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Lay Summary

Can early introduction of specialized palliative care limit intensive care, emergency and hospital admissions in patients with severe and very severe COPD? A randomized study

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1. Background

Chronic obstructive pulmonary disease (COPD) is a progressive lung disorder which evolves over several decades, and leads to increasing shortness of breath and impairment in activities of daily life, and exacerbations (aggravations) which may require hospitalizations. COPD results from either environmental exposure to pollutants or most often, exposure to tobacco smoke. It is presently the fourth leading cause of mortality and the 12th leading disability worldwide. Rates of mortality reach 36–50%, within 2 years after admission for an acute exacerbation. One out of eight hospital admissions in the UK per year are related to COPD with approximately 30% of patients admitted with COPD for the first time being re-admitted within 3 months.

While treatment with bronchodilators and corticosteroids may partially relieve symptoms and noninvasive ventilation (NIV: respiratory support provided through a nasal or facial mask and a device which insufflates intermittent positive pressure in the airways to decrease work of breathing) and/or oxygen therapy may prolong life, for many patients the course of the disease is one of inexorable decline: a prolonged period of disabling dyspnoea (shortness of breath) and increasingly frequent hospital admissions reflecting deteriorating lung function and usually presaging a premature death. It has long been recognized that, in this group of patients, both quality of life and survival is poor. For instance, in the Nocturnal Oxygen Therapy trial of long term oxygen therapy, one of 2 studies which showed in the early 1980's the positive impact on survival of using home oxygen for at least 15 hours/day in very severe COPD, disturbances in emotional (anxiety and depressive disorders) and social functioning (mainly social isolation) were common and there was a marked impairment in activities of daily living.

Despite these observations, the needs of these patients are typically poorly addressed, and many patients have limited access to specialists in palliative care services. Palliative care teams are best known through their clinical contribution in the field of oncology (cancer), but their holistic and symptom-based approach is perfectly appropriate for chronic disorders with a poor prognosis such as COPD. However, no early palliative care interventions studies are available for this particular population. Data from the UK suggest that patients with COPD are much less likely to die at home and to receive palliative care services than patients with lung cancer, although their life expectancy is quite similar, as is the distress related to their symptoms. Many studies have documented the burden of symptoms among patients with COPD. Although anxiety and depression are common in COPD, they are often not well recognized or treated, despite the fact that antidepressants can significantly improve mood among patients with COPD and depression.

Studies have also shown that only a minority of patients with moderate-to-severe COPD has discussed treatment preferences and end-of-life care issues with their physicians and most believe that their physicians do not know their preferences for end-of-life care. This leads to an unnecessarily high rate of admission to emergency wards, to intensive care units, to “aggressive” medical management such as mechanical ventilation (using a machine to support the work of breathing, either through a nasal or facial or mask, or through as tube placed in the patients’ airways – which requires a sedation), within the last months of patients with severe COPD, when compared for instance to cancer patients. Furthermore, in this “acute care” setting, control of symptoms such as shortness of breath, or pain is often suboptimal. A few studies suggest that both patients and their families or caregivers would prefer a different, more symptom-based, or comfort-based, and less aggressive medical management in the end of life period.

Advance directives – i.e. defining the patients’ desire as to the type of care he or she wishes to receive in an acute situation - may be especially useful among patients with COPD because of their likely trajectory of illness, with unpredictable exacerbations that may render them suddenly critically ill. Some patients with COPD have strong feelings about the situations in which they would want to forego cardio-pulmonary resuscitation (CPR) or, particularly relevant for COPD, mechanical ventilation for acute respiratory failure. Hospital admissions, especially when leading to the ICU are *per se* a source of anxiety, stress and distress.

To date, no early palliative care interventions studies are available for this particular population. Self-management strategies for COPD patients provided by a trained health professional can significantly reduce the utilization of health care services and improve health status. This approach of care can be implemented within normal practice.

2. Goals of the project

Our hypothesis is that the early introduction of specialized palliative care could decrease the use of intensive care units and hospital and emergency admissions of patients with severe and very severe COPD.

1. The primary objective of the study is to assess the effectiveness of the introduction of early specialized palliative care on hospital, intensive care unit and emergency admissions of patients with severe and very severe COPD

Secondary objectives were to measure:

2. the impact of early palliative on care on the mood and anxiety of patients with severe and very severe COPD
3. the impact of early palliative on the health-related quality of life of patients with severe and very severe COPD (i.e. the component of quality of life which relates to the medical condition of the patient, which is evaluated through specific validated scores).
4. the impact of early palliative care on the pattern of antibiotics used during the last month of life
5. the impact of early palliative care on advance care planning and end-of-life decision-making

3. Methods

The design of the study is that of a randomized controlled trial of [early palliative care combined with standard care] versus. [standard care alone].

The inclusion criteria were:

- COPD stage III or IV (FEV_1 < 50% predicted) defined according to GOLD (Global Initiative for Obstructive Lung Diseases; www.goldcopd.org) criteria (FEV_1/FVC < 70%: tests performed in a pulmonary function laboratory)

and/or

- Long term treatment with either domiciliary oxygen or home mechanical ventilation

and/or

- One or more hospital admissions in the previous year for an acute exacerbation

Exclusion criteria were mainly:

- Moderate or severe cognitive impairment (using the MMSE: Mini Mental State Examination score: a test for the detection of cognitive impairment or dementia; threshold value <23)

After giving written informed consent, patients were randomly (i.e. by chance) allocated to the “early palliative care” group or the “standard care only” group.

Intervention

Patients assigned to the early palliative care group met a nurse attached to the community ambulatory palliative care unit of Geneva University Hospitals (USPC) within three weeks of inclusion and then monthly thereafter for one year after inclusion.

The palliative care consultation focused on:

- Symptom management:
  - Assessment of symptoms with the Edmonton Symptom Assessment Scale (visual analog scales to measure 8 different important symptoms)
  - If intensity of pain, dyspnea, mood, anxiety and appetite are >4/10 and patient agreed: a consultation with a physician specialized in palliative care or other specialist was organized.
- Understanding of illness and coping with the disease was discussed
- Anticipation, decision-making, namely:
  - Completion of advance directives/advanced care-planning will be promoted.
  - Preferred place of care-death
- Support of relatives
- Social-spiritual needs
- Coordination between different health providers

Patients randomized to the control group did not meet with the palliative support team. All patients received standard care throughout the study period.

Measures

Baseline characteristics of the participants (such as: age, sex, having a partner, education and clinical characteristics, smoking habits, respiratory condition and symptoms, current medical condition and treatment, medical history) were measured and recorded.

Concerning the primary outcome, Hospital, ICU and emergency admissions were collected in both groups form the medical records once a month. Location and date of death was also collected.

Concerning the secondary outcomes of the study:

- The mood and the anxiety of the patients was measured with a self-assessment instrument: the Hospital Anxiety and Depression Scale (HADS) at 12, 24, 36 and 48 weeks after inclusion.
- Quality of life was measured with the SF-36 short form: a self-assessment scale validated in this population and the COPD Assessment Test (CAT): a short, simple instrument for quantifying the symptom burden of COPD in routine practice 12, 24, 36 and 48 weeks after inclusion.
- The prescription of antibiotics during the last month of life was collected
- Completion of advance directives, or documented preferences for resuscitation and location of death was collected from the medical records once a month.

4. Results

In spite of a prolonged recruitment period, and extension of screening for patient inclusion to private GPs, private pulmonologists, to another hospital belonging to the HUG complex (Geriatric ward), and increasing the availability of research nurses for inclusion, of the anticipated 160 patients, only 51 were finally included *(315 patients were screened for study inclusion)*. Of these, 1 died before the initial evaluation, and another subject refused the result of the randomization. Thus, results were based on 49 patients (23 in the control group, 26 in the early palliative care group).

Major reasons for difficulties encountered for study inclusion were: patient refusal (43%), cognitive disorders in patients screened (23%), co-morbidity limiting life expectancy (i.e.: cancer: 20%).

Patients were aged on average 71±8 years, on long term home oxygen therapy or non-invasive home mechanical ventilation (69%), most often with a higher level of education (67%), smokers (89%; 33% still active). All had a very severe respiratory limitation as assessed by the COPD assessment test (CAT: 88% scored > threshold value of 10).

HAD scores showed that 26% had anxiety disorders, and 16%: depression. For all items, socio-demographic and functional parameters, as well as score values at inclusion, there were no statistical difference between groups (which means that the randomization process worked correctly). Health related quality of life scores (SF-36) were markedly decreased (i.e.: worse than the general population) especially for items: “vitality”, “general health”, and “physical function”. Longitudinal follow-up of scores of quality of life, anxiety, and depression did show any visit or group effect: i.e. there was no difference between subjects with versus without the palliative care intervention. Number of exacerbations, emergency hospital admissions, and admissions to the Intensive Care Unit (ICU) did not differ between groups. There was a trend which just fell short of statistical significance for more frequent advanced care planning in the intervention group.

5. Significance of the results for science and practice

This study did not show any impact of monthly home visits by palliative care specialists over a 12-month intervention period, when compared to usual care, on exacerbations leading to hospital, emergency ward or ICU admission, in patients with severe and very severe COPD, most of whom were treated either with home oxygen or home mechanical ventilation. Scores for health related quality of life and emotional disorders evolved similarly during the study period in both groups. This study also demonstrated that it was much more difficult than anticipated to recruit patients for this type of evaluation (16% of 315 patients screened) in spite of an excellent knowledge of this population by the research team. Because the target number of subjects was not reached, our study does not have the power to exclude an impact of the palliative care intervention: this finding may result from too small sample sizes. The only clear trend was that of more frequent advanced care planning in the “intervention” group.

It seems quite possible that the impact of the palliative care intervention may have been masked by the already existing health care network supporting study patients (pulmonologists, specialized nurses for oxygen and/or home ventilation, home care nurses, physiotherapists and other care-givers), thus making it difficult to measure a “signal” on the different endpoints chosen.

Because of the importance of improving end-of-life care in severe COPD, further larger studies must be designed to explore whether there is a potential benefit of a palliative approach in this setting, and how this approach should best be implemented.