

## Sedated vs unsedated colonoscopy: A prospective study

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**Supported by** Partially by College of Medicine Research Center, Deanship of Scientific Research, King Saud University

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Received: November 17, 2013 Revised: January 1, 2014

Accepted: February 20, 2014

Published online: May 7, 2014

### Abstract

**AIM:** To compare sedated to unsedated colonoscopy in terms of duration, pain and the patient's willingness to repeat the procedure.

**METHODS:** Consecutive patients who underwent colonoscopies over a 2-year period were invited to participate. All patients who were to undergo our endoscopy unit were offered sedation with standard intravenous sedatives and analgesics, or an unsedated colonoscopy was attempted. Demographic details were recorded. The patient anxiety level prior to the procedure, time to reach the cecum, total discharge time, patient and endoscopist pain assessments, satisfaction after the examination and the patient's willingness to return for the same procedure in the future were recorded.

**RESULTS:** Among the 403 observed patients, more males were observed in the unsedated group (66.2% vs 55.2%,  $P = 0.04$ ). Additionally, the unsedated group patients were less anxious prior to the procedure (5.1 vs 6.0,  $P < 0.01$ ). The colonoscopy completion rates were comparable between the 2 groups (85.9% vs 84.2%,  $P = 0.66$ ). The time to reach the cecum was also comparable (12.2 min vs 11.8 min); however, the total discharge times were shorter in the unsedated group (20.7 min vs 83.0 min,  $P < 0.01$ ). Moreover, the average patient pain score (3.4 vs 5.7,  $P < 0.01$ ) was lower in the sedated group, while the satisfaction score (8.8 vs 7.8,  $P < 0.01$ ) was significantly higher. There was no significant difference, however, between the groups in terms of willingness to repeat the procedure if another was required in the future (83.3% vs 77.3%,  $P = 0.17$ ).

**CONCLUSION:** Unsedated colonoscopy is feasible in willing patients. The option saves the endoscopy units up to one hour per patient and does not affect the patient willingness to return to the same physician again for additional colonoscopies if a repeated procedure is needed.

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**Key words:** Sedation; Colonoscopy; Unsedated; Screening; Endoscopy

**Core tip:** Published information indicates that unsedated colonoscopies are acceptable in many countries; however, sedation is still a usual practice in many countries. Its burden includes escort requirement, time for recovery and activity restrictions. This study showed that unsedated colonoscopy is feasible in willing patients and it saves the endoscopy units up to one hour per patient. Contrary to some endoscopist's fears, patients were still willing to return to the same physician for colonoscopy if a repeat procedure was needed.

Aljebreen AM, Almadi MA, Leung FW. Sedated vs unsedated colonoscopy: A prospective study. *World J Gastroenterol* 2014; 20(17): 5113-5118 Available from: URL: <http://www.wjgnet.com/1007-9327/full/v20/i17/5113.htm> DOI: <http://dx.doi.org/10.3748/wjg.v20.i17.5113>

## INTRODUCTION

Colonoscopy has become an indispensable gastroenterologist tool, and although the procedure has evolved over time, discomfort and pain remain one of the major concerns for patients undergoing colonoscopies<sup>[1]</sup>. To overcome these concerns, endoscopists commonly use conscious sedation (CS); however, their use does have some drawbacks, especially for elderly patients<sup>[2,3]</sup>. Additionally, sedation has been identified as a colorectal cancer screening barrier for colonoscopy use, whereby 14% of patients cited the need for an escort and time-off following sedation as the reasons for non-adherence to the recommended screening<sup>[4]</sup>. Moreover, the limited procedure numbers that can be performed due to the prolonged turnaround time for the recovery time after sedation have also been described as a barrier for colonoscopy use. A United States study, based on detailed patient diaries, revealed that a median of 39.5 h is spent for colonoscopies. After a colonoscopy, the median recovery time is 1.8 h and an additional 15.8 h is required to return to daily routines<sup>[5]</sup>.

Published information indicates that unsedated colonoscopies are acceptable in many countries<sup>[6-11]</sup>. In the United States, unscheduled and unsedated colonoscopies have been offered to approximately 1% to 2%<sup>[12]</sup> of patients who are without an escort.

The main objective of this study was to compare sedated with unsedated colonoscopies in terms of time until discharge, willingness to repeat the procedure with the same endoscopist if future colonoscopies are required, pain levels and the patient and physician satisfaction levels.

## MATERIALS AND METHODS

### *Patients and methods*

Consecutive patients undergoing colonoscopy at our endoscopy unit from January 2010 to December 2012 were invited to participate in the study by a research assistant.

As is our practice, all patients who were to undergo colonoscopy in our endoscopy unit were offered sedation with standard intravenous sedatives and analgesics or an attempt at an unsedated colonoscopy. No attempt was made to pressure or coerce patients into having unsedated procedures. Patients were only excluded if they were undergoing both gastroscopy and colonoscopy at the same time, if interventional procedures were planned ahead of the colonoscopy or if they refused to participate in the study. All endoscopists, including supervised gastroenterology fellows, were invited to participate in the performance of sedated or unsedated colonoscopy examinations.

Demographic details, including age, gender, education level, prior endoscopic procedures, CS experience, weight and the procedure indications were recorded. Additionally, patient anxiety levels prior to the procedure were assessed using a 0-10 scale, whereby 0 indicated no anxiety at all, 5 indicated moderate anxiety and 10 indicated extreme anxiety.

Patients who choose to have sedation were given intravenous pethidine and midazolam in a ratio of 25:1 mg before the colonoscopy initiation. Additionally, dosages were adjusted according to the patient's age and weight. Patients who chose the non-sedated arm were given the option to ask for sedation if they felt it was necessary for procedure continuation.

The endoscopic findings and immediate complications (within 24 h of the procedure) were recorded in addition to documenting the quality of the preparation. All patients were monitored for cardiorespiratory depression with a pulse-oximeter.

Data recorded during the procedure included the time required to reach the cecum, patient discharge times from the endoscopy unit, any interventional procedures (such as biopsies or polypectomies), any medications given, the maximum drop in systolic blood pressure from baseline and the need for supplemental oxygen.

The time required to reach the cecum was the time from colonoscope insertion into the anus to the identification of all cecal landmarks. The discharge time was the time from colonoscope insertion until the patient was released from the endoscopy unit.

Just before releasing the patient from the endoscopy unit, a research assistant (non-blinded) asked the patient about their pain score and satisfaction level. Pain was evaluated by a visual analog scale from 0 to 10 (0: no pain, 10: worst pain). According to the scale in Table 1<sup>[10]</sup>, the endoscopist was asked to rate the patient's pain level during the procedure, his procedure satisfaction level and the technical ease of the procedure just after procedure completion. Patients were also asked about their willingness to return to the same physician again, if a repeat colonoscopy procedure were required. The King Khalid University Hospital Institutional Review Board approved this study.

### *Statistical analysis*

To estimate the sample size, we assumed that patients receiving routine sedation would find the procedure to be very acceptable and would have a mean pain score of 2. The smallest difference in pain score that was clinically important to detect was judged to be 2 units or a mean score of 4. Thus for mean pain score values of 2 and 4, estimated standard deviations of 2.5 and 3.5, respectively,  $\alpha$  of 0.05, and power of 0.8, recruitment of 74 participants was required.

Data analyses included descriptive statistics computed for continuous variables, including means, standard deviations, minimum and maximum values as well as 95%CI. Frequencies were used for categorical variables. Univariate

**Table 1 Pain and satisfaction scores**

Pain and satisfaction scores	
Doctor's assessment of the patient's discomfort level	
5	Patient complained bitterly; asked to stop multiple times; numerous delays; pain very distracting for doctor
4	Patient complained multiple times; asked to stop; several delays; would not allow repeat examination with this level of discomfort
3	Few transient delays; overall pain reasonable; doctor would be comfortable repeating examination with this pain level
2	Minor transient pain on insertion only or withdrawal only; patient would do very well with a repeat examination with this level of sedation
1	No pain
Overall level of satisfaction with colonoscopy	
	Very satisfied with examination
	Somewhat satisfied with examination
	Somewhat unsatisfied with examination
	Very unsatisfied with examination

**Table 2 Patient characteristics *n* (%)**

Characteristics	Sedated	Unsedated	<i>P</i> value
Total	270	133	
Male	149 (55.2)	88 (66.2)	0.04
Female	121 (44.8)	45 (33.8)	
Average age (yr)	43.4 ± 17	48.4 ± 13.7	0.002
Outpatient	180 (66.7)	119 (89.5)	0.001
Weight (kg)	70.2 ± 18.2	77.9 ± 16.7	0.0004
Smoking	25 (9.3)	12 (9.1)	0.72
NSIADs use	50 (18.7)	20 (15)	0.4
Education level			
Less than high school	111 (41.1)	63 (47.4)	0.67
High school	44 (16.3)	22 (16.5)	
Some college	36 (13.3)	14 (10.5)	
College or more	70 (25.9)	32 (24.1)	
Physicians	9 (3.3)	2 (1.5)	
Abdominal pain	139 (51.5)	74 (55.6)	0.45
IBS	67 (24.8)	47 (35.3)	0.03
IBD	23 (8.5)	12 (9.1)	0.85
Previous pelvic surgery	35 (13)	29 (22)	0.03
Previous abdominal surgery	65 (24.1)	39 (29.3)	0.28
Anxiety level prior to colonoscopy	6.1 ± 3.7	5.2 ± 3.6	0.008
Previous sedated colonoscopy	50 (18.5)	11 (8.3)	0.0003
Previous sedated gastroscopy	55 (20.4)	8 (6)	0.0001
Preparation quality			
Good	139 (50.2)	64 (48.1)	0.72
Fair	92 (34.1)	51 (38.3)	
Poor	39 (14.1)	18 (13.5)	

Data are frequency counts (percentage of total) or mean ± SD. IBS: Irritable bowel syndrome; IBD: Inflammatory bowel disease.

and multivariate logistic regressions were used to examine associations between independent and dependent variables. The independent variables included: age, gender, anxiety level, patient pain score, patient satisfaction level, physician pain level assessment, physician satisfaction level, education level and prior pelvic surgery history. Additionally, odds ratios (OR) and 95%CI were calculated.

We used the STATA 11.2 software package (Stata Corp, TX, United States) for our analyses. A statistical significance threshold of  $P = 0.05$  was adopted. No attempt at imputation was made for missing data.

## RESULTS

The patient demographic details are shown in Table 2.

A total of 403 patients were enrolled in the study with a mean age of 45.1 years (16) (range was from 9 to 85 years) and 58.8% of the subjects were male. 372 (92.3%) patients were Saudis, 37 (9.2%) were smokers, 35 (8.7%) were known to have inflammatory bowel disease (IBD) and 70 patients (17.5%) had a history of non-steroidal anti-inflammatory medication use. There were more males in the unsedated group (66.2% vs 55.2%,  $P = 0.04$ ) and they were older (48.5 vs 43.4,  $P = 0.002$ ), more likely to be outpatients (89.5% vs 66.7%,  $P = 0.001$ ) and had fewer previous sedated colonoscopies and gastroscopies than the sedated group (8.3% vs 18.5%,  $P = 0.0003$  and 6% vs 20.4%,  $P = 0.0001$ , respectively). Prior to the procedure, the sedated group patients were more anxious (6.1 ± 3.7, 95%CI: 5.7-6.6) than the unsedated group patients (5.2 ± 3.6, 95%CI: 4.6-5.8) ( $P = 0.009$ ). Additionally, the education level of these patients was less than high school in 174 (43.2%), high school in 66 (16.4%), some college in 50 (12.4%), 102 (25.3%) had completed college or higher level of education and 11 (2.7%) were physicians. There were no significant differences between the groups.

The procedure outcomes are shown in Table 3. The colonoscopy completion rates between the 2 groups were comparable (85.9% vs 84.2%,  $P = 0.66$ ), while the terminal ileum intubation rates were 41.8% in the sedated group compared with 27.7% in the unsedated group ( $P = 0.01$ ).

The average midazolam and pethidine dosages used to achieve CS were 3.3 ± 1.3 mg and 43.4 ± 20.2 mg, respectively. Eight patients in the unsedated group required sedation after starting the procedure, with average midazolam and pethidine dosages of 2.5 and 40 mg, respectively.

Only 4 patients (1.5%) in the sedated group had transient oxygen desaturation, and no other complications were observed in either group.

Although the time required to reach the cecum was comparable between the sedated (12.2 ± 9.4 min, 95%CI: 11.1-13.4) and unsedated groups (11.8 ± 8.8 min 95%CI: 10.2-13.3,  $P = 0.68$ ), the total discharge time for the sedated group was 82.9 ± 58.4 min (95%CI: 75.9-89.9) vs 20.7 ± 21.8 min (95%CI: 16.9-24.5) for the unsedated group ( $P < 0.0001$ ). The average technical ease according to the

Outcomes	Sedated ( <i>n</i> = 270)	Unsedated ( <i>n</i> = 133)	<i>P</i> value
Completed	232 (85.9)	112 (84.2)	0.66
TI intubation	97 (35.9)	31 (23.3)	0.01
Findings			
Normal	126	55	0.34
Diverticulosis	14	13	0.09
Ulcerative colitis	18	9	1.00
Crohn's disease	22	1	0.001
Polyps	36	21	0.54
Tumor	16	3	0.13
Incomplete endoscopy reason			
Poor preparation	7	4	0.76
Pain	12	12	0.077
Technical difficulty	6	4	0.74
Obstruction	7	1	0.28
Others	6	0	0.18
Time to cecum (min)	12.2 ± 9.4	11.8 ± 8.8	0.68
Total time until discharge	83 ± 58	20.7 ± 21.8	< 0.0001
Average technical ease	8 ± 1.8	7.9 ± 2	0.45
Polypectomy	4	3	0.63
Complications			
Oxygen desaturation	4 (1.5)	0	NA

Data are frequency counts (percentage of total) or the mean ± SD. CD: Crohn's disease; TI: Terminal ileum; UC: Ulcerative colitis; NA: Not applicable.

endoscopist was 8 ± 1.8 among the sedated group and 7.9 ± 2 in the unsedated group; however, no significant differences were observed between the groups (*P* = 0.45).

The average pain score reported by the patients was 3.4 ± 3.4 (95%CI: 3-3.8) in the sedated group vs 5.7 ± 3.2 (95%CI: 5.2-6.3) in the unsedated group (*P* < 0.0001), while the average pain score as assessed by the physician was 3.3 ± 2.6 (95%CI: 3-3.6) in the sedated group vs 4.1 ± 3 (95%CI: 3.6-4.6) in the unsedated group (*P* = 0.007) (Table 4). According to the endoscopists, 235 (87.3%) sedated group patients had no pain (20.8%) or complained of minor transient pain (49.4%) or little transient pain (17.1%), while only 34 (12.7%) patients complained multiple times (10.4%) or complained bitterly (2.3%). In contrast, 108 unsedated group patients (81.2%) had no pain (11.3%) or complained of minor transient pain (55.6%) or little transient pain (14.3%), while only 25 (18.8%) patients complained multiple times (12%) or complained bitterly (6.8%). A *P* = 0.03 was noted between the sedated and unsedated groups. According to the patients, 7 (2.6%) of the sedated group had a very bad experience compared with 10 (7.5%) of the unsedated group (*P* = 0.0001).

The average patient satisfaction score was 8.8 ± 2.2 (95%CI: 8.5-9) in the sedated groups vs 7.7 ± 2.6 (95%CI: 7.3-8.2) in the unsedated group (*P* < 0.0001). Moreover, 81.6% of the sedated group were very satisfied compared with 66.2% of the unsedated group (*P* = 0.0001), while only 3% of the sedated group were unsatisfied compared with 8.3% of the unsedated group (*P* = 0.02). In line with the patient satisfaction after the procedure, the average physician satisfaction after the procedure was significantly

Pain score and anxiety level	Sedated ( <i>n</i> = 270)	Unsedated ( <i>n</i> = 133)	<i>P</i> value
Average pain score by the patient	3.4 ± 3.4	5.7 ± 3.2	< 0.0001
Average pain score <i>via</i> physician assessment	3.3 ± 2.5	4.1 ± 3	0.007
Average patient satisfaction score	8.8 ± 2.2	7.7 ± 2.6	< 0.0001
Patient satisfaction			
Very satisfied	221 (81.9)	88 (66.2)	0.0007
Somewhat satisfied	36 (13.3)	27 (20.3)	0.08
Somewhat unsatisfied	5 (1.9)	7 (5.3)	0.07
Unsatisfied	8 (2.9)	11 (8.3)	0.02
Physician assessment of the patient discomfort level			
No pain	56 (20.8)	15 (11.3)	0.02
Minor transient pain	133 (49.4)	74 (55.6)	0.24
Few transient pain	46 (17.1)	19 (14.3)	0.56
Complained multiple times	28 (10.4)	16 (12)	0.01
Complained bitterly	6 (2.2)	9 (6.8)	0.007
Could not recall the procedure	124 (45.9)	5 <sup>1</sup> (3.8)	< 0.0001
Patients willing to repeat the procedure	225 (83.3)	103 (78.6)	0.16
Average physician satisfaction	8.4	7.8 ± 1.9	0.001

Data are frequency counts (percentage of total) or mean ± SD. <sup>1</sup>All received sedation.

different between the sedated group (8.4 ± 1.6, 95%CI: 8.2-8.6) and unsedated group (7.8 ± 1.9, 95%CI: 7.6-8.3) (*P* = 0.01).

Additionally, 45.9% of the sedated group did not remember the procedure, compared with 3.7% of the unsedated group, and 8 patients (6%) of the unsedated group asked for sedation after the procedure began.

83.3% sedated group patients were willing to repeat the colonoscopy in the future if needed compared with 78.6% of the unsedated group. No significant difference was observed between the groups (*P* = 0.27).

Following univariate analyses (Table 5), male gender, lower anxiety scores prior to the procedure, high patient and physician satisfaction scores and a higher education level predicted the willingness to repeat the procedure in the future if required, while higher pain scores (whether assessed by the patient or the physician), higher anxiety level prior to the procedure, female gender, pelvic surgery and irritable bowel syndrome histories all predicted an unwillingness to repeat the procedure with the same sedation. With the multivariate analyses, however, only a higher satisfaction level (OR: 0.53, *P* = 0.01, 95%CI: 0.32-0.89) and a higher education level (OR: 1.37, *P* = 0.01, 95%CI: 1.05-1.79) predicted patient willingness to repeat the procedure by the same endoscopist if needed in the future.

## DISCUSSION

Although sedation remains the dominant practice in the United States (US), unsedated colonoscopies have continued to be practiced in many parts of the world<sup>[13]</sup>. Twenty-eight percent of the US community<sup>[14]</sup> and 75%

**Table 5** Univariate analysis of potential predictors of the willingness to repeat the colonoscopy

Variable	Odds ratio	P value	95%CI
Age	1.02	0.04	1.00-1.04
Gender (female)	0.44	0.002	0.26-0.74
Anxiety	0.85	0.003	0.79-0.92
Patient satisfaction score	1.43	0.0001	1.29-1.59
Physician satisfaction score	1.20	0.004	1.06-1.38
Prior pelvic surgery	0.45	0.01	0.25-0.83
Physician assessment of pain	0.84	0.001	0.77-0.92
Education level: college or more	3.04	0.003	1.45-6.37
Patient pain score	0.84	0.0001	0.78-0.90
Time to cecum	1.00	0.92	0.97-1.02
Ability to recall the procedure	0.82	0.49	0.47-1.40
Discharge time	1.00	0.20	0.99-1.00
Abdominal pain	0.78	0.35	0.47-1.31
IBS	0.56	0.03	0.33-0.96
Physician assessment of discomfort level			
Complained multiple times	0.16	0.001	0.06-0.46
Complained bitterly	0.11	0.001	0.03-0.39
Technical ease	1.14	0.03	1.01-1.29

IBS: Irritable bowel syndrome.

of Veterans Affairs<sup>[15]</sup> patients accept the on-demand sedation option. Amongst these, 77% to 81% were completed without sedation and reported minimal discomfort. With good bowel preparation, the cecal intubation success rate during unsedated colonoscopies, provided in as-needed or on-demand sedation forms, is > 90% when the attending staff performed the examinations<sup>[10,14-16]</sup>.

Despite the significant difference between the groups in our study in terms of patient and physician pain assessments and satisfaction in favor of sedation, there was no significant difference found with regard to the willingness to repeat the procedure by the same physician if required in the future (83.3% vs 78.6%). One potential explanation for this finding is that the measured pain and satisfaction level differences, although significantly different, were not great enough to be clinically important. Among the 451 who underwent unsedated screening colonoscopies, Thiis-Evensen *et al*<sup>[7]</sup> found the rate of cecal intubation was 82%, 90% of these patients stated that they would undergo a repeat colonoscopy in 5 years. In another smaller study among 40 patients who underwent "sedation on demand" colonoscopy, 93% of these patients were willing to undergo another colonoscopy without prior sedation<sup>[17]</sup>. In a more recent US study, among 578 patients (27.6%) who chose to start the procedure without sedation, 81.1% of those completed the examination without medication and 97.4% were satisfied with their comfort level during the procedure and were willing to have their next colonoscopies performed without sedation<sup>[18]</sup>. Comparing sedated colonoscopy to "sedation on demand", Terruzzi *et al*<sup>[19]</sup> showed that the proportion of those stating they would not undergo a colonoscopy again in the future (22% vs 9.7%,  $P < 0.005$ ) was significantly higher in the "on demand" sedation group.

The cecal intubation rate has been traditionally used as one of the benchmarks in studies investigating the use (or

foregoing) of CS for colonoscopy procedures. In our study, the cecal intubation rate was the same between the sedated (85.9%) and the unsedated groups (84%). In general, the cecal intubation success rate during unsedated colonoscopy was > 90% when the attending staff performed the examinations<sup>[10,14,20]</sup>, but was only 81% in the hands of supervised trainees<sup>[18]</sup>, which was also the case in our study.

Although the discharge time was significantly shorter in the unsedated group, given no recovery time was needed, we found no differences between the groups when we compared cecum times. Consistent with our study, Petrini *et al*<sup>[14]</sup> demonstrated that the cecum times were comparable for both sedated and unsedated groups (9.71 min vs 9.87 min). When comparing sedated colonoscopy to "sedation on demand", Rex *et al*<sup>[10]</sup> observed that cecum times were significantly shorter in the sedated groups; however, the discharge times were significantly longer (55 min vs 10 min).

The factors that predicted willingness to attempt an unsedated colonoscopy, with a high performance success level and maintenance of satisfaction, included male gender, older age, abdominal pain absence, prior abdominal surgery, previous endoscopic procedure experience, the instruments used, endoscopist skill and higher education levels, particularly graduate level education<sup>[1,10,21-23]</sup>.

In our study, male gender, lower anxiety score prior to the procedure, high patient and physician satisfaction scores and higher education levels all predicted the willingness to repeat the procedure in the future if required.

Despite the significant publications regarding sedation free colonoscopy, we think our study was closer to reality than what is observed in most endoscopy units, in terms of gastroenterology trainee involvement. Additionally, we demonstrated that unsedated colonoscopy can save up to 62 min per patient, which is a very important factor in most busy academic endoscopy units, and despite the pain scores, this finding was statistically significantly higher in the unsedated group. Moreover, the willingness to undergo the same procedure without sedation was similar in the sedated group, which is an important factor for endoscopists to consider if they consider performing unsedated colonoscopy on their patients. In contrast, the shortcomings of this study included the small study size, lack of documentation of the patient acceptance rate for unsedated colonoscopy, the non-randomized and unblinded design, and asking about the patient satisfaction level just after the procedure.

In conclusion, unsedated colonoscopy is feasible in patients who are willing to undergo this procedure without sedation and can save endoscopy units up to one hour per patient. Additionally, contrary to some endoscopists' fears, patients are still willing to undergo the same procedure in the future if required.

## ACKNOWLEDGMENTS

This project is supported by College of Medicine Research Center, Deanship of Scientific Research, King Saud University.

## COMMENTS

**Background**

The main objective of the study was to compare sedated with unsedated colonoscopies in terms of time until discharge, willingness to repeat future procedures with the same endoscopist, pain levels and patient and physician satisfaction levels.

**Research frontiers**

Published information indicates that unsedated colonoscopies are acceptable in many countries. There are many reasons why some patients prefer to undergo colonoscopy without sedation. No escort requirement, fear of the usual sedation-related complications and restrictions on activities for almost one full day are the common reasons why patients choose unsedated colonoscopy.

**Innovations and breakthroughs**

Despite involving gastroenterology trainees in this study and despite the observation that the pain score was statistically significantly higher in the unsedated group, this study showed that unsedated colonoscopy is feasible in willing patients. This option saves endoscopy units up to one hour per patient, and contrary to some of endoscopists fears, patients are still willing to return to the same physician again for future colonoscopies if a repeat procedure is needed.

**Applications**

Unsedated colonoscopy is a good option for some patients. It can save endoscopy units up to one hour per patient. It does not decrease patient willingness to undergo future colonoscopies in future.

**Peer review**

This is a well-written and interesting study. This needed to be done as a sham controller randomized controlled trial giving saline versus conventional sedation. Instead the authors simply asked patients whether they wanted sedation or not making the results un-interpretable as the amount of bias introduced is enormous - those willing to consider not having sedation are a completely different cohort of patient in many ways

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**P- Reviewers:** Deutsch JC, Gaya DR, Shehata MMM  
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ISSN 1007-9327



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