Telehealthcare for Chronic Obstructive Pulmonary Disease in Switzerland Is Feasible and Appreciated by Patients

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Key Words

Telehealthcare · Telemedicine · Chronic obstructive pulmonary disease management · Acute exacerbations of chronic obstructive pulmonary disease

Abstract

Background: Earlier detection of acute exacerbations (AE) of chronic obstructive pulmonary disease (COPD) could reduce emergency admissions and hospitalisations. Studies investigating COPD management programs supported by telehealthcare (THC) have shown conflicting results. **Objectives:** To test the feasibility, safety and acceptance of THC for COPD. **Methods:** Patients daily filled out an online questionnaire focused on the detection of AECOPD. The THC platform is integrated in a comprehensive electronic patient data repository, which has to be available for all patients in Switzerland by law by 2017. The study team called the patient by phone in case of suspected AECOPD. **Results:** Of 339 screened patients, 14% were included. Main reasons for exclusion were missing technical equipment and unwillingness to participate in a study (50%). Data completeness was 88%; 94% completed the study. The current THC approach triggered 230 telephone calls, which led to the verification of 60 AECOPD in 22 patients. Three AECOPD were not de-

tected. Sensitivity, specificity, positive and negative predictive value of the questionnaire-based THC approach in detecting AECOPD was 95, 98, 26 and 99.9%, respectively. Overall patient satisfaction in respect to their health condition improved significantly (VAS 8–8.7; $p = 0.002$). **Conclusions:** Adding THC to state-of-the-art COPD management is feasible in a selected subgroup of patients. We estimate that up to 50% of COPD patients could be eligible for a THC strategy. Patient compliance, acceptance and satisfaction were very high. With the proposed approach, we missed only very few AECOPD events. However, a telephone-based verification of THC alerts was required. Overall, in this proof-of-concept study, we experienced a positive effort-to-benefit ratio.

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Introduction

The optimal care of patients with chronic diseases like chronic obstructive pulmonary disease (COPD) requires a treatment network involving the patient, general practitioner (GP), specialists, home care providers and the hospital. The availability of accurate information between these partners is a relevant problem – sometimes even relevant for the patients' safety. Organisational barriers

complicate the optimisation of processes, despite modern communicative devices being implemented in different aspects of daily life [1].

COPD is the most common pulmonary disease, its prevalence increasing with age (reported up to >20% in adults >60 years), and is the fourth leading cause of death in the world [2]. In our current health care environment, consultation intervals of COPD patients are purely based on personal judgement of the treating physicians, disease severity and patient preference, but not on the current and constantly changing state of health of the individual patient. As a result, most patients with stable COPD are seen too often and some patients with an unstable disease course are seen too seldom. Both scenarios result in a waste of health care resources. Important disease events like acute exacerbations of COPD (AECOPD) often remain unreported, leading to negative consequences for disease course (e.g. faster decline of forced expiratory volume in 1 second) and quality of life (QoL) [3]. By earlier detection of these events, emergency admissions and hospitalisations could be reduced.

Different studies investigating multidisciplinary COPD management programs supported by telemedicine (more or less synonymously used terms are 'telehealth', 'telehealthcare', 'telemonitoring', 'home telemonitoring', 'e-health', 'mobile health' and 'connected health') have shown conflicting results [4, 5]. In the following, the term 'telehealthcare' (THC) will be used. THC is a complex intervention, with information from the patient being electronically transferred over a distance to healthcare professionals, who analyse this information and give immediate and personalised feedback and advice to the patient [6]. A Cochrane review from 2012 summarized 10 randomised controlled trials regarding THC and found an improvement in QoL, as evaluated by St. George's Respiratory Questionnaire (SGRQ), in 2 of these randomised controlled trials. Further, a reduction in the number of emergency department (ED) visits, hospital admissions and exacerbations was described. The studies were not powered to detect survival benefit and, thus, no mortality benefit for the THC groups could be detected. The authors stated, however, that the evidence base for these findings is small [6]. The trial procedures of all these investigations were not homogenous, which is given due to the nature of different health care settings.

With the current study, we aimed to test the safety and feasibility of adding THC to our current COPD outpatient management. The primary objective was to assess the achievable data completeness, frequency of use, safety, patient acceptance and satisfaction with this new kind

of care. We aimed to design a THC approach which could be feasible for large-scale implementation in our e-health care system in Switzerland in the future.

Materials and Methods

This study has been approved by the Swiss Institutional Review Board (swissethics, trial number CTU-14/035).

Trial Design

This is a single centre, one-arm, prospective feasibility and safety trial, conducted over 1 year from February 2015 to January 2016 in the Clinic for Pulmonology and Sleep Medicine, Cantonal Hospital St. Gallen, St. Gallen, and the patients' homes in Switzerland. The trial language was German.

THC Procedure

To achieve the best possible compliance and data completeness, we kept the trial intervention as simple as possible. The THC platform is integrated in an electronic patient data repository (Evi-ta, Swisscom), which has to be available for all patients in Switzerland by law by 2017. The platform has been supplemented by a COPD plug-in adapted by Swisscom according to our suggestions (fig. 1). Patients used their own technical devices (tablet, smartphone or computer) to enter all required information.

Patients were instructed to answer 8 questions online every morning (once daily), as early as possible, with 'yes' or 'no' (fig. 1; translation: (1) Do you have more dyspnoea today, exceeding your usual variation? (2) Do you have more sputum today, exceeding your usual variation? (3) Is your sputum today more yellow or green, exceeding your usual variation? (4) Do you have more cough today, exceeding your usual variation? (5) Do you feel febrile today? (6) Do you feel like having a common cold today? (7) Do you feel unwell today, exceeding your usual variation? (8) Did you start to take your emergency medication within the last 24 h?). In case of not entering the answers until 11:30 a.m., a reminder SMS was automatically sent to their mobile phone. Further, an 'emergency plan' was provided online. This plan contained a detailed instruction how to behave in case of serious subjective deterioration and provided important phone numbers [2].

All entered answers were analysed in the late morning by the study team (pulmonologist together with a study nurse) Monday through Friday (fig. 1). The study team reacted according to a pre-specified action plan as outlined in the following. If at least two of the questions were answered with 'yes' on two consecutive days, a red signal in the 'cockpit' was generated (fig. 1), indicating suspected AECOPD. The patient was called by phone to evaluate the situation. All actions taken from then on were in the responsibility of the pulmonologist conducting the phone call (e.g. instructing the patient to change or administer self-medication, to consult the GP, to come to our outpatient clinic for clinical judgement or to come to our ED). After deciding on the next clinical steps, the patient was advised to call our team in case of any deterioration or missing improvement. The next phone call from us was conducted not before the symptoms had gone back to baseline and then had worsened again, in terms of a new episode of possible AECOPD. All actions were documented in the appropriate case report forms.

Fig. 1. Left upper part: patient view of the e-health platform. By hitting 'COPD STUDIE', patients were transferred to the questionnaire. Left lower part: screenshot of daily online questions to be answered by the patients ('yes' or 'no'; translation in the text). Right part: 'cockpit' of the study team with colour-coded alerts in the right column under 'Status' (red = AECOPD suspected, need

for telephone call; yellow = more symptoms than usual, but for <24 h; green = not more symptoms than usual; grey = questions not answered). Under 'Wochenstatus' the alerts of the last 7 days are displayed. Patients could make comments and ask questions (blue speech bubble).

Selection of Subjects

Inclusion criteria were COPD GOLD B-D, age ≥ 40 years and ability to use the technology. Exclusion criteria were other significant lung diseases (e.g. interstitial lung disease, cystic fibrosis, and pulmonary arterial hypertension), active malignant disease, inability to provide informed consent or to follow trial procedures, insufficient knowledge of trial language, institutionalised (nursing home) patients or palliative patients, known or suspected non-compliance and drug or alcohol abuse. Patients were only withdrawn from the trial according to their own preference. Consecutive COPD patients were recruited from daily clinical practice and were included in the study after giving written informed consent. Trial participants were not given any payment or compensation.

Endpoints

Primary endpoints were data completeness/frequency of use, defined as the percentage of days with completely answered questions; patient acceptance, defined as the percentage of patients completing the study, and patient satisfaction with care (comparison of beginning versus end of study period). To assess the last point, patients were asked 'How satisfied are you in general regarding your COPD management?' at the beginning and end of the study and marked their answer on a visual analogue scale ranging from 1 to 10 (10 = best value). Secondary endpoints were: safety in terms of sensitivity of the THC approach to detect AECOPD events; number of AECOPD (mild: worsening of symptoms, self-managed by the patient and did not require treatment with sys-

Table 1. Baseline characteristics

Number of patients included	48
Mean age, years (range)	63 (43–81)
Male gender, %	50
Smoking status (never/current/former), %	0/35/65
Mean pack years (range)	58 (30–150)
GOLD stage, % of patients	
2	20
3	42
4	38
GOLD risk class, % of patients	
B	16
C	16
D	68
Mean FEV ₁ , % predicted (range)	38 (15–71)
Mean SGRQ score (range)	47.2 (12–83)
Pharmacotherapy for COPD, % of patients	
SAMA	13
SABA	35
LAMA	92
LABA	98
ICS	66
Methylxanthines	0
Systemic corticosteroids	9
Mucolytics	11
LTOT, % of patients	27
NIV, % of patients	11
Comorbidities, % of patients	
Arterial hypertension	48
Coronary artery disease	17
Diabetes	9
Renal failure	7
Congestive heart failure	4
Pulmonary hypertension	2
History of myocardial infarction	0

GOLD = Global Initiative for Obstructive Lung Disease; FEV₁ = forced expiratory volume in 1 s; SAMA = short-acting muscarinic antagonists; SABA = short-acting beta agonists; LAMA = long-acting muscarinic antagonists; LABA = long-acting beta agonists; ICS = inhalative corticosteroids; LTOT = long-term oxygen therapy; NIV = noninvasive ventilation.

temic corticosteroids or antibiotics; moderate: requirement for treatment with systemic corticosteroids or antibiotics or both; severe: hospitalisation, including an emergency room visit of longer than 24 h); ED admissions, hospitalisations and days in hospital due to AECOPD; health-related QoL (SGRQ); mortality; number and duration of telephone contacts, and cost-benefit analysis.

Statistical Considerations

This pilot study is in essence exploratory, aiming at assessing the feasibility and safety of a novel THC procedure. Endpoints were analysed using descriptive statistics. The exacerbation rate was modelled using negative binomial regression [19]. The estimates and 95% confidence intervals (CI) are reported.

Fig. 2. Study flow chart.

Results

This study was conducted over 12 months from February 1, 2015 to January 31, 2016 in the Clinic for Pulmonology and Sleep Medicine, Cantonal Hospital St. Gallen, St. Gallen, Switzerland. Of 339 screened patients, 48 (14%) were included. Mean age was 63 years (range 43–81 years). The baseline characteristics of included patients are summarised in table 1. The main reason for exclusion was missing technical equipment (27%). The distribution of all reasons for exclusion is demonstrated in figure 2. The mean follow-up was 231 days (range 47–349 days).

Primary Endpoints

Data completeness: patients answered the daily online questions in 88% of days (9,819/11,087 patient days). 94% (45/48) of the patients completed the study (= patient acceptance); in all three quitters, the reasons were technical problems. One of them was overcharged by daily handling of the system, probably due to insufficient cognitive ability. The other two patients had technical problems with their own equipment. Satisfaction with COPD care improved from average 8.0 to 8.7 points on a visual analogue scale ($p = 0.002$).

Fig. 3. Distribution of exacerbation rates (average 2.1, 95% CI: 1.4–3.2).

Secondary Endpoints

With the THC procedure, we detected 60 episodes of AECOPD (mild: 3; moderate: 57) in 22 patients. In total, 3 episodes of AECOPD were not detected, and these patients had to present at the ED. The average rate of AECOPD was 2.1 per patient-year (95% CI: 1.4–3.2; fig. 3).

The first of the missed cases had a very rapid deterioration within hours (in the morning, no more symptoms than usual were evident), so that it was not possible to detect it with our THC algorithm. The second one had already been contacted by us shortly before and did not call us back to inform us about the deterioration as it would have been required by our intervention algorithm. The third one did not answer the online questions in the last 4 days before presentation at the ED, so that it was impossible to be detected by our system. This patient died shortly after presentation due to respiratory failure. None of the other study patients was hospitalised for COPD. In the two hospitalised patients, the length of hospital stay due to AECOPD was 30 and 7 days. The overall hospitalisation rate was 0.099 per patient-year.

Thus, the sensitivity of the THC procedure in detecting AECOPD was 95% and specificity was 98%. The positive predictive value (PPV) of the ‘alert system’ for AECOPD before conducting the phone call was 26% and the negative predictive value (NPV) was 99.9% (these values were calculated based on the following numbers: true

positive = 60 questionnaires, false positive = 170, true negative = 9,586, false negative = 3). In order to validate AECOPD, 230 phone calls were conducted in 38 patients (7.6 phone calls per patient-year) with a mean duration of 4 min (29 min per patient-year). An integrated overview of all phone calls and exacerbations is shown in figure 4.

Health-related QoL as assessed by SGRQ did not change significantly (beginning of study period: mean 47.2 points; end of study period: mean 50.2 points; $p = 0.9$).

Cost-benefit analysis: as mentioned above, we conducted on average 29 min of phone calls per patient-year, which cost 85 Swiss francs according to our national reimbursement system. Further, 28 times in total, we recommended presenting to the GP or to our outpatient clinic. Assuming a consultation duration of 30 min each, this costs 2,476 Swiss francs in total or 82 Swiss francs per patient-year. Respecting the average rate of AECOPD of 2.1 per patient year in our study, it would cost 80 Swiss francs per patient-year to detect one AECOPD early.

Discussion

In this proof-of-concept trial, 14% of screened patients were included. The main reason for exclusion was missing technical equipment (27%). This can be partly explained by the relatively high average age of the patient population of interest. We are convinced that this factor will continuously decrease over time, as people will get more and more used to technical devices and online applications [7]. A relevant part of patients was excluded due to our – for the pilot trial – intentionally strictly chosen exclusion criteria. By only excluding patients, who are really not able to follow the procedures or are not interested, we could reach up to 50% of COPD patients with THC.

In eligible patients, we found excellent data completeness and patient acceptance. Smith et al. [8] performed a very similar THC intervention in Pennsylvania and documented nearly identical data completeness (86%). In our study, satisfaction with care was already high initially and further improved over the study period. Consistent with our findings, Wang et al. [9] found that chronically ill patients who are supported by health-related smartphone apps feel more secure, knowing that they are closely monitored by a healthcare team. This aspect has been confirmed by others [10–13]. Another systematic review also describes a generally high patient satisfaction and a sub-

Fig. 4. Integrated overview of all phone calls and all exacerbations. The x-axis describes the time from inclusion for each patient. On the y-axis, all 48 patients are listed. The grey bars indicate the study duration of each patient. Every dot and triangle corresponds to one phone call. Dots indicate that the daily online questions have been answered on this day ('available'). The size of the dot corresponds

to the number of 'yes' answers (2–8). Triangles indicate that the daily questions have not been answered on this day ('not available'). Grey colour of a dot or a triangle means that the suspected exacerbation was not confirmed. The other colours (green, yellow and red) indicate the severity in case of confirmed exacerbations (mild, moderate and severe, respectively).

jectively improved healthcare provision by THC programs [14]. Feasibility and acceptability of a THC procedure to support self-management in COPD has also been shown by Hardinge et al. [15].

With our THC procedure, we were able to detect 95% of acute exacerbations very early in the course, meaning a very high sensitivity, and immediately initiated an emergency treatment if needed. None of the detected patients presented at the ED or had to be hospitalised for AECOPD. Due to the study design, we do not have a control group, but our hospitalisation rate of 9.9% per patient-year is low, when exemplarily compared to 22% in the landmark study by Hurst et al. [16], indicating a possible reduction of hospitalisations by the use of THC. In contrast, the number of AECOPD (2.1 per patient-year) was higher than expected from the literature (e.g. 1.21 per patient-year in the above-mentioned study) [16]. This seems plausible because in the average setting without

THC, many exacerbations remain unreported, leading to negative consequences for disease course and QoL [3].

While sensitivity, specificity and NPV were very high, meaning that the hazard of missing an exacerbation with the current THC procedure was very low, the PPV was low (26%), resulting in a 'number needed to call' of ~4 patients to confirm one exacerbation. The current algorithm led to approximately half an hour of telephone calls per patient-year, which is in the time dimension of a single outpatient visit. In our outpatient setting, COPD patients depending on disease severity are evaluated 1–4 times per year (meaning 0.5–2 h of consultations per year). According to our national reimbursement system, with our proposed system it would cost 80 Swiss francs per patient-year to detect one AECOPD early, so that the herein expended effort is not disproportionate, which has been a possible concern [10, 12, 17]. It is also conceivable to replace outpatient visits in stable patients by THC in

the future to save resources. The final cost-effectiveness remains to be proven [18]. Nevertheless, the PPV should be further improved.

One limitation of our proof-of-concept study is the sample size. Nevertheless, we think that it was sufficient to answer the primary endpoints. With our strict exclusion criteria, we probably included the most capable and motivated patients in terms of a selection bias limiting the generalizability of our study results to an unselected COPD patient cohort.

The main strength of our THC procedure is the high sensitivity and NPV for detecting or excluding AECOPD, which gives us confidence in this process and encourages us to follow our efforts to further develop this kind of healthcare provision and hopefully integrate it in standard care in the future.

In conclusion, adding THC to a state-of-the-art COPD management is feasible in a selected group of patients. We showed excellent data completeness and patient ac-

ceptance and a high and improved satisfaction with care. We estimate that up to 50% of COPD patients could be eligible for THC. Our THC procedure had very high sensitivity, specificity and NPV, but a low PPV for detecting or excluding AECOPD. The expenditure of time seems not disproportionate. As a next step, a randomised controlled trial is required to test, whether the proposed THC approach can reduce emergency hospitalisations and deterioration of QoL due to AECOPD.

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