

Application of failure mode and effect analysis in reducing perioperative deep vein thrombosis of lower extremities in patients with lung cancer

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Abstract

Objective: Cancer-related thrombosis is a leading cause of death in cancer patients, with venous thromboembolism being the most common venous thromboembolism (VTE). There are several risk factors playing a major role in developing venous thromboembolism. Such risk factors are analysed and investigated in the present study. Aim: To investigate the use of failure mode and effect study in minimizing perioperative deep vein thrombosis of the lower limbs in lung cancer patients.

Methods: In this study, 80 lung cancer patients from our hospital were randomly assigned as a control group and a study group. The control group receives traditional nursing care, whereas the research group receives FMEA management based on the control group's results. The two groups' failure mode Risk Priority Number (RPN) values, intervention impact, and nursing service satisfaction are compared.

Results: The RPN values of the six failure modes were much lower after FMEA adoption than before. The difference was considerable ($P < 0.01$); in the study group, blood flow velocity, DVT incidence, and duration of stay were considerably lower than in the control group. The circumference of the lower limbs of the study group was substantially higher than of the control group, the difference was significant ($P < 0.01$); the study group's nursing care satisfaction was better than that of the control group.

Conclusion: The use of failure mode and impact analyses can help prevent perioperative deep vein thrombosis of the lower extremities in lung cancer patients. [*Ethiop. J. Health Dev.* 2022; 36(3): 00-00]

Keywords: failure mode, effect analysis, lung cancer; perioperative period; deep vein thrombosis, lower extremities.

Introduction

Deep vein thrombosis (DVT) of lower limbs is formed when blood coagulates abnormally in the deep vein and blocks the vascular lumen, resulting in a sudden decrease in limb perfusion and threatening the viability of the limb (1). In 1865, Armand Trousseau reported the first analysis on the connection between thrombosis and cancer (2). Numerous studies have since then demonstrated that thrombosis is a major complication for cancer patients, contributing to the second-leading cause of cancer death (3). Cancer thromboembolism can range from arterial or venous thromboembolism to disseminated intravascular coagulation (4). Although there is a well-established relationship between cancer

and thromboembolic disease, the mechanisms that enhance thromboembolic events in cancer patients remain unknown and appear to be complex (5).

Cancer patients are commonly hypercoagulable or prothrombotic as they have abnormalities in all three major factors of Virchow's triad, which play major roles in thrombosis, such as stasis of blood flow, endothelial injury, and hypercoagulability, the latter including abnormalities in the coagulation and fibrinolytic pathway and platelet activation (6). The precise processes causing Virchow's triad anomalies in cancer patients, particularly the impact on the host haemostatic system to promote the prothrombotic state, are unknown and may be tumour specific, as various cancer types have variable risk rates for cancer-associated thrombosis

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(7).

Of all the cancers, lung cancer, as a kind of clinical malignant tumor, is one of the world's biggest causes of cancer-related death (8). By far the most common treatments include chemotherapy, radiotherapy and surgery, postoperative patients prone to complications such as lower limb venous thrombosis. Therefore, patients with Lung cancer in perioperative should be nursed accordingly, which can effectively avoid or reduce the incidence of postoperative complications. Failure mode and effect analysis (FMEA) is a management process (9) that analyzes problems from a prospective perspective, evaluates high-risk medical procedures, and identifies potential risk factors, so as to prevent risks. FMEA has the advantages of teamwork, systematic, prospective and quantitative analysis of adverse events (10). Therefore, it is of positive significance to cooperate with effective nursing to prevent DVT in the perioperative period of lung cancer to ensure the surgical effect, improve patient satisfaction and promote postoperative rehabilitation.

Materials and methods

General information

From October 2019 to October 2020, only 80 patients were admitted to our hospital and accepted to participate in this study. The selected research subjects were split into 2 groups using the random number table approach: control group (n=40) and test group (n=40). There were 21 men and 19 females in the control group, all of them were 44~72 years old, with an average age of (62.4±6.6) years. The study group consisted of 22 men and 18 women aged 44~72 years, with a mean lifespan of (61.5±7.2) years. The fundamental data of participants in the 2 groups was processed using statistical software, and there was no statistically relevant variation was observed ($P > 0.05$). ($P > 0.05$).

Inclusion criteria: (1) All patients were clinically diagnosed with lung cancer; (2) The patient is conscious and can communicate normally; (3) The patient has no coagulation dysfunction; (4) Know the diagnosis and treatment plan, and voluntarily sign for confirmation. Exclusion criteria: (1) patients with kidney disease or other serious diseases; (2) Important data of patients is incomplete; (3) the existence of consciousness or cognitive dysfunction, mental diseases; (4) patients or their family members refused to participate in the study; (5) The patient had a preoperative history of

radiotherapy and chemotherapy; (6) Survival time of patients is less than 1 year. The hospital ethics committee authorised this study.

Materials and Methods

The 40 participants in the control group got regular perioperative nursing care, such as vital sign monitoring, and the 40 participants in the test group underwent FMEA care based on the control group. The specific operations were as follows: (1) To clarify the theme. Retrospective study of lung cancer surgery patients in normal care to reduce adverse events associated with less extremities deep vein thrombosis, such as lack of personalized and targeted nursing, proposed "The implementation of FMEA reduces the perioperative frequency of lower extremity deep vein thrombosis in lung cancer patients", the theme of the set "50% lower incidence of lower extremity deep vein thrombosis" goal, start the FMEA management mode. (2) Set up the FMEA nursing team. According to the research topic to determine the FMEA team member criteria: (1) Bachelor degree or above, or intermediate or above professional title; More than 8 years of working experience; Familiar with the perioperative nursing process of lung adenocarcinoma patients. The final selected team members include: FMEA leader 1, FMEA backbone members 5, recorder 1. The head nurse as the group leader organizes the members to carry out the training within the group, so that the members are familiar with and master the relevant knowledge of FMEA, and is responsible for the implementation of FMEA program; 5 key members are responsible for the perioperative nursing of lung cancer patients, and carry out targeted nursing; The recorder is responsible for recording and collating adverse events in the patient. (3) Develop the perioperative nursing flow chart for lung cancer patients, find out the potential failure mode and staging reasons. According to the clinical practice experience and the brainstorming method adopted by the team members, the specific procedures of perioperative nursing for lung cancer patients were listed, and the failure modes and causes of nursing for preventing perioperative deep vein thrombosis of lower limbs in lung cancer patients were analyzed. The flow chart is as follows: (1) The cases and nursing data of patients with deep venous thrombosis of lower extremity in the routine nursing group were collected, and the causes of the failure of deep venous thrombosis of lower extremity in the perioperative nursing group were summarized and

developed. The questionnaire was filled out among ordinary nurses, and the causes of the failure of deep venous thrombosis of lower extremity in the perioperative nursing group were preliminarily collected. (2) To search the literatures related to perioperative deep venous thrombosis of lower extremity in lung cancer patients, and to supplement relevant data on the results collected in the earlier stage; (3) According to the analysis results of the above two stages, group members were organized to discuss the problems existing in the nursing process and reach a consensus. (4) Calculate the execution risk score RPN. According to the discussion, the failure mode of lower extremity deep vein thrombosis (DVT) in the perioperative nursing process of lung cancer patients was formulated by the team members, so as to conduct RPN score to evaluate the risk of the process and find out the high-risk nursing factors of perioperative DVT. RPN value is composed of three key factors: probability of occurrence (O), probability of detection (D) and probability of danger (S). The formula is $RPN=O \times D \times S$. Each score was 1-10, and the higher the RPN value was, the higher the probability of lower extremity deep vein thrombosis (DVT) errors during nursing was, the higher the failure risk was. $RPN < 125$ was considered low risk, A risk level of 125-300 was deemed medium, while a risk level of >300 was considered severe (11-12). (5) Develop preventive measures and redesign the nursing process. Prioritize the improvement based on the size of the RPN value. Team members list all failure modes, the selection before 6 kinds of RPN value higher failure mode, insufficient including preoperative evaluation and preoperative education, early postoperative not timely guide the rehabilitation exercise, postoperative observation is not careful, postoperative rehydration fluids or improper enough drinking water, diet nursing, analyze its influence factors, make improvement measures and the reengineering process, training nurses master the implementation method. In addition, monitoring and evaluation are carried out in combination with on-site observation (13). The failure modes of perioperative DVT nursing for lung cancer patients are shown in Table 1.

Observation indexes

(1) RPN value: RPN value of 6 failure modes before and after implementation of FMEA was calculated to evaluate the risk index in the perioperative nursing process of lung cancer patients. (2) The peripheral diameter and blood flow velocity of lower extremities of patients in both groups were measured by special person 7 days after surgery, and the incidence of DVT was calculated. (3) The length of hospital stay of patients in the two groups was counted. (4) Collection of nursing service satisfaction: the satisfaction of patients and their families with postoperative nursing service was evaluated through the satisfaction questionnaire, which was divided into satisfied, basically satisfied and dissatisfied. Satisfaction = (satisfied number + basically satisfied number)/total number of patients.

Statistical analysis

For statistical assessment, SPSS 17.0 software was utilised, data was represented as [n (%)], the χ^2 test was performed to compare groups, and bar charts were created with GraphPad Prism 5 software. $P < 0.05$ denotes a substantial difference, whereas $P < 0.01$ denotes an extraordinarily significant difference.

Results

Comparison of RPN values of 6 failure modes during FMEA implementation. As can be seen from Table 2, the RPN value of the patients with inadequate preoperative assessment before the implementation of FMEA was 214.85 ± 18.32 , and the RPN value after implementation was 106.47 ± 11.54 . Before and after FMEA, the RPN value of the patients with insufficient preoperative education was 189.11 ± 17.52 and 98.12 ± 12.36 , respectively. The RPN of early postoperative rehabilitation without timely guidance was 362.17 ± 20.85 and 117.98 ± 18.75 before and after FMEA. The RPN values before and after FMEA were 218.74 ± 20.73 and 113.43 ± 16.37 , respectively. The RPN of insufficient fluid or drinking water after operation was 171.39 ± 16.12 , 88.17 ± 12.86 , and the RPN of improper diet nursing was 149.85 ± 17.38 , 85.36 ± 13.58 , respectively, before and after FMEA. To sum up, After the implementation of FMEA, RPN values for the six failure modes were much lower than before FMEA adoption, and the difference was significant ($P < 0.01$).

Table 1. The failure mode in the perioperative DVT nursing process of lung cancer (13)

Failure mode	Failure reason	Measures
Inadequate preoperative evaluation	(1) Advanced age; (2) a long history of smoking; (3) abnormal coagulation function; (4) dehydration; (5) Inadequate assessment of past history and lifestyle.	(1) Ask patients to stop smoking and drink more water; (2) frequently massage the lower limbs; (3) Analyze the causes of abnormal coagulation function of patients, and use anticoagulant drugs if necessary; (4) Formulate standardized assessment standards and procedures, and train nurses.
Insufficient preoperative education	(1) Young nurses are inexperienced in DVT propaganda and education; (2) Patients have insufficient awareness of DVT prevention.	(1) Strengthen DVT teaching and training for young nurses and improve young nurses' teaching skills; (2) Strengthen the propaganda and education on DVT for patients, and emphasize the necessity and importance of preventing DVT.
Early postoperative time is not timely Directing Rehabilitation Exercise	(1) In the early postoperative period, the patient was not guided and assisted in shaking the head of the bed, sitting up and moving down the ground; (2) Patients are reluctant to move early due to pain and drainage tube.	(1) Strengthen the learning of postoperative rehabilitation exercise after radical resection of colon cancer, and set up the relevant assessment system; (2) strengthen the management of postoperative analgesia, and encourage early activities of patients.
Postoperative condition observation is not carefully	(1) The obvious swelling and pain of the lower extremity after surgery was not paid attention; (2) Nurses do not shift carefully.	(1) To strengthen the learning of the early clinical manifestations of DVT; (2) Closely observe the lower limbs of the patients after surgery, and strengthen the management of the shift system.
Insufficient fluid supply after surgery (Patient's blood concentration)	(1) The nurse failed to correctly judge the patient's general condition in time; (2) Wrong calculation of patient inflow and outflow.	(1) Strengthen the study of the clinical manifestations of dehydration, carefully observe the patient's general condition, and report to the tube bed doctor in time for treatment; (2) Strengthen the study of fluid rehydration for patients after abdominal surgery, accurately record the postoperative inflow and outflow of patients, and timely report to the tube bed doctor for adjustment when there is a big difference in the inflow and outflow.
Improper diet care	(1) The patient's old age, memory decline, unable to accurately remember the nurse's entrust; (2) Patients and their family members lack dietary awareness and do not pay attention to healthy diet; (3) Food education is not timely and in place.	(1) Repeatedly instructing patients about diet-related matters, and repeatedly checking whether the patient's diet meets the requirements; (2) Strengthen communication with family members and let them participate in the diet supervision process; (3) Strengthen the study of diet nursing, and immediately start diet education when patients are admitted to hospital.

Table 2. Comparison of RPN values in 6 failure modes before and after implementation of FMEA

Group Inadequate amount of fluid or water after surgery improper diet care	Pre	Post	Statistic	P
	implementation	implementation		
Inadequate preoperative evaluation	214.85±18.32	106.47±11.54**	31.658	0.000
Insufficient preoperative education	189.11±17.52	98.12±12.36**	26.840	0.000
Delay of early postoperative rehabilitation exercise	362.17±20.85	117.98±18.75**	55.077	0.000
Careless observation of postoperative condition	218.74±20.73	113.43±16.37**	25.215	0.000
Inadequate amount of fluid or water after surgery	171.39±16.12	88.17±12.86**	25.524	0.000
Improper diet care	149.85±17.38	85.36±13.58**	18.492	0.000

Compared with before implementation: **P<0.01

Table 3 results show that the next week diameter of the research group after 7 FMEA implementation is 21.32±0.29 cm, while that of the control group is 22.17±0.36; The blood flow velocity was 0.98±0.24 m/s in the study group and 0.67±0.19 m/s in the control group. The frequency of DVT was 7.5% in the control group and 2.5% in the study group. The prolong hospital hospitalization in the control group was 22.18±1.78 days, whereas it was 18.35±1.58 days in the research group.

The prolong hospital hospitalization in the control group was 22.18±1.78 days, and that in the study group was 18.35±1.58 days. In conclusion, the blood flow velocity, the incidence of DVT, and the duration of hospitalisation in the study group after 7 days of FMEA were considerably lower than those in the control group, whereas the circumference of the lower limbs was significantly increased (P<0.01).

Table 3. Comparison of intervention effects (n, %)

Group	Control group (n=40)	Research group (n=40)	Statistic	P
Peripheral diameter of lower limbs (cm)	22.17±0.36	21.32±0.29 **	11.629	0.000
Blood flow velocity (m/s)	0.67±0.19	0.98±0.24 **	6.405	0.000
Incidence of DVT n (%)	3 (7.5%)	1 (2.5%) **	5.39	0.000
Duration of hospital stay /d	22.18±1.78	18.35±1.58**	10.177	0.000

Compared with the control group: **P<0.01

Comparison of nursing satisfaction after FMEA implementation

The satisfaction findings (Table. 4) revealed that the

study group's overall satisfaction rate was 97.5 %, much higher than the control group's satisfaction rate of 80 %, and the difference was significant (P<0.01).

Table 4. Comparison of nursing satisfaction between the two groups (n, %)

Group	Control group (n=40)	Research group (n=40)	Statistic	P
Satisfactory	24 (60%)	29 (72.5%)		
Basically satisfactory	8 (20%)	10 (40%)		
Not satisfied	8 (20%)	1 (2.5%)		
Total satisfaction	32 (80%)	39 (97.5%) **	5.362	0.000

Compared with the control group: **P<0.01

Discussion

Patients with deep vein thrombosis in the lower extremities had a higher risk of being diagnosed with cancer than the general population in a nationwide population-cohort study, owing mostly to smoking-related cancers. Incidence of cancer mainly elevated during the first 6 months of follow-up and steadily increased after a year. The frequency of the check-ups will depend on the type of cancer and treatment, as well as the general health of the patient. Some people have check-ups every 3–6 months for the first few years after treatment, then less often after that (14). Furthermore, the overall cancer risks, as well as the timing of the correlation during the follow-up period, were comparable to the risk of VTE (15). It has been speculated that the mechanism behind these studies may involve occult cancers that lead to deep venous thrombosis in the lower extremities before clinical manifestations are apparent. Thus, reverse causality may be the basis for the observed association, suggesting that deep venous thrombosis of the lower extremities is part of the observed tumor phenomenon. Deep vein thrombosis (DVT) of the lower limbs is an acute, painful condition that requires need rapid diagnosis and therapy, and it may also reveal an underlying cancer. The discovery that the cancer risk was halved after six months suggests that some cancers are insidious and are only exposed during deep vein thrombosis in the lower extremities. It has been reported that 7% ~ 45% of patients undergoing surgery for malignant tumors will have different degrees of lower extremity deep vein thrombosis (16). Occult cancer can lead to lower extremity deep vein thrombosis in a variety of ways, and embolism caused by occult cancer itself or complex atrial fibrillation may lead to lower extremity deep vein thrombosis (17). There is also evidence that many cancers can cause hypercoagulability and prethrombotic states, both of which can raise the risk of venous thrombosis (18). Prothrombotic mechanisms in cancer include tumour cells' ability to produce and release procoagulants as well as interact physically with blood cells, including platelets. Other process of prothrombogenesis in malignancies include the production of reactant and inflammation in the acute phase, parabalnemia, and compression. Malignancies associated with venous thrombosis in the lower extremities include anal, anal, peritoneal, and peritoneal cancers. Because of the cancer's closeness to the vein

serving the lower limbs, the vascular wall may be compressed and disrupted, resulting in thrombus development or peripheral embolism.

Common cancers and previous venous thrombosis of the lower extremities lead to an increased burden of complications resulting in increased mortality. Deep vein thrombosis (DVT) of the lower extremity is an adverse prognostic factor for post-operative mortality in colon, lung, bladder, and breast cancers. Slow venous blood flow, venous wall injury and blood hypercoagulation are the three main factors of deep venous thrombosis of lower limbs (19). Malignant tumor itself has a procoagulant effect, but lung cancer surgery is more traumatic to patients, and the postoperative recovery time is longer. The time of surgical anesthesia is long, the venous return is blocked, and the patient's blood flow will be significantly reduced. In addition, surgical trauma can stimulate endogenous coagulation factors, resulting in platelet activation, decreased fibrinolysis, and decreased antiplatelet factors. Due to the need of fasting and water abstaining before surgery, the gastrointestinal pressure is reduced, and the significant loss of water in the blood leads to the easy formation of DVT in the lower limbs of some patients after surgery. FMEA, which originated in the 1950s, is a risk assessment method used to determine potential risks and safety hazards, and has been gradually applied in the medical field in recent years (20-22). FMEA is a complex management concept that may involve a variety of work flows and analytic approaches. It is more methodical and forward-thinking than other risk management strategies, and it may successfully prevent the occurrence of risks. It primarily consists of team organisation, analysis of existing workflow, fault causes, and influencing factors, the RPN value being calculated at the same time, putting forward improvement measures based on the RPN value of each factor analysis result, following up on the implementation of improvement measures, and evaluating their effectiveness. Based on the investigation, the RPN values of six modes were analysed. Previously Zupa et al. (23) believes that FMEA can be applied in any medical process that will affect the safety of patients. At present, the research of FMEA in the prevention of postoperative DVT mainly focuses on orthopedic surgery. Zhenliang et al. (24) showed that nursing management based on FMEA theory, risk determination through quantitative indicators and formulation of

preventive measures can effectively reduce the incidence of DVT and ensure the smooth recovery of orthopedic surgery patients. Chen Meilan et al. (25) applied FMEA to post-operative nursing of artificial hip replacement and found that FMEA could accurately grasp the key work in the nursing process, effectively prevent the occurrence of DVT and improve the quality of nursing work.

Conclusion

Through the study, we believe that whether FMEA has a good application prospect for the formation of deep venous thrombosis of lower limbs in lung cancer patients during perioperative period. Therefore, in this study, patients with lung cancer were collected and randomly divided into control group and research group. The control group was given routine care, and the research group was implemented FMEA management method on the basis of routine care given by the control group. We statistically analyzed the RPN values of 6 failure modes before and after the implementation of FMEA, the comparison of intervention effects, the incidence of DVT, and the satisfaction rate of patients and their families to nursing care. The results showed that after the implementation of FMEA, the RPN values of the 6 failure modes were significantly lower than before, the lower limb circumference and the incidence of DVT in the study group were significantly lower than the control group, and the blood flow velocity was significantly higher than the control group. In addition, the nursing satisfaction rate of the study group was significantly higher than that of the control group. For patients with perioperative lung cancer, FMEA fully mobilizes nurses' subjective initiative and risk awareness, makes use of their own professional knowledge and work experience to conduct intra-group discussion, deeply analyzes the causes of DVT, and implements targeted intervention measures to reduce the risk of DVT.

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Conflict of interest

The author declares that no conflict of interest is associated with this study.

Reducing perioperative deep vein thrombosis

Authors' contribution

This study was done by the author named in this article, and the author accept all liabilities resulting from claims which relate to this article and its contents.

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