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Original Article

Failure mode and effects analysis on the control effect of multi-drug-resistant bacteria in ICU patients

Lixia Lin[1*], Rui Wang[1*], Taiming Chen[1], Jing Deng[2], Yujuan Niu[1], Min Wang[1]

[1]Department of Emergency Intensive Care Unit, The First Affiliated Hospital of Hainan Medical University, Haikou 570102, Hainan, China; [2]Department of Cardiology, The First Affiliated Hospital of Hainan Medical University, Haikou 570102, Hainan, China. [*]Equal contributors.

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Abstract: Objective: The failure mode and effect analysis of the prevention and control in intensive care unit (ICU) patients with multi-drug-resistant (MDR) bacterial infection were explored and analyzed in this research. Methods: A total of 251 critically ill patients who were hospitalized in the ICU from June to December 2019 were selected as the control group, and another 258 patients who were hospitalized in the ICU from January to June 2020 were set as the observation group. The control-group patients received conventional ICU care, the observation group was treated by the failure mode and effects analysis (FMEA), and then the prevention and control effect of the two nursing modes on multi-drug-resistant bacteria infection in the two groups were compared accordingly. Results: The RPN values of the five highest-level factors in the nursing process were critically lower after the improved interventions than before the improvement. The infection rate of MDR bacteria in the observation group was obviously lower than that in the control group (14.73%, 26.69%, χ^2=11.1233, P=0.0009). In addition, the mortality rate of patients with MDR in the observation group was remarkably lower than that in the control group, and the difference was statistically significant (5.26%, 22.39%, χ^2=5.2405, P=0.0221). The satisfaction of the observation group with the ICU treatment was critically higher than that of the control group, and the difference was statistically significant (89.53%, 76.49%, χ^2=15.4094, *P*=0.0001). Conclusion: Through the application of FMEA to prevent MDR bacterial infection in ICU patients, nursing staff can accurately pay attention to the keynotes in nursing process, and as such reduce the proportion and mortality of MDR infection in ICU patients and promote the patients' satisfaction with nursing, which are all worthy of clinical application.

Keywords: Failure mode and effects analysis (FMEA), ICU, multi-drug-resistant bacteria infection, prevention and control

Introduction

The majority of patients who are admitted to intensive care units (ICU) are critically ill. As these patients are in critical condition and require long periods of hospitalization, and the fact that in most cases, they need to undergo a variety of interventional examinations and treatments; the possibility of iatrogenic infection is greatly increased. At the same time, with the extensive use of broad-spectrum antibacterial drugs in clinical treatment in recent years, the drug resistance of bacteria in patients has continued to be enhanced, and the incidence of multi-drug-resistant (MDR) bacterial infection has been increasing annually [1, 2]. The treatment of MDR bacterial infection is difficult, and it easily causes an explosive epidemiological trend. In addition, it is also one of the main factors causing multi-system organ failure in patients, thus increasing the mortality rate of ICU patients [3, 4]. MDR bacteria may put clinical treatment into a situation where no medicine is available. Therefore, how to take effective measures to reduce the infection of MDR bacteria and improve the treatment effect and prognostic quality of life of ICU patients is a primary problem faced by hospitals. FMEA is a risk management method that analyzes problems through a forward-looking perspective. It identifies potential risk factors in the medical care process, and finds any possible errors before the occurrence of adverse events and helps to prevent them [5, 6]. Based on the *Technical*

Manual for the Prevention and Control of Multi-drug-resistant Bacteria Infections [7] and the application of FMEA, this study summarized the causes of MDR infection in ICU patients and took corresponding preventive measures, which achieved satisfactory prevention and control effects. The report is as follows.

Material and methods

General materials

A total of 251 severely ill patients who were hospitalized in the ICU from June to December 2019 were selected as the control group, and 258 counterparts from January to June 2020 were selected as the observation group. Patients with MDR infection before being transferred to the ICU were excluded. The study was approved by the ethics committee of our hospital, and we obtained with informed consent by patients or their family members. Inclusion criteria: (1) Patients confirmed by clinical examination with a critical condition and those who needed intensive care in the ICU; (2) Patients aged ≥18 years old; (3) Patients who voluntarily signed the informed consent. Exclusion criteria: (1) Patients with pre-existing infectious diseases before enrollment; (2) Those who stayed in the ICU for over 30 days; or (3) Patients with mental illness or disturbance of consciousness.

Methods

The control-group subjects received nursing care of conventional ICU measures. Based on FMEA risk management, we adopted its analysis methods to identify and evaluate the nursing risk for MDR infection in ICU patients, found out the highest-risk factors of infection, and developed corresponding preventive measures for implementation. The specific procedures were as follows: (1) Set up an FMEA team in the ICU ward. The team consisted of 7 personnel in the ICU Nursing Department, which included 1 head nurse and 6 senior nurses. The team members had bachelor degrees or above and had a rich ICU nursing experience, and they received standardized training in the knowledge of FMEA prior to the implementation of the activities. The team was leading by the head nurse, who was responsible for the assessment of ICU nursing staff and the follow-up monitoring of the implementation of intervention measures. (2) Identification and cause analysis of potential failure modes. The team members collected and sorted out the past ICU cases with MDR infection, and conducted brainstorming meetings to analyze and discuss the possible MDR infections during nursing processes. Then the potential failure modes were summarized step by step, and the possible causes were found out. (3) The implementation of risk scores and the formulation of preventive measures. The risk priority number (RPN) scores of failure modes listed were performed by the team members [8], RPN = (S) × (O) × (D), where S is the severity of the risk, O is the frequency of failure modes, and D is the detectable degree of the risk. The grades of S, O, and D are all 1-10 points respectively, and a higher RPN score reveals a greater risk of failure. The team members identified the failure mode according to RPN, analyzed the causes, and formulated corresponding preventive measures. (4) The development of standardized nursing work flow for ICU patients. According to the failure mode and the corresponding preventive measures, and combined with the actual situation of the ICU care in our hospital and nursing work experience, the team members developed a standardized nursing workflow for ICU patients, and required the nursing staff to strictly follow the standardized procedures.

Evaluation method

(1) The RPN values of the nursing process failure modes before (control group) and after (observation group) implementation of improved interventions were compared and evaluated by FMEA team members. (2) The bacterial infection rate and outcome of MDR in both groups of ICU patients were compared.

Evaluation method of satisfaction

A nursing satisfaction questionnaire was issued one day before the patient was transferred out of the ICU, and the patient scored the care anonymously. The full score of the questionnaire was 100 points, among which those with a total score of less than 60 points was considered dissatisfied, 60 to 79 points were basically satisfied, and 80 points or above were considered satisfied.

Table 1. Comparison of general information between the two groups

Item	Control group (n=251)	Observation group (n=258)	χ^2/t	*P*
Gender (M/F, number of cases)	127/124	131/127	0.0016	0.9681
Age ($\bar{x}$±g, years old)	47.18±5.63	48.27±3.55	2.6202	0.0091
Time from onset to admission	5.22±1.07	5.39±1.21	1.6107	0.1079
Diagnostic categories (number of cases)			1.4855	0.6856
Severe pneumonia	85	78		
Orthopedic surgery	43	51		
Abdominal surgery	52	60		
Respiratory failure	71	69		

Statistical analysis

We adopted SPSS 26.0 statistical software for statistical analysis and processing. The measurement data were represented by ($\bar{x}$±SD) and the enumeration data were represented by percentage; *t*-test of independent samples was used to compare the results between groups, paired t-test was used for comparison before and after treatment within the group, and χ^2 test was performed for the results. *P<0.05* was considered statistically significant.

Results

Clinical materials

There were 127 males and 124 females in the control group who were aged between 23-77 years old, and the average age was (47.18±5.63) years. The average time from the onset of the disease to admission was 1-15 hours, with an average time of (5.22±1.07) h. The diagnostic categories in the control group were as follows: 85 cases of severe pneumonia, 43 cases of orthopedic surgery, 52 cases of abdominal surgery and 71 cases of respiratory failure. In the observation group, there were 131 males and 127 females who were aged between 22-76 years old, and the average age was (48.27±3.55) years. The average time from onset of the disease to admission was 1-17 hours, with an average time of (5.39±1.21) h. The diagnostic categories in the observation group were as follows: 78 cases of severe pneumonia, 51 cases of orthopedic surgery, 60 cases of abdominal surgery and 69 cases of respiratory failure. There were statistically insignificant differences between the two groups in terms of gender, age, time from onset to admission, diagnosis category and other general data (*P>0.05*), as shown in **Table 1**.

Failure modes and interventions in the nursing process of MDR infections in ICU patients

The five failure modes, including the patient assessment, interventional examination and treatment, operator preparation, cleaning and disinfection, and antimicrobial treatment, were analyzed to summarize the causes of each failure mode and its RPN score, and the corresponding intervention measures were proposed according to the causes. The patient assessment RPN score was (192.63± 14.37) points, interventional examination and treatment RPN score was (239.87±23.53) points, operator preparation RPN score was (251.25±17.49) points, cleaning and disinfection RPN score was (189.47±15.34) points, and the RPN score for the application of antibacterial drugs was (212.52±11.28) points. The detailed description is in **Table 2**.

Comparison of RPN value of nursing process failure mode before (control group) and after (observation group) implementation of improved interventions

The RPN values of the five high-level factors of the nursing process after the improved interventions were critically lower than those before the interventions, as shown in **Table 3** and **Figure 1**.

Comparison of bacterial infection rate of MDR and disease outcome between the two groups of ICU patients

The bacterial infection rate of MDR in the observation group was obviously lower than that in the control group (14.73%, 26.69%, χ^2=11.1233, *P*=0.0009). The mortality rate of patients with MDR infections in the observation group was remarkably lower than those in the

Table 2. Failure modes and interventions in nursing process of MDR infections in ICU patients

Failure mode	Cause	RPN (point, $\bar{x}\pm p$)	Interventions
Assessment of patients	All patients were in critical condition with low immunity and certain infectivity of bacteria.	192.63±14.37	Precautions shall be taken for ICU patients. Strict contact isolation measures are applied to patients with highly suspected MDR infection or colonization. The closed disposable sputum suction tube is used to carry out sputum suction operation, ensuring that items in contact with the patient are used separately to avoid cross-infection.
Interventional examination and treatment	The invasive operations such as tracheotomy, endotracheal intubation, indwelling urinary catheter, and deep venous catheterization destroy the defense barrier of the patient's body.	239.87±23.53	Strictly implement the aseptic procedures, and carry out local skin disinfection with bactericidal drugs (2% chlorhexidine solution) before invasive operation; Strengthen oral cleaning care for patients with orotracheal intubation; Clean the ventilator pipes and humidification system in time.
Preparation by operators	Poor compliance of hand hygiene. As operators ignore hand hygiene, the contaminated hands transmit drug-resistant strains to susceptible hosts, thus increasing the chance of cross-infection.	251.25±17.49	Strictly enforce hand hygiene standards, raise the attention of medical staff, and strengthen the compliance.
Cleaning and disinfection	The bed unit is not only easily to be polluted by frequent contact with human body, but also a source of pollution for bacterial cultivation, storage and dissemination.	189.47±15.34	Strengthen the cleaning and disinfection work, and open the department windows regularly to keep the indoor air fresh; Ensure that the surfaces of each bed unit, equipment and facilities and objects that frequently touched by patient are wiped and disinfected with the specified duster cloth; Bed unit ozone stenlizer is applied for terminal disinfection.
Use of antibiotics	The abuse of antibacterial drugs leads to the development of resistant-strains in patients.	212.52±11.28	Strengthen the management of rational use of antibiotics in clinical practice, strictly implement the basic principles, and implement reasonable administration plan.

Table 3. Comparison of RPN values of nursing process failure modes before (control group) and after (observation group) the implementation of improved interventions

Failure mode	Control group (n=251)	Observation group (n=258)	T	*P*
Assessment of patients	192.63±14.37	83.74±9.25	101.9296	0.0000
Interventional examination and treatment	239.87±23.53	98.62±7.48	91.7754	0.0000
Preparation by operators	251.25±17.49	91.87±9.59	127.9337	0.0000
Cleaning and disinfection	189.47±15.34	73.79±6.46	111.4010	0.0000
Use of antibiotics	212.52±11.28	85.43±7.34	151.0623	0.0000

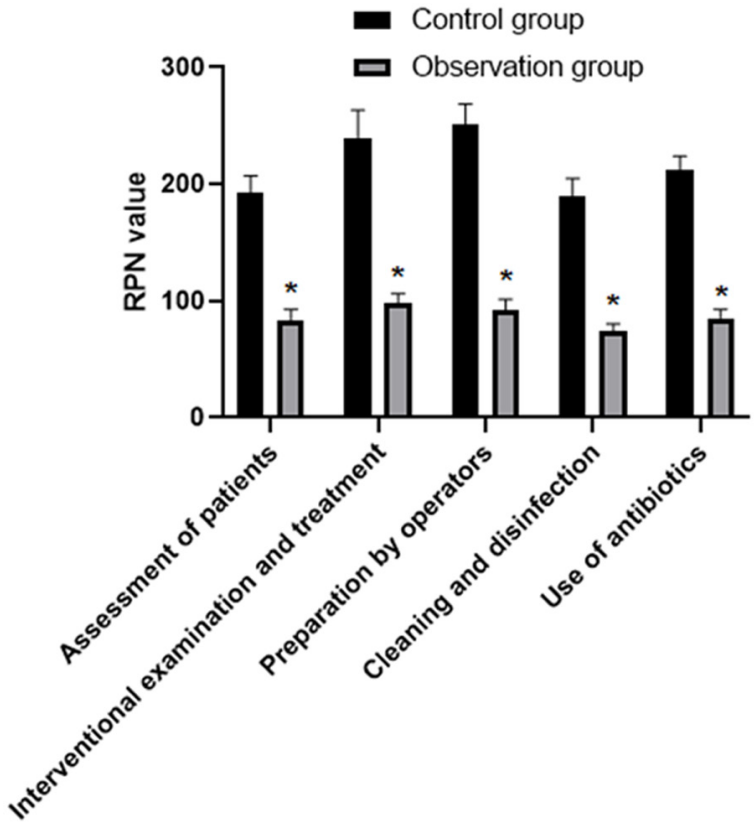

Figure 1. Comparison of RPN values of nursing process failure modes before (control group) and after (observation group) the implementation of improved intervention. Note: Compare with control group, *P<0.05.

Table 4. Comparison of bacterial infection rate and outcome of multi-drug resistant bacteria in two groups of ICU patients [n, (%)]

Group	Infections	Outcome	
		Recovery	Die
Control group (n=251)	67 (26.69)	52 (77.61)	15 (22.39)
Observation group (n=258)	38 (14.73)	36 (94.74)	2 (5.26)
χ^2	11.1233	5.2405	
P	0.0009	0.0221	

control group, and the difference was statistically significant (5.26%, 22.39%, χ^2=5.2405, *P*=0.0221) (**Table 4**).

Comparison of nursing satisfaction between the two groups during ICU treatment

The satisfaction during ICU treatment of the observation group was remarkably higher than that of the control group (89.53%, 76.49%, χ^2=15.4094, *P*=0.0001) (**Table 5**).

Discussion

The ICU is a department with high medical risks, and inpatients admitted are usually in critical condition. MDR bacterial infections can very easily cause explosive epidemics, which not only brings great difficulty to clinical treatment, but also increases the risk of adverse events and easily leads to medical disputes [9, 10]. Moreover, once MDR bacterial infection occurs in ICU patients, the therapeutic effect will be greatly reduced, which is not conducive to the quality of prognosis. Therefore, the implementation of a reasonable and effective risk management mode plays a crucial role in reducing the infection rate of MDR bacterial infection in ICU patients. The traditional risk management mode mainly aims to formulate improvement measures based on reviewing the causes of adverse events that have occurred, and ultimately avoids the recurrence of similar adverse events. Although such a risk management mode can effectively reduce the incidence of adverse

Table 5. Comparison of nursing satisfaction between the two groups during ICU treatment [cases, (%)]

Group	Satisfied	Basically satisfied	Dissatisfied	Total satisfaction	χ^2	*P*
Control group (n=251)	85 (33.86)	107 (42.63)	59 (23.51)	192 (76.49)	15.4094	0.0001
Observation group (n=258)	149 (57.75)	82 (31.78)	27 (10.47)	231 (89.53)		

events, it ignores the potential risk factors during the nursing process [11, 12]. The failure mode and nursing mode of effect analysis is a new risk management method that combines theoretical knowledge and practical experience, and its core is to emphasize "prevention in advance" [13]. The FMEA nursing mode is divided into three steps: Firstly, the possible failure in the nursing process and the possible adverse consequences after the failure are assumed. The second is to analyze the reasons, that is, analyze the causes of failure in the assumed nursing process. Finally, the corresponding interventions are formulated according to the possible causes analyzed, achieving the goal of reducing medical care risks [14-16]. FMEA has been widely used in medication safety, nursing procedures, medical procedures, etc., and it has achieved satisfactory sound effects [17-19].

In this study, the FMEA model was used for risk management of 258 ICU patients. First we established an ICU FMEA team to fully mobilize the subjective initiative and creativity of team members. The team members used their previous work experience to conduct an in-depth analysis and discussion on the factors that related to MDR bacterial infection in ICU patients, and formulate the corresponding nursing interventions according to the factors to ensure safe and effective care could be given to ICU patients. During the implementation of risk management, risk management was carried out for the high-risk procedures of MDR-infection, such as patient assessment, interventional examination and treatment, operator preparation, cleaning and disinfection, antibacterial drug use and other nursing processes. Key points were highlighted and operational procedures were standardized. In particular, the pathogenic bacteria carried by the operator's hand are the main pathogen of nosocomial infection. Due to the large number of critical patients and heavy workload in the ICU ward, nursing staff often ignore cleaning and disinfect their hands. Literature shows that the microbial contamination of ICU nursing staff's hands is quite serious, especially when their hands are not washed after contacting the patient's filth, the bacterial contamination rate can reach as high as 100% [20, 21]. Therefore, it is necessary to strictly implement hand hygiene regulations, improve the attention of medical personnel to hand hygiene, and strengthen their compliance with medical behavior. Studies have reported that the sampling results of multiple parts of the surface of the bed unit and treatment equipment facilities are consistent with the pathogenic bacteria cultured in blood or sputum of ICU patients [22, 23]. Therefore, strict cleaning and disinfection is one of the crucial measures to control the outbreak of MDR bacterial infection [24]. The key to the prevention of nosocomial infection is to establish a feasible and standardized prevention and control system, improve the execution of interventions, strictly implement the aseptic operation procedures, and strengthen the rational use and management of antimicrobial agents in clinical practice [25]. In this research, the RPN values of the five highest-level factors of the nursing process after the improved interventions were critically lower than those before the improvement of interventions, suggesting that the risk factors of causing MDR bacterial infection in ICU patients are remarkably reduced after the implementation of the FMEA nursing mode. The infection rate and mortality of MDR infection in the observation group were remarkably lower than that in the control group, and the nursing satisfaction of the observation group was obviously higher than that of the control group, indicating that the implementation of FMEA nursing mode can effectively control the outbreak of MDR bacterial infection, and at the same time promote the patients' satisfaction with clinical nursing.

In conclusion, through the application of FMEA to prevent MDR bacterial infection in ICU patients, nursing staff can accurately pay attention to the keynotes in the nursing process, and reduce the rate and mortality of MDR infection

in ICU patients, which is worthy of clinical application.

Disclosure of conflict of interest

None.

Address correspondence to: Rui Wang, Department of Emergency Intensive Care Unit, The First Affiliated Hospital of Hainan Medical University, No. 31 Longhua Road, Haikou 570102, Hainan, China. Tel: +86-0898-66753902; E-mail: wangrui20180518@163.com

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