ML and SK designed the study and wrote the initial protocol. JF and ML drafted the manuscript. SK and ML are coordinating the study with supervision from MK. All authors read, provided comments and approved the final version of the manuscript.

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**References**


