COVER PAGE

Tittle of the Study: Does Using Abdominal Binder Really Benefit During Colonoscopy ?: A Prospective, Randomized, Double-Blind, Sham-Controlled Trial

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Study Protocol

Introduction

Colonoscopy is considered the primary screening test for colorectal cancer screening worldwide (1). Researches show that by 2030, 24 million colonoscopy procedures will be required for colorectal cancer screening in the USA (2).

Cecal intubation time (CIT) is one of the quality indicators in colonoscopies (3). Looping is the most common challenge endoscopists encounter, and this prolongs the CIT and can cause pain and several adverse events such as colon perforation and spleen injury (4). Position change and manual pressure are the best known two methods to prevent looping (5). In recent studies, various abdominal compression devices have been used to reduce CIT by reducing looping. In the systematic review and meta-analysis conducted in 2019, the limited number of trials on abdominal compression devices were studied and conflicting results were observed. Meanwhile, significant heterogeneity was detected among these studies (p=0.0006, I2=%83) (6).

Objectives: Prolongation of cecal intubation time (CIT) directly affects the comfort of the patient and the colonoscopist. In this study, the effectiveness of using an abdominal binder (AB) during colonoscopy on procedure time and colonoscopy outcomes was investigated. We hypothesized that the use of AB would reduce the CIT and the need for auxiliary maneuvers by reducing the looping.

1. Bénard F, Barkun AN, Martel M, et al. Systematic review of colorectal cancer screening guidelines for average-risk adults: Summarizing the current global recommendations. WJG. 2018 Jan 7;24(1):124–38.
2. Joseph DA, Meester RGS, Zauber AG, et al. Colorectal Cancer Screening: Estimated Future Colonoscopy Need and Current Volume and Capacity. Cancer. 2016 Aug 15;122(16):2479–86.
3. Ruiz-Rebollo ML, Alcaide-Suárez N, Burgueño-Gómez B, et al. Tasa de detección de adenomas e intubación cecal: indicadores de calidad de la colonoscopia. Gastroenterología y Hepatología. 2019 Apr;42(4):253–5
4. Wallace MB, Wang KK, Adler DG, et al. Recent Advances in Endoscopy. Gastroenterology. 2017 Aug;153(2):364–81.
5. Zhao S, Yang X, Meng Q, et al. Impact of the supine position versus left horizontal position on colonoscopy insertion: a 2-center, randomized controlled trial. Gastrointestinal Endoscopy. 2019 Jun;89(6):1193-1201.e1
6. Nishizawa T, Suzuki H, Higuchi H, et al. Effects of Encircled Abdominal Compression Device in Colonoscopy: A Meta-Analysis. J Clin Med. 2019 Dec 19;9(1):11.

Methods

- It is a randomized double-blind sham-device-controlled study

Intervention Group: Patients randomized to Abdominal Binder Intervention Group will have the abdominal binder secured firmly between Spina iliaca anterior superior and subcostal area to the abdomen just prior the colonoscopy.

Sham Group: Sham Group will have the abdominal binder secured firmly between Spina iliaca anterior superior and subcostal area to the abdomen just prior the colonoscopy but it will be loosened just prior the procedure

- Inclusion criteria: The patients who performed the given bowel cleansing before the procedure and who were American Society of Anesthesiologists Class (ASA) ≤III
- Exclusion criteria: Patients with known anesthesia or analgesic allergy, patients undergoing multiple procedures simultaneously, pregnant patients, patients with a history of colorectal surgery, patients with active inflammatory bowel disease, patients with a history of intra-abdominal malignancy, patients with liver cirrhosis or ascites, and patients with giant ventral hernia.
- Outcomes:

  Primary outcome of this study is CIT.

  The main secondary outcomes are the cecal intubation length (CIL) (the length of the colonoscope needed to reach the cecum from the anus) and manual pressure and position change requirement during the procedure. Other secondary outcomes were the colonoscopy completion rate, the need for extra narcotic analgesic drugs, the pain and comfort level reported by the patient, and colonoscopy results. Patients whose colonoscopy procedure could not be completed (excessive looping, poor bowel cleansing, etc.) were excluded from the primary outcome analysis but were included in the secondary outcome analysis. Subgroup analysis was performed for age (≥60 and <60), gender (female and male), and obesity (obese and non-obese). No adverse events occurred in any of the procedures.

Statistical Analysis Plan (SAP)

In sample size calculation, CIT and SD were used with the help of literature data. It was found that 326 patients (163 per group) were required to detect a 60-second difference in CIT (SD 192 secs), with 80% power and two-sided alpha 0.05. Again, with the help of literature data, the frequency of the auxiliary maneuvers was estimated and it was calculated that 324 patients were required for a 20% reduction in the auxiliary maneuvers. In case of becoming lost to follow up and withdrawal, the number of patients was expanded by 5%, and a total of 346 patients, 173 patients in each group, were included in the study.

Descriptive statistical methods (mean, standard deviation, frequency, percentage, minimum, maximum) were used for evaluating the study data. The eligibility of the quantitative data to normal distribution was tested by Shapiro-Wilk test and graphical analyses. Independent t-test was used to compare normally distributed quantitative variables such as mean CIT and CIL between two groups. For the comparison of qualitative data (e.g., manual pressure and position change), Pearson chi-square test, Fisher's exact test, and Fisher-Freeman-Halton exact test were used. The statistical significance level was accepted as $p<0.05$. For statistical analyses, NCSS (Number Cruncher Statistical System) 2007 (Kaysville, Utah, USA) program was used.

Informed Consent Form (ICF)

1- Tittle of the Study: Does Using Abdominal Binder Really Benefit During Colonoscopy

2- Objectives: Colonoscopy procedure; It is the examination of the last part of the large intestine and small intestine with the help of a video camera by entering the tube from the anus. In this way, diseases of the large intestine (cancer, polyps, etc.) can be diagnosed and treated. The biggest challenge of the process; It is because of the technical difficulties experienced in the advancement of the hose in the intestine, which negatively affects the patient comfort and the procedure time is prolonged. The aim of this study is to investigate whether the abdominal corset worn before colonoscopy can be a solution to the technical difficulties experienced during the procedure. Abdominal corset will be used in addition to standard traditional methods (position change, hand-assisted pressure application to the abdomen, etc.).

3- The Place (s) of the Research: Sehit Prof. Dr. İlhan Varank Training and Research Hospital

4- Time Envisioned for You to Continue Research: 3 month

5- Estimated Number of Volunteers Expected to Participate: 346

6-All of the Methods to be Followed and Actions to be Taken: Before the colonoscopy procedure, a standard elastic abdominal binder will be attached to your abdominal area. At the end of the procedure, these binders will be removed and you will be asked to fill out a questionnaire showing your pain level.

7-Possible Benefits: We think that you will feel less pain during the procedure as the procedure is easier, more comfortable and completed in a shorter time.

8-Possible Disturbances and Risks That May Bring You: No risk situation is foreseen.

9-Compensation (Insurance) and / Or Treatments to be Provided to the Volunteer: No compensation and / or treatment will be given to the volunteer.

10-Payments for Transportation, Food and Expenses to be Made to the Volunteer: No transportation, meal or payment will be made to the volunteer.

11-Participation in and Leaving Research: Participation in this research is entirely voluntary. You have the right not to participate in the study or to quit at any time. In addition, the responsible investigator may exclude you from the study if necessary. There will be no penalty or loss of benefits you are entitled to for not participating, leaving or dismissed from the study. You or your legal representative will be informed in a timely manner when new information regarding the research subject and that may affect your willingness to continue research is obtained.

12-Responsibilities of Volunteers: You should not remove the binder that is worn before the procedure until the process is completed. You need to fill in a questionnaire showing the level of pain after the procedure.

13- Confidentiality: Records that will reveal your identity will be kept completely confidential, will not be disclosed to the public, and your identity will be kept secret even if the results of the research are published. If you sign this form, people participating in the study (audiences, reviewers), ethics committee, institution and other relevant health authorities may have direct access to the original medical records of the volunteer, but this information will be kept confidential.

14-Situations or Reasons for the Termination of the Volunteer's Participation in the Research: You have the right to leave the job at any time.

15-Access to Post-Study Research Products: In case of publication of the study results, you can access medical academic sites on the internet (You can get the relevant internet addresses if you request).

16-Contact Person: Dr. Beslen Göksoy (Tel: +90 534 953 01 12)

I,……. I have read all the explanations on the Informed Consent Form. Written and verbal explanation about the above subject and purpose of the research was given to me by the physician named below. I fully understood the scope and purpose of the study I was asked to participate in, and my responsibilities as a volunteer. I had the opportunity to ask questions and discuss the work and got satisfactory answers. I was also told verbally about the possible risks and benefits of the study. I know that I have voluntarily participated in the research, that I can leave the study with or without justification at any time, and that I can be excluded from the research by the researcher regardless of my will, and my current treatment will not be negatively affected when I leave the study.

In this conditions;

1) I agree to participate in the said Clinical Trial of my own free will without any pressure or coercion.
2) If necessary, my personal information can be accessed by the persons / institutions specified in the legislation,
3) I consent to the information obtained in the study (provided that my identity information is kept confidential) to be used for publication, archiving and, if necessary, transferred outside our country for scientific contribution.

Volunteer (In his own handwriting)
Name and surname:
Signature:
Address:

Telephone No, Fax No, if available:

Date (day / month / year):…. /…. /….

For Those Under Guardianship or Guardianship

Parent or Guardian (in his own handwriting)

Name and surname:

Signature:

Address:

Telephone No, Fax No, if available:

Date (day / month / year):… /…. /….

The Researcher Participating in the Research Team and Making the Statements

Name-Surname: Beslen Göksoy

Signature:

Date (day / month / year):… /…. /… ..