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Original Articles

Moderate level sedation during endoscopy: a prospective study using low-dose propofol, meperidine/fentanyl, and midazolam

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Background

Propofol provides several benefits over benzodiazepine and narcotic agents as a sedative medication for endoscopic procedures, including faster recovery and improved patient satisfaction. However, its use generally has been limited to anesthesiologists because of the risks associated with deep sedation.

Methods

One hundred patients undergoing colonoscopy or EGD were sedated with low-dose propofol, midazolam, and fentanyl (or meperidine). Depth of sedation was assessed at 2-minute intervals by an independent observer by using the American Society of Anesthesiologists criteria. Recovery time was determined by using paired neuropsychometric tests. A post-procedure satisfaction survey and 24-hour follow-up questionnaires were administered.

Results

For colonoscopy and EGD, respectively, the mean propofol dose was 98 mg and 79 mg, the mean midazolam dose was 0.9 mg and 0.8 mg, the mean fentanyl dose was 69 mcg and 63 mcg, and the mean meperidine dose was 42 mg (for both procedures). There were 628 assessments of the level of sedation performed during 74 colonoscopies and 101 assessments during 26 EGDs. The level of sedation was minimal in 77%, moderate in 21%, and deep in 2% of assessments. Nine of the 13 episodes of deep sedation were recorded during colonoscopy and 4 during EGD. In no instance was more than a single assessment of deep sedation recorded during one procedure. Ninety-eight percent of patients were satisfied with the sedation, and 71% returned to their usual activities within 2 hours of discharge. There was no serious adverse event.

Conclusions

Endoscopic sedation with low-dose propofol, a narcotic agent, and midazolam produces a moderate level of sedation. The quality of sedation and measures of recovery are comparable with the results reported with standard-dose propofol.

There is increasing interest in propofol as a sedative agent for endoscopic procedures.^{[1] [2] [3] [4] [5] [6] [7] [8] [9]} Compared with benzodiazepines and opioids, the drugs most often used for endoscopic sedation, induction of sedation is more rapid and recovery time shorter with propofol, thereby improving patient flow through the endoscopy unit^[10] and, possibly, patient satisfaction with endoscopy. The American Society of Anesthesiology (ASA) has defined 4 levels of sedation: minimal, moderate, deep sedation, and, finally, general anesthesia (Table 1). The sedation level for endoscopic procedures induced with an opioid and a benzodiazepine, referred to as “conscious sedation,” generally is considered to be moderate. In contrast, propofol is considered to induce deep sedation, with potential loss of ventilatory drive or significant impairment of upper airway protective reflexes and, in some instances, general anesthesia. The ASA practice guidelines^[11] state that physicians administering standard-dose propofol should be equipped and trained to recover a patient from general anesthesia. Consequently, the use of propofol generally has been limited to anesthesiologists and other physicians with experience in airway management.

ASA Level	Responsiveness	OAAS scale
Minimal	Patient responds appropriately to normal volume verbal cues by using either a verbal or physical response without delay or hesitation.	5
Moderate	Patient responds purposefully to verbal or light tactile stimulus. The patient response may be either verbal or physical (e.g, opening eyes, turning the head toward directional of voice, purposeful movement of an arm or leg, or follows request to change position).	2–4
Deep	The patient fails to respond to either verbal or light tactile stimuli, as described below.	1

ASA, American Society of Anesthesiology; OAAS, Observer Assessment Alertness/Sedation.

At present, many endoscopic examinations in the United States are performed with the assistance of an anesthesiologist whose responsibilities consist of the administration of sedative medication(s) (propofol in most instances) and patient monitoring. The cost of this approach is high, however, and this practice is discouraged by the American Society for Gastrointestinal Endoscopy.^{[12] [13]} A few gastroenterologists have begun to administer propofol themselves, sometimes with the assistance of a specially trained nurse.^{[9] [10] [14] [15] [16] [17] [18] [19]} A protocol for endoscopic sedation was developed for use in our endoscopy unit that consists of “low-dose propofol” combined with an opioid and midazolam.^[20] Initial experience with this regimen suggested that it usually produced a moderate instead of a deep level of sedation. The present study systematically evaluated the depth of sedation obtained with this protocol in patients undergoing endoscopy.

1. Patients and methods

Consecutive patients presenting for elective outpatient colonoscopy or EGD in two private practices (L.B.C., J.A.) were invited to enroll in the study (target 100 participants). It was anticipated that this number would permit detection of deep sedation episodes occurring at a frequency of at least 5%. Patients were excluded if one of two designated independent observers (see below) was not available to record data; if the patient was unable to perform the neuropsychometric testing because of color blindness, illiteracy, or motor impairment; if the patient declined to participate; or if the patient was to undergo more than one endoscopic procedure. Clinical criteria for patient exclusion from propofol-based sedation in our practice have been described previously.^[20] These are the following: age less than 18 years; ASA class IV; allergy to propofol, soybeans, or eggs; history of seizure disorder, sleep apnea, or difficult intubation; a short, thick neck; inability to open the mouth widely; and pregnancy. The

study protocol was approved by our institutional review board. Verbal and written consent was obtained from each patient.

One of two independent observers (D.A.W., C.D.H.) was assigned to each enrolled patient and followed that patient throughout the office visit, collecting data, and administering all tests. Demographic information was obtained from each patient, including date of birth, gender, and years of education. Clinical information, including height, weight, use of alcohol and tobacco, current medications, general health, past illnesses, and previous experience with endoscopy, was obtained. One of 5 ASA risk classes was assigned to each patient.

The protocol for medication administration was previously reported.^[20] In brief, the choice of opioid (meperidine or fentanyl) was made by the endoscopist (L.B.C., J.A.) according to personal preference. The opioid and midazolam were given by intravenous bolus injection at the start of the procedure, and propofol then was administered in intravenous boluses of 5 to 15 mg, as determined by patient comfort level and physiologic parameters, at the direction of the gastroenterologist.

1.1 Endoscopic monitoring, sedation, and recovery

During the endoscopic examination, patients were monitored according to a protocol described by Cohen et al.^[20] In summary, heart rate, blood pressure, blood oxygen saturation (Sao₂), and electrocardiograph were monitored by using an automated device (Datascope 3000; Datascope Corp., Montvale, N.J.). Respiratory activity and end-tidal carbon dioxide were recorded by using an automated carbon dioxide detector (Poet TE; Criticare Systems, Inc., Eaukasha, Wis.). In addition, the endoscopy assistant visually monitored chest excursion and respiratory effort and rate. Supplemental oxygen was withheld unless the Sao₂ decreased below 90% for 30 seconds despite use of jaw thrust. A second assistant was not routinely present within the endoscopy room but was recruited if a complex therapeutic procedure, such as a difficult polypectomy, was undertaken. Equipment for full resuscitation was available in the endoscopy procedure room. All endoscopic assistants and physicians were trained in advanced cardiac life support.

One of the two independent observers was present throughout each endoscopic procedure. This individual was solely responsible for assessing and recording medication administration, times and time intervals related to the procedure, patient physiologic parameters, and level of sedation.

Times and intervals recorded for all patients were the following: (1) start of sedation (first drug bolus), (2) start of the endoscopic examination (insertion of the endoscope), (3) completion of the examination (removal of the endoscope), (4) "recovery time" (time interval between the endoscope removal and the start of the final psychometric assessment), and (5) "discharge time" (time interval between endoscope removal and departure from the endoscopy unit). "Induction time" was defined as the total elapsed time between "start of sedation" and "start of examination."

Baseline, maximum, and minimum values were recorded for each physiologic parameter. All adverse events, including use of supplemental oxygen, administration of naloxone or flumazenil, use of any form of ventilatory support, including an oral or nasopharyngeal airway, and administration of a pressor agent, were recorded. Hypotension was defined as a decrease in systolic and/or diastolic blood pressure by greater than 20 mm Hg. Bradycardia was defined as a heart rate less than 50 beats per minute.

The independent observer assessed the level of sedation every 2 minutes throughout the procedure, beginning with insertion of the endoscope and ending with removal of the instrument. The ASA criteria for minimal, moderate, and deep sedation were used ([Table 1](#)). To determine the level of sedation, a standardized protocol was used. "Response" was defined as any verbal or purposeful physical reaction to a verbal or tactile stimulus. The observer first spoke the patient's name, once in a normal voice, and a second time, in a louder voice. If the patient failed to respond, a light tactile stimulus on the shoulder was provided, followed within several seconds, if necessary, by a second light stimulus. Patients who failed to respond to these 4 stimuli were considered to be deeply sedated. No communication was permitted between the endoscopy staff and the observer during the examination, and all results were concealed from the other investigators until completion of patient enrollment.

Patients were transferred to a recovery area, which consisted of a 10 × 12-foot room with a single stretcher, upon

completion of the endoscopic procedure. After an initial 10-minute recovery period, patients were assessed for alertness and suitability for testing. If the patient appeared somnolent or expressed a desire to delay testing, recovery was allowed to continue. Thereafter, patients were re-evaluated at 5-minute intervals until they were ready for testing.

1.2 Neuropsychologic tests

A 3-test panel of neuropsychologic tests was chosen, based upon previous work by Sipe et al.,^[10] to provide a balanced evaluation of cognitive and motor functions. The Symbol Digit Test requires the subject to match numbers to nonsense symbols during 90 seconds. The Stroop Color Word Test tests the ability to correctly describe the color of ink in a series of non-matching color words (e.g., of "blue" written in green ink). Patients were given 45 seconds to identify as many colors as possible. The Trail Making Tests involves connecting a series of circles in correct numerical (1 to 2, 2 to 3, etc.) or alphabetical (1 to A, 2 to B, etc.) order. Time to completion for each Trail Making Test was recorded by using a stopwatch and was rounded to the nearest second.

Before the first testing session, patients were instructed in the performance of the 3 tests. The first panel of tests was administered before the endoscopic examination, and test scores were determined to establish a baseline performance for each patient. An identical test panel was re-administered after recovery from sedation (as described above) and repeated at 5-minute intervals as necessary. Recovery was complete when a minimum of two of 3 post-procedure test scores matched or exceeded baseline values.

1.3 Discharge evaluation and 24-hour follow-up

Upon completion of testing, patients dressed and were offered a beverage and a snack. Before discharge, the patients completed an anonymous and confidential Patient Satisfaction Questionnaire, modified from Sipe et al.,^[10] to evaluate their endoscopy experience ([Appendix A](#)). Patients also were contacted by telephone 24 hours after the procedure and a follow-up questionnaire was completed ([Appendix B](#)).

1.4 Statistical analysis

Statistical analyses were performed by using statistical software (SAS V8.2; SAS Institute, Cary, N.C.). Descriptive statistics and frequency distributions were calculated for specific variables. The data were analyzed by using the two-sample *t* test or the chi-square test for categorical data. Small sample tests were applied when appropriate. Statistical significance was defined as a *p* value <0.05. Bonferroni adjustments for multiple testing were incorporated.

2. Results

2.1 Patient analysis and endoscopic variables

One hundred patients (mean age 57 years; range 24 to 84 years) were enrolled. The majority were in excellent health (95% ASA I or II).

The analysis of the endoscopic procedures is detailed in [Table 2](#). Colonoscopy accounted for the majority (74%). The mean time for induction, examination, recovery, and discharge for colonoscopy was, respectively, 3 (1) minutes, 18 (6) minutes, 14 (5) minutes, and 47 (11) minutes. The comparable mean times for EGD were, respectively, 4 (2), 8 (5), 16 (5), and 42 (9) minutes. All EGDs and colonoscopies were completed successfully. No procedure was terminated because of inadequate patient analgesia.

Table 2. Details of sedation medications and endoscopic procedures	
Colonoscopy (n = 74) No. (SD), range	Gastroscopy (n = 26) No. (SD), range

Medication*		
Meperidine (mg) (n = 30)	42 (14), 0–75	42 (16), 25–75
Fentanyl (mcg) (n = 68)	69 (11), 50–75	63 (13), 0–75
Midazolam (mcg) (n = 100)	0.9 (0.2), 0.5–1.0	0.8 (0.3), 0–1
Propofol (mg) (n = 100)	98 (44), 30–250	79 (46), 10–190
Endoscopic procedure		
Induction time (min)	3 (1), 1–6	4 (2), 2–10
Duration of examination (min)	18 (6), 8–43	8 (5), 5–30
Recovery time (min)	14 (5), 5–30	16 (5), 10–30
Discharge time (min)	47 (11), 26–81	42 (9), 30–60

* Two patients were given only midazolam and propofol.
SD, Standard deviation.

2.2 Analysis of medication administration

The details with regard to medication administration are given in [Table 2](#). All 100 patients received midazolam, and 98 were given an opioid, either meperidine (n = 30) or fentanyl (n = 68). Two patients received only midazolam and propofol. The mean dose of propofol was 98 (44) mg (range 30–250 mg) for colonoscopy and 79 (46) mg (range 10–190 mg) for EGD. During colonoscopy, the doses of meperidine, fentanyl, and midazolam given were, respectively, 42 (14) mg (range 0–75 mg), 69 (11) mcg (range 50–75 mcg), and 0.9 (0.2) mg (range 0.5–1.0 mg); the respective doses for EGD were 42 (16) mg (range 25–75 mg), 63 (13) mcg (range 0–75 mcg), and 0.8 (0.3) mg (range 0–1 mg).

2.3 Level of sedation during endoscopy

There were 628 assessments of the depth of sedation during 74 colonoscopies (mean 8.5 per case) ([Fig. 1](#)). Of these, 489 (78%) were categorized as minimal, 130 (21%) moderate, and 9 (1%) as deep sedation. During 26 EGDs, 101 assessments were recorded (mean 3.6 per case), of which 76 (75%) were minimal, 21 (21%) were moderate, and 4 (4%) were deep sedation. The difference in frequency of deep sedation episodes during EGD and colonoscopy (4% vs. 1%) was not statistically significant.

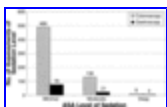


Figure 1. The ASA level of sedation assessed at 2-minute intervals during 100 consecutive endoscopic examinations.

An in-depth analysis of the episodes of deep sedation was performed ([Table 3](#)). Overall, 13 episodes of deep sedation were observed during 729 determinations (2%), 9 during colonoscopy, and 4 during EGD. In no instance was more than a single assessment of deep sedation recorded during one procedure. The 9 episodes of deep sedation during colonoscopy occurred an average of 10.4 minutes after the start of sedation. In the EGD group, 3 of the 4 episodes of deep sedation were recorded at the first assessment of sedation level (i.e., upon intubation of the esophagus). Consequently, there was a total of 23 assessments of sedation level within 2 minutes of the deep sedation episodes; of these, 12 were recorded as minimal and 13 as moderate. Within the EGD group, the patients in whom deep sedation occurred tended to be older (68 vs. 53 years) and mean ASA class tended to be higher (2.3 vs. 1.8), although neither variable was statistically significant. With respect to all other variables, patients in whom deep sedation occurred were similar to the overall EGD population. Deep sedation during colonoscopy was associated with longer procedure time (23 vs. 17 minutes; $p < 0.01$) and lower body mass index (22 vs. 25 kg/m²; $p < 0.01$). Other variables, including height, previous endoscopy experience, smoking, alcohol use, education level, medication dosage, and recovery time, were comparable between patients in whom deep

sedation occurred and patients undergoing colonoscopy in whom this level of sedation was not reached.

	EGD (N = 26) Deep sedation episode			Colon (N = 74) Deep sedation episode		
	Yes (N = 4)	No (N = 22)	p Value	Yes (N = 9)	No (N = 65)	p Value
Patient demographics						
Age (y) [*]	68	53	0.09	55	58	0.52
ASA Class (%)						
I	25	36	0.99	78	37	0.03
II	25	55	0.59	22	62	0.03
III	50	9	0.10	0	1.5	0.99
BMI (kg/m ²) [*]	25	24	0.48	22	25	<0.01
Medication dosage						
Propofol (mg) [*]	50	84	0.18	81	100	0.22
Midazolam (mg) [*]	0.8	0.8	0.99 [†]	0.9	0.9	0.43 [†]
Meperidine (mg) [*]	37	44	0.99 [†]	0	44	n/a
Fentanyl (mcg) [*]	0.0	64	n/a	75	67	0.09 [†]
Endoscopic features						
Procedure time (min) [*]	6	8	0.12	22	17	<0.01
Time until deep score (min) [*]	3			10		
ASA level 2 min after deep sedation						
Minimal	2			4		
Moderate	2			5		
Recovery time (min) [*]	14	16	0.32	14	14	0.78
* Data expressed as mean.						
† p Value for an exact test on binomial proportions.						
ASA, American Society of Anesthesiology; BMI, body mass index.						

2.4 Safety data

No serious complication occurred during the study. Transient oxygen desaturation requiring supplemental oxygen (SaO₂ < 90% for >30 seconds) by nasal cannula occurred once during colonoscopy and once during EGD.

Hypotension (a decrease in systolic/diastolic blood pressure >20 mm Hg) developed in 41 patients (41%), and bradycardia (pulse <50/min) occurred in 5 patients (5%). All episodes of hypotension and bradycardia were transient, and administration of a pharmacologic agent or other therapeutic intervention was not required for any patient. There was no perforation or death; no patient required assisted ventilation or hospitalization.

2.5 Patient assessment and satisfaction with sedation

Patient perception of the endoscopic experience is shown in [Table 4](#). The immediate post-procedure

questionnaire was completed by 100 patients; 92 completed the 24-hour post-procedure survey (8 patients failed to respond to 3 follow-up telephone calls). Eighty-six percent of patients described their overall satisfaction with the sedation as "excellent," 12% rated it "good," and 2% described it as "fair." When asked to rate the degree of pain or discomfort experienced during the endoscopy, 70% of patients reported no discomfort, 26% described it as mild, and 4% as moderate discomfort. Ninety percent of patients rated the level of sedation as "adequate," 8% believed that they received "too little," and 2% stated that they were given "too much."

		No. (%)
How much discomfort or pain did you feel? (n = 100)	None	70
	Mild	26
	Moderate	4
	Severe	0
Rate the level of sedation received during the endoscopic exam (n = 100)	Adequate	90
	Too little	8
	Too much	2
Rate your overall satisfaction with the endoscopic sedation (n = 100)	Excellent	86
	Good	12
	Fair	2
	Poor	0
Did you require additional sleep during the day after your procedure? (n = 92)	Yes	26 (28)
	No	66 (72)
How much sleep did you require? (n = 92)	None	66 (72)
	<2 h	17 (18)
	2-4 h	7 (8)
	4-6 h	2 (2)
When did you resume your normal daily activities? (n = 92)	<2 h	65 (71)
	2-4 h	17 (18)
	4-6 h	2 (2)
	>6 h	8 (9)
How did the sedation you received compare with previous endoscopic procedures you have undergone? (n = 62)	Better	32 (60)
	Same	15 (28)
	Worse	6 (12)
	Unable to respond	9 (14)

The survey conducted 24 hours after discharge found that 71% of patients returned to normal activities within 2 hours of discharge, 18% within 2 to 4 hours, and 11% required 4 or more hours before resumption of activities.

Most patients (72%) did not require additional sleep after discharge from the endoscopy unit, although 26 (28%) slept for periods of time that ranged from “less than 2 hours” ($n = 17$) up to “4 to 6 hours” ($n = 2$). Sixty-two patients in this study had previously undergone endoscopy; 53 (85%) had sufficient recall of the prior examination to compare the two procedures and 9 (15%) were unable to provide a comparison. Thirty-two patients (60%) rated sedation during the present examination “better” than during the last procedure, 15 (28%) stated that the two procedures were the “same,” and 6 (12%) were less satisfied with the current procedure.

2.6 Psychometric assessment

The results of psychometric evaluation are shown in [Figure 2](#). The patients took the post-procedure tests a mean of 14 (5) minutes and 16 (5) minutes after the completion of, respectively, colonoscopy and EGD. The mean scores recorded at baseline and after the procedure were not significantly different for the Symbol Digit Test (48.8 [10.7] vs. 51.0 [12.2]; $p = 0.176$) and the Stroop Test (39.1 [10.8] vs. 41.3 [10.6]; $p = 0.212$). For the Trail Making Test, the post-procedure times for Parts A and B were slightly lower than at baseline (Part A: 41.2 [16.8] seconds vs. 37.4 [20.8] seconds; $p = 0.003$) (Part B: 58.6 [42.8] seconds vs. 51.0 [32] seconds; $p = 0.006$).

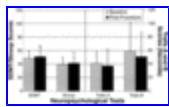


Figure 2. Results of paired psychometric testing performed before sedation (baseline) and after recovery (after procedure). Bars represent mean (standard deviation). ? $p = 0.1$; ♦ $p = 0.21$; ? $p < 0.01$ (both).

3. Discussion

To determine whether propofol can be administered safely and effectively without deep sedation, the level of sedation obtained during routine endoscopy in 100 consecutive patients receiving a combination of low-dose propofol, a narcotic agent, and midazolam was assessed in the present study. An independent observer, recording depth of sedation at 2-minute intervals, rated the level as minimal in 77% of determinations and moderate in 21%. Deep sedation was recorded in only 13 instances, less than 2% of all assessments. Four episodes of deep sedation were recorded during EGD and 9 during colonoscopy, all of which were brief and limited to a single event. There was no instance where deep sedation lasted longer than 2 minutes. Physiologic parameters remained stable throughout these episodes of deep sedation, and supplemental oxygen was needed in only two cases. Recovery time for these 13 patients did not differ from that for the total study population.

Several steps were taken to ensure accuracy and consistency in assessing level of sedation. All assessments were made by one of only two independent observers, and there was no verbal contact between the observer and the endoscopist during the examinations. Furthermore, each observer followed a uniform, well-defined sequence of verbal and tactile stimuli for each assessment (see PATIENTS AND METHODS). Although this method of assessing sedation has not been formally validated, our experience suggests that it is accurate, easy to apply, and easy to learn.

There are several reasons why it is unlikely that the dosages of sedative drugs given during this study were less than those typically administered when using the protocol. First, all assessments of sedation level, as well as data concerning patient satisfaction and recovery time, were concealed from the endoscopists until the study was completed. Second, patient satisfaction scores were consistent with previous experience when using an identical sedation protocol.^[20] Third, the mean dose of propofol actually was higher than that in our retrospective study (98 mg vs. 63 mg),^[20] while the dosages of midazolam and opioid were the same. Consequently, it is our belief that the depth of sedation measured in the current study is a true reflection of the level of sedation necessary to achieve a satisfactory experience for patients during endoscopy.

Rudner et al.^[21] used a slightly different sedation protocol and noted findings with regard to depth of sedation that were similar to those of the present study. They compared 50 patients sedated with remifentanyl (mean dose 230 mg) plus low-dose propofol (mean 47 mg) (“sedation” group) with 50 patients who received “total intravenous anesthesia” (TIVA group) with propofol (mean 85 mg) plus relatively large doses of fentanyl (mean 140 mcg) and midazolam (mean 3.4 mg). Bispectral index (BIS) measurements were used to evaluate electroencephalographic parameters as an independent measure of level of sedation. Patients in the sedation group remained responsive, confirmed by the ability to “communicate ... at any time during the procedure,” and their BIS scores were equal to

minimal sedation. In contrast, patients in the TIVA group were deeply sedated by both clinical criteria (i.e., patient asleep, no response to nail bed pressure) and BIS scores in the deep sedation range. All patients in the TIVA group were pain free during the examination, while 74% of those in the sedation group rated the examination as painless, and 26% assessed discomfort as "low intensity." Recovery time, quantified by using the scale of Aldrete and the Modified Post Anesthesia Discharge Scoring System, was significantly shorter in the sedation group (8 minutes) than the TIVA group (31 minutes). No serious adverse effect was noted in either group. The results of Rudner et al.^[21] support those of the present study: that endoscopy can be performed safely and effectively at a moderate level of sedation by combining low doses of propofol with a narcotic agent and/or benzodiazepine.

The mean time of induction of sedation during colonoscopy and EGD in the present study was, respectively, 3 and 4 minutes. These values are comparable with the induction times for propofol in other studies. For example, Vargo et al.^[7] reported an induction time of 3.9 minutes when using propofol alone during ERCP and EUS. Sipe et al.,^[10] in a study comparing propofol with meperidine/midazolam for sedation during colonoscopy, recorded induction times of, respectively, 2.1 and 7.0 minutes. Therefore, the addition of a narcotic agent and benzodiazepine to low-dose propofol does not appreciably alter the time required for the induction of sedation.

Recovery time after endoscopy was quantified by using a panel of 3 tests to assess cognition, memory, attention, concentration, and motor function.^[22] These included the Symbol Digit Modalities Test, a screening tool for cerebral dysfunction^[23]; the Stroop Color Word Test, designed to measure attention and inhibition of conditioned reflexes^[24]; and the Trails Tests Part A and B, to assess complex visual scanning and motor speed.^[25] The mean recovery time for colonoscopy was 14 minutes and, for EGD, 16 minutes. Sipe et al.,^[10] by using the same panel of tests to assess recovery in 40 patients sedated with propofol (monotherapy) during colonoscopy, also noted a recovery time of 14 minutes. In other studies of propofol for endoscopy, recovery times have ranged from 18 to 19 minutes.^{[7] [15] [26]} From these data, it is our conclusion that the use of small doses of a narcotic agent and midazolam in combination with low-dose propofol does not prolong patient recovery.

It was anticipated that a short recovery time would be accompanied by a rapid return to full activity. Telephone surveys conducted 24 hours after discharge revealed that 72% of patients did not require additional sleep after discharge and that 71% resumed normal activities within 2 hours of departure from the unit. Walker et al.^[9] reported similar results when using propofol monotherapy, noting that 76% of 1009 survey respondents stated that they could return to normal activities within 2 hours. It is our impression that patients are more awake, have improved recall for discussion of the procedure, and are able to resume usual activities sooner after sedation with propofol combination therapy compared with conventional sedation. However, comparative studies are needed to confirm these observations.

In the current study, 98% of patients rated overall satisfaction with the sedation for endoscopy as either excellent (86%) or good (12%). Similarly, 90% of the patients felt that the level of sedation was adequate. Patient satisfaction was re-assessed 24 hours after the procedure to ensure that drug-induced euphoria did not account for the high ratings. The results again indicated a high level of patient satisfaction, comparable with that noted in other studies of propofol.^{[1] [7] [8] [10] [15] [16] [26]} Therefore, the use of propofol for endoscopic sedation, either alone or in combination with other medications, results in patient satisfaction levels of 90% or better.

Propofol is a potent hypnotic agent with potentially life-threatening side effects, including loss of protective airway reflexes and respiratory depression. In 3 large series that used standard-dose propofol monotherapy,^{[6] [9] [14]} only 15 of more than 13,000 patients (0.1%) required short-term ventilatory support, either via a mask ($n = 12$) or a nasopharyngeal tube ($n = 3$). Endotracheal intubation was not required for any patient, and there was no death. Serious adverse events also have been reported with combination therapy. Clarke et al.^[19] reported the experience of a group of Australian "general practitioner sedationists" with propofol, fentanyl, and midazolam with more than 28,000 endoscopic procedures. The frequency of serious adverse events was 2.5 per 1000 (0.25%). A series of 819 consecutive endoscopic examinations performed with low-dose propofol in which there was no serious adverse event recently was reported by us; similar results have been obtained in several smaller studies.^{[2] [8] [15] [16] [21]} It is likely that refinements in the choice and the dosage of synergistic agents will further improve the safety profile of propofol.

The present study demonstrates that sedation for endoscopy can be safely and effectively accomplished when using a drug regimen that combines small doses of midazolam and a narcotic agent with low-dose propofol. The level of sedation achieved with this protocol is almost always mild-to-moderate instead of deep. It is our belief that this sedation protocol provides the benefits achieved with propofol monotherapy, including fast recovery and

return to normal activity, quick turnaround time in the endoscopy unit, and excellent patient satisfaction, but at a lesser depth of sedation. Randomized trials of propofol-based sedation regimens vs. conventional sedation protocols are needed. Our anticipation is that propofol will become the preferred drug for sedation during GI endoscopy.

Acknowledgement

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Appendix A Patient satisfaction questionnaire

1.	How was the sedation for your procedure? (circle one)			
	Excellent	Good	Fair	Poor
2.	Do you think you needed any adjustment in the amount of sedation you received?			
	Needed more	Right amount	Needed less	
3.	Do you remember the start of the procedure when the scope was inserted?			
	Yes	No		
4.	Do you remember being awake during the procedure?			
	Yes	No		
5.	Do you remember the end of the procedure when the scope was removed?			
	Yes	No		
6.	Do you remember leaving the procedure room?			
	Yes	No		
7.	How much discomfort or pain did you experience during the procedure?			
	None	Mild	Moderate	Severe

Appendix B 24-hour telephone survey

1.	Did you experience any adverse reactions from the endoscopic procedure or sedation?		
	Yes_____	No_____	If yes, describe: _____ _____
2.	On the day of your endoscopic examination, what time you resume your normal activities?		
	Time at resumption of normal activities (h:min):	____:_____	
	Time at completion of endoscopic procedure (h:min):	____:_____	
	Time between completion of exam and resumption of normal activities (h:min):	____:_____	
3.	Types of activities performed after the procedure: _____		
4.	Did you require additional sleep during the daytime after the procedure?		
	Yes_____	No_____	Time (h:min)_____
5.	How did the sedation you received during this procedure compare with previous endoscopic procedure you		

have undergone?

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