Application of Healthcare Failure Mode and Effects Analysis to Improve Dialysis Adequacy in Maintenance Hemodialysis Patients: Postprint

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Abstract

Objective: To investigate the adequacy of maintenance hemodialysis using Healthcare Failure Mode and Effects Analysis (HFMEA) to improve dialysis quality and increase survival rates in hemodialysis patients. Methods: Seventy-eight patients undergoing maintenance hemodialysis at Zhongshan Hospital Xiamen Branch, Fudan University from January to December 2021 were included and divided into an adequate group (spKt/V$ $1.2) and an inadequate group (spKt/V<1.2) based on single-pool urea clearance index (spKt/V) results. HFMEA was employed to measure and analyze the causes of inadequate hemodialysis and to develop improvement measures. Results: After implementing management using HFMEA, the adequacy of dialysis in hemodialysis patients improved significantly, with 15 cases (19.23%) in the inadequate group before implementation and 2 cases (2.56%) after implementation; the difference was statistically significant (P=0.002). Conclusion: Managing with HFMEA can improve dialysis adequacy in hemodialysis patients, which has positive significance for reducing dialysis complications, improving patients' quality of life, and increasing survival rates.

Full Text

Using Healthcare Failure Mode and Effect Analysis to Improve Adequacy of Maintenance Hemodialysis

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Abstract

Objective: To explore the adequacy of maintenance hemodialysis using Healthcare Failure Mode and Effects Analysis (HFMEA) to improve dialysis quality and survival rates in hemodialysis patients.

Methods: Patients undergoing maintenance hemodialysis at Xiamen Branch of Zhongshan Hospital, Fudan University were enrolled and divided into standard (spKt/V $\geq$ 1.2) and non-standard (spKt/V $<$ 1.2) groups based on single-pool urea clearance index (spKt/V) results. HFMEA was employed to measure and analyze causes of inadequate hemodialysis and formulate improvement measures.

Results: Management using HFMEA significantly improved dialysis adequacy. The proportion of patients not meeting standards decreased from [pre-implementation value] to [post-implementation value] ($P < 0.05$).

Conclusion: Application of HFMEA methodology can improve dialysis adequacy in hemodialysis patients, which has positive significance for reducing dialysis complications, improving quality of life, and increasing survival rates.

Keywords: healthcare failure mode and effect analysis; maintenance hemodialysis; dialysis adequacy; dialysis complications; quality of life

Hemodialysis is a blood purification therapy that uses diffusion and ultrafiltration principles to replace partial excretory function of the kidneys, representing one of the most effective treatments for end-stage renal disease (ESRD). Adequate hemodialysis refers to effective removal of uremic toxins and retained water in ESRD patients, providing patient comfort during dialysis, effective control of complications, and enabling patients to achieve good survival, quality of life, and certain social activity capabilities. For hemodialysis patients, whether dialysis is adequate represents an important factor affecting prognosis and quality of life. Currently, changes in urea before and after dialysis are primarily measured to reflect adequacy of a single hemodialysis session. Commonly used clinical indicators for evaluating dialysis adequacy include urea (small molecular solute) clearance index (Kt/V), online urea clearance monitoring (OCM), and urea reduction ratio (URR). Kt/V is now the most widely accepted and applied method for measuring dialysis dose in clinical practice. The KDOQI guidelines

updated in 2015 similarly state that small molecular solute clearance rate is currently the best indicator for evaluating hemodialysis adequacy, recommending measurement using a formal urea kinetic model method, i.e., blood sampling to measure urea clearance. For hemodialysis patients receiving dialysis three times weekly, single-pool urea clearance index (spKt/V) is recommended as the preferred method for evaluating dialysis adequacy. Currently, the "Chinese Clinical Practice Guidelines for Hemodialysis Adequacy" recommend the spKt/V target value.

Healthcare Failure Mode and Effects Analysis is a reliable risk management method that can prospectively and systematically conduct quantitative assessment of potential failures in a process, identify and analyze potential causes of failure, develop improvement measures, and establish standards, thereby effectively reducing or avoiding problem occurrence. Its core principle is predictive assessment of medical processes and implementation of countermeasures before medical risk events occur, thus effectively reducing related risk events. This study applied HFMEA to assess potential failure modes and causes affecting dialysis adequacy during hemodialysis treatment, conducted cause analysis on key links, implemented nursing interventions for unsafe potential factors, continuously improved regulations, refined nursing operation procedures, implemented nursing measures, and strengthened supervision, thereby promoting patient medical safety, reducing dialysis complications, improving quality of life, and increasing survival rates while achieving health economics optimization.

1. Materials and Methods

1.1 Study Population

This study enrolled maintenance hemodialysis patients at a tertiary Grade A comprehensive teaching hospital between [start date] and [end date]. Inclusion criteria: age $\geq$ 18 years, receiving maintenance hemodialysis treatment. Exclusion criteria: patients with infection, malignant tumors, other hypercatabolic diseases, or other active diseases. All patients were divided into standard (spKt/V $\geq$ 1.2) and non-standard (spKt/V $<$ 1.2) groups based on single-pool urea clearance index (spKt/V) results, with patients in the non-standard group receiving HFMEA management intervention.

1.2 HFMEA Implementation

Team Formation and Training: An HFMEA management team for the hemodialysis unit was established, including head nurses, nurses, and physicians, all with college-level education or higher. The team studied HFMEA management knowledge, mastered assessment and analysis methods, collected relevant data, applied HFMEA steps to deconstruct and analyze the entire hemodialysis treatment process, conducted risk assessment on operational procedures and patient evaluation affecting dialysis adequacy, proposed improvement recommendations, formulated plans, implemented nursing measures, and conducted

timely tracking and evaluation.

Process Mapping and Identification: The process included pre-dialysis assessment, physician orders, equipment and consumables preparation, patient weight measurement, blood sampling, dialysis initiation, dialysis parameter setting, pre-termination blood sampling, and dialysis termination.

Critical Value Calculation: Failure modes in each dialysis treatment link were analyzed, and "O, D, S" level evaluation criteria were established. Occurrence (O), Detectability (D), and Severity (S) were each divided into five levels with assigned scores. "O" refers to the likelihood of the failure mode occurring; "D" refers to the probability that current medical nursing measures can detect the failure mode when it occurs; "S" refers to the harm caused when the failure mode occurs. Risk Priority Number (RPN = O × D × S) was calculated, with a value range of 1-125, reflecting the priority order for improvement. Higher scores indicate greater RPN risk and greater need for improvement.

Intervention Development: Based on HFMEA analysis results of the hemodialysis process, failure mode factors were analyzed and improvement measures were formulated.

1.3 Statistical Methods

SPSS software was used for statistical analysis. Measurement data were expressed as mean ± standard deviation ($\bar{x} \pm s$) and compared using t-tests. Count data were expressed as percentages (%) and compared using ^{2} tests. The significance level was set at $\alpha = 0.05$, with $P < 0.05$ considered statistically significant.

2. Results

This study included [number] maintenance hemodialysis patients, with an average age of [age] years and average dialysis vintage of [duration] years, all receiving dialysis three times weekly for [hours] hours per session. Based on single-pool urea clearance rate (spKt/V) results, patients were divided into standard (spKt/V $\geq$ 1.2) and non-standard (spKt/V $<$ 1.2) groups, with [number] cases in the non-standard group. The standard group had average spKt/V of [value], while the non-standard group had average spKt/V of [value].

HFMEA was applied to deconstruct and analyze the entire hemodialysis treatment process, conducting risk assessment on all details affecting dialysis adequacy and implementing improvement measures. After [duration] months of implementation, the standard group had average spKt/V of [value], while the non-standard group had average spKt/V of [value]. Patients with inadequate dialysis decreased from [pre-implementation number] to [post-implementation number], with the adequacy rate significantly higher after implementation ($P < 0.05$).

3. Discussion

3.1 Factors Influencing Dialysis Adequacy

Dialysis adequacy in uremic maintenance hemodialysis patients is influenced by many factors, including inadequate pre-dialysis assessment, poor patient compliance, insufficient dialysis time, inadequate blood flow during dialysis, vascular access recirculation, excessive interdialytic weight gain, small dialyzer surface area, and partial dialyzer clotting.

3.2 Analysis of Causes for Inadequate Dialysis

Among patients not meeting spKt/V standards, [number] cases exhibited poor compliance, strongly requesting early termination due to personal reasons (e.g., family matters requiring temporary leave or inability to tolerate 4-hour dialysis), resulting in insufficient dialysis time. For these patients, enhanced health education was provided about the importance of adequate dialysis, while dialysis protocols were adjusted with personalized treatment modes such as sequential dialysis to improve tolerance and ensure prescribed dialysis duration was achieved. Internet-based medical nursing services were implemented, with relevant health education pushed through the department' s public account. Communication with patients and families was strengthened to arrange treatment time reasonably and improve compliance.

[Number] patients had atrial fibrillation and could not tolerate 4-hour dialysis. After adjusting to 3.5-hour sessions, spKt/V gradually improved and reached standards. [Number] patients experienced inadequate blood flow due to vascular access issues. After administering urokinase in the lock solution post-dialysis, blood flow improved. [Number] patients had outflow tract stenosis of arteriovenous fistula and underwent balloon dilation, with postoperative swelling treated with papaya wine compresses, resulting in improved blood flow and increased spKt/V. [Number] patients had excessive interdialytic weight gain due to volume overload. Through intensive health education and dietary guidance, weight gain was controlled, and spKt/V improved and reached standards.

[Number] patients had incorrect weight measurement methods due to advanced age and poor vision. The "Xuetoutong" software was installed, allowing automatic upload of weight values to electronic medical records after scanning, ensuring correct dialysis prescriptions. The verification system was revised to add mid-dialysis and pre-termination checks, resulting in improved spKt/V for these patients.

3.3 Application of HFMEA in Dialysis Adequacy

Clinical research and practice confirm that inadequate dialysis causes various complications. Hemodialysis involves complex operations with significant risks, requiring healthcare staff to possess strong professional knowledge and operational skills to ensure safe treatment. This study applied HFMEA to analyze

factors affecting dialysis adequacy and implemented nursing interventions for unsafe factors. Healthcare staff fully considered residual renal function while combining patient age, gender, weight, blood pressure, mental status, and nutritional status to develop personalized dialysis treatment plans. During dialysis, patient condition changes were closely monitored, complications were promptly identified and managed, and patient tolerance was improved to achieve adequate dialysis.

The "Xuetoutong"software automatically uploaded and saved patient weight values. Internet-based medical nursing services were implemented with multimedia health education, including "Kidney Friend Clubs," educational videos, lectures, materials, WeChat public accounts, and one-on-one remote education. Patients learned about the hazards of excessive weight gain and controlled water intake during interdialytic periods. They were taught to record dietary notes, based on which nurses provided targeted dietary guidance. Regulations and operation procedures were continuously improved, and supervision was strengthened to promote patient safety, reduce complications, improve quality of life, and increase survival rates.

Results showed that after implementing HFMEA-based nursing, dialysis adequacy in maintenance hemodialysis patients was significantly higher than before implementation. For hemodialysis patients, scientific application of HFMEA can effectively improve dialysis adequacy, reduce complication rates, and increase nursing satisfaction, demonstrating significant clinical effects worthy of attention and promotion.

Conflict of Interest Statement: The authors declare no conflicts of interest.

Hemodialysis Adequacy Influencing Factors Hazard Analysis Evaluation Criteria[6]

Hemodialysis Adequacy Influencing Factors Risk Priority Number Level Assessment Table

Risk Assessment Results for Each Link of Hemodialysis Adequacy Influencing Factors

Hemodialysis Adequacy Failure Cause Analysis and Improvement Measures

Note: Figure translations are in progress. See original paper for figures.