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ARTICLE

Evaluating the Impact of the Failure Mode and Effects Analysis Nursing Approach on Complications of Chronic Obstructive Pulmonary Disease Patients With Respiratory Failure

Deli Xie[1], Xiuyun Zheng[1,*], Lingcong Peng[1,*]

[1]Department of Respiratory and Critical Care Medicine, The First Affiliated Hospital of Wenzhou Medical University, Wenzhou, Zhejiang, China

*Correspondence: 1912383929@qq.com (Xiuyun Zheng); penglingcong55@163.com (Lingcong Peng)

Abstract

Aims/Background Noninvasive intermittent positive pressure ventilation is a widely used approach for managing Chronic obstructive pulmonary disease (COPD) complicated with respiratory failure. Treatment procedures often result in severe complications, requiring the implementation of proactive and effective nursing measures. Therefore, this study investigated the impact of failure mode and effects analysis (FMEA) on preventing complications in COPD patients with respiratory failure and assessed its influence on negative emotions, hope level, and quality of life.

Methods This retrospective study included 356 patients with COPD combined with respiratory failure who underwent treatment in the First Affiliated Hospital of Wenzhou Medical University, China, between January 2023 and December 2023. Patients receiving usual care were included in the care-as-usual (CAU) group (n = 204), and those who underwent FMEA were assigned to the FMEA group (n = 152). Baseline characteristics and clinical data were compared between the two groups. Furthermore, the Self-rating Anxiety Scale (SAS), Self-rating Depression Scale (SDS), Herth Hope Index (HHI) and 36-item Short-Form were collected and comparatively analyzed between the two groups.

Results The FMEA group exhibited a significantly lower incidence of facial compression injury, dry mouth, phlegm obstruction, flatulence, bronchiectasis, and aspiration pneumonia than the CAU group ($p < 0.05$). After the intervention, the SAS and SDS scores were significantly reduced in the FMEA group than in the CAU group ($p < 0.001$). The temporality and future, positive readiness and expectancy, interconnectedness, and HHI scale total scores were significantly higher in the FMEA group compared to the CAU group ($p < 0.05$). The physiological function, role-physical, body pain, general health perceptions, vitality, social functioning, role-emotional, and mental health of patients were significantly higher in the FMEA group than in the CAU group ($p < 0.05$).

Conclusion The application of the FMEA nursing approach helps reduce the risk of complications in patients with COPD combined with respiratory failure, while effectively reducing anxiety and depression, improving their hope level and enhancing their overall quality of life. These observations offer a basis for preventing complications, and provide a reference for the formulation of nursing plans for these patients in clinical practice.

Key words: healthcare failure mode and effect analysis; chronic obstructive pulmonary disease; respiratory failure; complications; emotional regulation; hope; quality of life

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Introduction

Chronic obstructive pulmonary disease (COPD) is a common respiratory disease characterised by persistent airflow restriction (Olortegui-Rodriguez et al, 2022). The incidence of COPD continues to increase annually due to certain factors like unhealthy lifestyles, an aging population, and environmental determinants (Christenson et al, 2022). Respiratory failure is a common and life-threatening complication of COPD (MacLeod et al, 2021). Noninvasive intermittent positive pressure ventilation is a widely used treatment approach for COPD complicated by respiratory failure. This approach allows for automatic air leakage compensation, adjustable and autonomous control of respiratory frequency, and substantial improvement in airflow restriction, thereby helping in the restoration of ventilation function (Raveling et al, 2021). However, most COPD patients are elderly, and their low tolerance for non-invasive ventilators, coupled with the severe systemic effects of the illness, leads to poor treatment compliance (Boussaïd et al, 2016; Shah et al, 2022). Furthermore, ventilator treatment can cause various complications (Bowdle et al, 2023), leading to anxiety, depression, and other negative emotional states, emphasizing the inclusion of proactive and effective nursing interventions.

Routine nursing care usually addresses clinical symptoms of patients, following standardized protocols based on physician advice. However, during this approach, nursing staff often ignore the psychological well-being of patients, resulting in inadequate risk awareness and limited ability to predict and manage complications. Therefore, implementing preventive nursing approaches is crucial for reducing the risk of complications in COPD patients with respiratory failure, decreasing negative emotions, and improving their quality of life.

Failure mode and effects analysis (FMEA) is a proactive reliability analysis approach within nursing management that focuses on identifying and preventing potential problems (Liu et al, 2020a; Rahman et al, 2023). This method systematically evaluates potential and existing failure modes, identifies associated risks, quantifies them, and prioritizes area of improvement. By implementing targeted interventions and measures, FMEA serves as an effective tool to solve defects and facilitate continuous improvement (Choi and Lee, 2022; Rusu et al, 2020).

Since 2008, the international organization for Standardization Technical Committee has recognized FMEA as a viable approach to assessing high-risk processes, resulting in its widespread utility in medical risk management across developed countries (Chilakamarri et al, 2021; Pino et al, 2019). For example, La Russa et al (2022) reported that the FMEA approach can improve clinical risk management in hemodialysis facilities. Similarly, Lin et al (2021) observed that the FMEA nursing model effectively can prevent multi-drug resistant bacterial infection and improve nursing satisfaction among critically ill intensive care unit (ICU) patients. Liu et al (2020b) conducted a prospective study on 104 pregnant women with a history of cesarean section and reported that the FMEA method promotes vaginal delivery rates and reduces the risk of uterine rupture. During coronavirus disease 19 (COVID-19) pandemic, the FMEA approach was found effective in reducing infection in operating room nursing, ensuring the safety of patients (Meziane et al, 2023). He et al

(2023) adopted the FMEA method to optimize the emergency endoscopy process for esophagogastric varicose hemorrhage (EGVB), effectively improving treatment quality and nursing safety. In the drug management process, Chirmule et al (2020) and Lin et al (2022) used FMEA model to identify existing problems and applied corresponding improvement measures, leading to enhanced medication safety for cancer patients. Jain (2017) found that the FMEA is an effective proactive risk assessment tool that can improve drug management processes.

The use of non-invasive ventilator is now common in clinical settings; however, the success of postoperative rehabilitation relies not only on medical technology but also on perioperative nursing care. Currently, there is a lack of standardized protocols for nursing care before and after treatment. Clinical nursing often depends on retrospective analysis to address errors after adverse events, which fails to achieve proactive feedback and real-time process monitoring.

At present, domestic research on FMEA remains in its infancy, with no reported application in the nursing management of COPD. To address this gap, this retrospective study analyzed 356 COPD patients with respiratory failure who received non-invasive ventilator treatment. The study revealed that the FMEA nursing mode is effective in preventing complications, reducing negative emotions, improving patients' hope level, and enhancing their quality of life.

Methods

Research Subjects

This retrospective study enrolled 356 COPD patients with respiratory failure who were hospitalized and treated in the First Affiliated Hospital of Wenzhou Medical University, China, between January 2023 and December 2023.

Inclusion and Exclusion Criteria

Inclusion criteria were set as follows: (1) Individuals meet the diagnostic criteria for COPD and respiratory failure (Vogelmeier et al, 2017) and are aged 18–85 years, (2) those receiving non-invasive positive pressure ventilation (NIPPV), and (3) are conscious and capable of autonomous expectoration.

Exclusion criteria included patients with (1) severe cardiopulmonary failure, (2) combined with infectious diseases, (3) speech or hearing impairment, (4) coexisting respiratory diseases, (5) diseases of the blood system or immune system, (6) severe disturbance of consciousness or shock state, (7) serious mental illness, (8) a history of pulmonary embolism, tuberculosis, hemoptysis, pneumothorax, or thoracic surgery, (9) diagnosis of malignant tumors, and (10) with incomplete clinical data.

Experimental Design

Baseline Characteristics and Clinical Data

The baseline characteristics and clinical data of 356 COPD patients with respiratory failure were retrospectively analyzed. The baseline characteristics included age, sex, duration of COPD, body mass index (BMI), diabetes, and hypertension. Clinical data included the occurrence of complications during hospitalization, which

included facial compression injury, dry mouth, phlegm obstruction, flatulence, septic shock, bronchiectasis, and aspiration pneumonia. Furthermore, Self-rating Anxiety Scale (SAS) score, the Self-rating Depression Scale (SDS) score, Herth Hope Index (HHI) score, and 36-item Short-Form (SF-36) score were collected and comparatively analyzed.

Anxiety/Depression SAS/SDS

SAS and SDS, as reported by Jegede (1979), mainly assess the subjective feelings of the respondents. Each scale contains 20 items, with scores ranging from 1to 4 points, where 1 point indicates "no or very little time", a score of 2 means "sometimes", 3 shows "considerable time", and 4 indicates "most or all of the time". The total score is multiplied by 1.25 to obtain the standardized score. According to the Chinese standard, a score >50 shows anxiety or depression, a score <50 indicates no anxiety or depression, and higher scores represent significant anxiety or depression tendencies.

Hope Level

The HHI evaluated the hope level (Benzein and Berg, 2003). The scale includes 12 items, including temporality and future (4 items), positive readiness and expectancy (4 items), and inter-connectedness (4 items). Items are scored from 1–4 points, where 1 point indicates "very opposed", a score of 2 means "against", a score of 3 means "agree", and a score of 4 means "strongly agree". Total scores in HHI range from 4 to 48 points, with a higher score indicating a higher hope level.

Quality of Life

It was assessed using the SF-36 (Ware and Sherbourne, 1992), which includes 8 health concepts and 1 self-rated health change (not included in the score). These 8 health concepts are physiological functioning (10 items), role-physical (4 items), body pain (2 items), general health perceptions (5 items), vitality (4 items), social functioning (2 items), role-emotional (3 items), mental health (5 items). Scores of each dimension are standardized employing the formula as follow:

Standard Score = (initial score – lowest possible score)/(highest possible score – lowest possible score) $\times$ 100%.

A higher score indicates a better quality of life.

Grouping of Study Participants

Patients receiving usual care were included in the care-as-usual (CAU) group (n = 204) and those receiving FMEA were assigned to the FMEA group (n = 152).

The CAU patient group received routine care, including creating patient case files, providing health education, assisting patients to adopt the correct NIPPV therapeutic position, guiding oxygen therapy and sputum excretion methods, offering medication guidance, monitoring changes in vital signs, and maintaining the ward environment such as humidity, temperature, and cleanliness.

The FMEA patient group received care based on the FMEA nursing model, which involved the following steps:

(A) FMEA management team formation: The team consisted of two attending respiratory medicine physicians (serving as the group leader and deputy group leader, responsible for the formulation of the nursing plan) and 8 nurses with a minimum of 3 years clinical nursing experience. All members were systematically trained in the FMEA concept through 3 rounds of training:

• Theoretical training: Delivered through presentations (PPT) covering the basic concept of FMEA, history of development, operation steps, current application, and relevant nursing cases.

• Literature review: Team members collaboratively reviewed and analyzed relevant literature on FMEA applications and enhanced their understanding.

• Case analysis: Team members practices FMEA implementation scenario simulation, process analysis, and reengineering to understand its operational steps and precautions.

(B) Evaluation of failure causes and risk priorities:

• The risk factors affecting complications, psychological state, and quality of life in COPD patients with respiratory failure were identified via literature review and clinical experience.

• Group discussions determined potential failure modes, their causes and consequences.

• The risk priority number was computed using the following formula: risk priority number (RPN) = O (occurrence frequency) × D (inability to detect them) × S (failure severity).

• High-scoring risk factors were labeled as failure modes and targeted nursing interventions were implemented accordingly.

(C) Implementation of the FMEA nursing model:

• As shown in Table 1, intervention plans targeting complications, psychological status, and quality of life were developed based on risk factor analysis.

• Preventive and control measures were observed and further improved as required.

(D) Quality control:

• The entire nursing process was standardized and recorded, including the changes in the patient's condition, treatments, and specific nursing measures.

• Preparation of emergencies was ensured, such as readiness of rescue items and clear shift arrangements.

• An internal rectification system was developed to perform regular inspection and quality assessments.

• Performance assessments were linked to nursing evaluations and promotions to ensure adherence and accountability.

Statistical Analysis

Statistical analysis was conducted using SPSS 25.0 software (International Business Machines Corporation, Armonk, NY, USA). Categorical variables, such as gender, diabetes, hypertension, and complications, were represented by [n (%)], and the chi-squared or chi-square correction formula was used for comparison. Measurement data, including age, COPD course, BMI, SAS score, SDS score, HHI

Table 1. FMEA nursing mode-specific scheme.

Failure mode and failure cause	Intervention measure
Before treatment: patients lack trust in medical staff; Inadequate health education; Inadequate preparation; Patient compliance was poor.	(1) Development of trust and a sense of security with patients and their families. During the first interaction, nurses and doctors should be polite, behave professionally, and introduce themselves. (2) The nursing staff should explain to patients and their families the necessity, safety, purpose, estimated time, and precautions associated with using non-invasive ventilation devices. (3) Evaluate the patient's facial condition, assess the size and fit of the nose mask, and ensure the selection of a comfortable and appropriately fitting mask, ensuring no air leakage. (4) Before treatment, nursing staff should communicate with patients to assess their psychological state and address concerns. (5) Scenario simulation should be organized to familiarize patients and their families with the process. (6) Non-invasive ventilators should be avoided within 60 minutes after the patient has eaten.
In the treatment: long treatment time, patients are prone to anxiety, fear; A series of complications may occur during treatment; Patients have poor comfort and low cooperation.	(1) Upon boarding the plane, nursing should remain at the patient's bedside for 15 minutes to provide psychological support and guide them to an appropriate position to ensure an unobstructed upper airway. (2) Allow family members to stay by the patient's bedside to reduce psychological distress. Ensure the patient is in a comfortable and stable state of mind and instruct the family members to timely inform the nursing staff of any discomfort during treatment. (3) Intermittent use of nose mask to relieve facial muscle pressure, ensuring the skin remains clean and dry. (4) Instruct patients with stomach flatulent to breathe only through their nose, reduce swallowing, talk less, and use gestures to reduce air ingestion into the stomach. (5) For those experiencing oropharyngeal dryness, provide humidification care, allow occasional water intake, or use normal saline nasal drops to relieve symptoms. (6) Dynamic assessment of the patient's cough and sputum, timely cleaning of secretions, and removal of oral secretions and vomit to prevent respiratory blockage and choking. (7) Adjust the appropriate temperature and humidity, monitor the ECG and the blood gas index of the patient in real time, and adjust the parameters as necessary based on the patients' condition. (8) The tracheal tube balloon pressure value was strictly controlled at $>$20 cm H_2O, and the residual matter accumulated in the subglottic airway and above the balloon was removed by intermittent extraction method. The moist heat exchanger was used as the airway humidification disposal tool, and the guide wire was heated in the loop to avoid the colonization and growth of pathogenic bacteria in the humidifier. (9) If the low tidal volume or low pressure of the ventilator alarm, symptoms such as shortness of breath, cyanosis, and blood oxygen saturation decreased, provide immediate oxygen inhalation or assisted ventilation. If necessary, assist the physician in repositioning the tube.

Table 1. Continued.

Failure mode and failure cause	Intervention measure
Post-treatment: malnutrition; Poor self-care ability; Lack of confidence in treatment; Lack of discharge guidance	(1) Patients should be instructed to take semi-liquid, easily digestible food, that follows the principles of being low-irritation, high fiber, and high protein. For patients, unable to eat, provide nasogastric feeding for nutritional support, ensuring an adequate supply of nutrients and hydration. (2) After the patient is withdrawn from the machine, the rehabilitator should formulate an exercise training plan for the patient, with the rehabilitation nurse assisting in its implementation. Exercise should follow a gradual and progressive strategy, including aerobic exercise, lip contraction breathing, and abdominal breathing. (3) Perform oral care for patients, and select appropriate nursing solution according to the oral condition of patients. (4) Provide targeted psychological counseling to patients with low confidence or bad mood. Invite patients with good recovery to share their experiences in the rehabilitation process, helping to reduce negative feelings and boost recovery confidence. (5) Create a WeChat group before discharge to facilitate communication. Schedule the first follow-up calls within 1 week of discharge and conduct a monthly home visit for patients residing in the same city.

FMEA, failure mode and effects analysis; ECG, electrocardiogram.

Table 2. Comparison of baseline clinical characteristics between the two groups.

Variables	FMEA group (n = 152)	CAU group (n = 204)	χ^2/t	p-value
Average age (Mean ± SD, years old)	70.64 ± 8.93	70.22 ± 8.40	0.464	0.643
Gender [n (%)]			0.507	0.477
Male	92 (60.53)	131 (64.22)		
Female	60 (39.47)	73 (35.78)		
COPD course (Mean ± SD, years)	9.66 ± 3.15	9.55 ± 3.12	0.344	0.731
BMI (Mean ± SD, kg/m^2)	20.79 ± 2.08	20.60 ± 2.03	0.871	0.384
Diabetes mellitus [n (%)]			0.587	0.443
Yes	32 (21.05)	50 (24.51)		
No	120 (78.95)	154 (75.49)		
Hypertension [n (%)]			0.005	0.941
Yes	46 (30.26)	61 (29.90)		
No	106 (69.74)	143 (70.10)		

FMEA, failure mode and effects analysis; CAU, care-as-usual; COPD, Chronic obstructive pulmonary disease; BMI, body mass index.

score, and SF-36 score, were assessed for normality utilizing the Kolmogorov-Smirnov normality test. These data were expressed as (Mean ± SD). Independent sample *t*-test was used for inter-group comparison, while paired sample *t*-test was used for intra-group comparison. A *p*-value of less than 0.05 was considered statistically significant.

Results

Comparison of Baseline Clinical Characteristics

No significant differences were observed in baseline clinical characteristics, such as age, gender, COPD course, BMI, and the prevalence of diabetes and hypertension, between the two groups ($p > 0.05$, Table 2).

Comparison of Complication Rates

The incidences of facial compression injuries, dry mouth, phlegm obstruction, flatulence, bronchiectasis, and aspiration pneumonia were significantly lower in the FMEA group than the CAU group ($p < 0.05$). However, there was no statistically significant difference in the incidence of septic shock between the two groups ($p > 0.05$, Table 3).

Comparison of Negative Emotions (Anxiety, Depression)

Before the intervention, there were no significant differences in the SAS and SDS scores between the two groups ($p > 0.05$). After the intervention, SAS and SDS scores in both groups were significantly lower than before the intervention levels ($p < 0.05$). Furthermore, post-intervention SAS and SDS scores of the FMEA group were substantially reduced than those in the CAU group ($p < 0.001$, Table 4).

Table 3. Comparison of complication rates between the two groups [n (%)].

Grouping	n	Facial compression injury	Dry mouth	Phlegm obstruction	Flatulence	Septic shock	Bronchiectasia	Aspiration pneumonia
FMEA group	152	2 (1.32)	5 (3.29)	3 (1.97)	3 (1.97)	1 (0.66)	1 (0.66)	2 (1.32)
CAU group	204	14 (6.86)	20 (9.80)	15 (7.35)	19 (9.31)	5 (2.45)	10 (4.90)	13 (6.37)
χ^2		6.244	5.661	5.250	8.094	0.781	3.918	5.519
p-value		0.012	0.017	0.022	0.004	0.377	0.048	0.019

Table 4. Comparison of SAS and SDS scores before and after intervention between the two groups (Mean ± SD, points).

Grouping	n	SAS score		SDS score	
		Before intervention	After intervention	Before intervention	After intervention
FMEA group	152	50.64 ± 7.61	40.91 ± 6.32*	49.70 ± 6.94	37.41 ± 5.81*
CAU group	204	50.49 ± 6.93	44.81 ± 6.85*	49.19 ± 7.23	41.21 ± 6.12*
t		0.199	5.492	0.664	5.919
p-value		0.842	<0.001	0.507	<0.001

Notes: "*" indicated that a significant difference existed in the comparison of data before and after intervention in the same group ($p < 0.05$). SAS, Self-rating Anxiety Scale; SDS, Self-rating Depression Scale.

Comparison of Hope Level

Before the intervention, no significant difference was observed in the HHI scores between the two groups ($p > 0.05$). After the intervention, scores for temporality and future, positive readiness and expectancy, inter-connectedness score, and the overall HHI scale in the two groups were significantly higher than pre-intervention levels ($p < 0.05$). Additionally, the scores in the FMEA group were substantially higher than those in the CAU group ($p < 0.05$, Table 5).

Comparison of Quality of Life

After the intervention, the physiological function, role-physical, body pain, general health perceptions, vitality, social functioning, and role-emotional, and mental health of patients in the FMEA group were significantly higher than those in the CAU group ($p < 0.05$, Table 6).

Discussion

COPD, combined with respiratory failure, is a common disease in respiratory medicine, and its case fatality rate continues to increase, particularly among elderly patients with declining health (Bemand et al, 2023). The effect of noninvasive ventilation is significant, but it carries a high risk of associated complications.

In this study, the FMEA model was integrated into the clinical nursing care of patients with COPD combined with respiratory failure. An FMEA nursing team was established, with members undergoing comprehensive training and assessment.

Table 5. Comparison of HHI scale scores between the two groups before and after intervention (Mean ± SD, points).

Grouping	n	Temporality and future		Positive readiness and expectancy		Inter-connectedness		Total points	
		Before intervention	After intervention	Before intervention	After intervention	Before intervention	After intervention	Before intervention	After intervention
FMEA group	152	5.86 ± 1.80	9.43 ± 1.91*	7.20 ± 1.94	10.04 ± 2.08*	6.50 ± 1.71	11.81 ± 1.85*	19.57 ± 3.12	31.28 ± 3.28*
CAU group	204	5.76 ± 2.08	8.48 ± 2.28*	6.89 ± 2.05	9.39 ± 1.85*	6.34 ± 1.71	9.49 ± 1.69*	19.00 ± 3.24	27.36 ± 3.29*
t		0.462	4.184	1.453	3.115	0.856	12.309	1.657	11.152
p-value		0.644	<0.001	0.147	0.002	0.393	<0.001	0.098	<0.001

Notes: "*" indicated that a significant difference existed in the comparison of data before and after intervention in the same group ($p < 0.05$). HHI, Herth Hope Index.

Table 6. Comparison of SF-36 scores between the two groups after intervention (Mean ± SD, points).

Grouping	n	Physiological function	Role-physical	Body pain	General health perceptions	Vitality	Social functioning	Role-emotional	Mental health
FMEA group	152	64.44 ± 12.47	66.46 ± 10.04	69.06 ± 11.24	72.47 ± 11.46	75.03 ± 6.14	75.16 ± 6.08	73.97 ± 9.93	74.48 ± 9.04
CAU group	204	59.93 ± 12.07	63.99 ± 6.33	66.45 ± 6.55	63.36 ± 6.65	65.42 ± 6.79	66.68 ± 6.53	66.68 ± 10.35	65.81 ± 9.24
t		3.442	2.843	2.753	9.425	13.748	12.473	6.686	8.840
p-value		<0.001	0.005	0.006	<0.001	<0.001	<0.001	<0.001	<0.001

Notes: SF-36, 36-item Short-Form.

Using data from literature review and previous clinical experience, the team members conducted an in-depth analysis of complications and negative emotions in these patients. They found critical failure points, analyzed underlying reasons, calculated risk values, and optimized high-risk elements to develop standardized nursing procedures and protocols.

The results indicated that the FMEA group had significantly lower incidences of facial compression injury, dry mouth, phlegm obstruction, flatulence, bronchiectasis, and aspiration pneumonia than in the CAU group. This improvement can be due to personalized care approaches, such as adjusting nasal mask size and tightness before initiating ventilation and optimizing mask positioning and ventilation pressure during treatment. Furthermore, the nursing staff had expertise in ventilator operation and guided patients to adopt appropriate positions facilitating rapid adaptations to ventilation, and ensuring effective patient-machine coordination.

Secondly, we provide adequate nutrition through dietary care, which reduces the negative impact of the intake of irritating food on gastrointestinal function and improves the patient's immunity. Early pulmonary rehabilitation training enhanced respiratory muscle function, improved skeletal muscle strength, and promoted lung ventilation recovery, thereby reducing the occurrence of ventilator associated pneumonia (VAP) and nosocomial infection caused by long-term mechanical ventilation and hospitalization. Yu et al (2022) found similar benefits to early bedside rehabilitation in promoting gastrointestinal recovery and reducing hospital stays in mechanically ventilated cases.

Furthermore, humidification care reduces the risk of dry mouth and nasal discomfort. Al Ashry and Modrykamien (2014) highlighted the significance of external humidifiers in reducing airway damage due to dry gases during mechanical ventilation. Previous studies underscored the effectiveness of the FMEA approach in decreasing nosocomial infections, including during pandemics (Ye et al, 2024), multi-drug-resistant bacteria infections during maxillofacial surgeries (Xu et al, 2021), and central line-associated bloodstream infections in neonatal intensive care units (Chandonnet et al, 2013). Our study is the first to confirm the efficacy of the FMEA approach in alleviating complications among COPD patients, offering a novel framework for enhancing patient outcomes.

COPD patients usually experience substantial psychological stress due to multiple factors, such as long-term suffering, treatment challenges, and economic burdens, resulting in anxiety and depression. In this study, medical staff implemented health education to help patients understand the role, safety, and benefits of noninvasive ventilators. Scenario simulation further promoted patients' acceptance of ventilator therapy by increasing their familiarity with the procedure and eliminating the fear of mechanical ventilation equipment. Additionally, the FMEA nursing mode included reviewing patient history to collect baseline characteristics and information, preparing patients before the procedure, providing care during ventilations, closely monitoring post-ventilation rehabilitation, and offering discharge guidance and follow-up. These measures, performed with professional expertise, strong theoretical knowledge, effective communication, and familial support, improved patients' trust in healthcare providers, encouraged cooperation during treatment, and

enhanced confidence in overcoming their disease. Therefore, the FMEA group showed significantly lower SAS and SDS scores than those in the CAU group after the intervention.

A recent study by Yang et al (2022) investigated the psychological effects of FMEA mode on appendicitis patients, and reported consistent findings like those in our study. They reported that FMEA promoted recovery outcomes for these patients by reducing anxiety and depression and the risk of postoperative complications (Yang, 2025). Other studies also underscore the positive role of FMEA mode in improving treatment compliance and satisfaction. For example, Hosoya et al (2015) and Armitage et al (2011) reported that the FMEA mode improved drug compliance in patients with chronic myeloid leukemia and AIDS, respectively. Similarly, Janofsky (2009) revealed that the FMEA model reduced the risk of suicide in hospitalized psychiatric patients. Furthermore, Yang et al (2022) also demonstrated higher treatment satisfaction among patients with acute ischemic stroke receiving FMEA emergency mode. Moreover, this study indicated significantly higher HHI and SF-36 scores in the FMEA group compared to the control group, suggesting that this nursing approach improved patients' hope level and quality of life. These improvements are likely attributed to reduced risk of complications and reduction of negative emotions, highlighting the efficacy of the FMEA mode in patient care.

The limitations of this study are as follows: (1) This is a single-center study, and the generalizability of its findings to other regions or hospitals needs further validation. (2) Due to study limitations, such as follow-up time, the incidence of complications was only evaluated until hospital discharge, excluding complications that might occur during the post-discharge period at home. (3) Using subjective retrospective questionnaires, such as the SAS, SDS, HHI, and Health status Questionnaire (SF-36), may introduce bias into our results. (4) The FMEA framework itself has certain limitations, which are highly subjective, and the formulation of the nursing protocol is impacted by the professional experience and knowledge base of the nursing team members. (5) Although the baseline characteristics such as age, gender, course of the disease, BMI, diabetes, and hypertension were compared and observed to have no significant difference between the two study groups, the study design did not exclusively control for these above potential confounding factors. Differences in patient compliance and nursing team experience may have impacted the outcomes.

Innovation of this study: This study explores incorporating the FMEA nursing model into the care of COPD combined with respiratory failure, offering a novel strategy to address both the physical and psychological needs of these patients. To date, no similar observation has been reported in this area. In future research, we plan to conduct multicenter studies to expand the sample size and enhance the generalizability of our results. Additionally, we aim to refine the classification of research samples, extend the follow-up time, and establish rigorous inclusion criteria for group members. We aim to provide multi-stage and more comprehensive training to ensure optimal implementation of this nursing approach. Through continuous optimization of our nursing plan, we aim to increase the credibility of our results and facilitate the broader adoption of this approach in clinical practice.

Clinical practical significance of this study: The FMEA approach is an effective risk management tool. This study uses the FMEA method to identify potential risk factors that could impact complications, psychological status, and quality of life in patients with COPD combined with respiratory failure during treatment. By conducting a comprehensive analysis of failure causes, this study underscores key focus areas for future nursing models. These findings offer a basis for preventing complications, reducing negative emotions, and enhancing the quality of life for such patients. Additionally, this study serves as a valuable reference for formulating tailored nursing plans in clinical practice.

Conclusion

Applying the FMEA nursing model helps reduce the risk of complications in patients with COPD combined with respiratory failure while effectively reducing anxiety and depression, improving their hope level and overall quality of life.

Key Points

- The FMEA nursing model is beneficial in reducing the risk of complications in COPD patients with respiratory failure.
- The FMEA nursing model can alleviate negative emotions, such as anxiety and depression, in COPD patients with respiratory failure.
- The FMEA nursing model can enhance the hope level and improve the overall quality of life of COPD patients with respiratory failure.

Availability of Data and Materials

The data used to support the findings of this study are included within the article, and during the present study are available from the corresponding authors on reasonable request.

Author Contributions

DX and XZ designed this study; DX, XZ, and LP implemented the nursing plan; DX and XZ collected the data; DX and XZ analyzed the data; DX, XZ, and LP participated in the drafting of the manuscript, and all authors participated in critical revisions of important knowledge content. All authors read and approved the final manuscript. All authors fully participated in the work, took public responsibility for the appropriate parts of the content, and agreed to take responsibility for all aspects of the work to ensure accuracy or completeness of any issues related to it.

Ethics Approval and Consent to Participate

The data of the subjects in this study came from the First Affiliated Hospital of Wenzhou Medical University, after approval by the Institutional Ethical Committee of First Affiliated Hospital of Wenzhou Medical University (KY2024-R238). The

study followed the ethical guidelines set out in the Declaration of Helsinki and the principles of confidentiality, and patients were informed of the study and signed informed consent.

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Conflict of Interest

The authors declare no conflict of interest.

References

Al Ashry HS, Modrykamien AM. Humidification during mechanical ventilation in the adult patient. BioMed Research International. 2014; 2014: 715434. https://doi.org/10.1155/2014/715434

Armitage G, Hodgson I, Wright J, Bailey K, Mkhwana E. Exploring the delivery of antiretroviral therapy for symptomatic HIV in Swaziland: threats to the successful treatment and safety of outpatients attending regional and district clinics. BMJ Quality & Safety. 2011; 20: 52–59. https://doi.org/10.1136/bmjqs.2009.034512

Bemand TJ, Chatoor R, Natale P, Strippoli G, Delaney A. Acetazolamide for metabolic alkalosis complicating respiratory failure with chronic obstructive pulmonary disease or obesity hypoventilation syndrome: a systematic review. Thorax. 2023; 78: 1004–1010. https://doi.org/10.1136/thorax-2023-219988

Benzein E, Berg A. The Swedish version of Herth Hope Index–an instrument for palliative care. Scandinavian Journal of Caring Sciences. 2003; 17: 409–415. https://doi.org/10.1046/j.0283-9318.2003.00247.x

Boussaïd G, Lofaso F, Santos DB, Vaugier I, Pottier S, Prigent H, et al. Factors influencing compliance with non-invasive ventilation at long-term in patients with myotonic dystrophy type 1: A prospective cohort. Neuromuscular Disorders. 2016; 26: 666–674. https://doi.org/10.1016/j.nmd.2016.07.014

Bowdle A, Jelacic S, Brosseau L. Respirators and complications of airway management. Anaesthesia. 2023; 78: 392–393. https://doi.org/10.1111/anae.15883

Chandonnet CJ, Kahlon PS, Rachh P, Degrazia M, Dewitt EC, Flaherty KA, et al. Health care failure mode and effect analysis to reduce NICU line-associated bloodstream infections. Pediatrics. 2013; 131: e1961–e1969. https://doi.org/10.1542/peds.2012-3293

Chilakamarri P, Finn EB, Sather J, Sheth KN, Matouk C, Parwani V, et al. Failure Mode and Effect Analysis: Engineering Safer Neurocritical Care Transitions. Neurocritical Care. 2021; 35: 232–240. https://doi.org/10.1007/s12028-020-01160-6

Chirmule N, Khare R, Khandekar A, Jawa V. Failure Mode and Effects Analysis (FMEA) for Immunogenicity of Therapeutic Proteins. Journal of Pharmaceutical Sciences. 2020; 109: 3214–3222. https://doi.org/10.1016/j.xphs.2020.07.019

Choi H, Lee SK. Failure mode and effects analysis of telehealth service of minority elderly for sustainable digital transformation. Computers in Biology and Medicine. 2022; 148: 105950. https://doi.org/10.1016/j.compbiomed.2022.105950

Christenson SA, Smith BM, Bafadhel M, Putcha N. Chronic obstructive pulmonary disease. Lancet. 2022; 399: 2227–2242. https://doi: 10.1016/S0140-6736(22)00470-6.

He H, Wang F, Zhou C, Liu X. Optimization of the emergency endoscopy process for patients with esophagogastric variceal bleeding using failure mode and effect analysis. American Journal of Translational

Research. 2023; 15: 3365–3374.

Hosoya K, Mochinaga S, Emoto A, Yokoo H, Tokushima H, Egoshi M, et al. Failure mode and effects analysis of medication adherence in patients with chronic myeloid leukemia. International Journal of Clinical Oncology. 2015; 20: 1203–1210. https://doi.org/10.1007/s10147-015-0843-2

Jain K. Use of failure mode effect analysis (FMEA) to improve medication management process. International Journal of Health Care Quality Assurance. 2017; 30: 175–186. https://doi.org/10.1108/IJHCQA-09-2015-0113

Janofsky JS. Reducing inpatient suicide risk: using human factors analysis to improve observation practices. The Journal of the American Academy of Psychiatry and the Law. 2009; 37: 15–24.

Jegede RO. Psychometric characteristics of Yoruba versions of Zung's self-rating depression scale and self-rating anxiety scale. African Journal of Medicine and Medical Sciences. 1979; 8: 133–137.

La Russa R, Fazio V, Ferrara M, Di Fazio N, Viola RV, Piras G, et al. Proactive Risk Assessment Through Failure Mode and Effect Analysis (FMEA) for Haemodialysis Facilities: A Pilot Project. Frontiers in Public Health. 2022; 10: 823680. https://doi.org/10.3389/fpubh.2022.823680

Lin L, Wang R, Chen T, Deng J, Niu Y, Wang M. Failure mode and effects analysis on the control effect of multi-drug-resistant bacteria in ICU patients. American Journal of Translational Research. 2021; 13: 10777–10784.

Lin S, Wang N, Ren B, Lei S, Feng B. Use of Failure Mode and Effects Analysis (FMEA) for Risk Analysis of Drug Use in Patients with Lung Cancer. International Journal of Environmental Research and Public Health. 2022; 19: 15428. https://doi.org/10.3390/ijerph192315428

Liu HC, Zhang LJ, Ping YJ, Wang L. Failure mode and effects analysis for proactive healthcare risk evaluation: A systematic literature review. Journal of Evaluation in Clinical Practice. 2020a; 26: 1320–1337. https://doi.org/10.1111/jep.13317

Liu Y, Zhu W, Le S, Wu W, Huang Q, Cheng W. Using healthcare failure mode and effect analysis as a method of vaginal birth after caesarean section management. Journal of Clinical Nursing. 2020b; 29: 130–138. https://doi.org/10.1111/jocn.15069

MacLeod M, Papi A, Contoli M, Beghé B, Celli BR, Wedzicha JA, et al. Chronic obstructive pulmonary disease exacerbation fundamentals: Diagnosis, treatment, prevention and disease impact. Respirology. 2021; 26: 532–551. https://doi.org/10.1111/resp.14041

Meziane S, Taous M, Bourkhiss B. Mitigating the risk of COVID-19 infection in the operating room: Using healthcare failure mode and effect analysis. Perioperative Care and Operating Room Management. 2023; 31: 100319. https://doi.org/10.1016/j.pcorm.2023.100319

Olortegui-Rodriguez JJ, Soriano-Moreno DR, Benites-Bullón A, Pelayo-Luis PP, Huaringa-Marcelo J. Prevalence and incidence of chronic obstructive pulmonary disease in Latin America and the Caribbean: a systematic review and meta-analysis. BMC Pulmonary Medicine. 2022; 22: 273. https://doi.org/10.1186/s12890-022-02067-y

Pino FA, Weidemann DK, Schroeder LL, Pabst DB, Kennedy AR. Failure mode and effects analysis to reduce risk of heparin use. American Journal of Health-System Pharmacy. 2019; 76: 1972–1979. https://doi.org/10.1093/ajhp/zxz229

Rahman M, Zhang R, Gladstone DJ, Williams BB, Chen E, Dexter CA, et al. Failure Mode and Effects Analysis for Experimental Use of FLASH on a Clinical Accelerator. Practical Radiation Oncology. 2023; 13: 153–165. https://doi.org/10.1016/j.prro.2022.10.011

Raveling T, Vonk J, Struik FM, Goldstein R, Kerstjens HA, Wijkstra PJ, et al. Chronic non-invasive ventilation for chronic obstructive pulmonary disease. The Cochrane Database of Systematic Reviews. 2021; 8: CD002878. https://doi.org/10.1002/14651858.CD002878.pub3

Rusu I, Thomas TO, Roeske JC, Mescioglu I, Melian E, Surucu M. Failure mode and effects analysis of linac-based liver stereotactic body radiotherapy. Medical Physics. 2020; 47: 937–947. https://doi.org/10.1002/mp.13965

Shah AJ, Florman K, Kaushal N, Kwong HF, Karoshi A, White L, et al. Factors Affecting Domiciliary Non-Invasive Ventilation Compliance. Lung. 2022; 200: 457–462. https://doi.org/10.1007/s00408-022-00557-8

Vogelmeier CF, Criner GJ, Martinez FJ, Anzueto A, Barnes PJ, Bourbeau J, et al. Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Lung Disease 2017 Report. GOLD Executive Summary. American Journal of Respiratory and Critical Care Medicine. 2017; 195: 557–582. https://doi.org/10.1164/rccm.201701-0218PP

Ware JE, Jr, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Medical Care. 1992; 30: 473–483.

Xu Y, Wang W, Li Z, Wang Y, Cai Y, Chen Y. Effects of healthcare failure mode and effect analysis on the prevention of multi-drug resistant organisms infections in oral and maxillofacial surgery. American Journal of Translational Research. 2021; 13: 3674–3681.

Yang Y, Chang Q, Chen J, Zou X, Xue Q, Song A. Application of Integrated Emergency Care Model Based on Failure Modes and Effects Analysis in Patients With Ischemic Stroke. Frontiers in Surgery. 2022; 9: 874577. https://doi.org/10.3389/fsurg.2022.874577

Yang Y. Impact of FMEA-Based Nursing on Postoperative Condition of Appendicitis Patients. Alternative Therapies in Health and Medicine. 2025; 31: 343–347. https://alternative-therapies.com/oa/pdf/9839.pdf

Ye M, Tang F, Chien CW, Chuang YC, Liou JJH, Qu X. Application of failure mode and effect analysis in ICU admission of potentially COVID-19 infected patients. American Journal of Infection Control. 2024; 52: 552–562. https://doi.org/10.1016/j.ajic.2023.12.012

Yu T, Cai F, Jiang R. Effects of Early Bedside Cycle Exercise on Gastrointestinal Function in Intensive Care Unit Patients Receiving Mechanical Ventilation. Frontiers in Medicine. 2022; 9: 823067. https://doi.org/10.3389/fmed.2022.823067