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ORIGINAL RESEARCH

Automated Oxygen Delivery in Home Setting for Patients with COPD on Long-Term Oxygen Therapy – A Randomized Crossover Feasibility Trial

Linette Marie Kofod[1,2], Ejvind Frausing Hansen[3], Morten Tange Kristensen[4,5], Barbara Cristina Brocki[6], Elisabeth Westerdahl[7]

[1]PMR-C, Department of Physio- and Occupational Therapy, Copenhagen University Hospital, Hvidovre, Denmark; [2]School of Medical Sciences, Faculty of Medicine and Health, Örebro University, Örebro, Sweden; [3]Department of Pulmonology, Copenhagen University Hospital, Hvidovre, Denmark; [4]Department of Physical and Occupational Therapy, Copenhagen University Hospital, Bispebjerg-Frederiksberg, Copenhagen, Denmark; [5]Department of Clinical Medicine, University of Copenhagen, Copenhagen, Denmark; [6]Department of Physiotherapy and Occupational Therapy, Aalborg University Hospital, Aalborg, Denmark; [7]University Health Care Research Center, Faculty of Medicine and Health, Örebro University, Örebro, Sweden

Correspondence: Linette Marie Kofod, Department of Physio- and Occupational Therapy, Copenhagen University Hospital- Hvidovre, Kettegaard Allé 30, Hvidovre, 2650, Denmark, Tel +45 38621619, Email linette.marie.kofod@regionh.dk

Rationale: Patients with COPD on long-term oxygen therapy (LTOT) have an unmet need for oxygen adjustments during sleep, rest, and activity, documented by continuous monitoring of oxygen saturation (SpO_2). While emerging technology enables automated adjustments, its feasibility in home settings remains uncertain. This randomized crossover trial evaluated the feasibility and preliminary effects of continuous automated oxygen titration at home.

Methods: The intervention period involved four days of automated oxygen titration targeting a SpO_2 of 90–94% using a Bluetooth-connected electronic device and wrist pulse oximeter, forming a closed-loop system. Oxygen flow (0.9–6.8 L/min) was continuously adjusted based on SpO_2. During the control period, patients received their usual fixed dose oxygen. Feasibility was defined as time with automated titration, time within target SpO_2 and patient acceptance. Additionally, health status was measured using the Clinical COPD Questionnaire (CCQ, minimal important difference 0.4).

Results: Twelve patients (8 men, mean (SD) age 72.9 (5.5) years) on LTOT with an oxygen dose of 2.0 (0.8) L/min were included. Each patient provided more than 217,000 paired SpO_2 and oxygen flow data points. Oxygen flow was automatically adjusted for a median of 77 h (IQR 68.0–84.3), covering 83% of the time. Time within target SpO_2 increased from 52% (42–63) to 86% (75–90) during the intervention. All patients used the full available flow range. The CCQ score improved by 0.74 (0.47) points; $p < 0.001$.

Conclusion: Automated oxygen titration is feasible in the home setting, achieving more time with normoxia, but it required a wide flow range and continuous SpO2 monitoring. The patients reported a clinically relevant reductions in COPD symptoms measured with CCQ. The clinical importance of controlling SpO_2 needs to be examined in a larger study.

Plain Language Summary:

Why was the study done?

Patients with COPD who use home oxygen often need different amounts during rest, activity, or sleep. Standard oxygen therapy provides a fixed amount, which may not meet these changing needs. This study tested whether oxygen could be adjusted automatically at home to better match each patient's needs.

What did the researchers do and find?

Twelve patients on home oxygen used a new system that adjusted the oxygen flow automatically based on their blood oxygen levels. The system used a wrist-worn monitor and aimed to keep oxygen levels within a target range (90–94%).

The system worked well, automatically adjusting oxygen for the largest part of the time but using a wide range of oxygen flow. Time spent in the target range increased from 52% with usual therapy to 86% with the automated system. The patients reported improvements in both breathlessness and mental well-being.

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What do these results mean?

Automatic oxygen adjustment at home is possible and helps patients spend more time with adequate oxygen levels. It needs continuous monitoring and flexible oxygen settings. This approach could improve comfort and quality of life for patients using home oxygen.

Keywords: automated oxygen titration, long-term oxygen therapy, closed-loop, activities of daily living, oxygen saturation, technology

Introduction

Oxygen is essential for human life. Regrettably, some patients with advanced COPD develop a reduced ability to deliver sufficient oxygen to the blood, resulting in chronic respiratory failure with the constant need of oxygen supplementation.

In acute settings, it is recommended to maintain target oxygen saturation using conservative oxygen doses in patients with acute hypoxemic respiratory failure, as this approach is associated with reduced mortality.[1–3] Several studies found that electronic, closed-loop devices, which automatically adjusts oxygen in response to the saturation, were more accurate in keeping the recommended saturation compared to manual adjustments.[4–8]

In contrast, our understanding is limited when it comes to maintaining target saturation during daily living in the home setting. Home oxygen is prescribed based on arterial blood gas analysis to achieve a partial pressure of oxygen (PaO_2) >8.0 kPa, corresponding to a peripheral oxygen saturation (SpO_2) of 90% at rest.[9,10] Although patients with COPD on long-term oxygen therapy (LTOT) use this prescribed fixed oxygen dose, continuous monitoring of oxygen saturation has revealed an unmet need for oxygen adjustments, depending on whether the patients are sleeping, sitting, or engaging in daily activities.[11,12] These fluctuating oxygen needs lead to episodes of desaturation and hypoxemia.[12–16] Clinical benefits of minimizing these episodes of hypoxemia are particularly evident during walking tests.[17–19] Optimizing patients' oxygen saturation by using the electronic devices for automated oxygen titration increased the patients' walking capacity and alleviated dyspnea.[17–19] Furthermore, improved oxygenation enhanced the patients' ability to perform activity of daily living (ADL) and reduced their perceived breathing effort during an ADL-test.[20] These results suggest, that increasing time spent with normoxia may benefit patients in daily life.

Automated oxygen titration technology has entered the home setting, enabling a closed-loop system to adjust oxygen delivery in real time based on oxygen saturation measurements. It requires the patients to wear a pulse oximeter that communicates with the oxygen delivery system, which then dynamically adapts the oxygen flow to each situation. When SpO_2 falls below the lower threshold, the system increases the oxygen flow, and when it rises above the upper threshold, the flow is reduced. This process is repeated continuously, creating a feedback loop between monitoring and oxygen delivery, without manual adjustments. Around-the-clock monitoring of oxygen saturation and consequently continuous adjustments of the oxygen flow in the home setting represent a new approach, and it remains unclear how, or even if, such oxygen titration could be effectively managed. The patients may face practical or technical challenges, and their acceptance of automated titration is unknown. Therefore, before conducting a larger trial, it is necessary to determine whether the intervention can be safely and reliably applied in the home setting. The aim of this randomized crossover study was to evaluate the feasibility of automated oxygen titration as response to the saturation during daily living for four days in the home of patients with COPD on LTOT. Feasibility was defined as successful time during which the patients' oxygen was automatically titrated, the patients' willingness toward the intervention, and clinically relevance.

Methods

Study Design

This randomized crossover feasibility trial was conducted in the homes of 12 patients with COPD on LTOT. The patients were recruited from two departments of pulmonology at Copenhagen University Hospital, Hvidovre and Copenhagen University Hospital, Bispebjerg-Frederiksberg, Denmark, from January to December 2023 in connection with a scheduled study visit.[20]

The study complies with the Declaration of Helsinki and was approved by The Committees on Health Research Ethics in the Capital Region of Denmark (H-22032988) and the Danish Data Protection Agency j.nr. P-2022-625. The

study was registered at ClinicalTrials.gov (NCT05556187), and the reporting followed the CONSORT statement for randomized pilot and feasibility trials.

Participants

Inclusion criteria included patients with COPD and chronic respiratory failure with resting hypoxemia ($PaO_2 \leq 7.3$ kPa), who were receiving LTOT according to the international criteria for home oxygen therapy,[9] had the ability to walk independently (with or without a walking aid), and were cognitively able to participate. Exclusion criteria were an exacerbation in COPD treated with either antibiotics or prednisolone within the preceding three weeks or comorbidities known to impact physical functioning. Additionally, before randomization, each patient underwent two venous blood gas tests: the first with their usual oxygen dose and the second after 20 minutes of 8 L/min of oxygen. Venous blood gases (instead of arterial blood gases) were used to minimize discomfort to the patients.[21] The blood samples were analyzed for pH-value and $PvCO_2$. The patients were excluded if they exhibited a drop in pH to <7.31 on 8 L/min of oxygen flow or an increase in the partial pressure of carbon dioxide within venous blood ($PvCO_2$) of >1 kPa compared to their usual fixed oxygen dose.

Included patients provided written informed consent before participation.

Intervention

The Automated Oxygen Period

The intervention period consisted of four days with a continuous titration of the oxygen flow aiming at a target saturation between 90% and 94% using an electronic closed-loop device installed in the patients' homes. If SpO_2 dropped below 90% or exceeded 94% the oxygen flow was automatically adjusted according to the algorithm in the device.

The Fixed Dose Period

For the control period, the patients received their usual fixed oxygen flow for four days while monitoring and collecting data on SpO_2 and heart rate.

The two periods were scheduled on comparable days to minimize significant variations in social or physical activities; however, no specific washout time was planned. In both periods, daily steps were monitored with an accelerometer, and the patients used their usual portable oxygen concentrator when being outdoors.

Study Technology and Data Capture

The Automated Oxygen Period

A closed-loop device O2matic Home Oxygen Treatment (HOT) (O2matic Ltd., Herlev, Denmark) was used for automated oxygen titration. Oxygen was supplied either by the 9 L/min Invacare Platinum 9 concentrator (Invacare Ltd. Brøndby, Denmark) or by the 10 L/min Caire NewLife Intensity concentrator (Medical Danmark Ltd., Ejby, Denmark), connected to the HOT device using a tube.

The patients wore the Nonin Wrist Pulse Oximeter (Nonin Medical, Inc., USA) with the sensor well-attached to a finger using a sensor tape, Figure 1. The pulse oximeter transmitted data on SpO_2 and heart rate to the HOT device via Bluetooth. The adjustments on oxygen were done every second based on average SpO_2 for the last 15s. The SpO_2 target interval and a flow range was set at the beginning of the intervention, and only the investigator had access to modify these settings. A previous study identified a mean oxygen demand of 8 L/min during a walking test.[18] Therefore, the aim was an oxygen flow from 0.5 to 8.0 L/min. However, the concentrators were only able to deliver a stable flow between 0.8 and 6.8 L/min. In case the patients removed the pulse oximeter (or experienced a general loss of signal) for more than two minutes the flow would return to usual flow ± 1 L/min and stay there until the signal was restored.

Data Collection

The close-loop device transmitted raw real-time data (recordings each second of heart rate, SpO_2, and oxygen flow) to an app on the patient-tablet. These data were relayed via Wi-Fi to a secure web platform (Microsoft Azure), where it could be accessed by the principal investigator. The patients could also view their real-time data on the tablet. For purpose of analysis, raw data could be extracted and downloaded from the platform as CSV files.

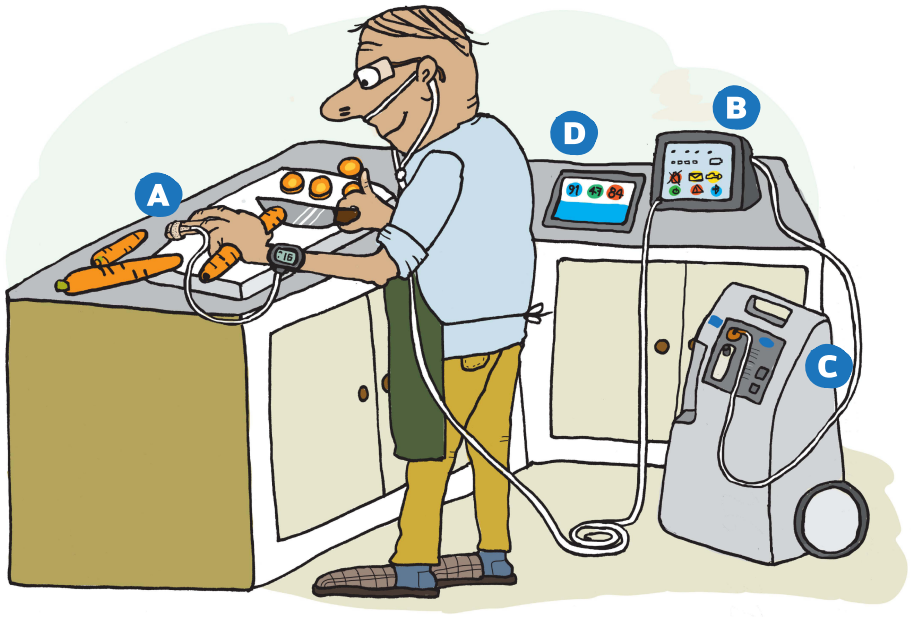

Figure 1 Artistic presentation of the automated oxygen delivery setup. (**A**) Pulse oximeter, which transmits oxygen saturation data via Bluetooth to the closed-loop devise, (**B**) Closed-loop device, that titrates oxygen via the high-flow nasal cannula to the patient, (**C**) Oxygen concentrator, (**D**) Patient tablet, displaying the current saturation, oxygen flow and heart rate. The patient tablet also transmits information via Wi-fi to the online platform.

In case of a temporary disconnection to the patient-tablet, raw data were stored locally on the closed-loop device and transmitted once the connection was restored. After these periods, the online platform provided aggregated data files, derived from the raw recordings, which contained only summary information: total time with automated oxygen titration, and average values for SpO_2, oxygen flow, and heart rate. For purpose of analysis, only the duration of automated oxygen titration was used from these aggregated files.

The Fixed Dose Period

During the fixed dose period, the patients wore the same wrist pulse oximeter as during the intervention. Since automated oxygen titration could only be administered in the patient's home, we instructed the patients to remove the pulse oximeters when leaving the house during the control period, so that data were only collected when being indoors.

Data Collection

The data on SpO_2 and heart rate were stored locally in the wrist oximeter. CSV files, used for analysis, were generated using Nonin's nVISION Data Management Software. The batteries in the pulse oximeter needed to be changed every second day, and when removed, it resulted in a reset of date and time in the system. As a result, the collected data during the fixed dose period were untransparent, regarding the exact date and time.

Step Counts

The physical activity was monitored equally in both study periods using the SENS motion accelerometer (SENS innovation ApS, Denmark) placed with a patch above the patients' knee. It continuously recorded movements, which were synchronized via an app to a web server. The system has been validated in hospitalized patients, showing accuracy even in older individuals taking small steps.[22] Summary files containing information on steps were accessed from SENS online platform and used for analysis.

Outcome

Feasibility

The goal of this study was for patients to wear the pulse oximeter continuously during the daytime while having their oxygen adjusted automatically. We defined three key areas that needed to be fulfilled for it to be considered feasible: time when the patients were automatically titrated, patients' willingness toward the intervention and clinical relevance. Prior to the study, we established the following criteria:

1) Data were successfully transmitted from the wrist pulse oximeter to the closed-loop device and further to the cloud solution (<10% data loss),
2) The patients wore the wrist pulse oximeter for more than 50% of the daytime (08:00–20:00),
3) The time spent within target saturation was statistically different between arms and in favour of automated oxygen titration with a difference of at least 10%,
4) The patients were at least as active with automated oxygen titration as with usual fixed oxygen therapy, measured by the activity sensor,
5) The patients were safe with no serious adverse events, leading to unscheduled healthcare contacts.

Rationale for criteria 1, *Titration time*: Both raw and aggregated data received on the platform were proof of "the time when the patients were automatically titrated". The 10% threshold was based on experiences from three earlier studies on automated oxygen delivery.[7,18,20]

Rationale for criteria 2, *Patient willingness*: We considered patients' willingness to wear the wrist pulse oximeter in the daytime from 8 a.m. to 8 p.m. as essential for continuous oxygen titration.

Rationale for criteria 3 and 4, *Clinical relevance*: If automated oxygen titration did not improve oxygen saturation, it was deemed irrelevant. Therefore, we evaluated: differences in time spent with normoxia (SpO2 90–94%), moderate hypoxemia (SpO2 85–89%), severe hypoxemia (SpO2 < 85%) and hyperoxemia (SpO2 > 94%). Step count was monitored to ensure comparable activity levels across study periods, thereby minimizing potential confounding from differences in activity-related desaturation episodes.

Rationale for criteria 5, *Patient safety*: The setup was considered non-feasible if it posed notable risks to the patient, such as unscheduled contacts to the hospital due to acute-on-chronic respiratory failure.

Secondary outcome

At study start, after four days intervention, and after four days of usual care, the patients were assessed using the health status Clinical COPD Questionnaire (CCQ), 24-hour version.[23] The CCQ is validated in Danish, consists of ten questions across three domains: symptoms, mental state, and functional state. Each question is scored from 0 to 6, with a higher score indicating a lower health status. A Minimal Important Difference (MID) of 0.4 is considered clinically relevant.[24]

The patients' oxygen flow was compared between both study periods.

Variables

We included the following variables to describe the characteristics and clinical profile of the patients: age, gender, body mass index (BMI), pulmonary function and duration of LTOT, all of which were extracted from the patients' medical records. Additionally, the patients were asked about their perceived dyspnea at rest, measured using the Borg CR10 dyspnea scale, their marital status, need for a walking aid, and frequency of engaging in activities outside their home. The patients also completed the modified Medical Research Council Dyspnea Scale (mMRC) and the COPD Assessment Test (CAT).

Randomization and Blinding

The patients were randomized after inclusion to either the automated oxygen period followed by the fixed dose period, or vice versa. The randomization list was computer-generated and compiled for each patient in REDCap electronic data capture tools (REDCap Consortium, Nashville, US) hosted at Capital Region of Denmark.

Neither the patients nor the investigator were blinded.

Statistical Considerations

Due to the feasibility design of the present study, a formal sample size calculation was not performed. In a non-feasibility design, CCQ could be a primary outcome, which would require 42 patients to detect a MID of 0.4 with a standard deviation of 0.9. For the purpose of this feasibility study, we selected a sample of 12 patients, as we considered this number sufficient to assess feasibility. Furthermore, this sample size provided an adequate basis for evaluating variations in SpO_2 intervals and generating preliminary insights into the CCQ outcome.

For the analysis on the patients' SpO_2 and oxygen use in this study, only *raw data* extracted from CSV files were used. In the evaluation of Criteria 1, however, both raw and aggregated data were applied to obtain a more complete estimate of the 'titration time'.

Continuous variables were examined for normality. Those meeting normality assumptions were analyzed with a paired *t*-test and presented as mean (standard deviation (SD)). For not normally distributed variables, the Wilcoxon signed-rank test was used, with data presented as median with interquartile range (IQR). CCQ was tested in a two-way ANOVA with treatment, period and an interaction term between treatment and period as explanatory variables to account for carryover effect bias. IBM SPSS Statistics for Windows, ver. 29.01 was used for all statistical analyses. GraphPad Prism version 10.1.2 for Windows was used to create the figures.

Results

Thirty-two patients were screened for eligibility, of whom 13 met the inclusion criteria and consented to participate, Figure 2. One patient was subsequently excluded after venous blood gas analysis revealed a PCO_2 of 11.3 kPa and a pH decrease from

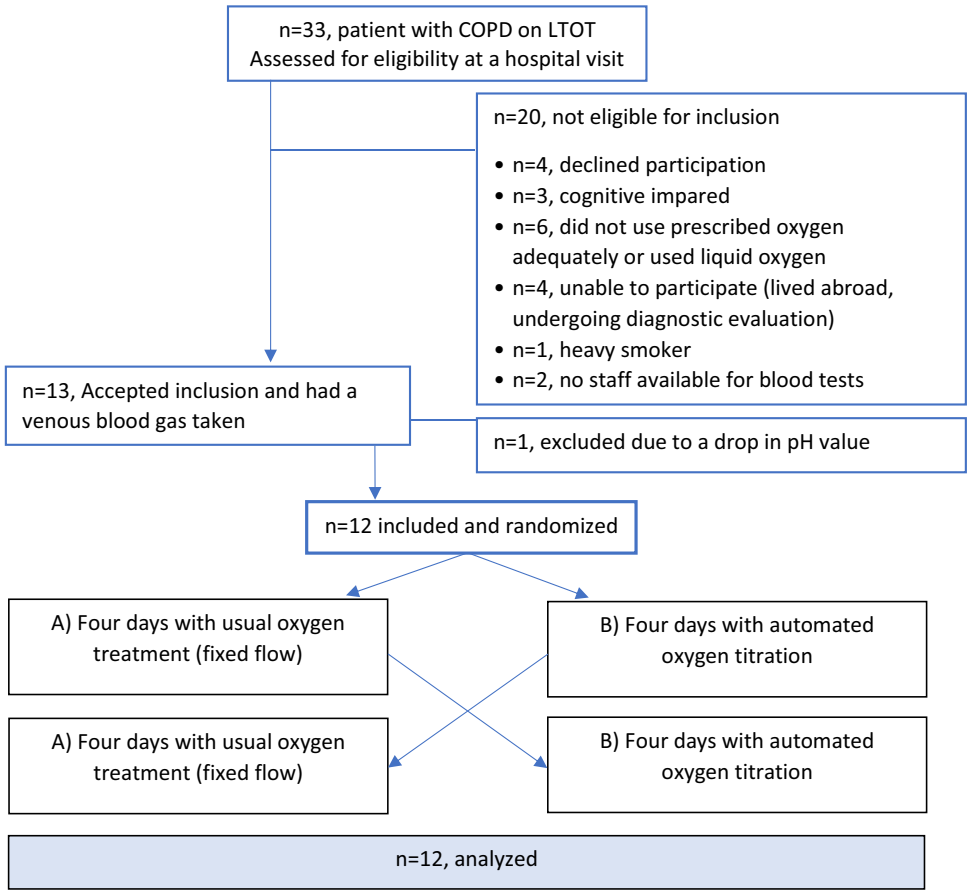

Figure 2 Flow diagram of inclusion of patients.

7.30 to 7.28 following 20 minutes with 8 L/min oxygen. Accordingly, 12 patients (four women and eight men) with a mean (SD) home oxygen dose of 2.0 (0.7) L/min were randomized, Table 1. All patients completed the study.

Feasibility

During the four days of automated oxygen intervention, the equipment was installed for a median duration of 96 h (IQR 94.7–96.0). Detailed raw data were received for each patient for 69.5 h (53.3–82.8), providing more than 217,000 paired data points on SpO_2 and oxygen flow per patient during the automated oxygen period, Table 2.

Criteria 1, *Titration time*: Raw and aggregated data showed that the patients' oxygen flow was automatically titrated for 77 h (68.0–84.3), corresponding to 83% (74–88) of the possible time. The remaining 17% reflected periods when patients left their homes, removed the pulse oximeter for showering or battery changes, or experienced unintentional signal loss and disconnection.

Table 1 Characteristics and Clinical Profile of the Study Patients with COPD on LTOT, n=12

Variables	
Male/Female, no.	8/4
Age, years	72.9 (5.5)
Body Mass Index, kg/m^2	26.2 (8.5)
LTOT flow, usual fixed dose, Liters/min	2.0 (0.7)
Time with LTOT, months, median (IQR)	15 (5–36)
SpO_2 at rest with LTOT, %	92 (2)
Borg CR10 dyspnea at rest, score 0-10	1.3 (1.1)
CAT score, 0-40	17.2 (5.8)
mMRC, 0–4, median (IQR)	3.0 (3-3)
mMRC, 0/1/2/3/4, no.	0/0/1/9/2
Hospital admissions the last year, 0/1/2/3/4, no.	6/4/1/1
FEV_1, liter	0.91 (0.22)
FEV_1, % of predicted	35 (12)
FVC, liter	2.08 (0.83)
FEV_1/FVC, ratio	0.55 (0.44)
Former tobacco user, no. (%)	12 (100)
Pack years	44.5 (27.6)
CCQ, 0–6, total baseline score	2.8 (0.96)
CCQ-subscore: Symptoms	2.3 (1.1)
CCQ-subscore: Functional state	3.7 (1.1)
CCQ-subscore: Mental state	2.4 (1.6)
Marital status, no. (%)	
Lives with spouse	9 (75)
Lives alone	3 (25)
Walking aid, no. (%)	
Rollator	8 (66.6)
No walking aid	4 (33.3)
Receives pulmonary rehabilitation (PR), no. (%)	
Outpatient PR	8 (66.6)
Tele-PR	2 (16.7)
No PR	2 (16.7)
Engages in activities outside their home (self-assessed), no. (%)	
Rarely	4 (33.3)
Regularly	2 (16.7)
Often	6 (59)

(*Continued*)

Table 1 (Continued).

Variables	
Lives in, no. (%)	
House	4 (33.3)
Apartment in building without lift	4 (33.3)
Apartment on ground floor or in building with lift	4 (33.3)

Notes: Data are presented as mean (standard deviation), unless otherwise specified.
Abbreviations: IQR, interquartile range; LTOT, long-term oxygen therapy; mMRC, modified Medical Research Council Dyspnea Scale; CAT, COPD assessment test; SpO_2, peripheral oxygen saturation; FEV_1, forced expiratory value in the first second; FVC, forced vital capacity; CCQ, Clinical COPD Questionnaire.

Table 2 Patient Reported Outcome and Physiological Parameters, n=12

Variable	The Automated Oxygen Period	The Fixed Dose Period	Difference	*P*-value
24-hours Clinical COPD Questionnaire (CCQ)				
CCQ total, score 0–6	1.95 (0.82)	2.69 (0.77)	0.74 (0.47)	<0.001
CCQ symptoms	1.69 (0.68)	2.44 (0.91)	0.75 (0.54)	<0.001
CCQ functional state	2.60 (1.25)	3.10 (0.99)	0.50 (1.10)	0.14
CCQ mental state	1.13 (1.37)	1.92 (1.64)	0.79 (0.84)	0.007
Pulse oximeter data				
Hours with raw data	69.5 (53.3–82.8)	66.0 (30.5–86)	3.5 (−16.3–31.3)	0.4
Heart rate, bpm	79.4 (10.7)	80.8 (9.9)	1.5 (5.8)	0.4
Avg. SpO_2, %	91.9 (0.9)	92.0 (1.9)	0.1 (1.5)	0.8
Avg. O_2 flow, L/min	2.4 (0.8)	2.0 (0.8)	0.3 (1.0)	0.3

Notes: Data presented as mean (Standard deviation) or median with (interquartile range). SpO_2%: peripheral oxygen saturation, bpm: beats per minute, CCQ: The Clinical COPD Questionnaire. CCQ is assessed at the end of each period. Pulse oximeter data represent the mean values across the two periods, respectively.

Criteria 2, *Patient willingness*: Raw data were received for 35.5 h (26.3–42.5) for each patient in the daytime period, constituting 75% (64–88) of the time. Of the 12 patients, 11 patients wore the pulse oximeter for at least 50% of the time in the automated oxygen period.

Criteria 3, *Clinical relevance*: Time spent with SpO_2 of 90–94% differed significantly between periods: 52% (42–63) with fixed oxygen flow versus 86% (75–90) with automated titration, $p = 0.002$. Correspondingly, significant differences in favor of the automated oxygen intervention were also observed in time spent with moderate hypoxemia, $p = 0.003$, severe hypoxemia $p = 0.004$, and hyperoxemia $p = 0.01$, as illustrated in Figure 3.

Criteria 4, *Clinical relevance*: The patients took 2,297 (1,519–3,106) steps daily in the fixed dose period and 2,366 (1,236–3,703) steps during the automated oxygen period, with no significant difference between periods, $p = 0.7$.

Criteria 5, *Patient safety*: Unintended events were observed during the intervention, none which required hospitalization or unscheduled healthcare visits. Some events triggered system alarms, primarily due to insufficient oxygen supply, see Table 3. The patients expressed annoyance with the noise from the concentrator, the bulkiness of the pulse oximeter, and the frequent use of batteries.

Secondary Outcome

The total score in the CCQ improved significantly by a mean of 0.74 (0.47) points favoring the automated oxygen intervention, $p < 0.001$, Table 2. Eleven of the twelve patients met or exceeded the MID of 0.4, with individual changes presented in Figure 4.

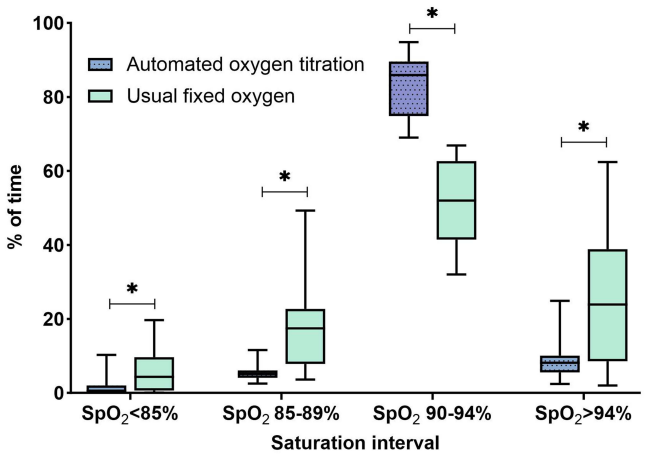

Figure 3 Percentage of time spent within oxygen saturation (SpO_2) intervals. Boxplot illustrating median, interquartile range, minimum and maximum time spent in the various intervals. X-axis: Four predefined oxygen saturations intervals. Y-axis: Percentage of time over a total period of four full days. Statistics: Wilcoxon signed-rang test, $^*p \leq 0.01$.

No difference in mean oxygen flow between periods was observed, $p > 0.3$, Table 2. However, all 12 patients used the full range of possible oxygen flow during the automated oxygen period. During 34 (18)% of the measured time, the patients' oxygen flow was titrated up compared to their usual fixed oxygen dose, and in 38 (27)% of the time it was decreased, Figure 5.

The test for carryover-effect showed neither significant difference in CCQ total score between the two periods nor significance of an interaction term between treatment and the period.

Discussion

We found that continuous automated oxygen titration in the homes of patients with COPD on LTOT was both feasible and well tolerated, with high patient compliance. For more than 80% of the day, the patients' oxygen flow was titrated based on their saturation, resulting in a significant improvement in oxygenation at home compared to using their fixed dose. Furthermore, the patients reported a lower symptom burden, as measured by the CCQ, indicating a more positive perception of health status when oxygen saturation was improved.

Table 3 Outlining Of Incidents During The Automated Oxygen Period

1. HOT Device Failure	
Incident	One patient experienced repeated alarm indicating the need for device repair.
Action and Solution	After restarting the device, the patient went to bed and, without hearing aids, did not hear the alarm from HOT and concentrator. The patient's husband heard the alarms and restarted the device until it was replaced the next day.
Consequences	5-10 minutes without oxygen. The patient received oxygen after her husband reactivated the system.
2 Loss of electricity	
Incident	One patient experienced a device shut down while at rest, possibly due to loss of electricity. HOT has a battery backup and a visual alert indicator as well as an audible alarm before shutdown. It is unclear if the "low battery" alarm was present or if the patient did not hear it.
Action and Solution	The oxygen supply was interrupted (as HOT turned off), triggering the concentrator alarm. The patient responded to the alarms and reactivated the system.
Consequences	5-10 minutes without oxygen. The patient received no oxygen for the minutes from the time of alarm until the cables were checked and the devices were turned back on.

(*Continued*)

Table 3 (Continued).

3 Shut Down of HOT Due to Lack of Oxygen	
Incident	Three patients experienced an alarm followed by a shutdown, triggering the concentrator alarm. This occurred while they moved around with a high oxygen demand. If HOT registers unsatisfactory oxygen flow for two minutes, it alarms and shuts down completely, stopping oxygen delivery. The issue stemmed from the concentrator's inability to deliver a higher amount than 6.8 L/min. The patients' profile was set to give up to 8 L/min. When SpO_2 dropped, HOT required more oxygen quickly, exceeding the concentrator's capacity.
Action and Solution	The concentrator needed to be restarted, and HOT needed to be turned on again. The patient's profile was changes so that the highest amount of oxygen was fitted to what the concentrator could deliver.
Consequences	5-10 minutes without oxygen. The patients received no oxygen supply during the process from alarm to restarting of the system. One patient switched to usual fixed flow until contact person arrived.
4 HOT in alarm while leaving home	
Incident	One patient came home from grocery shopping to find the HOT device in alarm. The patient had left the house without turning off the HOT device, but she had turned off the concentrator, leading to an oxygen shortage and alarm.
Action and Solution	HOT needed to be turned off and on again.
Consequences	The patient was unable to turn off the HOT device, so she wrapped it in towels and hid it in the laundry basket in the bathroom. She received oxygen from her portable oxygen device until she switched to her usual fixed dose. Called her contact person.
5 Tablet disconnected	
Incident	Unstable Bluetooth connection between HOT device and patient tablet happened on a regularly basis for most patients.
Action and Solution	Sometimes connection restored automatically, sometimes a reactivation of the app on the tablet was necessary. Occasionally, the tablet needed a restart.
Consequences	Loss of "raw data". The patients were not able to follow their SpO_2, heart rate and oxygen flow on the tablet, but still received automated titration.
6 Pulse oximeter disconnect	
Incident	Unstable Bluetooth connection and/or finger sensor instability. Every patient lost "signal" at some point.
Action and Solution	Bluetooth reconnected automatically. Two patients moved HOT to a new position when going to bed and placed it back again in the morning. One patient consequently lost connection in his bathroom due to poor signal.
Consequences	In case of more than two min signal loss the oxygen flow returned to usual fixed dose.

Notes: HOT: The closed-loop device for automated home oxygen therapy. The event table was constructed from cases that either required assistance to be resolved or were reported by patients.

Feasibility, Titration Time and Patient Acceptance

Our feasibility criteria were necessarily pragmatic, as no prior experience existed with continuous automated oxygen titration in this setting. One reasoning in defining the criteria, was that if the patients removed the wrist pulse oximeter for more than half of the day (criteria 2), this would indicate such limited engagement with titration that continuous automated adjustment would be of little value. The 10% threshold (in criteria 1) was intended to represent unintended loss of data; however, we soon realized that we could not distinguish between unintended data loss and deliberate (voluntary) removal of the oximeter. We also predefined the daytime as the relevant observation period since we expected patients to remove the oximeter at night. In practice, however, patients were highly motivated to keep their saturation within target, and all 12 participants wore the oximeter continuously, day and night. As a result, we obtained substantially more data than anticipated: 83% of the total four-(24h)-day study period. Importantly, the remaining 17% of missing data included both unintentional loss (criteria 1) and voluntary removal (criteria 2). Thus, taken together, data completeness clearly exceeded our predefined feasibility criteria and confirmed that technical performance and patient adherence were better than expected.

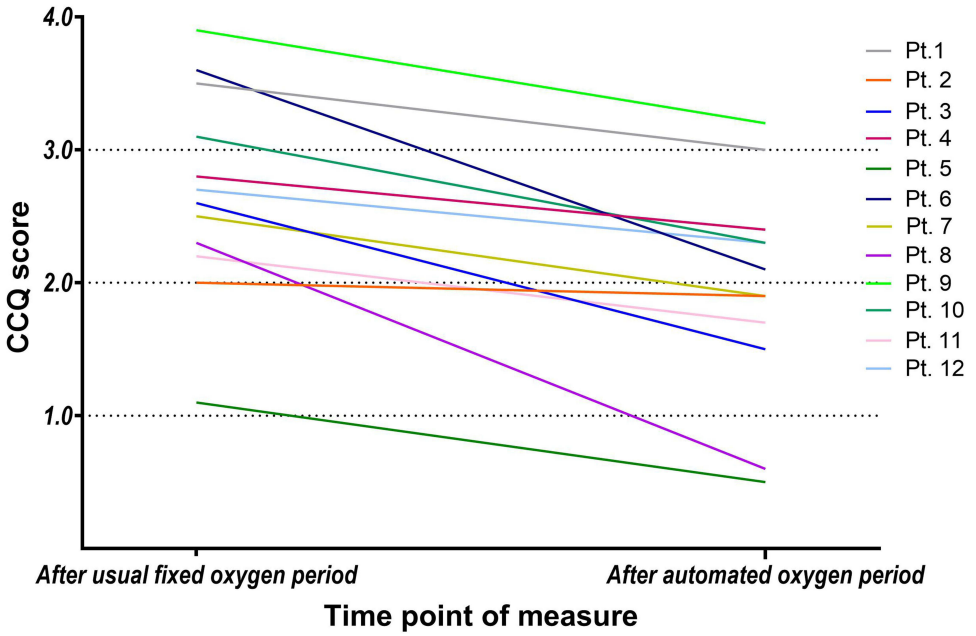

Figure 4 Individual scores in the CCQ. Individual 24-hour Clinical COPD Questionnaire (CCQ) scores, with higher scores indicating poorer health status. Measurements were taken after the period of usual fixed oxygen dosing and after the period of automated oxygen titration. Each line represents an individual patient. Eleven of the 12 patients showed an improvement in CCQ score of at least the minimal important difference (0.4).

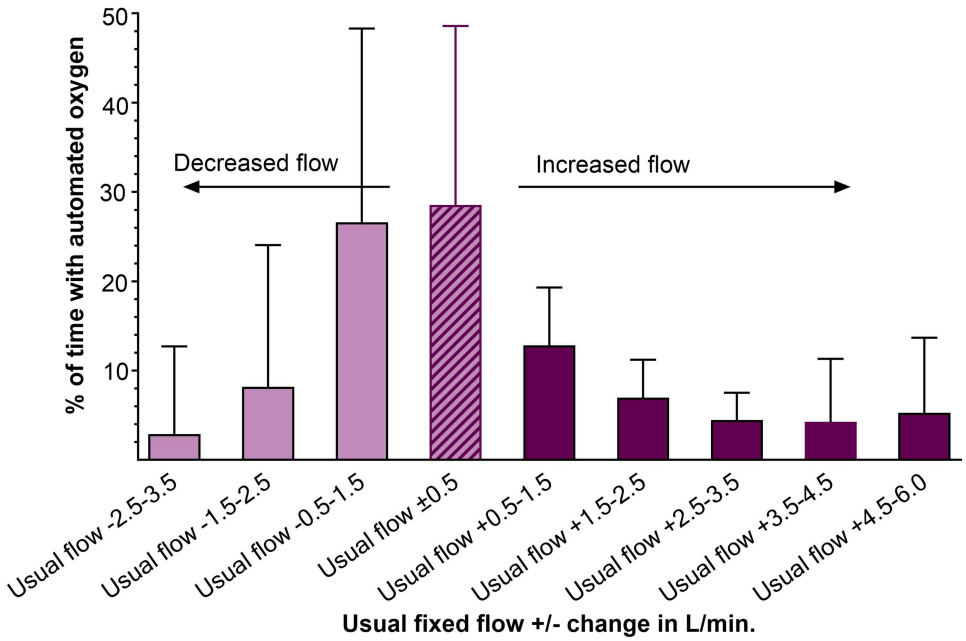

Figure 5 Various oxygen flow used during the automated oxygen period. The percentage of the time the patients spent using various oxygen flows during automated titration, expressed as changes in 1 L/min intervals from their usual fixed flow ±0.5 L/min. The striped bar represents the 29% (20) of the time, where the patients received their usual oxygen flow. The light purple bars indicate the percentage of time patients experienced decreased oxygen flow compared to their usual flow, while the dark purple bars represent the time in which the oxygen flow was increased.

Target Saturation and Oxygen Flow

Notably, the patients were within the target range only about half of the time (52%) while using their prescribed oxygen dose at home. Given that the prescribed dose is intended to ensure adequate oxygenation, this highlights a substantial gap between intended and actual treatment effect. The mean oxygen flow and mean saturation levels were nearly identical

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across both study periods, but the patients' fluctuating oxygen needs throughout the day, required full use of the device's flow capacity. In 71% of the time where the patients used automated oxygen delivery, their oxygen flow was automatically adjusted to a different rate than their usual fixed dose. Not only did the oxygen flow increase with up to additional 5 L/min in the automated period but more than 33% of the time, the patients' oxygen flow was reduced compared to their usual fixed dose. This highlights the fluctuating oxygen needs at an individual level for each patient. This variability in oxygen flow corresponded to the significant improvements in the time spent within the target saturation increasing from 52% to 86% of the day and thereby fulfilling feasibility criteria 3.

Fluctuating oxygen needs and time spent with hypoxemia have also been observed during walking, as well as in more home-related settings, such as during an ADL test.[17–20] In a study in ADL context, the mean oxygen flow increased from 1.6 to 5.2 L/min, while the time spent with severe hypoxemia (SpO2 < 85%) decreased by 30% to 17%.[20] These improvements in oxygen saturation led to enhanced performance and reduced experiences of dyspnea.

As mentioned, the patients spent approximately 22% of the day with SpO_2 below 90% while using their usual fixed oxygen flow. This is slightly different from a study by Sliwinski et al, in which patients spent 30% of the day with hypoxemia.[12] Patients are typically more active when being outdoors; thus, probably also more frequently experiencing hypoxemia, and this could explain the differences in time spent with hypoxemia between the present study and Sliwinski's, where patients also were monitored while outdoors.

Sliwinski did not report how long patients maintained a saturation above 94%. However, Zhu et al argued that oxygen flow rates should be reduced during rest, as patients' oxygen saturation were often too high.[11] In the present study, we found that patients with usual oxygen dose spent 24% of their time with saturation above the target range while at home. This corresponds to six hours per day with hyperoxemia, during which the patients could use a lower oxygen flow or, depending on the degree of respiratory failure, take a break from the nasal cannula. In line with this, Ekström et al recently found that patients could pause oxygen therapy for up to nine hours per day without any consequences on mortality or hospitalization.[25] However, they did not monitor for how long time the patients were well treated without hypoxemia.[25] The NOTT and MRC studies from the 1980s established that reducing hypoxemia at rest by increasing PaO_2 above 8 kPa reduces mortality.[26,27] Oxygen use for 24 hours was found to be more beneficial than 12 hours, and 15 hours was better than no oxygen at all. However, it remains unclear whether the critical factor is the overall duration of oxygen therapy or the time spent with effective oxygen therapy (PaO_2 > 8 kPa).

Health Status and Daily Step Counts

Health status, evaluated using the CCQ, could potentially detect improvements in patients' ability to move with less dyspnea and participate in more social activities. In our 12-patient feasibility study, the CCQ overall score significantly favored the automated oxygen period, with a difference of 0.74 point, which is almost the double of the 0.4 MID established for the CCQ in this population. Both the symptoms and mental state domains of the CCQ showed significant improvement, supporting the hypothesis that optimized oxygenation can alleviate dyspnea, as also observed during walking and in ADL. Patients with advanced COPD often report a markedly impaired health-related quality of life (HRQoL),[28,29] particularly those receiving long-term oxygen therapy (LTOT).[30] Interventions that enhance oxygen delivery have shown meaningful clinical benefits in this patient group. High-flow nasal cannula (HFNC) therapy has been shown to stabilize SpO_2 more effectively than usual oxygen therapy with fewer episodes of desaturation, which has led to reductions in exacerbation rates, hospital admissions, and improvements in subjective symptom scores.[31–33] In line with this, Sandau et al reported that automated oxygen titration enhanced patients' sense of safety during acute exacerbations,[34] which, together with the improved health status observed in our study and findings from HFNC research, supports the notion that optimized and individualized oxygen delivery contributes positively to patient-perceived outcomes.

The patients in the present study were generally inactive with approximately 2,300 steps per day with no difference between periods, which aligns with what is previously reported for this severely ill group (2,400 to 3,800 steps per day).[35] Our criteria 4 for feasibility related to physical activity (no difference between periods) was met. The study was not powered to find any difference in step counts and given the short, indoor-only intervention and the difficulty of changing habits we did not expect to find a difference between periods.

An essential factor in evaluating feasibility before considering a larger trial or implementation is the patients' attitude toward the intervention. This includes the perceived burden of the technology and how well it aligns with what patients find personally meaningful and effective. Patients' experiences are reported in a separate paper, gathered through qualitative interviews with the involved patients in the present study.[36]

Equipment Challenges

The proper solution for maintaining a target saturation emerged with the introduction of automated closed-loop devices for home use. Effective automated oxygen administration (based on continuous saturation monitoring during daytime and automatic oxygen adjustments) depends on optimization of all system components. This includes the closed-loop device, the pulse oximeter, and the oxygen concentrator, as well as reliable Wi-Fi and coordination between these elements. A well-designed nasal cannula capable of delivering flows above 5 L/min without causing discomfort to the patient is also preferable. Early in the study, it became apparent that the concentrators were unable to sustain an 8 L/min flow, leading us to lower the maximum flow for consistent performance. Furthermore, the standard concentrator, typically used for flow rates higher than 5 L/min, was notably noisy and the reason for the patients' primary complaints. The pulse oximeter was by many found to be uncomfortable for constant wear and too demanding in battery use.

Adding an electronic device to the patient's oxygen therapy system increases the risk of unintended events and system alarms. Some of these alarms are appropriate as they alert to an undesirable situation such as low oxygen flow. Acting on alarms under current conditions requires that the patients have both auditory and visual awareness, along with sufficient cognitive capacity to respond adequately to alarms or, at a minimum, switch to their standard treatment if needed. As shown in Table 3, some minor events, including system alarms, were observed. None resulted in patient harm, thereby fulfilling feasibility criteria 5 regarding patient safety.

Strength and Limitation

A key strength of the present study is the home setting, where patients behaved as they typically would, without the need for round-the-clock support. They engaged in their usual daily activities and moved around with their normal level of physical activity. This provided valuable insight into how automated oxygen titration might function in real-world conditions and its potential impact on patients' daily lives. We believe, the data we received were reflective of real-life scenarios.

Another strength is the extensive amount of data collected for each patient. We collected data over two four-day periods, providing a detailed overview of time spent in different SpO_2 intervals with and without the automated oxygen delivery. The same wrist pulse oximeter ensured consistent saturation measurements during both periods.

A central limitation of this study is the non-blinded design, which may have influenced patient-reported outcomes such as the CCQ. Although patients reported clinically relevant improvements with increased time in normoxia, the small sample size and lack of blinding mean these findings should be interpreted as indicative rather than conclusive. The mental state domain of the CCQ addresses anxiety and worries about disease progression. As highlighted in the previous qualitative work, patients strongly associate desaturation with dyspnea and distress, and simply knowing that oxygen titration was being automated may have alleviated anxiety and improved self-reported well-being, independent of physiological effects. Nevertheless, whether perceived or real, such reductions themselves can be meaningful for the patients. In addition, the option for patients to directly contact the investigator in case of problems may have provided a reassuring effect, potentially amplifying the sense of safety across both study arms. Furthermore, the short intervention period may have increased patients' willingness to tolerate the noise from the oxygen concentrator and wearing the wrist pulse oximeter. Both aspects were among the most frequent issues criticized by the patients, and over longer durations they may lead to fatigue and reduce the feasibility of the intervention in routine practice, underscoring a pressing need for better oxygen delivery technology.

A large, long-term trial is needed to confirm the preliminary positive effects on health status, including outcomes such as hospitalization and mortality. Such a study should also rigorously address cost-effectiveness, providing a clearer basis for future clinical and economic decision-making.

Conclusion

In the home setting, it was feasible to increase the time that patients with stable COPD on long-term oxygen therapy spent within target saturation from 52% to 86% of the day using automated oxygen titration. This improvement in oxygen saturation appeared to be associated with better patient-perceived health status, reflecting reduced symptom and cognitive burden, such as dyspnea and worries in daily life. These findings need to be confirmed in a larger RCT with a longer follow-up period. Despite promising advances in digital technologies for home oxygen therapy, the need for technical equipment updates and further development still remains.

Data Sharing Statement

Due to Danish national legislation (Data Protection Act §10 and the Data Disclosure Proclamation Act), public deposition of raw data is not permitted. Pseudonymized data can only be shared following approval by the Danish Data Protection Agency and, in compliance with Capital Region data governance. Researchers interested in accessing the data may contact the corresponding author to discuss the procedure. However, any official request for access must be approved by the Danish Data Protection Agency; the authors cannot grant access independently.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

This paper is based on the thesis of Linette Marie Kofod. It has been published on the institutional website of Örebro University, Sweden, https://www.diva-portal.org/-smash/record.jsf?pid=diva2:1955394. The authors original manuscript has been uploaded as a preprint on medRxiv: https://www.medrxiv.org/content/10.1101/2025.01.23.25320958v1. One of the investigators (Ejvind Frausing Hansen) is a co-inventor of the closed-loop device and holds shares in O2matic Ltd. Neither the company nor the funders had influence on the protocol, the data analysis, or the writing of the scientific paper. The authors report no other conflicts of interest in this work.

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