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ORIGINAL RESEARCH

Impact of the structured risk management model on emergency digestive endoscopy safety

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Abstract

Background: Emergency digestive endoscopy is essential for diagnosing and treating acute conditions such as upper gastrointestinal bleeding and biliary obstruction in the emergency department. However, the urgent and unpredictable nature of these cases poses challenges to nursing care, particularly in maintaining patient safety and ensuring timely and efficient procedures. Failure Mode and Effects Analysis (FMEA) is a structured risk management approach which can be of help in these situations. **Methods**: This retrospective analysis included 105 patients who underwent emergency digestive endoscopy in the emergency department between October 2022 and October 2024. The patients were divided into a group which received FMEA-enhanced nursing (n = 55) and a control group (n = 50, conventional nursing), and collected data included adverse event rates, nursing quality scores and procedure-related efficiency indicators. **Results**: The observation group demonstrated lower rates of adverse events and higher nursing quality scores than the control group (both $p < 0.05$). Moreover, the procedure completion time was significantly reduced in the observation group ($p < 0.05$). **Conclusions**: The FMEA risk management model can effectively improve nursing safety and procedural efficiency in emergency digestive endoscopy, offering a valuable strategy to enhance acute care delivery in emergency department settings.

Keywords

Emergency endoscopy; FMEA risk management; Acute care nursing; Procedural efficiency; Risk score; Safety

1. Introduction

Emergency digestive endoscopy is essential for the rapid diagnosis and treatment of acute gastrointestinal conditions, such as upper gastrointestinal bleeding and acute cholangitis, which are frequently encountered in the emergency department (ED) [1, 2]. These procedures are performed under considerable time pressure and are associated with risks including exacerbation of bleeding, infection, and patient instability. Therefore, effective, and timely nursing support is essential to ensure procedural safety and therapeutic success [3].

Failure Mode and Effects Analysis (FMEA) is a structured risk management approach that systematically identifies potential points of failure within clinical workflows, allowing for proactive interventions to improve safety and efficiency [4]. Although FMEA has demonstrated utility in elective endoscopy settings [5, 6], its use in emergency digestive endoscopy has not been well studied.

This study aims to evaluate the impact of FMEA-based nursing interventions on procedural safety, nursing quality and operational efficiency in emergency digestive endoscopy within the ED setting.

2. Materials and methods

2.1 Study design and patient selection

This retrospective study analyzed clinical data from 105 patients who underwent emergency digestive endoscopy in the ED of our hospital between October 2022 and October 2024. The patients were divided into two groups based on the nursing approach recorded in the medical records: an observation group (55 cases) and a control group (50 cases).

The study inclusion criteria comprised (1) acute conditions requiring emergency endoscopy (*e.g.*, gastrointestinal bleeding, biliary obstruction); (2) age between 18 and 75 years; (3) procedure performed in the ED; and (4) availability of complete clinical data. Cases with the following criteria were excluded: (1) underwent elective endoscopy; (2) had severe comorbidities preventing endoscopic intervention; and (3) were transferred to another facility during treatment.

2.2 Nursing interventions

As a retrospective study, nursing interventions implemented were based on information retrieved from existing case records.

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The control group received conventional ED nursing care, including initial patient assessment, pre-procedure preparation, intra-procedural vital sign monitoring, routine post-procedural care, and emergency response measures as needed.

In the observation group, nursing care was conducted using the FMEA model, in addition to the conventional procedures described above. The FMEA implementation included the following components:

(1) Team formation: A multidisciplinary risk management team was established, consisting of one endoscopy unit director, two attending physicians, two anesthesiologists, one head nurse, two digestive care nurses and two endoscopy nurses. All members underwent standardized training on FMEA principles. The team defined the quality improvement theme as "Improving Nursing Quality and Patient Satisfaction in Digestive Endoscopy through the Application of the FMEA Risk Management Model".

(2) Workflow definition: The emergency endoscopy process was standardized into the following stages: ED triage and assessment $\rightarrow$ rapid preparation $\rightarrow$ endoscopic intervention $\rightarrow$ post-procedural stabilization.

(3) Failure mode identification: Potential failure modes were identified based on a review of 30 patients who had experienced complications (*e.g.*, bleeding, hypoxia). Using brainstorming and structured analysis, failure risks such as delayed preparation, equipment malfunction and infection were evaluated across key domains, including personnel, equipment, and environment. Each failure mode was scored using the Risk Priority Number (RPN) framework: RPN = Occurrence (O) $\times$ Severity (S) $\times$ Detectability (D), with each factor scored from 1 to 10. The total RPN ranged from 1 to 1000, with higher scores indicating greater risk. Based on this analysis, ten key failure modes were identified.

(4) Development of the risk control plan: Tailored risk mitigation strategies were formulated according to the identified failure modes and guided by clinical relevance and literature review. These strategies were integrated into the clinical workflow. Details of the final plan are presented in Table 1.

2.3 Observation indicators

As this was a retrospective study, all outcome indicators were obtained from existing medical records.

(1) Nursing Quality Assessment: Nursing quality was evaluated by a trained assessment team using a standardized scoring protocol. The assessment process involved the following steps:

① Team composition: The evaluation team consisted of ten members, including one hospital nursing manager, five clinical nurses, one quality control specialist, and three professionals from related departments.

② Training and preparation: Before assessment, all team members received training to ensure familiarity with the scoring system, survey instruments and evaluation procedures. Members were required to understand criteria for each dimension assessed, including disinfection practices, basic nursing care, risk identification, service attitude and emergency response capability.

③ Assessment plan development: A detailed plan was formulated based on hospital-specific conditions, specifying the timing, content, and sample size of the evaluation.

④ Assessment implementation: (1) Survey distribution: A self-developed survey was distributed to nursing staff, patients, and related personnel. A total of 120 surveys were distributed, with 105 valid responses collected for statistical analysis. (2) On-site observation: The team directly observed nursing activities, including staff behavior and service attitude, to support the evaluation with real-time data.

⑤ Scoring criteria: Each of the five dimensions, disinfection, basic care, risk assessment, service attitude and emergency capability, was scored on a 0–100 scale, with higher scores indicating higher nursing quality. Final scores were derived by integrating both survey responses and on-site observation findings.

⑥ Data analysis: Collected data were statistically analyzed to compare nursing quality scores between the observation and control groups.

⑦ Feedback and improvement: Assessment results were communicated to the relevant nursing staff to support targeted quality improvement and staff training initiatives.

(2) Adverse events included both nursing-related errors and patient complications. Nursing errors included missing instruments, handover mistakes and patient complaints. Patient complications included exacerbation of bleeding, infections, and respiratory distress. The incidence of adverse events was calculated as: Adverse Event Rate (%) = (Number of nursing adverse events + Number of patient complications)/Total number of cases $\times$ 100%.

(3) Efficiency Metrics: Efficiency was assessed using two indicators: (1) the time interval from ED arrival to completion of the endoscopic procedure, and (2) the rate of successful discharge from the ED versus admission to inpatient care.

2.4 Statistical analysis

Statistical analyses were conducted using the SPSS software (version 22.0; IBM Corp., Armonk, NY, USA). Continuous variables with a normal distribution were presented as mean $\pm$ standard deviation ($\bar{x} \pm s$) and compared between groups using the independent samples t-test. Categorical variables were expressed as percentages and analyzed using the chi-square (χ^2) test. A p-value of < 0.05 was considered to indicate statistical significance.

3. Results

3.1 General information

Baseline characteristics of the two groups are summarized in Table 2. No statistically significant differences were found in age, sex distribution, type of endoscopic examination, history of previous endoscopy, constipation or abdominal surgery between the observation and control groups (all $p > 0.05$), indicating that the two groups were comparable.

TABLE 1. Failure mode analysis and improvement measures for digestive endoscopy.

Time point	Failure mode	Risk analysis				Treatment measures
		O	S	D	RPN	
Examination appointment period						
	① The responsible nurse lacked relevant professional knowledge and experience to provide detailed instructions to the patient regarding pre-examination precautions	3	4	7	84	① All medical staff underwent standardized professional training and assessments.
	② There was ineffective communication between the doctor and the patient, leading to delays in the examination, causing long waiting times	8	3	1	24	② Patients were informed in advance about the importance of segmented, time-based appointments and the expected waiting time for the examination.
	③ The appointment process was not strictly followed, leading to mix-ups in patients' examinations or patients using another person's identity information for the examination	2	6	7	84	③ During the appointment process, nurses strengthened communications with patients, carefully verified the patient's information (including gender, name, age, symptoms, and examination site), and documented the information in a case memorandum.
Gastrointestinal preparation						
	① Before the endoscopy, the required medication was not promptly administered to the patients	4	5	5	100	① The responsible nurse provided instructions and informed the patient about intestinal preparation and examination precautions. A designated person was assigned to administer and record the handover of medications.
	② Inadequate health education led to misunderstandings by patients and insufficient gastrointestinal preparation	4	6	6	144	② Educational materials for endoscopic examination were posted on the outer walls of the examination room.
Endoscopic examination						
	① There was no standardized wristband management	2	2	2	8	① The patients were required to wear standardized wristbands, with the responsible nurse supervising the verification process.
	② Endoscopic equipment was not adequately disinfected or cleaned, due to insufficient disinfection equipment, limited availability of trained personnel, inadequate cleaning procedures or improper disinfection techniques	4	6	5	120	② Strict adherence to the Hospital Infection Management Guidelines and Endoscopic Disinfection Operating Standards was implemented. Measures included increasing the number of available endoscopes, standardizing disinfection protocols, assigning dedicated and trained personnel for cleaning tasks, and ensuring that endoscopes were promptly cleaned before being transferred to the disinfection room. Equipment such as flowing water disinfection tanks, ultrasonic cleaners and high-pressure water guns was utilized. Disinfectants were managed by qualified personnel. All disinfection tools and sinks were cleaned daily, and routine inspections were conducted by the hospital infection control department to ensure thorough and effective disinfection.

TABLE 1. Continued.

Time point	Failure mode	Risk analysis				Treatment measures
		O	S	D	RPN	
Endoscopic examination						
	③ Errors in examination results due to poor cooperation among medical staff, malfunctioning equipment or incorrect report writing	5	4	4	80	③ Before diagnosis and treatment, nurses collaborated with physicians to ensure that all examination equipment was functioning properly. Medical staff received targeted training to improve operational proficiency. Report writing was organized in advance to minimize delays and errors. When issuing examination reports, nurses carefully verified patient information to prevent inaccuracies, such as incorrect entries or missing treatment forms.
	④ Poor monitoring of patient conditions, failure to promptly identify adverse reactions and complications during the examination	5	6	7	210	④ Communication among doctors, nurses and patients was strengthened for timely complication identification and prompt reporting to the attending endoscopist for intervention. For instance, in cases of decreased blood oxygen saturation, pressurized oxygen was administered immediately, and oral or nasal airways were used when necessary. In the event of a laryngeal spasm, the following stepwise management protocol was implemented: (1) Remain calm and ensure the patient is in a safe environment; (2) Rapidly assess respiratory function and level of consciousness; (3) Administer high-concentration oxygen using a mask with positive pressure ventilation if indicated; (4) Relieve airway obstruction using oropharyngeal or other appropriate airway devices; (5) Administer muscle relaxants or medications such as atropine to relieve the spasm, and sedatives as needed to reduce patient anxiety; (6) If ventilation remains ineffective, proceed with endotracheal intubation to secure the airway and initiate mechanical ventilation; (7) Continuously monitor vital signs and provide supportive treatment; (8) In severe or unresponsive cases, escalate to advanced medical care or refer the patient as appropriate.
Return to the ward						
	① Critical patients did not strictly follow the handover process	3	4	6	72	① Patient transfers were conducted following the Inpatient Safe Transfer System. The endoscopy handover form was completed, and patient transport was arranged in a standardized manner. Each patient had a resuscitation kit for emergency supplies during transfer. Upon return to the ward, the responsible nurse provided additional education regarding post-procedure precautions.

O: Occurrence; S: Severity; D: Detectability; RPN: Risk Priority Number.

TABLE 2. Comparison of baseline characteristics between the two groups.

Variables	Observation group (n = 55)	Control group (n = 50)	χ^2/t	p
Age ($\bar{x} \pm s$)/yr	42.85 ± 5.45	43.25 ± 5.34	0.379	0.863
Gender (male/female)	29/26	26/24	0.006	0.941
Examination type (n (%))				
Gastroscopy	16 (29.09)	14 (28.00)		
Colonoscopy	15 (27.27)	16 (32.00)	0.292	0.864
Endoscopy	24 (43.64)	20 (40.00)		
Previous endoscopic examination history (n (%))	21 (38.18)	21 (42.00)	0.159	0.690
History of constipation (n (%))	15 (27.27)	11 (22.00)	0.391	0.532
History of abdominal surgery (n (%))	20 (36.36)	21 (42.00)	0.350	0.554

3.2 Nursing quality

As shown in Table 3, the nursing quality scores were significantly higher in the observation group compared to the control group in all evaluated domains, including rapid response, risk mitigation, and procedural support ($p < 0.001$ for all comparisons).

3.3 Adverse events

The incidence of adverse events was significantly lower in the observation group compared to the control group ($p = 0.001$), with notably fewer occurrences of infections, handover errors, and patient complaints (Table 4).

3.4 Efficiency

Lastly, our analysis showed that patients from the observation group had significantly shorter procedure completion times and a higher ED discharge rate than the control group (both $p < 0.05$; Table 5).

4. Discussion

In recent years, medical technology has significantly expanded the clinical application of digestive endoscopy, enabling direct visualization of gastrointestinal lesions, thereby providing reliable evidence for diagnosis and treatment planning [7, 8]. Among its uses, emergency digestive endoscopy plays a central role in managing acute gastrointestinal disorders. These conditions are often characterized by sudden onset and rapid progression, necessitating timely and accurate intervention to reduce complications and improve patient outcomes [9]. In the ED, the effectiveness of emergency endoscopy relies not only on technical execution but also on the efficiency and precision of nursing care, which is essential for stabilizing patients and supporting procedural success [10, 11].

The FMEA risk management model, which involves the identification of potential failure modes, risk prioritization, and the implementation of targeted control measures, serves as an effective framework for improving nursing quality and the disinfection standards of endoscopic equipment [12]. In this study, the observation group demonstrated significantly higher nursing quality scores across all evaluated dimensions, rapid response, risk mitigation and procedural support, compared to the control group. These findings suggest that the integration of FMEA into clinical nursing practice can enhance the overall quality of care during emergency digestive endoscopy.

Based on these, we found that the following key factors could explain this improvement. First, systematic risk assessment played a central role. Based on the FMEA framework, the team conducted interdisciplinary discussions to identify failure modes across human, technical, and environmental domains. The RPNs were calculated, and tailored solutions were developed for each identified failure. This structured risk identification and mitigation process contributed to optimizing the nursing workflow, enhancing patient safety, and improving care quality. By enabling staff to anticipate and prevent potential failures, the FMEA model facilitated a proactive approach to clinical risk management, reducing the likelihood of omissions and errors during the endoscopy process. Second, the model strengthened rapid response and risk mitigation capabilities. The establishment of clear workflows and defined responsibilities allowed staff to respond promptly to unexpected events. Professional training ensured that nurses were familiar with standard operating procedures, particularly for urgent situations. High-risk steps, such as pre- and post-procedure preparation, anesthesia management, and vital sign monitoring, were addressed in advance. These improvements contributed to better management of intraoperative complications and more consistent procedural outcomes [13–15]. Third, procedural support was enhanced through improved team coordination, optimized communication, and the integration of appropriate equipment and technology. By reinforcing collaboration across all stages of the endoscopy process, the risk of information loss or communication errors was reduced, ultimately improving work efficiency and the continuity of care. Fourth, the FMEA model supported ongoing training and continuous quality improvement. Regular professional education increased the nursing staff's theoretical knowledge and practical skills, thereby improving team performance and confidence in managing emergency cases. Moreover, the establishment of feedback mechanisms enabled timely evaluation of adverse events and care quality indicators, thereby allowing the team to identify weaknesses and implement corrective measures and ensuring sustained improvements in nursing services over time [16–18].

TABLE 3. Comparison of nursing quality scores between the two groups (points, $\bar{x} \pm s$).

Group	n	Rapid response	Risk mitigation	Procedural support
Observation group	55	91.80 ± 1.40	92.30 ± 1.20	93.86 ± 1.53
Control group	50	82.50 ± 1.60	83.90 ± 1.50	84.95 ± 1.21
t		31.762	31.819	33.312
p		<0.001	<0.001	<0.001

TABLE 4. Comparison of adverse events between the two groups, n (%).

Group	N	Nursing error			Patient complications			Total events
		Missing examination instruments	Handover errors	Patient complaints	Respiratory distress	Infection	Bleeding exacerbation	
Observation group	55	0 (0.00)	2 (3.63)	1 (1.82)	1 (1.82)	1 (1.82)	0 (0.00)	5 (9.09)
Control group	50	3 (6.00)	4 (8.00)	5 (10.00)	3 (6.00)	2 (4.00)	1 (2.00)	18 (36.00)
χ^2	-							11.086
p	-							0.001

TABLE 5. Comparison of procedural efficiency between the two groups.

Group	n	Procedure completion time (min), $\bar{x} \pm s$	ED discharge rate (%)
Observation group	55	45.20 ± 5.30	35 (63.64)
Control group	50	58.70 ± 6.10	22 (44.00)
t/χ^2	-	12.132	4.069
p	-	<0.001	0.044

ED: emergency department.

The incidence of adverse events in the observation group was significantly lower than that in the control group, suggesting that nursing risk management based on the FMEA model can effectively reduce the occurrence of such events due to the systematic structure of the FMEA model, which comprises four core stages: identification of failure modes, risk assessment, development of targeted improvement measures, and evaluation. The cyclic implementation of these stages enables early detection and resolution of problems, thereby enhancing the continuity, standardization, and effectiveness of nursing management and risk control strategies [19]. An in-depth assessment of infection control practices in the hospital's digestive endoscopy unit was conducted during the development of improvement measures, leading to the formulation of specific and targeted interventions to address identified issues. This comprehensive strategy ensured the smooth and standardized execution of all stages of the digestive endoscopy process, from pre-examination to during the examination and post-examination [20].

In addition, regular inspections by the hospital's infection control department, both on a daily and monthly basis, reinforced adherence to protocols and helped identify and correct deficiencies in disinfection and infection prevention practices. Scientific and feasible improvement strategies were developed through structured discussion and root-cause analysis of adverse events, which contributed to improved nursing efficiency and reduced nursing-related risks, including hospital-acquired infections associated with digestive endoscopy procedures. Furthermore, patients were comprehensively assessed from multiple dimensions, including personal medical history, medication use, lifestyle factors, and examination findings, which enabled early identification of risk factors, allowing for the implementation of targeted preventive measures and improved perioperative risk stratification. These efforts not only minimized intraoperative and postoperative complications but also enhanced the overall quality of care, including psychological support and patient satisfaction. Effective health education and communication further supported this process. By clearly explaining the procedure, expected outcomes and potential risks, patients were better informed and more engaged in their care. During the examination, timely communication between nursing staff and the endoscopist facilitated the immediate recognition and management of emerging complications. Additionally, informing patients about possible post-procedural issues and the need for follow-up ensured better long-term care and improved adherence to treatment recommendations. Thus, clarifying the anatomical focus of the examination and preparing instruments and diagnostic accessories in advance helped reduce procedural delays and minimized the risk of avoidable adverse events.

The FMEA model is based on a cyclical process of risk identification, assessment, targeted improvement, and continuous updating in response to patterns of clinical risk events, thereby enabling proactive intervention and systematic management [21]. In recent years, its application in nursing risk management has shown substantial effectiveness. For instance,

Hu L *et al.* [22] reported that the use of FMEA improved the ability of oral healthcare workers to prevent needlestick injuries, significantly reduced the incidence of such events, and enhanced management satisfaction. Similarly, He H *et al.* [12] demonstrated that FMEA-based interventions reduced the incidence of adverse events in patients undergoing optimized surgical procedures. These findings suggest that the integration of FMEA into clinical workflows can improve both patient safety and treatment outcomes.

The application of FMEA analysis and optimization in the process of emergency endoscopy can maximize patient safety and treatment outcomes, as well as improve both medical quality and nursing safety. Sun L *et al.* [23] demonstrated that the FMEA model can allow nursing managers to transition from passive post-event treatment of medication-related safety incidents to proactive pre-event prevention and has significantly enhanced medication safety management and reflects continuous improvement in nursing quality, ensuring nursing safety. Likewise, the study by Zheng J *et al.* [24] showed that applying FMEA in digestive endoscopy, particularly through the standardization of cleaning and disinfection processes, significantly improved staff knowledge and technical skills, ultimately reducing the occurrence of procedural errors. The present findings are consistent with previous reports. This study demonstrates that FMEA effectively reduces adverse events by addressing high-risk factors such as delayed preparation, equipment malfunction, and insufficient procedural oversight, thereby confirming the value of this model in emergency digestive endoscopy risk management.

The significantly shorter procedure completion time and higher ED discharge rate observed in the observation group support the positive impact of FMEA-based nursing interventions on procedural efficiency. Several factors likely contributed to these differences. First, process optimization played a central role. The implementation of the FMEA risk management model enabled systematic identification and refinement of each step in the emergency digestive endoscopy workflow. By analyzing risks at key stages, nursing staff were able to streamline procedures, eliminate unnecessary steps, and accelerate the overall process. Second, enhanced teamwork and communication supported timely care delivery. The FMEA model emphasizes interdisciplinary collaboration and accurate information transfer across all phases of care, which minimized delays caused by miscommunication and helped ensure that procedures were completed as scheduled, thereby facilitating timely discharge [25, 26]. Third, rapid response capability was improved through structured FMEA training. Nursing staff became more adept at recognizing and managing intraoperative complications or sudden clinical changes, which allowed for rapid and appropriate intervention during emergencies, reducing delays and promoting quicker recovery and discharge. Fourth, effective risk mitigation strategies were developed in advance. By anticipating high-risk events and implementing preventive protocols, the nursing team reduced the occurrence of intraoperative complications, which contributed to smoother procedures and improved patient recovery [27]. Fifth, comprehensive patient management further contributed to improved outcomes. In the observation group, healthcare providers conducted thorough preoperative assessments, postoperative monitoring, and individualized health education, which facilitated early patient adaptation and reduced hospitalization duration, increasing the likelihood of discharge directly from the ED. Sixth, ongoing evaluation and feedback helped maintain continuous quality improvement. Regular review of procedure completion times and discharge rates allowed the nursing team to identify areas for improvement and implement timely adjustments. This feedback loop supported sustained enhancements in care efficiency and discharge readiness. Taken together, the shorter procedure times and increased ED discharge rates in the observation group suggest that the FMEA model contributes to optimizing acute care workflows. In the context of high patient turnover and resource constraints typical of EDs, such improvements are particularly valuable. These findings further support the role of FMEA in enhancing nursing safety, efficiency, and overall care quality in time-sensitive clinical settings.

However, this study had several limitations that should be clarified. First, the relatively small sample size and single-center design may restrict the generalizability of the findings. Second, baseline data regarding patients' comorbidities and clinical backgrounds were not comprehensively analyzed, which may have introduced uncontrolled confounding variables. Third, factors influencing postoperative complications and examination duration were not examined in detail, and no subgroup analyses were performed based on population characteristics, specific endoscopic procedures, or physician experience. Thus, future research should involve larger sample sizes, multi-center participation, and more diverse patient populations. In-depth analysis of risk factors associated with postoperative complications and stratified analyses based on demographic and procedural variables would further improve the accuracy and clinical relevance of the findings.

5. Conclusions

In conclusion, implementing the FMEA risk management model in emergency digestive endoscopy nursing could significantly enhance procedural safety, improve nursing quality and increase operational efficiency within the ED, and therefore could be recommended as a structured approach for optimizing acute care delivery in time-sensitive clinical settings.

AVAILABILITY OF DATA AND MATERIALS

The authors declare that all data supporting the findings of this study are available within the paper and any raw data can be obtained from the corresponding author upon request.

AUTHOR CONTRIBUTIONS

QD, AYY—designed the study and carried them out; prepared the manuscript for publication and reviewed the draft of the manuscript; QD, AYY, MLZ, QFL, YFT—interpreted the data. QD, AYY, MLZ, QFL, YFT—supervised the data collection. QD, AYY, MLZ—analyzed the data. All authors have read and approved the manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Ethical approval was obtained from the Ethics Committee of Affiliated Hangzhou First People's Hospital (Approval no. KY-20240522-0098-01). Written informed consent was obtained from legally authorized representatives for anonymized patient information to be published in this article.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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