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Use of Patient Abdominal Compression Device Reduces Staff Musculoskeletal Pain Associated With Supporting Colonoscopy

Results From a Randomized Controlled Trial

ABSTRACT

Work-related musculoskeletal disorders occur frequently among the endoscopy staff, and patient-handling duties involved with colonoscopy—applying manual pressure and repositioning patients—are particularly physically demanding. This study explored whether the use of a lower abdominal compression device (ColoWrap), previously shown to reduce the need for manual pressure and patient repositioning, would diminish the frequency of staff-reported musculoskeletal pain. A randomized, blinded, sham-controlled clinical trial was performed at the University of North Carolina Hospitals. Three hundred fifty patients had either ColoWrap or a sham device applied before colonoscopy. The primary outcome was the frequency of staff-reported musculoskeletal pain after assisting with colonoscopy. In the intention-to-treat analysis, which included procedures in which ColoWrap was removed, there was no statistical difference in the frequency of staff-reported pain in the control versus ColoWrap arm (4.6% vs. 3.4% of procedures, $p = .59$). However, when ColoWrap was used as directed (e.g., remained in place for the duration of the procedure), the frequency of staff-reported musculoskeletal pain was significantly reduced (4.6% vs. 0.7% of procedures, $p = 0.04$). Use of ColoWrap as directed was also found to be independently associated with reduced odds of staff-reported pain relative to the sham arm (OR = 0.12; 95% CI [0.02, 0.95]). When used as directed, ColoWrap reduced the frequency of musculoskeletal pain experienced related to assisting with colonoscopy and may reduce the risk of musculoskeletal disorders and injuries among the endoscopy staff.

Background

In the United States (U.S.), the rate of work-related musculoskeletal disorders (MSDs) is higher in healthcare than for most other industries (Occupational Safety and Health Administration [OSHA], 2013). Nurses and the hospital staff are at particular risk—in large part due to patient-handling activities required in providing direct patient care (Koppelaar, Knibbe, Miedema, & Burdorf, 2009). Costs associated with these injuries are substantial. Nurses and patient aides average five to six lost workdays per year due to MSDs sustained on the job (Tveito et al., 2014). The average direct cost per claimed injury related to patient handling is $15,600 (OSHA,

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2011). Indirect costs such as diminished productivity, re-staffing expenses, and increased liability raise the total cost per claimed injury by two to four times (OSHA, 2011). In aggregate, overexertion-related MSDs, caused primarily by patient handling (Centers for Disease Control and Prevention, 2013), are estimated to cost the U.S. healthcare industry more than $1.7 billion on an annual basis (Dressner, 2017). Musculoskeletal disorders among healthcare workers also affect patient care. Work-related injuries contribute to understaffing and are associated with nurse burnout, both of which reduce patient safety and satisfaction (Nahrgang, Morgeson, & Hofmann, 2011; Spence Laschinger & Leiter, 2006; Vahey, Aiken, Sloane, Clarke, & Vargas, 2004).

Published studies indicate that endoscopy nurses and staff sustain work-related MSDs at a rate that is comparable with or greater than nurses in other subspecialties (Drysdale, 2007, 2011, 2013). On an annual basis, 25%–33% of endoscopy nurses report missing workdays due to MSDs, particularly due to upper extremity pain (Drysdale, 2011, 2013). Neck and back injuries are common among the endoscopy staff (Drysdale, 2014), and anecdotally, tendonitis and carpal tunnel syndrome are also frequently reported.

The patient-handling duties of endoscopy personnel are unique (Biggers, 2018). During colonoscopy, nurses and aides are frequently required to provide sustained, manual abdominal pressure and patient repositioning to mitigate looping and facilitate insertion of the colonoscope (Crockett et al., 2016; Xhaja & Church, 2014). Each of these maneuvers requires substantial physical exertion—especially when they are performed on patients with a large abdomen and/or high body mass index (BMI) or when sustained pressure is required for a long duration (Box 1).

ColoWrap is a recently developed compression device that is applied to a patient's lower abdomen just prior to colonoscopy for splinting the sigmoid and transverse colon during the procedure to facilitate scope insertion. In previous studies, use of ColoWrap has been shown to reduce the need for manual pressure and patient repositioning and shorten insertion time during colonoscopy (Crockett et al., 2016; Hamade et al., 2019).

The aim of this study was to determine whether use of ColoWrap reduces the occurrence of musculoskeletal (MSK) pain among the endoscopy staff assisting with colonoscopy. We hypothesized that ColoWrap would reduce the occurrence of MSK pain, ostensibly by minimizing the need for manual abdominal pressure and patient repositioning during the procedure.

BOX 1. A Perspective From the Field: Manual Abdominal Pressure During Colonoscopy

Many times during colonoscopy, endoscopy technicians or nurses are asked to apply abdominal pressure to facilitate cecum intubation. The application of abdominal pressure reduces looping of the colonoscope within the abdomen. Intensive manual abdominal pressure using the back, shoulders, wrists, and arms for a prolonged time can be exhausting to the staff and ultimately cause physical injury. The staff may also be asked to reposition the patient during the procedure due to inability to advance the colonoscope; this adds to the physical demands of supporting the procedure. One other aspect to consider is the physical ability of the endoscopy staff. Not only the height and physical size of the endoscopy staff but also gender may play a part in the success of the procedure when manual abdominal pressure is required, as a small-framed female endoscopy nurse may not have the ability to apply the manual abdominal pressure required to reduce looping and advance the scope.

An alternative to manual abdominal pressure would alleviate the physical stress and possible injury of the endoscopy staff. As awareness of ergonomics and safe patient handling continues to grow, endoscopy units would be well-advised to implement an alternative method to apply abdominal pressure to alleviate staff fatigue, injury, and burnout.

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Methods

Study Design and Population

The present study is a secondary analysis of clinical trial data from a previous study (Crockett et al., 2016) and examines the effect of the ColoWrap intervention on staff-reported MSK pain. In the original study, a randomized, blinded, sham-controlled clinical trial was performed to determine whether use of the ColoWrap device reduced insertion time and need for manual pressure and patient repositioning during colonoscopy. At a single center with multiple endoscopy facilities (University of North Carolina Hospitals), outpatients undergoing elective colonoscopy between the ages of 40 and 80 years were recruited for participation from April 2013 to March 2014. Inclusion criteria included healthy subjects (American Society of Anesthesiologists Class I–III) who completed the entire purgative preparation prior to their procedure, described adequate cleansing, and could understand and read English. Exclusion criteria included a known history of incomplete colonoscopy, problems with

sedation or anesthesia, pregnancy, unsedated procedures, multiple planned procedures (e.g., bidirectional endoscopy), previous colon resection, known or suspected inflammatory bowel disease, history of colorectal cancer or other intra-abdominal malignancy, patients with recent wounds or skin rash on the anterior abdominal wall, history of cirrhosis or ascites, and known ventral hernia. Patients with BMI greater than 40 kg/m^2 or waist circumference more than 45 in. were also excluded because of the manufacturer-recommended size limits of the device used in this study. This research was approved by the University of North Carolina Institutional Review Board, and all participants provided written informed consent. The study was registered prior to initiation (ClinicalTrials.gov No. NCT02025504). This article is reported in accordance with the CONSORT guidelines (Boutron et al., 2008; Schulz, Altman, Moher, & Group, 2010). All authors had access to the study data and reviewed and approved the final manuscript.

Study Procedures and Device Description

Age, gender, race, height, weight, and waist circumference were recorded in all subjects prior to their procedure. Body mass index was calculated using the standard formula. All participants completed a study questionnaire regarding medical history, reason for colonoscopy, and concomitant gastrointestinal disorders. Once enrolled, participants were randomized to either the intervention arm or the sham arm. Randomization was stratified by gender and was performed using a web-based portal linked to a previously computer-generated randomization table that was concealed to study coordinators, investigators, all clinical staff members, and participants.

The study coordinators obtained the randomization assignment and then fitted the intervention or sham device in a private bay alone with the patient. No other study or procedural personnel were present during application of the device (or sham) to preserve blinding. For participants randomized to the intervention arm, a lower abdominal compression device (ColoWrap, LLC, Durham, NC) was applied around the circumference of the lower abdomen, just below the umbilicus.

Designed specifically for splinting during colonoscopy, ColoWrap consists of a neoprene-composite primary wrap that provides adjustable, uniform compression to the lower abdomen and a secondary support strap that allows focused compression to be iteratively applied to the sigmoid and transverse colon (Figures 1 and 2). Although the manufacturer now offers the device in several sizes, the regular size (100 cm) ColoWrap was used on all participants in the study for uniformity. In addition, to maintain blinding, the secondary strap was engaged preemptively during application to target the sigmoid region. The staff were not

FIGURE 1. ColoWrap device (ColoWrap, LLC).

able to adjust the secondary strap during the procedure. Once applied, participants were asked to assert that the wrap was fastened tightly but not uncomfortably.

In participants randomized to the sham arm, a sham device, similar in appearance to the intervention (same color, logo, and material) was placed loosely around the lower abdomen such that no pressure was applied. All devices (intervention or sham) were applied by one of two coordinators (H.C. and R.K.) to ensure standardized application.

After application of either the study device or the sham, an opaque sheet was placed transversely over the participants and was kept in place for the duration of the procedure. All patients were then placed in the left lateral decubitus position and underwent anesthesiologist-administered sedation and colonoscopy per standard procedure. Propofol was used in the vast majority of cases, and conscious sedation with fentanyl and midazolam was used in two cases. Patients and study coordinators were unblinded to the intervention, but endoscopists, nurses, technicians, and anesthesiologists were blinded to treatment assignment. Manual pressure and patient position

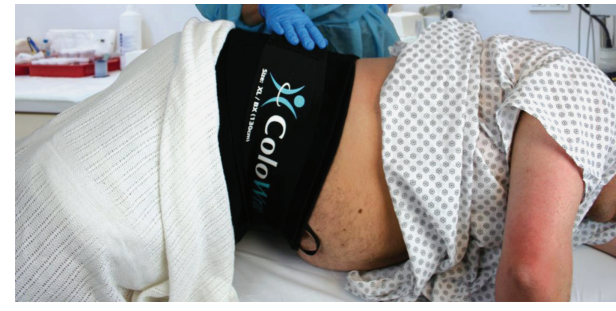

FIGURE 2. ColoWrap device in situ.

change were performed by an endoscopy nurse or technician at the discretion of the endoscopist. Endoscopists or anesthesiologists could remove the study device at any point during the procedure for clinical or safety reasons; when this occurred, it was classified as a protocol deviation.

Data Collection

The primary outcome for this study was the frequency of staff-reported MSK pain immediately after assisting with a colonoscopy. All procedures were performed with a physician endoscopist, anesthesiologist, or certified registered nurse anesthetist, and two additional endoscopy staff members present in the room. During each procedure, one of the two endoscopy staff members was responsible for directly assisting the physician and applying manual abdominal compression or repositioning the patient if required. Immediately following each procedure, using the questionnaire shown in the Supplemental Digital Content Figure (available at: http://links.lww.com/GNJ/A61), the study assistant asked this staff member if he or she had experienced pain at one of four sites during the examination. These sites included the lower back, upper back, neck, and upper extremities. Staff responses were recorded electronically.

Data Analysis

Descriptive statistics and bivariate analyses were used to compare participant, procedural, and staff-reported pain characteristics between the ColoWrap and sham arms by using Student's *t* test and Wilcoxon's rank sum for continuous variables and Pearson's chi-squared tests for categorical variables. Staff-reported pain data were collected on a per procedure basis, by anatomical site. The staff could indicate multiple sites of pain following a single procedure. Multivariate logistic regression was performed to assess whether ColoWrap use was associated with reduced staff pain. Differences were considered statistically significant at an α level of less than .05. All analyses were performed by using STATA 13 (StataCorp, College Station, TX).

Results

Subjects

The study included 350 participants, who were divided into two arms of 175 (Table 1). There were no significant differences between the two groups in age, gender, race, or BMI. A majority underwent colonoscopy for screening or surveillance purposes. Both groups predominantly had 'good' or 'excellent' bowel prep and had comparable withdrawal times; approximately 70% of the cases were performed by the senior faculty. Sixty-two percent of participants in the sample were women who were equally distributed between the two arms of the study.

Staff-Reported Pain

Overall, the endoscopy staff reported suffering MSK pain in 4% (14) of procedures across both arms of the study. Pain in the upper extremities was most frequently reported and was indicated in 100% ($n = 14$) of the pain-inducing procedures (Figure 3). Reports of pain in the lower back ($n = 1$), upper back ($n = 2$), and neck ($n = 1$) were less common.

ColoWrap Versus Sham

In an intention-to-treat analysis (Table 2), there were no differences between the sham and ColoWrap groups in frequency of staff-reported pain (4.6% vs. 3.4%, $p = .59$). However, within the ColoWrap group, there were 31 procedures in which ColoWrap was removed prematurely due to physician preference. When ColoWrap remained in place for the entire examination (e.g., was used as directed) (Table 2), staff-reported pain was significantly reduced in the ColoWrap study arm relative to the sham (4.6% vs. 0.7%, $p = .04$). Using ColoWrap as directed was also independently associated with reduced odds of staff-reported pain relative to the sham arm (OR = 0.12; 95% CI [0.02, 0.95]) (Table 3).

Discussion

Previous studies have demonstrated a high frequency of MSDs among endoscopy nurses and technicians. These injuries are a primary cause of burnout and turnover among endoscopy personnel, place a substantial financial burden on health systems, and ultimately result in diminished quality of care and patient satisfaction (Charney & Schirmer, 2007; Sorour & El-Maksoud, 2012; Vahey et al., 2004). Given the frequency and significance of these MSDs, there is a clear need for interventions that minimize the risk of staff injury. Patient handling is a primary risk factor for MSDs, and within endoscopy, the two most common patient-handling tasks are manual abdominal pressure and patient repositioning during colonoscopy. ColoWrap is a lower abdominal compression device that has been shown to reduce the need for these tasks; however, the extent to which use of such a device may mitigate MSDs among the endoscopy staff remains unclear.

In this randomized, sham-controlled study, we assessed the impact of a lower abdominal compression device on staff-reported MSK pain immediately following colonoscopy. The study specifically focused on

TABLE 1. Characteristics of Study Population and Procedures

Characteristics	Sham (n = 175)	ColoWrap (n = 175)	p
Age, n (%)			.24
<50 years	7 (4)	13 (7)	
50–60 years	63 (36)	74 (42)	
61–70 years	71 (41)	60 (34)	
≥70 years	34 (19)	28 (16)	
Gender, n (%)			1.00
Female	108 (62)	108 (62)	
Male	67 (38)	67 (38)	
BMI, n (%)			.86
<25	73 (42)	70 (40)	
25–30	62 (35)	67 (38)	
31–40	40 (23)	38 (22)	
Colonoscopy indication, n (%)			.83
Diagnostic	15 (9)	16 (9)	
Screening/surveillance	159 (92)	157 (91)	
Aronchick bowel prep score, n (%)			.77
Poor	4 (2)	3 (2)	
Fair	17 (10)	23 (13)	
Good	71 (41)	70 (40)	
Excellent	83 (47)	79 (45)	
Withdrawal time, mean ± SD, min	12.5 ± 5.7	11.56 ± 6.1	.20
Endoscopist experience, n (%)			.79
Fellow	26 (15)	23 (13)	
Junior faculty	33 (19)	30 (17)	
Senior faculty	116 (66)	122 (70)	

Note. BMI = body mass index.

the staff member responsible for directly assisting the physician, including applying abdominal pressure and repositioning the patient, during the procedure. When ColoWrap was used as directed (e.g., remained in place for the duration of the procedure), both the frequency and likelihood of staff-reported MSK pain were substantially reduced.

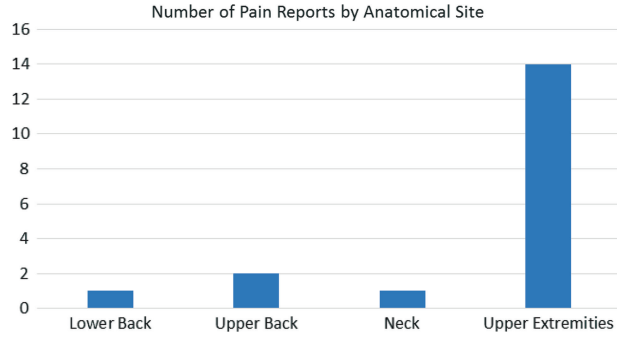

FIGURE 3. Number of musculoskeletal pain reports by anatomical site.

This outcome was likely due to the fact that the lower abdominal compression device reduced the need for manual abdominal pressure. Indeed, the study revealed a clear association between the use of manual pressure and staff-reported MSK pain. During procedures in which staff pain occurred (Table 4), manual pressure was used more frequently (100% vs. 39% of procedures, $p < .001$) and for longer durations (>3 minutes; 93% vs. 35% of procedures, $p < .001$) than in colonoscopies in which the staff reported no pain. In a multivariate analysis, manual pressure in excess of 3 minutes was also independently associated (OR = 92.1; 95% CI [10.6, 797.4]) with increased risk of staff pain (Table 3). As ColoWrap is known to reduce the need for manual pressure, it is logical that use of the device would demonstrate a reduction in staff-reported pain.

TABLE 2. Association Between ColoWrap and Pain, Bivariate

Characteristics	Sham (*n* = 175)	Wrap (*n* = 175)	*p*	Wrap Used as Directed[a] (*n* = 144)	*p*
Any pain	8 (4.6)	6 (3.4)	.59	1 (0.7)	.044
Pain lower back	0 (0)	1 (0.6)	1.00	1 (0.7)	.45
Pain upper back	1 (0.6)	1 (0.6)	1.00	1 (0.7)	1.00
Pain neck	0 (0)	1 (0.6)	1.00	1 (0.7)	.45
Pain upper extremity	8 (4.6)	6 (3.4)	.79	1 (0.7)	.044

[a]This analysis excludes the 31 procedures within the ColoWrap arm in which the device was removed prematurely.

In addition, the relationship between manual abdominal pressure and staff-reported pain appeared to be mediated by patient body habitus, with obese patients posing a greater risk for staff pain when sustained manual pressure was needed (Tables 5 and 6). This finding may further explain the observed benefit of ColoWrap use in reducing staff-reported MSK pain, as previous studies have indicated that the device may be particularly effective in reducing the need for manual pressure in obese patients (Crockett et al., 2016).

Overall, the endoscopy staff experienced MSK pain in nearly one out of every 20 colonoscopies. The implications of these data are significant. Although at first glance, pain being reported in one in 20 colonoscopies may seem infrequent, endoscopy staff routinely assist with 10 or more procedures in a single day. Based on the frequency of reported pain found in this study, the average endoscopy staff member may be experiencing MSK pain due to colonoscopy-related patient handling on at least a weekly basis. The association found between staff-reported pain and the application of manual pressure also raises questions about the sustainability of this technique. The study results indicate a need to reduce the use of manual abdominal pressure and certainly show that decreasing long duration pressure, particularly in obese patients, should be a goal of interventions to mitigate MSDs among the endoscopy staff.

Strengths of this study include its randomized design, use of sham controls, and blinding, all of which minimize bias and confounding. In addition, the finding that proper use of the abdominal compression device reduced staff-reported MSK pain is bolstered by data from the study substantiating the relationship between staff-reported pain and manual abdominal pressure, which ColoWrap is known to reduce. Other indicators of difficult colonoscopy such as increased looping, longer cecal intubation time, and less experienced endoscopists were also associated with greater staff-reported pain.

Limitations

One limitation of this study is that the primary endpoint was staff-reported pain, which represents just

TABLE 3. Univariate and Multivariable Analyses of Factors Associated With Pain

Characteristics	Pain at Any Site (*n* = 14), OR [95% CI]	
	Univariate	Multivariable[a]
Age 60+ years	1.78 [0.58, 5.42]	–
Male gender	1.22 [0.41, 3.59]	–
Obese	1.42 [0.43, 4.65]	–
Senior endoscopist	0.17 [0.05, 0.57]	–
CIT ≥10 min	4.39 [1.46, 13.21]	3.26 [0.96, 11.07]
Manual pressure >3 min	81.96 [10.47, 641.49]	92.13 [10.64, 797.44]
Position change	2.51 [0.30, 21.08]	2.06 [0.22, 18.86]
Moderate to excessive looping	18.24 [5.74, 57.94]	22.72 [6.08, 84.90]
Moderately to extremely difficult	6.97 [2.26, 21.45]	7.01 [2.12, 23.24]
ColoWrap ITT	0.74 [0.25, 2.18]	0.81 [0.27, 2.43]
ColoWrap used as directed[b]	0.10 [0.01, 0.80]	0.12 [0.02, 0.95]

Note. CI = confidence interval; CIT = cecal intubation time; ITT = intention to treat; OR = odds ratio.

[a]Multivariable model adjusted for age (continuous), gender, BMI (continuous), and endoscopist.

[b]This analysis excludes the 31 procedures within the ColoWrap arm in which the device was removed prematurely.

TABLE 4. Association Between Patient/Procedure Characteristics and Assistant Pain, Bivariate

Characteristics	Pain Yes (*n* = 14)	Pain No (*n* = 365)	*p*
Participants			.56
Age, mean ± *SD*	61.8 ± 10.0	60.4 ± 8.3	
Age			.69
<50 years	1 (7.1)	19 (5.7)	
50–59 years	4 (28.6)	133 (39.6)	
60–69 years	5 (35.7)	126 (37.5)	
70–79 years	4 (28.6)	58 (17.3)	
Gender			.72
Female	8 (57.1)	208 (61.9)	
Male	6 (42.9)	128 (38.1)	
BMI, mean ± *SD*	27.7 ± 5.6	26.5 ± 4.2	.31
Obese (BMI ≥30)	4 (28.6)	74 (22.0)	.76
Waist circumference, mean ± *SD*	37.5 ± 4.5	35.6 ± 4.2	.10
Prior hysterectomy	4 (28.6)	55 (16.4)	.27
History of IBS	2 (14.3)	23 (6.9)	.26
Constipation at least once per week	1 (7.1)	43 (12.8)	1.00
History of diverticulosis	1 (7.1)	46 (13.7)	.70
Procedure			
Bowel prep			.013
Good or excellent	9 (64.3)	294 (87.5)	
Poor or fair	5 (35.7)	42 (12.5)	
Endoscopist			.001
Fellow	2 (14.3)	47 (14.0)	
Junior faculty	8 (57.1)	55 (16.4)	
Senior faculty	4 (28.6)	234 (69.6)	
Looping			<.001
No or some looping	5 (35.7)	304 (90.5)	
Moderate to excessive looping	9 (64.3)	30 (8.9)	
Procedure difficulty			<.001
Not or slightly difficult	5 (35.7)	267 (79.5)	
Moderately to extremely difficult	9 (64.3)	69 (20.5)	
Cecal intubation time, mean ± *SD*	11.5 ± 5.9	6.5 ± 4.0	<.001
Ancillary maneuver performed			
Any manual pressure	14 (100)	130 (38.7)	<.001
Manual pressure >3 min	13 (92.9)	46 (35.4)	<.001
Position change	1 (7.1)	10 (3.0)	.37

Note. BMI = body mass index; IBS = inflammatory bowel syndrome.

one measure of the numerous MSDs known to affect the endoscopy staff. However, it is worth noting that many MSDs in endoscopy are associated with repetitive motion, which causes chronic inflammation over time. As pain is a known indicator of inflammation, it is reasonable to infer that a reduction in the frequency of MSK pain would likely lower the risk of MSDs associated with chronic overuse and inflammation, such as tendonitis and carpal tunnel syndrome.

TABLE 5. Association Between Patient/Procedure Characteristics and Staff Pain Among Patients Requiring Prolonged Pressure, Bivariate

Characteristics	Pain Yes (n = 13)	Pain No (n = 46)	P
Participants			
Age,			.81
<50 years	0 (0)	1 (2.2)	
50–59 years	4 (30.8)	16 (34.8)	
60–69 years	5 (38.5)	20 (43.5)	
70–79 years	4 (30.8)	9 (19.6)	
Gender			.55
Female	7 (53.9)	29 (63.0)	
Male	6 (46.2)	17 (37.0)	
BMI, mean ± *SD*	28.4 ± 5.3	24.6 ± 3.8	.005
Obese (BMI ≥30)	4 (30.8)	3 (6.5)	.017
Waist circumference, mean ± *SD*	38.2 ± 3.9	33.9 ± 4.0	.0014
High waist circumference[a]			
<40 in. male/<35 in. female			
≥40 in. male/≥35 in. female			
Prior hysterectomy	3 (23.1)	10 (21.7)	1.00
History of IBS	1 (7.7)	4 (8.7)	1.00
Constipation at least once per week	1 (7.7)	9 (19.6)	.43
History of diverticulosis	1 (7.7)	6 (13.0)	1.00
Procedure			
Bowel prep			.13
Good or excellent	9 (69.2)	40 (87.0)	
Poor or fair	4 (30.8)	6 (13.0)	
Endoscopist			.16
Fellow	2 (15.4)	16 (34.8)	
Junior faculty	7 (53.9)	55 (23.9)	
Senior faculty	4 (30.8)	19 (41.3)	
Looping			.25
No or some looping	5 (38.5)	26 (56.5)	
Moderate to excessive looping	8 (61.5)	20 (43.5)	
Procedure difficulty			.98
Not or slightly difficult	4 (30.8)	14 (30.4)	
Moderately to extremely difficult	9 (69.2)	32 (69.6)	
Cecal intubation time, mean ± *SD*	12.0 ± 5.8	12.3 ± 5.7	.84
Ancillary maneuver performed			
Any manual pressure	13 (100)	46 (100)	1.00
Manual pressure >3 min	13 (100)	46 (100)	1.00
Position change	1 (7.7)	9 (19.6)	.32
ColoWrap			
Sham	7 (53.9)	25 (54.4)	
ColoWrap ITT	6 (46.2)	21 (45.7)	.97
ColoWrap used as directed[b]	1 (7.7)	9 (19.6)	.43

Note. BMI = body mass index; IBS = inflammatory bowel syndrome; ITT = intention to treat.

[a]Defined as 40 in. or more for males and 35 in. or more for females.

[b]This analysis excludes the 31 procedures within the ColoWrap arm in which the device was removed prematurely.

TABLE 6. Logistic Regression With Univariate and Multivariable Analyses of Factors Associated With Pain Among Patients Who Received Prolonged Manual Pressure

Characteristics	Pain at Any Site (n = 13), OR [95% CI]	
	Univariate	Multivariable[a]
Age 60+ years	1.32 [0.35, 4.94]	–
Male gender	1.46 [0.42, 5.07]	–
Senior endoscopist	0.63 [0.17, 2.35]	–
Obese	6.37 [1.21, 33.52]	6.63 [1.20, 36.65]
High waist circumference[b]	4.22 [1.13, 15.72]	5.95 [1.29, 27.45]
CIT ≥10 min	0.66 [0.19, 2.27]	0.69 [0.20, 2.42]
Position change	0.34 [0.04, 2.99]	0.30 [0.03, 2.82]
Moderate to excessive looping	2.08 [0.59, 7.33]	1.96 [0.55, 7.01]
Moderately to extremely difficult	0.98 [0.26, 3.74]	1.28 [0.31, 5.34]
ColoWrap ITT	1.02 [0.30, 3.51]	1.07 [0.30, 3.77]
ColoWrap used as directed[c]	0.34 [0.04, 2.99]	0.37 [0.04, 3.29]

Note. CI = confidence interval; CIT = cecal intubation time; ITT = intention to treat; OR = odds ratio.

[a]Multivariable model adjusted for age (continuous), gender, endoscopist.

[b]Defined as 40 in. or more for males and 35 in. or more for females.

[c]This analysis excludes the 31 procedures within the ColoWrap arm in which the device was removed prematurely.

Other considerations include the fact that propofol anesthesia was used for almost all cases, potentially limiting applicability to settings in which conscious sedation is employed. In addition, because of the blinding methodology of the study, the lower abdominal compression device could not be adjusted intraprocedurally. This may have affected the efficacy of the device in the study, as intraprocedural adjustment has since been found to be an important factor in optimally facilitating scope insertion and is now recommended by the manufacturer (ColoWrap, LLC). Finally, because of constraints that limited the device used in the study to a single size (five sizes are now offered by the manufacturer), the obese patient population within the study was restricted to patients with a BMI between 30 and 40 kg/m^2. Given the finding that manual pressure applied to obese patients may pose an increased risk of staff injury, evidence of ColoWrap effectiveness in minimizing staff pain in procedures involving patients with a BMI greater than 40 kg/m^2 seems a worthwhile focus for future studies.

Conclusion

In this study, we demonstrated that ColoWrap, a lower abdominal splinting device known to reduce the need for manual pressure and repositioning, minimized the frequency of staff-reported MSK pain when it was used as directed. This study is the first to show a conclusive link between the use of a device alternative to manual abdominal pressure during colonoscopy and fewer instances of MSK pain among the endoscopy staff. These results suggest that employing ColoWrap in lieu of manual abdominal pressure may prevent MSDs in the endoscopy staff. Further research is needed to solidify evidence around this relationship and to determine ideal use for the device to maximize benefits for the staff and patients. ✪

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