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ARTICLE
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Adverse events in gastrointestinal endoscopy: a cohort of 62,088 procedures performed

Eventos adversos em endoscopia gastrointestinal: uma coorte de 62.088 procedimentos realizados

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ABSTRACT

Introduction: Endoscopes have greatly contributed to the prevention and treatment of various pathologies. However, despite the considerable advance in hospital care made possible by the advent of such equipment, the use of these devices has brought, beyond the obvious benefits, the risk of transmission of infection. **Objective:** To identify the incidence of adverse events (AD) related to endoscopic procedures. **Method:** Retrospective cohort study at a Digestive Endoscopy Service located in Salvador, BA. Gastrointestinal procedures, passive reports by patients and reports reported by endoscopists, between 2016 and 2018, were included in this cohort. Data collection occurred between October and November 2018, using our own instrument. **Results:** From 2016 to 2018, 21,827 colonoscopies, with an incidence of AE of 0.200%, were performed, and 40,261 upper digestive endoscopies, with incidence of AE of 0.080%, were also performed. In those years, the service performed 62,088 endoscopies, with a total incidence of AE of 0.100%. The most frequent adverse events were bacteremias, mucosal laceration, pain and abdominal distension, with an incidence of 0.030%, 0.010%, 0.010% and 0.010%, respectively. **Conclusions:** This study identified the incidence of AE related to endoscopic exams, contributing to the formation of data in the area of Brazilian gastrointestinal endoscopy. The incidence of 0.100% of AE identified here is much lower than the data in the international literature, as well as the incidence of the types of adverse events identified, signaling to the control of risks, quality and safety of the endoscopy service studied.

KEYWORDS: Endoscope; Patient Harm

RESUMO

Introdução: Os endoscópios muito têm contribuído para a prevenção e tratamento de várias patologias. Entretanto, a despeito do avanço considerável na assistência hospitalar possibilitada pelo advento desses equipamentos, a utilização desses dispositivos trouxe para além dos evidentes benefícios, o risco de transmissão de infecção. **Objetivo:** Identificar a incidência de eventos adversos (EA) relacionados a procedimento endoscópico. **Método:** Estudo de coorte retrospectiva em um Serviço de Endoscopia Digestiva localizado em Salvador, BA. Fizeram parte desta coorte os procedimentos gastrointestinais, as notificações passivas feitas pelos pacientes e notificações relatadas pelos endoscopistas entre 2016 e 2018. A coleta de dados ocorreu entre outubro a novembro de 2018, com instrumento próprio. **Resultados:** Durante 2016 e 2018 foram realizados 21.827 colonoscopias, com uma incidência de EA de 0,200% e 40.261 endoscopias digestivas altas com incidência de EA de 0,080%. Nesses anos, o serviço realizou 62.088 endoscopias, com uma incidência total de EA de 0,100%. Os EA mais frequentes foram: bacteremias, laceração de mucosa, dor e distensão abdominal, com incidência de 0,030%, 0,010%, 0,010% e 0,010%, respectivamente. **Conclusões:** Este estudo identificou a incidência de EA relacionados aos exames endoscópicos, contribuindo para a formação de dados na área da endoscopia gastrointestinal brasileira. A incidência de 0,100% de EA aqui identificada é muito menor do que os dados da literatura internacional, bem como a incidência dos tipos de eventos adversos identificados, sinalizando para o controle de riscos, qualidade e segurança do serviço de endoscopia estudado.

PALAVRAS-CHAVE: Endoscópio; Dano ao Paciente

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INTRODUCTION

Over the last decades, fast technological progress in the health area has driven the increase of several products in hospital care, including endoscopic equipment.

Flexible endoscopes were introduced in the 1960s and have since been used worldwide to detect, diagnose and treat several medical conditions, with a decisive contribution to the prevention and treatment of various conditions. However, despite the significant progress in hospital care enabled by such equipment, the use of these devices has, in addition to the obvious benefits, increased the risk of transmission of infections more than any other health product[1,2,3,4].

According to the risk of infection transmission, endoscopes are classified as: critical (those that access sterile areas of the body) and semicritical products (those that contact mucous membrane surfaces). This equipment must be cleaned and decontaminated according to its hazard rating. Critical endoscopes, like arthroscopes and laparoscopes, must be sterilized before use. Semicritical endoscopes, like digestive endoscopes, bronchoscopes and colonoscopes, minimally require high-level disinfection[4,5].

According to the literature, various microorganisms are involved in endoscope-associated infections, like Hepatitis B and C viruses, *Salmonella* sp, *Staphylococcus aureus, Klebsiella pneumonia, Enterococcus* spp, *Pseudomonas aeruginosa*, Mycobacteria, parasites, among others[2,4,5,6,7], which points to the infectious risks related to these procedures and makes infection prevention an important objective to ensure patient safety[1,2,3,4].

Endoscope-related infections can be transmitted in many ways: a) patient-to-patient microorganisms through contaminated equipment; b) from the gastrointestinal tract to susceptible organs of the body, through the bloodstream during endoscopy and c) from the patient to endoscopy professionals and perhaps from professionals to patients[3].

To date, most episodes of endoscopy-related pathogen transmission have been associated with failure of the cleaning, disinfection, rinsing or storage processes of these devices. There are no reported cases of infection transmission when endoscope reprocessing is done according to well-established protocols[1,2,3,4,5,6,7,8,9,10,11,12].

Generally speaking, endoscope reprocessing is a multi-step process that makes contaminated endoscopes safer for their next use. It includes meticulous cleaning, complete immersion in a high-level disinfectant/sterilizer, rinsing with potable water, irrigation of internal channels with 70% alcohol, drying and storage[1,2,4,5,6,7,8].

Some factors may contribute to failure in endoscope reprocessing, like: complex endoscope structure that makes cleaning and disinfection difficult (channels, closed angles, joints, long length); lack of standardized and properly enforced decontamination protocols; insufficient devices to meet the demand of procedures; poor training of professionals responsible for cleaning and disinfecting equipment; contamination of water used to rinse equipment, failure of cleaning and disinfection of such equipment, among others[10,12,13,14,15,16,17].

Some studies point to the importance of biofilm growth in endoscope channels. Not only does this compromise the cleaning and disinfection process, but it also contributes to the antimicrobial resistance phenomenon and consequent decontamination failure[5,6,7,8]. The emergence of carbapenen-resistant enterobacteria in patients undergoing endoscopic retrograde cholangiopancreatography has raised infection control questions in these units[5,11].

Infection data associated with endoscopic procedures are published frequently. The American Association of Gastrointestinal Endoscopy estimates an infection rate of one for every 1.8 million endoscopic procedures performed in the United States[7,8,9,10]. Although this incidence is considered low in relation to the number of procedures performed, it is a frequent infection related to the use of medical devices. Additionally, it is assumed that the true incidence of infection transmission may not be identified due to inadequate or non-existent systems of surveillance and monitoring of adverse events (AE) after these exams. In this context, it is difficult to assess the real risk of infection for patients undergoing endoscopy[3,5,7,8,10].

Given the relevance of problems related to the use of endoscopic equipment for public health, and in view of the scarcity of data published about AE in Brazilian endoscopy services, this study sought to answer the following guiding question: what is the incidence of AE related to gastrointestinal endoscopic procedures in Brazil? In this sense, it aimed to identify the incidence of AE related to gastroendoscopic procedures.

METHOD

This is a dynamic retrospective cohort study conducted at a Digestive Endoscopy Service located in the city of Salvador, state of Bahia, Brazil. The service is private and health insurance-based. It exclusively performs digestive and colonoscopic endoscopic procedures on a day hospital basis, with a volume of approximately 90 daily procedures.

This institution was chosen because it is the service that performs the largest number of outpatient endoscopic procedures in the state of Bahia and because the authors of this study work in the aforesaid institution.

In this service, all patients are instructed verbally and with the help of a booklet to report any symptoms after endoscopic procedures. In the case of patient notification, the Hospital Infection Control Service conducts an epidemiological investigation to identify whether the symptoms reported by the patients are associated with the endoscopic procedure done at the institution.

This cohort included the notifications of AE reported by patients, as well as those reported by endoscopists in the period between 2016 and 2018, during which 62,088 gastroendoscopic procedures were done at the institution.

Data collection was performed from October to November 2018, with the help of a proper instrument to record the variables of interest to this research: number of endoscopic procedures done, number of related AE and description of these events. Data from AE reports related to endoscopic procedures prepared by the Hospital Infection Control Service of the studied institution were used. Data were stored and analyzed using Epiinfo software.

This study used primary and unpublished data. It did not have interviews with human beings either individually or collectively, which means it is exempt from submission to the Research Ethics Committee according to article VII of Resolution n. 466 of December 12, 2012, which deals with research ethics. Contact was made with the Board to expose the research objectives, receive permission to conduct the research, ensuring the confidentiality of the collected data. It was approved by the institution's Ethics Committee under Opinion n. 022/2018.

RESULTS

Table 1 describes the number of endoscopic procedures done in the service from 2016 to 2018 (January to November), as well as the identified AE. During this period, 21,827 colonoscopic procedures were performed, with a total incidence of AE of 0.200%. 40,261 upper digestive endoscopies were performed and the total incidence of AE was 0.080%. In the years of this study, the service performed 62,088 endoscopic procedures, with a total incidence of AE of 0.100%. The incidence of 0.100% of AE is observed between 2016 and 2017, with a decrease to 0.080% in 2018.

The Figure shows the number of AE notified in colonoscopy and upper digestive endoscopy procedures in the years studied.

It is observed that there was no significant variation of AE in these years. The incidence of AE in colonoscopy ranged from 0.200% to 0.100% and the incidence of upper digestive endoscopy from 0.100% to 0.060%, with a decreasing trend in 2018.

The percentage distribution of reported AE in the studied service is described in Chart 2.

Chart 2 describes the AE identified in the period. Bacteremia, mucosal laceration, pain and abdominal distension are the most frequent events, with a total incidence of 0.030%, 0.010%, 0.010% and 0.010%, respectively. There were three cases of intestinal perforation after colonoscopy with an incidence of 0.010%.

DISCUSSION

Worldwide data on AE related to flexible gastrointestinal endoscopy are scarce. For the North American Society of Gastrointestinal Endoscopy, AE related to gastrointestinal endoscopy are rare and include infection, perforation, and hemorrhages[12].

Chart 1. Incidence of adverse events reported in colonoscopy and endoscopy procedures from 2016 to 2018, Salvador, Bahia, Brazil.

Years	N. colonoscopic procedures	N. of adverse events in colonoscopy (%)	N. of upper digestive endoscopy procedures	N. of adverse events in upper digestive endoscopy (%)	Total endoscopic procedures and adverse events (%)
2016	7,741	15 (0.200%)	13,739	14 (0.100%)	21,480 (29 - 0.100%)
2017	7,752	12 (0.100%)	14,274	11 (0.100%)	22,026 (23 - 0.100%)
2018 (Jan to Nov)	6,334	8 (0.100%)	12,248	8 (0.060%)	18,582 (16 - 0.080%)
Total	21,827	35 (0.200%)	40,261	33 (0.080%)	62,088 (68 - 0.100%)

Source: Infection Control Service of the institution.

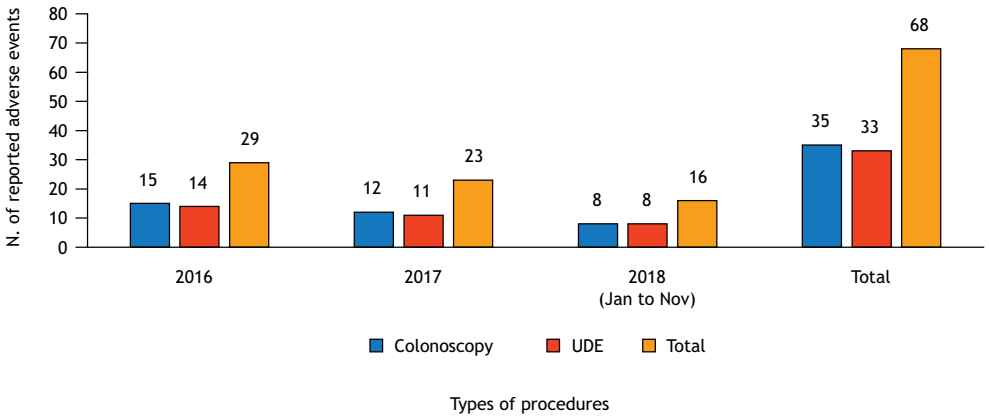

Figure. Incidence of adverse events reported in colonoscopy and upper GI endoscopy procedures from 2016 to 2018, Salvador, Bahia, Brazil.

Chart 2. Percentage distribution of adverse events occurred at the endoscopy service studied from 2016 to 2018, Salvador, Bahia, Brazil.

N. of reported adverse events		
AE	**N.**	**%**
Bacteremia	22	0.030
Mucosal laceration	10	0.010
Abdominal pain	11	0.010
Abdominal distension	7	0.010
Bronchial aspiration	4	0.006
Intestinal perforation*	3	0.010
Rectal bleeding*	4	0.006
Colitis	3	0.010
Diarrhea	3	0.010
Thrombophlebitis	1	0.001

* To calculate the percentage of intestinal perforation and rectal bleeding, we used the total number of colonoscopic procedures described in Chart 1.

The literature reports that the incidence of bacteremia after upper digestive endoscopy with or without biopsy is less than 8%, and this event varies according to the procedure. There are reports of rates from 0% to 53% after esophageal sclerosis, from 1% to 25% after varicose vein ligation and from 2% to 54% after esophageal dilation. Other infectious complications reported after upper digestive endoscopy include: endocarditis, meningitis and/or brain abscesses and bacterial peritonitis[4,13,15,16].

The incidence of bacteremia after colonoscopy, with or without biopsy and polypectomy, ranges from 0% to 25% and from 0% to 1% after rectosigmoidoscopy. Other complications include: appendicitis, bacterial peritonitis, endocarditis, and septicemia[13-18].

Our cohort study of 62,088 gastroendoscopic procedures revealed a total incidence of AE of 0.200% for colonoscopy and 0.080% for digestive endoscopy, with an overall AE rate of 0.100% (68/62,088). These data are lower than those reported in the literature described above, which reports a total incidence of bacteremia of less than 8% for upper digestive endoscopy and a range from 0 to 25% for colonoscopy.

When we compare the indicators identified in this study with the literature data, questions arise about the methodology used in the referred studies, type of population studied and follow-up of these patients after endoscopic procedures. These are important questions for the purpose of evaluation and comparisons between international indicators and our indicators.

The patients who undergo endoscopic procedures in the service studied here are monitored after the examinations, as they are oriented verbally and with the help of a booklet to report any signs and symptoms present after discharge. Additionally, the endoscopists work in the institution and report the AE identified in their patients. In this sense, the indicators come from an AE notification surveillance system after the procedures. Despite its arguably "passive" methodology, it enables data collection in the follow-up after endoscopic examinations. This type of information is missing in international studies, which also hinders the comparison of the indicators of this study with those referred to in literature.

The most frequent AE identified in our study were bacteremia (0.030%), mucosal laceration (0.010%), abdominal distension and pain (0.010%) and intestinal perforation after colonoscopy (0.010%). Bacteremia is the most common AE, and this indicator is also lower than the post-gastrointestinal endoscopy bacteremia data reported in the world literature ("less than 8%"[4] and range from 0 to 25%[12]).

The risk of complications and severe AE following colonoscopy has important implications for the benefits of the colorectal cancer screening program[19]. A meta-analysis study of 1,074 papers identified an intestinal perforation rate after colonoscopy of 0.5/1,000 and of 0.8/1,000 after colonoscopy with polypectomy[20]. Another study that evaluated the incidence of complications within 30 days after colonoscopies with 21,375 patients found an intestinal perforation rate of 0.2/1,000 examinations[21]. Our study identified a total incidence of AE in colonoscopy of 0.2/21,827 examinations. This indicates a low incidence of complications related to this procedure, which is so important for colorectal cancer surveillance and prevention.

The ratio of intestinal perforation *versus* colonoscopic procedures is also the subject of some studies. The literature records the ratio of one intestinal perforation for every 11,000 colonoscopic procedures[13]. Our research identified a perforation ratio of one for every 7,275 colonoscopic procedures performed, an indicator also lower than that described in the literature. It reveals a low ratio of colonoscopy-related intestinal perforation in the researched service.

When analyzing all the AE identified in this study, we observed that only bacteremia can be associated with failure in endoscopic equipment reprocessing. Considering that the incidence of bacteremia identified in this service is much lower than the literature data, we find this indicator also an indirect parameter of the quality of the high level cleaning and disinfection processes adopted there. This is relevant because effective endoscope reprocessing is key to endoscopic patient safety[22,23].

CONCLUSIONS

This study identified the incidence of AE related to endoscopic procedures in a Brazilian service, thus contributing to the production of an AE database in the area of Brazilian gastrointestinal endoscopy.

Despite the robustness of the data, this study has a limitation, since the AE identified here originate from passive patient reporting and endoscopists' information, which may contribute to the omission of other AE, and thus not reflect the actual AE

rate of this service. Ideally, there should be an active epidemiological surveillance system to search for these events after any procedure performed on each patient.

The epidemiological indicators of AE presented here are lower than the endoscopy AE indicators found in international literature. Despite the aforesaid difficulty in comparing these data, the incidence of 0.100% of AE identified here is much lower than what is found in international literature, as well as the incidence of the identified types of AE. This suggests the level of risk control, quality and safety of the endoscopy service under study.

These findings encourage continued efforts to maintain the safe objectives of the endoscopic practices of the presented service.

REFERENCES

1. FunK SE, Reaven NL. High-level endoscope disinfection processes in emerging economies: financial impact of manual process versus automated endoscope reprocessing. J Hosp Infect. 2014:86(4):250-4. https://doi.org/10.1016/j.jhin.2014.01.007
2. Spinzi G, Fasoli R, Centenaro R, Mindi G. Reprocessing in digestive endoscopy units in Lombardy: results of regional survey. Dig Liver Dis. 2008;40(11):890-6. https://doi.org/10.1016/j.dld.2008.02.017
3. Wuh SB, Shen B. Health care-associated transmission of hepatitis B and C in endoscopy units. Clin Liver Dis. 2010;14(1):61-8. https://doi.org/10.1016/j.cld.2009.11.012
4. Heeg P. Reprocessing endoscopes: material recomendatios with a special emphasis on cleaning: the german perspective. J Hosp Infect. 2004;56(Supl 2):23-6. https://doi.org/10.1016/j.jhin.2003.12.034
5. Muscarella LF. Risk of transmission of cabapenem-resistant Enterobacteriaceae and related "superbugs" during gastrointestinal endoscopy. World J Gastrointest Endosc. 2014;6(10):457-74. https://doi.org/10.4253/wjge.v6.i10.457
6. Brock AS, Steed LL, Freeman J, Garry B, Malpas P, Cotton P. Endoscope storage time: assessment of microbial colonization up to 21 days after reprocessing. Gastrointest Endosc. 2015;81(5):1150-4. https://doi.org/10.1016/j.gie.2014.09.053
7. Lee DH, Kim DB, Kim HY, Baek HS, Know SY, Lee HL el al. Increasing potential risk of contamination from repetitive use of endoscope. Am J Infect Control. 2015;43(5):13-17. https://doi.org/10.1016/j.ajic.2015.01.017
8. Hervé RC, Keevll CW. Persistent residual contamination in endoscope channels: a fluorescence epimicroscopy study. Endoscopy. 2016;48(7):609-16. https://doi.org/10.1055/s-0042-105744
9. Snyder GM, Wright SB, Smithey A, Mizrahi M, Sheppard M, Hirsch EH et al. Randomized comparison of 3 high-level disinfection and sterilization procedures for duodenoscopes. Gastroenterology 2017;153(4):1018-25. https://doi.org/10.1053/j.gastro.2017.06.052
10. Brandabur JJ, Leggett JE, Wang L, Bartles RL, Baxter L, Diaz GA et al. Surveillance of guidelines practices for duodenoscope and linear echoendoscope reprocessing in a large healthcare system. Gastrointest Endosc. 2016;84(3):392-9. https://doi.org/10.1016/j.gie.2016.03.1480.
11. Muscarella LF. Evaluation of the risk of transmission of bacterial biofilms and *Clostridium difficile* during gastrointestinal endoscopy. Gastroenterol Nurs. 2010;33(1):28-35. https://doi.org/10.1097/SGA.0b013e3181cd199f
12. ASGE Standards of Practice Committee, Ben-Menachem T, Decker GA, Early DS, Evans J, Fanelli RD et al. Guideline adverse events of upper GI endoscopy. Gastrointest Endosc. 2012;76(4):707-18. https://doi.org/10.1016/j.gie.2012.03.252
13. Heudorf V, Exner M. German guidelines for reprocessing endoscopes and endoscopy accessories: guidelines compliance in Frankfurt / Main, German. J Hosp Infect. 2006;64(1):69-75. https://doi.org/10.1016/j.jhin.2006.04.014
14. Kovaleva J, Peters FTM, Mei HC, Gedener JE. Transmission of infection by flexible gastrointestinal endoscopy and bronchoscopy. Clin Microbiol Rev. 2013;26(2):231-54. https://doi.org/10.1128/CMR.00085-12
15. ASGE Quality Assurance In Endoscopy Committee, Peterson BT, Chennat J, Cohen J, Cotton PB, Greenwad DA, et al. Multisociety guidelines on reprocessing flexible gastrointestinal endoscopes: 2011. Gastrointest Endosc. 73;(6):1075-84. https://doi.org/10.1016/j.gie.2011.03.1183
16. Hubner N, Assadian O, Polderack R, Duty O, Schwarzer H et al. Endowashers: an overlooked risk for possible pos-endoscopic infection. GMS Krankenhhyg Interdiszip. 2011;6(1). https://doi.org/10.3205/dgkh000170
17. Muscarella LF. Inconsistencies in endoscope-reprocessing and infection control guidelines: the importance of endoscopy drying. Am J Gastroenterol. 2006;101(9):2147-54. https://doi.org/10.1111/j.1572-0241.2006.00712.x
18. Coser RB, Dauo MB, Martins LCP, Alvarenga GF, Crusz CA et al. Complicações em colonoscopia: experiência uni-institucional com 8.968 pacientes. Rev Col Bras Cir. 2018;45(4). https://doi.org/10.1590/0100-6991e-20181858
19. Reumkeus A, Rondagh EJ, Bakker CM, Winkens B, Masclee AA, Sanduleanus S et al. Post-colonoscopy complications: a systematic review, time trends and meta-analysis of population-based studies. Am J Gastroenterol. 2016;111(8):1092-101. https://doi.org/10.1038/ajg.2016.234

20. Ko CW, Riffles S, Michaelis L, Morris C, Holub J, Shapiro JA, Ciol MA et al. Serious complications within 30 days of screening and surveillance colonoscopy are uncommon. Clin Gastroenterol Hepatol. 2010;8(2):166-73. https://doi.org/10.1016/j.cgh.2009.10.007

21. Weber DJ, Rutala WA. Assessing the risk of disease transmission to patients when there is failure to follow recommended disinfection and sterilization guidelines. Am J Infect Control. 2013;41(5 Suppl):S67-71. https://doi.org/10.1016/j.ajic.2012.10.031

22. Jung M, Beilenhoff U. Hygiene: the looming achilles hell in endoscopy. Visc Med. 2016;32(1):21-8. https://doi.org/10.1159/000443626

Conflict of Interest

Authors have no potential conflict of interest to declare, related to this study's political or financial peers and institutions.