IMPACT OF RISK MANAGEMENT BASED ON FMEA THEORY ON THE PREVENTION OF DEEP VEIN THROMBOSIS IN POSTOPERATIVE PATIENTS WITH PULMONARY NODULES

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ABSTRACT

Introduction*: To investigate the impact of risk management intervention based on failure mode and effect analysis (FMEA) theory on the prevention of deep vein thrombosis (DVT) in patients after pulmonary nodule surgery.*

Materials*: Ninety-six patients with pulmonary nodules included in our hospital from January 2020 to December 2021 were selected for the study.*

Methods: *Ninety-six postoperative patients with pulmonary nodules included in our hospital from January 2020 to December 2021 were selected for the study. The patients were numbered in order of surgery time and divided into control group (48 cases) and observation group (48 cases) according to the random number table method. The patients in the control group were subjected to conventional nursing interventions, while the patients in the observation group were given risk management interventions based on FMEA theory. The failure mode RPN score, pulmonary function index, recovery and incidence of DVT were compared between the two groups.*

Results*: After the intervention, the RPN values of each failure mode were lower in the observation group than in the control group (P<0.05). The incidence of DVT was lower in the observation group than in the control group (P<0.05). The forced expiratory volume in the first second (FEV1), forced vital capacity (FVC) and FEV1/FVC were better in both groups 7 days after surgery than before surgery (P<0.05), and the levels of these pulmonary function indexes were better in the observation group compared with the control group (P<0.05). The time of tracheal tube removal, time of drainage tube removal, postoperative activity time and hospitalization time were shorter in the observation group than in the control group (P<0.05).*

Conclusion*: By implementing risk management interventions based on FMEA theory in postoperative patients with pulmonary nodules, it can reduce the incidence of DVT, improve patients' pulmonary function, and accelerate the recovery process.*

Keywords: *failure mode and effect analysis, pulmonary nodules, deep vein thrombosis.*

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Introduction

Pulmonary nodules are a group of multisystemic, multiorgan granulomatous diseases with an incidence of 10%-20% in China. If left untreated, they are prone to lung cancer[1]. Thoracic pulmonary nodule resection is an effective treatment for pulmonary nodules, with a 5-year survival rate approaching 100% after surgery[2-3]). Patients undergoing thoracoscopic pulmonary nodule resection are mostly associated with strong physical and psychological stress due to surgical trauma and fear of postoperative complications[4].

The FEMA model of care is a new approach to risk management that combines theoretical knowledge and practical experience, with an emphasis on "prevention beforehand" at its core[5]. FMEA is a systematic and step-by-step process that begins with the selection of a well-defined process to evaluate and assemble a multidisciplinary team. Afterwards, the selected process and sub-processes are mapped using the collective knowledge of the team and focusing on the key components of the process. Once the processes are mapped, the team brainstorms to identify potential failure modes for each sub-process. Then, the team identifies the

possible effects and causes of the potential failure modes. The expertise and personal experience of team members, as well as literature information, play a role in this step. Next, the team prioritizes the potential failure modes based on their severity, frequency, and detectability. The risk priority number (RPN) is calculated by multiplying these three parameters together, and the calculated RPN is used to prioritize the failures. Finally, the team redesigns or modifies the process to avoid or minimize failures, followed by implementation and analysis of the effectiveness of the modified process[6].

Currently, FMEA has been widely used in medication safety, nursing procedures, and medical procedures with satisfactory results[7-9]. It has been shown[10] that FEMA interventions can reduce the risk of DVT in patients with PICC cannulation. This study included 96 postoperative patients with pulmonary nodules treated by thoracoscopic surgery and aimed to investigate the impact of risk management interventions based on FMEA theory on the prevention of DVT in postoperative patients with pulmonary nodules.

Research Objectives and Methods

Object of the study

Ninety-six patients with pulmonary nodules included in our hospital from January 2020 to December 2021 were selected for the study.

Inclusion criteria: (1) meet the diagnostic criteria related to pulmonary nodules (11); (2) meet the indications for thoracoscopic pulmonary nodule resection; (3) voluntarily cooperate with the study and sign the informed consent form.

Exclusion criteria: (1) combined with liver, kidney, heart and other important organ dysfunction; (2) combined with critical illness; (3) presence of cognitive dysfunction or psychiatric disorders; (4) contraindication to surgery; (5) age >75 years.

They were numbered according to the time sequence of surgery and divided into a control group (48 cases) and an observation group (48 cases) according to the random number table method. In the control group, the patients' ages ranged from 23 to 75 years, with a mean of 54.04±5.72 years. In the observation group, the patients were 23-75 years old, with an average age of 57.70±5.73 years. The general data of gender, age, education level, lesion diameter and lesion location of the two groups were not statistically different (P>0. 05). The study was approved by the hospital medical ethics committee.

Methods

The control group implemented conventional care until the patients were discharged from the hospital

Before surgery, nursing staff carried out verbal education on disease knowledge, surgical procedures and precautions to prepare patients for preoperative work. During surgery, routine operating room nursing was performed and the physicians were actively cooperated with to complete the surgery. After the operation, the patient was given real-time ECG monitoring, and conventional antibiotic treatment and analgesia were administered as prescribed by the doctor. In addition, patients were encouraged to perform appropriate rehabilitation training within the limits of physical tolerance, and were given scientific dietary management and life guidance.

The observation group applied risk management interventions based on FMEA theory on the basis of the control group

Establishment of a nursing team

The nursing team was composed of 1 nurse leader, 1 nurse in charge and 4 responsible nurses. The nurse leader trained and evaluated the other team members, and the main contents were FMEA theory and application, DVT risk identification, DVT prevention strategy. The team members can enter the intervention phase after passing the assessment. The nurse leader was responsible for the overall arrangement of nursing work, and the other members were responsible for collecting data and implementing risk prevention and control strategies.

Implementation of FMEA-based nursing model

(1) Define the topic: The team members investigated the current situation of DVT in the postoperative care of pulmonary nodules and reviewed the relevant literature to define the topic as "reducing the incidence of DVT in patients with pulmonary nodules".

(2) Failure mode determination: ① Determine the flow chart: the team members investigated the patient's medical record data and conducted a detailed analysis of the nursing process for patients with DVT, while reviewing relevant literature. On the basis of FMEA theory, the postoperative care process for patients with pulmonary nodules was developed: basic patient assessment (medical history, medication history, habits) –> tracheal and

drainage tube operation (catheter insertion, catheter fixation) –> patient management (health education, management compliance) –> daily care (extubation operation, monitoring and preventive measures). ② Calculation of the RPN value of each failure mode: we reviewed domestic and international data, analyzed the factors affecting the occurrence of DVT in patients after pulmonary nodule surgery, and used the FMEA risk analysis formula to calculate the RPN value of the failure risk of each link in the postoperative care process of pulmonary nodule surgery according to the actual situation of patients[12]. RPN = severity of effect (S) × Omission frequency (O) × detection failure level (D). A higher RPN value indicated a higher risk of failure, and an RPN ≥ 125 points meant that the model failed, that is, the risk of deep vein thrombosis was high and prevention strategies were needed.

(3) Develop risk prevention and control strategies: the intervention team members reviewed relevant literature, combined with clinical experience, used root cause analysis to analyze factors related to the occurrence of each failure mode (RPN ≥ 125 points), summarized the main causes of DVT, and implemented targeted risk prevention and control strategies, as shown in Table 1.

Risk Sessions	Cause Analysis	Risk Management Strategy
Patient Assessment	(1) Lack of systematic assessment mechanisms; (2) Failure to consider the patient's age, medical history, medication history, and adverse habits in a comprehensive manner.	(1) Develop an interview outline and assessment process in advance, and interview patients systematically to fully grasp their basic situation; (2) Establish a personal file for patients and record in detail their age, medical history, medication history, habits and other basic information.
Catheterization	(1) Difficulty in tracheal intubation and unscheduled extubation; (2) Drainage tube decannulation and obstruction.	(1) Know whether the tube is smooth and there is no gas inflow, and pay attention to the position of the tube to avoid skewing or twisting. Note the fixed position of the teeth in the middle of the procedure to avoid loosening, which can result in adverse reaction by biting the tongue. Regularly train nursing staff to enhance their ability to assess patient status and nursing skills operation. (2) Prohibit retraction treatment and follow medical advice to replace the drainage tube when necessary. Also explain the importance of the tube to the patient's family and properly fix the drainage tube and drainage bag to prevent pulling and dislodging.
Patient management	(1) Lack of awareness of pulmonary nodules; (2) Negative emotions affecting compliance.	(1) Health education, making disease-related knowledge in the form of video, text and pictures, and using WeChat to push it for patients, focusing on knowledge related to pulmonary nodules and the danger of DVT; (2) Pay attention to patients' mood fluctuations, analyze the reasons for mood fluctuations, and provide targeted psychological intervention and guidance to patients.
Daily Care	(1) Inadequate communication; (2) Lack of timely detection of changes in condition; (3) Lack of systemic thromboprophylaxis.	(1) Proactively ask patients how they feel and treat uncomfortable symptoms; (2) Strengthen catheter care, enhance catheter monitoring, regularly check catheter depth and fixation to avoid catheter displacement, dislodgement or blockage, and observe patients' skin color, temperature, limb swelling, and bleeding tendency; (3) Enhance thrombosis prevention: a. Assessment, using color doppler ultrasound to examine the vascular condition, combined with Khorana scoring model to assess the patient's risk of thrombosis [7]; b. Prevention, giving prophylactic doses of low molecular heparin to high-risk patients (contraindicated in bleeding patients), combined with limb massage and microwave therapy to promote blood circulation. In case of thrombotic signs, immediately report to the doctor for symptomatic management.

Table 1: FMEA-based nursing risk prevention and control strategies.

Observation indicators

(1) RPN value of failure mode: the RPN value of each failure mode was calculated and compared between the two groups of patients during the post-intervention care routine.

(2) Pulmonary function indexes: FEV1, FVC and FEV1/FVC were measured before and 7 days after surgery.

(3) Recovery: the time of tracheal tube removal, time of drainage tube removal, postoperative activity time and hospitalization time were compared between the two groups.

(4) DVT: the diagnostic criteria of DVT in the "Guidelines for the diagnosis and treatment of DVT (3rd edition)"[13] formulated by the Vascular Surgery Group of the Chinese Medical Association, combined with the follow-up color doppler ultrasound examination after 1 month, were used to determine the DVT according to whether there was a blocking signal of blood flow.

Statistical analysis

SPSS 18.0 software was used for data processing, and the measurement data were expressed as mean ± standard deviation (x ± s) using t-test. Count data were expressed as rate (%), and X^2 test was used for comparison. The difference was considered statistically significant at P<0.05.

Results

Comparison of the RPN values of each failure mode between the two groups of patients

After implementing the risk management intervention based on FMEA theory, the RPN values of each failure mode in the observation group were lower than those in the control group, and the difference was statistically significant (P<0.05), as shown in Table 2.

Comparison of pulmonary function indexes between the two groups

Group	Number of cases	Patient factors	Catheter factors	Health education	Daily care
Control group	48	112.25±16.27	115.36±15.48	108.46±12.51	106.34±12.52
Observation group	48	82.23±9.62	83.02±8.54	79.28±6.80	68.06±6.84
t-value		17.478	19.095	16.624	18.068
P-value		0.000	0.000	0.000	0.000

Table 2: Comparison of RPN values for each failure mode in the two groups (points).

Before surgery, there was no statistical difference in FEV1, FVC and FEV1/FVC between the observation group and the control group (P>0.05). The above pulmonary function indexes were better in both groups at 7 d postoperatively compared with those before surgery. Moreover, the above pulmonary function indexes were better in the observation group compared with the control group at 7 d postoperatively (P<0.05), as shown in Table 3.

Group	Number of cases	FEV1 (L)		FVC (L)		FEV1/FVC (%)	
		Pre-operative	Postoperative 7 days	Pre-operative	Postoperative 7 days	Pre-operative	Postoperative 7 days
Control group	48	1.76 ± 0.44	2.28 ± 0.56*	2.65 ± 0.62	3.45 ± 0.72*	63.92 ± 6.56	68.76 ± 7.63*
Observation group	48	1.83 ± 0.52	2.68 ± 0.65*	2.88 ± 0.63	3.96 ± 0.78*	65.69 ± 6.47	73.94 ± 7.82*
t-value		1.068	2.657	1.010	2.982	0.428	3.157
P-value		0. 501	0.006	0.324	0.014	0. 649	0.007

Table 3: Comparison of pulmonary function indexes between two groups of patients.

Comparison of postoperative rehabilitation of patients in the two groups

The time of tracheal tube removal, time of drainage tube removal, postoperative activity time and hospitalization time were shorter in the observation group than in the control group, and the differences were statistically significant (P<0.05, Table 4).

Group	Number of cases	Time of extubation (h)	Time of drain removal (h)	Time of postoperative activity (d)	Length of hospitalization (d)
Control group	48	3.54 ± 0.65	89.32 ± 11.64	3.14 ± 0.45	9.89 ± 2.15
Observation group	48	2.86 ± 0.52	78.63 ± 8.85	2.86 ± 0.43	7.92 ± 2.10
t-value		6.572	4.351	3.026	4.564
P-value		0.000	0.000	0.000	0.000

Table 4: Comparison of postoperative recovery between two groups of patients.

Comparison of the incidence of DVT in the two groups

After the implementation of risk management intervention based on FMEA theory, the incidence of DVT in the observation group was lower than that in the control group, and the difference was statistically significant (P<0.05), as shown in Table 5.

Group	Number of cases	Incidence of DVT (%)
Control group	48	14.58 (7/48)
Observation group	48	4.16 (2/48)
t-value		6.365
P-value		0.028

Table 5: Comparison of the incidence of DVT in the two groups.

Discussion

Thoracoscopic pulmonary nodule resection is a minimally invasive technique that is widely used in clinical practice. Compared with traditional surgery, it has the characteristics of small incision, good efficacy and quick recovery, thus gradually becoming the preferred option for pulmonary nodule treatment. A study[2] confirmed that patients with pulmonary nodules treated with thoracoscopic pulmonary nodule resection had a survival rate of 100% at 5 years after surgery. However, improper care of patients undergoing surgery for pulmonary nodules can lead to complications such as heavy intraoperative bleeding, pleural reactions, postoperative hemoptysis/pneumothorax, incisional infections and even pulmonary infections.

Also, postoperative patients are susceptible to increased risk of DVT and catheter occlusion due to factors such as disease, body coagulation mechanism and catheter maintenance quality. Therefore, there is an urgent need for effective clinical care to enhance the clinical outcomes of patients and accelerate their recovery.

The FMEA theory-based risk prevention and control model of care is a model of care guided by the FMEA theory. It analyzes the problem through a prospective perspective, identifies potential risk factors in the medical process, and finds any possible errors before adverse events occur to help prevent them[14]. In a study by Pang[15], the FMEA model was applied to patients undergoing chemotherapy for malignancy to reduce the risk of patient complications and improve clinical outcomes by identifying and evaluating potential failures in care in advance and implementing targeted risk prevention measures. It was shown[16] that applying the FMEA model to assess risk factors for peritoneal dialysis-associated infections and implementing an improvement program can effectively reduce the incidence of peritoneal dialysis-associated infections and help improve the prognosis of peritoneal dialysis patients. A study by Xie showed[17] that FMEA management in perioperative care of elderly patients with liver cancer was effective in reducing the incidence of venous thromboembolism.

To study the application of risk prevention and control interventions based on FMEA theory to postoperative patients with pulmonary nodules, the FMEA theory was used as a guide to implement measures to clarify the topic, calculate the RPN values of each failure mode, risk analysis and risk management. The results of the study showed that after the risk management intervention based on FMEA theory, the RPN values of each failure mode were lower in the observation group than in the control group (P<0.05); the above-mentioned pulmonary function indexes were better in the observation group than in the control group at 7 d after surgery (P<0.05); the time to remove the tracheal tube, the time to remove the drainage tube, the time to postoperative activity and the hospital stay were shorter in the observation group than in the control group (P<0.05); the incidence of DVT was lower in the observation group than in the control group (P<0.05). The above results showed that the risk management intervention based on FMEA theory applied to the postoperative care of patients with pulmonary nodules could reduce patients' risk and

incidence of DVT, improve patients' lung function, and promote patients' postoperative recovery. The reason for this analysis is that the FMEA nursing model is to screen multiple failure factors with high risk through quantitative indicators and implement targeted risk prevention and control measures to nip the risk factors in the bud, thus effectively reducing the incidence of nursing risks, improving the quality of clinical care, and promoting patient disease recovery[18-20].

In conclusion, the implementation of FMEA-based risk management interventions for postoperative patients with pulmonary nodules can reduce the risk and incidence of DVT, which is important for improving patients' pulmonary function and promoting their postoperative recovery.

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