Effect of Abdominal Corset on Completion of Colonoscopy and Cecal and Ileocecal Intubation Time in Patients with Central Obesity: A Prospective Randomized Controlled Trial

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AIM: This work investigated the effect of an abdominal corset on the colonoscopy completion rate, as well as cecum and ileum intubation time, total colonoscopy time, and pain score in centrally obese patients.
METHODS: Patients were randomized into two groups, with 50 patients in each group. A colonoscopy was performed using the abdominal corset in Group 1 and the standard method in Group 2. The comparison between the groups evaluated demographic data, procedure details, circulatory dynamics, anesthesia data, and visual analogue scale (VAS).
RESULTS: Of the patients included in the study, 60 were female, and 40 were male, with a mean age of 57.3 ± 13.6 years. Cecal intubation time (Z: –2.66 p: 0.008), total colonoscopy time (Z: –2.180 p: 0.029), number of maneuvers (χ^2: 8.391 p: 0.039), and VAS (Z: –3.087 p: 0.002) were significantly lower in the abdominal corset group.
CONCLUSIONS: An abdominal corset that applies external abdominal compression reduces the cecal intubation time, the total colonoscopy time, the number of maneuvers, and the pain level.
CLINICAL TRIAL REGISTRATION: NCT03128645 (https://clinicaltrials.gov/study/NCT03128645?tab=results).

Keywords: colonoscopy; cecal intubation time; abdominal corset; VAS score

Introduction

Colorectal cancer (CRC) is the second leading cause of cancer-related deaths worldwide and the third most commonly diagnosed cancer. In addition, the incidence of CRC has steadily increased in developing and developed countries in recent years [1, 2].

Therefore, a colonoscopy is necessary for both the screening and treatment of colorectal cancer [3]. The use of colonoscopies is increasing worldwide [4]. Despite advances in colonoscopy equipment and staff training, the procedure can be uncomfortable for some people [5]. However, changing the patient's position and manually compressing the abdominal cavity during a colonoscopy are regularly practiced to prevent pain and complete the colonoscopy [6].

A successful colonoscopy depends on the ability to intubate the cecum, detailed and appropriate observation, and minimal patient discomfort during the procedure. Many patients have the misconception that a colonoscopy is an invasive procedure that is always painful and stressful. Therefore, the prospect of a colonoscopy may cause significant anxiety in patients [7].

In addition, an abdominal corset is a bandage wrapped around the abdomen that is frequently used after abdominal surgeries to protect the integrity of sutures and to support the incision site by providing immobilization [8].

During a colonoscopy, especially in obese patients, we require external manipulation support for difficult flexure passes. During this manipulation, the patient's abdomen is slightly compressed. Consequently, we wanted to investigate whether an abdominal corset would facilitate this procedure. Hence, the aim of this prospective randomized study is to investigate the effect of using an abdominal corset on a complete colonoscopy, cecal intubation time, and ileal intubation time. Thus, the benefits of an abdominal corset during a routine colonoscopy will be evaluated.

Materials and Methods

Study Design

This study is a prospective randomized controlled trial conducted in a tertiary education and research hospital, Kartal Kosuyolu Yüksek İhtisas Education and Research Hospital. Patients who presented to our clinic as outpatients and were scheduled for colonoscopy in accordance with American Society for Gastrointestinal Endoscopy (ASGE)

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Table 1. Baseline characteristics of patients.

Different variable		Group 1 (n = 50)	Group 2 (n = 50)	χ^2/Z/*t*-value	*p*-value
Age (mean ± SD)		56.48 ± 11.79	58.26 ± 15.3	–0.649	0.518[a]
Sex (mean ± SD)	Male	19 (38%)	21 (42%)	0.167	0.683[b]
	Female	31 (62%)	29 (58%)		
Body mass index (kg/m^2) median (IQR)		32.42 (3.65)	31.11 (2.74)	–1.362	0.173[c]
Waist hip ratio, median (IQR)		1.05 (0.1)	1.05 (0.07)	–1.234	0.217[c]
Colonoscopy indication	Screening	15 (30%)	14 (28%)	7.285	0.295[b]
	Rectal bleeding	11 (22%)	15 (30%)		
	Change of bowel habit	12 (24%)	6 (12%)		
	Anemia	8 (16%)	5 (10%)		
	Abdominal pain	3 (6%)	4 (8%)		
	Follow-up of polyps	1 (2%)	4 (8%)		
	Other	0	2 (4%)		

(Group 1, Abdominal corset group; Group 2, Control group; SD, standard deviation; IQR, interquartile range.)

[a] Student's *t*-test, [b] Chi-square test, [c] Mann-Whitney U test.

colonoscopy indication criteria were included in the study. Before the colonoscopy, patients were informed adequately about the procedure, and written informed consent was obtained according to Joint Commission International (JCI) and Ministry of Health criteria.

Study Population

Before the procedure, the following patient measurements were taken: height (cm), weight (kg), waist (cm), and hip (cm). Patients were selected according to the central obesity criteria set by the World Health Organization. To make the study more standardized and to minimize the error rate, the study was planned in central obese patients. Those with a body mass index (BMI) $\geq$30 and waist circumference $>$102 cm in men and $>$88 cm in women were considered centrally obese.

Inclusion criteria: Patients over age 18 who met the criteria for central obesity and underwent an elective colonoscopy between June 2017 and December 2017 were included in the study.

Exclusion criteria: This work excluded patients who underwent the procedure under emergency conditions, those whose procedure was terminated due to poor bowel preparation, patients with inflammatory bowel disease, severe arrhythmia, chronic obstructive pulmonary disease (COPD) patients, coronary artery disease (CAD) patients, patients with previous abdominal surgery, and patients without central obesity.

Patient Classification

The patients in the study were randomized into two groups with 50 subjects in each group. Group 1 included patients who used abdominal corsets during their colonoscopies, and Group 2 included patients who underwent colonoscopies employing the standard method. The abdominal corset used was made from elastic and had hook and loop closures.

Procedure

Standard colon preparation was performed with 500 mg Sennosid (XM solution®, Yenişehir Lab, Ankara, Türkiye) and 118 mL sodium dihydrogen/disodium phosphate enema (B.T. Enema®, Yenişehir Lab, Ankara, Türkiye). The patients fasted at least six hours. Patients were taken to the room where the procedure was to be performed, and intravenous access was established with a 20–22 G cannula in the back of the hand or forearm. A 1–2 mL/kg/hour 0.9% saline infusion was administered. All colonoscopies were performed by the same gastroenterology surgeon, with sedation administered by the same anesthesiologist and anesthesia technician.

Heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), and peripheral oxygen saturation (SpO_2) were monitored just before the procedure. A 60 mg propofol bolus injection was administered in patients under age 70 and 40 mg in patients between age 70–89, according to the age-adjusted standard protocol. An additional 20 mg dose of propofol was administered each time, with the total dose not exceeding 200 mg. After the response to verbal stimuli decreased and the corneal reflex disappeared, the procedure was initiated. During the process, according to the Ramsay sedation scale (RSS), the degree of sedation of the patients was $>$4. The level of bowel cleansing was classified according to the Aronchick Scale as inadequate (repeated preparation required), poor (semisolid stool could not be aspirated, and 90% of the mucosa was not visible), fair (semisolid stool could not be aspirated, but 90% of the mucosa was visible), good (clear liquid covers 25% of the mucosa, but 90% of the mucosa was visible), and excellent (95% of the mucosa was visible).

Data

The groups were compared with regard to the following: (1) demographic data (gender, body surface area, body mass in-

Table 2. Colonoscopy results.

Different variable		Group 1 (n = 50)	Group 2 (n = 50)	χ^2/Z	*p*-value
Cecal intubation rate n (%)		50 (100)	50 (100)	-	1.0[a]
Ileum intubation rate n (%)		49 (98)	49 (98)	0.000	1.0[a]
Cecal intubation time (minutes), median (IQR)		250 (130)	300 (150)	–2.66	0.008[b]
Ileum intubation time (minutes), median (IQR)		40 (77.5)	60 (27.5)	–0.712	0.476[b]
Total Procedure time (minutes), median (IQR)		700 (155)	720 (155)	–2.180	0.029[b]
Maneuver n (%)	No	34 (68%)	27 (54%)	8.391	0.039[a]
	Administered abdominal pressure	1 (2%)	8 (16%)		
	Change of position	9 (18%)	5 (10%)		
	Both maneuvers applied	6 (12%)	10 (20%)		
Colon preparation	Excellent	39 (78%)	41 (82%)	4.526	0.210[a]
	Good	9 (18%)	5 (10%)		
	Regular	0	3 (6%)		
	Bad	2 (4%)	1 (2%)		
	Inadequate	0	0		
Findings (n/%)	Polyps	6 (12%)	9 (18%)	0.706	0.401[a]
	Diverticulosis	7 (14%)	9 (18%)	0.298	0.585[a]
Complications		0	0	-	1.0[a]

(Group 1, Abdominal corset group; Group 2, Control group; IQR, interquartile range.)

[a] Chi-square test, [b] Mann-Whitney U test.

dex, waist to hip ratio, and indication for colonoscopy); (2) procedure details (cecal and ileal intubation rates and times, maneuvers (manual compression, position change), bowel cleansing level (pathologies detected); (3) circulatory dynamics (heart rate, SBP, DBP, SpO_2); (4) anesthesia data; (5) visual analogue scale (VAS). See Tables 1,2,3,4. Patients were informed about the 10-cm VAS at the endoscopy appointment or just before the procedure, and they were asked to rate the pain they felt during the procedure as 0 = no pain to 10 = most severe pain. Patients were asked to give a numeric value before discharge from the unit after the colonoscopy. The results were recorded on their forms.

Statistics

The Statistical Package for the Social Sciences (SPSS 22.0; SPSS Inc., Chicago, IL, USA) computer software was used for biostatistical analysis. The data obtained from the patients in the study were expressed as mean ± standard deviation values, and percentages where necessary. The distribution of the data was checked with the Kolmogorov–Smirnov test. The group analysis of normally distributed data was analyzed using a student's *t*-test. The Mann-Whitney U test was used for comparisons involving non-normally distributed data. And this non-normally values are expressed as median and interquartile range. Categorical groups were compared with the Chi-square test. $p < 0.05$ was considered statistically significant.

Results

During the study period, 100 patients were randomly selected and divided into two groups according to previously determined criteria. Of the patients included in the study, 60 were female, and 40 were male, with a mean age of 57.3 ± 13.6 years. When the baseline characteristics between the groups were analyzed, no statistically significant difference was found in terms of mean age, gender, body mass index, waist to hip ratio, or indication for colonoscopy (Table 1). When the colonoscopy results were analyzed, there was no difference in the rate of intubation of the cecum and ileum, duration of ileal intubation, detected pathologies, and complications in both groups. However, the cecal intubation time (*p*: 0.008), total procedure time (*p*: 0.029), and number of maneuvers (*p*: 0.039) were significantly lower in the group using abdominal corsets. There was no variation between the two groups in terms of colon preparation (*p*: 0.210). See Table 2.

There was no disparity between the groups in terms of circulatory dynamics (heart rate, HR, SBP, DBP, SpO_2) examined at the baseline, as well as at one, five, 10, and 20 minutes (Table 3). When the sedation doses administered were analyzed, no distinction was found between the groups. According to the visual analog scale results, the patient pain score was lower in the abdominal corset group (*p*: 0.002; see Table 4).

Table 3. Characteristics of circulation dynamics among groups.

	Heart beating				Systolic blood pressure				Diastolic blood pressure				SpO_2			
	Group 1 (n = 50)	Group 2 (n = 50)	*t*/*Z*-value	*p*-value	Group 1 (n = 50)	Group 2 (n = 50)	*t*/*Z*-value	*p*-value	Group 1 (n = 50)	Group 2 (n = 50)	*Z*-value	*p*-value	Group 1 (n = 50)	Group 2 (n = 50)	*Z*-value	*p*-value
Starting	83.9 ± 12.8*	79.8 ± 13*	1.567	0.120[a]	143.2 ± 16.9*	139.2 ± 16.5*	1.174	0.243[a]	80 (19)**	79 (14)**	–1.266	0.206[b]	99 (2)**	99 (2)**	–0.279	0.780[b]
1 min	80.5 ± 12.4*	76.5 ± 13*	1.552	0.124[a]	123 (20.5)**	120 (22.5)**	–1.647	0.100[b]	75 (14.5)**	72 (10)**	–1.524	0.128[b]	98 (2)**	99 (1)**	–1.417	0.156[b]
5 min	77.9 ± 11.7*	74.7 ± 11.4*	1.375	0.172[a]	130 (22.5)**	124 (16.5)**	–1.821	0.069[b]	80 (16)**	75 (10.5)**	–1.589	0.112[b]	99 (1)**	99 (1)**	–0.830	0.407[b]
10 min	78.5 ± 10.9*	75.2 ± 11.4*	1.493	0.139[a]	130 (22)**	125 (18)**	–1.657	0.098[b]	75 (12)**	70 (12)**	–1.635	0.102[b]	99 (1)**	99 (1)**	–0.882	0.378[b]
20 min	77 (11.5)**	79 (19)**	–0.546	0.585[b]	130 (15)**	126 (15.5)**	–1.395	0.163[b]	75 (11)**	72 (10.5)**	–1.695	0.09[b]	99 (1)**	99 (1)**	–0.855	0.393[b]

(Group 1, Abdominal corset group; Group 2, Control group; SpO_2, peripheral oxygen saturation; min, minutes; * mean ± standard deviation (SD); ** median interquartile range (IQR).)

[a] Student's *t*-test, [b]Mann-Whitney U test.

Table 4. Amount of medication used during the procedure and patient pain score.

	Group 1 (n = 50)	Group 2 (n = 50)	*Z*	*p*-value
Fentanyl (lg), median (IQR)	50 (0)	50 (0)	–0.977	0.328[a]
Propofol (mg) median (IQR)	100 (60)	100 (55)	–1.017	0.309[a]
Midazolam (mg), median (IQR)	1 (0)	1 (0)	–1.616	0.106[a]
Patient pain score median (IQR)	3 (1)	4 (2)	–3.087	0.002[a]

(Group 1, Abdominal corset group; Group 2, Control group; IQR, interquartile range.)

[a]Mann-Whitney U test, 0, no pain; 10, worst pain imaginable.

Discussion

In this prospective randomized trial, we found that an abdominal corset that applied external abdominal compression reduced the duration of the colonoscopy, the number of maneuvers performed, and the level of pain associated with the procedure. Although this method did not change the completion rate, it improved the overall satisfaction of patients by reducing their total times and pain scores.

A full colonoscopy is very important for colon cancer screening. However, obesity tends to reduce the complete colonoscopy rate (CCR). The main reason for this may be that it is difficult to minimize looping in an obese abdomen [9]. Centrally obese patients with a BMI $\geq$30 and a waist circumference $>$102 cm in men and $>$88 cm in women were included in this study.

Prechel and Hucke [10] reported that hand techniques that assist abdominal compression may shorten the cecal intubation time. In addition, they emphasized that the amount of pressure applied should always be considered to avoid harming the patient.

In 2007, Tsutsumi *et al*. [11] reported that the use of abdominal bandages reduced the patient's pain compared to traditional methods. However, this bandage is more difficult to use than the abdominal corset, as it is wrapped around the abdomen many times. If it needs to be removed during the procedure, this can add difficulty to the procedure. Toros *et al*. [12] reported that the abdominal corset was useful for reducing the degree of pain of the patient and making a colonoscopy easier and faster with less manipulation in their study of 216 patients. However, this study has limitations. The fact that it was not performed under anesthesia is one of them. If the corset is tightly tied, it will already cause pain and anxiety. Moreover, the respiratory rate, heart rate, and blood pressure were not reported in this study. No information about abdominal circumference was given, and the study was performed in a group of non-obese patients.

Liu *et al*. [13] reported in a prospective randomized study that abdominal bandages enabling abdominal compression significantly shortened the cecal intubation time and increased the rate of adenoma detection compared to a conventional colonoscopy in obese patients. Contrary to this study, we did not find a significant difference in the rate of adenoma detection in our study.

In their randomized study, Crockett *et al*. [14] failed to detect any benefit of the ColoWrap device in terms of cecal intubation time and assistive maneuvers in all patients undergoing colonoscopies. However, in subgroup analyses, they found a trend towards significantly lower mean cecal intubation time, manual abdominal pressure application, and fewer position changes in 78 participants with mild to moderate obesity (BMI $\geq$30 and $\leq$40 kg/m^2).

Abdominal compression devices can help stabilize the entire colonoscopy procedure by preventing it from looping during colonoscopy. This results in a more comfortable procedure and better patient comfort. Unlike manual abdominal pressure or position changes, these devices are easy to set up and provide effective pressure to aid the procedure. They are also reasonably priced and reusable, so they are not financially burdensome [15].

All three previous meta-analyses found that the use of abdominal compression devices significantly reduced the duration of cecal intubation and the frequency of postural changes and abdominal compression. However, these three studies also stated that more randomized controlled studies are needed [5, 15, 16].

Conclusions

An abdominal brace that applies external abdominal compression reduces cecal intubation time, total colonoscopy time, number of maneuvers, and pain level. We believe it is possible to perform a more comfortable procedure at a lower cost in the centrally obese patient group. However, further studies are needed to support this statement.

Availability of Data and Materials

Data for the study can be made available from the corresponding author upon request.

Author Contributions

EG and MD designed the research study. EG, OU and EP performed the research. ÖÖ, ASS analyzed the data. All authors have participated in drafting the manuscript. All authors revised the manuscript critically for important intellectual content All authors read and approved the final version of the manuscript. All authors have participated sufficiently in the work and agreed to be accountable for all aspects of the work.

Ethics Approval and Consent to Participate

Approval was obtained from the Clinical Trials Evaluation Board of Kartal Koşuyolu Yüksek İhtisas Education and Research Hospital (Registration No: 2017/3/19). Moreover, this study was administered according to the Helsinki Declaration. Patients were informed adequately about the procedure, and written informed consent was obtained according to Joint Commission International (JCI) and Ministry of Health criteria.

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Conflict of Interest

The authors declare no conflict of interest.

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