COVER PAGE

Tittle of the study: Use of abdominal binder in colonoscopies performed by trainees in Gastrointestinal Endoscopy: A randomized, double-blind, sham-controlled trial

NCT number: NCT05617521

Document date: 01/29/2023

Study Protocol

Introduction

Colonoscopy is widely used for the diagnosis and treatment of colon diseases, and is also the preferred screening test for colorectal cancer (CRC) worldwide.[1,2] The colonoscopy procedure is safe, well-tolerated, and accurate for examining the mucosa of the entire colon and distal terminal ileum. Nevertheless, it is technically demanding, even for the experimented endoscopists.[3] One of the most frequent difficulties is the looping of the sigmoid and transverse colon. Looping stretches the colonic mesentery, leading to pain and discomfort in patients.[4] Furthermore, looping prolongs the cecal intubation time (CIT), increases the number of incomplete procedures and the risk of associated complications, such as splenic injury and bowel perforation.[5,6]

Ancillary maneuvers, such as abdominal pressure and patient position change, can be used to avoid the formation of the loops, but their effectiveness is questionable.[7-9] The most used is the manual abdominal pressure, usually requiring to be exerted by an assistant, which may results in not effective uncontrolled compression.[10] An abdominal binder is an alternative that seeks to improve the effectiveness of the abdominal pressure, encircling the abdomen to exert the pressure in an uniformly distributed way for the entire duration of the colonoscopy.[11]

Several randomized controlled trials (RTCs) have evaluated the impact of abdominal compression devices during colonoscopy with contradictory results.[11-15] Two meta-analyses have revised these RTCs and both concluded that encircling abdominal devices reduces the CIT, the need for abdominal compression, and the frequency of postural change.[16,17] Nevertheless, the limitations of both meta-analyses due to the reduced number of RCTs and them heterogenicity are remarkable. In addition, the colonoscopies in all RCTs studies were performed by experienced endoscopists, who would have less trouble managing loops and it would minimize any benefit using the abdominal binder.[17,18]

This randomized trial was conducted to evaluate the effectiveness and safety of an abdominal binder use during colonoscopy performed by gastrointestinal endoscopy fellow trainees. We hypothesized that the abdominal binder use would facilitate and increase the effectiveness of the colonoscopy for inexperienced operators.

Methods

Trial design and population

It is a randomized, double-blind, sham-controlled study. The trial was performed at a single-center, Hospital Central Norte PEMEX, a tertiary center with a gastrointestinal endoscopy fellow trainee program with more than 10 years of experience. Outpatients between 20-80 years

scheduled for an elective colonoscopy were prospectively recruited for participation from November 2022 to January 2023. Inclusion criteria were patients with ingestion of the entire bowel preparation and categorized as American Society of Anesthesiologists Class (ASA) ≤III. Exclusion criteria were pregnancy, breastfeeding, multiple planned procedure, previous colorectal resection, history of intraabdominal malignancy, inflammatory bowel disease, liver cirrhosis or ascites, abdominal skin lesions, and anesthesia or analgesic allergy. This trial was conducted in accordance with the most recent version of the Declaration of Helsinki and approved by the local ethical committee. Written informed consent was obtained from all the patients before participation. This manuscript is reported in accordance with CONSORT guidelines.[19] All the authors had reviewed and approved the final manuscript.

Trial interventions and device description

Prior to the procedure, age, sex, height, weight, body mass index (BMI), and colonoscopy indication of all participants were recorded. Once enrolled, patients were randomized to either the abdominal binder (AB) group or the sham binder (SB) group in a 1:1 ratio. Randomization was performed using a web-based computer system (Research Randomizer, Geoffrey C. Urbaniak and Scott Plous) by an independent statistician who had no other intervention in the study. An independent operator printed the randomization number and group for each participant (either the AB or SB group) in individual cards, which were hidden in a locked black box by the same independent operator. Only the nurse, who fitted the abdominal binder to all the patients in a private space, had access to the cards. Randomized data and cards were concealed to study coordinators, endoscopists, clinical staff, and participants.

The abdominal binder used for the patients allocated in the AB group was the Revive 3-in-1 Postpartum Recovery Support Belt (KeaBabies® Co., CA, USA). Its price is $29.96. The device is manufactured in two size, One Size and X-Large. For the patients with a waist circumference >110 cm it was used the X-Large model. The three belts that make up the binder were fitted to all the participants. Once placed, the binder was adjusted to be located between the subcostal border and the anterior superior iliac spine. The participants were asked to confirm that the binder was fastened tightly but not uncomfortably. For the participants in the SB group the same binder was fitted, but once the patient was sedated, it was loosened by the same nurse. The participants wore a non-transparent gown over the binder so that it was not visible to the endoscopists.

Colonoscopy procedure details

Bowel preparation with 4 L of polyethylene glycol solution in split-dose (2 L at the afternoon of the day before and 5 h before the colonoscopy) was used in all the participants.[20] In this trial, all colonoscopy procedure were performed by two second-year fellow trainees in gastrointestinal endoscopy with 32 and 38 registered colonoscopies previous to the study.

A standard video-colonoscope (EC-3890Li, PENTAX Co., Tokyo, Japan) was used. All the patients were placed in the left lateral decubitus position. Sedation with propofol and fentanyl was initially performed in most cases, adding dexmedetomidine in one case. Then, the colonoscopy was started using standard maneuvers. Manual abdominal compression and postural change were conducted by a technician when required by the endoscopy trainee or the attending endoscopist. Endoscopist or anesthesiology were allowed to remove the binder at any time during the procedure if they resolve it was necessary for safety. Air insufflation was used during colonoscopy.

Outcomes

Primary outcome of this study was CIT (the time from the scope insertion to intubation of the cecum and visualization of the appendiceal orifice and ileocecal valvule). Main secondary outcomes were the cecal intubation length (CIL), ileocecal valve intubation time (IVIT), manual abdominal compression or postural change requirement, and the need for intervention by the attending endoscopist during the procedure. Other secondary outcomes included colonoscopy completion rate, trainee-reported insertion difficulty, adenoma detection, need for extra analgesic drugs, patient-reported pain, and satisfaction level at discharge of the endoscopy area. Before to leave the recovery room, the patients were asked for pain using a 10-point visual analog scale (VAS), and for satisfaction using a 5-point scale (5= very satisfactory, 4= satisfactory, 3= unsatisfactory, 2= very unsatisfactory, 1= extremely unsatisfactory) by an assistant blinded to the study.

Planed *a priori* subgroup analyses included stratification according to age, gender, and BMI. Participants with incomplete colonoscopy were excluded from the primary outcome analysis (CIT) and two of the main secondary outcomes (CIL and IVIT) yet included for the rest of the secondary outcomes. Primary analysis method was intention-to-treat (ITT), including all randomized participants. A per-protocol (PP) analysis method was also performed, excluding participants in the AB group whose binder was removed or loosened at any time of the procedure.

Bibliography

1. Rex DK, Schoenfeld PS, Cohen J, Pike IM, Adler DG, Fennerty MB, et al. Quality indicators for colonoscopy. Gastrointest Endosc. 2015;81(1):31–53.

2. Rex DK, Boland CR, Dominitz JA, Giardiello FM, Johnson DA, Kaltenbach T, et al. Colorectal cancer screening: Recommendations for physicians and patients from the U.S. Multi-Society Task Force on Colorectal Cancer. Gastrointest Endosc [Internet]. 2017;86(1):18–33. Available from: http://dx.doi.org/10.1016/j.gie.2017.04.003

3. Shahidi N, Ou G, Telford J, Enns R. Establishing the learning curve for achieving competency in

performing colonoscopy: A systematic review. Gastrointest Endosc [Internet]. 2014;80(3):410–6. Available from: http://dx.doi.org/10.1016/j.gie.2014.04.056

4. Cheng W Bin, Moser MAJ, Kanagaratnam S, Zhang WJ. Analysis of and mathematical model insight into loop formation in colonoscopy. Proc Inst Mech Eng Part H J Eng Med. 2012;226(11):858–67.

5. Kim SY, Kim HS, Park HJ. Adverse events related to colonoscopy: Global trends and future challenges. World J Gastroenterol. 2019;25(2):190–204.

6. Cho SB, Lee WS, Joo YE, Kim HR, Park SW, Park CH, et al. Therapeutic options for iatrogenic colon perforation: Feasibility of endoscopic clip closure and predictors of the need for early surgery. Surg Endosc. 2012;26(2):473–9.

7. Shah SG, Saunders BP, Brooker JC, Williams CB. Magnetic imaging of colonoscopy: An audit of looping, accuracy and ancillary maneuvers. Gastrointest Endosc. 2000;52(1):1–8.

8. Hsieh YH, Tseng KC, Chou AL. Patient self-administered abdominal pressure to reduce loop formation during minimally sedated colonoscopy. Dig Dis Sci. 2010;55(5):1429–33.

9. Zhao S, Yang X, Meng Q, Wang S, Fang J, Qian W, et al. Impact of the supine position versus left horizontal position on colonoscopy insertion: a 2-center, randomized controlled trial. Gastrointest Endosc [Internet]. 2019;89(6):1193-1201.e1. Available from: https://doi.org/10.1016/j.gie.2019.01.009

10. Hansel SL, Prechel JA, Horn B, Crowell MD, DiBaise JK. Observational study of the frequency of use and perceived usefulness of ancillary manoeuvres to facilitate colonoscopy completion. Dig Liver Dis. 2009;41(11):812–6.

11. Toyoshima O, Nishizawa T, Sakitani K, Yamakawa T, Yoshida S, Fukagawa K, et al. Colonoscopy using back brace support belt: A randomized, prospective trial. JGH Open. 2020;4(3):441–5.

12. Goksoy B, Kiyak M. The effectiveness of using an abdominal binder during colonoscopy: a randomized, double-blind, sham-controlled trial. Scand J Gastroenterol [Internet]. 2021;56(8):990–7. Available from: https://doi.org/10.1080/00365521.2021.1941238

13. Yu GQ, Huang XM, Li HY, Tang W, Hu DM, Lü MH, et al. Use of an abdominal obstetric binder in colonoscopy: A randomized, prospective trial. J Gastroenterol Hepatol. 2018;33(7):1365–9.

14. Crockett, Seth D., Cirri, Holly O., Renuka Kelapure et al. An Abdominal Compression Device Reduces Cecal Intubation Time for Some Obese Patients Undergoing Colonoscopy. Clin Gastroenterol Hepatol. 2018;72(23):2964–79.

15. Toros AB, Ersoz F, Ozcan O. Does a fitted abdominal corset makes colonoscopy more tolerable? Dig Endosc. 2012;24(3):164–7.

16. Zafar Y, Rashid AM, Siddiqi AK, Dar SH, Haider MB, Merza N, et al. Use of Abdominal Compression Devices in Colonscopy and Its Effect on Cecal Intubation Time : a Sytematic Review and Meta-Analysis. Gastrointest Endosc [Internet]. 2022;95(6):AB113. Available from: https://doi.org/10.1016/j.gie.2022.04.307

17. Nishizawa T, Suzuki H, Higuchi H, Ebinuma H, Toyoshima O. Effects of encircled abdominal compression device in colonoscopy: A meta-analysis. J Clin Med. 2020;9(1):1–8.

18. Bernstein C, Thorn M, Monsees K, Spell R, O'Connor JB. A prospective study of factors that determine cecal intubation time at colonoscopy. Gastrointest Endosc. 2005;61(1):72–5.

19. Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: Updated guidelines for reporting parallel group randomized trials. Open Med. 2010;4(1).

20. Saltzman JR, Cash BD, Pasha SF, Early DS, Raman Muthusamy V, Khashab MA, et al. Bowel preparation before colonoscopy. Gastrointest Endosc. 2015;81(4):781–94.