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Observation of the Preventive Effect of Failure Mode and Effects Analysis (FMEA) Combined with Traditional Chinese Medicine (TCM) Characteristic Nursing on Pressure Injuries in Patients with Kidney Disease

Lei Shen*

The First Traditional Chinese Medicine Hospital of Changde City, Changde 415000, Hunan, China

**Author to whom correspondence should be addressed.*

Abstract: *Objective:* To explore the practical effect of Failure Mode and Effects Analysis (FMEA) combined with traditional Chinese medicine (TCM) characteristic nursing in preventing pressure injuries in patients with kidney disease, providing a referenceable practical basis for clinical nursing work. *Methods:* From January 2023 to June 2024, 120 patients with kidney disease in the nephrology department of the hospital were selected and randomly divided into a control group and an intervention group, with 60 cases in each group. The control group received routine pressure ulcer prevention nursing, while the intervention group received additional FMEA management mode and TCM characteristic nursing. The incidence of pressure ulcers, injury staging, nutritional status, skin scores, and nursing satisfaction were compared between the two groups. *Results:* The incidence of pressure injuries in the control group was 20.00%, while that in the intervention group was only 5.00%. Moreover, the injuries in the intervention group were milder and occurred later on average, with statistically significant differences between the two groups ($P < 0.05$). In terms of nursing satisfaction, the intervention group reached 96.67%, significantly higher than the 83.33% in the control group, with this difference also passing statistical testing ($P < 0.05$). *Conclusion:* The combined application of FMEA and TCM characteristic nursing can effectively reduce the risk of pressure injuries in patients with kidney disease, improve their nutritional and skin status, and enhance nursing satisfaction, demonstrating high clinical promotion value.

Keywords: Failure mode and effects analysis; Traditional Chinese medicine characteristic nursing; Kidney disease; Pressure injuries

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1. Introduction

Pressure injuries are skin and subcutaneous tissue damage caused by prolonged pressure, severely affecting patients' quality of life and increasing the healthcare burden. Patients with kidney disease often suffer from complications such as edema, hypoproteinemia, and anemia due to impaired renal function, and some require long-term bed rest, resulting in a significantly higher risk of pressure injuries compared to ordinary patients. Currently, conventional preventive care is mostly passive intervention, making it difficult to comprehensively cover the complex risks of patients with kidney disease. Failure Mode and Effects Analysis (FMEA) is a proactive risk assessment tool that identifies risks and formulates measures to reduce the incidence of adverse events. Traditional Chinese medicine (TCM) nursing utilizes methods such as herbal external application and acupoint massage to improve blood and qi circulation, offering unique advantages in preventing pressure injuries [1]. This study combines both approaches to develop a targeted nursing plan for preventing pressure injuries in patients with kidney disease, exploring its clinical effects and providing practical evidence for optimizing nursing strategies.

2. Materials and methods

2.1. General information

From January 2023 to June 2024, 120 inpatients with kidney disease in the nephrology department of our hospital were selected, all meeting the diagnostic criteria for kidney disease, aged $\geqslant$ 18 years, with an expected hospital stay of $\geqslant$ 7 days, a Braden score $\leqslant$ 18, and providing informed consent. Patients with existing pressure injuries upon admission, severe underlying diseases, inability to cooperate with nursing care, or intolerance to TCM nursing were excluded. The patients were randomly divided into a control group and an intervention group, with 60 cases in each group. There were no statistically significant differences in baseline data (gender, age, type of kidney disease, Braden score, bed rest duration) between the two groups ($P > 0.05$), indicating comparability.

2.2. Nursing methods: Control group

Conventional preventive care for pressure injuries was implemented, with a nursing plan developed based on the "Guidelines for the Management of Pressure Injuries in Bedridden Patients" [2]: (1) Pressure relief care: Assist patients in turning over every 2 hours, using air mattresses, pressure-relieving pads, and other equipment to avoid prolonged pressure on local tissues; (2) Skin care: Clean the skin daily with warm water, keep it dry and clean, and avoid mechanical injuries such as friction and traction; (3) Health education: Explain pressure injury prevention knowledge to patients and their families, and guide family members in assisting with skin care and limb movement.

2.3. Nursing methods: Intervention group

On the basis of the control group's conventional care, FMEA combined with TCM characteristic nursing was implemented, with specific measures as follows:

2.3.1. FMEA risk assessment and intervention

(1) Establish an FMEA nursing team: The team consists of 8 members, including the head nurse of the

nephrology department, responsible nurses, attending physicians, dietitians, and rehabilitation therapists. The head nurse serves as the team leader, responsible for overall coordination; responsible nurses are in charge of clinical data collection and nursing implementation; attending physicians provide medical support; dietitians develop personalized dietary plans; and rehabilitation therapists guide functional exercises.

(2) Identify potential failure modes: Through clinical observation and case analysis, the team identifies potential failure modes for pressure injuries in patients with kidney disease, including: 1) delayed or improper turning; 2) improper use of pressure-relieving equipment; 3) inadequate skin cleaning; 4) insufficient nutritional supply; 5) impaired tissue repair due to hypoproteinemia.

(3) Risk assessment: The FMEA Risk Priority Number (RPN) assessment method is used to score each failure mode from three dimensions: severity (S), occurrence frequency (O), and detectability (D) (each dimension scored from 1 to 10 points). RPN = S × O × D, with higher RPN scores indicating higher risks. After scoring each failure mode, high-risk modes with RPN $\geqslant$ 80 points are selected and ranked: delayed turning (RPN = 90), insufficient nutritional supply (RPN = 85), decreased skin resistance due to edema (RPN = 82), and inadequate awareness among patients and their families (RPN = 80).

(4) Develop and implement improvement measures: To effectively avoid the risks associated with high-risk failure modes, the team needs to implement precise and systematic strategies, developing and implementing a series of targeted improvement measures. First, establish a comprehensive turning reminder mechanism by equipping the bedside with an electronic reminder device that actively prompts nurses to assist patients in turning over every 1.5 hours, while recording the turning time and position information in detail. Second, the development of personalized nutritional plans is essential. Dietitians need to tailor dietary plans based on the patient's renal function status and actual nutritional level. For patients with hypoproteinemia, increase the intake of high-quality protein under the professional guidance of a doctor, supplement with enteral nutrition preparations if necessary, and regularly monitor key indicators such as serum albumin and hemoglobin. Adjust the plan dynamically based on the monitoring results to lay a solid nutritional foundation for the patient's recovery. Finally, strengthening health education is an important guarantee for improving nursing effectiveness. Through one-on-one detailed explanations, intuitive video teaching, and distributing promotional brochures, comprehensively educate patients and their families about the risks and hazards of pressure injuries, prevention points, and TCM nursing-related knowledge.

2.3.2. TCM characteristic nursing

Referring to research progress on the application of TCM nursing interventions in preventing pressure injuries and considering the pathogenic characteristics of patients with kidney disease (mostly spleen and kidney deficiency, qi and blood insufficiency, and internal retention of dampness), the following TCM characteristic nursing measures were developed:

(1) Herbal external application care: Select 10g each of *Astragalus membranaceus*, *Angelica sinensis*, *Salvia miltiorrhiza*, and *Carthamus tinctorius*, grind them into a powder, mix with Vaseline to form a paste, and apply an appropriate amount to the bony prominences of patients (such as the sacrum, hips, and heels) once daily for 2 hours each time. Assess the patient's skin condition before application and observe for any allergic reactions.

(2) Acupoint massage: Select acupoints such as Zusanli, Xuehai, Pishu, and Shenshu, and massage them twice daily for 15 minutes each time. Zusanli invigorates the spleen and stomach, nourishes qi and blood;

Xuehai promotes blood circulation and removes blood stasis; Pishu invigorates the spleen and qi; Shenshu warms the kidney and strengthens yang. By stimulating these acupoints, regulate visceral function, improve blood and qi circulation, and enhance the body's vital qi. The massage intensity should be based on the patient's sensation of soreness and fullness, avoiding excessive force.

(3) Emotional nursing: Patients with kidney disease have a long course of illness and recurrent conditions, making them prone to anxiety and depression, which affects blood and qi circulation. Nurses use TCM emotional care methods, such as listening and counseling, music therapy (playing soothing TCM health music), and meditation relaxation, to communicate with patients for 15–20 minutes daily, alleviating negative emotions and maintaining a pleasant mood.

2.4. Observation indicators

(1) Incidence of pressure injuries: Observe and record the incidence, occurrence time, and staging of pressure injuries in both groups during hospitalization (refer to the staging criteria in the "Guidelines for the Prevention and Treatment of Pressure Injuries": Stage I: intact skin with non-blanchable erythema; Stage II: partial-thickness skin loss with blisters or superficial ulcers; Stage III: full-thickness skin loss with ulcers extending into subcutaneous fat; Stage IV: full-thickness tissue loss with ulcers extending into muscle and bone; Unstageable: depth of injury unknown) [3].

(2) Nutritional status: Collect fasting venous blood from patients before nursing and after 4 weeks of nursing to detect serum albumin and hemoglobin levels.

(3) Skin condition score: Use a skin condition assessment scale to score from five dimensions: skin color, temperature, humidity, elasticity, and integrity, with each dimension scored from 0 to 20 points and a total score of 0 to 100 points. Higher scores indicate better skin condition.

(4) Nursing satisfaction: Use a self-made nursing satisfaction questionnaire to survey patients and their families upon discharge. The questionnaire includes four dimensions: nursing attitude, nursing skills, nursing effects, and health education, with a total of 20 questions. Each question is scored from 1 to 5 points, with a total score of 100 points. $\geqslant$ 90 points indicate very satisfied, 80–89 points indicate satisfied, and $<$ 80 points indicate dissatisfied. Satisfaction = (number of very satisfied cases + number of satisfied cases) / total number of cases × 100%.

2.5. Statistical methods

Data analysis was performed using SPSS 26.0 statistical software. Measurement data are expressed as (Mean ± SD), with independent sample t-tests used for comparisons between groups and paired t-tests used for comparisons within groups. Count data are expressed as [n (%)], with x^2 tests used for comparisons between groups. The rank-sum test was used for comparing pressure injury stages. A P-value $<$ 0.05 was considered statistically significant.

3. Results

3.1. Comparison of the incidence of pressure injuries between the two groups of patients

The incidence of pressure injuries in the intervention group was 5.00%, which was significantly lower than that in the control group (20.00%), with a statistically significant difference (P $<$ 0.05) (**Table 1**).

Table 1. Comparison of the incidence of pressure injuries between the two groups of patients [n (%), Mean ± SD]

Group	Number of Cases	Number of Incidence Cases (Incidence Rate)	Injury Stage (Cases)	Mean Occurrence Time (days)		
			Stage I	Stage II	Stage III	
Control Group	60	12 (20.00)	7	4	1	8.5±1.8
Intervention Group	60	3 (5.00)	3	0	0	14.2±2.1
x^2/Z/t value	6.984	2.357	13.625		Stage III	
P value	0.008	0.019	< 0.001		1	8.5±1.8

3.2. Comparison of nutritional status between the two groups of patients before and after nursing care

Before nursing care, there was no statistically significant difference in the levels of serum albumin and hemoglobin between the two groups of patients ($P > 0.05$). After 4 weeks of nursing care, the levels of serum albumin and hemoglobin in both groups increased compared to those before nursing care, and the increase in the intervention group was greater than that in the control group, with a statistically significant difference ($P < 0.001$) (**Table 2**).

Table 2. Comparison of nutritional status between the two groups of patients before and after nursing care (Mean ± SD)

Group	Number of Cases	Time	Serum Albumin (g/L)	Hemoglobin (g/L)
Control Group	60	Before Care	32.5±3.1	95.3±10.8
		After Care	35.2±3.5	102.5±11.3
		t value	4.825	3.967
		P value	< 0.001	< 0.001
Intervention Group	60	Before Care	32.3±3.3	94.8±11.2
		After Care	38.6±3.2	115.8±10.5
		t value	10.562	12.384
		P value	< 0.001	< 0.001
Inter-group Comparison *t* value (After Care)			5.872	6.134
Inter-group Comparison *P* value (After Care)			< 0.001	< 0.001

3.3. Comparison of skin condition scores between the two groups of patients before and after nursing care

Before nursing care, there was no statistically significant difference in skin condition scores between the two groups of patients ($P > 0.05$). After 4 weeks of nursing care, the skin condition scores of both groups increased compared to those before nursing care, and the score in the intervention group was higher than that in the control group, with a statistically significant difference ($P < 0.001$) (**Table 3**).

Table 3. Comparison of skin condition scores between the two groups of patients before and after nursing care (Mean ± SD, points)

Group	Number of Cases	Before Care	After Care	*t* value	*P* value
Control Group	60	65.2±5.3	76.3±5.1	12.845	< 0.001
Intervention Group	60	64.8±5.5	89.5±4.2	25.632	< 0.001
Inter-group *t* value		0.412	15.286		
Inter-group *P* value		0.681	< 0.001		

3.4. Comparison of nursing satisfaction between the two groups

The nursing satisfaction in the intervention group was 96.67%, which was higher than that in the control group (83.33%), with a statistically significant difference ($P < 0.05$) (**Table 4**).

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

Group	Number of Cases	Very Satisfied	Satisfied	Unsatisfied	Satisfaction Rate
Control Group	60	28 (46.67)	22 (36.66)	10 (16.67)	50 (83.33)
Intervention Group	60	45 (75.00)	13 (21.67)	2 (3.33)	58 (96.67)
x^2 value					6.171
P value					0.013

4. Discussion

Pressure injuries are one of the common complications among nephropathy patients during hospitalization, and their occurrence is associated with various factors such as prolonged bed rest, nutritional disorders, edema, and decreased skin resistance [4]. Conventional nursing care primarily focuses on passive prevention, lacking systematic assessment of potential risks and targeted interventions, making it difficult to meet the complex nursing needs of nephropathy patients [5]. This study integrated the Failure Mode and Effects Analysis (FMEA) risk assessment tool with traditional Chinese medicine (TCM)-featured nursing care to construct a comprehensive nursing program, effectively reducing the risk of pressure injuries in nephropathy patients and achieving favorable clinical outcomes.

As a proactive risk assessment method, FMEA enables the active prevention and control of nursing risks by identifying potential failure modes, assessing risk levels, and formulating improvement measures [6]. In this study, the FMEA team systematically analyzed and identified high-risk modes such as delayed turning, inadequate nutritional supply, decreased skin resistance due to edema, and insufficient awareness among patients and their families. Targeted measures, including turning reminder mechanisms, personalized nutritional plans, edema nursing care, and enhanced health education, were formulated to reduce the risk of pressure injuries from the source. The results showed that the incidence of pressure injuries in the intervention group was 5.00%, significantly lower than the 20.00% in the control group, with delayed onset and reduced severity of injuries. This is consistent with the findings of Chen et al., who reported that FMEA-based nursing interventions improved the prognosis of mechanically ventilated patients, confirming the effectiveness of FMEA in nursing risk prevention and control [7].

According to TCM theory, the occurrence of pressure injuries in nephropathy patients is closely related to spleen and kidney deficiency, qi and blood deficiency, and blood stasis obstruction. Impaired qi and blood circulation lead to blood stasis obstruction, depriving local tissues of nourishment and making them prone to injury. In this study, TCM-featured nursing care adopted a holistic approach based on syndrome differentiation, incorporating measures such as herbal external application, acupoint massage, dietary regulation, and emotional nursing to regulate the patient's bodily state from multiple dimensions. Herbal external application used blood-activating and stasis-resolving herbs such as astragalus, angelica, *Salvia miltiorrhiza*, and safflower to improve local blood circulation and enhance skin resistance when applied to bony prominences. Acupoint massage selected acupoints such as Zusanli and Xuehai to stimulate meridian qi and blood circulation, regulate organ function, and improve overall nutritional status. Dietary regulation provided tailored diets based on the patient's constitution to invigorate the spleen and kidney, promote diuresis and reduce edema, and provide a material basis for skin repair. Emotional nursing alleviated negative emotions in patients, preventing emotional disorders from affecting qi and blood circulation. After nursing care, the serum albumin and hemoglobin levels, as well as the skin condition scores, in the intervention group were significantly higher than those in the control group, indicating that TCM-featured nursing care effectively improved the patient's nutritional status, enhanced skin health, and provided intrinsic protection against pressure injuries.

Nutritional status influences the occurrence and healing of pressure injuries. Nephropathy patients often suffer from nutritional disorders such as hypoalbuminemia and anemia due to impaired renal function, leading to decreased skin resistance and weakened tissue repair capacity [8]. In this study, the intervention group formulated personalized nutritional plans through FMEA and combined them with TCM dietary regulation to improve the patient's nutritional status. After nursing care, the serum albumin and hemoglobin levels in the intervention group were significantly higher than those in the control group, indicating that comprehensive nutritional interventions effectively corrected nutritional imbalances and laid an important foundation for preventing pressure injuries. Enhanced health education improved the awareness level of patients and their families, enabling them to actively cooperate with nursing work and reduce risks associated with inadequate nursing compliance, which was one of the important reasons for the superior nursing effects in the intervention group compared to the control group.

This study found that nursing satisfaction was significantly higher in the intervention group than in the control group, attributed to the more targeted nursing measures and more pronounced nursing effects in the intervention group. The implementation of FMEA made nursing work more systematic and standardized, while

TCM-featured nursing care embodied individualization and humanistic care. The combination of the two met the physiological needs of patients, paid attention to their psychological state, and improved the recognition of nursing work among patients and their families. Additionally, this study referenced multiple relevant research findings to ensure the scientific feasibility of the nursing program, with results mutually corroborating existing research conclusions, further confirming the effectiveness of FMEA combined with TCM-featured nursing care.

However, this study also had certain limitations: the sample size was limited, and the results of a single-center study may be biased; the follow-up period was short, and long-term effects were not observed; the mechanism of action of TCM-featured nursing care was not fully elucidated and requires further research. Future studies could expand the sample size, conduct multi-center research, extend the follow-up period, explore the mechanism of action, optimize the nursing program, and enhance its clinical application value.

5. Conclusion

In conclusion, FMEA combined with TCM-featured nursing care can effectively reduce the incidence of pressure injuries in nephropathy patients, alleviate the severity of injuries, improve nutritional status and skin health, and enhance nursing satisfaction through systematic risk prevention and control and TCM syndrome differentiation nursing. It is a scientific and effective nursing model worthy of clinical promotion and application.

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Disclosure statement

The author declares no conflict of interest.

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