

# Effects of Healthcare Failure Mode and Effect Analysis on the Prevention of Deep Venous Thrombosis in Elderly Patients Undergoing Femoral Fracture Surgery

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**Abstract:** *Purpose:* To evaluate the effects of healthcare failure mode and effect analysis (FMEA) on the prevention of deep venous thrombosis (DVT) in elderly patients undergoing femoral fracture surgery. *Methods:* Eighty elderly patients undergoing femoral fracture surgery who did not apply FMEA in Suzhou BenQ Medical Center from June 1, 2022 to May 31, 2023 were selected as the control group. According to the equal group experiment method, 80 elderly patients who were managed using FMEA from June 1, 2023 to May 31, 2024 were selected as the FMEA group. The control group received traditional nursing management, while the FMEA group applied FMEA to analyze failure causes, calculate Risk Priority Numbers (RPNs), identify failure modes with higher RPNs, analyze the influencing factors, develop improvement measures, and optimize processes. The RPN values and the incidence of DVT, as well as nursing satisfaction scores, were compared in the two groups. *Results:* Compared with the control group, the total RPN values of the FMEA group decreased significantly, with a reduction rate of 87.0%. Besides, the incidence of DVT was 1.3% in the FMEA group, lower than 10.0% in the control group (8/80). What's more, the patients in the FMEA group were more satisfied with the nursing service compared with the patients in the control group. *Conclusion:* The application of the FMEA in elderly patients undergoing femoral fracture surgery has demonstrated its potential to prevent the incidence of DVT, lower RPN values, and improve nursing satisfaction.

**Keywords:** Healthcare failure mode and effect analysis; Venous thrombosis; Femoral fracture

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# 1. Introduction

Deep venous thrombosis (DVT) is a prevalent complication among patients who have undergone surgery or have been bedridden for extended periods <sup>[1]</sup>. When DVT occurs, it can significantly impair the functionality of the lower limbs, ranging from reduced work capacity in mild cases to life-threatening Pulmonary Embolism (PE) in severe instances <sup>[2]</sup>. DVT is particularly common in individuals who have suffered major trauma or are elderly, especially during the immobilization period following major orthopedic surgeries <sup>[3]</sup>. Consequently, the prevention and management of DVT have emerged as crucial aspects of orthopedic clinical nursing.

Failure Mode and Effects Analysis (FMEA) is a proactive methodology that anticipates problems, assesses high-risk healthcare processes, pinpoints potential hazards, and implements preventive risk management strategies <sup>[4-6]</sup>. This study integrates FMEA into the postoperative nursing management of elderly patients with femoral fractures. Through the quantification of risk indicators and the formulation of tailored preventive measures, the aim is to significantly reduce the occurrence of DVT, ultimately facilitating a smoother recovery process for patients.

## 2. Methods

### 2.1. General information

Eighty elderly patients undergoing femoral fracture surgery who did not apply FMEA in Suzhou BenQ Medical Center from June 1, 2022 to May 31, 2023 are selected as the control group. According to the equal group experiment method, eighty elderly patients who are managed using FMEA from June 1, 2023 to May 31, 2024 are selected as the FMEA group. Inclusion criteria: (1) Patients aged  $\geq 60$  years; (2) Patients who met the indications for surgery; (3) Patients with normal cognitive and communicative functions; (4) Able to undergo rehabilitation training; (5) Willing to join in the study and sign the informed consent. Exclusion criteria: (1) Suffer from serious heart, brain, lung, and kidney diseases; (2) Unwilling to join in the study.

### 2.2. Ethics statement

This study is approved by the Institutional Review Board of the XX Medical Center (Approval No. SZMJYY20XXXX1401).

### 2.3. Establishment of FMEA team

The FMEA team consisted of 12 members, including one chief physician, one deputy chief physician, one deputy chief nurse, four supervisor nurses, and six senior nurses. All selected members received FMEA training for at least one month. The department held meetings regularly to brainstorm and analyze the main causes of hospital-acquired infections and lower limb deep venous thrombosis in elderly patients undergoing femoral fracture surgery in the control group, thus to assess risks and analyze mechanisms, and efficacy. After then, the risk priority number (RPN) is calculated using three dimensions, including severity (S), occurrence (O), and detection (D). In brief,  $RPN = S \times O \times D$ . Use numbers 1 to 10 to represent the degree of each dimension, with a larger number indicating a higher likelihood or severity of occurrence. Accordingly, the lowest RPN score is 1 point, and the highest score is 1000 points. The higher the score, the greater the risk of the failure mode. Calculating RPN values can help FMEA team members identify high-value failure modes that require priority attention. Sort the calculated RPN values from high to low, identify the top 4 failure modes, analyze and identify them using FMEA, identify hazardous

factors, improve techniques, and prevent failure from occurring according to the literature and clinical experience, as shown in **Table 1** <sup>[7, 8]</sup>.

**Table 1.** Causes of failure modes and improvement measures in elderly patients undergoing femoral fracture surgery

| Failure mode                              | Causes   | Improvement measures   | S | O | D | PRN |
|---|--|--|---|---|---|-----|
| Improper organizational system management | Lack of risk management awareness; incomplete risk classification; Lack of guidelines and standards for patient education  | Improve the risk classification management system. Using the Wells DVT score <sup>[7]</sup> patients with a thrombosis risk score greater than or equal to 3 should take anti thrombotic measures and ensure that the measures are implemented effectively; Develop management education standards and guidelines for DVT prevention to assist nurses in implementing phased preoperative and postoperative nursing guidance and education for patients.   | 7 | 7 | 6 | 294 |
| Irregularities in medical care procedures | Inadequate education and lack of effective communication with patients; Failure to observe the condition in a timely manner and failure to predict changes in risk factors; New nurses lack assessment ability   | Strengthen communication with patients; Nurses are required to pay attention to observing the peripheral circulation of the patient's limbs dynamically, such as skin color, temperature, pain, swelling, numbness, presence of arterial pulsation, sensory abnormalities, venous filling, etc; Establish a unified DVT assessment standard guideline within the department, using the Autar scale for clinical risk assessment <sup>[8]</sup> . The research group conducts extensive professional training for nurses, organizing one DVT theoretical learning and operational exercise for general nursing staff every week. The training exercises are conducted in the form of lectures, demonstrations, exercises, and random exams to prevent thrombosis. | 7 | 7 | 8 | 392 |
| Patient and family factors                | Elderly and weak individuals often have underlying diseases and are prone to sudden changes in their condition; Poor compliance and lack of cooperation with anticoagulant therapy; Lack of assistance from family members in postoperative rehabilitation exercise for patients | Nurses are required to pay more attention to elderly and weak individuals with underlying diseases, once abnormal changes occur, immediately identify the cause and take early intervention measures; For patients who do not cooperate with anticoagulant therapy, it is necessary to promptly clarify the reasons and provide corresponding explanations; For patients who lack assistance in postoperative rehabilitation training, arrange for dedicated personnel to assist.  | 6 | 6 | 7 | 252 |
| Equipment and environment                 | Incomplete physical therapy equipment and outdated auxiliary tools   | Apply to purchase physical therapy equipment and update auxiliary tools  | 5 | 7 | 3 | 105 |

\*Abbreviations: DVT for Deep Venous Thrombosis; S for severity; O for occurrence; D for detection; RPN for the risk priority number.

## 2.4. Observed indexes

The RPN value for each failure mode is calculated and compared in the two groups. The reduction rate = (RPN in control group – RPN in FMEA group / RPN in control group × 100%. The occurrence of DVT in the lower limbs is determined using Doppler ultrasound examination and compared in the two groups. Besides, the nursing satisfaction questionnaire designed by the researcher includes three aspects: Disease explanation (5 items), Postoperative functional exercise guidance (10 items), and Communication effectiveness (5 items), which is used to assess patients' satisfaction. Each item was divided into 5 grades from “very dissatisfied” to “very satisfied”, with a score of 1–5, and a total score of 100 points. The higher the score, the higher the patient satisfaction.

## 2.5. Statistical analysis

SPSS 22.0 is used to analyze the data. The measurement data are expressed as mean  $\pm$  SD and analyzed with a t-test, and the counting data are expressed in rate (%) and analyzed with a chi-square test.  $P < 0.05$  meant the difference is statistically significant.

## 3. Results

### 3.1. Comparison of general information between the two groups

There were no significant differences between the two groups in age, gender, married status, or education level (all  $P > 0.05$ ), as shown in **Table 2**, which meant that the two groups were comparable.

**Table 2.** Comparison of general information between the two groups

| General information    | Control group (n=80) | FMEA Group (n=80) | $t/\chi^2$ | $P$   |
|------------------------|----------------------|-------------------|------------|-------|
| Age (y)                | 69.63 $\pm$ 6.04     | 69.94 $\pm$ 6.73  | 0.31       | 0.758 |
| Gender                 |                      |                   | 0.43       | 0.511 |
| Male (%)               | 31 (38.8)            | 27 (33.8)         |            |       |
| Female (%)             | 49 (61.3)            | 53 (66.3)         |            |       |
| Married status         |                      |                   | 0.23       | 0.629 |
| Married (%)            | 49 (61.3)            | 46 (57.5)         |            |       |
| Other (%)              | 31 (38.8)            | 34 (42.5)         |            |       |
| Years of education (y) |                      |                   | 1.44       | 0.486 |
| ≤6 (%)                 | 53 (66.3)            | 56 (70.0)         |            |       |
| 6-12 (%)               | 19 (23.8)            | 20 (25.0)         |            |       |
| ≥12 (%)                | 8 (10.0)             | 4 (5.0)           |            |       |

\*Abbreviations: FMEA for Failure Mode and Effects Analysis.

### 3.2. FMEA reduced RPN values

Compared with the control group (total RPN values = 1043), the total RPN values of the FMEA group (total RPN values = 136) decreased significantly, with a reduction rate of 87.0%, indicating a significant improvement, as shown in **Table 3**.

**Table 3.** FMEA model reduced RPN values

| Item                                      | Control group (n=80) | FMEA group (n=80) | The reduction rate (%) |
|---|----------------------|-------------------|------------------------|
| Improper organizational system management | 294                  | 36                | 87.8                   |
| Irregularities in medical care procedures | 392                  | 56                | 85.7                   |
| Patient and family factors                | 252                  | 32                | 87.3                   |
| Equipment and environment                 | 105                  | 12                | 88.6                   |
| Total scores                              | 1043                 | 136               | 87.0                   |

\*Abbreviations: FMEA for Failure Mode and Effects Analysis.

### 3.3. FMEA reduced the incidence of DVT

The incidence of DVT was 1.3% in the FMEA group (1/80), lower than 10.0% in the control group (8/80) ( $P < 0.05$ ), indicating that FMEA could help reduce the incidence of DVT in elderly patients undergoing femoral fracture surgery, as shown in **Table 4**.

**Table 4.** FMEA model reduced the incidence of DVT

| Group         | <i>n</i> | DVT | DVT incidence rate (%) | <i>p</i> |
|---------------|----------|-----|------------------------|----------|
| Control group | 80       | 8   | 10.0                   | 0.034    |
| FMEA group    | 80       | 1   | 1.3                    |          |

\*Abbreviations: FMEA for Failure Mode and Effects Analysis; DVT for Deep Venous Thrombosis.

### 3.4. FMEA improved nursing satisfaction scores

The patients in the FMEA group were more satisfied with the nursing service compared with the patients in the control group, and the difference was statistically significant (all  $P < 0.05$ ), as shown in **Table 5**.

**Table 5.** Comparison of nursing satisfaction score between the two groups

| Group                         | Disease explanation | Postoperative functional Exercise guidance | Communication effectiveness | Overall satisfaction |
|-------------------------------|---------------------|--|-----------------------------|----------------------|
| Control group ( <i>n</i> =80) | 20.71 ± 2.17        | 43.79 ± 3.56                               | 22.00 ± 1.81                | 86.50 ± 4.98         |
| FMEA group ( <i>n</i> =80)    | 22.70 ± 1.72        | 46.96 ± 2.28                               | 22.95 ± 1.62                | 92.61 ± 3.18         |
| <i>t</i>                      | 6.42                | 6.72                                       | 3.50                        | 9.26                 |
| <i>p</i>                      | < 0.001             | < 0.001                                    | 0.001                       | < 0.001              |

\*Abbreviations: FMEA for Failure Mode and Effects Analysis.

## 4. Discussion

Elderly individuals, due to their weaker physical capabilities and limited mobility, are highly susceptible to femoral fractures resulting from falls, external impacts, and conditions like osteoporosis<sup>[9]</sup>. For these elderly patients with femoral fractures, prompt surgical treatment is essential to achieve favorable outcomes, shorten the duration of bed rest, and minimize the risks of disability and mortality<sup>[9]</sup>. However, during femoral fracture surgeries, elderly patients tend to have poor surgical tolerance, experience more intense stress reactions, and require longer periods of rehabilitation. These factors can contribute to coagulation disorders, slow down deep venous blood flow in the lower extremities, exacerbate venous dilation, blood stasis, and damage to venous wall endothelial cells, thereby increasing the risk of developing DVT<sup>[10, 11]</sup>. Consequently, preventing DVT holds significant importance in improving the prognosis of elderly patients undergoing femoral fracture surgery<sup>[11]</sup>.

FMEA is a robust and proactive analytical tool that anticipates and assesses the likelihood of medical events, implementing preventive measures tailored to the level of risk to minimize their occurrence<sup>[12]</sup>. Xu applied the FMEA framework to oral and maxillofacial surgery, and they found that FMEA for oral and maxillofacial surgery could prevent MDRO infections, improve the implementation of preventive and control measures, as well as oral self-care ability<sup>[13]</sup>. Besides, Davide found that the FMEA could reduce the risk of human error during laparoscopic surgery and improve patient safety<sup>[6]</sup>.

FMEA perfectly encapsulates the essence of high-quality nursing models by meticulously tackling every

aspect of management, establishing standardized and streamlined frameworks, and guiding the implementation of targeted and efficient nursing plans tailored to patients' needs <sup>[14, 15]</sup>. In the current study, the FMEA team convened meetings to scrutinize possible factors for postoperative DVT in elderly patients undergoing femoral fracture surgery. The analysis uncovered four high-risk indicators, including improper organizational system management, irregularities in medical care procedures, patient and family factors, and equipment and environment. Upon recognizing the failure modes and their underlying causes, targeted interventions were devised, resulting in a notable reduction in the RPNs across all four indicators. The overall RPN reduction rate reached 87.0%, underscoring the profound effectiveness of the implemented measures and the successful mitigation of risks. Notably, while 8 cases of DVT occurred in the control group, only 1 case was reported in the FMEA group. This underscores the effectiveness of utilizing FMEA principles in nursing management, where quantifying risk indicators and formulating preventive measures can drastically reduce the incidence of DVT, ensuring the smooth recovery of elderly patients undergoing femoral fracture surgery, thus improving nursing satisfaction.

## 5. Conclusion

In summary, the application of the FMEA in elderly patients undergoing femoral fracture surgery has demonstrated its potential to prevent the incidence of DVT, lower RPN values, and improve nursing satisfaction. However, the applicability of this model necessitates further analysis, given the constraints posed by limited follow-up time and sample size.

## Disclosure statement

The author declares no conflict of interest.

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