

Application of Bow-Tie Analysis to Improve Patient Safety – a Lesson Learned from Clinical Practice

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Abstract

Aim: This study aimed to assess the risk management of drug safety in an operating theater setting within a hospital-based treatment facility.

Materials and methods: This is a case study detailing a single patient. The bow-tie model was modified for analyzing medication errors in anesthesiology practice and implemented in the operating room of the university hospital. The diagram was created using well-established methods. The data was gathered using an online portal (www.rsps.bg) designed to evaluate hospital safety culture and report incidents.

Results: The Striped Bow Tie[®] methodology-built model illustrated the primary reasons for the medication error. The risk score was estimated to be 12 based on the specified parameters. The severity is rated on a 4-point scale ranging from catastrophic (4), critical (3), marginal (2), to negligible (1). The likelihood is assessed on a 5-point scale from frequent (5), probable (4), occasional (3), moderate (2), to unlikely (1). Preventive methods were suggested to minimize the risk, avert the incident, and manage the process.

Conclusion: The bow-tie approach is suitable and simple to apply in hospital anesthesia practice and serves as an essential instrument for analyzing medication safety risks. The analysis demonstrated systemic errors that led to the incident, including unrealized potential for continuing medical education and transforming the hospital into a place where clinicians can constantly learn by reporting adverse events and medical errors.

Keywords

bow-tie method, patient safety culture, medication error

INTRODUCTION

The World Health Organization is drafting a Global Action Plan for Patient Safety for the years 2021–2030.^[1] The document's primary principles include treating patients and their families as equal partners in providing safe health care, cultivating a strong safety culture, developing a method for reporting errors without fear of repercussions, and viewing mistakes as learning opportunities. After reviewing the ex-

isting global literature, it is clear that many countries need to alter their safety culture paradigm from a blame-oriented strategy to one based on trust. This blame-free approach emphasizes the importance of accountability.^[2-4] Research findings from both domestic and international studies indicate that 50% of all errors in medical practice are foreseeable but not always avoidable.^[5-8] Several studies indicate that approximately 90% of adverse events and just 10% to 20% of the medical errors are in fact recorded. Studies

show that between 90% and 95% of errors that are reported do not cause harm to the patient.^[9-11] Many countries, including our own, have a blame culture in which errors are frequently covered up, creating mistrust and a lack of accountability among the various involved parties – individual institutions, healthcare providers, and the general public, among them.^[6,8,12,13] Bulgarian authors have extensively researched patient safety. Katsarov's research highlighted organizational issues in hospital medical treatment, including the underreporting of medical errors and the necessity of implementing a reporting system.^[14] An important focus of safety research, particularly during the COVID-19 outbreak, is the documentation of errors in medical practice.^[15]

The different approaches outlined in the specialized literature, such as Brainstorming, Checklists, Event Tree Analysis (ETA), Swiss cheese model, Failure Mode and Effect Analysis (FMEA) are used to discover common causes of errors.^[16,17] The bow-tie analysis is a valuable method for proactively assessing and visualizing the risks, causes, and outcomes of anticipated adverse events in various industries such as chemical, aviation, etc.^[16,18-20] The bow-tie analysis has been used in healthcare for the past decade and has been established in other high-risk industries including the chemical and oil industries, and aviation for a long time.^[19] The model's graphical depiction and analysis aid in conducting a proactive safety risk assessment, highlighting the key causes and consequences of potential adverse events or errors.^[18] The bow-tie approach in hospitals helps to identify error reasons and provides specific prevention strategies for faster patient recovery post-accident. The Striped Bow-Tie risk assessment is a novel method developed in 2015 to address the constraints of conventional bow-tie analysis.^[16]

AIM

This study aims to assess the risk management about drug safety in the operating room of a hospital treatment facility.

MATERIALS AND METHODS

Setting and design

The study is a descriptive, epidemiological case report. It was conducted in a 400-bed university hospital affiliated to the Medical University of Plovdiv. The goal of the present study was achieved by gathering essential data through a web-based self-reported anonymous survey on hospital patient safety culture using the cross-culturally validated and adapted Bulgarian version of the HSOPSC questionnaire.^[21] The survey can be accessed on this website: www.rsp.bg. The healthcare workers were asked to explain an adverse event or error they had witnessed in an open-ended

question. A total of 10 patient safety incidents reported by healthcare professionals are available on the web platform. The hospital professionals participated voluntarily, and the confidentiality of the reported cases was guaranteed. The study is a part of an intra-university project No. 11/2016 and titled "Introduction of a web-based platform for registering and evaluating the level of hospital culture to ensure patient safety in medical facilities and conducting a representative study for the country." It has received approval from the University Commission on the Ethics of Science under reference number 05/19.10.2017.

Application of brainstorming technique

One of the 10 reported and discussed topics is the subject of the current study. Experts later assessed the input utilizing the brainstorming technique. The authors have organized one-day creative group-thinking session in June 2022 with methodologists and researchers as well as with an internal physician, a surgeon, an anesthesiologist, and a surgical nurse. Following the Brainstorming technique' principles and rules, the subsequent iterative process of consultation and revision resulted in redefining the reasons concerning patient safety and medication error.

Description of the bow-tie methodology to analyze and control clinical risks

The bow-tie risk analysis methodology was applied in a 400-bed university hospital specializing in active-care services. The bow-tie approach was implemented in the clinical context of the operating room. The tool examines the working circumstances of healthcare workers and identifies necessary preventive measures to reduce errors or lessen their impact. The method is frequently used in the system approach to identify and analyze errors in management and their causes. In contrast to the system approach, the individual method focuses on personal errors and seeks to assign blame for negligence, inattention, incompetence, etc.

The diagram was generated using MS Excel. The diagram illustrates the incident (top event) in its center, with layers of prevention on the left and layers of mitigation on the right. Potential consequences of undesirable outcomes are also listed on the right side of the bow tie diagram. The initial stage is to identify the hazards associated with the working environment, psychological climate, equipment, staff qualifications, and organization that may lead to the incident. The next steps include evaluating the likelihood and impact of the event happening.^[20] Likelihood is the measure of the possibility of an event occurring, measured on a 5-point scale: frequent (5), probable (4), occasional (3), moderate (2), and unlikely (1). The event's severity is directly proportional to the consequences, such as death, and is assessed using a 4-point scale: catastrophic (4), critical (3), marginal (2), and negligible (1) (**Table 1**). The risk assessment is evaluated as a product of the two

criteria – Likelihood and Severity of the incident.^[16]

$$\text{Severity} \times \text{Likelihood} = \text{Risk}$$

RESULTS

Clinical scenario

Anesthesia induction preparations commenced in the operating room at 4:00 PM. Besides the anesthesiologist, surgeons, a surgical and anesthesiologist nurse and students were present in the hall, approximately 16 people in total. The anesthesiologist advised the intravenous administration of the induction anesthetic thiopental at a dose of 250 mg. The young, inexperienced nurse anesthetist mistakenly heard the muscle relaxant tracrium 50 mg due to the abnormally noisy environment. Within 90 seconds of receiving the muscle relaxant, the patient’s respiratory muscles were paralyzed, leading to the suppression of spontaneous breathing with the patient remaining conscious. No complications occurred for the patient after appropriate and prompt interventions were taken.

Risk analysis, expert guidance and recommendations

An extensive investigation was conducted to brainstorm the most critical safety issues in the surgery room. Following the discussion, 12 incidences were identified: 11 near misses and one prescription error, which had the greatest potential for causing harm. A team of medical specialists thoroughly examined the primary causes associated with the medication error during surgery.

The medication error occurred due to insufficient communication between the anesthesiologist and the anesthesiologist nurse. Multiple factors played a role in this situation: the operation taking place late when the team was fatigued, the distracting noise in the environment, and the nurse anesthetist’s lack of experience in recognizing the typical sequence of induction medication and confirming any changes in appointments.

The innovative Striped Bow Tie® methodology was used to depict the sources and causes of the risk, particular preventive measures, and existing controlling systems to reduce harm to the patient in the reported instance (Fig. 1). No patient problems were recorded during the anesthetic and surgical process following prompt and sufficient interventions. Applying the bow-tie method to the specific clinical case enables the identification of the error’s drives, the drawing of lessons, and the proposal of subsequent measures and activities to correct and prevent the recurrence of the event. The diagram clearly illustrates the reasons for the error and the preventive steps that can be taken in a straightforward manner. Hence, the bow-tie technique is highly practical as it directs the focus of medical specialists

towards the crucial aspects that contributed to the error.

The experts participating in the analysis drew attention to the fact that any anesthesia should be administered following the priority concept outlined in the medical standard “Anesthesia and Intensive Care” to ensure the safety of every patient. According to the algorithms for the introduction and maintenance of anesthesia, the medication tracrium can be given before starting anesthesia induction only in specific situations by skilled anesthesiologists, with the necessary equipment for intubation and breathing available.

The risk level was estimated using the following formula:

$$\text{Severity} \times \text{Likelihood} = \text{Risk}$$

The reduction in the relative risk (RR) was assessed following the implementation of the mandatory preventative

Table 1. A risk matrix for assessment of the degree of risk according to the criteria of severity and likelihood of the event

<----- Severity of injury or illness consequence ----->				
Likelihood of occurrence or Exposure for select unit of time or activity	Negligible (1)	Marginal (2)	Critical (3)	Catastrophic (4)
Frequent (5)	5	10	15	20
Probable (4)	4	8	12	16
Occasional (3)	3	6	9	12
Moderate (2)	2	4	6	8
Unlikely (1)	1	2	3	4
Very high risk: 12 or greater; High risk: 7–11; Moderate risk: 4–6; Low risk: ≤ 3				

Source: ANSI/ASSP Z590.3-2021: Prevention Through Design and ASSP TR-31010-2020 Technical Report: Risk Management - Techniques for Safety Practitioners

measures based on Lyon B and Popov G’s model (Table 1). The residual risk of 4, determined on this basis, is deemed acceptable. To lessen the risk and prevent the event, it was recommended to administer thiopental within one minute and monitor the partial pressure of O₂ (Fig. 1).

Bow-tie analysis can be performed to qualitatively or semi-quantitatively demonstrate the effectiveness of controls, countermeasures, and risk mitigation strategies.^[19,22] The authors have contrasted the bow-tie analysis technique with other risk analysis approaches, providing practical

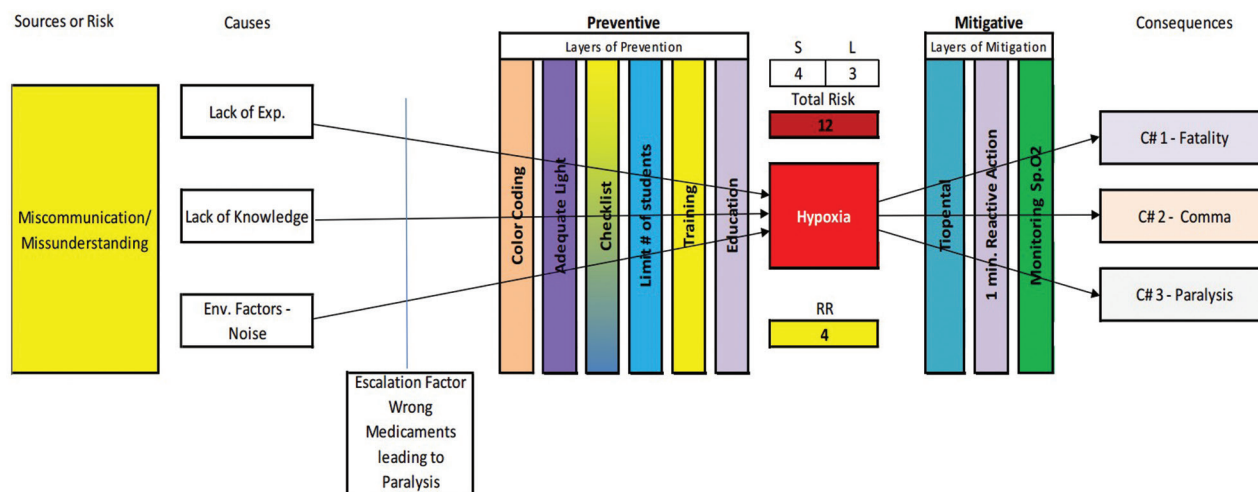


Figure 1. Schematic model of the Striped Bow-Tie® methodology for analyzing medication error risk (adapted from “Risk Assessment: A Practical Guide to Assessing Operational Risks” by Popov G, Lyon BK, Hollcroft B. 2022; John Wiley and Sons, Inc. Hoboken, New Jersey).

examples and emphasizing some of the method’s benefits. One major benefit of this method is that the diagram offers a rapid and straightforward overview of the overall processes being evaluated, allowing for a thorough evaluation of risk and the current control systems in place.^[7,16] Furthermore, participants can easily comprehend the strategy by visualizing the connections between the causes of the incident and the unfavorable repercussions. Bow-tie analysis could be considered an essential risk assessment tool in various industries, including healthcare, as it showcases both proactive and mitigating actions to prevent and address incident repercussions.

Study limitations

This study has some limitations. We relied on the anonymously self-reported adverse events, errors and near misses by the healthcare professionals on the web-based platform (www.rspg.bg). This single case study and its results of the risk analysis only apply to this particular case study and operational theater and cannot be generalized. However, the method is applicable to other operational and clinical settings.

Implications of the research

This study may contribute to nursing education in focus, particularly to continuous medical education (CME) related to patient medication safety in the operating room. We consider the reporting and description of the errors as well as the proposed measures to prevent them as valuable features of the study as shown in the bow-tie diagram. We also believe that such studies can be useful in encouraging the

healthcare professionals to report patient safety incidents in order to learn from them and improve patient safety culture.

CONCLUSION

The bow-tie analysis was implemented for the first time in the anesthesiology practice in our setting. The method serves as an exceptional risk communication tool and is suitable for use in hospital medical practice. Nevertheless, more profound findings can be derived from further observations. It could be successfully used to conduct a risk assessment of drug safety in the surgery room. The current study emphasized some concerns related to patient safety culture in operating theaters and provided solutions for them. Some untapped opportunities for enhancing the safety culture in medical staff’s continuing education include implementing specialized qualification courses to enhance practical skills, attending seminars and training sessions to improve workplace communication, and transforming the hospital into a learning organization that consistently learns from reported adverse events, near misses, and medical errors.

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Competing Interests

The authors have declared that no competing interests exist.

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Применение анализа «галстук-бабочка» для повышения безопасности пациентов — урок, извлечённый из клинической практики

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Резюме

Цель: Это исследование было направлено на оценку управления рисками безопасности лекарственных средств в условиях операционной в лечебном учреждении на базе больницы.

Материалы и методы: Это исследование случая, подробно описывающее одного пациента. Модель “галстук-бабочка” была модифицирована для анализа ошибок приёма лекарств в анестезиологической практике и внедрена в операционной университетской больницы. Диаграмма была создана с использованием хорошо зарекомендовавших себя методов. Данные были собраны с помощью онлайн-портала (www.rsps.bg), предназначенного для оценки культуры безопасности в больнице и сообщения об инцидентах.

Результаты: Модель, построенная на методологии Striped Bow Tie®, проиллюстрировала основные причины ошибок приёма лекарств. Оценка риска была оценена в 12 на основе указанных параметров. Серьёзность оценивается по 4-балльной шкале от катастрофической (4), критической (3), пограничной (2) до незначительной (1). Вероятность оценивается по 5-балльной шкале от частой (5), вероятной (4), случайной (3), умеренной (2) до маловероятной (1). Были предложены профилактические методы для минимизации риска, предотвращения инцидента и управления процессом.

Заключение: Анализ „галстук-бабочка“ подходит и прост в применении в анестезиологической практике больницы и служит важным инструментом для анализа рисков безопасности лекарств. Анализ продемонстрировал системные ошибки, которые привели к инциденту, включая нереализованный потенциал для непрерывного медицинского образования и прерывания больницы в место, где врачи могут постоянно учиться, сообщая о нежелательных явлениях и врачебных ошибках.

Ключови думи

метод «галстук-бабочка», культура безопасности пациентов, ошибка в приёме лекарств
