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CLINICAL RESEARCH

Patient safety in an endoscopy unit: an observational retrospective analysis of reported incidents

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Abstract
Introduction: Patient safety is a serious public health with serious implications on morbidity, mortality, and quality of life of patients, in addition to negatively affecting the public image of healthcare institutions and professionals. It requires further investigation, especially in specialties lacking published data, such as endoscopy.
Objective: To analyze patient safety incidents reported in a gastrointestinal endoscopy unit of a tertiary hospital in southern Brazil.
Methods: This retrospective, cross-sectional study quantitatively described patient safety incidents related to endoscopic procedures. The sample consisted of reports of incidents that occurred from 2015 to 2017. The data were descriptively analysed, and the study was approved by the relevant research ethics committee.
Results: Overall, 42,863 endoscopic procedures were performed and 167 reports were submitted in the period, accounting for a prevalence of incidents of 0.38%. Most incidents did not result in unnecessary harm to patients (76.6%). The most prevalent incidents were those related to patient identification, followed by those related to pathology exams, exam reports, gastrointestinal perforations, skin lesions, falls and medication errors. The rate of adverse events (harm to patient) in patients undergoing any endoscopic procedure was 0.06%.
Conclusions: The incidence of unnecessary harm (adverse event) associated with any endoscopic procedure was relatively low in this study. However, the identification of reported incidents is crucial for evaluating and improving the quality of care provided to patients.

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Introduction

Patient safety is a serious public health issue that has been the focus of a number of investigations worldwide. Healthcare-associated harm has serious implications on morbidity, mortality, and quality of life of patients, in addition to negatively affecting the public image of healthcare institutions and professionals.[1]

A milestone on the global patient safety movement was the publication of ''To err is human: building a safer health system'', an Institute of Medicine report[2] that estimated the number of deaths each year in United States (US) hospitals due to medical errors (between 44,000 and 98,000) and the total cost for the US government (between $17 billion and $29 billion). Subsequent evidence suggests that the figures are even higher (between 210,000 and 400,000 deaths),[3] and medical errors are described as the third leading cause of death in the US.[4]

Important advances seeking to minimize the impact of errors and ensure safety to patients, practitioners, hospitals, and society have been observed in the past decade, especially with initiatives such as the World Alliance for Patient Safety, launched by the World Health Organization (WHO).[5] In Brazil, the National Patient Safety Program sets out mandatory actions to be taken by healthcare facilities, such as the creation of patient safety committees, implementation of patient safety protocols, and management of patient safety incidents.[6]

The WHO describes a patient safety incident as any event or circumstance that could have resulted, or did result, in unnecessary harm to a patient. An adverse event, in turn, is defined as an incident that causes actual harm to a patient.[5]

There has been an important growth in the use of upper and lower gastrointestinal endoscopy in recent years. This minimally invasive method allows performing diagnostic and therapeutic approaches through direct visualization, biopsy, polyp removal, mucosal resection, and haemostasis of gastrointestinal bleeding.[7,8] Currently, upper gastrointestinal endoscopy has also been used in the treatment of obesity with minimally invasive procedures such as endoscopic intragastric balloon placement and, more recently, endoscopic sleeve gastroplasty.[9] The increasing demand for healthcare professionals and services that perform upper gastrointestinal endoscopy requires a greater focus on the availability of this procedure and its quality and safety indicators. Although teams involved in this type of procedure have gained practical experience, there are still few studies providing data on endoscopy-related incidents.

The scope of endoscopy safety studies ranges from the assistance level, including patient admission, data checking, and reason for treatment, to the procedural level, including trained teams, required equipment, proper environment to perform the procedure, adequate monitoring, and healthcare professional best prepared for administering sedation during the procedure.[10–14] A report from the United Kingdom (UK) government defines the following as eminently preventable incidents: failure to monitor and respond to oxygen saturation, patient misidentification, wrong endoscopic procedure, and misplaced nasogastric tubes.[15]

In this context, the aim of this study was to analyse reports associated with patient safety in an in-hospital gastrointestinal endoscopy unit.

Material and methods

The study was approved by the Research Ethics Committee of Hospital Ernesto Dornelles (approval number 83037718.5.0000.5304). The study was conducted in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments. For this type of study, formal consent is not required.

This retrospective, cross-sectional study quantitatively described patient safety reports related to endoscopic procedures performed at the Endoscopy Unit of Hospital Ernesto Dornelles, southern Brazil. This general hospital provides high-complexity services and has 320 beds for inpatients, including 40 in the intensive care unit (ICU). Created in 2014, the Endoscopy Unit has four examination rooms and performs, on average, 1,200 procedures per month. Upper gastrointestinal endoscopy, colonoscopy, nasoenteric tube placement, gastrostomy, and haemostasis of gastrointestinal bleeding are offered.

The study included all reports related to patient safety that the Endoscopy Unit staff (nurses, practical nurses, and physicians) sent to the Epidemiology and Risk Management Unit (which is responsible for patient safety policy) from January 1, 2015 to December 31, 2017. Standardized forms were used to ensure the anonymity of the reporting person.

Incidents were classified according to the WHO Taxonomy for Patient Safety[5] as follows: reportable circumstance, which is an event with significant potential for harm; near miss, which is an incident that did not reach the patient; no harm incident, which is an event that reached the patient and caused no harm; and adverse event, which is an incident that resulted in harm to the patient.

Based on the degree of harm, adverse events were classified as follows: mild, when symptoms are mild, harm is minimal, and no or minimal intervention is required; moderate, when the patient is symptomatic, requiring intervention (e.g., additional surgical procedure) and increased length of stay, causing permanent or prolonged harm; severe, when the patient is symptomatic, requiring life support or major surgical/medical intervention, shortening life expectancy or causing permanent or prolonged harm; death, when the event resulted in death or precipitated this outcome.[5]

When a report did not describe an incident (event or circumstance that could have resulted, or did result, in unnecessary harm to a patient),[5] it was classified as follows: healthcare-related event (when an unexpected event occurred in a medical procedure, which could not have been predicted or informed to the patient); nonconformity, when some inconsistency occurred in healthcare delivery, such as inadequately scheduled procedure, which included wrong date, unnecessary patient isolation, and patient with latex allergy scheduled to a service that does not offer this option; and others, when cases did not fit into the previously described categories, such as a suspended procedure due to inadequate clinical status or a cancellation requested by the patient.

Table 1 Demographic variables and characteristics of 167 reports of incidents and other events associated with patient safety.

Variables	n	%
Procedure		
Upper gastrointestinal endoscopy (UGIE)	50	29.9
Colonoscopy	42	25.1
UGIE + colonoscopy	26	15.6
Gastrostomy	15	9.0
Nasoenteric tube placement	12	7.2
Hemostasis of gastrointestinal bleeding	9	5.4
Others	13	7.8
Urgent procedure (yes)	7	4.2
Inpatient (yes)	66	39.5
Classification		
Incidents	111	66.5
Reportable circumstance	2	1.2
Near miss	38	22.8
No harm incident	45	26.9
Adverse event	26	15.6
Health care-related event	42	25.1
Nonconformity	6	3.6
Others	8	4.8
Time of occurrence		
Before procedure	67	40.1
During procedure	41	24.6
After procedure	59	35.3

The data were descriptively analysed through simple (*n*) and relative (%) frequency for categorical variables and through mean and standard deviation or median and interquartile range for quantitative variables.

Results

Overall, 42,863 procedures were performed and 167 reports were submitted (0.38%) in the study period. In 2015, there were 12,816 procedures and 33 reports (0.26%); in 2016, 14,592 procedures and 59 reports (0.40%); and in 2017, 15,455 procedures and 75 reports (0.48%). Demographic variables and characteristics of the 167 reports are shown in Table 1.

Of all events reported, 111 (66.5%) were considered incidents as described in the WHO taxonomy; thus, the rate of incidents was 0.25% (111/42,863). Most incidents did not result in unnecessary harm to patients (76.6%). However, in 26 cases, some degree of harm was identified: mild, 57.7%; moderate, 11.5%; severe, 23.1%; and death, 7.7%. The rate of adverse events in patients undergoing any endoscopic procedure was 0.06% (26/42,863). Regarding only the 111 reported incidents, those related to patient misidentification were most frequent (35%), followed by those related to pathology exams (13.5%), exam reports (12.6%), gastrointestinal perforations (6.3%), skin lesions (4.5%), falls (2.7%), and medication errors (2.7%).

Healthcare-related events accounted for 25.1% of all reports. They included desaturation (4.8%), bradycardia (1.8%), cardiac arrest (1.2%), aspiration (1.8%), and others (38.9%). The reported nonconformities consisted of inconsistencies in scheduled procedures (wrong date, patient with latex allergy scheduled to a service that does not offer this option, and unnecessary patient isolation), a procedure that did not meet the standards because there was no anaesthesiologist in the room, and a patient with gastrostomy tube who was fed through the cuff. Reports classified as ''others'' did not fit into the categories described above. In eight cases, patients did not undergo the procedure. Five procedures were suspended because patients' clinical status was inadequate, one procedure was suspended because the patient had not fasted, and two procedures were cancelled by the patients.

Most cases (105) did not require any additional intervention. However, 37.1% were managed with some type of evaluation or intervention, which increased the length of stay for 30.5% of patients. When an incident or healthcare-related event required intervention, medical evaluation was the most frequent approach (55), followed by need of ICU or emergency admission (38), diagnostic tests (36), medications (18), suspended procedure (16), calling a rapid response team (10), intubation (13), surgical procedure (6), mask ventilation (5), and need of repeating an exam (2).

Discussion

In the study period, there were 167 reports of incidents that occurred in the Endoscopy Unit. Of the events reported, 111 (66.5%) were considered incidents as described in the WHO taxonomy. Thus, the rate of incidents was 0.25% (111/42,863), and 23.4% of patients suffered some degree of harm. The rate of adverse events in patients undergoing any endoscopic procedure was 0.06% (26/42,863).

In Latin America, an estimated 10.5% of inpatients are affected by some type of adverse event during hospital stay, while the rate of preventable events is 58.9%.[16] In Brazil, the estimated incidence of patients undergoing adverse events is 7.6%, and 66.7% of those events are considered preventable.[17] In the present study, the overall rate of reports of incidents and adverse events was 0.38%. No equivalent studies were found to compare specific data from different gastrointestinal endoscopy units.

Regarding safety in gastrointestinal endoscopic procedures, which is the focus of this paper, all patients must be thoroughly evaluated, including before, during, and after any procedure. Having access to patient medical history is essential because previous health conditions may affect tolerance to the procedure, e.g., history of obstructive sleep apnea may indicate impaired ventilatory function with sedation.[18] Women of childbearing age should be asked about a possible pregnancy, especially in case of elective procedures that may be delayed, as sedative drugs may not be safe for pregnant patients. All medications and dosages used by patients should be recorded.[18] Informed consent should always be obtained prior to the procedure, with guidance on risks, benefits, and how sedation will be administered.[14,18]

The Brazilian National Health Surveillance Agency passed the Resolution of the Collegiate Board of Directors number 6, as of March 1, 2013, providing that an endoscopic procedure with deep sedation or non-topical anaesthesia requires a legally qualified professional to administer anaesthetics. In

addition, the patient should be monitored during the entire procedure until he/she is well enough to be transferred to the recovery room.[19]

Incidents might occur at different moments, such as arrival, admission, procedure, or even recovery from sedation. However, studies show that approximately half of significant adverse events occurring in gastrointestinal endoscopic procedures is associated with sedation.[10] In our study, 40.1% of all reports consisted of events that occurred before procedures, while 24.6% occurred during and 35.3% after procedures. When considering only the 26 adverse events reported in our evaluation, 73% occurred during, 23% after, and 3.84% before procedures. In our study, however, 50% of adverse events occurring during and after procedures were due to gastrointestinal perforation and gastrointestinal laceration/bleeding without perforation, 19.2% due to skin lesions, and 11.5% due to falls.

Among the major concerns in healthcare services, patient misidentification is known as a key problem in ensuring patient safety. In 2003, the Joint Commission had already placed improving patient identification as the first of its six International Patient Safety Goals.[20] Then, in 2007, the US organization published a report with solutions for patient safety, focusing on proper identification. This report had the alarming evidence that adverse events due to medication errors, transfusion errors, testing errors, and wrong person procedures most frequently derive from failure to correctly identify patients.[21] In our study, 39 reports were associated with patient misidentification, accounting for 23.4% of all reports (n = 167), and 82% of these patients had already been admitted. Misidentification included patients without identification wristband or with illegible identification wristband. No adverse events due to those errors were reported.

A Brazilian study conducted at a São Paulo state teaching hospital prepared an instrument that asked patients if they knew an identification wristband existed, if they had used it in the present admission, and if it had been removed and why.[22] The results showed that only 4.1% of patients were given an identification wristband at the time of admission. The situation is even more serious when considering that 20.8% of patients who were transferred from other hospitals to the study hospital had their wristband removed after admission. Additionally, 22% of patients had never used identification wristbands, demonstrating that the importance of this device remains poorly understood, as well as the need of ensuring that all patients and their beds are properly identified during the entire admission.[22]

In many places, the increased number of procedures requiring sedation, such as gastrointestinal endoscopies, has not been proportional to the availability of trained professionals to administer drugs for such purpose.[12] This fact, along with an apparent ease of administration of sedative techniques, has led to the appearance of non-anaesthesiologists in charge of inducing sedation.[12,13] All the guidelines reviewed by Wehrmann and Triantafyllou[13] established that the endoscopist is not able to single-handedly administer propofol sedation and monitor the patient; thus, another professional is required to perform those tasks, namely an anesthesiologist, a gastroenterologist trained in propofol administration, or a nurse trained in propofol administration. However, the use of propofol is still restricted to anesthesiologists in some countries.[13] In our unit, endoscopic procedures have anesthesiologists to monitor the patient and administer sedation.

With regard to endoscopy-associated complications, a US study that analysed 12,407 colonoscopies performed by eight gastroenterologists reported that perforation occurred in only two patients (0.016%).[23] In our study, 23,088 colonoscopies were performed and seven perforations occurred, accounting for 0.03%.

The risks identified for cardiopulmonary complications can be divided into: patient-specific: 1) ischemic heart disease; 2) moderate-to-severe lung disease; 3) inpatients; 4) oxygen saturation < 95%; 5) age > 70 years; 6) American Society of Anesthesiologists (ASA) class III and IV; or procedure-specific: 1) urgent procedures; 2) sedation method; 3) use of adjuvant sedative agents; 4) use of supplemental oxygen, which may conceal hypoventilation when only pulse oximetry is assessed.[11] In our study, there was no specific analysis for cardiopulmonary complications alone, as we included other incidents and adverse events. In addition, there was no statistically significant association between age and other variables such as patients with higher incidence of complications, in- or outpatients, and number of comorbidities reported. Conversely, patients undergoing urgent procedures had lower incidence of complications when compared with those undergoing elective procedures ($p = 0.05$).

Our analysis was based on reports that the Endoscopy Unit staff voluntarily sent to the Epidemiology and Risk Management Unit. We know that voluntary reporting alone is not optimal for the identification of incidents, but it must be encouraged by the staff coordination team.

Notification through computerized systems, although still incipient in many institutions, has been developed as a strategy for improving incident management.[24] A study conducted at Hospital das Clínicas of Ribeirão Preto School of Medicine observed an increase in the number of reports with the implementation of computerized reporting when compared to handwritten reporting. This may be explained by the fact that the electronic method is free of punishment; however, it still struggles with underreporting.[25] As our unit still lacks a computerized reporting system, all reports are handwritten, mostly by nurses and practical nurses. Thus, we know that our data may be incomplete because of underreporting.

The use of checklists is gaining ground in the debate over prevention of errors. A 2013 study reported an experience of introduction of a checklist into a gastrointestinal endoscopy unit, outlining lessons regarding team engagement and training, best method of implementation, and errors that were identified and could be corrected. As the article reinforces, preventing all possible errors during a procedure is unfeasible; however, a checklist can establish those amenable to identification and correction and can provide guidance such as avoiding that the patient enters the examination room without identification wristband, altering incorrect information about the patient, identifying allergies reported, checking informed consent, and preventing errors in the description of histopathological samples and other exam reports.[26] Our unit has already implemented a periodically updated checklist system that aims to reduce the occurrence of errors as much as possible. Our checklist is used at four different moments: at endoscopy unit

admission, in the examination room before and after the procedure, and finally in the recovery room.

The information obtained in this study allowed us to analyse the reports of incidents that occurred in the study period, with specific data on our Endoscopy Unit. To our knowledge, there are no similar studies addressing patient safety at an endoscopy unit, which makes our work original.

The limitations of this study include its retrospective design, which prevents the acquisition of further data. In addition, because the reports had to be submitted by healthcare professionals, a team member was responsible for notifying the Epidemiology and Risk Management Unit, which may have led to underreporting.

Conclusions

The study showed the incidents that occurred in the endoscopy unit in a hospital in southern Brazil, emphasizing the magnitude and characteristics of patient safety problems, especially with regard to underreporting. The data obtained can provide the basis for the development of monitoring and care strategies in other health institutions with regard to endoscopic procedures, creating learning opportunities and the potential for culture change and, with this, developing safer healthcare.

In the healthcare setting, providing care in line with the principles of quality management and free of unnecessary harm to patients, professionals, institutions and society is imperative. In view of the current rise of endoscopic procedures for diagnosis and treatment, as well as the lack of national studies addressing patient safety in this specialty, analysing patient safety incidents related to such procedures is required to broaden and strengthen the discussion, ensuring the continuous improvement of care processes and patient safety.

Conflicts of interest

The authors declare no conflicts of interest.

References

1. National Patient Safety Foundation (NPSF). RCA2: improving root cause analyses and actions to prevent harm. Boston, MA: National Patient Safety Foundation; 2015.
2. Committee on Quality of Health Care in America.Kohn LT, Corrigan JM, Donaldson MS, editors. To ERR is human: building a safer health system. Washington, DC: National Academies Press; 2000.
3. James JT. A new, evidence-based estimate of patient harms associated with hospital care. J Patient Saf. 2013;9:122–8.
4. Makary MA, Daniel M. Medical error—the third leading cause of death in the US. BMJ. 2016;353:i2139.
5. World Health Organization (WHO). The conceptual framework for the international classification for patient safety. Geneva, Switzerland: WHO; 2009.
6. Ministério da Saúde. Portaria nº 529, de 1º de Abril de 2013. Institui o Programa Nacional de Segurança do Paciente (PNSP). Brasília, DF: Diário Oficial da União; 2013.
7. Ono H. Early gastric cancer: diagnosis, pathology, treatment techniques and treatment outcomes. Eur J Gastroenterol Hepatol. 2006;18:863–6.
8. Loperfido S, Baldo V, Piovesana E, et al. Changing trends in acute upper-GI bleeding: a population-based study. Gastrointest Endosc. 2009;70:212–24.
9. Abu Dayyeh BK, Acosta A, Camilleri M, et al. Endoscopic sleeve gastroplasty alters gastric physiology and induces loss of body weight in obese individuals. Clin Gastroenterol Hepatol. 2017;15:37–43.
10. Aisenberg J. Endoscopic sedation: equipment and personnel. Gastrointest Endosc Clin N Am. 2008;18:641–9.
11. Cohen Lb. Patient monitoring during gastrointestinal endoscopy: why, when, and how? Gastrointest Endosc Clin N Am. 2008;18:651–63.
12. Van der Linden P. Sedation in gastrointestinal endoscopy: an anesthesiologist's perspective. Digestion. 2010;82:102–5.
13. Wehrmann T, Triantafyllou K. Propofol sedation in gastrointestinal endoscopy: a gastroenterologist's perspective. Digestion. 2010;82:106–9.
14. Feld AD. Endoscopic sedation: medicolegal considerations. Gastrointest Endosc Clin N Am. 2008;18:783–8.
15. Department of Health. The ''never events'' list for 2012/13. London, UK: Patient Safety and Investigations; 2012.
16. Ministerio de Sanidad y Política Social de España. Prevalencia de efectos adversos en hospitales de latinoamérica. Madrid, ES: Estudio IBEAS; 2010.
17. Mendes W, Martins M, Rozenfeld S, et al. The assessment of adverse events in hospitals in Brazil. Int J Qual Health Care. 2009;21:279–84.
18. Mitty RD, Wild DM. The pre- and postprocedure assessment of patients undergoing sedation for gastrointestinal endoscopy. Gastrointest Endosc Clin N Am. 2008;18:627–40.
19. Ministério da Saúde. Agência Nacional de Vigilância Sanitária. Resolução RCD nº 6, de 10 de Março de 2013. Dispõe sobre os requisitos de boas práticas de funcionamento para os serviços de endoscopia com via de acesso ao organismo por orifícios exclusivamente naturais. Brasília, DF: Diário Oficial da União; 2013.
20. Joint Commission. National patient safety goals. Oakbrook Terrace, IL: Joint Commission; 2006.
21. World Health Organization (WHO), Joint Commission International (JCI), WHO Collaborating Centre for Patient Safety Solutions. Patient safety solutions. Geneva, Switzerland: WHO; 2007.
22. Miasso AI, Cassiani SHB. Erros na administração de medicamentos: divulgação de conhecimentos e identificação do paciente como aspectos relevantes. Rev Esc Enferm USP. 2000;34:16–25.
23. Rathgaber SW, Wick TM. Colonoscopy completion and complication rates in a community gastroenterology practice. Gastrointest Endosc. 2006;64:556–62.
24. Gong Y, Kang H, Wu X, et al. Enhancing patient safety event reporting: a systematic review of system design features. Appl Clin Inform. 2017;8:893–909.
25. Capucho HC, Arnas ER, Cassiani SHB. Segurança do paciente: comparação entre notificações voluntárias manuscritas e informatizadas sobre incidentes em saúde. Rev Gaúcha Enferm. 2013;34:164–72.
26. Matharoo M, Thomas-Gibson S, Haycock A, et al. Implementation of an endoscopy safety checklist. Frontline Gastroenterol. 2014;5:260–5.