

Colonoscopy without sedation: Patient factors alone are less likely to influence its uptake

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Background and study aims: Conscious sedation during colonoscopy minimizes discomfort, improves polyp detection rates, and reduces technical failure, but carries medication-related risks and requires dedicated and costly recovery services. Sedation-free procedures may offer a safer alternative. We aimed to compare this group with those receiving sedation to determine differences in patient characteristics, cecal intubation rates, polyp detection rates, discomfort levels and safety in patients for whom anesthesia is high risk.

Patients and methods: Prospectively collected data from all colonoscopies performed over a 1-year period at three district general hospitals were analyzed. Conscious sedation was offered to all patients and outcomes in those who refused were compared with outcomes in those who received sedation.

Results: One hundred ninety-four of 1694 (11%) colonoscopies were performed without sedation

(61% male, $P < 0.001$) but rates varied between hospitals. Of these, 55% were American Society of Anesthesiologists (ASA) grade 3 or more and 5% experienced moderate discomfort, compared to 40% ($P < 0.0001$) and 10% ($P = 0.023$) respectively of those receiving sedation. They were more likely to have indications of rectal bleeding or frequency of stool and less likely to have anaemia or macroscopic inflammation at colonoscopy. Complications, completion, and polyp detection rates were similar in both groups.

Conclusions: Colonoscopy without sedation can be completed successfully in select patients without compromising comfort or polyp detection rates and is safe in those for whom anesthesia is high risk. It is therefore a safe alternative for clinicians concerned about sedation, but the findings suggest that hospital, rather than patient factors, may prevent its uptake.

Meeting presentation: Pilot data presented as a poster: "Colonoscopy without sedation: is it feasible?" at European Colorectal Congress, St. Gallen, Switzerland, 26–29th November 2012. Final data given as an oral short paper presentation: "Sedationless colonoscopy: Is there any difference in polyp detection and caecal intubation?" at the International Surgical Congress of the Association of Surgeons of Great Britain and Ireland (ASGBI), Glasgow UK on 1st–3rd May 2013.

Introduction

Colonoscopy is the most common investigation for colonic pathology. In the UK it has become more frequent since the introduction of national bowel cancer screening programs, with 36,460 procedures performed in the first 3 years after their establishment [1]. To maximize efficacy in both screening and non-screening cases, it must

be performed accurately and under conditions acceptable to the patient.

Sedation traditionally has been used to minimize technical difficulties [2] and studies demonstrate improved cecal intubation rates with it [3] and reduced patient anxiety about subsequent colonoscopy [4]. Sedation is not without risk as fewer than 1% of patients experience cardiovascular problems and respiratory distress is seen in up to 8 of every 1000 patients undergoing the procedure [5]. Sedation also places social and functional demands upon patients and, depending on the hospital's protocol, may require dedicated recovery time and an escort on discharge [6]. A study of screening colonoscopy at a university center reported a median of 20 minutes for the procedure and 21 hours for preparation, travel, and recovery [7]. Recently, sedation was found to have no effect on polyp or adenoma detection rate [3] while sedation-less procedures may reduce the cecal intubation rate [8], most likely from the

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discomfort associated with air insufflation [9]. However, pain may not be a limiting factor for intubation rates as Petrini et al. showed that of the patients offered sedation on demand, 81% underwent complete procedures without a sedative [10].

The aim of this study is to compare the level of discomfort in patients who underwent non-sedated colonoscopies (NSC) to those with sedation (SC), and to determine the effect on polyp detection and cecal intubation rates. We also assessed the effects of anaesthetic risk, indications, endoscopists, and pathology on outcomes.

Patients and methods

The prospectively accrued database (Unisoft®) of all colonoscopies performed at three district general hospitals in the UK between July 2011 and July 2012 was retrospectively analyzed. Sedation was routinely offered to all patients, however, 194 declined all medication. Throughout the procedure, patient comfort scores were obtained by two independent nurses using modified Glasgow comfort score descriptors, as outlined by the NHS Bowel Cancer Screening Programme (England, UK) [11] (Table 1). Staff at the three units are certified by the Joint Advisory Group on GI Endoscopy (JAG, UK). They performed colonoscopies in accordance with JAG's guidelines for bowel preparation, peri-procedure care, and recovery. Anaesthetic risk was assessed using the American Society of Anesthesiologists physical status classification system (ASA grade, Table 2). Details of age, sex, ASA grade, comfort scores, complications, cecal intubation rate and polyp detection rates were obtained. An adjusted cecal intubation rate was calculated by including patient discomfort and excluding poor bowel preparation and instrument inadequacy. Statistical analysis was performed using Chi-squared test, Student's *t*-test or Mann-Whitney, univariate analysis for odds ratios and a *P* value less than 0.05 was considered significant.

Table 1 Modified Glasgow Comfort Score descriptors.

Descriptor	Definition
No	No discomfort, resting comfortably throughout
Minimal	One or two episodes of mild discomfort, well tolerated
Mild	More than two episodes of discomfort, adequately tolerated
Moderate	Significant discomfort, experienced several times throughout the procedure
Severe	Extreme discomfort, experienced frequently during the procedure

Table 2 American Society of Anesthesiologists physical status classification system (ASA grade)

Classification	Definition
ASA I	A normal healthy patient
ASA II	A patient with mild systemic disease
ASA III	A patient with severe systemic disease
ASA IV	A patient with severe systemic disease that is a constant threat to life
ASA V	A moribund patient who is not expected to survive without the operation

Results

A total of 1694 colonoscopies were performed over a year, of which 194 were without sedation (11%). Table 3 summarizes the key findings for both SC and NSC patients. In both groups colonoscopies were completed within similar time frames ($P=0.590$). There was a male predominance in the NSC group (male to female ratio 1.6:1), which was not demonstrated in the SC group (1:1.2 $P<0.001$). There was no gender difference in discomfort levels ($P=0.102$). A single endoscopy unit carried out more colonoscopies without sedation than others within the organization (Hospital A, $P<0.0001$). However, after excluding those who performed less than 100 cases (none of whom carried out NSCs), there were no differences in the numbers or rates of incomplete colonoscopies performed by the 10 high-volume endoscopists ($P=0.105$). A greater proportion of patients were referred for bleeding ($P=0.034$) or frequency of stool ($P=0.036$), while fewer were likely to have anaemia ($P=0.014$). All ASA grades were represented in both groups but there were more grade 3 patients in the NSC group ($P=0.0003$). A greater proportion experienced lower levels of discomfort (no discomfort 43%, minimal 29%, 13% mild discomfort, $P<0.001$). Macroscopic inflammation was associated with more moderate and severe discomfort across both groups. There were a comparable number of complications; three cases of mechanical damage to scope and two cases of haemorrhage occurred in the sedated group. There were no sedation-related complications noted. After multivariate analysis, a higher ASA grade correlated to NSC ($p,0.001$). Polyps were found in 51 out of 194 NSC patients (26%) and comparable to the SC group (23% $P=0.249$). The rates of failed cecal intubation were also similar at 11% and 10% respectively ($P=0.624$). Incomplete colonoscopies in the NSC group were due to inadequate bowel preparation, angulation or fixity of the distal sigmoid, instrument inadequacy, and, in three cases, patient discomfort; the adjusted cecal intubation rate was 95.4% (Table 4).

Discussion

When compared to SC, NSC offers patients a safe investigation with shorter recovery time without the assistance of an escort and with return to normal daily activities afterwards. Anecdotally, NSC facilitates better communication between the endoscopist and the patient, which may assist in positional changes towards successful completion. In our study, all patients were offered sedation at the start, and if they refused, it was offered again if these patients experienced discomfort during the procedure. From our data, we could not determine why patients did not want sedation or why some patients who started without sedation required that treatment when difficulty was encountered. Of the 194 NSC patients, there was a male predominance. While colorectal adenoma is more prevalent in men [12], polyp detection rates were similar in both SC and NSC patients. Arguably this may suggest under-detection of polyps, but that is less likely because the procedures were performed by JAG-accredited and experienced screening endoscopists. A larger study may be needed to further address this issue. In addition, we included patients referred via the suspected cancer or screening pathways, who may have a higher risk for colorectal neoplasia, but a risk adjusted analysis of these factors requires a larger study.

As the level of discomfort experienced by patients was recorded at three sites within a single organization, interobserver varia-

Table 3 Analysis of patients undergoing colonoscopy with and without sedation.

Factor		Sedation (SC) n = 1500		No Sedation (NSC) n = 194		OR [CI]	P value
Age (years)		64 (14)		63 (15)		–	0.283
Time taken (minutes)		29 (13)		32 (18)		–	0.590
Sex	Male	694 (46)		119 (61)			<0.001
	Female	806 (54)		75 (39)			
Referral		Number	%	Number	%		
	Routine	922	62	101	52	–	0.026
	Urgent	558	37	88	45		
Unknown	20	1	5	3			
Hospital	A	539	36	96	49	–	<0.0001
	B	491	33	63	33		
	C	470	31	35	18		
ASA	1	438	29	28	14	–	0.0003
	2	448	30	56	29		
	3	478	32	85	44		
	4	113	8	22	11		
	Unknown	23	1	3	2		
Therapeutic		385	26	40	21	0.8 [0.5–1.1]	0.128
Inpatient		673	45	84	43	0.9 [0.7–1.3]	0.680
Screening		31	21	7	4	1.8 [0.8–4.1]	0.178
Surveillance		161	11	22	11	1.1 [0.7–1.7]	0.798
Indication ¹	Bleeding	317	21	54	28	1.4 [1.0–2.0]	0.034
	Anemia	125	8	6	3	0.4 [0.2–0.8]	0.014
	CIBH	297	20	51	26	1.4 [1.0–2.0]	0.036
Previous Resection(s)		45	3	9	5	1.6 [0.8–3.3]	0.225
Pathology ²	Polyps	351	23	51	26	1.2 [0.9–1.7]	0.249
	Inflammation	115	8	6	3	0.4 [0.2–0.9]	0.025
Done by 2nd endoscopist		217	15	29	15	1.0 [0.7–1.6]	0.858
Failed cecal intubation		153	10	22	11	1.1 [0.7–1.8]	0.624
Adjusted cecal intubation		1391	93	185	95	1.6 [0.8–3.2]	0.180
Discomfort	None	521	35	84	43	–	<0.001
	Minimal	529	35	57	29		
	Mild	269	18	25	13		
	Moderate	150	10	9	5		
	Severe	0	0	0	0		
	Unrecorded	31	2	19	10		
Complications		30	2	2	1	–	0.351
	Poorly tolerated	25		2			
	Damaged scope	3		0			
	Bleeding	2		0			

Age and time expressed as average (standard deviation). Significant values were $P < 0.05$, derived by Chi-square test, t-test or Mann-Whitney. Odds ratio were obtained by univariate analysis.

CIBH: change in bowel habit

¹ Only indications with significant P values are shown

² No significant differences were found for diverticular disease, strictures or radiation proctitis.

bility could have affected perception of patient discomfort. However, all units are certified by JAG and follow standard protocol for all procedures for recording discomfort. While endoscopist experience is known to affect polyp detection rates [13, 14], it was not controlled for in our study. Because all endoscopists were JAG accredited, it ensured that their skill levels were equal, and therefore, unlikely to influence outcomes.

Multivariate analysis of our results revealed that patients undergoing NSC were more likely to have more comorbidities as evidenced by higher ASA grades. NSC would certainly be a safer option given the risk that sedation poses to cardiovascular stability. We could not determine whether NSC was a patient's or endoscopist's choice, but exploring their motivations might help identify factors that could improve its uptake. We also demonstrated that some hospital units were more likely to use NSC than others, but the decision was not influenced by the endoscopist perform-

ing the procedure. Hospital factors that may affect decisions for NSC, such as outcome targets, patient information, informed consent, staff preferences and biases, warrant investigation even though they are likely to vary from one institution to another. Previous studies have highlighted how discomfort may limit the completion of the procedure, and advocated the benefits of water insufflation [15], sedation on demand (patient controlled), and sedation as needed (endoscopist controlled) [16]. Overall, we showed that NSC can be completed comfortably with minimal variation in technique, supporting previous findings of success more so in men, and that it had no effect on polyp detection rate [3]. Most patients tolerated the procedure well, with either no or minimal discomfort. Successful NSC is less likely with macroscopic inflammation as it was associated with significant discomfort.

Table 4 Depth of insertion of scope and reasons for failed cecal intubation in NSC patients.

Depth of Insertion	Total	Reason for Failed Intubation (n)
Cecum	115	
Terminal ileum/neo TI	57	
Anastomosis	1	
Proximal ascending	1	Inadequate bowel prep
Hepatic flexure	2	Discomfort (1) Bowel redundancy (1)
Mid transverse	3	Inadequate bowel prep (2) Discomfort (1)
Splenic flexure	3	Bowel prep (1) Instrument inadequacy (2) Excess looping (1)
Proximal descending	2	Inadequate bowel prep (2)
Distal sigmoid	5	Discomfort (1) Limited by angulation/fixated sigmoid (3) Inadequate bowel prep (1)
Rectum	3	Inadequate bowel prep (2) Solid stool obstructing lumen (1)
55 cm	1	Not recorded
Total completed	173	
Intubation rate	89%	
Adjusted intubation rate	95%	Allowing for inadequate bowel prep and instrument inadequacy

Our cecal intubation rate matched that of previous studies [8] and was similar to that achieved when sedation was used. The adjusted cecal intubation rate was 95.4%, which satisfies the standard set by the NHS Bowel Cancer Screening Programme [11]. In addition, polyp detection rates were comparable with both SC and NSC. That suggests that NSC with optimal bowel preparation and adequate instrumentation may achieve the high technical standards required by the screening program. It may also appeal to patients without an escort who are candidates for same-day discharge. A recent study showed that 56.2% of 964 patients were willing to undergo NSC, and that fear of procedure-related pain was inversely related to procedure acceptance [17]. As moderate discomfort was described in only 5% of cases, our study promotes NSC, or at least sedation on demand, although it critically lacked a post-procedure survey of patients' experience. Overall, our results confirm that NSC is a practical option for motivated patients who are adequately counselled prior to the procedure. It has the potential to avoid sedation-related complications, particularly in patients with multiple comorbidities, to prevent delay in discharge from hospital, and to allow near immediate return to normal activity. Therefore patient factors alone may not prevent its uptake.

Competing interests: None

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