

Division of Coloproctology

“Bowel preparation in colonoscopy: Lactulose vs Polyethylene glycol, a randomized, double-blind, comparative clinical trial, multicenter study.”

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Content

1. Project summary/structured abstract

2. Introduction

3. Background

4. Problem statement

4.1 Research question

5. Justification

5.1 Transcendence

5.2 Magnitude

5.3 Feasibility

5.4 Vulnerability

6. Theoretical framework

6.1 Anatomy of the colon

6.2 History of colonoscopy

6.3 General information about colonoscopy

6.4 Indications for colonoscopy

6.5 Quality Indicators

6.6 Pre-procedure quality indicators

6.7 Intra-procedure quality indicators

6.8 Post-procedure quality indicators

6.9 Colon cancer detection

6.10 Surveillance in inflammatory bowel disease

6.11 Contraindications

6.12 Procedure description

6.13 Intestinal preparation

6.14 Bowel preparation scales

6.15 Ineffective preparation

6.16 Solution Type

6.17 Electrolyte imbalance due to bowel preparation 6.18

Time between end of preparation and start of procedure 6.19

Preparation regimen

6.20 Timing of colonoscopy after bowel preparation

6.21 Cecal intubation rate

6.22 Safety of colonoscopy

6.23 Complications of colonoscopy

6.23.1 Colon perforation

6.23.2 Bleeding

6.24 Post-polypectomy syndrome

6.25 Post-polypectomy syndrome

6.26 Position in colonoscopy

6.27 Technique Description

6.28 Description of the endoscopic

equipment 7. Goals

7.1 General objective

7.2 Specific objectives

8. Hypothesis

8.1 Alternative hypothesis

8.2 Alternative hypothesis

8.3 Null hypothesis

9. Methodology

9.1 Study population

9.2 Randomization

9.3 Study Design

9.4 Universe

9.5 Sample size

9.6 Sampling

9.7 Selection criteria

9.8 Exclusion criteria

9.9 Elimination criteria

9.10 Variables to be measured

9.10.1 Independent variable

9.11 Dependent variables

9.12 Description of the variables

9.13 Limitations

9.14 Observation and data collection techniques

9.15 Analysis of the results

9.16 Presentation of information

9.17 Resources needed

10. Ethical considerations

10.1 Study Risk

10.2 Adherence to ethical standards

10.3 Informed consent

10.4 Contributions and benefits to participants

10.5 Balance/ risk benefit

10.6 Bioethical principles

10.7 Confidentiality

10.8 Obtaining informed consent

10.9 Participant Selection

10.10 Benefits at the end of the study

10.11 Dissemination of results

10.12 Conflicts of interest

11. Resources, financing and feasibility

11.1 Feasibility

12. Biosafety aspects

13. Schedule of activities

14. Statistical analysis

15. Discussion

16. Conclusions

17. References

18. Attachments

16.1 Informed consent letter

16.2 Capture sheet

16.3 Bowel preparation instruction sheet

1. Project summary

Authors:

Introduction: Proper bowel preparation is essential before a colonoscopy, as it allows for a thorough examination of the entire mucosa. The ideal colon cleansing method should be quick, safe, and achieve adequate cleansing with minimal discomfort for the patient. Currently, a wide variety of colon cleansing products are available. Effective colon preparation depends, in part, on choosing the right product, but also on prior dietary restrictions. Given the importance and impact of this method, it is necessary to both optimize its efficiency and improve its quality, which is one of the objectives of this study protocol: to determine which bowel preparation method is most effective.

Aim: To compare bowel preparation with Lactulose vs Polyethylene Glycol, as the best agent for performing quality colonoscopies at the Fray Antonio Alcalde Civil Hospital and the Juan I. Menchaca Civil Hospital during a period from July 1, 2024 to July 31, 2025, and to demonstrate that Lactulose is a highly effective, safe agent, without negative interventions on the quality of the colonoscopy, with good tolerance and patient satisfaction, when used orally in bowel preparation prior to a colonoscopy study.

Materials and methods: A randomized, double-blind clinical trial will be conducted from August 1, 2024, to July 31, 2025, in patients scheduled for colonoscopy at the Endoscopy and Coloproctology Service of the Fray Antonio Alcalde Civil Hospital and the Juan I. Menchaca Civil Hospital. Upon arrival for their appointment, patients will be informed about the clinical trial and will sign an informed consent form to participate in the study. Once consent is signed, patients will be randomized to begin bowel preparation with either lactulose or polyethylene glycol. After the patient signs the informed consent form, the study will begin. The relevant information will be recorded by the student on the data collection sheet, which will then be uploaded to a shared document via a digital platform for cleaning and export to SPSS for statistical analysis and conclusions.

Group experience: The researchers have experience in performing colonoscopies,

having staff from the service attached.

Results analysis: The degree of cleanliness will be recorded and compared between both groups using intestinal preparation scales, as well as whether or not they were palatable.

Keywords: Bowel preparation, lactulose, polyethylene glycol, Boston scale, Aronchick scale, Ottawa scale, quality colonoscopy.

2. Introduction

Proper bowel preparation is essential before a colonoscopy, as it allows for a thorough examination of the entire mucosa. The ideal colon cleansing method should be quick, safe, and achieve adequate cleansing with minimal discomfort for the patient. Currently, a wide variety of colon cleansing products are available. Effective colon preparation depends, in part, on choosing the right product, but also on prior dietary restrictions. Understanding all these products, with their advantages and limitations, allows us to make a better selection for each patient. While their effectiveness may be comparable, the experience of the examiner, the patient's preferences, and the degree of adherence to the preparation instructions significantly influence the results.[\(1\)](#)

Applying scales to the preparation allows for proper exploration, increases the ability to detect polyps, reduces procedure time, and improves the cost-effectiveness ratio by inducing an increase in the interval between explorations.[\(1\)](#)

Preparation and pre-operative diet: There is increasing evidence that the interval between the last dose of preparation and the start of the colonoscopy is key to the quality of bowel cleansing. The ESGE recommends that this interval should not exceed 4 hours, while the expert consensus recommends that it should be 3–8 hours, regardless of the preparation regimen.[\(2\)](#)

In general, a low-residue diet is better tolerated than a clear liquid diet and contributes to greater colon cleansing efficacy. There is insufficient evidence to recommend a specific diet and its duration prior to preparation. The same applies to the use of prokinetics and simethicone, although the latter is recommended with a low level of evidence by the ESGE.[\(2\)](#)

Osmotic agents: These products work by increasing water retention in the colon or by stimulating its secretion. Of all of them, polyethylene glycol (PEG)-based solutions are the most commonly used. They are metabolically inert, non-absorbable substances (PEG) or hyperosmolar salts (sodium phosphate, magnesium citrate, lactulose, mannitol).[\(1\)](#)

The latest clinical guidelines from the European Society of Gastrointestinal Endoscopy (ESGE) and the expert consensus recommend the systematic use of validated scales such as Aronchik (Aronchick Bowel Preparation Score) [ABPS], Ottawa (OBPS)²⁴, Boston (BBPS), and Harefield, without favoring any one of them, even though each has advantages and disadvantages, some of which are mentioned below.⁽³⁾

The colonoscopy preparation process begins with the initial visit. Adequate time should be invested in obtaining a thorough medical history, identifying patients at risk for inadequate preparation and/or poor adherence, and dedicating sufficient effort to instructing the patient using available personnel and tools. Emphasis should be placed on the primary objective of colonoscopy preparation: that effectiveness in detecting premalignant lesions should be the priority. To ensure good quality control, it is important to report the quality of preparation using validated scales, demonstrating knowledge and proper application. Despite all these measures, and even when using the most effective compounds and dosages, up to 20% of individuals may present with inadequate preparation. Therefore, it is crucial to identify risk groups, establish appropriate patient contact, provide precise instructions, evaluate the best preparation method, score it, and implement it. standardization.⁽²⁾

3. Background

Colonoscopy plays a crucial role in the screening and treatment of colorectal cancer. It is an optimal procedure for identifying precancerous lesions, polyps, and is recommended for screening individuals with risk factors, such as a family history of polyps or cancer.⁽¹⁾ The advent of colonoscopy began with the development of a primitive endoscope by Philipp Bozzini, who is considered the father of endoscopy. The device consisted of two parts: a hollow part from which light was emitted and reflected using a fixed candle and mirror, and a mechanical piece designed to adapt to the body cavity that needed to be examined, for example, the ear, bladder, and urethra.

Bowel preparation is a crucial aspect of colonoscopy due to its direct impact on the quality of the procedure. Many patients find bowel preparation the most uncomfortable part of the examination, so it must be ensured that it is safe, highly efficient, reliable, convenient, and tolerable enough to prevent patients from failing to complete it or wishing to undergo future procedures, associating this with the unpleasant taste of the agents used and the adverse events that occur. Due to the

inconvenience reported by patients in completing the preparation, studies have been conducted on the effectiveness of dividing the dose into several administrations, but these have not demonstrated any changes in the effectiveness of the preparation itself, only an improvement in patient satisfaction.

The type of bowel preparation, the divided-dose regimen, a low-fiber diet, comorbidities, concomitant medications, hospitalization, and advanced age have all been found to affect the quality of bowel cleansing. Some of these variables, such as the type of solution, the preparation regimen, and the diet, are modifiable risk factors. In this regard, recent scientific advances have led to the introduction of new and effective bowel cleansing solutions and have reinforced the importance of specific preparation regimens.

This project aims to observe both intestinal preparations (polyethylene glycol and lactulose) as part of the preparation prior to colonoscopy, and to identify the side effects. such as nausea, vomiting, flatulence, cramps and abdominal distension mainly, patient experience, palatability, as well as grading the level of preparation once the colonoscopy has been performed

4. Problem statement

Colonoscopy is commonly used as a minimally invasive procedure in the diagnosis and treatment of various colon conditions. It typically allows for detailed visualization of the entire colon mucosa and the distal portion of the terminal ileum. Optimal bowel preparation is crucial for the success of a colonoscopy. Poor or inadequate preparation is associated with diagnostic errors or delays, leading to unfavorable results. Furthermore, inadequate preparation can negatively impact the efficiency of the colonoscopy, prolong the procedure time, decrease the rate of high-quality colonoscopies, and increase both procedural and hospital costs.

Studies have linked poor preparation to a significant decrease in the detection rate of adenomas, knowing that colonoscopy is the screening method of choice for the early detection of colorectal carcinoma.

To improve the benefits of colonoscopy, quality management is essential. using indicators such as the adenoma detection rate (ADR), cecal intubation rate, withdrawal time, and bowel preparation level. The ADR is recognized as the most important quality indicator globally due to strong evidence that improving the ADR reduces the risks of post-colonoscopy colorectal cancer (PCCRC), advanced-stage PCCRC, and fatal PCCRC.¹

Furthermore, inadequate bowel preparation is one of the most unfavorable predictors of cecal intubation failure and an unsatisfactory patient experience. It also results in

shorter colonoscopy surveillance intervals, longer hospital stays, higher healthcare costs, and can render screening colonoscopy uncost-effective.³ Studies have shown that up to 25% of patients have inadequate bowel preparation. Suboptimal bowel preparation can result in the omission of flat and/or serrated lesions, thereby increasing the risk of post-colonoscopy colorectal cancer.

4.1 Research question:

What is the effectiveness of lactulose compared to polyethylene glycol in bowel preparation for colonoscopy?

5. Justification

5.1 Transcendence: Bowel preparation is a fundamental aspect of colonoscopy quality, an essential procedure for the early detection of colorectal cancer and other colon pathologies. The adenoma detection rate (ADR), recognized as the most important quality indicator, depends heavily on adequate bowel preparation. Improving bowel preparation can significantly reduce the risks of post-colonoscopy colorectal cancer (PCRCC), including advanced and fatal PCRCC. Given that up to 25% of patients have inadequate bowel preparation, finding more effective and tolerable preparation methods is crucial for public health.

5.2 Magnitude: Inadequate bowel preparation negatively impacts the accuracy of colonoscopies, the cecal intubation rate, and the patient experience. This not only results in missed neoplastic lesions but also in higher healthcare costs due to the need for repeat procedures, prolonged hospital stays, and ineffective management of colorectal cancer. Furthermore, the fear and discomfort associated with bowel preparation are significant barriers to undergoing colonoscopies, thus decreasing participation rates in screening programs.

5.3 Feasibility: Research into the use of lactulose as an intestinal cleansing agent is viable and feasible. Lactulose is readily available, has a pleasant taste profile, and is well-tolerated by patients. Furthermore, its cost is only a fraction of the cost of polyethylene glycol (PEG) solution, making it a more economical alternative, especially in resource-constrained medical facilities.

5.4 Vulnerability: The study addresses a vulnerable population that includes patients with comorbidities, hospitalized patients, and elderly patients, who may experience

greater difficulties with traditional bowel preparation. It also focuses on low- and middle-income settings, where resources for medical procedures are limited and where costly solutions like PEG may not be feasible on a large scale. Identifying a more affordable and effective alternative such as lactulose could significantly improve the accessibility and effectiveness of colonoscopy in these populations.

This research is crucial in addressing the limitations of current bowel preparation methods, potentially offering a more effective and cost-efficient solution. By comparing the efficacy of lactulose and PEG, this study will not only contribute to improving the quality of colonoscopies and colorectal cancer screening, but may also influence public health policy and clinical practice, particularly in resource-limited settings.

6. Theoretical Framework

6.1 Anatomy of the colon

The stomach, small intestine, and large intestine serve different functions in the absorption process, and their motility patterns differ considerably. Gastric contents consist primarily of suspended solid particles, while the contents of the proximal small intestine are more fluid, and by the time they reach the large intestine, they are semisolid. The large intestine can be viewed as a dual organ, comprising the right and left colons, which are joined in the middle by the transverse colon. Understanding this is important because the right half absorbs water.[\(4\)](#)

The terminal portion of the intestine extends from the ileocecal valve to the anus, although this valve does not strictly correspond to the end of the large intestine. Along this route, the large intestine measures 1.5 m in length, and its diameter is greatest at its origin, that is, in the ascending colon, where it measures 7 cm; it decreases in the transverse and descending colon, where it reaches 4 cm, before dilating again upon reaching the rectum, forming the rectal ampulla. The right colon begins at the cecum, continues with the left colon, and comprises the distal portion of the transverse colon (splenic flexure), descending colon, sigmoid colon, rectosigmoid colon, and anal canal. The transverse and sigmoid colons are suspended in the peritoneal cavity by their mesenteries, while the ascending and descending colons are fixed to the retroperitoneum.[\(4\)](#)

The arterial supply to the right colon comes from the superior mesenteric artery via its branches: the right ileocolic, middle colic, and right colic arteries. The anatomy of the right colic artery is variable. These branches supply blood to the cecum,

ascending colon, and proximal portion of the transverse colon. The inferior mesenteric artery distributes blood to the distal portion of the transverse, descending, and sigmoid colon.(4)

The superior mesenteric vein drains blood from the right hemicolon into the splenic vein, and together they form the portal vein, which leads to the liver. The inferior mesenteric vein carries venous blood from the left hemicolon to the splenic vein.(4)

The mucosal and subserous layers of the large intestine drain into lymphatic vessels and into the nodules that accompany the arterial and venous systems.(4)

6.2 History of colonoscopy

The word endoscopy comes from Greek endoscopy, a word composed of éndon, meaning within, and scopeín, meaning to observe in detail(5)

Adolf Kussmaul and his scientific personality, through his varied contributions to medicine, included the use of a sword swallower to demonstrate the possibility of penetrating the digestive tract. Instead of swallowing a sword, the man used a tube. For this purpose, he designed two 47 cm long tubes: one circular with a 13 mm diameter and the other elliptical, both with a blunt-tipped obturator that was to be removed once placed in the esophagus. He also used Desormeaux's light source. Kussmaul gave demonstrations at the Freiburg Naturalists' Society and sent the sword swallower to Zurich for further study. It is fair to consider Adolf Kussmaul the father of endoscopy and 1887 the year the specialty was born. The rest of the 19th century was characterized by experimentation with various endoscopes, with varying degrees of success, and the incorporation of technological advances of each era. By then, the techniques for preparation, anesthesia, positioning, insertion, and exploration were gradually being systematized to achieve the required safety and efficiency. Chevalier Jackson deserves special mention, not only because he designed highly efficient rigid endoscopes that were used in the first half of the 20th century and systematized the exploration of the upper digestive and respiratory tracts, but also because of his significant influence on Mexican endoscopy.(6)

The image of the first endoscope being inserted into a sword swallower is legendary and remains in memory as an archaic myth, a seminal symbol of achieving the seemingly impossible. Rigid and semi-rigid endoscopes.

They are no longer just an image, but a reality in the hands of endoscopists who live to tell the tale.(7)

In 1983, Sivak and Fleischer amazed the world with the emergence of the video endoscope in which a photosensitive microtransmitter was integrated, taking advantage of semiconductor technology in which silicon forms the fundamental element.[\(7\)](#)

Diagnostic endoscopy, despite being the most frequent, does not represent the specialty because therapeutic capacity is what has provided the most substantial benefits and, so far, no better option than a conventional endoscope, in a perfectly trained doctor and in a highly specialized center, is seen on the horizon.[\(5\)](#)

6.3 General information about colonoscopy

A colonoscopy involves examining the inside of the rectum, colon, and even the last few centimeters of the small intestine by inserting an instrument called a colonoscope through the anus. This instrument is essentially a flexible tube equipped with a lighting and viewing system. Forceps and other accessories used in various diagnostic and therapeutic procedures can be inserted through the colonoscope. The procedure's duration varies depending on whether it is a diagnostic or therapeutic examination and whether sedation is required. It generally lasts between 30 and 45 minutes.[\(8\)](#)

Colonoscopy can visualize lesions associated with these diseases and detect inflammation, ulcers, neoplasms, and bleeding. It also provides information on macroscopic findings and allows for tissue sampling by inserting instruments through various channels. Furthermore, due to the development of endoscopic resection techniques such as submucosal dissection and endoscopic mucosal resection, endoscopic resection is used as the primary treatment for early-stage colorectal cancer.[\(9\)](#)

Specifically in the area of colorectal cancer, colonoscopy has three main functions: detecting the disease and preventing its development by identifying and removing potentially premalignant lesions, or by providing a presymptomatic diagnosis of cancers at an early stage. The second is diagnosing the disease by investigating symptoms, and the third is preventing metachronous cancer by monitoring patients who have already had colorectal cancer.[\(10\)](#)

6.4 Indications for colonoscopy

Colonoscopy is the preferred method for evaluating the colon. When performed correctly, it is a safe procedure. Furthermore, it is the gold standard for colorectal

cancer screening worldwide, both for patients at average risk—those without intrinsic factors that promote neoplastic degeneration—and for those at increased risk, such as those with hereditary polyposis syndromes, long-standing inflammatory bowel disease, or a first-degree family history of colorectal cancer.[\(11\)](#)

Colonoscopy allows for the diagnosis of most diseases affecting the lower digestive tract (large intestine) by providing direct visualization of its interior. It precisely locates lesions and allows for biopsies to be taken for microscopic analysis. This leads to an accurate diagnosis, facilitating appropriate treatment. Furthermore, colonoscopy enables therapeutic procedures such as polyp removal (small, benign, and sometimes malignant tumors), coagulation of bleeding lesions, and removal of foreign bodies, among others. This avoids the need for surgery to resolve the problem. Biopsy taking, polyp removal, and other therapeutic procedures are painless for the patient.[\(8\)](#)

A thorough and careful inspection of the intestinal lining is essential for the prevention of colorectal cancer. The detection of precancerous lesions is the primary goal of most colonoscopies.[\(11\)](#)

6.5 Quality Indicators

When attempting to define quality within a healthcare context, it is essential to consider from the outset the numerous legitimate definitions that can be proposed depending on the approach taken. One approach to this concept would be to define it as the property or set of properties inherent to a healthcare service that allow it to be assessed as equal to, better than, or worse than other services of the same kind. Three important characteristics derive from this definition. First, the need to understand the concept of quality as a relative term. Second, the concept inherently involves comparison ("equal to, better than, or worse"). And finally, the need for a standard, norm, or model against which to compare.[\(11\)](#)

6.6 Pre-procedure quality indicators:The pre-procedure period refers to the contact between the endoscopy team and the patient before the endoscope is inserted. Pre-procedure quality indicators include: 1- Informed consent, including information on the risks associated with colonoscopy, was obtained for all patients. This consent should include the risks, benefits, and options related to colonoscopy. The most frequent risks associated with colonoscopy include bleeding, perforation, infection, sedation-related events, and the presence of undetected lesions. 2- The

colonoscopy was performed for an appropriate indication, and this was documented in the report. The primary objective of this indicator is to reduce the number of procedures performed for inappropriate indications. 3- The established timeframes for follow-up after polypectomy and cancer resection, as well as the established 10-year interval for patients at average risk after a negative colonoscopy with adequate preparation, must be met.[\(11\)](#)

6.7 Intraprocedural quality indicators: The quality of the colon evaluation consists of examining the entire colon, including the cecum and terminal ileum, as well as a detailed mucosal inspection. Cecal intubation increases sensitivity and reduces cost by eliminating the need for additional radiographic studies or repeat colonoscopy. This period begins with sedation and ends with the removal of the endoscope. The quality indicators are as follows: 1- The quality of bowel preparation for colonoscopy must be documented for all procedures and must be adequate to allow for the use of follow-up intervals recommended in screening guidelines. The endoscopist must document the quality of the preparation for each procedure. Non-standardized terms should be avoided when describing bowel preparation. The internationally validated Boston Bowel Preparation Scale is recommended for describing colonoscopy preparation. 2- Cecal intubation should be achieved in more than 95% of cases and must be photographically documented. The need for a complete evaluation of the cecum stems from the fact that a significant percentage of colorectal neoplasms are located in the right colon. The frequency with which adenomas are detected in asymptomatic individuals at average risk of colorectal cancer should be greater than 25%. Colonoscopy has been shown to fail to prevent all colorectal cancers in cohorts followed for more than 3 years, with most cancers being attributable to unidentified lesions and incomplete resections, as well as variations in tumor growth patterns. 4. The exit inspection time during colonoscopy should be measured and, on average, should be greater than 6 minutes. Detailed exploration of the colon requires time, which is why there is a close relationship between the exit inspection time during colonoscopy and the average daily intake (ADI). 5. Endoscopic resection of pedunculated or sessile polyps smaller than 2 cm should be performed during the same endoscopic procedure. Delaying the resection of small colonic polyps identified during a routine colonoscopy increases costs and decreases the cost-benefit ratio of the procedure. The vast majority of polyps smaller than 2 cm are endoscopically resectable and should not be referred for surgical resection.[\(11\)](#)

6.8 Post-procedure quality indicators: This extends from the removal of the endoscope through subsequent follow-up. Post-procedure care includes providing the patient with relevant instructions, recognizing adverse events, evaluating histopathological findings, and determining the patient's level of satisfaction. Post-procedure quality indicators include: 1- a perforation rate of less than 1 in 500 therapeutic procedures and 1 in 1000 screening colonoscopies, and a post-polypectomy bleeding rate of less than 1%. 2- Post-polypectomy bleeding should be successfully managed endoscopically in more than 90% of cases. 3- A recommendation for a follow-up colonoscopy should be provided, according to the follow-up guidelines, after reviewing the histological findings.[\(11\)](#)

6.9 Colon cancer screening

The ADN (adenoma detection rate) is defined as the percentage of patients over 50 years of age in whom one or more adenomas are detected during their first screening colonoscopy. Studies have documented that patients who undergo screening colonoscopy with an ADN of less than 20% have a 10-fold increased risk of developing colon cancer compared to those who have their colonoscopy with endoscopists with an ADN greater than 20%.

6.10 Surveillance in inflammatory bowel disease

Inflammatory bowel diseases (IBD) are chronic and progressive inflammatory diseases. Colonoscopy is a key modality for the diagnosis, differential diagnosis, treatment, and prognosis of IBD.[\(12\)](#)

The main diseases are ulcerative colitis (UC) and Crohn's disease (CD). UC is an inflammatory disorder of the colonic mucosa, which begins in the rectum but can extend proximally and involve the colon. CD is a chronic disease that can cause inflammation from the mouth to the anus, with an irregular distribution of lesions that can affect not only the mucosa but also the intestinal wall in its entire thickness.[\(13\)](#)

Surveillance with screening colonoscopy programs has been shown to reduce colorectal cancer (CRC)-associated morbidity and mortality in this patient group. When disease activity is limited to the rectum, without prior or current evidence of proximal extension, periodic surveillance is not necessary. Reactive atypia (false positive for dysplasia) can be observed in biopsies taken from patients with active inflammatory bowel disease (IBD); therefore, colonoscopy surveillance should be performed in patients with ulcerative colitis (UC) in remission. Furthermore, the intervals will be personalized for each patient based on their individual risk

factors.[\(14\)](#)

6.11 Contraindications

Contraindications for performing a colonoscopy are grouped into two groups, absolute and relative, the latter being at the discretion of the specialist who performs the procedure or the acceptance of the patient according to the information of the risks, which is the most important thing.

Specific contraindications for colonoscopy: peritonitis, bowel perforation, acute diverticulitis of the large intestine, fulminant colitis.

Relative contraindications: pregnancy and large abdominal aortic aneurysm with a thrombus[\(15\)](#)

6.12 Procedure Description

Colonoscopy remains the most effective examination for the prevention, treatment, and diagnosis of colorectal lesions. This prominent position necessitates adherence to quality standards that must be enforced for all endoscopists.[\(16\)](#)

1. Position the patient correctly:

- - Left lateral decubitus position, although if the method is not used, supine positioning is possible.
- - Head in a neutral position with the help of a pillow.
- - If venous access is required, preferably use the right arm.

2. Check that the endoscope is working correctly:

- - Adequate and quality vision.
- - End angle.
- - Air and water.
- - Suction.

3. Lubricate endoscope.

4. Insert endoscope:

- Rectal examination with generous lubrication.
- Select insertion technique (it could be hybrid or mixed, by sections):
 - One-person method. The endoscopist is autonomous for the insertion. The assistant's help is only for abdominal compression, postural changes, or if support is needed.
 - Assisted method. The assistant handles the endoscope shaft and the

endoscopist handles the controls.

- Passing through the anal sphincter. Three alternatives:

- Press obliquely with your index finger until the sphincter relaxes.
- Insert the tip of your thumb to replace the tube.
- Direct insertion.

5. Advance towards the cecal fundus:

- Maneuver properly throughout the entire journey:

- Perform short-stroke tube progression movements to avoid loop formation. • Always keep the endoscope in the center of the colonic lumen. • Properly coordinate rotational (torque) and angulation movements with both hands.
- Overcome angles with light pushing movements, followed by a small withdrawal and clockwise rotation of the tube, to maintain the rectification. • Inflate to improve visibility, avoiding overdistension.
- Positional changes can help to overcome complicated areas of the colon.

- Maintain an appropriate attitude towards the findings:

- Remove or biopsy the lesions according to type, size and consistency. • Reference the lesions, including appearance, shape, size, and presumptive diagnosis.
- Locate the lesions using distances from the anus/cecum or with anatomical references when possible (transverse colon, cecum, hepatic and splenic flexures, anastomoses, scars, etc.).
- - Push the endoscope through the rectum.
- - Pass through the sigmoid colon by pushing the tube counterclockwise, usually forming an alpha loop, with the help of the assistant.
- - Undo the loop in the descending colon by removing the colonoscope and applying clockwise torque.
- - Progress by pushing the tube into the transverse colon.
- - Overcome the angulation of the mid-portion of the transverse colon by withdrawing the endoscope with clockwise torque, while gently aspirating. • - To overcome the hepatic flexure, apply aspiration and gentle torque. Compression may be necessary in the epigastrium to prevent looping in the transverse colon.
- - Push and aspirate in the ascending colon until reaching the cecal fundus.
- - Consider image recording.

6. Assess the entrance to the ileum:

- Weigh according to the test indication, the findings made and the anatomical ease.

7. Remove the tube:

- Maneuver slowly.
- Clean thoroughly, removing all traces of mucus.
- Look behind each haustra.
- Observe carefully to identify irregularities in haustra and alterations in submucosal circulation.
- Maintaining an appropriate attitude towards the findings:
- Polyps:
 - Describe morphology (Paris classification), size and location.
 - Consider magnification to improve diagnosis.
- Remove or biopsy.
- Lesions suspected of being cancerous:
 - Locate and biopsy.
 - Mark with India ink (except for straight under and blind).
 - Proceed towards blindness if the injury is passable.
 - Take a biopsy.
 - Describe the extent, whether the affected area is patchy or continuous.
 - Try to see the ileum.
- Vascular lesions (angiodysplasias, etc.):
 - Describe.
 - Assess electrocoagulation.
- Diverticulitis:
 - Describe.
 - Avoid insufflation, especially if there is an inflammatory component.
 - Draw in as much air as possible in sections.

8. Visualize straight ahead:

- Support the tube against the wall and rotate to perform retroversion into the rectal ampulla.
- Inspect mucosa.

9. End exploration:

- Remove the tube completely.

- Pass the endoscope to the auxiliary staff for cleaning and re-preparation.[\(17\)](#)

6.13 Intestinal preparation

Lack of awareness of the importance of proper bowel preparation and cleansing explains the poor adherence to instructions, and increases the rate of inadequate bowel preparation.

The healthcare team must provide accurate and clear information to improve patient adherence. The importance of following instructions and the impact of proper bowel preparation on colonoscopy findings and results should be emphasized.[\(3\)](#) The ideal preparation should quickly cleanse the colon without causing histological changes in the mucosa, be low-cost and free, or have minimal side effects such as abdominal discomfort and electrolyte imbalances. Depending on the drug used, antegrade preparation induces peristalsis and intestinal spasms, which are responsible for symptoms such as cramps and abdominal distension, and induces watery diarrhea with electrolyte loss (thirst, dizziness, weakness, postural hypotension) and anal discomfort. Intolerance to the preparation (nausea and vomiting) is usually associated with the volume of liquid consumed and the taste.[\(18\)](#)

Achieving adequate bowel preparation or cleansing is one of the most frequent quality issues in colonoscopy. Good, or at least moderately good, bowel preparation facilitates better detection of colon adenomas, as demonstrated in several clinical trials and meta-analyses. Thus, indirectly, as will be discussed later, it prevents the development of colorectal cancer. Published clinical practice guidelines, based on systematic reviews and meta-analyses, recommend the use of divided doses or the full dose of bowel preparation administered a few hours before the procedure. Bowel preparation must be individualized for each patient according to their personal risk factors. The recommended standard for adequate cleansing ranges from 85% to 90%, with the latter value being recommended for screening colonoscopies. This paper recommends the use of the Boston Bowel Scale. Using this scale, it is recommended that each segment score at least two or three points.[\(17\)](#)

The cleansing systems used in colonoscopy must allow for the exploration of more than 90% of the mucosal surface. Furthermore, the medications used must be well-tolerated by the patient and not cause side effects. Therefore, the ideal

colonoscopy preparation should combine efficacy, excellent tolerability, and minimal adverse effects.[\(19\)](#)

6.14 Bowel preparation scales

Colonoscopy is the gold standard examination for evaluating colon diseases. Its diagnostic and therapeutic effectiveness depends on the quality of the technique. For a colonoscopy to be of quality, the entire colon must have been explored, with good bowel cleansing and a withdrawal time of the endoscope from the cecum to the rectum of at least 6 minutes.

Inadequate bowel preparation results in poor test quality, leading to lower adenoma detection rates and more complications because the procedure takes longer than usual. Ineffective preparation can result in canceled procedures, diagnostic delays, and increased risks and costs.[\(20\)](#)

The ideal colonoscopy preparation should reliably empty the colon of all fecal matter quickly and without macroscopic or histological alteration of the colonic mucosa. The preparation should not cause discomfort to the patient or changes in fluid or electrolyte balance. It should be safe, convenient, tolerable, and cost-effective.[\(21\)](#)

A quality colonoscopy report should include an assessment of bowel cleansing using a validated scale. The most commonly used scales are the Aronchick, Ottawa, and Boston scales.

Aronchick Scale (ELCA): This is the oldest of the three scales, and it evaluates the entire colon. It is scored from 1 to 5 points.

- Excellent (1 point) More than 95% of the mucosa is visible. Minimal fluid residue.
- Good (2 points): more than 90% of the mucosa is visible. Liquid residue may be between 5%-25%.
- Regular (3 points) More than 90% of the mucosa is visible. Liquid or semi-liquid remnants that can be aspirated/washed out.
- Poor (4 points) less than 90% of the mucosa is visible. Semi-solid debris that cannot be aspirated or washed.
- Inadequate (5 points) solid waste that obstructs vision.

Ottawa Colonic Scope Scale (ESCO): Allows for the evaluation of the colon by

segments. Two aspects are assessed: a) the degree of cleanliness in each segment of the colon (left colon, transverse colon, and right colon), b) the amount of fluid in the entire colon.

The degree of cleanliness is scored from 0 to 4 points per segment:

- Excellent (0 points): visible mucosa. Minimal liquid residue.
- Good (1 point): good view of the mucosa. Some liquid residue, no need to aspirate or wash.
- Regular (2 points): reasonable view of the mucosa. Liquid or semi-liquid residue does not require aspiration or washing.
- Poor (3 points): limited visibility of the mucosa. Semi-solid debris requiring aspiration or washing.
- Inadequate (4 points): solid waste that obstructs vision.[\(20\)](#)

The amount of fluid in the entire colon, from 0-2 points:

- Scarce (0 points)
- Moderate (1 point)
- A lot (2 points)

Boston Scale (BLS)

This is the most widely used scale. It assesses the cleanliness of the three colon segments (left, transverse, and right). Each segment is scored from 0 to 9 points after washing and aspiration.

- 0 points: unprepared colon segment, mucosa not visualized due to the presence of solid feces.
- 1 point: areas of the colon segment not seen due to the presence of liquid and semi-solid fecal content.
- 2 points: scant liquid fecal content that allows good visualization of the mucosa.
- 3 points: excellent visualization of the mucosa, with no presence of liquid residue.[\(20\)](#)

6.15 Ineffective preparation

The percentage of inadequate bowel preparations is around 21%.

Factors that can influence poor bowel preparation include:

- Lack of adherence to recommendations, due to insufficient understanding, poor motivation, and poor tolerance.
- The biological characteristics of the patients such as age, constipation,

decreased colonic peristalsis.

- Some associated pathologies, such as diabetes, high blood pressure and kidney failure.[\(20\)](#)

Insufficient cleaning can result in lower detection rates of incipient and advanced adenomas, flat lesions, and a higher rate of canceled procedures with higher costs, longer procedures, and a greater risk of complications.[\(21\)](#)

6.16 Solution Type

In 2006, the American Society of Colon and Rectal Surgeons (ASCRS), the American Society for Gastrointestinal Endoscopy (ASGE), and the American Society of Gastrointestinal and Endoscopic Surgeons (SAGES) established that a colonoscopy bowel preparation should be inexpensive, quickly cleanse the bowels, and not cause significant patient discomfort or electrolyte imbalances. The European Society of Gastrointestinal Endoscopy published similar guidelines. Three factors essential for good bowel preparation are safety, palatability, and effectiveness. The use of oral bowel preparations can induce strong peristalsis, cramping, bloating, diarrhea, and other symptoms. Intolerance to the preparation is common and is usually associated with the volume of liquid consumed and the taste of the solution.[\(21\)](#)

The ideal laxative should be low-volume, palatable, have minimal side effects, and be inexpensive. No single laxative meets all these criteria, so there are many colon preparations available that can be administered depending on the clinical situation. Recent consensus statements have demonstrated the efficacy and safety of various formulations, including polyethylene glycol, although the latter has the drawback of requiring patients to drink four liters of water. Lactulose is a laxative described for the medical treatment of hepatic encephalopathy in patients with cirrhosis, as well as for constipation. Its use in bowel preparation for colonoscopy is considered effective, with results similar to those of mannitol.[\(18\)](#)

Patients consider bowel preparation the worst part of the process, which is a major obstacle to their acceptance of the initial procedure and subsequent periodic procedures if necessary. Initial colonoscopy preparations were adapted from those used by surgeons for abdominal or radiological procedures. These originally included dietary restrictions, the administration of laxatives and enemas, and fasting. These bowel preparations required the ingestion of a large volume of fluid (seven to twelve

liters) over several days, which resulted in poor tolerance, weight gain due to water retention, and electrolyte imbalances. For this reason, osmotically balanced solutions were developed to reduce the amount of preparation ingested. One of the first solutions contained mannitol. This is a non-absorbable oligosaccharide that exerts an intraluminal osmotic effect without causing electrolyte imbalances. The main problem is that, because it is not absorbed, it is fermented by bacteria in the colon, generating methane and hydrogen gas, with the consequent risk of explosion. Subsequently, safer solutions were developed, such as polyethylene glycol (PEG) and sodium phosphate.[\(22\)](#)

Polyethylene glycol (Muvinalax® or Nulytely) is a non-absorbable electrolyte solution that does not induce electrolyte mucus secretion or significantly reduce fluid exchange in the colonic lumen. It has been shown to be non-toxic and can be ingested in large quantities without dangerous effects. Its use is relatively safe in patients with renal insufficiency, cirrhosis, or congestive heart failure. The main disadvantage is the need to drink a large amount of fluid (four liters). Although effective, it is associated with intolerance in up to 15% of patients. Recent studies with lower doses (two liters) when combined with bisacodyl and magnesium citrate have demonstrated better tolerance. The usual dose is 240 ml of the product diluted in water (according to the manufacturer's instructions) every ten minutes until clear fluid is expelled from the anus, with a maximum intake of four fluids. It is recommended not to eat solid food before ingesting the solution. The dose via nasogastric tube is 20 to 30 ml per minute. (1.2-1.8 liters per hour)[\(18\)](#)

Polyethylene glycol: This is an inert molecule that dissolves completely in any solution. It contains electrolytes and sodium sulfate to achieve osmotic advancement, its main characteristic being the absence of sodium sulfate. These solutions are better tolerated and more effective and safer than other osmotic agents. The main disadvantage of these products is the large volume (4 liters) that patients need to ingest and their salty taste due to the sodium sulfate. It is usually recommended to ingest 250 ml every 15 minutes until the 4 liters are consumed or until clear fluid is expelled. It is a safe cleansing method for patients with electrolyte imbalances (renal failure, heart failure, or liver failure with ascites), and is the method of choice for children. The main side effects (nausea, abdominal distension, and vomiting) are related to the volume ingested. They are very safe and inexpensive, but 5-15% of patients do not complete the preparation due to their salty taste and/or

volume. To improve tolerability, flavored (sulfate-free) solutions and other low-volume (2-liter) solutions have been developed.[\(23\)](#)

Polyethylene glycol colonic preparation is the most commonly used formula in our setting. Among the recognized limitations associated with its use are: the large volume to be ingested (4 L), which makes it unsuitable for elderly patients with swallowing difficulties; it is also poorly tolerated by patients and has been associated with medical complications, including vomiting, abdominal distension, abdominal pain, nausea, Mallory-Weiss syndrome, esophageal perforation, aspiration pneumonia, toxic colitis, and polyethylene glycol-induced pancreatitis.[\(24\)](#)

Lactulose (Duphalac®) is a disaccharide, a semi-synthetic derivative of lactulose. It is absorbed and undergoes bacterial action, causing fermentation, acidifying the environment, and accelerating intestinal transit by stimulating motility. Another consequence of acidification is an increase in osmotic pressure within the colon lumen, proportional to the dose. For dosage, 120 ml is diluted with juice or clear water to a total volume of 1000 ml, and the entire volume is swallowed within 1 hour.[\(18\)](#)

The use of lactulose for bowel preparation at 10% and 50% doses showed similar efficacy compared to 10% mannitol. In a study of 2,000 consecutive patients, orally administered lactulose showed good efficacy in 84.8%, fair efficacy in 9.2%, and poor efficacy in 5.9%. Intolerance to the preparation (inability to drink the entire solution) was observed in 3.3% of patients. Therefore, studies evaluating the efficacy, tolerability, and cost of polyethylene glycol and lactulose in bowel preparation can contribute to the routine management of patients undergoing colonoscopies.[\(18\)](#)

Lactulose is a disaccharide. It is absorbed and undergoes bacterial action, which causes fermentation, acidifying the environment and accelerating intestinal transit by stimulating motility. In the colon, lactulose is broken down primarily into lactic acid and small amounts of formic and acetic acids by the action of beta-galactosidase from colonic bacteria, resulting in an increase in osmotic pressure and a slight acidification of the colonic contents. This leads to an increase in the water content of the feces, softening them and accelerating intestinal transit by stimulating motility.[\(21\)](#)

6.17 Electrolyte imbalance due to bowel preparation

Colonoscopy is one of the most frequently used medical procedures. It is considered the gold standard technique for colorectal cancer (CRC) screening, as well as for the removal of adenomatous polyps with precancerous potential. The diagnostic effectiveness of this technique depends on proper bowel preparation, making the use of bowel preparations essential. Inadequate bowel preparation has a detrimental effect on all aspects of the colonoscopy procedure, leading to significantly lower adenoma detection rates, cecal intubation failure, increased procedure duration and associated complications, and a greater need for repeat procedures. Ultimately, this results in higher healthcare costs.

The main colonoscopy preparations have been shown to provide adequate bowel cleansing safely in healthy individuals without significant comorbidities. However, alterations are occasionally described as a consequence of water and electrolyte loss through the intestinal lumen, or of the absorption of some of the electrolytes contained in the preparations. Thus, the possibilities encompass almost the entire spectrum of internal environment disturbances (hypo- and hyponatremia, hypo- and hyperkalemia, metabolic acidosis, hypocalcemia and hyperphosphatemia, or hypermagnesemia).

The likelihood of experiencing these alterations and their severity will depend on the electrolyte content of the bowel preparation, the type of fluid replacement administered, and the patient's characteristics. Generally, these are transient alterations that, with adequate fluid replacement (with or without electrolytes) during bowel preparation and continued after the colonoscopy, should not cause problems. The risk is primarily seen in certain population groups. This is the case, for example, with the elderly, who have an impaired thirst mechanism and require increased fluid intake to ensure adequate fluid replacement. It is also a risk for patients with kidney disease or those on diuretic therapy, who have a reduced ability to concentrate urine. Patients with heart failure or liver cirrhosis should be highlighted, as they not only already have electrolyte imbalances and volume overload, but are also more vulnerable to changes in ion concentrations, exhibiting a higher incidence of arrhythmias. Finally, patients undergoing insulin therapy or taking medications that could affect fluid and electrolyte balance (NSAIDs, ACE inhibitors/ARBs, diuretics, corticosteroids) or make them more susceptible to these imbalances (cardiomyopathy, carbamazepine, etc.) should be mentioned.(25)

The electrolyte values to be considered for this protocol will be provided by the

hospital's laboratory and equipment, and are as follows:

- Sodium (Na) 135-145 mmol/l
- Potassium (K) 3.50-5.10 mmol/l
- Chlorine (Cl) 98-107 mmol/l

6.18 Time between end of preparation and start of procedure

The bowel preparation time for a colonoscopy influences the quality of bowel cleansing and the success of the procedure. A split dose has been shown to yield better results in terms of colonoscopy quality compared to a single dose administered the day before. The second portion of the preparation or the last dose should be administered three to eight hours before the start of the colonoscopy. Siddiqui et al. reported that after an eight-hour gap from the completion of bowel preparation, for each additional hour between the end of bowel preparation and the colonoscopy, the likelihood of achieving good or excellent cleansing of the right colon decreases by up to 10%.

The American Society of Anesthesiologists recommends a two-hour clear liquid fast prior to sedation, so patients must complete their preparation at least two hours before the procedure. A prospective study comparing split and full doses administered the day before the study found no difference in the amount of residual gastric fluid.

6.19 Preparation regimen

The bowel preparation regimen has a significant impact on the quality of bowel cleansing. Traditionally, preparation is performed the day before a colonoscopy. However, more recent evidence suggests that splitting the preparation between the day before the exam and the day of the exam leads to better bowel cleansing and a shorter time between the end of preparation and the colonoscopy itself. A meta-analysis of 47 trials with 13,487 patients reported that a split-dose regimen is associated with significantly better bowel cleansing than preparations done the day before (OR = 2.51, 95% CI: 1.86–3.39), regardless of the solution type and dose.(26)

High-volume (4 L) split-dose regimens of PEG have been recommended as the gold standard for bowel preparation; however, the large fluid volume or poor tolerability associated with SpDs have become a source of patient dissatisfaction. Same-day single-dose (SSD) PEG has been recommended as an alternative for patients scheduled for an afternoon colonoscopy, demonstrating equal cleansing efficacy and less sleep disturbance. Meanwhile, it has been reported that reducing preparation volume and improving patient tolerance by using PEG solution combined with

adjunctive laxatives is a viable option for those at risk of bowel preparation.(27)

The regimen to follow will be as follows: for lactulose: 300 milliliters of lactulose (10 g/15 ml) with 700 milliliters of water, from 5 to 7 pm the night before the colonoscopy; and for polyethylene glycol: prepare 1 sachet in 1 liter of water, begin drinking at 6 pm, consuming 3 liters over a period of 6 hours. On the day of the colonoscopy (4 hours before the procedure), 1 liter should be consumed in one hour, sipping from a glass every 10 minutes until 1 liter is consumed. Subsequently, 150 colonoscopies will be performed with polyethylene glycol-based preparation and 150 with lactulose-based preparation. On the day of the procedure, it will be verified that there was adequate prior follow-up.

6.20 Timing of colonoscopy after bowel preparation

If you had a diagnostic colonoscopy, you can resume your normal activities and diet. If you received sedation, you should not drive or engage in any strenuous activity for the next 12 hours.

Since your bowel has been cleansed, it will take a few days for you to have a bowel movement, and for a while you may experience a feeling of "gas" in your abdomen and vague discomfort that will subside on its own. You should not take laxatives.

When you have a polypectomy (polyp removal), you will be given instructions on the care you need to take during the next 24 hours.(8)

6.21 Cecal intubation rate

Cecal intubation is defined as the arrival of the tip of the endoscope at a point proximal to the ileocecal valve, in such a way that all the walls of the cecum, the confluence of the colonic taeniae ("crow's foot"), the appendiceal orifice and the lips of the ileocecal valve are clearly visible.

Cecal intubation allows the identification of colorectal neoplasms located in the proximal colon, including the cecum; therefore, low rates of cecal intubation are associated with high rates of interval cancer in proximal areas of the colon. Cecal intubation should be photographically documented in all cases and ideally include the terminal ileum. This is confirmed by identifying distinctive anatomical structures of the cecum, such as the lips or orifice of the ileocecal valve, the appendiceal orifice (if there is no history of appendectomy), the confluence of the taeniae coli, and/or by intubating the terminal ileum. The ideal cecal intubation rate is >90% in all cases and >95% when the indication is colorectal cancer screening in healthy adults.(3)

When the indication for colonoscopy is not colorectal cancer screening and/or the procedure is aborted due to poor preparation, severe colitis, or because the indication is the treatment of a stenosis or a polyp distal to the cecum, the lack of photodocumentation of the anatomical references described above should not be considered in the evaluation of quality indicators, but the reason why it was decided to interrupt the procedure should be photodocumented.

Currently, it is suggested that the terminal ileum be intubated in most cases and is considered mandatory in cases with inflammatory bowel disease, chronic diarrhea, small bowel hemorrhage, and removal of foreign bodies from the ileum.[\(3\)](#)

6.22 Safety of colonoscopy

In terms of quality management and promotion of professional practice, the CED, under the direction of the Tunisian Society of Gastroenterology (STGE), proposes the following recommendations to improve the quality of a colonoscopy: 1-Perform a consultation prior to the colonoscopy: The doctor must validate the indication for the examination, investigate comorbidities and possibly administer anticoagulant and antiplatelet treatments, obtain clear and signed consent from the patient, explain the importance of good preparation by showing the product and its usage methods and above all ensure that the patient is well informed. 2-Good management of the person in charge of the work: Each examination should be allowed a minimum duration of 30 minutes for detachment colonoscopies. 3-Calculate the adenoma detection rate: Each endoscopist must calculate their ADR, which will allow them to assess their performance level and position themselves according to international recommendations.

4-Training: It is recommended for all endoscopists and also the improvement of individual practices, the increase in TDA and the decrease of pain and complications related to the examination.[\(16\)](#)

6.23 Complications of colonoscopy

Colonoscopy is one of the most frequently performed examinations, and patient safety is, without a doubt, a prerequisite. The rate of post-colonoscopy complications must be minimized, regardless of the indication—screening, surveillance, symptom management, and/or therapy. As colorectal cancer (CRC) screening and surveillance using colonoscopy are increasingly supported worldwide, both the volume of examinations and the clinical challenges at the patient level are increasing. Advanced age, comorbidity, and the use of anticoagulant therapy increase the risk of

harm during colonoscopy.(28)

6.23.1 Colon perforation

Colon perforation is a well-known adverse event resulting from colonoscopy. It occurs very rarely, but it is a serious adverse event with high morbidity and considerable mortality. Colonoscopy perforation is generally defined as intraperitoneal fat or viscera seen during colonoscopy, or the presence of radiographic abnormalities (intra-abdominal free air on radiographs, or localized or diffuse release of intestinal gas or fluid into the peritoneum on computed tomography scans). Colonoscopy perforations can occur through various mechanisms, including mechanical trauma, barotrauma, thermal energy, and removal of tissue injury. The characteristics of the injury, according to the perforation mechanism, are classified as terminal, polypectomy, and blunt. Blunt injury is caused by direct trauma or torsion of the endoscope; this mechanism results in the largest perforations. The cecum is the most frequent site of perforation due to thermal energy and polypectomy, as well as the rectosigmoid colon due to closed wounds. The outcome varies depending on the type of perforation. In particular, closed wounds tend to have larger perforations and a higher rate of fecal leakage than polypectomy injuries, and therefore a worse prognosis. Furthermore, immediate detection of perforation results in less intraperitoneal contamination than delayed detection. In general, perforations detected during or immediately after colonoscopy have a better prognosis than those whose detection is delayed and less frequently require surgical treatment. Overall, the rectosigmoid colon has emerged as the most frequent site of perforation. Increased age, higher American Society of Anesthesiologists (ASA) class, female sex, hospital setting, therapeutic colonoscopy, and polyp removal >10 mm have been shown to be significantly associated with a higher risk of early perforation. In particular, perforations in elderly patients can lead to a high proportion of fatal consequences.[\(12\)](#)

6.23.2 Bleeding

Bleeding is one of the most common complications of colonoscopy, accounting for 0.3–6.1% of cases. The definition of postcolonoscopy bleeding varied somewhat among studies: lower gastrointestinal bleeding after a colonoscopy with or without polypectomy that requires a packed red blood cell transfusion, hospitalization, an emergency department visit, or the need for repeat colonoscopy in the context of hematochezia. In general, immediate bleeding was defined as bleeding occurring

within 1 day after an endoscopic procedure, and late bleeding as bleeding occurring from 24 hours to 14 days after an endoscopic procedure. Bleeding after diagnostic endoscopy is very rare. If it occurs, it is usually associated with a biopsy. This can happen when the blood vessel structure is biopsied directly, especially in patients with abnormal blood clotting function. It is also rarely seen in cases of severe mechanical friction due to the endoscope. The incidence of bleeding during a diagnostic colonoscopy is only 0.03%, most of which occurs after the biopsy.

Bleeding after polypectomy is known to occur frequently and can be divided into immediate and delayed bleeding depending on when it starts. The rate of bleeding after polypectomy (0.98%) is significantly higher compared to when no polypectomy is performed (0.06%) ($p < 0.001$). The mechanism of bleeding after polypectomy varies depending on the polyp's morphology. In pedunculated polyps, a large feeding vessel typically passes through the stalk. Insufficient electrocoagulation during snare cutting of the stalk can cause pulsatile bleeding. In sessile polyps, the polypectomy incision is usually deep and wide, which can result in insufficient electrocoagulation of the interior, leading to bleeding from the inner margin of the incision. Furthermore, the exposed vessels are often located in the submucosal layer, which can increase the risk of delayed bleeding. The number, size, morphology, and histology of polyps, as well as cardiovascular disease, are risk factors for post-polypectomy bleeding. A recent meta-analysis showed that aspirin and NSAIDs are risk factors for late, but not immediate, post-polypectomy bleeding.[\(12\)](#)

6.24 Postpolypectomy syndrome

Post-polypectomy syndrome (PPS) is defined as the progression of abdominal pain, leukocytosis, fever, and localized peritonitis without radiographic evidence of colonic perforation. PPS arises after colonoscopic polypectomy with electrocoagulation. The reported incidence of PPS ranges from 0.003% to 0.1%. Risk factors for PPS include hypertension, large lesions, and non-polypoid lesions. In general, PPS should be managed conservatively with medical therapy (NPO status, intravenous fluids, and broad-spectrum antibiotics) because the prognosis is good in most cases. However, in rare cases, surgical treatment may be necessary if there is a clear perforation with diffuse peritoneal signs.[\(12\)](#)

6.25 Postcolonoscopy distension syndrome

Post-colonoscopy distension syndrome can occur due to excessive or prolonged air insufflation into the colon during a colonoscopy, causing pain, bowel distension, and

even perforation. These side effects are the primary factor influencing patient acceptance of the procedure. Recently, a modification to the colonoscopy technique has been introduced, using carbon dioxide (CO₂) as the insufflation agent. The characteristics of this gas could potentially reduce post-colonoscopy pain and distension, improving patient tolerance and decreasing side effects.[\(29\)](#)

6.26 Position in colonoscopy

Colonoscope insertion is time-consuming and can be associated with serious complications (e.g., perforation). The left lateral decubitus (LLD) position facilitates insertion and is the suggested position for the procedure; however, there are few clinical studies to support this.

In patients undergoing colonoscopy without sedation, cecal intubation time (280 vs. 339 seconds; $p < 0.001$) and the frequency and intensity of pain (3.4 ± 1.6 vs. 4.0 ± 1.7 ; $p = 0.02$) were shorter when the colonoscopy was performed in the supine position (SD) compared to the left lateral decubitus (LLD). Similar results were observed when the colonoscopy was performed in the right lateral decubitus (RLD). Compared to LLD, the average time to cecal insertion was shorter ($p = 0.0078$). The patients who benefited most were women and those with prior abdominal surgery.

Although evidence is limited, performing a colonoscopy in DS or DLD offers benefits and improves insertion time and tolerance, especially in women and patients with previous abdominal surgery.[\(3\)](#)

6.27 Technique Description

The use of sedation has become widespread, as the unusual morphology of the sigmoid colon can necessitate often painful stretching of the mesentery to correct intestinal loops. Furthermore, insufflation increases patient discomfort. The drawback of sedation is that the absence of pain requires greater experience on the part of the examiner, and the caution of never proceeding without imaging, as the risk of perforation is higher if these precautions are not taken into account. The examiner's preferred position can be the gynecological position or the left lateral decubitus position.

After inserting the colonoscope into the rectum, holding the fiberscope with the left hand or allowing the assistant to hold it, while rotating it around its axis and guiding the tip from the head with the right hand, progress caudally, avoiding the various angles encountered. Once past the sigmoid colon, the next obstacle is the splenic flexure of the colon, which leads to the transverse colon, distinguishable by its triangular haustra. The hepatic flexure reveals a bluish-purple coloration

corresponding to the liver, which helps orient the colon during progression to the cecum. There, the ileocecal valve is usually visible at the crest of a fold; overcoming this fold allows visualization of the terminal ileum.(30)

6.28 Description of the endoscopic equipment

The colonoscope is used in diagnostic and therapeutic endoscopic procedures, allowing exploration of the colonic structure in all its segments. It has a control head containing the commands that enable the endoscopist to direct the distal tip, which houses the camera. It also allows for air injection, lens washing, suction, and the insertion of surgical instruments. On the right side is the connection for the air-water bottle, and on the left side of the suction equipment connector is the auxiliary adapter that allows water to be injected into the distal tip.

In our setting, the Fuji and Olympus CV 160 equipment was used, which, according to the manufacturer's specifications, the Olympus 16 video processor offers picture-in-picture viewing for any combination of endoscopy, fluoroscopy, ultrasound, laparoscopy, and endoscope position detection unit images.

7. Aim

7.1 General objective To compare bowel preparation with Lactulose vs Polyethylene Glycol, as the best agent for performing quality colonoscopies at the Fray Antonio Alcalde Civil Hospital and the Juan I. Menchaca Civil Hospital, during a period from July 1, 2024 to July 31, 2025

7.2 Specific objectives

- To demonstrate that Lactulose does not cause macroscopic changes in the colon mucosa: edema, hyperemia, hemorrhage;
- Demonstrate that Lactulose does not cause hydroelectrolytic alterations: variation in levels of sodium, potassium, chloride, phosphorus, magnesium, calcium, urea, creatinine and serum osmolarity.
- To demonstrate that the preparation with Lactulose generates less discomfort and greater tolerance, less occurrence of adverse effects such as nausea, dizziness, vomiting, abdominal distension and bad taste, as well as greater adherence to the dose by patients.
- Evaluate the quality of bowel preparation using the Boston score in each colonic segment
- Evaluate the quality of the colonoscopy using an adenoma detection rate

greater than 25% and a cecal cannulation rate greater than 95%.

8. Hypothesis

Bowel preparation with lactulose is more effective than the use of polyethylene glycol prior to a colonoscopy

8.1 Alternative hypothesis

Bowel preparation with lactulose is no more effective than the use of polyethylene glycol prior to a colonoscopy

8.2 Null hypothesis: There is no difference between the use of lactulose and polyethylene glycol.

9. Methodology

9.1 Study population

Adult patients scheduled for outpatient or inpatient colonoscopy.

9.2 Randomization

Patients will be randomly assigned to receive either polyethylene glycol or lactulose preparation. A randomization list will be generated and placed in sealed envelopes; neither the investigator nor the sub-investigators will know which preparation method each patient will receive. The personnel involved in creating the list and preparing the envelopes are part of the non-blinded team for this study and will not participate in performing the endoscopic procedures.

9.3 Study Design

Randomized double-blind clinical trial.

9.4 Universe

Patients who attend the Coloproctology service at Hospital Civil Fray Antonio Alcalde and Hospital Civil Juan I. Menchaca during a period from August 1, 2024 to July 31, 2025.

9.5 Sample size

Taking into consideration the results obtained by Zaho et al. 2019; and using the sample size formula for the difference of means of two independent samples; with a confidence level of 95%, a power of 80% and a two-tailed test. $K = 7.9$, $Var1 = 27.15$,

Var 25, M1 64.5 , M2 75, N=94.44.

$$n = \frac{k(Var1 + Var2)}{(M1 - M2)^2}$$
$$k = (Z_{\alpha} + Z_{\beta})^2$$

Adding the 10% loss: 149.6, rounding to 150 patients per group. With a total of 300 participants.

9.6 Sampling

Non-probabilistic by continuous inclusion.

9.7 Selection criteria:

1. Age:Participants must be 18 years of age or older at the time of the inclusion in the study.

2. Indication for Scheduled Colonoscopy:Participants must have a valid clinical indication for undergoing a scheduled colonoscopy, as part of a colorectal cancer screening program, assessment of gastrointestinal symptoms, follow-up of previously diagnosed colorectal pathologies.

3. Capacity to Provide Informed Consent:The participants They must have the physical and mental capacity to understand the nature of study and provide voluntary informed consent to to participate.

9.8 Exclusion criteria:

History of Intestinal Obstruction:Participants with a history of known or suspected bowel obstruction will be excluded from the study due to the potential risk associated with the administration of bowel preparers.

Known intolerance to lactulose or polyethylene glycol:Participants with a history of known intolerance to lactulose or polyethylene glycol will be excluded from the study due to the possibility of serious adverse reactions.

Pregnancy and breastfeeding: Pregnant or breastfeeding women will be excluded from the study due to a lack of data on the safety of bowel preparations in this population group.

Interfering Clinical Conditions (Comorbidities): Participants with medical conditions that may interfere with participation in the study or affect the interpretation of the results, such as uncompensated heart failure, chronic kidney disease, among others, will be excluded.

9.9 Elimination criteria

Voluntary Retirement:

Participants have the right to withdraw from the study at any time and for any reason. The decision to withdraw will be respected, and the reasons for withdrawal will be recorded in the study database.

Inability to Complete the Colonoscopy Procedure:

If a participant experiences technical difficulties during the colonoscopy procedure that prevent the proper assessment of the degree of colon cleansing, this will be considered grounds for removing the participant from the data analysis.

Inability to tolerate the bowel preparation agent:

If a participant experiences severe side effects or significant intolerance to the assigned bowel preparation agent, resulting in discontinuation of the bowel preparation procedure or colonoscopy, this will be considered grounds for removing the participant from the data analysis.

9.10 Variables to be measured

Degree of colon cleansing: It would be assessed using a standardized scoring system, such as the BBPS scale.

Tolerability: Adverse symptoms and the general tolerance of patients towards each bowel preparation product will be recorded.

Gastrointestinal side effects: Any gastrointestinal side effects experienced by patients during the bowel preparation process will be recorded.

Patient satisfaction and palatability:Data on overall patient satisfaction and the palatability of the agent with the bowel preparation process will be collected using a subjective rating scale.

9.10.1 Independent variable:

- Type of Bowel Preparer (lactulose / polyethylene glycol)

9.11 Dependent variables:

9.11.1 Degree of Colon Cleanliness (measured using the Boston Bowel Preparation Scale)

9.11.2 Cecal intubation rate

9.11.3 Cecal intubation time

9.11.4 Ileal intubation rate

9.11.5 Ileal intubation time

9.11.6 Polyp detection rate

9.11.7 Hydroelectrolytic imbalance in sodium, potassium or chloride

9.11.8 Change of position

9.11.9 Nausea or vomiting

9.11.10 Abdominal distension

9.11.11 Colic

9.11.12 Palatability

9.12 Description of the variables

VARIABLE	OPERATIONAL DEFINITION	CLASSIFICATION	MEASUREMENT SCALE	UNIT OF MEASUREMENT	MEASURING INSTRUMENT
Bowel preparation	Type of bowel preparation prior to colonoscopy, intake of polyethylene glycol or lactulose	Qualitative	Nominal (polyethylene glycol or lactulose)	Presence or absence	Data collection sheet

Degree of colon cleanliness	<p>Boston Scale: It consists of a semi-quantitative evaluation of the presence of stool and the visibility of the colonic mucosa in 3 segments evaluated based on their cleanliness</p>	Quantitative	Reason	<p>0 points: unprepared colon segment, with mucosa not visualized due to the presence of solid feces.</p> <p>1 point: areas of the colon segment not seen due to the presence</p>	<p>Boston Scale / Data Collection Sheet</p>
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				<p>of liquid and semi-solid fecal content.</p> <p>2 points: scant liquid fecal content that allows good visualization of the mucosa.</p> <p>3 points: excellent visualization of the mucosa, with no presence of liquid remains.</p>	
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Nausea or vomiting	Nausea: A feeling of illness or discomfort in the stomach that may be accompanied by an overwhelming	Qualitative	dichotomous nominal	Presence or absence	Data collection sheet
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	g urge to vomit; vomiting: The forceful expulsion of some or all of the stomach contents through the mouth				
Abdominal distension	It is a condition in which the abdomen feels full and tight. The abdomen may appear	Qualitative	dichotomous nominal	Presence or absence	Data collection sheet

	bloated.				
Colic	Acute and intense abdominal pain, unexpected and fluctuating, sometimes preceded by a vague feeling of discomfort	Qualitative	dichotomous nominal	Presence or absence	Data collection sheet

	affecting the viscera and hollow organs.				
Cecal cannulation time	Time frame in which intubation is achieved once the ileocecal valve has been identified	Quantitative	Reasons	Seconds	Data collection sheet

Cecal intubation rate	Percentage of patients in whom cecal intubation was successful ly cannulate d with respect to the total number of colonoscop ie s performed.	Quantitative	Reasons	Numerical	Data collection sheet
Ileal intubation rate	Percentage of patients in whom the ileocecal valve was successfull y	Quantitative	Reasons	Numerical	Data collection sheet

	cannulated with respect to the total number of colonoscop ie s performed.				
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Percentage of ileocecal valve cannulation	Proportion of patients in whom ileocecal valve cannulation is feasible	Quantitative	Reasons	Numerical	Data collection sheet
Polyp detection rate	Percentage of patients with at least one polyp detected during colonoscopy	Quantitative	Reasons	Numerical	Data collection sheet
Change of position	body posture or attitude used to perform the colonoscopy	Qualitative	Nominal /dichotomous	supine position/ right lateral decubitus	Data collection sheet
Hydroelectrolytic imbalance of sodium,	It is the increase or decrease, beyond normal	quantitative	Dichotomous	Sodium (Na) 135-145 mmol/l	Data collection sheet

potassium or chloride	levels, of water and/or one or more electrolytes in the body.			Potassium (K) 3.50-5.10 mmol/L Chlorine (Cl) 98-107	
Palatability	It is used to refer to the quality of a food that is pleasing to the palate..	quantitative	dichotomous	presence or absence	Data collection sheet

9.13 Limitations

Each teaching hospital, such as the Fray Antonio Alcalde Civil Hospital and the Juan I. Menchaca Civil Hospital, employs different methods for practicing and studying colonoscopies, and has a diverse patient population. The indications for these procedures vary depending on whether the colonoscopy is for diagnosis or screening. The hospital also utilizes different anesthetic methods, and staff includes interns, resident physicians, and attending physicians responsible for their respective services. Furthermore, the colonoscopy equipment at each hospital, including its operation, cleaning, and maintenance, should be considered.

9.14 Observation and data collection techniques

This study will be carried out in the coloproctology service of the Fray Antonio Alcalde Civil Hospital and the Juan I. Menchaca Civil Hospital, hospitals where the data will be collected and subsequently the analysis of the results of the study will be carried out.

The observed data will be collected on a data sheet and subsequently integrated into an electronic statistical database in a document shared via a digital platform, which will be used for this research project. Later, they emptiedThe data obtained through the observation units in each of the collection tools generated and intended for this purpose by the responsible researcher, comprehensively identifying each of the data

in order to have all the sensitive information for research, ensuring the least possible bias for the same.

9.15 Analysis of the results

Once the variables are categorized, the statistical analysis (patient characteristics, endoscopist characteristics, and indications) and per-protocol analysis (insertion time, use of loop reduction maneuvers, polyp detection, percentage of ileocecal valve cannulation, and ileocecal valve cannulation time) will be described. Continuous variables will express data were presented as mean with ranges (SD) or median with interquartile range and compared using Student's t-test or the non-parametric Mann-Whitney test, as appropriate. Categorical data where they will analyze using the chi-square test. P-values < 0.05 were considered statistically significant, and all tests were performed two-sided. Multiple linear regressions and multivariate logistic regressions were performed using the following variables: age, sex, and body mass index (BMI). The model was constructed using stepwise regression. All statistical analyses were performed using SPSS Statistics v22.

9.16 Presentation of information

The information obtained from this research will be presented in tables and graphs according to the nature of the data.

9.17 Resources needed

Human resources

The participants in the development of the work will be the responsible researcher and the members of the Coloproctology service, who are the listed sub-researchers.

Material resources and infrastructure

The hospital's own resources will be used, so no external financing will be needed.

Diffusion

The dissemination of the final results of this research will be presented at conferences and events; as well as publication of results in an indexed journal related to the proposed topic.

10. Ethical considerations:

This research protocol will be submitted for evaluation and approval by the Ethics and Research Committees of the Fray Antonio Alcalde Civil Hospital, as well as the

respective committees of each participating institution. It will also be registered with ClinicalTrials.gov to obtain a registration number and track the study. Informed consent for our study has been obtained (Appendix 1), which specifies the risks and benefits of our project, which aims to compare the time to arrival at the ileocecal valve during colonoscopy in the supine position vs lateral left in patients of the Fray Antonio Alcalde Civil Hospital and the Juan I. Menchaca Civil Hospital.

10.1 Study Risk

In accordance with Article 17 of the Regulations of the General Health Law Regarding Research, the risk of this project corresponds to research with a higher than minimal risk, since minimally invasive surgical procedures will be performed for diagnostic purposes, including general anesthesia and invasion of the lower digestive tract. It is guaranteed that the names of potential participants will remain anonymous at all times, with each being assigned an individual registration number and corresponding entry in the spreadsheet.

In accordance with Title Three of the Regulations of the General Health Law on Research, concerning the investigation of new prophylactic, diagnostic, therapeutic, and rehabilitation resources, information is provided regarding the probable adverse effects and complications associated with the procedure. These are the same as those performed routinely, such as intestinal perforation, abdominal pain, distension, and peritonitis, and occur in a low incidence of less than 5%. The unit has the personnel and physical resources to handle any emergencies. Should such an event occur, the study will be suspended or canceled.

10.2 Adherence to ethical standards

In all cases, diagnostic procedures will be collected and stored in accordance with institutional guidelines in a database, with strict data privacy. This will be done while adhering to the fundamental principles of morality, ethics, and law established in the General Health Law, the General Health Law on Biomedical Research, the Nuremberg Code of 1947, and the Declaration of Helsinki as amended.

- Article 21 of the Regulations of the General Health Law on Biomedical Research states that a precise explanation will be provided regarding how the project will be carried out, its purpose, and its benefits. Each potential participant will have the freedom to decide whether or not to participate, as well as whether or not to continue in the proposed research. This decision will not affect their rights in any way. Furthermore, in accordance with Title Three

of the Regulations of the General Health Law on Research, concerning the investigation of new prophylactic, diagnostic, therapeutic, and rehabilitation resources, information is provided on the probable adverse effects and complications associated with the procedure. These are no different from those routinely performed, such as intestinal perforation, abdominal pain, distension, and peritonitis, with a low incidence of less than 5%. Therefore, it is categorized as a risk greater than minimal, and the unit has the personnel and physical resources to address the emergency. Should such an event occur, the study will be suspended or canceled.

- Declaration of Helsinki, adopted by the 64th General Assembly, Fortaleza, Brazil, October 2013, establishes the benefit and autonomy of potential participants as the guiding principle throughout the research process. This protocol adheres to this declaration, taking into account the health, well-being, and rights of participants, and ensuring that procedures with inherent risks are carried out without increasing predetermined risks, as it is a minimally invasive procedure. The protocol always protects the life, health, dignity, integrity, and, above all, the confidentiality of participants' personal information.
- The Nuremberg Code outlines the ethical standards for experimentation on human subjects. It was published on August 20, 1947, as a result of the Nuremberg Trials (August 1945 to October 1946), in which, along with the Nazi hierarchy, several physicians were convicted for egregious human rights abuses. It is the first document to explicitly establish the obligation to obtain informed consent, an expression of patient autonomy. This research adheres to this code, providing participants with a clear and concise explanation of the informed consent process. Those who agree will be required to authorize and sign the consent form. Those who decline to participate will still receive the same high-quality care.

10.3 Informed consent

All participants included in the research protocol must understand the importance and purpose of an informed consent form, as well as have any questions they may have about the study answered before signing. The document will be provided to and requested from each participant. This form uses simple and accessible language, emphasizing their free choice to participate or remain in the study without affecting or diminishing the care they receive at the various institutions participating in this project, or their work activities within the institute. The study population is considered

a dependent population according to the General Health Law regarding research. The 2013 Declaration of Helsinki will be taken into account, adhering to the autonomy of the beneficiary and respecting their decision to participate or not in the study.

10.4 Contributions and benefits to participants

Participation in this study will not generate any financial benefit for participants; however, the intention of this study is to generate highly relevant scientific knowledge applicable to healthcare. If, during the study, a participant experiences any health issues related to the study, they will be immediately referred to the emergency department for appropriate evaluation.

10.5 Balance / risk benefit

Given that the information will be obtained through a minimally invasive method, specifically diagnostic colonoscopy, the procedure carries a greater than minimal risk to the patient. However, these risks are not as high as those associated with a routine procedure, as they are the same as those already established and described in the literature. While the short-term benefits are not immediately clear, they will have a positive impact on the average time required to perform the colonoscopy. This includes reduced time spent in the endoscopy suite, maximizing effective surgical time, decreasing the dosage of anesthetic sedation, improving airway positioning, and increasing colonoscopist productivity in the long term. The ethical principles of respect for persons, justice, beneficence, non-maleficence, and the autonomy of participants, as described in the 1979 Belmont Report, will be taken into account.

10.6 Bioethical principles

- Fairness. This study does not discriminate based on age, race, or sex for participation. The healthcare personnel population was selected using a convenience sampling technique, and all individuals who meet the selection criteria and agree to participate in the study are eligible.
- Non-maleficence. The present study does not increase the risks of a minimally invasive procedure beyond those already established and described in the literature, such as post-procedure pain, abdominal distension, and intestinal perforation.

- **Beneficence.** This study does not represent an immediate benefit for the participant, but it will generate information on how to improve colonoscopy times, as well as decrease the risk of complications in the procedure, reduce sedation time, and maximize the productivity of the endoscopist/coloproctologist in our unit.
- **Autonomy.** The participant has the informed decision to participate or not in the study, always taking into account their freedom and respecting their autonomy, without it affecting their work area or their medical care within the institute.

10.7 Confidentiality

The data of participants who agree to participate in the study will be kept strictly confidential. Each participant will be assigned a number for identification purposes throughout the study. Complete data will only be available to the researchers responsible for the protocol, who are obligated not to disclose the participants' identities during the study or even during the dissemination of the results.

10.8 Obtaining informed consent

Informed consent forms will be obtained from all participants by researchers at participating institutions, or by their designated representatives at each institution. The consent process will take place before the colonoscopy. Participants will be given a clear and concise explanation of the consent form and have their questions about the study and their participation answered. The consent form must contain information about the study in clear and understandable language and must be given freely and without coercion, as established in the 1979 Belmont Report.

10.9 Participant Selection

A randomized sample of patients undergoing diagnostic colonoscopy at the Coloproctology/Endoscopy service who meet the inclusion criteria will be selected. The study's objective will be explained to them in detail, ensuring that ethical principles are upheld and that no manipulation, coercion, or interference with the results of their diagnostic examination within the institute is present. Participant selection will not discriminate against patients based on physical characteristics, gender, race, religion, or socioeconomic status.

10.10 Benefits at the end of the study

The benefit of this study is purely scientific, as no profit is being sought for any of the

participants. However, the results could demonstrate the efficiency of performing a diagnostic procedure to standardize a technique, thereby obtaining better results and optimizing the use of resources in our unit. Should any participant require interruption of the study or immediate medical or surgical attention, they will be referred to the appropriate physician and the designated area within our unit to receive the best possible medical care.

10.11 Dissemination of results

The publication of the results will be internal and/or in relevant medical-scientific journals that will be available for consultation by professional staff in the medical field.

10.12 Conflict of interest

The researchers declare no conflict of interest for conducting this study.

11. Resources, financing and feasibility

The resources and financing for this study will be covered by the members participating in this research protocol; likewise, given its characteristics, no additional materials, supplies, staff time, or patient time will be required beyond the established protocols; because the procedure manual for performing colonoscopies in the Coloproctology service establishes this, and it will not be necessary to make modifications or alterations to it.

In other words, the routine preparation is covered by the patient, and the proposed alternative has a lower cost than what is currently used.

11.1 Feasibility:

ANDThe Fray Antonio Alcalde Civil Hospital has the teaching and research coordination as well as trained personnel in the general surgery service and its personnel in the area of coloproctology and endoscopy for the application of said study protocol, there are directors in the unit and inter-institutional ethics committee who will be in charge of reviewing and authorizing the preparation and application of this protocol.

12.Biosafety aspects

Data will be obtained through colonoscopies performed at the Coloproctology Department of the Fray Antonio Alcalde Civil Hospital. These are minimally invasive procedures, with serious complications reported in less than 1% of patients; these

complications are inherent to the procedure. There is no greater risk or added risk associated with changing position, and therefore no greater risk to the health or physical integrity of the patient, the healthcare staff of the Fray Antonio Alcalde Civil Hospital, or the environment. This approach avoids unnecessary suffering or harm, both physical and mental, to patients, as dictated by the 1947 Nuremberg Code.

13. Schedule of activities

Activities	2025									
	March	April	May	June	July	Aug	Sep	Oct	Nov	Dec
Defining the topic										
Literature review										
Protocol development										
Submission for authorization										
Data collection and fieldwork										
Coding, processing, and statistical analysis										
Writing statistical analyses										
Protocol editing										
Presentation/publication of results										

14. Statistical analysis:

The validated dataset, originally compiled using hospital computers and electronic databases and subsequently exported to Microsoft Excel, was imported into IBM SPSS v25 for statistical analysis. Descriptive statistics were used to summarize the characteristics of the study population. Quantitative variables, including age, coagulation time, and withdrawal time, were compared between groups using the Student's t-test for independent samples, after assessing normality (Kolmogorov-Smirnov) and homogeneity of variances (F-test). Categorical variables, such as sex, comorbidities, and cecal cannulation, were analyzed using the chi-square test to evaluate independence between groups. Statistical significance was set at $p < 0.05$, and the analyses provided a basis for drawing evidence-based conclusions.

15. Discussion

In this study, two bowel preparation regimens, Lactulose and Polyethylene Glycol (PEG), were compared with the aim of determining whether significant differences existed in the quality of colonic cleansing, endoscopic parameters, and diagnostic yield, using a non-inferiority approach. The available literature has previously explored this comparison; for example, the clinical trial by Aliaga Ramos et al. reported superiority of lactulose preparation, achieving higher polyp detection rates compared with PEG. These findings have generated interest regarding the potential

diagnostic benefit of lactulose as an alternative to conventional PEG-based preparations.

In line with this line of research, the randomized study published by Rashid et al directly compared lactulose with PEG in 40 patients and also found no significant differences in the quality of bowel preparation as measured by the Boston score. The authors reported similar values between groups (6.25 ± 0.786 vs. 6.35 ± 0.813 ; $p = 0.59$), concluding that both options are equally effective in achieving adequate colon cleansing.

In our analysis, the interpretation of the results indicates that the groups showed homogeneity in their demographic and clinical characteristics, which helps minimize bias and increases the certainty that the outcomes can be attributed to the type of preparation used. The absence of differences in age, sex, and comorbidities indicates an adequate allocation process and a balanced comparison between the groups.

Regarding the quality of bowel cleansing, no significant differences were found in the Boston Bowel Preparation Scale, either in individual segments or in the total score, suggesting equivalent efficacy between lactulose and PEG. This result is consistent with previous reports by both Aliaga Ramos and Rashid et al., reinforcing the idea that lactulose is a valid alternative with outcomes comparable to PEG for optimizing endoscopic visualization.

Similarly, cecal intubation showed equivalent rates between groups, with no significant differences in the technical success of the procedure or the time required. Although the overall intubation rate (94.25%) was slightly below the international standard (>95%), it remained within the acceptable range, indicating that the choice of preparation did not affect endoscopic performance.

With respect to diagnostic yield, no significant differences were observed in the ADR (Adenoma Detection Rate). Although the PEG group showed a slightly higher proportion of polyp detection, the lack of statistical significance suggests that this difference could be due to chance. This finding is consistent with the results of the study by Rashid et al, which also reported no differences in the detection of neoplastic lesions between lactulose and PEG. Despite the above, in the present study, a slight trend towards the detection and excision of early colorectal cancer lesions was confirmed, as well as the identification and excision of sessile lesions with high-grade dysplasia; due to the limited population in which this sub-analysis

could be carried out, these findings should be interpreted with caution, due to the low percentage of ADR.

The only parameter that showed a significant difference was the indication for the procedure due to rectal bleeding, which was more frequent in the PEG group. However, this finding was not related to variations in the main outcomes and did not impact the quality of preparation or lesion detection; therefore, its clinical relevance is limited.

Overall, the interpretation of these results confirms that lactulose and polyethylene glycol are clinically equivalent options for bowel preparation prior to colonoscopy. Both demonstrated similar efficacy and diagnostic performance. These findings support the individualized selection of bowel preparation based on availability, patient tolerance, cost, and institutional resources, without compromising the quality or diagnostic utility of the procedure.

Nonetheless, certain limitations should be taken into account when evaluating these findings. Although the trial employed randomization, patient adherence and tolerance to the preparatory solutions may have influenced outcomes and could not be fully controlled. The study was also conducted in two hospital units within the same region, which may restrict the generalizability of the results to other populations or clinical settings. Furthermore, despite the absence of reported adverse events, the sample size and follow-up duration might not have been sufficient to capture rare complications. In addition, it is important to mention that this study did not consider the use of medications that can alter abdominal motility and therefore the outcome of colonic preparation, such as tricyclic antidepressants (TCAs) and opioids. Medi These considerations suggest that while the current evidence supports equivalence between lactulose and PEG, further studies in more diverse populations and settings may strengthen these conclusions.

16.Conclusions

The results of this study demonstrate that bowel preparation with Lactulose and Polyethylene Glycol provides equivalent performance across all evaluated parameters. The quality of bowel cleansing, measured using the Boston Bowel Preparation Scale, was similar in both groups, with no significant differences in any colon segment or in the total score. Likewise, endoscopic performance, including cecal intubation rate and intubation time, showed no differences between the two

preparations, indicating that the choice of bowel preparation does not influence the technical ease of the procedure. Similarly, polyp detection and ADR were comparable, suggesting that neither preparation confers a diagnostic advantage over the other. Altogether, these findings support the conclusion that both preparations are clinically equivalent and can be used interchangeably in clinical practice, with the final choice depending on availability, patient tolerance, cost, and institutional criteria, without compromising procedure quality or diagnostic yield.

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18.Attachments

16.1 Informed consent letter (August 1, 2024, to July 31, 2025)

Guadalajara, Jalisco, Mexico, on _____ of _____ 202__.

Fray Antonio Alcalde Civil Hospital.

Annex: Informed Consent Letter

RESEARCH PROJECT TITLE:

"Bowel preparation in colonoscopy: Lactulose vs Polyethylene glycol, a randomized, double-blind, comparative clinical trial, multicenter study."

Principal Investigator: Dr. Roberto Ulises Cruz Neri

Affiliation: Division of Coloproctology, Fray Antonio Alcalde Civil Hospital. Contact telephone number: +52 33 3452 0518

President of the research ethics committee: Juan Luis Soto Mancilla

Affiliation: Ethics Committee of the "Fray Antonio Alcalde" Civil Hospital. Contact phone number: 39424414

Please read this document carefully.

You are invited to participate in this research project because it meets the necessary criteria. Please read the following material to understand your participation in this project and make a free and informed decision. Feel free to ask any questions you may have.

Study objective: To compare bowel preparation with lactulose vs Polyethylene glycol...as the best agent for performing quality colonoscopies at the Fray Antonio Alcalde Civil Hospital, the Juan I. Menchaca Civil Hospital, and the José Vicente Villada Regional General Hospital No. 220. Furthermore, it was demonstrated that lactulose is a highly effective and safe agent, with no negative impact on colonoscopy quality, good tolerance, and high patient satisfaction when used orally for bowel preparation prior to a colonoscopy.

What does your participation consist of?

The protocol does not require extra appointments, except if during the colonoscopy any lesion such as polyps, ulcers, or active bleeding is found that requires follow-up and/or treatment by the Proctology service in the outpatient clinic.

If you decide to participate, the following will occur: the type of bowel preparation for your colonoscopy will be randomly selected, **sedation will be provided** randomly by the anesthesiology team, the colonoscope will be inserted, and subsequently, the quality of bowel cleansing will be evaluated.

Are there any potential risks and drawbacks for you?

The risk of this project corresponds to research involving greater than minimal risk, since minimally invasive endoscopic procedures will be performed for diagnostic purposes, which include **sedation** and invasion of the lower digestive tract and

which, for the purposes of this study, are not increased, in addition to a possible electrolyte imbalance due to intestinal preparation.

Do you receive any benefits for participating?

You will not receive payment for your participation, nor does it involve any expense for you; although there may not be any direct benefits for you, the results of this study will provide relevant information and increase scientific knowledge.

Information on treatment outcomes and alternatives (clinical trials)

The results will be kept confidential by the researcher and will be provided to those who request them, who should contact the principal investigator. In the event of any condition requiring the interruption of the study, the successful outcome of the study and the patient's well-being will take precedence.

Will your data be kept confidential?

The information you provide is strictly confidential and will be kept safe and secure. Only the research team will have access to this information. When the results of this study are published or presented at forums or conferences, no information will be included that could reveal your identity. By signing this form, you authorize the use of your information.

How will your samples be stored and handled?

- You can withdraw your consent for your samples to be used for future research. In this case, your samples will be destroyed only after they are no longer needed for the main study. This can be done at any time, for any reason. This will not affect your access to the medical care you receive.
- Your samples may also be shared with other researchers for scientific research purposes. Before being shared with research partners, your samples will be labeled with a code number that is different from your primary study number. Your samples will not contain any personally identifiable information. Your samples will not be sold, loaned, or given to any independent group for their use. Other researchers working with the principal investigator of this study are not authorized to share the samples with any unauthorized third party. The principal investigator will control what is done with your samples, under the institutional regulations protecting patient confidentiality.
- The samples will be used exclusively for health-oriented scientific research. Under no circumstances will they be used for commercial purposes.

What if you decide not to continue participating?

Your participation is entirely voluntary. If you choose not to participate, the results of your medical care will not be affected. If you decide to participate and later change your mind, you may withdraw from the study at any time.

If you give your consent, please read and then sign below.

This consent form contains important information. It will help you decide whether you want to participate in this study. If you still have any questions, please ask the study doctor or a member of the study staff before signing this form.

Agreement to participate in the study:

- I have read this information.
- It is written in language that I can read and understand.
- This study has been explained to me.
- All my questions about the study and the possible risks have been answered to my satisfaction.
- Based on this information, I voluntarily agree to participate in this study.

_____	_____
Name of the person giving consent	Signature

_____	_____
Witness 1 Name Signature	

_____	_____
Witness 2 Name Signature	

By signing this form, I have not waived any of my legal rights as a research participant. I may be asked to complete additional questionnaires related to my participation in this study.

I have also received a copy of this consent form.

_____	_____	_____
Name of the principal investigator	Signature	Date



COLONOSCOPY DATA COLLECTION FORM

Personal Information						Colonoscopy date:					
Name:											
Age:		Sex: M () F ()		Medical record:							
Occupation:		Employed ()				Unemployed ()					
Education level:		None ()		Primary school ()		Secondary school ()		High school ()			
Bachelor's degree ()											
Past Medical History											
Comorbidities:		None ()		Diabetes mellitus ()		Hypertension ()		HIV infection ()			
Cancer ()											
Other (specify):											
Previous Colorectal Surgery:				YES () NO ()		Date of previous surgery:					
Specify:											
Anal fissure ()		Hemorrhoids ()		Fistula ()		Fournier's gangrene ()		Abscess ()			
Partial colectomy ()		Colectomy / Colostomy ()		Partial colectomy + Ileostomy ()		Ileostomy without colectomy () Other ()					
Indication for Colonoscopy											
LGB ()		Colorectal cancer screening ()		Known colorectal cancer ()		Inflammatory bowel disease ()					
Diverticular disease ()											
Other (specify): ()											
Bowel Preparation											
Type of preparation:						Preparation intake:					
Lactulax ()						Complete () Incomplete ()					
Posfosoda () Nulytely ()											
	1	2	3	4	5	6	7	8	9	10	
Palatability											
Assessment											
Sweet taste:											
Salty taste:											
Bitter taste:											
Sour taste:											
Residual taste :											
Adverse Effects	Nauseas		Vomiting		Abdominal pain		Abdominal distension				
	YES ()	NO ()	YES ()	NO ()	YES ()	NO ()	YES ()	NO ()	YES ()	NO ()	
Endoscopic Equipment											
Colonoscope:						Technique:					
FUJIFILM BL 7000 () OLYMPUS ()						Two-hand technique ()					
						Four-hand technique ()					
Starting position:						Left lateral decubitus ()					
Supine position ()											
Final position:						Left lateral decubitus ()					
Supine position ()											
Colonoscopic Findings											
Please specify the number of polyps found in each segment, and classify each polyp according to the Kudo and Paris classifications.											
Finding/Segment	Rectum	Sigmoid	Desc	Trans	Asc	Cecum					

Diverticula												
Polyps	Pedicated	< 5mm										
		> 5mm										
	Sessile	< 5mm										
		> 5mm										
Ulcers	<5 mm											
Bleeding	Active											
	Inactive	Hematin										
		Fibrin										
Boston Bowel Preparation Score												
Descending				Transverse				Ascending				Total score
0	1	2	3	0	1	2	3	0	1	2	3	
Ileocecal valve cannulation: (YES) (NO)				MINUTES:				SECONDS:				
Cecal Visualization: (YES) (NO)				MINUTES:				SECONDS:				
Withdrawal Time:				MINUTES:				SECONDS:				
Normal colonoscopy: (YES) (NO)				Biopsy performed: (YES) (NO)								
LABORATORIES												
	NA		K		CL		Ca		P		Cr	Urea
Pre:												
Post:												

16.3 Bowel Preparation Instruction Sheet

LACTOSE

1 DAY BEFORE YOUR COLONOSCOPY

--/--/----

BEGIN BOWEL PREPARATION AS INDICATED BELOW:

PRESENTATION

Lactulax /lactulose syrup 10g/15ml Oral /Bottle with 125 ml and measuring cup

2 bottles of Lactulax (125 ml each bottle = 250 ml total) or 1 bottle (200 ml)

+

800 ML (400 ml x BOTTLE) OF WATER

7-10 PM

TIPS

- Strained broths, tea and coffee WITHOUT MILK, PULP-FREE juices, fresh water, gelatin, electrolytes, Gatorade/Powerade. AVOID RED COLOR
- You can consume as much liquid as you like; it is very important to stay hydrated throughout the preparation. However, you may only consume liquids until 11:00 PM the day before your test. FROM THIS MOMENT ON, YOU MUST FAST.
- If you take any medication for hypertension, diabetes, or another systemic disease, take it with LITTLE WATER at your usual time.

DATE OF COLONOSCOPY

--/--/----

Coloproctology area, FAA Civil Hospital "Julio Clement Room"

SODIUM PHOSPHATE

1 DAY BEFORE YOUR COLONOSCOPY

__/__/----

BEGIN BOWEL PREPARATION AS INDICATED BELOW:

PRESENTATION

Sodium Phosphate/ PS PHOSPHOSODA syrup 2.71 g/ 1.2 g/ 5 ml (45 ml bottle)

In the morning

1 BOTTLE OF PHOSPHOSODA (45 ML)

+

1/2 GLASS (120 ML) OF WATER OR SUGAR-FREE LIME FLAVOR DRINK

At night

1 BOTTLE OF PHOSPHOSODA (45 ML)

+

1/2 GLASS (120 ML) OF WATER OR SUGAR-FREE LIME-FLAVORED DRINK

Followed by 1 glass of water (240 ml)

TIPS

- Strained broths, tea and coffee WITHOUT MILK, PULP-FREE juices, fresh water, gelatin, electrolytes, Gatorade/Powerade. AVOID REDNESS
- You can consume as much liquid as you like. It is very important to stay hydrated throughout the preparation; however, you may only consume liquids until 11:00 PM the day before your procedure. FROM THIS TIME ON, YOU MUST FAST.
- If you take any medication for hypertension, diabetes, or another systemic disease, take it with a SMALL AMOUNT OF WATER at your usual time.

COLONOSCOPY DATE

Coloproctology Department, FAA Civil Hospital *Julio Clement Room*