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ORIGINAL RESEARCH

Reasons for Hospital Admissions in Chronic Hypercapnic COPD Patients on Long-Term Nocturnal Noninvasive Ventilation – A Prospective Observational Study

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Background: Non-invasive ventilation (NIV) is vital for managing chronic hypercapnic respiratory failure in COPD patients, yet the impact of handling issues like mask compliance triggering hospitalisations is often underestimated.

Methods: A prospective, monocentric observational study was performed in COPD patients hospitalized for acute exacerbation with established home NIV therapy. Various questionnaires (CAT, SRI, BORG) and blood gas analysis were used to determine the severity and cause of respiratory insufficiency.

Results: 59 patients (mean age 66.57 years ± 9.42, mean BMI 26.99 ± 8.63) were included. 54.24% were female (n=32). The overall cohort had a mean exacerbation rate of 2.24 ± 1.48 within the last 12 months prior to admission. Patients were divided into 4 sub cohorts based on their exacerbation trigger: infection (n=25), handling problem (n=12), non-infection (n=8), and an overlap cohort with evidence of both handling problem and non-handling problem (n=14). Significant differences exist when comparing exacerbation rate (handling-issue cohort: 2.58 ± 1.68 vs infection cohort: 1.76 ± 1.13, p=0.043), total hospital stay (handling-issue cohort: 9.25 ± 5.94 days vs infection cohort: 12.96 ± 5.76 days, p=0.039). There was no significant difference in health-related quality of life measured by the SRI (Summary Score 40.6±12.3 vs 46.8±14.2; p=0.103).

Discussion: In our study, we were able to show that handling problems are associated with frequent exacerbations, cause long hospitalisation periods and are associated with a reduced aspects of quality of life. Patient education and training should therefore play a key role in the treatment of patients.

Keywords: COPD, NIV, hospital admission, handling problems, adherence, hypercapnic respiratory failure

Introduction

The high prevalence of patients with COPD represents a significant challenge for healthcare systems.[1] As a progressive disease, COPD is frequently leads in unplanned hospitalisations due to the worsening of symptoms and pulmonary infections.[2] These unplanned hospitalisations substantially increase disease burden, negatively impacting patients' quality of life and imposing considerable financial strain on healthcare systems.[3–6]

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Patients with severe respiratory insufficiency have reduced life expectancy and require special expertise in their treatment. The primary therapeutic approach for these patients is non-invasive ventilation (NIV), typically self-administered by the patient in a home setting. NIV has demonstrated efficacy in improving health-related quality of life (HRQoL) and reducing mortality and exacerbation rates.[7] Effective NIV therapy, however, relies heavily on high patient adherence, including consistent use of high ventilation pressures for prolonged periods—typically at least eight hours daily.[8] In clinical practice, adherence can be compromised by practical handling issues such as mask intolerance, discomfort, and air leakage, limiting treatment effectiveness and potentially precipitating exacerbations or therapy discontinuation.[9,10]

Due to these limitations, alternative approaches like nasal high-flow therapy are currently being investigated, particularly for COPD patients who struggle with NIV adherence.[11] Clearly identifying specific reasons for unplanned hospitalisations in this patient group is essential, as such admissions significantly impair HRQoL. Yet, detailed data on the causes of hospital admissions among COPD patients with chronic respiratory insufficiency undergoing long-term NIV are lacking, even though these patients represent the largest subgroup of home mechanically ventilated individuals in Europe.[12]

Therefore, the aim of this study is to identify the main reasons for hospitalization among COPD patients receiving NIV, to evaluate the influencing factors and to identify potential targets for interventions aimed at reducing hospitalization rates.

Methods

The study was conducted as a prospective, monocentric, observational study at the Department of Pneumology, Cologne-Merheim Hospital, Cologne, Germany, in association with the University of Witten/Herdecke, Witten, Germany. The study protocol for data collection was approved by the Ethics Committee for Human Studies at the University of Witten/Herdecke in Witten, Germany (Proposal no. 89/2015). The study was conducted in accordance with the Declaration of Helsinki (last revised in 2013) and the Good Clinical Practice Guidelines. Prior to the commencement of the study, written informed consent was obtained from all participants. The study from which the data were analyzed was prospectively registered in the German Clinical Trials Register (DRKS00008942) on the date indicated. The STROBE statements for cohort studies were adhered to in the presentation of the results of this study.

Data Collection and Patient Characteristics

Data were collected between 08/2015 and 12/2020. Study eligibility was assessed for all hospitalized COPD patients on long-term NIV.

Patients were eligible for inclusion if they were ≥ 18 years of age, had already been using an out of hospital chronic nocturnal NIV at the time being admitted to hospital and were diagnosed with COPD GOLD III or IV defined by a FEV1/FVC < 70% and FEV1 < 50% of the predicted. Patients were excluded if they were not able to sign the written consent form.

Study Design

Being a real-life prospective cohort study its aim was to investigate patient characteristics, admission characteristics and ventilatory characteristics in chronic hypercapnic COPD patients acutely admitted to hospital due to worsening of respiratory symptoms. The following patient characteristics were evaluated: age, height, weight, smoking status, oxygen use and history, blood values as hemoglobin, serum uric acid and inflammatory markers (serum C-reactive protein), use of medication and history, and the number of exacerbations during the last 12 months. Initial ventilatory settings and changes during the current hospital stay were evaluated, including modes, individual settings, and types of masks. Therapy adherence was quantified in terms of the number of hours per day.

HRQoL was determined using the Severe Respiratory Questionnaire (SRI), which is validated specifically for patients suffering from chronic respiratory insufficiency.[13–16] The SRI contains 49 items with seven subscales measuring different aspects of HRQL (respiratory symptoms, physical functioning, accompanying symptoms and sleep, social relationships,

anxiety, psychological well-being, social functioning). The subscales can be aggregated into a summary scale. Each scale produces a score (0–100), with higher scores indicating a higher HRQL.

The symptom burden was determined using the CAT score, and the dyspnea using the BORG scale.[17] The above-mentioned characteristics were assessed at two different points of time, the first being right upon admission and the second one being shortly before discharge.

All data were recorded on a standardized case report form (CRF), pseudonymized and electronically archived.

The primary outcome measure was to assess the reason for admission and the relative distribution of all reasons within the overall cohort. Key secondary outcome measures were the individual patient characteristics and ventilatory settings of each patient and to compare the mean characteristics of each cohort against the other cohorts. Due to missing data and technical incompatibilities between various home NIV devices and the hospital's data extraction software, a comprehensive assessment of ventilatory settings was not possible in all patients. Therefore, the analysis of ventilatory parameters was limited to expiratory positive airway pressure (EPAP), inspiratory positive airway pressure (IPAP), and breathing frequency.

Reasons for Hospital Admissions

The reason for hospitalisation was determined for all included patients. A distinction was made as to whether the admission was due to an infection, handling issues which included the following: ventilator-related problem, application errors, mask leakage, application time below the recommended duration of use, pressure sores, deventilation syndrome et cetera. or other causes, such as admission due to an acute cardiac event.[18]

Statistical Anaylsis

The study was designed as a pilot study with sample size calculation based on the primary endpoint, the reason for hospitalization in COPD patients receiving home NIV. Previous studies have shown that approximately 33% to 50% of hospitalizations in this population are related to handling problems.[19,20] Based on this expected distribution and assuming a drop-out rate of 10%, a sample size of 87 patients was determined to be sufficient for reliable subgroup analysis.

Data are generally presented as mean ± standard deviation (SD). For variables that did not follow a normal distribution, median values and interquartile ranges (IQR) are additionally provided. Distribution normality was assessed using the Shapiro–Wilk test. Subgroups were compared using appropriate statistical tests selected according to the data distribution and variance homogeneity. Normally distributed data with equal variances were analyzed using Student's *t*-test; Welch's test was applied in the case of unequal variances. For non-normally distributed variables, the Mann–Whitney *U*-test was used for comparisons. Ordinal and categorical variables were compared using the chi-squared test (χ^2).

The primary endpoint was the frequency of hospital admissions categorized into: a) acute infectious events (eg, pneumonia), b) handling-related issues, c) overlap (handling issues and acute infections), and d) other reasons. Handling problems included ventilation issues, technical device problems, or reduced adherence to NIV.

All p-values reported are one-sided and were not adjusted for multiple testing; a p-value <0.05 was considered statistically significant. Statistical analyses were performed using SPSS software version 29.0 (IBM Corp).

The assessed patient-, admission-, and ventilatory settings were analyzed, and the means and standard deviations of each subcohort were compared to the other cohorts using the *t*-test. All reported p-values are one-sided and have not been adjusted for multiple testing. A p-value of less than 0.05 was considered to indicate statistical significance.

Results

A total of 86 acute hospitalised COPD patients with long-term NIV therapy were screened between August 2015 and December 2020. Of these, 59 patients were enrolled in the study (Figure 1). The demographic characteristics of the study population are presented in Table 1. Of the total cohort, valid device-based data on average daily NIV usage were available for only 19 patients. Among these, the mean usage was 4.29 hours per day, ranging from 0.10 to 15.89 hours.

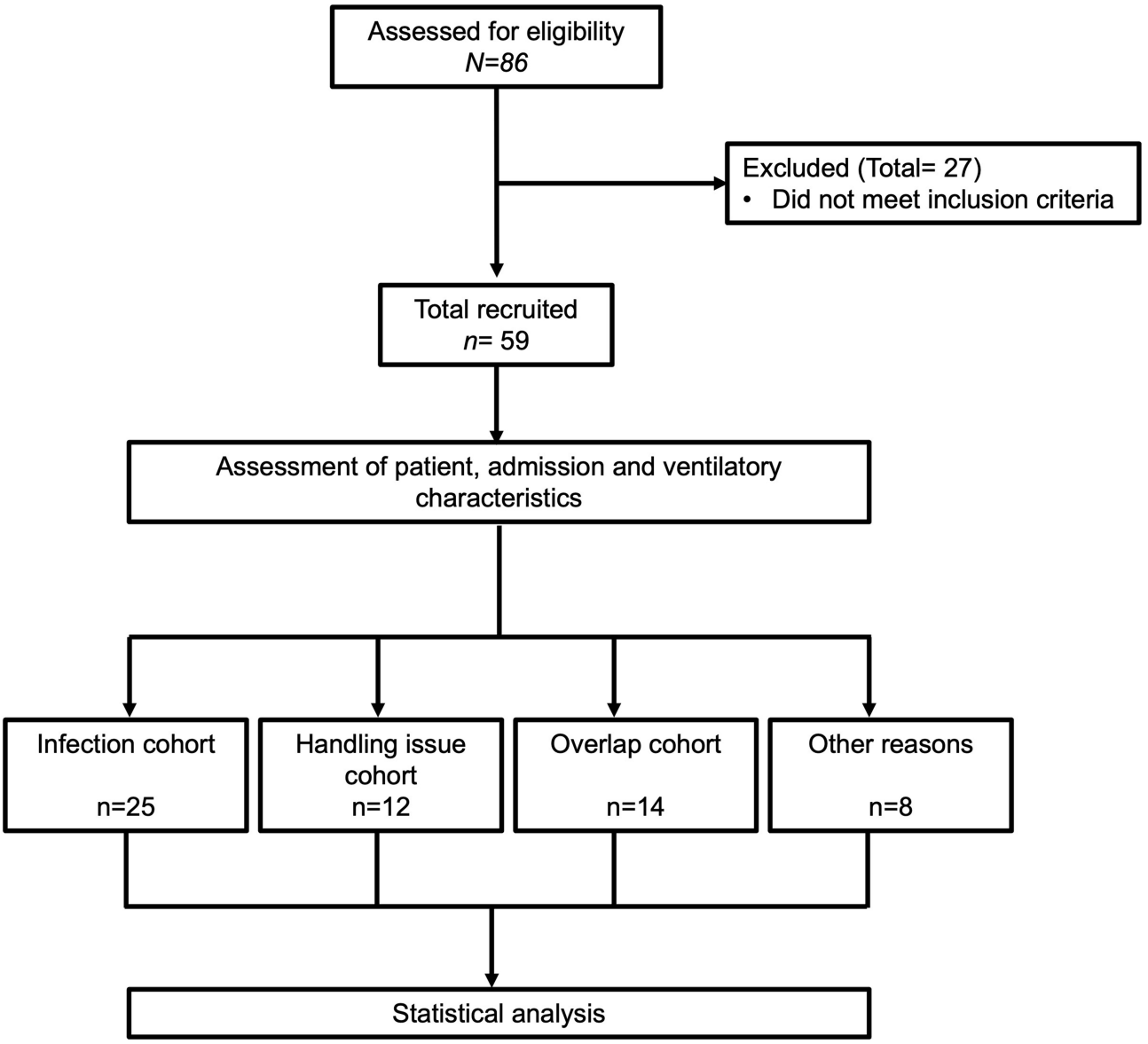

Figure 1 Flow diagram of subject recruitment and data availability.

Primary Analyses

The patients were divided into four subgroups based on their reason for hospitalization. The first subgroup included patients with infection (n=25), the second with handling issues (n=12), and the third with an overlap-cohort with handling

Table 1 Demographics and Clinical Characteristics of COPD Patients Enrolled in the Study

Demographic and Clinical Parameter	Infection Cohort	Handling-issue Cohort	Overlap Cohort	Other
Participants	25	12	14	8
Age at enrolment [years]	69.1±10.2	66.9±7.8	64.0±9.0	62.7±9.0
Gender [%female]	68	50	35.71	50

(*Continued*)

Table 1 (Continued).

Demographic and Clinical Parameter	Infection Cohort	Handling-issue Cohort	Overlap Cohort	Other
BMI [kg m^{-2}]	26.7±7.9	27.2±9.1	25.2±6.4	30.7±13.1
Package years	48.4±28.2	61.6±23.0	55.6±26.2	58.8±24.9
Supplemental oxygen [%yes]	92	100	92	75
Supplemental oxygen flow [l/min]	1.8±0.9	2.3±0.8	1.9±0.9	1.4±0.9
Exacerbations within past 12 months [numbers per year]	1.8±1.1	2.6±1.7	2.4±1.3	3.0±2.1
IPAP [mbar]	22.2±5.0	23.2±6.6	23.6±4.0	23.5±3.5
EPAP [mbar]	6.1±1.7	6.5±1.6	6.3±1.3	6.3±1.6
Frequency [1/min]	15.6±2.5	15.8±2.5	16.9±1.8	16.9±1.3
Hemoglobin [g/dl]	13.2±1.4	12.4±3.2	13.0±2.2	11.5±2.2
CRP [mg/dl]	54.1±68.1	14.3±15.6	24.7±26.0	11.8±7.6
Leukocytes [/µL]	12.7±6.8	8.7±2.7	10.8±3.6	12.6±3.6
pH-value	7.36±0.09	7.36±0.06	7.39±0.05	7.37±0.07
$PaCO_2$ [mmHg]	61.7±20.1	65.8±11.1	60.9±13.6	52.9±7.7
PaO_2 [mmHg]	73.9±27.3	64.9±19.3	66.5±16.0	85.5±14.3
$HCO3^-$ [mmol/l]	31.0±5.1	32.3±3.8	31.8±3.7	28.2±5.1
Time spent on ICU n=9 [days]	0.7±2.0	0.8±1.6	0	0.3±0.7
Time spent on IMC n=36 [days]	6.3±6.1	4.8±6.7	8.3±9.6	2.4±5.6
Time spent normal unit [days]	5.9±6.4	3.7±3.8	2.9±3.9	7.0±2.8
Time spent in hospital in total [days]	13.0±5.8	9.3±5.9	11.2±8.2	9.6±5.6

Notes: Data are presented as mean ± SD, n or (%) unless otherwise indicated.
Abbreviations: BMI, body mass index; IPAP, inspiratory positive airway pressure; EPAP, expiratory positive airway pressure; CRP, C-reactive protein; PaCO2, arterial carbon dioxide tension; PaO2, arterial oxygen tension; HCO3-, arterial bicarbonate; ICU, intensive care unit; IMC, intermediate care unit.

and non-handling issues (n=14). The fourth subgroup comprised patients with other reasons for hospitalisation (n=8). The demographic characteristics are shown in Table 2. The inspiratory pressures observed in all four groups were comparable to those typically observed during high-intensity non-invasive ventilation (NIV). The highest number of exacerbations was observed in the cohort with handling issues, with an average of 2.6±1.7 per year. However, the symptom burden, as measured by the CAT score and the BORG scale, was almost similar in all four cohorts (Table 2). The mean duration of hospitalisation was 9.6±5.6 days in the cohort with other hospitalisation reasons, with a maximum of 13.0±5.8 days observed in the infection cohort. There was no significant difference between the four cohorts in terms of health-related quality of life as measured by the SRI. As the sample size of groups such as "other" was too small, a valid comparison was not possible.

Secondary Analyses

The two clean cohorts (ie, those free of selection bias, with no overlap between handling and infection were compared to ascertain if those struggling with handling issues exhibited significant differences from those admitted due to infection-triggered hospitalization (Table 3).

The demographic characteristics of both groups did not differ significantly in most items (Table 3). The main findings were that the duration of the total hospitalisation was shorter in the handling-issue cohort in comparison to the infection-

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Table 2 Symptom Burden and Health-Related Quality of Life: Comparison of Study Cohorts

Parameter	Infection Cohort (n=25)	Handling-Issue Cohort (n=12)	Overlap Cohort (n=14)	Other (n=8)
Symptom burden				
CAT	27.0±6.6	27.7±3.6	26.0±4.8	28.3±5.0
BORG	6.8±2.3	6.9±2.5	5.4±2.9	7.0±2.3
Health related quality of life				
SRI summary score	46.8±14.2	40.6±12.3	43.5±13.2	32.2±13.5
SRI subscale scores				
Respiratory complaint	44.8±22.0	38.8±14.0	38.4±12.7	33.2±18.5
Pulmonary functioning	30.6±17.9	29.9±23.0	30.5±21.5	12.0±10.6
- Attendant symptoms and sleep	51.6±25.2	46.1±21.5	54.1±17.4	43.3±16.8
Social relationships	67.0±20.4	48.6±21.0	54.5±22.4	52.1±21.7
Anxiety	33.3±23.9	38.8±25.5	38.2±26.2	27.5±19.3
Psychological well-being	54.0±18.1	41.0±16.7	49.4±15.2	28.5±14.2
Social functioning	46.4±17.5	41.2±15.5	39.5±20.2	28.9±13.9

Notes: Data are presented as mean ± SD, n or (%) unless otherwise indicated.
Abbreviations: CAT, COPD assessment test; SRI, severe respiratory questionnaire.

Table 3 Comparison of Demographical, Clinical, Ventilatory, and Inflammatory Parameters Between Infection-Related and Handling-Related Hospital Admissions in COPD Patients on Long-Term NIV

Demographic and Clinical Parameter	Infection Cohort	Handling-Issue Cohort	p-Values
Participants [n]	25	12	
Age at enrolment [years]	69.1±10.2	66.9±7.8	0.259
BMI [kg * m^{-2}]	26.7±7.9 24.06 (21.43–31.7)	27.2±9.1 26.16 (19.56–30.76)	0.481
Package years	48.4±28.2 40 (37.5–55)	61.6±23.0 54 (50–76.25)	*0.024*
Supplemental oxygen [%yes]	92	100	0.0008
Supplemental oxygen flow [l/min]	1.8±0.9 2 (1–2)	2.3±0.8 2 (2–3)	*0.*058
Exacerbations within past 12 months [numbers per year]	1.8±1.1	2.6±1.7	0.085
IPAP [mbar]	22.2±5.0 22 (19.5–26.0)	23.2±6.6 25 (15.5–28.0)	0.415
EPAP [mbar]	6.1±1.3 6 (5–7)	6.5±1.6 7 (5–7)	0.256
Frequency [1/min]	15.6±2.5 16 (15–17)	15.8±2.5 16 (14–18)	0.481

(*Continued*)

Table 3 (Continued).

Demographic and Clinical Parameter	Infection Cohort	Handling-Issue Cohort	p-Values
Hemoglobin [g/dl]	13.2±1.4 13.0 (12.1–14.1)	12.4±3.2 12.4 (10.7–15.6)	0.144
CRP [mg/dl]	54.1±68.1 27.7 (12.1–65.0)	14.3±15.6 6.8 (3.1–28.3)	*0.003*
Leukocytes [/µL]	12.7±6.8 10.2 (8.2–15.4)	8.7±2.7 8.2 (6.7–11.1)	*0.036*
pH-value	7.36±0.09 7.40 (7.29–7.44)	7.36±0.06 7.35 (7.33–7.41)	0.299
$PaCO_2$ [mmHg]	61.7±20.1 56.3 (48.1–72.2)	65.8±11.1 66.6 (55.6–75.5)	0.08
PaO_2 [mmHg]	73.9±27.3 69.3 (62.2–82.3)	64.9±19.3 67.15 (48.5–79.2)	0.18
$HCO3^-$ [mmol/l]	31.0±5.1 30.9 (26.4–34.2)	32.3±3.8 31.0 (29.7–34.3)	0.331
Time spent on ICU; n=9 [days]	0.7±2.0	0.8±1.6	0.451
Time spent on IMC; n=36 [days]	6.3±6.1	4.8±6.7	0.158
Time spent normal unit [days]	5.9±6.4	3.7±3.8	0.383
Time spent in hospital in total [days]	13.0±5.8 13.0 (8.5–15.0)	9.3±5.9 7.5 (6.0–10.0)	*0.006*
CAT	27.0±6.6	27.7±3.6	0.381
BORG	6.8±2.3 7.0 (5–9)	6.9±2.5 7.0 (5.5–9)	0.445

Notes: For normally distributed variables, data are presented as mean ± standard deviation (SD). For non-normally distributed variables, both mean ± SD and median (interquartile range, IQR) are reported. Categorical variables are shown as n (%). A p-value < 0.05 was considered statistically significant.

Abbreviations: BMI, body mass index; IPAP, inspiratory positive airway pressure; EPAP, expiratory positive airway pressure; CRP, C-reactive protein; PaCO2, arterial carbon dioxide tension; PaO2, arterial oxygen tension; HCO3-, arterial bicarbonate; ICU, intensive care unit; IMC, intermediate care unit; CAT, COPD assessment test.

associated cohort, but still within the range of a prolonged hospital stay. The symptom burden experienced by both groups was comparable in terms of the CAT score and the BORG scale. Inflammation surrogate parameters were significantly increased in the infection-associated cohort. The handling-issue cohort had a higher flowrate of LTOT. Regarding the SRI, the only significant difference was observed in the social relationships and psychological well-being subscales. No significant differences were observed in the remaining subscales or the summary score (Figure 2).

Discussion

It is to the authors' knowledge that this study is the first to make a comparison between the reasons for hospitalisation with a particular focus on the handling of NIVs as a possible cause, and infection-related hospitalisations. The principal findings can be summarised as follows:

Firstly, it was found that at least half of the patients, were hospitalized, because of handling errors, or at the very least, related reasons.

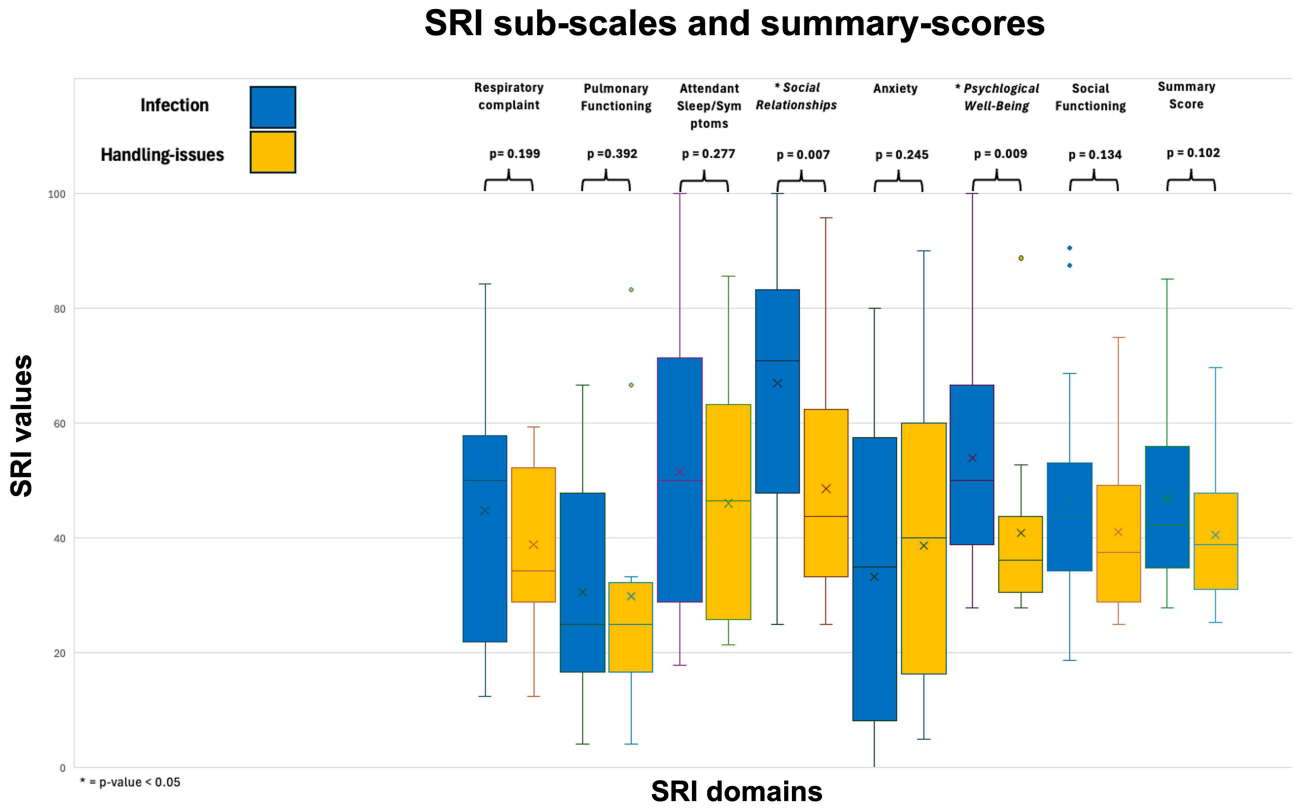

Figure 2 Box-and-whisker plots of SRI subscale and summary scores for the infection-related and handling-related admission cohorts.
Notes: * indicates statistically significant differences ($p < 0.05$).

Secondly, these errors were associated with long hospital stays, which were shorter than those associated with infections and comparable symptom burden as indicated by the CAT score and the BORG dyspnoea scale.

Thirdly, the exacerbation rate was found to be higher in the cohort with NIV handling issues than in the infection cohort.

Fourthly, the overall HRQoL, as reflected in the SRI summary score, exhibited a tendency towards lower levels in patients with handling errors, although this was not statistically significant. Nevertheless, the subscales of the SRI also demonstrated a notable discrepancy, indicating diminished reduced psychological well-being and social relationships in COPD patients with NIV handling issues.

The results of this study provide initial indications that problems related to the handling of long-term NIV therapy in patients with COPD may be associated with clinically relevant outcomes, such as exacerbation frequency and disease burden. Notwithstanding our inability to substantiate any significant disparities in mortality between the two primary cohorts, it is well documented in the literature that an exacerbation is a significant predictor of mortality.[21] Furthermore, it is well documented in the literature that the appropriate use of non-invasive ventilation (NIV) is able to reduce mortality.[22,23] As the primary objective of high-intensity non-invasive ventilation (NIV) is to achieve a substantial reduction of carbon dioxide, the utilization of elevated inspiratory pressures may present a significant challenge for the patient. One of the most reported side effects of this therapy is discomfort and pressure points resulting from the mask. It is therefore imperative that healthcare professionals address these issues in order to optimise therapy adherence and patient comfort. A number of studies have demonstrated that the provision of appropriate NIV training can reduce the incidence of handling issues and the increase therapy adherence.[24–26] The core content of educational programs was behavioral trainings, while more complex elements including telemonitoring remain a topic of ongoing research.[27,28] Further research is required to ascertain the impact of educational programmes on reducing hospitalisation rates and to determine the mortality associated with handling-related hospitalisations.

This study has several limitations. First, the recruitment period was extended due to the COVID-19 pandemic, and the originally calculated sample size could not be fully achieved, which may affect the representativeness of the cohort. Second, as a prospective observational study, the findings represent associations and do not establish causality. The small subgroup of patients with isolated handling issues limits the strength of intergroup comparisons. Furthermore, the specific causes of handling issues (eg, mask leakage, intolerance, technical difficulties) could not be systematically distinguished due to overlapping symptom patterns in the acute care setting. Adherence data and details regarding oxygen and NIV therapy were often missing due to heterogeneous documentation and technical limitations in device data retrieval. Previous NIV duration could also not be reliably determined.

Future studies should aim to systematically record handling-related problems under standardized conditions and in larger patient cohorts, in order to define their impact more precisely and to evaluate the potential of targeted interventions.

Conclusion

In conclusion, our findings suggest that management-related problems with long-term NIV may be a relevant and possibly underestimated cause of hospital admissions in COPD patients. These issues appear to occur at least as frequently as infection-related causes. Further studies are needed to characterize specific handling problems in detail and to develop strategies that may help reduce avoidable hospitalizations and improve patient outcomes.

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Disclosure

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