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# Re-admission and quality of life among patients with chronic obstructive pulmonary disease after telemedicine video nursing consultation - a randomized study

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ABSTRACT

**Background:** Our previous study showed a reduced cumulative length of re-admission stays due to chronic obstructive pulmonary disease (COPD) exacerbations during one year after telemedicine video consultation (TVC). The current study evaluated the effects of TVC on the length of re-admission stays within 12 months follow up post-TVC compared to phone call follow up or COPD usual care in a randomized study. Our secondary aim was to assess the impact of TVC on the frequency of re-admissions within 12 months of follow up. Patient satisfaction, hospital anxiety and depression scale (HADS) and COPD assessment test (CAT) scores were also evaluated.

**Methods:** The study was a prospective randomized study of COPD patients who after hospital discharge for acute COPD exacerbations, were randomized to monitoring by TVC at home compared to phone call follow up for two weeks by a specialist nurse at the hospital or usual COPD care. Prospectively, we compared the cumulative durations and frequencies of hospital re-admissions due to COPD exacerbations within 12 months follow up after TVC, phone call follow up or usual COPD care.

**Results:** Among 173 COPD patients followed for 12 months, 99 were re-admitted. The median cumulative length of re-admission stays per patient within 12 months post-TVC did not differ from those followed by phone calls or with usual COPD care. The number of patients re-admitted and the number of re-admissions due to COPD exacerbations were also equal in the three groups. Patient satisfaction was high among those followed by TVC and phone calls, and the HADS and CAT scores favorably declined from baseline to post-intervention in patients followed by TVC and phone calls.

**Conclusions:** The study could not demonstrate a beneficial effect of TVC on the cumulative length of re-admission stays or on the number of re-admissions within 12 months following an acute COPD hospital stay, as compared to those followed by phone calls or with usual COPD care. Patient satisfaction was high among those followed by TVC and phone calls, and the declines in HADS and CAT scores seem to be consequences of increased empowerment and competence for good self-care in COPD patients, remaining through the one-year observation period.

**Key words:** COPD; telemedicine video-consultation; hospital readmission stays; quality of life.

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**Ethics approval and consent to participate:** This study was approved by the Regional Board of Research Ethics in Norway (Committee's reference number: 2013/1886/Rek sør-øst). All participants signed a written informed consent to participate prior to the study.

**Consent for publication:** Written informed consent for the publication of study results was obtained from all participants.

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## Introduction

Chronic obstructive pulmonary disease (COPD) is a progressive lung disease causing significant and lasting morbidity, disability and increased mortality [1]. Acute exacerbations are common and require frequent and urgent hospital admissions with high social costs [2]. Patients discharged from hospital following COPD exacerbations have a high readmission rate [3]. Besides, as the severity of the disease increases, exacerbations are more frequent, and the hospitalisation frequency increases [2]. The rate of re-admission within one year in a Danish study was 46% [4], while British reports have suggested that 30% were re-admitted within 90 days [5]. For the individual patient with COPD exacerbation, the consequences can be severe, such as loss of pulmonary function [6], prolonged impairment, reduced quality of life [7] and increased risk of mortality [8]. Patients often are discharged in a vulnerable situation, at a high risk of relapse and need of re-admission. Telemedicine has been evoked as a potential tool in the care of COPD patients, as a supplement to usual care. Among the earliest experiences with the use of COPD video communication in Denmark, expanded telemedicine video consultation (TVC) with monitoring of the patient at home showed a borderline significant absolute reduction of about 10-14% in the early readmission risk by the TVC intervention, shorter hospital stay and earlier treatment of exacerbations with rapid efficacy and less drug use. Patient satisfaction was high [9]. Since then, several studies have been directed towards the ability of telemedicine monitoring of COPD patients to prevent exacerbations leading to hospital re-admissions, but with divergent results regarding health care outcomes [10-14]. The meta-analysis by Yang *et al*. [15], including a total of 31 reports over randomized controlled trials where comprehensive nursing intervention (CNI) and telemonitoring have been examined, concluded that both reduced all-cause readmissions, a key goal in the care of COPD patients. In COPD care there is a need for care delivery models that encourage prevention and self-management [16]. In a previous, retrospective study of COPD patients discharged from the hospital, we showed that the re-admission length within 12 months post-TVC was markedly reduced compared to pre-TVC. The patient satisfaction was high [17].

The main objective of this randomized, prospective study was to evaluate the efficacy on re-admissions of TVC at home as compared to telephone follow up or only best standard practice (BSP) COPD care. The major endpoints were the cumulative days and numbers of re-admission due to COPD exacerbation during the first year following discharge after hospitalization. Moreover, we wanted to assess patient satisfaction related to TVC, as compared to follow up by telephone call or BSP COPD care.

## Methods

### Study design

This study was conducted as a prospective, randomized unicenter study of a population of COPD patients discharged from Stavanger University Hospital, Norway, after treatment for an acute COPD exacerbation. Patients fulfilling the inclusion criteria were consecutively enrolled from December 2014 to March 2019 and randomized to 2 weeks of monitoring by TVC between the specialist respiratory nurse and the COPD patient at home, to telephone follow up from a specialist nurse or to a control group receiving BSP COPD care. Two weeks intervention was based on the benefits observed among the Danish patients who had the TVC equipment at home for about one week followed by at least one phone call [9] and our pilot study published in 2014 [17]. The main purpose was to teach patients to increase empowerment, self-care and correct medication in a more stabilized condition than the acute phase of hospitalization. Our primary endpoint was the cumulative number of days of re-admission due to acute COPD exacerbations during one year of follow up. The secondary endpoint included the frequency of hospital re-admissions due to COPD exacerbation during one-year follow up and the time to the first hospitalization. Admissions due to other causes than acute COPD exacerbations have not been included in this study. The index hospitalization was not included. Additionally, we wanted to assess the quality of life by the COPD assessment test (CAT) and the hospital anxiety and depression scale (HADS) [18] before and for 12 months post-intervention. Finally, all patients were requested to complete a questionnaire (Table 1) assessing patient satisfaction and impact on patient's quality of life. The questionnaire was similar to the one used in our pilot study [17] to patients monitored by TVC, a modified version to patients followed by telephone consultations or usual COPD care. The questionnaire was sent to the patient by mail one month post-discharge. All answers were registered anonymously.

### Study population

All COPD patients living in the Southern part of the Rogaland County in Western Norway, with a habitual value of $FEV_1$ <50%, and/or emphysema with gas diffusion ($DL_{CO}$) <50% in a stable phase and/or chronic respiratory failure due to COPD, were screened and enrolled at discharge after an emergency hospitalization for COPD exacerbation at Stavanger University Hospital. Additional inclusion criteria comprised willingness to participate and age >40 years. Patients with active malignant or any other disease with a prognostic life expectancy shorter than 12 months, patients previously included in the study, residents of in-service-housing with care or nursing homes, inability to communicate and inappropriately available internet and telephone coverage were defined as exclusion criteria. Thus, patients with hearing impairment, aphasia or dementia were excluded from the TVC service and the study. Patients were also excluded if they were discharged to a service home with supervision or to a nursing home. Written informed consent to participation in the study and to publication of study results was obtained from each participant.

COPD exacerbation was defined as an increased need for COPD medication due to worsened dyspnoea, cough or increased amount of purulent sputum (not due to any other underlying lung or heart disease), with or without pneumonia.

### Randomization procedure

Randomization was done at Stavanger Research Department *via* a computer-generated allocation sequence unknown to the research group.

Study participants who had given written informed consent were randomized immediately prior to discharge from the hospital to a randomization number, which identified a numbered, sealed envelope with written content of randomization result; TVC, telephone follow up or BSP COPD care.

## Data collection

### Baseline data

All baseline data were collected regarding demographics, co-

morbidity, risk factors including admissions due to COPD exacerbations the preceding 12 months, general condition, lung function test, blood gas values, BNP and maximum TnI during hospital stay, need for ventilatory support and COPD medication (before, during and after hospital stay).

### Follow up data

After discharge from the hospital, patients were monitored for one year by reviewing hospital records by the project doctor regarding primary and secondary endpoints and confounding variables (other emerging diseases, smoking, introduction of ambulatory oxygen therapy, lung rehabilitation after the index stay).

Medical records were scrutinised for re-admissions due to COPD exacerbations for 12 months follow up. Length and frequency of hospital stay(s) due to COPD exacerbations, and clinical data were recorded. Finally, all patients were requested to complete a questionnaire concerning patient satisfaction and impact on patients' quality of life. The TVC nurse recorded the number of acute consultations during the period of home monitoring. CAT and HADS scores were registered at inclusion, within 3 weeks post-discharge and after 6 and 12 months.

## Intervention

Treatment of COPD exacerbation was in accordance with Norwegian National guidelines for prevention, diagnosis and monitoring of individuals with COPD and included bronchodilators inhaled by nebulizer, systemic steroids, antibiotics, oxygen supply, chest physiotherapy and when needed non-invasive ventilatory support (NIV) according to BTS guidelines [19].

### Telemedicine video-consultation, patient monitoring and follow up

The telemedicine equipment consisted of a tablet with a web camera and microphone, through which the patient at home and the specialist respiratory nurse in the hospital were able to communicate, and also comprised requisites to measure the patient's oxygen saturation and heart rate. The tablet was installed at the patient's home within 24 hours of discharge. The results were transferred to the hospital by a secure internet line. The patients contacted the nurse according to daily appointments for TVC on weekdays during the day-time for 2 weeks and in case of acute need for consultation whenever necessary, 24 hours a day.

As described in our pilot study [17], the nurse during the TVC made clinical observations according to a checklist shown in our previous publication [17], measured oxygen saturation and heart rate, and according to an algorithm advised the patient how to cope with COPD related symptoms, use of medication and how to maintain the activity of daily life and physical activity. The nurse could confer the patient with the doctor in the hospital, a physiotherapist or an occupational therapist, or advise the patient to consult a general practitioner or a home care nurse.

### Telephone consultations

Patients randomized to follow up by telephone were contacted once a day by one of the two-trained nurses who evaluated the condition and advised on further handling according to the same template used in the TVC.

## Statistical analysis

Anonymized data were continuously entered into the database, and double-checked for incorrect entries, before transferring to SPSS Statistics version 25 for statistical analyses. Differences in patient characteristics, frequency of re-admissions and cumulative number of re-admission days between the intervention and control groups were tested by chi-square test or Fisher's exact test for categorical variables and by One-Way Analysis of Variance or One-Way ANOVA on Ranks for continuous data, depending on whether data were normal or skewed. The Shapiro-Wilk test for normality was performed to study the distribution of parameters. Normally distributed data were given as mean±SEM, while variables with more skewed distributions were given as median and upper and lower quartiles (IQR). A $p<0.05$ was considered statistically significant. To examine the dependency of hospital re-admission days on potential determinants, a linear regression analysis was performed.

**Table 1. Questions to patients regarding patient satisfaction and user friendliness of TVC equipment.**

| | |
|---|---|
| 1. | How do you usually feel at discharge from hospital after COPD exacerbation?<br>Very safe – Safe – Unsafe – Very unsafe |
| 2. | At discharge this time I felt<br>Very safe – Safe – Unsafe – Very unsafe |
| 3. | Retrospectively, if you could choose, would you prefer a telephone consultation or a tele-video-consultation?<br>I would prefer talking to the nurse by phone<br>I would prefer the tele-video-consultation |
| 4. | How do you consider the significance of the TVC /phone call follow up for your ability to cope with your COPD related problems?<br>Great significance – some significance – no significance |
| 5. | Which of the following statement fits you best concerning your experience of user-friendliness of the TVC equipment?<br>It was easy to operate the TVC equipment<br>It was a bit difficult to operate the TVC equipment<br>I could not manage to operate the TVC equipment |
| 6. | Who was operating the tele-video conferencing system at home?<br>You, every time<br>A friend or a relative operated the tele-video-conferencing system every time<br>Different persons operated the tele-video-conferencing system every time<br>The tele-video-conferencing system was not in use |

Question 1-3 to all patients, question 4 to patients followed by TVC and phone-calls, question 5 and 6 to patients followed by TVC.

Multiple logistic regression analysis was further performed with a re-admission endpoint (yes/no) as the dependent variable, odds ratio presented at 95% confidence interval (CI). Potential prognostic indicators were implemented in these models as potential confounding factors. The statistical significance level was set to $p<0.05$. In the case of an expected 3-day reduction in the length of hospital stay in patients re-admitted within one year after TVC following a hospital stay due to acute COPD exacerbation, power calculation showed the need for a sample size of 180 patients in the study, randomized to 3 arms, (TMV, telephone follow up, BSP COPD care), to give a power of 80%. The calculations were performed for a significance level of 0.05.

The study was approved by the Regional Board of Research Ethics and conducted in accordance with the Declaration of Helsinki [20,21]. The legal and security aspects have been taken care of through data transfer, on the recommendation of the Norwegian Data Protection Authority (DPA), without objections.

## Results

### Patients demographics and clinical characteristics

A total of 180 patients were consecutively included in the study, out of whom 7 patients withdrew from the study at their own discretion. There was no intergroup difference in drop-out between the groups. The remaining 173 patients were randomized to the TVC group (n=57), the telephone group (n=59) or the BSP COPD care group (n=57). The patients were followed for 12 months or until death. Nineteen patients died during the 12-month follow up. Three of these belonged to the TVC group as compared to sixteen equally divided between the groups followed by telephone calls and BSP COPD care, respectively. The general baseline demographic and clinical characteristics of the study population are summarized in Table 2. There were no intergroup differences between the groups regarding demographics. The age was 68 (±1.16) years [mean (SEM)], and the majority of the participants were women. The co-morbidity was quite significant but did not differ between the groups. All patients in the three groups had a severely deteriorated lung function according to COPD Gold Guidelines stage III-IV. The $FEV_1$ value was 0.88 liter (l) (0.67-1.19) [median (25-75% percentiles)], [(38.0% of predicted value) (27.2-46.5%;] [median (25-75% percentiles)]. Forty-eight patients (27.8%) were classified in COPD Gold stadium IV, with $FEV_1 \leq$ 30% of expected. There was no intergroup difference regarding the need for ventilatory support at home. Forty-one percent of the entire population had been admitted within 12 months pre-intervention, with no intergroup difference (Table 2). At admission, there were no intergroup differences regarding ongoing COPD inhalation therapy. More than 70% of patients in each group inhaled long-acting muscarin antagonists (LAMA), and 68.2.% of patients inhaled combination products of long-acting beta-2-agonist and corticosteroid (LABA/ICS) as part of the ongoing regular medication, reflecting the high symptom burden of COPD in this population. During index admission, 91.9% of patients received treatment with nebulized ipratropium and salbutamol, 96% were treated with systemic corticosteroids, and 90.2% received antibiotics, with no intergroup differences in the in-hospital medical treatment. Ongoing regular medication was similar at inclusion and at discharge from index hospital stay. Respiratory failure with a need for oxygen supply during hospital stay was reported among 48 patients in the phone call follow up group (81.4%), and among 35 patients in the TVC and BSP COPD care groups (61.4%), and

**Table 2.** **Baseline demographic and clinical characteristics.**

| Intervention group* | TVC (n=57) | Phone calls (n=59) | BSP COPD care (n=57) | p |
|---|---|---|---|---|
| Sex male[#] | 15 (26.3) | 21 (35.6) | 26 (45.6) | NS |
| Age [mean (SEM)] | 69.0 (1.169) | 68.64 (1.161) | 68.07 (1.134) | NS |
| Living alone[#] | 28 (49.1) | 19 (32.2) | 24 (42.1) | NS |
| Home nurse[#] | 9 (15.8) | 17 (28.8) | 12 (21.1) | NS |
| CAT score[3] | 21.5 (0.93) | 23.1 (0.81) | 23.8 (0.98) | NS |
| Cardiovasculary disease[#] | 20 (35.1) | 27 (45.8) | 25 (43.9) | NS |
| Heart failure[#] | 3 (5.3) | 10 (32.2) | 6 (10.5) | NS |
| Depression[#] | 17 (29.8) | 14 (23.7) | 16 (28.1) | NS |
| Osteoporosis[#] | 9 (15.8) | 16 (27.1) | 14 (24.6) | NS |
| Current smoker[#] | 13 (22.8) | 17 (28.8) | 17 (22.8) | NS |
| Ex-smoker[#] | 57 (100.0) | 59 (100.0) | 55 (96.5) | NS |
| BMI ($kg/m^2$)° | 22.5 (0.705) (n=56) | 24.0 (0.653) | 22.3 (0.738) (n=54) | NS |
| $FEV_1$ (liter)[§] | 0.89 (0.68-1.23) | 0.87 (0.67-1.20) | 0.90 (0.69-1.18) | NS |
| $FEV_1$ (%)[4] | 38.70 (31.80-46.25) | 40.30 (26.28-47.08) | 36.80 (26.50-46.30) | NS |
| LTOT at home[#] | 6 (10.5) | 15 (25.4) | 10 (17.5) | NS |
| NIV at home[#] | 1 (1.8) | 5 (8.5) | 3 (5.3) | NS |
| Previous acute NIV[#] | 10 (17.5) | 11 (18.6) | 13 (22.8) | NS |
| Previous respirator[#] | 5 (8.8) | 5 (8.5) | 11 (19.3) | NS |
| PAH# | 4 (7.0) | 5 (8.5) | 5 (8.8) | NS |
| Admitted the preceding year[#] | 26 | 25 | 20 | NS |

*Group 1 was followed by TVC, Group 2 by telephone contact and Group 3 by Best Standard Practise COPD care; [#][n (%)], p>0.05; °mean (SEM); [§]median (25-75% percentile); Age; one way analysis of variance, $FEV_1$; one way ANOVA on ranks and chi-square test for categorical variables; LTOT, long term oxygen treatment; NIV, non-invasive ventilatory support.

13.3% of all patients presented with pH<7.35 and hypercapnia in need of non-invasive ventilatory support, according to BTS guidelines [19]. During the TVC monitoring period 5 patients started systemic steroid therapy and additional 5 patients started combination therapy of systemic steroids and antibiotics. In the phone-call follow up group 11 patients received systemic steroid therapy, out of whom 5 patients also were treated with antibiotics. Four patients made 8 emergency calls during the TVC period. In the phone-call-follow up group 5 patients made 11 emergency calls.

## Follow up data

### Frequency of re-admission due to acute COPD exacerbations

Ninety-nine patients (57.2%) were re-admitted due to COPD exacerbation during the 12 months follow up period. They were older [age 69.8 years (±0.87)] [mean (SEM)] than those not re-admitted [66.9 years (±1.00)] [mean (SEM)], p= 0.03, however, there was no inter-group difference in age among the re-admitted. In the TVC group the re-admitted consisted of a relatively higher proportion of men as compared to the others. We noticed an equal distribution of re-admitted patients among the groups followed by TVC [n=32 (56.1%)], telephone calls [n=38 (64.4%)] and BSP COPD care [n=29 (50.9%)], p>0.05. Also, the total number of readmissions due to COPD exacerbations was equal in the groups (Table 3). Both the proportion of patients without any re-admission and the proportion with frequent ≥2 per year) re-admissions were equally occurring in the three groups compared (Table 3). Nor as early as 6 months following TVC could we observe any favor regarding the number of re-admissions in the TVC group as compared to the others (data not shown). In our population, a total of 41 % had been admitted within 12 months pre-intervention. Those who were re-admitted had a higher number of hospital stays the preceding year [1.22 (±0.141)] [mean (SEM)] as compared to those not re-admitted [0.61 (0.21)] [mean (SEM)], p= 0.01. They also had a lower $FEV_1$ of 0.80 l (0.61 -1.11) *versus* 0.96 l (0.82-1.26) [median (25-75% percentiles)], p<0.001. In the multiple regression analysis admittance due to COPD exacerbation in the previous 12 months was the strongest predictor for re-admission [Odds ratio (OR) of 1.35 (95% CI 1.04-1.75)], p=0.027. Higher age was associated with a minor increased risk of re-admittance in our study [OR 1.06 (95% CI 1.01-1.11), p=0.019. Patients who were readmitted *versus* those who were not did not differ in terms of sex, cardiovascular morbidity, blood gas values, smoking, or low BMI (<20).

In the multiple logistic regression model neither sex nor $FEV_1$, cardiovascular disease, low BMI, current smoking or living alone were associated with re-admission or time to re-admission. At the first re-admittance, 94 patients (95.0%) were in need of systemic corticosteroids, 85 (85,9%) of antibiotics and 75 (75.8%) of oxygen supply. We found no intergroup difference regarding the need for treatment with antibiotics (p=0.39), systemic steroids (p=0.28) and oxygen (p=0.67). Moreover, the patients in the three groups had equal levels of C-reactive protein (CRP), leucocytes, brain natriuretic peptid (BNP) and troponin I (TnI) at the first re-admittance. At twelve months follow up 10 patients in the TVC group had started home oxygen treatment, as compared to only 2 and 4 patients in the phone call follow up group (p=0.042) and the BSP COPD care group, respectively, while the total number of patients with long term oxygen treatment was equal among the groups. The patients in the three groups did not differ regarding the need for domiciliary help and home nursing, and they had an equal score on the medical research council dyspnea scale (MRC) of 3.5 in groups 1 and 4 in the two others. Nine and eleven patients in groups 1 and 2, respectively, had attended a pulmonary rehabilitation course during the 12-month follow up, as compared to only 4 patients in group 3.

### Length of re-admission hospital stays and time to re-admission due to acute COPD exacerbations

The cumulative length of re-admission hospital stays (days; mean±SEM) due to COPD exacerbations within 12 months did not differ between the patients randomized to follow up by TVC, phone calls or BSP COPD care after the initial hospital stay for COPD exacerbation (Table 4). Nor as early as 6 months follow up could we observe any difference (data not shown). Moreover, the time to the first re-admission was similar in the three groups (Table 5). Those who had been admitted the year before the index hospital stay, did not reduce their re-admission stays during the following

**Table 3. Patients with 0, 1 or >2 re-admissions due to COPD exacerbations within 12 months follow up after hospitalization with COPD exacerbation, according to mode of follow up.**

| Number of re-admissions | 0 | 1 | >2 | Total number of re-admissions (n) |
|---|---|---|---|---|
| TVC (n=57) [n (%)] | 25 (43.9) | 15 (26.3) | 17 (29.8) | 71 |
| Phone-calls (n=59) [n (%)] | 21 (35.6) | 18 (30.5) | 20 (33.9) | 93 |
| BSP COPD care (n=57) [n (%)] | 28 (49.1) | 10 (17.5) | 19 (33.3) | 66 |

Number of patients with 0, 1 or ≥2 re-admissions within 12 months follow up after TVC as compared to phone calls or no extra-ordinary follow up; No intergroup difference in patients with > 2 re-admissions, p=0.88, chi square.

**Table 4. Cumulative number of days in hospital per patient during re-admissions for 12 months follow up after hospitalization with COPD exacerbation, according to the mode of follow up (mean ±SEM).**

| Mode of follow up | TVC (n=57) | Phone-calls (n=59) | BSP COPD care (n=57) |
|---|---|---|---|
| Days in hospital | 7.02±1.48 | 8.29±1.43 | 7.46±1.58 |

No intergroup difference regarding days in hospital 12 months following intervention, p=0.829 (one way analysis of variance).

year [paired *t*-test (two-tailed), p>0.05]. The number of hospital re-admission days was related to the number of COPD exacerbations in the previous 12 months (p=0.008), but not the time to re-admission (p=0.114).

### Patient satisfaction, symptom burden and HADS score

The response rate to the patient satisfaction survey was 86%. While 23 patients in the TVC group responded retrospectively that they generally had felt safe or very safe when discharged from the hospital without TVC, the number doubled to 46 patients who reported safety when discharged to TVC at home, p<0.001. A similar observation was made regarding those who were discharged to follow up by phone calls, while there was no change in reporting a feeling of safety in patients in the usual COPD care group. Among patients followed by TVC, 77.6% found that TVC had great importance for the further management of their COPD-related problems, while 45.1% of patients followed by phone calls reported the same (p=0.002). Almost 96% of patients found the telemedicine equipment easy to operate, and 98% of patients reported that they handled the tele-video conferencing system on their own. Moreover, 97% of patients regardless of group preferred TVC over only phone calls. All patients in the TVC group would like to do another try and recommend TVC for follow up after a COPD exacerbation. Patients who were followed by regular phone calls had similar positive experiences. There were only a few technical issues; the TVC was occasionally cancelled due to internal IT issues. The HADS scores [mean (SEM)] were equal among the three groups at inclusion, p=0.673 (ANOVA) (Table 6). From baseline to post-intervention the scale values favorably declined among patients followed by TVC (p=0.059) and phone calls (p<0.01), but not among patients given only BSP COPD care (p=0.173) (paired *t*-test). The scores remained unchanged for the rest of the follow up period. Examining the hospital depression and anxiety scores separately, the anxiety score declined significantly from 6.02 (0.75) at baseline to 4.83 (0.61) [mean (SEM)] in the TVC group (p=0.028) and from 6.18 (0.70) to 4.58 (0.65) [mean (SEM)] in the phone call follow up (p=0.008) group following the intervention. The decreased levels remained unchanged throughout the observation period. A similar reduction was not found in the BSP COPD care group measured simultaneously. However, there was no intergroup difference in the change of the hospital anxiety score from baseline to post-intervention (p=0.128) or from baseline to 12 months follow up (p=0.549). A similar decrease in hospital depression score was not found, but patients in the BSP COPD as the only ones receiving care experienced an increase. Parallel to the decline in HADS-score from baseline to post-intervention, we found a similar decrease in the CAT-scores in patients followed by TVC and phone calls, reflecting an experience of decreased total subjective symptom burden of the COPD patient. In patients with CAT-scores at all 4 measurement points (n=37), the CAT-score declined from 20.8 (1.08) [mean (SEM)] to 14.1 (1.27) in the TVC group (p<0.001) and from 22.7 (1.07) to 19.1 (1.16) in the phone call follow up group (p<0.01), with no intergroup change. The decreased levels remained unchanged throughout the observation period; the patients still had lower CAT scores at 12 months follow up than at inclusion. A similar reduction was not found in the BSP COPD care group. At inclusion, the CAT scores [mean (SEM)] were equal among the three groups, p=0.198, Table 2.

## Discussion

This randomized study could not demonstrate a reduction in either the length or the frequency of hospital re-admissions in patients with COPD during a 12-month observation period following TVC for two weeks after a hospital stay due to COPD exacerbation, as compared to follow up by phone calls or only BSP COPD care. Nor as early as after 6 months could we see any difference in the number of re-admissions or length of stay in hospital between the 3 groups. Our hypothesis of the reduced readmission hospital bed days for COPD exacerbations following TVC was derived from our findings in our previous retrospective observational pilot study [17] showing a markedly reduced number of hospital bed days following TVC as compared to the preceding 12 months without TVC. However, an equal frequency of re-admissions the year after as compared to the year before TVC was observed in our previous retrospective study.

The results presented in this report are based on the experience from the early start of TVC at our site and on the Danish pioneer study using similar equipment and short duration of intervention [9], demonstrating a 10-14% reduction in early re-admissions due

**Table 5. Days from discharge after hospitalization for COPD exacerbation to first re-admission, according to the mode of follow up (mean ±SEM).**

| Mode of follow up | TVC (n=57) | Phone-calls (n=59) | BSP COPD care (n=29) |
|---|---|---|---|
| Days to first re-admission | 01.56 (20.5) | 85.42 (14.42) | 98.72 (20.27) |

p=0.786, one way ANOVA.

**Table 6. HADS score (mean ±SEM) at baseline, post-intervention (3 weeks post-discharge), at 6 and 12 months follow up (for patients with four registrations).**

| | Baseline | Within 3 weeks post-discharge | 6 months follow up | 12 months follow up |
|---|---|---|---|---|
| Group 1 (n=39) | 11.03 (1.15) | 9.46 (1.14) | 9.00 (0.98) | 9.05 (1.13) |
| Group 2 (n=37) | 11.08 (0.96) | 8.78 (1.06) | 8.57 (0.86) | 9.14 (0.98) |
| Group 3 (n=33) | 12.27 (1.15) | 13.76 (1.32) | 12.61 (1.20) | 12.18 (1.45) |

Group 1 was followed by TVC, Group 2 by telephone contact and Group 3 by Best Standard Practise COPD care; no intergroup difference in HADS score at baseline (p=0.673), one way ANOVA; change from baseline to within 3 weeks post-discharge: G1 p=0.059, G2 p<0.01, G3 p=0.173, paired *t*-test; changes from 3 weeks-post discharge to 6 months follow up: G1 p=0.584, G2 p=0.78, G3 p=0.439, paired *t*-test; changes from 6 months to 12 months follow up: Group 1 p=0.939, Group 2 p=0.438, Group 3 p=0.705, paired *t*-test; no intergroup difference in the change of HADS score from baseline to 3 weeks post-discharge (p=0.128); one way analysis of variance.

to COPD exacerbations in the TVC group as compared to a control group, with a use of TVC for only one week following discharge after hospital stay for COPD exacerbation.

Thus, the results of our prospective randomized study cannot position TVC as used in our model as an important contribution to the standard management of these patients. The reason for choosing this approach was the knowledge of COPD patients being in a vulnerable state when discharged from hospital after a COPD exacerbation, at high risk of prolonged impairment of health status, as the exacerbation is still ongoing at the time of discharge [22], and the patient is at a higher risk for a new event [2,23]. Moreover, at a time of expected high motivation among the patients, the specialist respiratory nurse in our TVC team not only daily monitored and advised each patient according to personal needs to improve the actual health condition, but as previously described, also great effort was invested in advising and teaching each patient to increase the empowerment and competence for good self-care, concerning correct medication use, inhalation technique, appropriate physical activity, pulmonary drainage, dealing with stress and anxiety to prevent and to cope with future exacerbations. However, our study has not been designed to directly evaluate the influence of TVC on each of those factors. As in our pilot study [17], an interdisciplinary team was available for consultation when needed, including among others a physiotherapist and an occupational therapist, who could for example easily facilitate home conditions.

Our approach differs from most studies exploring the effect of TVC in COPD, by not offering a long-term TVC for early detection of COPD exacerbation, but aiming to increase the patient's empowerment and competence for good self-care. The hypothesis in many studies has been that daily TM monitoring of patient's vital signs and symptoms would detect changes in the clinical status of COPD patients sufficiently early to improve care and decrease healthcare resource utilization by decreasing unscheduled visits to the family physician or specialist, home visits, ED visits, and hospitalizations [13,24].

The short duration of our study of only 2 weeks intervention could be considered as a limitation of the study design and negatively affect the results of the study, as compared to the beneficial outcomes observed in the long-term data collected by Dal Negro and Hodder, implementing several years of home telemedicine [25].

Even such long-term interventional studies have shown conflicting results. Recently, Pinnock *et al*. [26] published their findings from a large randomized study with patients with COPD recruited through general practice and reported that TM had no effect on hospital admissions or quality of life, and in keeping with this, Hamad *et al.* [27] failed to establish the value of TM in the early detection of COPD exacerbations. Also other randomized controlled trials have concluded that there were no between-group differences in hospital admissions [28,29]. The impact of TM on the length of hospital stay is also inconclusive with reports of a decrease [29,30].

A previous history of COPD exacerbation has been shown to be the most reliable predictor of new COPD exacerbations [2]. Moreover, data from the Evaluation of COPD Longitudinally to Identify Predictive Surrogate Endpoints (ECLIPSE) [2] showed that 33% with COPD stage 3 and 47% with stage 4, defined according to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) [30], had ³2 exacerbations in the first year of follow up. Our observations are in accordance with these findings, as 32.4% of our patients, who are all characterized by COPD stage 3-4, with a median $FEV_1$ of 38 %, had ³2 re-admissions during the observation period. In our population, a total of 41% had been admitted within 12 months pre-intervention. Those who were re-admitted had a higher number of hospital stays the preceding year [mean 1.22 (SEM 0.141)] as compared to those who were not re-admitted [0.61 (0.21)], p= 0.01. They also had a lower $FEV_1$ of 0.80 l (0.61-1.11) *versus* 0.96 l (0.82-1.26) [median (25-75% percentiles], p<0.001. In the multiple regression analysis admittance due to COPD exacerbation the previous 12 months was the strongest predictor for re-admission [odds ratio of 1.35 (CI 1.04-1.75)], p=0.027. The number of COPD exacerbations the previous 12 months was also associated with the cumulative number of re-admission days (p=0.008). The frequency of exacerbations has been shown to contribute to disease progression [31]. Long-term data from previous research [32] investigating the natural history of the disease suggested a rapid decline in health status after the second severe exacerbation and high mortality following every severe exacerbation requiring hospitalization. In according with previous observations [9,33] higher age was associated with an increased risk of re-admittance in our study. Patients re-admitted as compared to those who were not, did not differ regarding sex, cardiovascular morbidity, blood gas values, smoking or low BMI (<20). In the multiple logistic regression model neither sex nor $FEV_1$, cardiovascular disease, low BMI, current smoking or living alone were associated with re-admission or time to re-admission.

For the majority of our patients, the need for re-admission has been decided by the occurrence of a serious event, as 85.9 % of patients re-admitted required antibiotic therapy, 95% needed systemic steroids and 75.8% needed oxygen therapy during the first re-admission. Thus, these re-admissions are hard to avoid, and the irreversible and progressive nature of COPD can contribute to the inevitable exacerbations and hospitalization. All of our patients had a serious burden of disease, possibly explaining the evitable and long hospital stays, necessary to cope with our seriously deteriorated COPD patients with complicated co-morbidity (Table 2). The high mortality rate also reflects this advanced disease condition with serious prognostic outcomes. The population of COPD patients in our study is therefore a topic for reflection when designing a study to show the effect of TVC on hospitalizations for COPD exacerbations. The serious burden of disease of the COPD patients in our study might have been the major reason why we could not show a beneficial effect of TVC on the total number of re-admission hospital days or the number of re-admissions due to COPD exacerbations. Moreover, since the implementation of the new "Coordination Reform" in the Norwegian health care policy in 2012, transferring more responsibility to the municipality health care system, the patients admitted to hospitals, present with an even higher burden of disease and higher treatment level, and they consequently spend more days in hospital to recover, why the length of the hospital stay will possibly not be influenced by TVC. The population in the Danish [9] study showing an early re-admission risk by the TVC intervention, was quite similar to ours. That study also failed to show a significant reduction in hospital stay length. Furthermore, the study's non-randomized interventional design made it vulnerable to imbalances in baseline prognostic factors. The target group for such an intervention model as ours should therefore be defined carefully in future studies, and a more flexible, individually adapted model for TVC monitoring of patients might even contribute to increased periods free of re-admissions, rather than the strict, pre-determined period of 14 days of TVC monitoring used in our study, irrespective of patient condition and needs. Despite our lack of demonstrating a protective effect of TVC regarding re-admittance due to COPD exacerbation, the patients reported a high degree of self-perceived patient satisfaction and increased coping skills following TVC, of major importance for the feeling of safety at home. For our COPD patients with a high prevalence of depression (Table 2), our interpretation is that the increased coping skills following TVC or phone call follow up have contributed to the reduced HADS scores observed post-follow up. The parallelly observed reduction of also the CAT score in these two groups mirrors the subjective experi-

ence of the decreased total burden of COPD symptoms and makes the strains of COPD in daily life easier to cope with. As the major benefit was related to the anxiety score, the feeling of safety seems to be of major importance for the daily level of functioning at home. However, experiences regarding self-perceived patient satisfaction and also impact on HADS score described in the literature have been diverse [34].

## Conclusions

In this prospective, randomized study we could not demonstrate a reduction neither in the number of re-admission days nor the frequency of re-admissions due to COPD exacerbations for one year post-TVC for 2 weeks following hospitalization for COPD exacerbation, as compared to patients followed by telephone calls or "usual COPD-care". However, the patient satisfaction among patients followed by TVC was high, and the reduced HADS and CAT scores in patients followed by TVC and phone calls as compared to best standard practice COPD care is of major importance for the quality of life and the ability of coping with everyday life challenges among COPD patients. The benefits, remaining persistent throughout the one year observation period, seem to be the consequence of increased empowerment and competence for good self-care in the COPD patients. Other models of TVC follow up should be evaluated in future prospective, randomized studies.

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## Abbreviations

BMI: body mass index;
BNP: brain natriuretic peptide;
BSP: best standard practice;
CAT: COPD assessment test;
COPD: chronic obstructive pulmonary disease;
$DL_{CO}$: diffusing capacity for carbon monoxide;
$FEV_1$: forced expiratory volume in first second;
HADS: the hospital anxiety and depression scale;
HR: hazard ratio;
LABA/ICS: long-acting beta-2-agonist and inhalation corticosteroid;
LAMA: long-acting muscarin antagonist;
LTOT: long-term oxygen treatment;
NIV: non-invasive ventilatory support;
OR: odds ratio;
SEM: standard error of the mean;
TnI: troponin I;
TVC: telemedicine video-consultation.

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