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A Randomized Controlled Trial of Anoscopy and Manual Abdominal Compression to Increase Patient Comfort after Colonoscopy

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Authors' contributions

This work was carried out in collaboration among all authors. Author GKU designed the study, wrote the first draft of manuscript. Author HSG Managed the analysis of the study and wrote the last draft of manuscript. Author AK Performed the statistical analysis. All authors read and approved the final manuscript.

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ABSTRACT

Background/Aim: Colonoscopy may be associated with pain due to distension of colonic mesentery and air insufflation into the colonic lumen, although Sedo-analgesia may increase the tolerability of the procedure. This randomized, prospective, controlled study based on our clinical observations aimed to explore the sustainability of comfort provided by intraoperative sedation by allowing gas discharge via anoscopy while patients were still sedated.
Methods: The patients that underwent colonoscopy for colorectal cancer screening were considered for this study and a total of 100 patients were (61 male and 39 female) were included in this study. Colonoscopy procedures were carried out by two experienced endoscopists who are adequately trained. Following the colonoscopy, 50 patients in the study group were administered a disposable anoscope with sterile, water-soluble, lubricant gel while the effect of sedation was still maintained. Endoscopist compressed four abdominal quadrants for 5 seconds to evacuate gas and

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reduce distension during anoscopy. The anoscope was then removed and the patients were woken from anesthesia. The patients in the control group did not undergo anoscopy following a colonoscopy.

Results: Both groups were similar in terms of sex distribution, presence of polyps, procedural time, and midazolam and propofol doses. Only age was greater in the study group. Significant differences were detected between the mean pain scores of each of the three measurements ($p<0.05$). The anoscopy group had a significantly lower mean pain score.

Conclusion: Our study showed that pain and bloating were reduced at the end of the procedure and and 24th hours after the procedure when anoscopy was performed following a colonoscopy. Anoscopy group also had a higher proportion of patients accepting a repeat procedure ($p<0.05$). Even if not used on a routine basis, anoscopy may be used in select patients with excess distension after the colonoscopy procedure.

Keywords: Colonoscopy; pain; abdominal compression: anoscopy.

1. INTRODUCTION

Colonoscopy is the most important technique used for the evaluation of colonic disorders and colon cancer screening [1]. The procedure may be associated with pain due to distension of colonic mesentery and air insufflation into the colonic lumen, although Sedo-analgesia may increase the tolerability of the procedure. After the completion of the procedure, pain, bloating, and anxiety may develop as a result of residual air in the colonic lumen, which may cause patients to refuse follow-up colonoscopy procedures owing to bad experiences with the procedure [2]. Moreover, monitoring for a longer period of time may be necessary after the procedure which may result in personnel requirements and workforce loss [3].

Many former studies with contradicting results have explored the effects of a variety of techniques to increase patient comfort in colonoscopy including administration of CO_2 instead of room air, application of rectal tube after the procedure left lateral patient positioning, or application of colonic decompression [3-7]. This randomized, prospective, controlled study based on our clinical observations aimed to explore the sustainability of comfort provided by intraoperative sedation by allowing gas discharge via anoscopy while patients were still sedated.

2. MATERIALS AND METHODS

This prospective, randomized, controlled the study was conducted on patients who underwent colonoscopy at Başkent University Faculty of Medicine, Department of Gastroenterology between May 1, 2015, and August 31, 2015. All patients were older than 18 years.

The patients that underwent colonoscopy for colorectal cancer screening were considered for this study. Patients who were in need of urgent colonoscopy for rectal bleeding, who could not be cooperated with the colonoscopy team (due to previous cerebrovascular event, dementia, mental retardation etc.), who have uncontrolled hypertension, cardiac arrhythmia, advanced heart, lung or kidney disease, who had a previous colonic surgery, personal history of CRC/polyp, inflammatory bowel disease or in whom caecum could not be accessed for various reasons were excluded. The required minimum number of observations was calculated 42 to reveal the significance of a 2-unit the difference on an average between pain scores of both methods. The power of such a test was calculated 95% and alpha level 0.05. A total of 100 patients were (61 male and 39 female) were finally enrolled and included in this study. The study patients were randomly allocated by a computer software program (Microsoft Excel Random Generator) and fifty patients were projected to be enrolled in the study group in which anoscopy was to be performed and another 50 patients in the control group in which no anoscopy was to be performed. Bowel preparation was performed in 100 patients using 4L polyethylene glycol lavage. Patients with incomplete colonoscopy because of poor bowel preparation (Boston Bowel Preparation Scale 0–1) were also excluded.

Colonoscopy procedures were carried out by two experienced endoscopists (more than five years' experience with >500 annual colonoscopies with more than 95% caecal intubation rate) using high definition i-Scan (HD i-SCAN) colonoscopy with an EPK-i5000 processor (Pentax, Tokyo, Japan) at the endoscopy unit in our hospital. The examination was considered completed if the

caecum was reached and a minimum endoscope withdrawal time of 6 minutes. The timer was stopped whenever a polyp was found and removed and was restarted once the reexamination of the colonic mucosa continued. Sedation with propofol was performed by anesthesiologists in all cases. Analgesics or antispasmodic agents were not used in any of the patients. Following the colonoscopy, 50 patients in the study group were administered a disposable anoscope (standard speculum anoscope with 89 mm operating length and 14 mm aperture) with sterile, water-soluble, lubricant gel while the effect of sedation was still maintained. Endoscopist compressed four abdominal quadrants for 5 seconds to evacuate gas and reduce distension during anoscopy. The anoscope was then removed and the patients were woken from anesthesia. The patients in the control group did not undergo anoscopy following a colonoscopy.

2.1 Data Collection

Age, sex, history of abdominal surgery, presence of diverticula, procedure time, and presence of colonic polyps were recorded for all patients (Table 1). Bowel cleansing was scored (1: good, 3 bad) after the procedure. The patients were monitored by an endoscopy nurse and at 15^{th} and 30^{th} minutes after the procedure, and pain according to a 10-cm visual analog scale (0: no pain, 10: intolerable pain) was marked at each monitoring time point. Pain level was determined by the same nurse according to the Wong-Baker FACES Pain Rating Scale. The patients were called via telephone by the same nurse at 24^{th} hour after the procedure to be questioned about pain, bloating, rectal bleeding, anal pain, as well as about procedural satisfaction level and whether they would have a repeat colonoscopy in case it was required again.

2.2 Statistical Analysis

Chi-Square test was used to compare the anoscopy and non-anoscopy groups concerning clinical and demographic properties including sex, history of abdominal surgery, and presence of polyps; independent samples t-test was used to compare age, procedure time, midazolam dose, and propofol dose. Mann Whitney-U test was used to determine the differences between both groups' pain scores at the end of the procedure, and 15, 30 minutes and 24 hours after the procedure.

3. RESULTS

Both groups were similar in terms of sex distribution, presence of polyps, procedural time, and midazolam and propofol doses. Only age was greater in the study group. The descriptive statistics of the study population were shown in Table 2.

The means, standard errors, and confidence intervals at a significance level of 95% of the pain scores of the anoscopy and non-anoscopy groups at the end of and at 15, 30 minutes and 24 hours after the procedure was presented on the Table. Significant differences were detected between the mean pain scores of each of the three measurements ($p<0.05$). The anoscopy group had a significantly lower mean pain score.

There was a moderate correlation between VAS pain levels and the pain level determined by the nurse according to the Wong-Baker FACES Pain Rating Scale following the procedure. The kappa statistics calculated were 63%.

The two groups had significantly different procedural satisfaction levels ($P=0.00$). The anoscopy group had a satisfaction level of 100% while the other group had a satisfaction level of 68%.

4. DISCUSSION

Our study showed that pain and bloating were reduced at the end of the procedure and 24^{th} hours after the procedure when anoscopy was performed following a colonoscopy. Anoscopy group also had a higher proportion of patients accepting a repeat procedure ($p<0.05$).

Colonoscopy is the gold standard method to diagnose colon cancer. However, pain and bloating during and after colonoscopy procedure create a negative patient opinion about the procedure. Therefore, it is important to increase procedural quality. Previous studies in the literature have reported that insufflation of CO_2 instead of air at colonoscopy increases patient comfort during and after colonoscopy [7]. Its disadvantage, however, is the requirement of a special system and equipment.

Two former studies have employed rectal tube placement to reduce distension after colonoscopy. The one conducted by Steinberg

Table 1. Frequency distribution of clinical and demographic of patients with and without anoscopy

		Anoscopy	Non-Anoscopy	P value
Sex	Male	26	35	0.065
	Female	24	15	
Ratio of previous abdominal surgery	Yes	15	12	0.499
	No	35	38	
Presence of polyps	Yes	15	10	0.248
	No	35	40	

Table 2. Descriptive statistics of the sample group

	Anoscopy	N	Mean	Std. Error Mean	95% Confidence Interval for Mean [LB., UB.]	P
VAS pain score 15 minutes after the procedure	Not performed	50	39.800	4.125	[31.510, 48.091]	0.000
	Performed	50	4.800	1.518	[1.749, 7.851]	
VAS pain score 30 minutes after the procedure	Not performed	50	14.400	3.053	[8.265, 20.535]	0.000
	Performed	50	0.600	0.444	[-0.291, 1.491]	
VAS pain score 24 hours after the procedure	Not performed	50	14.400	3.053	[8.266, 20.535]	0.000
	Performed	50	0.600	0.444	[-0.291, 1.491]	
Procedural time	Not performed	50	18.04	0.579	[16.880, 19.200]	0.978
	Performed	50	18.02	0.618	[16.780, 19.260]	
Midazolam dose	Not performed	50	1.66	0.067	[1.524, 1.796]	1
	Performed	50	1.66	0.067	[1.524, 1.796]	
Propofol dose	Not performed	50	87.20	5.577	[75.992, 98.407]	0.111
	Performed	50	75.40	4.774	[65.806, 84.994]	
Age	Not performed	50	47.80	2.236	[43.306, 52.294]	0.011
	Performed	50	55.46	1.926	[51.590, 59.331]	

found a reduced bloating in patients in whom rectal tube was used [3]. Hilzernat et al, on the other hand, reported similar pain and bloating in similar study design [4] although it should not be overlooked that these patients were administered fentanyl during the procedure. The rectal tube can only decompress the rectum and sigmoid colon, but the air remains in the more proximal sections. In our study, we demonstrated that air in the colonic lumen can be more easily evacuated with mild compression from the abdominal wall during anoscopy. Furthermore, procedures in the rectal tube studies were completed with the tubes left in the anal canal, which may lead to patient discomfort. In the present study, anoscope was removed before patients are woken and none of them reported anal discomfort.

The study by Lee JG also reported a reduced rate of complaints immediately after total colonic decompression after colonoscopy, although the rate of complaints was essentially unchanged at 24^{th}-48^{th} hours [6]. Colonoscopy becomes more difficult and painful in women due to a longer colon and previous pelvic surgeries [8]. In our study, both groups had similar female-to-male ratios and procedural times.

Our study revealed that the anoscopy group had a greater mean age. Patients of advanced age usually show better compliance with the colonoscopy procedure. There is, however, no clear information regarding post-procedural differences [9]. Further studies are needed on this subject.

Our study has several limitations. First, it was a single-center study, and the investigators were not blinded to the study arms. Second, the small patient population and the retrospective nature of the study do not allow us to draw any strong conclusion about the effectiveness of the procedure. And finally, the groups were not equal concerning age and the tolerance of colonoscopy is better in elderly patients. Larger series with prospective study design is needed to confirm the effectiveness of this approach.

5. CONCLUSION

Our study showed that post-procedural pain was reduced by anoscopy after colonoscopy. Anoscopy, which is free of additional risk after colonoscopy, safe in experienced hands, and low-cost, may increase patient comfort. Favorable experiences of patients about the procedure may ease follow-up protocols when necessary. Even if not used on a routine basis, anoscopy may be used in select patients with excess distension after the colonoscopy procedure.

CONSENT AND ETHICAL APPROVAL

Signed Informed consent was demanded in all cases. The study was approved by the local Ethics Committee of Baskent University. Each patient provided informed consent following the Helsinki Declaration.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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