Adaptation and application of the surgical safety checklist in endoscopy procedures of the digestive system

Adaptação e aplicação do checklist de cirurgia segura em procedimentos endoscópicos do sistema digestório

Adaptación y aplicación de la lista de verificación de cirugía segura en procedimientos endoscópicos del sistema digestivo

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ABSTRACT: Objective: To adapt, validate, and apply the Surgical Safety Checklist, proposed by the World Health Organization (WHO), for use in endoscopy procedures of the digestive system. **Method:** This is a methodological, field-based, quantitative study conducted at an endoscopy center in Vale do Paraíba, on the outskirts of São Paulo, in three phases: adaptation of the WHO's Surgical Safety Checklist for endoscopy procedures, validation by a group of seven expert judges, and application to 59 patients undergoing endoscopy and colonoscopy procedures. **Results:** The judges' level of agreement was above 80% on all analyzed items from the adapted checklist, on a 4-point Likert scale, regarding content, structure, presentation, and relevance. When applied in 59 endoscopy procedures (upper approach: endoscopy; and lower approach: colonoscopy), it demonstrated excellent applicability and adherence at the three moments (sign in/before, timeout/during, and sign out/after the procedure). **Conclusion:** The adapted checklist, titled Patient Safety Checklist for Endoscopy Procedures, was developed, validated, and specifically applied to endoscopy procedures. It is of paramount importance for patient safety and offers benefits to the multidisciplinary team and the institutions where these interventions take place.
Keywords: Checklist. Patient Safety. Diagnostic Techniques and Procedures. Endoscopy. Colonoscopy.

RESUMO: Objetivo: Adaptar, validar e aplicar o *Checklist* de Cirurgia Segura, proposto pela Organização Mundial da Saúde (OMS), para utilizar em procedimentos endoscópicos do sistema digestório. **Método:** Estudo metodológico, de campo, quantitativo, realizado em um centro de endoscopia do Vale do Paraíba, interior de São Paulo, em três fases: adaptação do *Checklist* de Cirurgia Segura da OMS para procedimentos endoscópicos, validação por um grupo de sete juízes especialistas e aplicação a 59 pacientes submetidos a procedimentos de endoscopia e colonoscopia. **Resultados:** O nível de concordância dos juízes foi acima de 80% em todos os itens analisados do *checklist* adaptado, numa escala do tipo Likert de 4 pontos, quanto a conteúdo, estrutura, apresentação e relevância. Aplicado em 59 procedimentos de endoscopia (via alta: endoscopia e via baixa: colonoscopia), revelou ótima aplicabilidade e adesão nos três momentos (*sign in*/antes, *timeout*/durante e *sign out*/depois do procedimento). **Conclusão:** O *cheklist* adaptado foi construído, denominado *Checklist* de Segurança do Paciente em Procedimentos Endoscópicos, validado e aplicado especificamente em procedimentos endoscópicos, sendo de suma importância para a segurança dos pacientes e oferecendo benefícios à equipe multiprofissional e às instituições onde ocorrem essas intervenções.
Palavras-chave: Lista de checagem. Segurança do paciente. Técnicas e procedimentos diagnósticos. Endoscopia. Colonoscopia.

RESUMEN: Objetivo: Adaptar, validar y aplicar la Lista de Verificación (Checklist) de Cirugía Segura, propuesta por la Organización Mundial de la Salud (OMS), para su uso en procedimientos endoscópicos del sistema digestivo. **Método:** Estudio metodológico, de campo y cuantitativo, realizado en un centro de endoscopia de Vale do Paraíba, interior de São Paulo, en tres fases: adaptación de la Lista de Verificación de Cirugía Segura de la OMS para procedimientos endoscópicos; validación por un grupo de siete jueces expertos; y aplicación a 59 pacientes sometidos a procedimientos de endoscopia

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Received: 11/11/2025. Accepted: 01/08/2026
https://doi.org/10.5327/Z1414-44251065

y colonoscopia. **Resultados:** El nivel de concordancia de los jueces fue superior al 80% en todos los ítems analizados de la lista adaptada, mediante una escala de tipo Likert de 4 puntos, en cuanto a contenido, estructura, presentación y relevancia. Su aplicación en 59 procedimientos de endoscopia (vía alta: endoscopia y vía baja: colonoscopia) reveló una excelente aplicabilidad y adherencia en los tres momentos (**sign in**/antes, **timeout**/durante y **sign out**/después del procedimiento). **Conclusión:** Se construyó la lista adaptada, denominada **Lista de Verificación de Seguridad del Paciente en Procedimientos Endoscópicos**, la cual fue validada y aplicada específicamente en el área. Esta herramienta resulta de suma importancia para la seguridad de los pacientes y ofrece beneficios tanto al equipo multiprofesional como a las instituciones donde se realizan estas intervenciones.

Palabras clave: Lista de Verificación. Seguridad del Paciente. Técnicas y Procedimientos Diagnósticos. Endoscopía. Colonoscopía.

INTRODUCTION

Many efforts are made to promote patient safety in healthcare institutions, and the complexity of this sector contributes to the occurrence of adverse events. In 1999, a report entitled "To Err Is Human — Building a Safer Health System" was published in the United States of America (USA). Based on the collected data, it was estimated that failures contributed to the deaths of 180 thousand patients that year[1].

In the healthcare system, providing care that does not harm patients should promote safe processes, enabling to identify and establish barriers to prevent potential failures[1].

In Brazil, Hospital Accreditation began in 1999 and was a turning point in the evaluation of quality in health services, establishing standards and requirements to be developed by institutions in order to guarantee, primarily, patient safety, as well as efficient structure and management[2].

In 2004, the World Health Organization (WHO) launched the World Alliance for Patient Safety, aiming at raising awareness and promoting strategies to improve patient safety. With the goal of reducing harm and establishing safety standards for surgical patients, in 2007 and 2008, the "safe surgery saves lives" was implemented, with the creation of the Surgical Safety Checklist[3].

At the time, a group of experts developed such a checklist, composed of three moments: sign in/identification: before induction of anesthesia; timeout/confirmation: before skin incision; and sign out/registration: at the end of surgery, before patient leaves the operating room (OR)[3].

In Brazil, after the creation of the National Patient Safety Program (*Programa Nacional de Segurança do Paciente* – PNSP), through the NOTIVISA portal, the computerized system of the Brazilian Health Regulatory Agency (ANVISA), notifications of serious adverse events (SAEs) became mandatory in 2013. Following event notification, ANVISA monitors the occurrences and their respective outcomes[4].

Healthcare institutions must ensure patient safety in all procedures, not only in surgeries performed in the surgical center (SC), but also in outpatient procedures, such as those undergoing examinations using flexible or rigid endoscopes[5,6].

Endoscopy procedures are considered critical; yet, there is a lack of indicators to measure the quality of the provided care. In 2004, the first scale to evaluate endoscopy units through scoring was developed in the United Kingdom, reducing waiting times and identifying service gaps. Patients were more satisfied and there was a decrease in adverse events, in such a way that its use was adopted in other European countries and in Canada[7].

In 2009, the Standards for Evaluation and Quality Assurance of Digestive Endoscopy were published in Portugal, according to which there is a recommendation to evaluate the quality of endoscopy procedures in three moments: before, during, and after the examination. Important indicators in the period preceding the examination were described: indication, informed consent, clinical history and risk stratification, antibiotic prophylaxis, examination readiness, sedation and anticoagulation strategy[8].

Quality indicators at the time of examination include photographic documentation, patient monitoring, medication, and drugs used to reverse sedation. Post-examination quality indicators are discharge from endoscopy unit, patient guidance, specimen follow-up for anatomopathological examination, examination report, report of complications, patient satisfaction, communication of the performed examination report, and need for anticoagulation[8].

In Brazil, ANVISA Board Resolution (*Resolução da Diretoria Colegiada* – RDC) No. 6, of March 10, 2013, "Provides for the Good Operating Practices requirements for endoscopy services with access to the body through exclusively natural orifices." In the aforementioned resolution, the standards and actions that an endoscopy department must follow to ensure quality and safety in the services performed are described[6].

Every endoscopy service must keep a daily record of the procedures performed, containing data on patients and professionals as well as equipment identification. The patient's medical record is a requirement that must be complied with. The recording of adverse events and patient support measures is of utmost importance, as is the recording of all controlled medications and the traceability of materials and equipment used in examinations[6].

RDC No. 6/2013 is of paramount importance for endoscopy services, as it provides specific recommendations for quality and safety in care; preventive maintenance of equipment; infection control of endoscopy procedures; processing of endoscopy materials and equipment; support for emergency care; means for patient transfer in case of incidents or complications; and training of professionals working in the endoscopy room[6].

Also described by the Portuguese Society of Digestive Endoscopy (*Sociedade Portuguesa de Endoscopia Digestiva* – SPED), informed consent is a mandatory practice, and must be obtained and documented before sedation or analgesia, except in emergency situations. All complications, from the most common to the most serious, should be described in this document, including perforation, bleeding, and complications related to sedation and/or anesthesia[7].

The examination should only be performed with the presence of a companion, and a nursing consultation is recommended before the procedure to assess the patient's physical and psychological conditions, their understanding capacity, to provide guidance on preparation, and to promote user embracement[9].

Information for preparing for upper gastrointestinal endoscopy (endoscopy) and lower gastrointestinal endoscopy (colonoscopy) procedures should be clear, especially regarding bowel preparation. Inadequate bowel preparation is a major impediment to colonoscopy, causing patient anxiety, rescheduling of the examination, re-exposure to sedatives, and risks inherent in the procedure[7].

Post-endoscopy follow-up should take place in the post-anesthesia care unit, maintaining control of vital signs through monitoring and, if necessary, carrying out actions according to institutional protocols, recording the procedures performed, and discharging the patient only after careful assessment of their level of consciousness and motor activity and in the presence of a companion[10].

However, in many healthcare services, there is underreporting of adverse events, and the endoscopy sector is no different. This fact makes it difficult to study and analyze events that may result in errors and harm to patients. Given this scenario, the need arose to develop, validate, and apply a surgical safety checklist specific to endoscopy procedures via the upper or lower approaches.

OBJECTIVES

Adapt the WHO's Surgical Safety Checklist for use in endoscopy procedures of the digestive system;

Validate the Surgical Safety Checklist through a group of judges experts in endoscopy;

Apply the adapted checklist in an endoscopy center located in Vale do Paraíba, on the outskirts of the state of São Paulo, Brazil.

METHODS

Ethical aspects

For the study to be carried out, the project was approved by the clinic's legal representative and the managers of the involved areas. After obtaining the necessary authorizations, it was submitted for review and approval by the Research Project Management System and the Research Ethics Committee, via Plataforma Brasil (CAAE 1350.1219.6.0000.0071 and Opinion No. 3.352.290), in accordance with the ethical standards and precepts established in Resolution No. 466/2012 of the National Health Council.

The Informed Consent Form was applied to the judges who validated the adapted checklist (phase 2 of the research) and to the patients eligible to compose the sample (phase 3 of the research).

Study design

This is a mixed-methods (methodological and field) prospective study with quantitative data analysis, carried out in three phases: adaptation of the Surgical Safety Checklist, validation of the checklist by a panel of judges, and application of the adapted checklist at an endoscopy center.

Study location

The study was performed at an endoscopy clinic located in the city of Taubaté, in Vale do Paraíba region, on the

outskirts of the state of São Paulo, Brazil. In the 900-m² clinic, an average of 3 thousand multidisciplinary appointments are carried out per month, comprising 14 specialties, including psychotherapy, nutrition, and respiratory physiotherapy. The team consists of 23 employees, three interns, two temporary workers, and 36 physicians.

The focus is on the specialty of diseases of the digestive system; the patient is seen and referred to surgery at partner hospitals; a large proportion of the surgeries are bariatric. To assist in diagnoses, an average of 400 upper gastrointestinal endoscopies (endoscopies), lower gastrointestinal endoscopies (colonoscopies), esophageal manometry, esophageal pH monitoring, bioimpedance analysis, fine-needle aspiration biopsy (FNAB), hydrogen breath test, and exercise stress test are performed.

The clinic holds international certification from the Surgical Review Corporation (SRC), and its chief executive officer (CEO) has earned the Surgeon of Excellence seal. In October 2017, it received level 1 certification from the National Accreditation Organization (*Organização Nacional de Acreditação* – ONA), being the first in this segment to achieve such certification in the Vale do Paraíba region.

Instruments and operational procedures for data collection

In this study, three instruments were used: the first was adapted; the second, used for validation; and the third was validated and applied in practice. The instrument for validating the checklist by the judges consists of characterization (judge number, age, sex, education background, time since graduation, and academic degree) and evaluation of the checklist topics regarding content, structure and presentation, relevance, and suggestions.

The second instrument was used in the third phase of data collection, with patients undergoing endoscopy, after the adaptation and validation of the checklist by the judges, and consisted of two parts: characterization of the sample (sex, age, comorbidities, medication use, previous procedures, type of anesthesia, procedure performed, and duration of the procedure) and the adapted checklist, which consists of sign in, timeout, and sign out, following recommendations of the WHO (Appendix).

Data collection took place in three phases:

- Phase 1. Adaptation of the Surgical Safety Checklist, which included the creation of the checklist according to the model proposed by the WHO, in addition to a literature review on the subject, considering the researcher's participation, contributing with experience in assisting patients undergoing endoscopy and bariatric surgery. The adapted checklist was developed following the WHO's own recommendations: clarity, theoretical basis for the steps, and ease of understanding.
- Phase 2. Validation of the checklist by a panel of expert judges. The judges were responsible for validating the items according to their degree of importance and relevance, that is, by analyzing the content of the checklist and proposing adjustments they deemed necessary to the items. The panel of judges consisted of seven experts: two nurses with at least two years of experience in endoscopy, two gastroenterologists, two anesthesiologists, and a nurse specializing in patient quality and safety. The selection of an odd number of expert professionals aimed to provide a tie-breaking criterion in the evaluations of each category. The minimum level of agreement was 80% for each of the items evaluated. A four-point Likert scale was used: 1 (inadequate), 2 (partially adequate), 3 (adequate), and 4 (totally adequate). The judges were initially approached via email, with a description of the project, its purpose, and its importance. Upon agreeing to participate in the study and signing the Informed Consent Form, each judge returned a copy via email in PDF format and the original document via mail, using the National Express Delivery Service (*Serviço de Encomenda Expressa Nacional* – Sedex). After the judges' evaluation, the proposed suggestions were incorporated into the checklist.
- Phase 3. Application of the adapted checklist (Appendix). Once the adapted checklist, titled "Patient Safety Checklist for Endoscopy Procedures," was validated, the instrument was applied by the researcher at the aforementioned endoscopy center to patients undergoing elective endoscopy and colonoscopy who agreed to participate in the research by reading and signing the Informed Consent Form.

Sample

The sample from the third phase of the research consisted of 59 patients who underwent endoscopy and colonoscopy in December 2019. The inclusion criteria were: adult patients (≥18 years) of both sexes who underwent elective endoscopies

and colonoscopies; and the exclusion criterion was: patients who underwent examinations on an emergency basis.

Statistical procedures

The statistical analysis of the data was performed by professionals, with the checklist validation calculations being carried out by expert judges, considering an 80% agreement level for each of the evaluated items.

Data on patients' characterization were described using absolute frequencies and percentages for categorical variables, or means and standard deviations or medians and quartiles, as well as minimum and maximum values, for numerical variables. The distributions of the numerical variables will be assessed using histograms and boxplots.

The profile of adherence to the checklist was described by procedure type (endoscopy or colonoscopy) in each phase (sign in, timeout, and sign out), and data were analyzed using the SPSS program. The results were presented in tables and graphs, in absolute and percentage numbers, and were expressed as mean and standard deviation (maximum, minimum), considering a 5% significance level.

RESULTS

Adapting the Surgical Safety Checklist for endoscopy procedures

The checklist was adapted to the specific context of the endoscopy center where the research was conducted, requiring the changes shown in Chart 1.

In addition to the adjustments made to the three stages of the checklist, the following items were included:

- Patient must have a companion; if not accompanied, the examination will be suspended;
- Jewelry and prostheses should be removed;
- Preparation should be properly performed (fasting and/or bowel preparation);
- Cardiologist evaluation (>65 years);

Chart 1. Comparison between the Surgical Safety Checklist proposed by the World Health Organization and the checklist adapted for endoscopy procedures.

Surgical Safety Checklist (WHO)	Patient Safety Checklist for Endoscopy Procedures (adapted by Belania Luz and Rachel Carvalho)
Before induction of anesthesia	Before the procedure
Identity	Patient's name and date of birth (identification label)
Surgical site	Excluded (does not apply to endoscopy and colonoscopy)
Procedure	Exam to be performed checked
Consent	Informed Consent Form signed
Designated site / not applicable	Excluded (does not apply to endoscopy and colonoscopy)
Pulse oximeter in the patient and working	Excluded from this moment Included as pulse oximetry monitoring at the time (during the procedure)
Difficult airway / risk of aspiration	Excluded (does not apply to endoscopy and colonoscopy)
Risk of blood loss	Excluded (does not apply to endoscopy and colonoscopy)
Before skin incision	During the endoscopy procedure
Before patient leaves operating room	Post-endoscopy
Name of the procedure registered	Complete account in the medical record
Instrument, dressing, and needle counts are correct / not applicable	Excluded (does not apply to endoscopy and colonoscopy)
Sample for anatomopathological examination (patient's name included)	Biopsy vial removed and stored
Equipment problem that must be resolved	Excluded
Surgeon, anesthesiologist, and nursing team review essential concerns for patient recovery and management	Excluded

WHO: World Health Organization; Endoscopy: upper gastrointestinal endoscopy; Colonoscopy: lower gastrointestinal endoscopy.

- Screening for at-risk patients, according to protocol (colonoscopy ≥65 years);
- Assessment of history in the medical record and together with the patient;
- Aspirated medication, according to institutional protocol, with warning label on the syringe (high-alert medication);
- Venous access placement, as per examination.

Several warning signs were discussed, highlighted as follows:

- Beware:
  - Organized room and material replenishing;
  - BP (SBP ≥200 mmHg or DBP ≥100 mmHg);
  - Axillary temperature (Tax ≥37.8 °C);
  - Respiratory rate (dyspnea);
  - All equipment tested.

All items related to the second stage (timeout/before skin incision) were excluded and adapted to:

- Monitoring with pulse oximetry;
- Supplementation with an oxygen catheter at 3 L/min;
- Identification on biopsy vial;
- Checking inflation and aspiration of the endoscope;
- Expected critical events:
  - Ineffective breathing pattern (obese individuals);
  - Nausea and vomiting (patient positioning);
  - Risk of falling when removing the patient from the gurney.

In the third stage (sign out), the following items were included:

- Monitoring of vital signs;
- Provide guidance on post-procedure care, explain it, and hand it out in writing, in the presence of the companion;
- Discharge guidance.

Judges' evaluation of the patient safety checklist in endoscopy procedures

The panel of judges consisted of seven experts: two nurses, two gastroenterologists, two anesthesiologists, and a nurse specializing in patient quality and safety. We selected professionals with employment relationships in centers and clinics and who are familiar with the reality found on the outskirts of the state, where patient safety is often intuitive and empirical.

There were four men and three women among the judges, aged between 37 and 70 years, two of whom had a Master's degree and one had a PhD, and they worked in the field of education; the others were specialists. The shortest time of experience with endoscopy of one of the judges was four years, and the time since graduation ranged from 10 to 40 years. Five specialists worked in small endoscopy centers in the Vale do Paraíba region, one worked in a small city in the state of Rio de Janeiro, and one in the city of Fortaleza (state of Ceará).

To evaluate the instrument, a four-point Likert scale was used, considering: 1 (inadequate), 2 (partially adequate), 3 (adequate), and 4 (totally adequate). The instrument was evaluated in terms of content, structure, presentation, and relevance. In Table 1, we present the results obtained from the judges' evaluation of each item. The judges agreed on all items, with the adequacy of the evaluated items exceeding 80%.

The seven judges assigned scores of 3 and 4 (adequate and totally adequate) to all items in each of the evaluated criteria. No scores of 1 or 2 (inadequate or partially adequate) were assigned by the judges; thus, agreement exceeded 80% on all evaluated items.

The judges made some suggestions regarding the descriptions of the analyzed items, which were promptly accepted, adding important information to the checklist:

- Jewelry and prostheses should be removed: they suggested adding the type of prosthesis:
  - Revised: jewelry and dental prostheses should be removed.
- Cardiologist evaluation (>65 years): they suggested including medical history and weight.
  - Revised: cardiologist evaluation (>65 years) or as needed (comorbidities, body mass index [BMI] equal to or greater than 35 kg/m^2).
- Screening for at-risk patients according to protocol (colonoscopy ≥65 years): they suggested adding "as needed."
  - Revised: screening for at-risk patients according to protocol (colonoscopy ≥65 years) or as needed (comorbidities, BMI equal to or greater than 35 kg/m^2, and special patients).

The sample consisted of 59 patients who underwent endoscopy and colonoscopy at the research's main clinic, the majority (64.4%) being women. The patients' ages ranged from 25 to 68 years, with a mean of 46 years and a standard deviation of 10 years; most (56.9%) had no comorbidities and used medications (51.7%), while the vast majority (91.4%) had previously undergone surgery. All patients were sedated and most of them (66.1%) underwent endoscopy (Table 2).

Table 1. Judges' evaluation of the checklist adapted for endoscopy procedures.

Judges' evaluation	Number	Percentage (%)
Content		
Information/content is consistent with the needs of the target audience.		
Inadequate	0	0.0
Partially adequate	0	0.0
Adequate	6	85.7
Totally adequate	1	14.3
Information/content is important for the safety of the target audience during endoscopy procedures.		
Inadequate	0	0.0
Partially adequate	0	0.0
Adequate	0	0.0
Totally adequate	7	100.0
The checklist assists in performing a safer procedure.		
Inadequate	0	0.0
Partially adequate	0	0.0
Adequate	0	0.0
Totally adequate	7	100.0
The checklist can be used for contributions to the scientific community.		
Inadequate	0	0.0
Partially adequate	0	0.0
Adequate	0	0.0
Totally adequate	7	100.0
The checklist meets the objectives of institutions that provide care to the target audience.		
Inadequate	0	0.0
Partially adequate	0	0.0
Adequate	0	0.0
Totally adequate	7	100.0
Structure and presentation		
The checklist is appropriate for the target audience.		
Inadequate	0	0.0
Partially adequate	0	0.0
Adequate	0	0.0
Totally adequate	7	100.0
The items are presented in a clear and objective way.		
Inadequate	0	0.0
Partially adequate	0	0.0
Adequate	1	14.3
Totally adequate	6	85.7
The information is scientifically accurate.		
Inadequate	0	0.0
Partially adequate	0	0.0
Adequate	1	14.3
Totally adequate	6	85.7

Continue...

Table 1. Continuation.

Judges' evaluation	Number	Percentage (%)
There is a logical sequence of the proposed items.		
Inadequate	0	0.0
Partially adequate	0	0.0
Adequate	1	14.3
Totally adequate	6	85.7
The items are well-structured in terms of agreement and spelling.		
Inadequate	0	0.0
Partially adequate	0	0.0
Adequate	1	14.3
Totally adequate	6	85.7
The writing style is consistent with the checklist's proposal.		
Inadequate	0	0.0
Partially adequate	0	0.0
Adequate	1	14.3
Totally adequate	6	85.7
Information is consistent.		
Inadequate	0	0.0
Partially adequate	0	0.0
Adequate	0	0.0
Totally adequate	7	100.0
The overall presentation is adequate.		
Inadequate	0	0.0
Partially adequate	0	0.0
Adequate	1	14.3
Totally adequate	6	85.7
Relevance		
It prioritizes key information for applying the checklist.		
Inadequate	0	0.0
Partially adequate	0	0.0
Adequate	1	14.3
Totally adequate	6	85.7
It allows the checklist to be applied in other contexts.		
Inadequate	0	0.0
Partially adequate	1	14.3
Adequate	0	0.0
Totally adequate	6	85.7
The content of the checklist is necessary for the safety of the target audience.		
Inadequate	0	0.0
Partially adequate	0	0.0
Adequate	1	14.3
Totally adequate	6	85.7
The checklist is suitable to be applied by professionals to the target audience.		
Inadequate	0	0.0
Partially adequate	0	0.0
Adequate	1	14.3
Totally adequate	6	85.7

Table 2. Characterization of patients who compose the sample.

Variable	n	%
Sex (n=59)		
Women	38	64.4
Men	21	35.6
Comorbidities (n=58)		
Yes	25	43.1
No	33	56.9
Use of medications (n=58)		
Yes	30	51.7
No	28	48.3
Previous surgeries (n=58)		
Yes	53	91.4
No	5	8.6
Type of anesthesia (n=59)		
Sedation	59	100.0
Procedure performed (n=59)		
Endoscopy	39	66.1
Colonoscopy	13	22.0
Endoscopy+colonoscopy	07	11.9
Age – years (n=59)		
Mean and standard deviation	46	10
Minimum and maximum	25	68
Median and interquartile range	46	16

Application and evaluation of the patient safety checklist in endoscopy procedures

The checklist adapted for endoscopy procedures has three application moments: before, during, and after the examination, respectively, sign in, timeout, and sign out.

Regarding the items applied before the examination, there was adherence to the checklist in most of the items analyzed for the three types of procedures (Table 3).

The items applied during the procedure/timeout (second moment of the checklist) also showed good adherence for all three types of procedures (Table 4).

All items applied after the procedure/sign out (third moment of the checklist) showed high adherence rates for all types of procedures (Table 5).

DISCUSSION

There are several studies on the adaptation and implementation of the Surgical Safety Checklist in hospitals, but its development and application aimed at guiding patient safety specifically for endoscopy procedures are still rare in the literature, especially when considering small centers and clinics.

The lack of notification is worrisome because we do not know for certain the extent of "errors" related to endoscopy procedures, as the culture of notification is still a paradigm to be broken, as well as the fact that health institutions should be prepared to deal with these notifications, as they often result in no positive changes[11].

Endoscopy procedures are invasive, allowing physicians to visualize organs and body cavities using an endoscope, whose purpose is diagnosis and therapeutic procedures[9].

Although endoscopy procedures under sedation are considered simple and safe, there are risks[12]. According to research, using the WHO's Surgical Safety Checklist is a practice that can help reduce errors, as it decreases reliance on memory and intuition, in addition to being low-cost for healthcare services[13].

Authors of studies conducted in Canada, the USA, and Asia demonstrated a decrease in complication rates, from 11 to 7, and in mortality in major surgeries, from 1.5 to 0.8, during the perioperative period since the implementation of the checklist[14]. In a study conducted in Colombia, the authors described a reduction in adverse events from 7.26 to 3.29 in a general hospital in the country[15].

Taking this into consideration, and based on a literature review and the specific characteristics of the endoscopy center where it was implemented, we decided to adapt and apply the Surgical Safety Checklist for use in gastrointestinal endoscopy procedures, considering it an instrument that helps professionals verify crucial points in the care process and contributes to minimizing risks in these procedures.

It is noteworthy that the WHO Surgical Safety Checklist is not intended to be comprehensive; therefore, the WHO encourages adaptation according to the needs and particularities of the health institution[5,16].

In the second phase of this research, the content of the adapted checklist was validated by seven judges. For the instrument to be validated, the described items required an 80% agreement from the judges, as considered in a study conducted by Universidade Estadual de Campinas. The authors indicate that if a study includes six or more judges, a concordance rate higher than 78 is recommended[16,17].

We did not find recommendations in the literature for an exact number of judges, which may vary depending on the study, but it is recommended that they be experts on the addressed topic[17,18] and for them to be in an odd number, in order for there to be a tiebreaker, if necessary.

Table 3. Rate of adherence to the checklist at the first moment (sign in/before the procedure).

Checklist items	Endoscopy		Colonoscopy		Endoscopy+colonoscopy	
	n	%	n	%	n	%
Patient is accompanied; if "No," the exam will be suspended (n=58).						
Yes	38	100.0	13	100.0	07	100.0
No	00	0.0	00	0.0	00	0.0
Does not apply	00	0.0	00	0.0	00	0.0
Jewelry and dental prostheses were removed.						
Yes	28	71.8	05	38.5	05	71.4
No	02	5.1	03	23.1	00	0.0
Does not apply	09	23.1	05	38.5	02	28.6
The patient's name and date of birth match those on the identification label.						
Yes	39	100.0	13	100.0	07	100.0
No	00	0.0	00	0.0	00	0.0
Does not apply	00	0.0	00	0.0	00	0.0
The exam to be performed was checked.						
Yes	39	100.0	13	100.0	07	100.0
No	00	0.0	00	0.0	00	0.0
Does not apply	00	0.0	00	0.0	00	0.0
Preparation was properly performed (fasting and/or bowel preparation).						
Yes	39	100.0	13	100.0	07	100.0
No	00	0.0	00	0.0	00	0.0
Does not apply	00	0.0	00	0.0	00	0.0
Cardiologist evaluation (>65 years or as needed – comorbidities, BMI equal to or greater than 35 kg/m^2)						
Yes	05	12.8	00	0.0	01	14.3
No	01	2.6	00	0.0	00	0.0
Does not apply	33	84.6	13	100.0	06	85.7
Screening for at-risk patients according to protocol (colonoscopy ≥65 years) or as needed (comorbidities, BMI equal to or greater than 35 kg/m^2, and special patients).						
Yes	04	10.3	00	0.0	01	14.3
No	00	0.0	00	0.0	01	14.3
Does not apply	35	89.7	13	100.0	05	71.4
Assessment of history in the medical record and together with the patient.						
Yes	38	97.4	13	100.0	07	100.0
No	00	0.0	00	0.0	00	0.0
Does not apply	01	2.6	00	0.0	00	0.0
High risk of falls (use of cane, claudication).						
Yes	05	12.8	00	0.0	01	14.3
No	21	53.8	09	69.2	04	57.1
Does not apply	13	33.3	04	30.8	02	28.6
Informed Consent Form signed.						
Yes	38	100.0	13	100.0	07	100.0
No	00	0.0	00	0.0	00	0.0
Does not apply	00	0.0	00	0.0	00	0.0

Continue...

Table 3. Continuation.

Checklist items	Endoscopy		Colonoscopy		Endoscopy+colonoscopy	
	n	%	n	%	n	%
Known allergy.						
Yes	11	28.2	03	23.1	04	57.1
No	28	71.8	09	69.2	03	42.9
Does not apply	00	0.0	01	7.7	00	0.0
Aspirated medication according to institutional protocol, with warning label on the syringe (high-alert medication).						
Yes	39	100.0	13	100.0	07	100.0
No	00	0.0	00	0.0	00	0.0
Does not apply	00	0.0	00	0.0	00	0.0
Venous access placement as per examination.						
Yes	39	100.0	13	100.0	07	100.0
No	00	0.0	00	0.0	00	0.0
Does not apply	00	0.0	00	0.0	00	0.0

Table 4. Rate of adherence to the checklist at the second moment (timeout/during the procedure).

Checklist items	Endoscopy		Colonoscopy		Endoscopy+colonoscopy	
	n	%	n	%	n	%
Monitoring with pulse oximetry.						
Yes	39	100.0	13	100.0	07	100.0
No	00	0.0	0	0.0	00	0.0
Does not apply	00	0.0	0	0.0	00	0.0
Supplementation with an oxygen catheter at 3 L/min.						
Yes	25	64.1	11	84.6	07	100.0
No	14	35.9	02	15.4	00	0.0
Does not apply	00	0.0	00	0.0	00	0.0
Identification on biopsy vial.						
Yes	39	100.0	13	100.0	07	100.0
No	00	0.0	00	0.0	00	0.0
Does not apply	00	0.0	00	0.0	00	0.0
Checking inflation and aspiration of the endoscope.						
Yes	38	97.4	13	100.0	07	100.0
No	01	2.6	00	0.0	00	0.0
Does not apply	00	0.0	00	0.0	00	0.0

In this research, we decided to send the material to the judges electronically, except for two of them, who preferred printed copies.

Regarding the return of the instrument, the deadline was 15 days, starting from the date the questionnaire was received. All the judges returned the material within the deadline stipulated by the researcher. Setting a deadline helps with project management and is recommended by researchers.

The adapted checklist, titled Patient Safety Checklist for Endoscopy Procedures, was validated in the first round. In the sum of the adequate and totally adequate scores, the statistical analysis proved that all items reached percentages above 80, demonstrating a high approval rate and making it possible to maintain the items and proceed to the third stage of the research.

The implementation of a new instrument, such as a checklist, involves changes throughout the care process and

Table 5. Rate of adherence to the checklist at the third moment (sign out/after the procedure).

Checklist item	Endoscopy		Colonoscopy		Endoscopy+colonoscopy	
	n	%	n	%	n	%
Complete account in the medical record.						
Yes	38	97.4	13	100.0	07	100.0
No	01	2.6	00	0.0	00	0.0
Does not apply	00	0.0	00	0.0	00	0.0
Biopsy vial removed and stored.						
Yes	39	100.0	13	100.0	07	100.0
No	00	0.0	00	0.0	00	0.0
Does not apply	00	0.0	00	0.0	00	0.0
Monitoring of vital signs.						
Yes	39	100.0	13	100.0	07	100.0
No	00	0.0	00	0.0	00	0.0
Does not apply	00	0.0	00	0.0	00	0.0
Provide guidance on post-procedure care, explain it, and hand it out in writing, in the presence of the companion;						
Yes	39	100.0	13	100.0	07	100.0
No	00	0.0	00	0.0	00	0.0
Does not apply	00	0.0	00	0.0	00	0.0
Discharge guidance.						
Yes	39	100.0	13	100.0	07	100.0
No	00	0.0	00	0.0	00	0.0
Does not apply	00	0.0	00	0.0	00	0.0

also in the behavior of the entire team involved[19,20]. However, the imposition of protocols by institutions is not enough; it is important that the professionals involved understand the magnitude of the process so that they accept the new instrument and introduce it into their daily practice[6].

The tool was applied by the researcher herself in 59 endoscopy procedures at the study's main clinic. Among the patients who comprised the sample, there was a prevalence of women, with an average age of 46 years, consistent with a study conducted by a Brazilian researcher in the state of Minas Gerais, who reported that 56.7% of the subjects in her research were women, possibly demonstrating a greater demand for health services by this population[21,22].

Considering the full completion of the Surgical Safety Checklist, a study in Canada stood out, whose authors showed a high level of adherence to its completion, with values close to 97[21,22].

It is worth emphasizing that periodic evaluation of adherence to the checklist is paramount, investing in actions focused on patient safety, and the availability of an organizational system capable of providing a structure to ensure the continuity of these processes.

Furthermore, we highlight the need to use indicators to observe the effectiveness of the checklist and, through this process, demonstrate the real importance of adhering to the Patient Safety Checklist for Endoscopy Procedures, which is characterized by the reduction of errors in endoscopy and colonoscopy procedures.

Study limitation

One limitation of this study is its application in a single endoscopy center; therefore, further studies on the applicability of the checklist here developed and validated can and should be conducted.

Contributions to the field

In the literature, little is found about care, events, and incidents in endoscopy procedures; nonetheless, this sector is worth of

attention like any other in terms of patient safety. Given the complexity of the activities carried out by the team responsible for providing care to patients undergoing endoscopy and colonoscopy, in this study, we aimed to make a significant contribution to ensuring that the endoscopy sector offers greater safety and quality to its target audience. Furthermore, the checklist here adapted, validated, and implemented can be applied in any endoscopy center, whether clinics or hospitals, where such interventions are made available.

CONCLUSION

The adaptation of the WHO's Surgical Safety Checklist was based on the literature, by verifying its applicability to gastrointestinal endoscopy procedures. Named as Patient Safety Checklist for Endoscopy Procedures, it was applied at three moments (sign in / before, timeout / during, and sign out / after the procedure), and items were modified with the exclusion, inclusion, and complementation of specific information for the procedures.

The adapted checklist was validated by seven expert judges (nurses, gastroenterologists, and anesthesiologists), whose degree of agreement was greater than 80 in each of the evaluated items, demonstrating the instrument's adequacy in terms of content, structure, presentation, and relevance.

The adapted checklist was applied to 59 patients undergoing endoscopy and colonoscopy, demonstrating a high degree of adherence at all three moments of the checklist (before, during, and after the procedure).

The adapted and validated checklist was applied at the endoscopy center where the study was carried out. It is suggested that this checklist be the subject of further studies after its implementation in the service, enabling the comparison of results before and after its application. This process may contribute to a reliable analysis of the results, demonstrating improvements in the quality of the provided service and in the safety of patients undergoing endoscopies and colonoscopies.

FUNDING

None.

CONFLICT OF INTERESTS

The authors declare there is no conflict of interests.

AUTHORS' CONTRIBUTION

RC: Project administration, Formal analysis, Methodology, Writing – review & editing, Supervision, Validation, Visualization. BRL: Conceptualization, Data curation, Investigation, Methodology, Writing – original draft, Validation.

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Appendix. Patient Safety Checklist for Endoscopy Procedures (Belania Luz and Rachel Carvalho)

Before the endoscopy procedure	Yes	No	Does not apply	Observation
Patient is accompanied (if "No," the exam will be suspended)				
Jewelry and dental prostheses removed				
The patient's name and date of birth match those on the identification label				
Exam to be performed checked				
Preparation was properly performed (fasting and/or bowel preparation)				
Cardiologist evaluation (≥65 years) or as needed (comorbidities, BMI equal to or greater than 35 kg/m^2)				
Screening for at-risk patients according to protocol (colonoscopy ≥ 65 years), or as needed (comorbidities, BMI equal to or greater than 35 kg/m^2, and special patients)				
Assessment of history in the medical record and together with the patient				
High risk of falls (use of cane, claudication)				
Informed Consent Form signed				
Known allergy				
Aspirated medication, according to institutional protocol, with warning label on the syringe (high-alert medication)				
Venous access placement as per examination.				
Beware: • Organized room and material replenishing • BP (SBP ≥ 200 mmHg or DBP ≥ 100 mmHg) • Axillary temperature (Tax ≥ 37.8ºC) • Respiratory rate (dyspnea) • All equipment tested.				
During the endoscopy procedure	**Yes**	**No**	**Does not apply**	**Observation**
Pulse oximetry monitoring				
Supplementation with an oxygen catheter at 3 L/min				
Identification on biopsy vial				
Checking the inflation and aspiration of the endoscope				
Expected critical events: • Ineffective breathing pattern (obese individuals) • Nausea, vomiting (patient positioning) • Risk of falling when removing the patient from the gurney				
After endoscopy procedure	**Yes**	**No**	**Does not apply**	**Observation**
Complete account in the medical record				
Biopsy vial removed and stored				
Monitoring of vital signs				
Provide guidance on post-procedure care, explain it, and hand it out in writing (in the presence of the companion)				
Discharge guidance				
Caption: BP: blood pressure; SBP: systolic blood pressure; DBP: diastolic blood pressure; Tax: axillary temperature.				