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Original Article

Optimization of the emergency endoscopy process for patients with esophagogastric variceal bleeding using failure mode and effect analysis

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Abstract: Objective: To optimize the emergency endoscopy process for patients with esophagogastric variceal bleeding (EGVB) using failure mode and effect analysis (FMEA). Method: In this retrospective analysis, we enrolled patients who were hospitalized in Ganzhou People's Hospital from January 2021 to December 2021. They were divided into 51 cases before and 51 cases after the intervention according to the time of FMEA model intervention. The risk of unsafe transport, endoscopic hemostasis success rate, RPN (risk priority number) value, dual venous access time, resuscitation success rate, emergency endoscopy timeout execution rate, patient health education awareness rate, and endoscopic ligation of esophageal varices (EVL) procedure volume were compared accordingly before and after the procedure. Results: After the FMEA intervention, the emergency endoscopy process for EGVB patients was optimized, the risk of unsafe transport for emergency EGVB endoscopy was reduced, and the success rate of emergency endoscopic hemostasis for patients was improved. Also, the failure mode of RPN values greater than 12 was improved. After the countermeasures were implemented, the resuscitation success rate of EGVB patients reached 95%, the safe transport pass rate increased from 88% to 98.7%, and the patient health education awareness increased from 69% to 92%. The number of EGVB patients who underwent EVL surgery ranked second in the province. The waiting time, gastric function recovery time, dual venous access time, and hospital stay of patients who underwent the optimized procedure were significantly shorter compared to those before implementation (all $P<0.01$). The incidence of adverse events was significantly lower in patients who underwent the optimized procedure compared to the pre-implementation period ($P<0.01$). Conclusion: Applying FMEA to analyze and optimize the process of EGVB patients undergoing emergency endoscopy can maximize patient life safety and treatment safety, as well as improve medical quality and care safety.

Keywords: Emergency endoscopy process, optimization, esophagogastric variceal bleeding, failure mode and effect analysis

Introduction

Esophagogastric variceal bleeding (EGVB) is one of the major causes of death due to cirrhosis. EGVB is characterized by high blood loss, rapid changes in disease, and aggressive onset, with a mortality rate of 6.8%-10% [1]. Therefore, early and accurate diagnosis and treatment of this disease is crucial to reduce mortality [2]. Emergency endoscopy, which involves endoscopy and treatment of patients within 24 to 48 hours after upper gastrointestinal bleeding, is one of the main and preferred methods for the treatment of EGVB [3]. However, there are medical risks involved in the process of emergency endoscopy. In addition, there may be a series of risks caused by process defects, such as inaccurate assessment of patient tolerance, inadequate preparation for the examination, changes in disease during transport, and complications of endoscopic procedures [4].

Failure Mode and Effects Analysis (FMEA) is a systematic and forward-looking quantitative approach to risk assessment. FMEA is used to evaluate a number of processes, identify where and how they may fail, and assess the risks, thus providing guidance for determining preventive and countermeasures in the process [5].

FMEA can be used for both the analysis of existing processes and the analysis of new processes, and is very suitable to analyze the risks of manual cleaning and sterilization of flexible endoscopes [6]. After implementing targeted improvement measures, the risk priority number (RPN) values of the top 5 patients decreased and the cleaning pass rate increased compared to the previous ones [7]. Zhai Yi et al. used FMEA to manage patients undergoing gastrointestinal endoscopy [8]. The results showed that the implementation of FMEA resulted in a significant decrease in the RPN values, which promoted the early recovery of digestive function and reduced the length of hospital stay and adverse events in terms of safety of care.

In recent years, the safety risks of emergency endoscopy have grown to prominence in esophagogastric variceal bleeding due to increased regionalization of the Emergency Department [9]. System engineering approaches are increasingly being used to improve healthcare systems and reduce failures; however, while these approaches are often applied in operating room settings [10], they have yet to be applied to high-risk communication scenarios in emergency endoscopy. We presented failure mode and effect analysis (FMEA) as a specific system engineering methodology that can be applied to the emergency endoscopy process to reduce failures in communication during inter-hospital transfer. We also applied FMEA in a quality improvement initiative in our institution to demonstrate the potential for this methodology to reduce errors and improve patient safety.

Therefore, the aim of this study was to optimize the emergency endoscopy process for patients with esophagogastric variceal bleeding (EGVB) using failure mode and effect analysis (FMEA). We analyzed the causes of malfunctions or hidden problems and took measures to optimize the examination process to maximize the life safety and treatment of EGVB patients, and improve medical quality and nursing safety.

Methods

Construction of the project team

The FMEA team consisted of staff from the Emergency Department and Department of Gastroenterology of Ganzhou People's Hospital, including an attending physician, a director of nursing, a head nurse, and four nurses from the gastrointestinal endoscopy unit. All team members received systematic FMEA training and were clear on all steps of management. We presented conceptual description of FMEA along with the examples of FMEA application to facilitate interpretation and implementation.

Analysis of process

Drawing of emergency endoscopy process for EGVB patients

The procedure for emergency endoscopy of an EGVB patient is shown in **Figure 1**. Failure modes are identified from the flow to determine the cause of the risk.

FMEA technique

As a prospective risk analysis technique, FMEA is able to identify and eliminate known or possible failures to enhance the reliability and safety of complex systems, and it can provide valuable information for risk management. The first step in FMEA is listing all possible failure modes of a specific product or system through brainstorming. After that, critical analysis is performed on the recognized failure modes by considering the risk factors of occurrence (O), severity (S), and detection (D). Here, O is the probability of a failure, S is the severity of a failure, and D is the probability of not detecting a failure. The aim of FMEA is to prioritize failure modes so as to assign the limited resources to the high-risk vulnerabilities. The following contents display the implementation procedure of FMEA.

Enumeration of failure modes and assessment of risk causes

The failure modes that occur during the focused process are listed. All available failure modes or possible reasons are listed as follows: (1) Inadequate assessment of the condition; (2) Inadequate management of critically ill patients; (3) Failure to establish a process for diagnosis and treatment of ruptured esophagogastric fundic variceal bleeding; (4) Inadequate assessment of patient tolerance for emergency endoscopy; (5) Inadequate nursing assessment of the condition; (6) Lack of specialist nursing skills; (7) Poor prognostic judgement by young nurses; (8) Inadequate grasp of

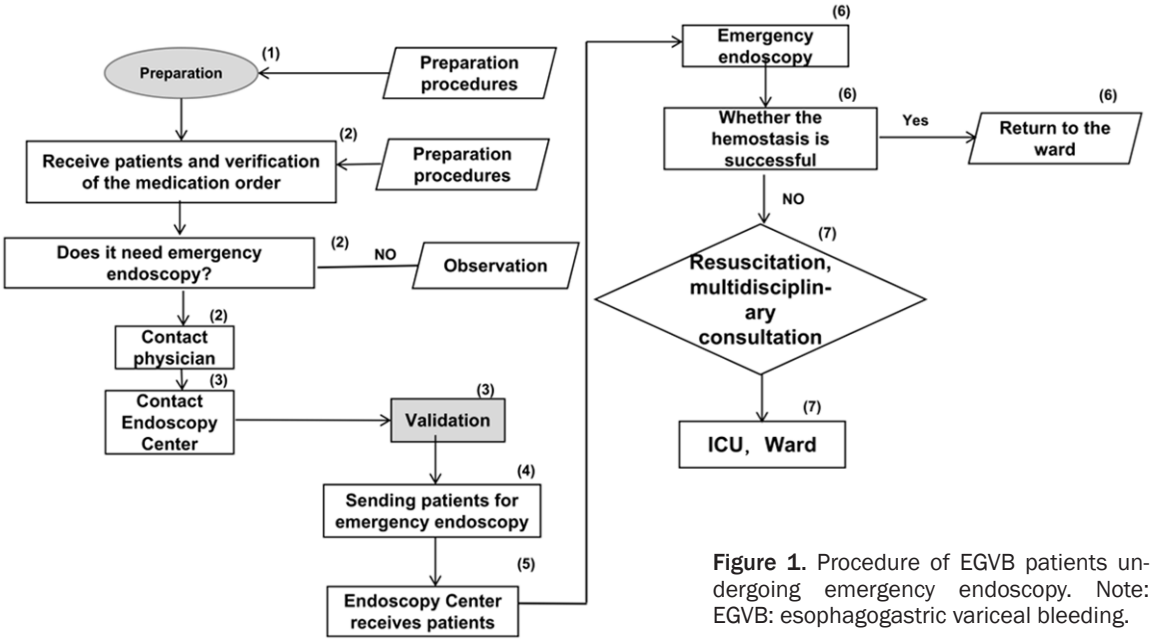

Figure 1. Procedure of EGVB patients undergoing emergency endoscopy. Note: EGVB: esophagogastric variceal bleeding.

relevant disease indications by nurses; (9) Failure to establish the corresponding clustered nursing process; (10) Young nurses who are underqualified and do not cooperate with the resuscitation of critically ill patients; (11) Sudden change in condition during transfer and untimely handling; (12) Unskilled in transfer process; (13) Insufficient technical strength of physicians; (14) Inadequate nursing cooperation; (15) No handover from endoscopy room to ward nurses; (16) Inadequate handover sheet; (17) Insufficient knowledge of disease promotion by nurses; (18) Single form of missionary education and lack of information.

Determination of the priority of failure by evaluating the cause of failure mode and its possible risk

The risk priority number (RPN) is calculated by hazard analysis (severity, frequency of occurrence) and decision tree analysis. Higher RPN value indicates higher safety risk. Based on the decision tree analysis, emergency measures and improvement measures were selected and identified, and items with RPN greater than 12 were listed as improvement priorities for this activity (**Table 1**).

Improvement measures

Procedure of diagnosis and treatment of EGVB: The process of emergency endoscopy and the process of centralized care were developed [11] (**Figures 2**, **3**). According to the opinions of the Expert Consensus on the Process of Emergency Diagnosis and Treatment of Acute Upper Gastrointestinal Bleeding, the medical and nursing staffs jointly developed the process of diagnosis and treatment of EGVB specialist patients, the process of emergency endoscopy, and the process of centralized nursing [12]. At the same time, the above processes were incorporated into special training, the contents were pasted on the wall, and the whole staff was trained and assessed to ensure that everyone passed the process.

Green channel of 24 h emergency endoscopy for EGVB patients [13]: The endoscopy room is on duty 24 hours a day and is seamlessly connected to the wards. Patients requiring urgent endoscopy and treatment were notified by the ward physician to undergo examination. For patients who require ventilators and cannot be transported, emergency bedside endoscopy was performed to ensure maximum safety and timeliness of examinations.

Establishment of an intensive care unit for centralized management of EGVB patients [14]: Intensive care units were established to improve the success rate of EGVB patients. Senior physicians and nurses were included. Physicians were attending physician or above, and nurses were selected by the hospital's

Table 1. Failure mode survey of EGVB patients undergoing emergency endoscopy

Procedure		Step 4: Hazard analysis										Step 5: Action strategy	
Main flow	Sub-flow	Failure mode		Cause of occurrence	Risk analysis			Decision tree analysis				Type of operation	Improvement plan
					S	IR	WTI	WTI	WTI	WTI	WTI		
Receive patient	Poor evaluation of patients' condition by physicians and nurses	2A1	Poor assessment of the condition	No procedures for diagnosis and treatment have been established	4	4	16	→	N	N	Y	Control	Establish the diagnosis and treatment process of esophageal and gastric varices bleeding and provide training
				Insufficient training	4	3	12	→	N	N	Y		
		2A2	Poor management of critically ill patients	No qualified doctors were fixed for management	4	4	16	→	N	N	Y	Control	Uniformly manage critical patients, and fix two attending physicians to manage ICU
Receive patient		2B1	Poor assessment of the condition	No cluster care process has been established	4	4	16	→	N	N	Y	Control	Establish the cluster nursing process and special nursing emergency plan for patients with EGVB
				Inadequate preoperative preparation	4	3	12	→	N	N	Y		
		2B2		Inadequate training	4	4	16	→	N	N	Y	Control	Formulate the training program for nurses in the Department of Gastroenterology, specialized nursing workbook, specialized emergency plan and operation standard of endoscopic nursing for gastroenterology nurses
Safe transport of patient	4C In transit	4C	Untimely treatment of the disease during transit	Unskilled transfer process and insufficient emergency drill	4	4	16	→	N	N	Y	Control	Revise the process and system of patient safe transport and rehearse the emergency plan
Undergo emergency endoscopy	6B Endoscopic therapy	6B1	No evaluation before, during and after treatment	No evaluation form has been established	4	4	16	→	N	N	Y	Control	Establish the evaluation list of endoscopic patients and conduct standardized evaluation before, during, and after treatment. The evaluation rate of endoscopy patients should add up to 100%

Note: WTI: Whether to improve; S: Severity; IR: Incidence rate; EGVB: Esophagogastric variceal bleeding.

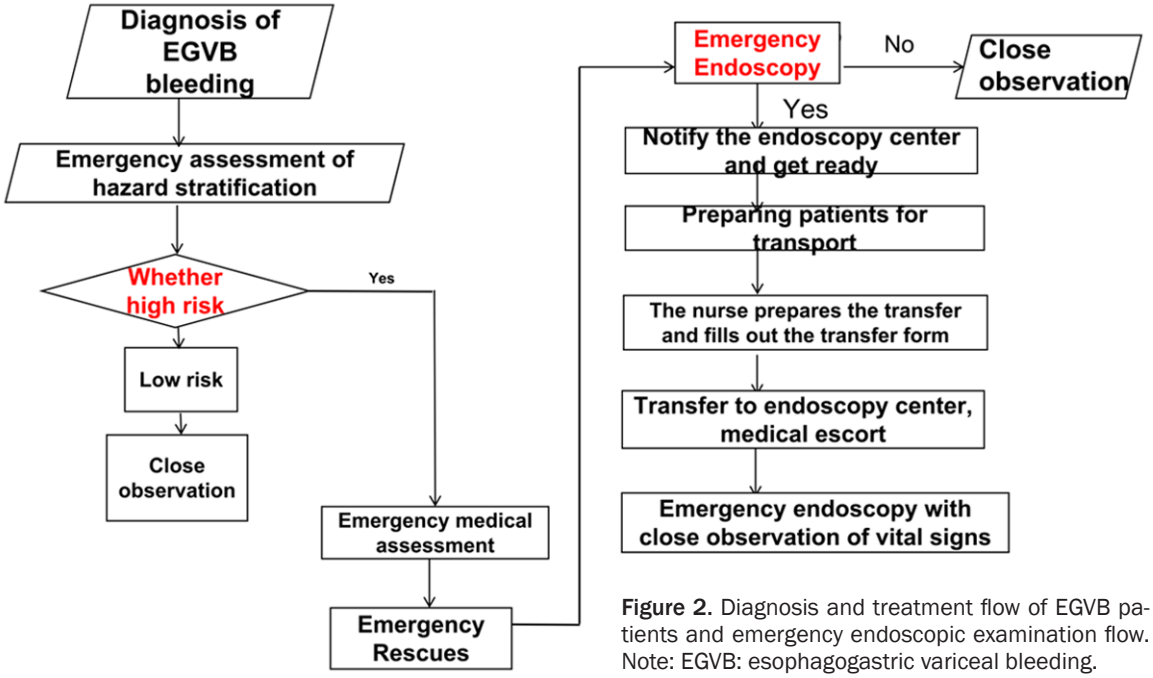

Figure 2. Diagnosis and treatment flow of EGVB patients and emergency endoscopic examination flow. Note: EGVB: esophagogastric variceal bleeding.

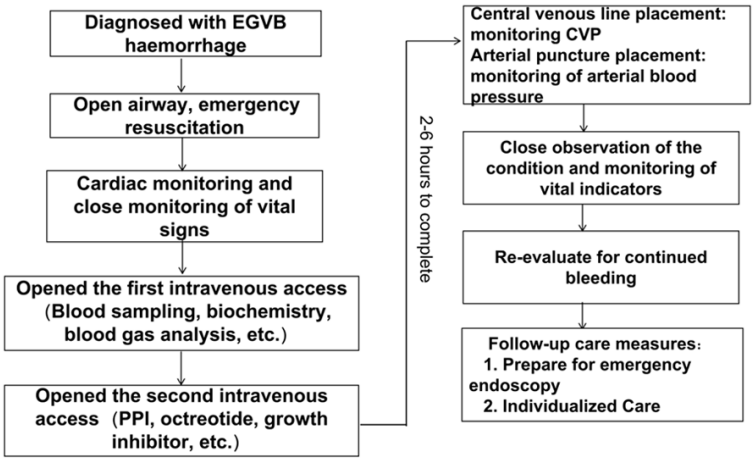

Figure 3. Cluster nursing process for EGVB patients. Note: EGVB: esophagogastric variceal bleeding.

senior responsibility group to manage patients in a unified manner. A regional responsibility system was implemented to further standardize the management of critically ill patients and improve the qualification rate of management.

Revision of the system and process for safe patient transport: Emergency plan drills for the safe transfer of EGVB patients were conducted every six months to improve the emergency handling ability of medical staff (**Figure 4**) [15]. The drills use cases designed by the OSCE assessment. Nurses are assessed to comprehensively evaluate the patient's condition, the risk of transport, the emergency response, and prevention ability in the face of the risk, and the communication with and humanistic care of the patient during the transport. In order to improve the qualification of safe transfer of critically ill patients, the department has set up a quality control group for safe patient transfer. A checklist for safe transfer of critically ill patients has been developed, and nursing managers and the head of the quality control team have conducted monthly quality control checks through site visits and interviews. Those who failed were included in the performance assessment of the month. Through the implementation of this system and procedure, the pass rate for safe transfer of EGVB patients increased from 88% to 98.7%.

Strengthening specialized training: With the help of academician Li Zhaoshen's team [16], professors from the academician's team gave monthly hands-on endoscopy training to doctors and nurses to further improve their technical strength. A training program for gastroenter-

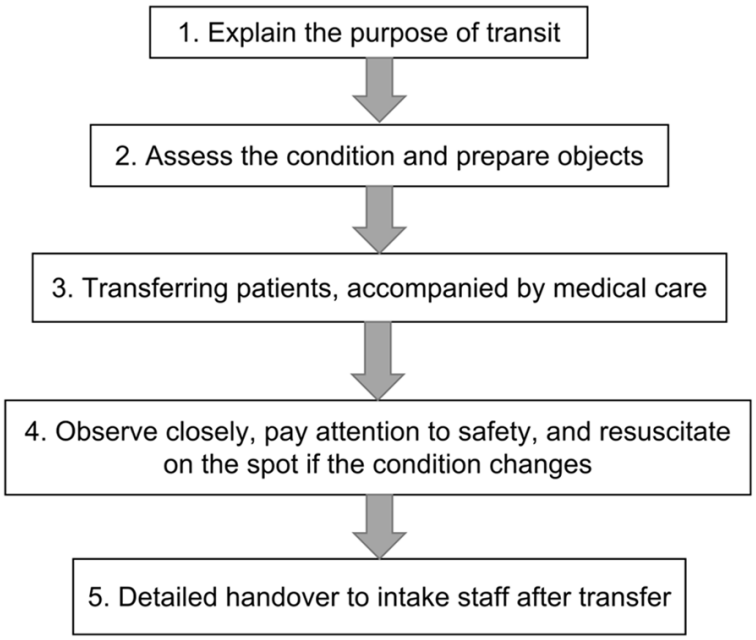

Figure 4. Safe transport of EGVB patients. Note: EGVB: esophagogastric variceal bleeding.

ology nurses [17], a specialty nursing workbook, a specialty emergency plan, and an endoscopy nursing practice specification were developed. Training on disease etiology, pathogenesis, and standardized treatment was provided through physician lectures, room visits, and nursing reports of typical cases to provide nurses with a comprehensive grasp and evaluation of awareness and to improve nurses' judgment and specialty nursing competence [18].

Implementation of patient safety verification and evaluation: In response to the lack of pre-, mid-, and post-endoscopic treatment assessments, the department developed an operational safety check for patients in the endoscopy center in accordance with the hospital's JCI accreditation requirements, and conducted operational and operational safety checks and timeouts for all patients undergoing emergency endoscopy. To further implement the safety assessment, a nursing assessment checklist for patients undergoing endoscopy was developed. The nursing assessment checklist included preoperative, intraoperative, and postoperative assessments to further ensure the safety of the patient's life in multiple dimensions, including vital signs, pain assessment, falls, preoperative preparation, and postoperative education [19]. The implementation of this measure resulted in a 100% safety check and timeout implementation rate for patients.

Comparison of waiting time, recovery of gastric function, and length of hospital stay before and after implementation

The waiting time for endoscopy (the average interval between the end of medication administration and the beginning of endoscopy), the time to gastrointestinal function recovery, and the length of hospital stay were compared before and after implementation.

Comparison of the incidence of adverse reactions before and after implementation

The incidence of nursing safety-related adverse events, including medications, falls, and patient transport (unclear handover, blood pressure drop, respiratory arrest, arrhythmias, and other adverse events) was compared before and after implementation.

Statistical analysis

SPSS 26.0 statistical software was used for statistical analysis. The measured data were represented by (X±SD) and the enumerated data were represented by percentage. Independent t-test was used to compare the results between groups, paired t-test was used for comparison before and after treatment within group, and χ^2 test was performed for the enumerated data. $P<0.05$ was considered significant.

Results

Comparison of implementation effects

The execution rate of medical orders by the nurses was improved, the health education awareness rate of EGVB patients increased from 69% to 92%, and the execution rate of emergency endoscopy timeout reached 100%. After the implementation of a series of measures, the resuscitation success rate of EGVB

Table 2. Comparison of implementation rates of medical orders (%)

Group	Number of cases	Time of double venous access	Awareness rate of health education	Timeout implementation rate	Success rate of rescue	Pass rate of safe transshipment
Before implementation	51	8.5 min	69%	78%	86%	88%
After implementation	51	4.5 min	92%	100%	95%	98.7%
χ^2	-	5.341	0.457	11.247	3.241	2.345
P	-	0.001	0.003	0.002	0.001	0.002

Table 3. Comparison of waiting time and recovery time of gastric function before and after implementation

	Waiting time (min)	Time of double venous access (min)	Gastric function recovery time (h)	Length of hospital stay (d)
Before implementation	60.15±5.69	8.54±2.14	3.27±0.58	3.10±0.22
After implementation	49.63±6.13	4.51±1.63	2.67±0.71	2.54±0.15
t	7.184	11.714	11.647	21.744
P	0.0001	0.0001	0.0003	0.0002

Table 4. Comparison of graded occurrence of adverse reactions before and after implementation (examples)

Group	Grade I	Grade II	Grade III	Grade IV	Total
Before implementation	6	4	2	0	12
After implementation	2	1	1	0	4
χ^2	-	-	-	-	6.354
P	-	-	-	-	0.037

patients reached 95%, the safe transfer rate increased from 88% to 98.7%, and the EVL procedure volume reached the second highest in the province. The optimization of the emergency endoscopy process for EGVB patients not only fought for patients' survival chances but also maximized their life safety, and further improved medical safety and nursing quality (**Table 2**).

Comparison of patients' waiting time and gastric function recovery time before and after implementation

The waiting time, dual intravenous access time, gastric function recovery time, and hospitalization time of the patients after implementation were significantly shortened (waiting time: (60.15±5.69) vs (49.63±6.13); dual intravenous access time: (4.51±1.63) vs (8.54±2.14); gastric function recovery time: (3.27±0.58) vs (2.67±0.71), and hospitalization time: (3.10±0.22) vs (2.54±0.15)) after implementation (all P<0.01, **Table 3**).

Comparison of incidence of adverse reactions before and after implementation

The incidence of adverse events after implementation was lower compared with that before implementation (P<0.01). Most of the post-implementation nursing safety adverse events were related to medications and diet, while the pre-implementation ones were mainly related to medications and other types (**Tables 4** and **5**).

Comparison of prognosis before and after implementation

These patients were followed up 1 year later. In the 102 consecutive patients, 61 (59.8%) suffered variceal rebleeding, including 39 patients in the before implementation group, and 22 in the after implementation group (P<0.05) (**Table 6**). By using univariate analysis, the presence of fundal varices and FMEA implement appeared to be predictors of rebleeding, with an approximately 2-fold risk for patients with EGVB and

Table 5. Comparison of types of adverse reactions before and after implementation (cases)

	Informed consent	Drug	Fall/fall out of bed	Medical equipment	Pipeline	Diet	Transport of patient
Before implementation	3	5	3	0	1	1	0
After implementation	1	2	1	0	0	0	0
χ^2	0.112	0.261	0.143	0.354	0.189	0.116	-
P	0.46	0.37	0.47	0.25	0.31	0.41	0.33

Table 6. Comparison of prognosis before and after implementation (examples)

	Number of cases	Variceal rebleeding	Survival
Before implementation	51	39 (76.4%)	39 (76.5%)
After implementation	51	22 (44%)	44 (86.3%)
χ^2	-	8.984	3.281
P	-	0.002	0.06

Table 7. Predictive values for rebleeding

Variable at baseline	No rebleeding (n=41)	Rebleeding (n=61)	HR	95% CI	*P* value
Men	21	33	1		0.55
Women	20	28	0.65	0.17-2.52	
Site of varices					
Esophagus and stomach	14	16	1.25	0.35-4.42	0.73
Fundus	17	28	5.07	1.40-18.4	0.01
Cardia	10	17	0.31	0.06-1.50	0.11
FMEA implement					
Before	34	48	1		
After	7	13	0.41	0.20-0.72	0.001
Medical equipment					
No	23	36	1		
Yes	18	25	1.97	0.49-7.98	0.33
Pipeline					
No	19	35	1		
Yes	22	26	2.98	0.33-1.89	0.43

FMEA, Failure mode and effect analysis.

with fundal varices and before FMEA implement (hazard ratio [HR] 2.21, P Z.01; and HR 2.07, P Z.03, respectively) (**Table 7**). On the other hand, 19 patients died. Of these 19 deaths, none was caused by variceal bleeding. Causes of death were as follows: infection (n=9), GI bleeding caused by a pill-induced esophageal ulcer (n=6), and other reasons (n=4). The two groups did not differ in terms of survival (P>0.05).

Discussion

Esophagogastric fundic variceal bleeding (EGVB) is the most serious complication of cirrhosis in the decompensated phase [20]. The disease is aggressive and has a high mortality rate. A series of interventions, including the establishment of procedures and systems, can be used to help medical staff to provide timely and effective treatment and care for patients with EGVB during the acute bleeding phase and to create good conditions for patient treatment [21, 22].

FMEA is a prospective risk management tool that can be used to analyze existing processes or new processes. Although FMEA is a complex and time-consuming analysis method, it is suitable for processes, including pharmacy and

pharmaceuticals. FMEA is a systematic and progressive process [23]. FMEA begins by selecting a well-defined process to evaluate, forming a team of multidisciplinary personnel, and using the collective knowledge of the team to map the selected process by focusing on the key components of the main process and subprocesses of the process [24, 25]. After mapping the processes, the staff brainstormed to identify potential failure modes for each subprocess and identified the possible factors affecting failure modes, assessed the severity, frequency, and detectability of the possible failure modes, prioritized the failure modes, and used the calculated RPNS to prioritize the failures. Finally, the process was redesigned or modified to avoid or reduce risk, and then the effectiveness of the modified process was implemented and analyzed [26]. The application of FMEA allows the medical staff to sort out the problems of EGVB patients undergoing emergency endoscopy in a more detailed manner, identify the most fundamental causes, and make improvements [27]. Only by predicting risks in advance and implementing risk management and preventive measures can the occurrence of adverse events be reduced, thus improving the success rate of resuscitation, prolonging survival, and improving the quality of life of EGVB patients. It is also an effective management tool to ensure the safety and quality of medical and nursing care [28]. Medical staff use FMEA management tools to identify weaknesses in processes, analyze the presence of failure modes, and implement improvement measures to reduce the risk of EGVB patients. The results of this study showed that the implementation rate of medical orders by nurses improved, the time to establish dual venous access was reduced from 8.5 min to 4.5 min, the health education awareness rate of EGVB patients increased from 69% to 92%, and the timeout implementation rate for emergency endoscopy was 100%. After the implementation of a series of measures, the resuscitation success rate in EGVB patients reached 95%, the safe transfer rate increased from 88% to 98.7%, and the EVL procedure volume reached the second highest in the province. After implementation, the waiting time, double venous access time, gastric function recovery time, and hospitalization time of patients were significantly shortened. The incidence of adverse reactions was significantly lower after implementation compared to that before implementation.

Nevertheless, there are a few limitations of this process. FirstI our application of FMEA involved a qualitative analysis on a process of communication, which is an abstract concept with no established scale to assess severity and consequently may limit generalizability. SecondI, we also recognize that our findings are specific to emergency endoscopy process and may not be readily generalizable to different disease processes that may involve different care procedures and therapeutic guidelines. Therefore, large sample studies of FMEA use in more areas are needed.

In summary, optimizing the process for EGVB patients undergoing emergency endoscopy can ensure patients' chances of survival, maximize their life safety, and further improve the quality and safety of medical and nursing care.

Disclosure of conflict of interest

None.

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