Division of Coloproctology

“Randomized, single-blind clinical trial comparing left lateral decubitus position vs. supine decubitus position for performing colonoscopies, multicenter study.”

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CONTENT:

4. **Problem statement and research question**
5. **Justification**
6. **Theoretical framework**
    - **6.1** Anatomy of the colon
    - **6.2** History of endoscopy and colonoscopy
    - **6.3** General information about colonoscopy
    - **6.4** Indications for colonoscopy
        - **6.4.1** Colon cancer screening
        - **6.4.2** Surveillance in inflammatory bowel disease
    - **6.5** Contraindications
    - **6.6** Safety and complications of colonoscopy
        - **6.6.1** Colon perforation
        - **6.6.2** Bleeding
        - **6.6.3** Post-polypectomy syndrome (PPS)
        - **6.6.4**Post-colonoscopic dilation syndrome
        - **6.6.5** Abdominal discomfort and pain
    - **6.7** Position in colonoscopy and its clinical implications
    - **6.8** Duration of the colonoscopy
        - **6.8.1** Difficult colonoscopy and loop formation
    - **6.9** Description of the technique
    - **6.10** Description of the endoscopic equipment
    - **6.11** Bowel preparation
        - **6.11.1** Factors that influence the quality of bowel preparation
            - **5.11.1.1** Type of solution and tolerability
            - **5.11.1.2** Preparation regimen
                - **5.11.1.3** Time of the colonoscopy after bowel preparation
    - **6.12** Cecal intubation rate
    - **6.13** Terminal ileal intubation rate
    - **6.14** Polyp detection rate
    - **6.15**Quality indicators in colonoscopy
7. **Goals**
    - **7.1** General objective
    - **7.2** Specific objectives
8. **Hypothesis**

9. **Methodology**
    - **9.1** Studio design
    - **9.2** Universe
    - **9.3** Population
    - **9.4** Sample size
    - **9.5** Sampling
    - **9.6** Selection criteria
        - **9.6.1** Inclusion criteria
        - **9.6.2** Exclusion criteria
        - **9.6.3** Elimination criteria
    - **9.7** Definition of the variables
    - **9.8** Randomization
    - **9.9** Observation and data collection techniques
    - **9.10** Analysis of the results
    - **9.11** Presentation of information
    - **9.12** Resources needed
        - **9.12.1** Human resources
        - **9.12.2** Material resources and infrastructure
    - **9.13** Diffusion
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** Conflict of interest
11. **Resources, financing and feasibility**
12. **Biosafety aspects**

1. **Summary of the work / structured abstract**

Authors:

INTRODUCTION: Colonoscopy is currently a minimally invasive procedure used for both diagnosis and treatment by endoscopists, gastroenterologists, and colorectal surgeons. Given the importance and impact of this method, it is necessary to optimize its efficiency and improve its quality. This is one of the objectives of this study protocol, which aims to determine the fastest and least complicated position for performing a colonoscopy without compromising its effectiveness.

AIM: To determine the effectiveness of the left lateral decubitus position*vs*supine position for time of arrival at the cecum, percentage and time to intubate the ileocecal valve, polyp detection rate and formation of loops requiring reduction maneuvers and/or changes in patient position in patients undergoing colonoscopies at the Fray Antonio Alcalde Civil Hospital,and Regional General Hospital No. 220 “José Vicente Villada” during a period from July 1, 2024 to July 31, 2025.

MATERIALS AND METHODS:A single-blind, randomized 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 José Vicente Villada Regional General Hospital No. 220. 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 randomly assigned to undergo colonoscopy in either the left lateral decubitus or supine position.

Once the patient has signed the informed consent form, the study will be conducted. The student will record the relevant information on the data collection sheet, which will then be entered into the system.document shared via digital platform to perform cleaning of it andThe statistical package should be exported to SPSS for data analysis and to draw conclusions.

GROUP EXPERIENCE: The researchers have experience in performing colonoscopies, having staff from the service attached.

RESULTS ANALYSIS: The following will be recorded and compared between both groups: time to reach the cecum, percentage and time to intubate the ileocecal valve, formation of loops requiring reduction maneuvers and/or changes in patient position, and detection rate of polyps and adenomas.

KEYWORDS: Endoscopy, colonoscopy, position variety.

2. Introduction

Colonoscopy is currently one of the most widely used procedures for the study and treatment of patients with gastrointestinal conditions, including colorectal cancer and inflammatory bowel disease.(1)In the area of colorectal neoplasia, colonoscopy has three main functions: detecting the disease and preventing its development by detecting and removing potentially premalignant lesions, as well as providing an early diagnosis of cancers.(2)In fact, more than 15 million colonoscopies are performed in the United States each year, and it is estimated that the study reduces the risk of death from colorectal cancer by more than 60%.(3)However, there are some situations in which performing a colonoscopy is contraindicated, including the presence of peritonitis, intestinal perforation or colonic necrosis, severe coagulopathy, severe thrombocytopenia, severe neutropenia, and very uncooperative or agitated patients.(4).

The effectiveness of colonoscopy is crucial for carrying out an accurate examination of the entire colorectal mucosa, which is why the quality of the procedure has been a subject of study in recent years.(2)Among the various factors that influence the quality of a colonoscopy is bowel preparation, which is essential for an accurate procedure. Inadequate preparation can hinder the detection of lesions, since in patients with little or no preparation, the colonoscopy will usually be incomplete and require repeat examination. In patients who proceed with the colonoscopy despite poor bowel preparation, the presence of stool results in poor visualization of the colonic mucosa, thus affecting the ability to detect polyps, especially those smaller than 5 mm. Therefore, the type of solution and its tolerability, the preparation regimen, and the timing of bowel preparation are all considerations to evaluate when performing a colonoscopy.(5).

The position during colonoscopy is another factor that can influence its effectiveness. Traditionally, colonoscopy begins and ends (if no position changes occur) in the left lateral position. However, recent evidence suggests that the supine position may alleviate the disadvantages of the left lateral position by decreasing the frequency of position changes and abdominal pressure, potentially resulting in easier insertion in the supine position compared to the left lateral position. Nevertheless, few studies have evaluated the impact of the supine position during colonoscopy insertion.(6).

3. Background

Techniques to improve the effectiveness of colonoscopy, as well as methods to ensure patient comfort during the procedure, are essential for its success. There is ample evidence regarding withdrawal maneuvers to increase adenoma detection; however, there is limited information on the optimal insertion technique for colonoscopy. Conventionally, colonoscopy begins with patients in the left lateral decubitus position. However, it has been observed that in this position, air can escape from the left colon, causing it to collapse and creating sharp curves that can be difficult to overcome.(4).

In a randomized clinical trial conducted by Vergis*et al.*., the initial prone position was compared*vs*The left lateral position for colonoscopy. In this study, the authors reported no benefit of the prone position over the conventional left lateral position. On the contrary, the prone position led to an increased time to reach the cecum, which they attributed in part to a longer time to reach the transverse colon when patients were prone. Regarding patient comfort, no significant differences were observed between the two positions.(7)Another study conducted by the same group of researchers in London aimed to compare the initial left lateral position*vs*The right lateral position was reported to have a faster average time to reach the cecum if the colonoscopy was started with patients in the right lateral position compared to the left lateral position. In addition, the level of comfort was higher in patients who started in the right lateral position, especially in women who had previously undergone abdominal surgery.(8).

On the other hand, few studies have focused on evaluating the impact of the supine position on colonoscopy insertion, especially in patients without sedation. In a previous study by Zhao*et al.*They observed that cecal intubation time was significantly shorter in patients who began colonoscopy in the supine position; similarly, descending colon intubation time was also shorter in these patients. Furthermore, the supine position was associated with lower pain scores, less frequent position changes, and a reduced need for abdominal compression. Therefore, the authors concluded that initiating colonoscopy in the supine position is a cost-effective and convenient method for reducing cecal intubation time, decreasing pain, and improving colonoscopy acceptance in patients without

sedation.(6)However, further studies are needed to support the effectiveness of this position for performing colonoscopies.

4. Problem statement and research question

Colonoscopy is the most widely used method for the treatment and diagnosis of colon diseases. It is a procedure that involves examining the inside of the rectum and colon by inserting an instrument known as a colonoscope. The diagnostic accuracy of colonoscopy requires a detailed visualization of the colonic mucosa. However, despite being a widely used technique, there is a risk of various adverse effects. Colon perforation is a serious complication with a relatively high mortality rate. The reported perforation rate ranges from 0.005% to 0.085%. On the other hand, bleeding is a more common adverse event than perforation. Recent studies have reported that post-colonoscopy bleeding occurs in 0.001% to 0.687% of cases.

Inserting a colonoscope is technically challenging; however, few randomized clinical trials have been conducted to determine the optimal patient position during colonoscope insertion. One previous study compared the initial supine position with the initial left lateral position and found that cecal intubation times decreased and patient comfort scores improved with the supine position. Patient positioning during colonoscopy has been proposed as a simple and cost-effective technique to increase luminal distension and improve navigation through the large intestine.

Based on the above, using the initial supine position could be a convenient method to reduce cecal intubation time, alleviate pain, and improve patient acceptance of colonoscopy without sedation. However, further research is needed in this area to establish the advantages of the initial supine position over other classically used positions such as the lateral decubitus position.

Therefore, we ask the following research question:

Is there a significant difference in the effectiveness and comfort of performing a colonoscopy when comparing the left lateral decubitus position with the supine decubitus position?

5. Justification

Colonoscopy is currently one of the most widely used procedures for the study and treatment of patients with gastrointestinal conditions, including colorectal cancer and inflammatory bowel disease. The effectiveness of colonoscopy depends on the accurate examination of the entire colorectal mucosa. Colonoscopy is a complex

procedure, so insertion techniques aim to shorten the bowel over the colonoscope, allowing for controlled, safe, and effective withdrawal.(1).
Previous studies have reported cecal intubation rates ranging from 72.7% to 95.5%; furthermore, according to a previous meta-analysis, the total number of missed polyps varies considerably across studies, ranging from 14% to 30%.(9,10).

Colonoscopy conventionally begins with patients placed in the left lateral decubitus position; however, during this initial position, air escapes from the left colon, causing it to collapse and creating sharp curves that can be more difficult to manage.(8)Few randomized studies have been conducted to determine the optimal patient position during colonoscope insertion. In general, evidence has suggested that the supine position may alleviate the disadvantages of the left lateral decubitus position. A reduction of 41 seconds in the median cecal intubation time has even been reported in the supine group compared to the left lateral decubitus group.(6).However, more evidence is needed to support the effectiveness of the initial supine position.

The institute has subjects for study and analysis within a defined time and physical space. Furthermore, the hospital has the necessary material resources and instruments to conduct this research.

The study will be limited only to patients who are beneficiaries of the hospital; furthermore, since it is a single-blind randomized clinical trial, the endoscopists in the study cannot be blinded, so the researcher's bias will not be excluded.

6. Theoretical framework

6.1 Anatomy of the colon

The colon begins at the junction of the terminal ileum and the cecum, extending from 90 to 150 cm towards the rectum, being longer in more women by +/- 10 cm and is made up of 7 parts; cecum, ascending colon, transverse colon, descending colon, sigmoid colon, rectum and anal canal(11).

The cecum is the largest portion of the colon, approximately 7.5 to 8.5 cm in diameter. It has a thin muscular wall, making it vulnerable to perforation and less prone to obstruction. The ascending colon is usually fixed to the retroperitoneum; its length is variable, and its average diameter is 5-7 cm. The hepatic flexure marks the

transition to the transverse colon, which is intraperitoneal and mobile. Its means of fixation are the gastrocolic ligament and the mesentery of the colon, making it more susceptible to the formation of loops and kinks during colonoscopy. It can be short or so redundant that it extends into the hypogastrium, thus favoring the formation of loops during colonoscopy. The greater omentum inserts on its anterior and superior border; these attachments explain the triangular appearance of the colon during colonoscopy. The splenic flexure marks the transition from the transverse colon to the upper colon.al colonDescending colon. The junctions between the splenic flexure and the spleen via the ileocolic ligament form a pronounced flexure, which is sometimes accentuated in the left lateral decubitus position. The descending colon is variable in length and is fixed to the retroperitoneum, meaning it is not mobile. The sigmoid colon is the narrowest part of the colon but is also highly mobile. It is located in the left lower quadrant, but it can be so redundant and mobile that it can shift to the right lower quadrant. Similarly, the mesentery can be very long and have a narrow base, which predisposes to volvulus in this area, as well as the appearance of loops of bowel during colonoscopy. For this reason, most endoscopists and gastroenterologists recommend performing colonoscopies in the left lateral decubitus position, allowing the mesentery to shift towards the abdominal wall and iliac crest, thus reducing its mobility.

The rectum, for its part, measures approximately 12-15 cm in length and is divided into three sections: the upper intraperitoneal third, the middle retroperitoneal third, and the lower extraperitoneal third. Three distinct submucosal folds, called the valves of Houston, extend into its lumen; two of these valves are on the left and one on the right. The fold formed in the middle is called the valve ofKohlrausch. The anatomical anal canal extends from the pectinate and dentate lines to the anal verge, measures 2 to 3 cm, and corresponds to the first portion evaluated in colonoscopy, where the following are observed: longitudinal folds called anal columns or columns of Morgagni and between these are the anal sinuses.

6.2 History of endoscopy and colonoscopy

The word*endoscopy*It comes from Greekendoscopy, a word composed of éndon, which means*within*and scopeín, which means*observe in detail*(12)The first historical evidence of the study of cavities dates back to the 18th century, where with a series

of mirrors and light obtained from the sun and candles, certain cavities such as the oral cavity, nasal cavity, anal canal and vagina could be observed.

In the mid-1800s, numerous scientists attempted to build endoscope-like instruments, but it wasn't until 1853 that Desormeaux developed the first open-tube endoscope, which was used to examine the urethra and bladder, and thanks to whom the term endoscope was first used in 1865(13)It wasn't until the late 1800s that Adolf Kussmaul, using the sword-swallowing technique, visualized the esophagus, earning him the title of the father of endoscopy. Until the 20th century, attempts to create endoscopes followed the same principle of rigid endoscopy. In 1928, Schindler began work on a flexible endoscope, and years later, in 1983, Sivak and Fleischer created the video endoscope, which astonished the medical and scientific community with its ability to convert images from analog to digital.(14).

Exploration of the colon and rectum began with the work of Howard A. Kelly in 1894, who developed the first long (30 cm) rigid rectosigmoidoscope. In 1903, James P. Tuttle, with the assistance of the Rochester Electrical Surgical Instrument Company, developed a rectosigmoidoscope with an electric illumination system, capable of reaching as far as the cecum.(15).

Fiber optics in colonoscopy was introduced in 1963 by Robert Turrell(16)Years later, in 1969, at Beth Israel Medical Center in New York, Wolff and Shinya performed one of the first modern colonoscopies, using a colonoscope developed in Tokyo by Dr. Niwa and Dr. Yamagata. In addition, Dr. Shinya developed a wire-loop cautery device that allowed for the immediate removal of polyps, eliminating the need for a second, repeat procedure.(3).

A major clinical benefit was the ability to expand the usefulness of the colonoscope not only for taking biopsies, but also for removing polyps.(16), and the early detection and treatment of colorectal cancer, becoming the industry standard.

6.3 General information about colonoscopy

Colonoscopy is currently one of the most widely used procedures for the study and treatment of patients with gastrointestinal conditions, including colorectal cancer and inflammatory bowel disease.(1)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; diagnosing the disease by investigating symptoms; and preventing metachronous cancer by monitoring patients who have already had colorectal cancer.(2).

The effectiveness of colonoscopy in fulfilling these functions depends on a precise examination of the entire colorectal mucosa; therefore, colonoscopy quality has become a subject of study in recent years. Consequently, several colonoscopy quality indices have been developed that focus on the thoroughness of the examination and patient satisfaction.(2).

Colonoscopy is a complex procedure because the colon is a six-foot-long muscular tube coiled within a small abdominal cavity. This tube has varying degrees of fixation, and its configuration involves unpredictable twists and turns of varying sharpness. Insertion techniques aim to shorten the bowel over the colonoscope so that withdrawal can be controlled, safe, and effective. Effective examination requires a cooperative and ideally maneuverable patient, with a systematic and unhurried withdrawal process.

6.4 Indications for colonoscopy

The American Society for Gastrointestinal Endoscopy (ASGE), after reaching a consensus, established several indications for colonoscopy, including chronic abdominal pain, evaluation of abnormalities in barium enema or other imaging studies, evaluation of unexplained and suspected gastrointestinal bleeding, screening and follow-up in colorectal cancer, follow-up in inflammatory bowel disease, and significant diarrhea of unexplained origin.There are also therapeutic indications for interventions such as homeostasis, polypectomies, removal of foreign bodies, decompression of acute colonic dilation or colonic volvulus, palliative treatment of obstruction or hemorrhage due to neoplastic lesions of the colon, marking of the location of lesions, among others(17,18).

6.4.1 Colon cancer screening

One of the main indications is screening and polypectomy, as the latter is associated with a decreased risk of developing colorectal cancer. This is based on the fact that adenomas are detected in 20-30% of asymptomatic patients, representing a population with an average risk of colorectal cancer, and of these, 10% have hyperplastic polyps.(17).

6.4.2 Insurveillance in inflammatory bowel disease

Patients with long-standing inflammatory bowel disease have an increased risk of developing colorectal cancer; in fact, the cumulative risk of developing it is estimated to be 2% over 10 years, 8% over 20 years, and 18% over 30 years in patients with ulcerative colitis.(17,19)Due to the high risk, monitoring through colonoscopy and biopsy is necessary.

6.5 Contraindications

Contraindications for performing a colonoscopy are grouped into two categories: absolute and relative. The latter are determined by the specialist performing the procedure or by the patient's acceptance based on information about the risks, which is the most important factor.(20).

Absolute:

- Peritonitis
- Intestinal perforation
- Recent acute myocardial infarction
- Recent pulmonary thromboembolism
- Acute diverticulitis with signs of sepsis

Relatives:

- Acute uncomplicated diverticulitis
- Ascites or peritoneal dialysis
- Massive bleeding
- Cardiopulmonary instability

- Recent intestinal surgery
- Pregnancy in the second and third trimesters
- Contraindication to anesthetic drugs

6.6 Complications of colonoscopy

Even under the best conditions, various complications can arise during a colonoscopy. These are rare, but when they occur, they tend to be serious. A 2016 meta-analysis of post-colonoscopy complications mentions that the main related complicationssonPerforation, bleeding, and post-colonoscopy distension syndrome are common adverse events. These events occur in approximately 0.3% to 1.3% of cases.(21).

The incidence of post-colonoscopy complications increases in elderly patients or in patients with inflammatory bowel disease(22), however,Lippert et al in 2015 demonstrated that colonoscopy is safe and feasible in elderly patients, although the complication rate (perforation rate: 0.408%, bleeding rate: 0.136%) increases slightly in elderly patients compared to the generally recognized complication rates in younger patients(23)On the other hand, in the case of patients with Inflammatory Bowel Disease who undergo therapeutic endoscopy, according to a 2007 systematic review, it is estimated that there may be significant complications in 2% of those who undergo therapeutic endoscopy.(24)**.**

6.6.1 Colon perforation

Perforation is the most serious and feared complication for endoscopists. According to the latest updates, the estimated global incidence is 0.016–0.8% for diagnostic colonoscopies and 0.02–8% for therapeutic colonoscopies.(21).

Colonoscopy perforation is defined as intraperitoneal fat or viscera observed during colonoscopy, or the presence of radiological abnormalities such as free intra-abdominal air on x-rays, or localized or diffuse release of intestinal gas or fluid into the peritoneum on computed tomography.(22)These perforations can occur through various mechanisms, including mechanical trauma from the endoscope itself, as well as barotrauma, thermal energy, and/or removal of a lesion in the colonic mucosa.

It is documented that approximately 45-60% of incidental perforations are detected during colonoscopy, although many are not immediately recognizable. The most frequent site of perforation during a colonoscopy is the sigmoid colon (60%), followed by the ascending colon and cecum (15-20%), and the transverse and descending colon (10% each). This correlates with the sigmoid colon being the site with the highest frequency of conditions such as polyps, adhesions, and diverticula, and the most difficult to maneuver. There are three therapeutic options for the treatment of incidental endoscopic perforation: endoscopic repair, conservative/expectant management, and conventional open surgery. The choice depends on the operator's skill, the patient's overall condition, and the availability of the surgical team.(25).

6.6.2 Bleeding

According to the Endoscopy Quality Task Force of the American Society for Gastrointestinal Endoscopy (ASGE) and the American College of Gastroenterology, post-polypectomy bleeding occurs in <1% of cases(26), and represents between 0.3 and 6.1% of complication cases.

The definition of post-colonoscopy bleeding varied in different studies; however, a Korean research group proposed a comprehensive definition in 2016 in the World Journal of Gastroenterology, defining it as “lower gastrointestinal bleeding after a colonoscopy with or without polypectomy that requires a red blood cell transfusion, hospitalization, an emergency room visit, or the need to repeat the colonoscopy in the context of hematochezia.”(22)and divides it into immediate bleeding, which occurs within the first 24 hours after the study, and delayed bleeding, which occurs between 24 hours and 14 days after the endoscopic procedure. However, bleeding after a diagnostic colonoscopy is very rare, and if it does occur, it is generally associated with biopsy sampling. The same Korean group mentions that “the post-polypectomy bleeding rate (0.98%) is significantly higher compared to when a polypectomy is not performed (0.06%) ($P<0.001$).”(22).

Various endoscopic hemostatic techniques are used for this purpose, with contact methods such as endoscopic clips being preferred. Chemical hemostatic agents such as epinephrine and sclerosing agents are available; however, their use as monotherapy is associated with a high rebleeding rate of up to 20%. Commonly used

thermal techniques for hemostasis include bipolar probe coagulation and argon plasma coagulation.(27).

6.6.3 Post-polypectomy syndrome (PPS)

Post-colonial polypectomy (PCP) is defined as the progression of abdominal pain, leukocytosis, fever, and localized peritonitis without radiographic evidence of colonic perforation. It typically occurs after colonoscopic polypectomy with electrocoagulation, and its incidence has been reported to range from 0.003% to 0.1%. Risk factors associated with PCP include hypertension, large lesions, and polyps.(22)Fortunately, this complication does not require surgical treatment, and it usually resolves without progressing to a perforation, so it is managed with intravenous fluids, antibiotic therapy and fasting until the symptoms resolve.

6.6.4 Post-colonoscopic distension syndrome

Post-colonoscopy distension syndrome is caused by excessive air insufflation into the colon during a colonoscopy, resulting in significant pain that is often difficult to distinguish from perforation. It is usually a minor, non-serious, but bothersome complication, sometimes requiring a digital rectal examination upon removal of the endoscope.(28).

6.6.5 Abdominal discomfort and pain

The most commonly reported adverse event is abdominal distension (25%) followed by abdominal pain/discomfort (5%-11%)(29)Abdominal pain during a colonoscopy is commonly caused by colonoscope loops or excessive insufflation of air. Post-procedure pain, on the other hand, is usually caused by distension from the insufflated gas, and this symptom lessens and resolves after passing flatus a few hours after the procedure.

6.7 Position in colonoscopy and its implicationsclinics

Conventionally, colonoscopy begins with patients placed in the left lateral position.(7)It is well described that when starting in this position, the air that rises

from the left side of the colon causes curves in the sigmoid colon that make it difficult to insert the colonoscope into the cecum. Therefore, a change in the initial position of the patient when performing a colonoscopy has been proposed, with the aim of preventing the cavity from filling with air and reducing intestinal angulation, fecal residue, among other things.

The studyROLCOLA study conducted in 2015 reported that patients randomly assigned to begin colonoscopy in the right lateral position experienced shorter cecal insertion times and less discomfort. The benefits of the right lateral position are thought to arise from the effect of gravity on theshortenand straighten the left colon in a manner analogous to that achieved by immersion in water or exchange techniques(8,30).

Another similar study evaluated the effectiveness of initiating colonoscopy in the prone position compared to the classic (left lateral) position; however, no benefit was observed in terms of time to reach the cecum or patient comfort for those who began the colonoscopy in the prone position compared to the left lateral position. In contrast, there was an increase in the time to reach the cecum when patients were placed in the prone position, leading to the conclusion that the initial prone position was more technically challenging than the initial left lateral position. This was attributed to greater difficulty in navigating the left colon when patients began the procedure in the prone position.(7).

In the discussion of a meta-analysis conducted by a group of Japanese researchers in 2020 that included ten Randomized Clinical Trials with a total of 2083 participants, they mention that the initial supine and downward-leaning positions could allow for a shorter mean cecal insertion time and a decrease in the need to change positionFrom the initial position during the colonoscopy, the left lateral position was found to be more effective, and the supine position reduced patient pain. However, it was also noted that there were no statistically significant differences in the proportion of successful cecal insertion between the supine and downward-leaning positions and the initial left lateral decubitus positions, with the latter increasing the need for a change of position.(31)This study group finally mentions that they could not reach a definitive conclusion regarding the efficacy and safety of the initial colonoscopy

position, mentioning the importance of analyzing the clinical context and taking into account the endoscopist's preferences.

Another study conducted in 2022 by a US group concluded that initiating colonoscopy in the prone position significantly reduced the need for external abdominal pressure or patient repositioning compared to the left lateral decubitus position. This study also resulted in a reduction in musculoskeletal injury rates, making the procedure safer for patients.(32).

Another study group from Singapore, conducting a meta-analysis in 2020, indicated that the endoscopist's preference and experience play a significant role in determining the effectiveness of colonoscopy. They cited several studies that examined the effects of the endoscopist's perception of the difficulty of performing a colonoscopy using the left lateral decubitus, supine, and prone positions. One study showed that maneuvering in the left colon can be more difficult when performed in the prone position, while others found that starting in the supine and left lateral decubitus positions made the maneuvers easier. However, these discrepancies regarding positioning were based on the endoscopist's experience, with more experienced endoscopists perceiving less of a difference.(27).

Therefore, it should be considered that changes in position from left lateral to supine or right lateral generally require only a few seconds in minimally sedated patients. In contrast, changing to the prone position is usually more complicated and requires more attention to medical devices from nursing staff. Furthermore, changing to the prone position requires a certain degree of upper body strength from the patient. These obstacles could cause delays that would not be offset by the potential benefits of the prone position in preventing bowel loop formation.

during the colonoscopy(33).

Few studies have evaluated the impact of the supine position on colonoscopy insertion. Traditionally, colonoscopy is initiated and completed (if no position changes occur) in the left lateral decubitus position. Overall, evidence has suggested that the supine position may alleviate the disadvantages of the left lateral decubitus position. Zhao*et al.,*They reported a 41-second reduction in the median cecal intubation time

in the supine group compared to the left lateral decubitus group; however, pain scores in women remained high even in the supine group, indicating that further approaches to alleviate patient discomfort are warranted. Based on their findings, the authors report that the significant decrease in the frequency of position changes and abdominal pressure may reflect easier insertion in the supine position.(6).

6.8 Duration of the colonoscopy

The duration of a colonoscopy begins with the insertion of the colonoscope through the anus and ends with its removal. It consists of two phases: the insertion phase, which is measured from its entry through the anus until it reaches the cecum, and sometimes the terminal ileum; and the withdrawal phase, which ends when the colonoscope is completely removed. This is highly relevant because, as an invasive procedure that can be performed under sedation.It is important to focus the time on this procedure and to perform it in the shortest possible time, without losing sight of the main purpose, which is the diagnosis of the main colonic pathologies.(34).

The American Gastroenterological Association, in its AGA Clinical Practice Update on Strategies to Improve the Quality of Screening and Surveillance Colonoscopy: Expert Review, indicates that the duration of a colonoscopy should be less than 10 minutes from insertion to cecal intubation and more than 5 minutes to avoid the risk of excessive manipulation and intestinal perforation. Similarly, the withdrawal time should be more than 6 minutes, with approximately 9 minutes being ideal for performing a colonic examination. Therefore, the ideal time for performing a colonoscopy is estimated to be approximately 12 to 19 minutes. However, this may be extended when a procedure is performed or if the colonoscopy is difficult.(1).

6.8.1 Difficult colonoscopy and loop formation

A difficult colonoscopy is defined as a colonoscopy in which the endoscopist finds it difficult to pass the colonoscope to reach the cecum despite different maneuvers; however, it is important to differentiate it from the interruption of the colonoscopy, which is a difficult colonoscopy in which it is decided to interrupt it due to excessive manipulation, lack of preparation, or obstruction.

Several factors increase the duration of cecal intubation, including female sex, inadequate bowel preparation, advanced age, constipation, low body mass index,

patient pain, previous hysterectomy, and diverticular disease. Loop formation is the primary consequence of a difficult colonoscopy. Studies, such as that by Douglas K, indicate that approximately 75% of patients undergoing colonoscopy develop some type of loop, 90% of which are located in the sigmoid colon. The most common is the "N" loop, where the mesentery of the sigmoid colon elongates, causing pain and minimal progress, thus increasing the colonoscopy time.

There are certain maneuvers to reduce and correct this type of loop; however, there are different types of loops, such as alpha loops or inverted alpha loops. Alpha loops advance less, but this does not cause pain. The most common maneuvers are performed by the endoscopist without the aid of any special equipment. The first of these is the removal of the colonoscope and its clockwise rotation to reduce an N-shaped loop. Counterclockwise rotation of the colonoscope reduces alpha loops and helps improve advancement. Other existing maneuvers to improve colonoscope passage include extrinsic abdominal compression, either with manual compression of the abdominal wall towards the sigmoid colon or the use of an abdominal binder with regulated pressure. Colonoscopy with an ultrathin instrument is beneficial for colonic obstructions caused by tumors; colonoscopes as thin as 7 mm with a working channel are available. In a study by Ito and colleagues involving 100 patients with stenotic colorectal cancer in whom a standard pediatric colonoscope could not pass through the CRC stenosis, cecal intubation was achieved in 58% of patients using the ultrathin colonoscope. This has also been demonstrated in Crohn's disease.

Rigid overtube colonoscopy, wire reinforcement colonoscopy, balloon-assisted colonoscopy, and water-assisted colonoscopy are other types of maneuvers that have been experimental in certain countries, without standardized techniques and with questionable utility even without conclusive scientific evidence, in addition to being techniques not used in our unit.

6.9 Description of the technique

There are three described methods for performing a colonoscopy. The first requires two operators to control the equipment; one holds the handpiece and the other the insertion tube. This technique has the advantage that the endoscopist can focus solely on the image. The second is called "one person, two hands," in which the

endoscopist controls the handpiece with two hands while simultaneously controlling the insertion, not at the same time, but in stages. The third and final method, recommended by the European Gastroenterology Association, requires greater skill but is considered the standard technique. It is called "one person, one hand," in which the handpiece is controlled with one hand and the insertion with the other.(35).

When the patient is positioned in the left lateral decubitus position, the lower limbs are flexed towards the abdomen, in the Sims' position. If the patient is in the supine position, the same maneuver is performed, supporting the lower limbs by the feet to keep them fixed and prevent extension, in the lithotomy position. The perineal and anal area is inspected, followed by a pre-lubricated digital rectal examination, assessing anal sphincter tone, the presence of masses, and the prostate gland in men. This provides indirect information about the preparation. Another important factor is the examiner's comfort; it is recommended that the examination table be at hip level. To avoid postural injuries, the endoscopic equipment should preferably be placed on the side of the endoscopist's dominant hand for better handling.

The equipment should be inserted gently, at an oblique angle and anteriorly, carefully controlling the length inserted. This length should be sufficient to pass the sphincters without exceeding resistance, as there is a risk of perforation from the rectum. There are six basic movements of the insertion tube performed throughout the procedure: advancement, withdrawal, clockwise rotation, counterclockwise rotation, and raising and lowering. The tube should be inserted at least 20-30 cm from the...againTo maneuver and transmit force when inserting the tube. Upon inserting the endoscope, the first thing encountered is the rectal mucosa. At this point, the rectum is insufflated and distended, revealing the lumen and allowing the endoscope to be guided over the intestinal lumen. Only then can advancement be performed. Subsequently, the Houston valves will be encountered. The distal portion of the rectal ampulla is called the first blind spot, as many colonic lesions that go unnoticed are located here. Therefore, if the endoscope has a retroversion function, it can be useful. Advancement continues through the sigmoid colon. In case of loss of the intestinal lumen, it is recommended to gently retract, reposition, and check the intestinal lumen. This maneuver is called the crab maneuver; it serves to introduce the colon into the instrument, not the instrument into the colon.

There is an anatomical angle formed by the sacrum and the promontory, which displaces the sigmoid colon anteriorly into the abdominal cavity. This, combined with the significant mobility of the mesentery, creates an area prone to the formation of "N-loops" or "alpha loops." The formation of these loops can be detected by a paradoxical movement on imaging, where the tube is inserted but does not advance or even retracts. At this point, correction maneuvers are recommended. One is to rotate the tube clockwise and then withdraw it. Another maneuver is to remove the tube and apply gentle pressure to the abdomen. Advancing the tube with a loop present is dangerous and increases the risk of perforation or mucosal necrosis. To try to prevent loop formation, the amount of air administered should be reduced, or even minimized, to decrease sigmoid elongation and the formation of acute angles that are difficult to overcome. Applying external pressure to the abdomen offers minimal assistance. Resolving loops formed in the sigmoid colon is one of the most important steps for successful cecal intubation; otherwise, the chance of success is lower, and the cecal intubation success rate is reduced by approximately 20%. Once the descending colon is reached with the straightened instrument, advancement is rapid due to its straight and fixed configuration in most cases. Passing through the splenic flexure requires, first and foremost, avoiding the formation of loops again in the sigmoid colon. To do this, torque must be maintained, and the lumen of the transverse colon must be centered in the field of vision, always with the least amount of air possible. Occasionally, anatomical variations exist in some patients where an angle forms at the midpoint of the transverse colon. This angle can be bypassed by following the direction of the teniae coli, which guide the intubator toward the intestinal lumen.

Once past the hepatic flexure, with the instrument adjusted, firm pressure is applied and the colonoscope is inserted. Advancement is usually very slow in this area. Deep inspiration helps to lower the diaphragm and the hepatic flexure, so when the lumen of the ascending colon (right colon) is seen, air is drawn in to retract and bring the cecum closer to the tip of the instrument. The anatomical landmarks for identifying the cecum are the appendiceal orifice, the crow's foot (or goose's foot), and the ileocecal valve. It is important to have these clearly defined, as it is easy to make mistakes in the cecal region.

If the straightened colonoscope is properly inserted without loops, the total length inside the patient should be 60 to 80 cm. Finally, an important aspect of colonoscopy is the retrospective view after withdrawal of the instrument, as this is considered a blind spot during the examination.(36).

Although there are numerous mentions of the use of artificial intelligence in colonoscopies, representing the latest in minimally invasive technologies, software has been established to identify, based on algorithms, the quality of a colonoscopy performed, as well as the identification of malignant or inflammatory lesions.(37).

6.10 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.(38).

6.11 Bowel preparation

Proper bowel preparation is essential for accurate colonoscopy, as inadequate preparation could impair the detection of lesions. Furthermore, differences in colorectal physiology among patients necessitate a tailored approach to bowel preparation. For patients with high-risk colon, the approach to colorectal cleansing must be rigorous. For those with average-risk colon, suboptimal preparation should result in shorter surveillance intervals.(5).

6.11.1 Factors that influence the quality of bowel preparation

The quality of a colonoscopy depends entirely on adequate bowel preparation, which can affect the accuracy of the diagnosis and the adenoma detection rate; in this regard, it has been reported that the type of bowel preparation, the divided-dose regimen, the low-fiber diet, comorbidities, concomitant medications, hospital status, and advanced age affect the quality of bowel preparation(39).

6.11.1.1 Type of solution and tolerability

Various laxatives with different efficacy and tolerability have been studied, including polyethylene glycol plus ascorbate (PEG-ASC) (4 L, 2 L and 1 L), 2 L of PEG plus citrate, 2 L of PEG plus bisacodyl, magnesium citrate plus picosulfate (MCSP), andtrisulfate(magnesium sulfate, sodium sulfate, and potassium sulfate), also known as oral sulfate solution (OSS). A meta-analysis of PEG solutions reported that high-volume, divided-dose PEG was more effective compared to low-volume regimens.(39).

However, because high-volume solutions can reduce patient compliance, resulting in suboptimal bowel preparation, new low-volume laxatives have been introduced in the last decade. Randomized controlled trials comparing the 2 L PEG plus citrate formulation to the 4 L PEG formulation observed similar cleansing efficacy (73.6%).*vs.*72.3%, but with greater tolerability (25.4% vs. 37.0%, $p < 0.01$) and acceptability (93.9% vs. 82.2%, $p < 0.001$) (19).

A 1-liter, very low-volume PEG-ASC solution has also been introduced to improve the patient experience during colonoscopy by reducing total oral fluid intake. This very low-volume solution was developed by increasing the ascorbate content, which enhances the laxative effect and allows for administration in a smaller volume. Several controlled trials have evaluated the efficacy of 1 liter of PEG-ASC compared to 2 liters of PEG-ASC, observing similar results between the two solutions.(40).

A prospective, multicenter study evaluated the efficacy of 1 L PEG-ASC bowel preparation compared to 2 L and 4 L PEG preparations in a cohort of 1289 patients. In this study, successful bowel cleansing was achieved in 72.4%, 74.1%, and 90.1% ($p < 0.001$), respectively, while high-quality right colon cleansing was achieved in 15.9%, 12.0%, and 41.4% ($p < 0.001$) for the 4-L, 2-L, and 1-L PEG preparation groups, respectively.(41).

6.11.1.2 Preparation regimen

The 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 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 day-preparations (OR = 2.51, 95% CI: 1.86–3.39), regardless of solution type and dose.(42).

Two other meta-analyses compared split-dose bowel preparation with same-day bowel preparation and found similar results in terms of bowel preparation quality, patient willingness to repeat it, and overall tolerability.(43,44).

6.11.1.3 Time of the colonoscopy after the Bowel preparation

The timing of bowel preparation administration has been described as having a significant impact on both its tolerability and efficacy. Some authors report a negative correlation between the start of the colonoscopy, the interval since the last dose of bowel preparation, and mucosal cleansing, and recommend performing the colonoscopy before bowel preparation is complete to improve the quality of the examination.(45).

In accordance with Eun*et al.*. (46)Patients with intervals of 7 hours or less between the start of PEG intake and the start of colonoscopy had better bowel preparation than patients with intervals of more than 7 hours.

6.12 Cecal intubation rate

Both the time and success rate for reaching the cecum depend on the endoscopist's experience. High levels of experience (more than 9 years) areassociatewith a cecal intubation rate >94%, while in those without experience with a low number of annual colonoscopies (<200) they only manage to reach the cecum in 88.5% of all cases(47).

In addition to the endocopyrist's experience, previous studies have identified several factors that affect prolonged cecal intubation time, including age, sex, BMI, adipose tissue, waist circumference, diverticulosis, bowel preparation status, and prior abdominal or pelvic surgery. Understanding the factors that affect the rate of prolonged cecal intubation is important for achieving complete colonoscopies, as it will reduce the colonoscopist's workload or procedural fatigue, patient discomfort, and the risk of complications. According to Young et al., advanced age (≥ 70 years) and poor bowel preparation (BBPS score 5) are significant predictors of cecal intubation time.(48).

In addition to the above, the initial position and the change of position during the colonoscopy have also been suggested as factors that influence the cecal intubation rate(49).

6.13 Terminal ileal intubation rate

Terminal ileal intubation is a useful tool for identifying ileal Crohn's disease and for confirming the completion of colonoscopy when classic cecal landmarks are not safely observed.Reported rates of ileal intubation during colonoscopy vary widely. National and international endoscopy organizations, such as the American Society for Gastrointestinal Endoscopy, the Canadian Gastroenterological Association, and the European Society for Gastrointestinal Endoscopy, do not establish a minimum or suggested intubation rate.(9,50).

Previous studies have shown that transient ileoscopy (TI) has inconsistent performance but can be useful in patients with diarrhea. Despite this, there does not appear to be a clear consensus on when ileoscopy should be attempted. To date, no randomized controlled trials have evaluated ileal intubation times; therefore, the evidence consists mainly of observational studies. Ileal intubation rates in prospective studies ranged from 72.7% to 95.5% of colonoscopies in which ileal intubation was planned. Studies have suggested that ileal intubation adds an average of 3.4 minutes to the total procedure time.(9).

6.14 Polyp detection rate

Several studies have reported considerable polyp error rates. Some authors performed consecutive examinations to find missed lesions. According to a meta-analysis, the total number of missed polyps varies considerably across studies, ranging from 14% to 30%.

According to a meta-analysis, the total number of missed polyps varies considerably across studies, ranging from 14 to 30%.

It has been reported that non-adenomatous polyps can be more easily missed due to the smaller size of the hyperplastic lesions. In general, large polyps measuring ≥10 mm rarely escape the endoscopist's attention (2%), while medium-sized polyps (5 to 9 mm) are missed in 13% of procedures, and small lesions (1 to 5 mm) are missed in 26%.

6.15 In indicators of quality of colonoscopy

There are multiple indicators that help us objectively determine the quality of the colonoscopy.(51,52), which include:

- Appropriate indication: this must be documented in each procedure, and in the event that the colonoscopy is performed without a standardized indication, i.e., those established by the ESGE (European Society of Gastrointestinal Endoscopy) and the ASGE (American Society for Gastrointestinal Endoscopy)(53,54)The intervention must be justified, aiming for inappropriate indications to be less than 20%, since various studies have reported an inappropriate indication rate of 21 to 39% of colonoscopies.(18,55).
- There is no published data regarding the appropriate waiting time for diagnostic tests, but it is considered that to maintain acceptable quality in outpatients with digestive symptoms, it should be less than 4 weeks, while for urgent and hospitalized patients the test should be performed during said hospitalization.(18).
- Informed consent must be obtained from all patients before the procedure, and the patient must be informed about the risks and benefits of the procedure, as well as warning signs of a possible complication associated with the test.

- Post-polypectomy, post-cancer resection, and post-inflammatory bowel disease (IBD) screening intervals are established to minimize risks and maximize cost-effectiveness. These intervals are recommended based on the best available evidence, starting with confirmation of a colon free of neoplastic lesions after adenoma resection or surgery. For these intervals to be effective, it must be assumed that colonoscopies will be completed with a properly prepared colon and performed carefully.(56)Despite this, it has been shown that the recommended confidence intervals frequently shorten.(57,58)That is, control colonoscopies are performed in unnecessary cases, so it is necessary that medical societies and endoscopy units continuously promote these criteria.
- Proper bowel preparation: Colonic preparation should be reported in the endoscopy report using validated assessment scales(59)The quality criterion is achieving adequate preparation in more than 95% of examinations, as poor preparation hinders proper examination because the colon mucosa cannot be visualized. Protocols should emphasize the benefit of beginning preparation 8 to 12 hours before the examination and concluding 4 to 6 hours prior to the procedure to ensure optimal colon cleansing.(18).
- Capability and aptitude during endoscope insertion and withdrawal: refers to the ability to reach the cecum in less than 10 minutes with good visualization of the mucosa, proper handling of angulation ability, distension mobility, and suction and cleaning of the lens.
- Cecal intubation rate: this should be higher than 90% of all colonoscopies and 95% of those performed for screening.(60,61)since a significant fraction of neoplasms are located in this portion, which necessitates its exploration in all colonoscopies(62).
- Screening for adenomas in asymptomatic individuals: This is a quality measure because the primary goal of colonoscopy in most indications is the detection of neoplastic lesions. It has been shown that less efficient examiners fail to detect more than 50% of polyps larger than 1 cm.(63,64)and that the efficiency of the explorer may be a more crucial variable in predicting the presence of adenomas than the demographic factors themselves.
- Endoscope withdrawal time: the average withdrawal time from the cecum should be equal to or greater than 6 minutes; however, more recent studies

indicate that there are other relevant factors such as compulsive review of the colonic surface, emphasizing the folds,flexuresand valves and proper insufflation(65)However, these technical aspects do not have an objective measurement, so the withdrawal time will continue to be considered a quality factor.

- Colonoscopy tolerance: This should be determined in each procedure, with the aim of achieving good or very good tolerance rates in more than 95% of colonoscopies, for which a visual analog scale can also be used.(18)Consensus guidelines for the administration of sedatives have been published by different medical societies, establishing tolerance for the examination with a reduced risk of associated adverse effects.(66)Another aspect to consider is inflation, and it has been shown that the use of carbon dioxide (CO2) allows for this.reabsorbaFaster gas delivery, improving patient well-being(67)However, its use is not currently a standard.

7. Goals

7.1 General objective

To analyze the impact of the left lateral decubitus position compared to the supine decubitus position on the quality and effectiveness of colonoscopies at the Fray Antonio Alcalde Civil Hospital and the Regional General Hospital No. 220 “José Vicente Villada”.

7.2 Specific objectives

1. Describe the general characteristics of patients undergoing colonoscopy
2. Compare the time and rate of cecal intubation in patients with initial left lateral position and supine position.
3. Compare the percentage of loop formation and the need to perform loop rectification maneuvers
4. Compare the percentage of position change in patients with initial left lateral position and supine position.
5. Compare the intubation time of the descending colon in patients with left lateral initial position and supine position.
6. Evaluate pain scores in patients with initial left lateral position and supine position.
7. Compare the polyp detection rate between both positions.

8. Hypothesis

The supine position improves cecal reach time, ileocecal valve intubation percentage and time, polyp detection rate, and decreases the percentage of loop formation requiring reduction maneuvers and/or patient position changes compared to the lateral decubitus position in patients undergoing diagnostic colonoscopy.Fray Antonio Alcalde Civil Hospitaland Regional General Hospital No. 220 “José Vicente Villada” during a period from August 1, 2024 to July 31, 2025.

Null hypothesis: The supine position does not improve the time to reach the cecum, the percentage and time of ileocecal valve intubation, the polyp detection rate, and does not decrease the percentage of loop formation requiring reduction maneuvers and/or changes in patient position compared to the lateral decubitus position in patients undergoing diagnostic colonoscopy.Fray Antonio Alcalde Civil Hospitaland Regional General Hospital No. 220 “José Vicente Villada”.

Alternative hypothesis: The left lateral position improves the time to reach the cecum, the percentage and time of ileocecal valve intubation, the polyp detection rate, and decreases the percentage of loop formation requiring reduction maneuvers and/or position changes in patients undergoing diagnostic colonoscopy.Fray Antonio Alcalde Civil Hospitaland Regional General Hospital No. 220 “José Vicente Villada”.

9. Methodology

9.1 Studio design

Single-blind randomized clinical trial.

9.2 Universe

Patients attending the Coloproctology serviceFray Antonio Alcalde Civil Hospitaland Regional General Hospital No. 220 “José Vicente Villada” during a period from August 1, 2024 to July 31, 2025.

9.3 Population

Patients with an indication for colonoscopy in the Coloproctology serviceFray Antonio Alcalde Civil Hospitaland Regional General Hospital No. 220 “José Vicente Villada” during a period from August 1, 2024 to July 31, 2025.

9.4 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: 17.15, Var 15, M1 64.5 , M2 75, N=45.44.

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

$$k = (Z_\alpha + Z_\beta)^2$$

Adding the 10% loss: 49.9, rounding to 50 patients per group. With a total of 100 participants.

9.5 Sampling

Non-probabilistic by continuous inclusion.

9.6 Selection criteria

9.6.1 Inclusion criteria

- Patients with an indication for colonoscopy in the Coloproctology service
- Patients of both sexes
- Patients aged between 18 and 79 years
- Patients who agree to undergo the colonoscopy and sign the informed consent form for participation in the protocol

9.6.2 Exclusion criteria

- Patients under 18 years of age or over 80 years
- Those patients who do not wish to participate in the study or who do not sign the informed consent
- Pregnant women
- Patients with a history of colonic resection, ostomy status, severe cardiopulmonary and renal diseases, major psychiatric disorders, therapeutic colonoscopy, or any contraindication to colonoscopy
- Failure to comply with the bowel preparation regimen
- Active bleeding during the procedure
- Known patients diagnosed with colorectal cancer
- Patients with grade 3 obesity

9.6.3 Elimination criteria

- Poor bowel preparation with Boston less than 6
- Patients with colonic lesions that hinder the passage of the colonoscope
- Patients with insufficient sedation that requires temporarily stopping the study
- Intestinal perforation during the study
- Inability to reach the cecum despite loop reduction maneuvers
- Anesthesiology department indicated that the study should be suspended.

9.7 Definition of the variables

Time:

- Conceptual definition:a specific period during which an action takes place or an event unfolds

- Operational definition: time elapsed between the introduction of the colonoscope through the anus, until it reaches the ileocecal valve
- Category: dependent
- Variable type: quantitative
- Measurement scale: ratios
- Unit of Measurement: seconds

Body position:

- Conceptual definition: attitude or posture of the body with respect to its anatomical axis.
- Operational definition: body attitude or posture used to perform the colonoscopy
- Category: Independent
- Variable type: qualitative
- Measurement scale: nominal / dichotomous
- Unit of measurement: supine position / right lateral decubitus

Age:

- Conceptual definition: time that a person has lived.
- Operational definition: that referred to by the patient in years
- Variable type: quantitative
- Measurement scale: ratios
- Unit of measurement: completed years

Sex:

- Conceptual definition: biological and physiological characteristics that define men and women.
- Operational definition: as referred by the patient
- Variable type: qualitative
- Measurement scale: nominal dichotomous
- Unit of measurement: man / woman

Weight:

- Conceptual definition:force with which the Earth attracts a body, by the action of gravity
- Operational definition: the weight reported by the patient in kilograms
- Variable type: quantitative
- Measurement scale: continuous / measurement
- Unit of measurement: kilograms / grams

Size:

- Conceptual definition: Height of a person measured from the sole of the foot to the top of the head
- Operational definition: the one provided by the patient
- Variable type: quantitative
- Measurement scale: continuous / measurement
- Unit of measurement: meters / centimeters

Body mass index (BMI):

- Conceptual definition:Body mass index (BMI) is a number that is calculated based on a person's weight and height.
- Operational definition: a person's weight in kilograms is divided by the square of their height in meters, and the calculation is (kilograms) ÷ (meters of height squared) = BMI
- Variable type: quantitative
- Continuous measurement scale / measurement
- Measurement unit: Less than 18.9 = underweight, 18.50 to 24.99 = normal weight, 25.00 to 29.99 = overweight, 30.00 to 34.99 = mild obesity, 35.00 to 39.99 = moderate obesity, Greater than 40.0 = morbid obesity

Polyp detection rate:

- Conceptual definition: percentage of patients with at least one polyp detected during colonoscopy.

- Operational definition: percentage of patients with polyp detection during colonoscope insertion with respect to the total number of colonoscopies performed
- Variable type: quantitative
- Measurement scale: ratios
- Unit of measurement: numerical

Percentage of ileocecal valve cannulation:

- Conceptual definition: proportion of patients in whom it is feasible to annul the ileocecal valve
- Operational definition: percentage of patients in whom the ileocecal valve was successfully cannulated with respect to the total number of colonoscopies performed.
- Variable type: quantitative
- Measurement scale: ratios
- Unit of measurement: numerical

Cecal cannulation time:

- Conceptual definition: time interval in which, once the ileocecal valve has been identified, intubation is achieved
- Operational definition: time elapsed between arrival at the cecum and intubation of the ileocecal valve with visualization of the ileal mucosa
- Variable type: quantitative
- Measurement scale: ratios
- Unit of Measurement: seconds

9.8 Randomization

Patients will be randomly assigned to either the supine or left lateral decubitus position. A randomization list will be generated and placed in sealed envelopes that will be opened at the time of the colonoscopy. The person who generates the list will not participate in data acquisition and analysis.

9.9 Observation and data collection techniques

This study will be carried out in the coloproctology service of the Fray Antonio Alcalde Civil Hospital and Regional General Hospital No. 220 “José Vicente Villada”, hospitals in which 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.

9.10 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 arewill expressData 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 werethey 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.

9.11 Presentation of information

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

9.12 Resources needed

9.12.1 Human resources

The participants in the development of the work will be the responsible researcher and the student in charge of collecting and analyzing the information.

9.12.2 Material resources and infrastructure

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

9.13 Diffusion

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 lateralleft in patients of theFray Antonio Alcalde Civil Hospital and Regional General Hospital No. 220 “José Vicente Villada”.

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.
- The 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 funding for this study will be covered by the members participating in this research protocol. If additional resources are required, they will be obtained from the appropriate authorities. Physical materials such as pens, paper, printouts, photocopies, a digital stopwatch, and computer equipment will be used for this study. Human resources will be provided.will employ the endoscopy and coloproctology service of our unit, as well as to collect the data and the analysis.

Feasibility: The 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.

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 preparation is routinely covered by the patient, and the proposed alternative has a lower cost than what is currently used.

12. Biosafety aspects

Data will be obtained through colonoscopies performed in the service ofColoproctology Department of the Fray Antonio Alcalde Civil HospitalThese are minimally invasive procedures, with serious complications reported in less than 1% of patients; these complications are inherent to the procedure. It does not entail any greater or added risk compared to changing position, and therefore does not pose a greater risk to the health or physical integrity of the patient, the healthcare staff at the Fray Antonio Alcalde Civil Hospital, or the environment, thus avoiding unnecessary physical or mental suffering or harm to patients, as dictated by the Nuremberg Code of 1947.

13. Schedule of activities

Actividades	2024								2025											
	May	Jun	Jul	Ago	Sep	Oct	Nov	Dic	Ene	Feb	Mar	Abr	May	Jun	Jul	Ago	Sep	Oct	Nov	Dic
Delimitación del tema																				
Revisión bibliográfica																				
Elaboración del protocolo																				
Envío para autorización																				
Recolección de datos y trabajo de campo																				
Codificación, procesamiento y análisis estadístico																				
Redacción de análisis estadístico																				
Edición de protocolo																				
Presentación / publicación de resultados																				

14. Results

A total of 144 patients undergoing colonoscopy were analyzed, with 40 patients (27.6%) at Hospital Civil Fray Antonio Alcalde and 104 patients (71.7%) at Hospital General Regional No. 220 "José Vicente Villada." The average age was 57.7 years (SD ±12.2). Regarding the primary objective of the study, the overall cecal intubation rate was 99.3% (143/144), with no statistically significant differences when comparing the LLD and SP. The time to reach the cecum showed similar means between both positions (528.5 ± 264.4 seconds vs. 490.6 ± 308.0 seconds), with no significant differences ($p = 0.47$, 95% CI -112.01 – 117.01). Regarding comfort and additional maneuvers, which included loop formation and the need for rectification maneuvers, it was observed that in the LLD position, position changes were necessary in 33.33% of patients, while in the supine group, the percentage was 31.82%. These percentages suggest that, regardless of the institution, the need for repositioning is frequent and without statistical significance. In the analysis of polyp detection, the overall rate was 20.7%.

15. 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.

Comparisons between the left lateral decubitus (LLD) and supine position (SP) groups were performed according to the type of variable. Continuous variables, including time to cecal intubation, were compared using the Student’s t-test for independent samples. Categorical variables, including cecal intubation rate, need for position change during the procedure, and polyp detection rate, were analyzed using the chi-square when appropriate.

Effect estimates were reported with 95% confidence intervals (95% CI). A two-sided p value < 0.05 was considered statistically significant. All analyses were conducted according to the intention-to-treat principle, including all randomized patients who underwent colonoscopy.

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17. Attachments

16.1 Informed consent letter

Annex: Informed Consent Letter

RESEARCH PROJECT TITLE:

"Multicenter, single-blind, randomized clinical trial comparing left lateral decubitus position vs. supine decubitus position for performing colonoscopies."

Principal Investigator: Dr. Roberto Ulises Cruz Neri
Affiliation: Division of Coloproctology of the Fray Antonio Alcalde Civil Hospital
Contact phone number: + 52 33 34 52 05 18

Chair of the research ethics committee: Juan Luis Soto Mancilla
Affiliation: Committee of ethicsof the Civil Hospital Fray Antonio Alcalde
Contact phone number: + 52 39 42 44 14

Registration number:
Guadalajara, Jalisco, on _____ of _____ 202__.
Fray Antonio Alcalde Civil Hospital.

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:

We consider it important to carry out the present study since in our country there is no study that documents whether the initial position when performing the colonoscopy in left lateral decubitus or in supine decubitus favors the performance of the colonoscopy.

Objective: To determine the effectiveness of the left lateral decubitus position vs. supine decubitus position for performing a quality colonoscopy in patients undergoing colonoscopies at the Fray Antonio Alcalde Civil Hospital, Juan I. Menchaca Civil Hospital, and Regional General Hospital No. 220 "José Vicente Villada".

You have been invited to participate because you meet the criteria for a diagnostic colonoscopy. Please read the information and ask any questions you may have before deciding whether or not to participate in the study.

What does their 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 choose to participate, the following will occur: The position for the start of the colonoscopy will be randomly selected, sedation will be administered by the anesthesiologist, and the colonoscope will be inserted, with timing starting until it reaches the cecum. Subsequently, timing will begin from the moment the cecum is visualized until the ileocecal valve is cannulated. Simultaneously, the presence of polyps, bowel loop formation, and the need for bowel reduction maneuvers will be assessed.

Are there any potential risks and drawbacks for you?

The risk of this project corresponds to an investigation with a higher than minimal risk, since minimally invasive endoscopic procedures will be performed for diagnostic purposes, which include general anesthesia and invasion of the lower digestive tract and which, for the purposes of this study, are not increased.

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.

What if you decide not to continue participating?

Your participation is entirely voluntary, if you decide **NO** Participation will not affect the results of your desk research. If you decide to participate and later change your mind, you can 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 consult the study physician.thea oneof the studio staff members<u>before</u>to sign in this way.

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.

_____ I _____

Name of the person giving consent Signature

_____ I _____

Witness 1 Name Signature

_____ I _____

Witness 2 Name Signature

By signing this form, I have not waived any of my legal rights as a research participant. Therefore, I have no objection to completing any additional questionnaires I may be given to register my participation.
I have also received a copy of this consent form.

_____ I _____ I ____/___/___

Name of the Principal Investigator Business Date

16.2 Gantt Timeline

Activities	2024								2025											
	May	June	July	Aug	Sep	Oct	Nov	Dec	Janu	Feb	March	April	May	June	July	Aug	Sep	Oct	Nov	Dic
Topic definition																				
Literature review																				
Protocol development																				
Submission for authorization																				
Data collection and fieldwork																				
Coding, processing, and statistical analysis																				
Writing of statistical analyses																				
Protocol editing																				
Presentation/Publication of results																				

16.3 Data collection sheet

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: Lactulax ( ) Fosfosoda ( ) Nulytely ( )									**Preparation intake:** Complete ( ) Incomplete ( )	

	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 ( )

Endoscopic Equipment						
Colonoscope: FUJIFILM BL 7000 ( ) OLYMPUS ( )					**Technique:** Two-hand technique ( ) Four-hand technique( )	
Starting position: Supine position ( ) Left lateral decubitus ( )						
Final position: Supine position ( ) Left lateral decubitus ( )						
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	**Pedicled**	**< 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:							