Nonanesthesiologist-administered propofol sedation for colonoscopy is safe and effective: a prospective Spanish study over 1000 consecutive exams

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Background and study aims **Propofol is increasingly being used in sedated colonoscopy. This paper assesses the safety and efficacy of nonanesthesiologist-administered propofol in a large series of colonoscopies.**

Patients and methods **A prospective registry of consecutive American Society of Anesthetics (ASA) class I and II outpatients undergoing colonoscopy was carried out. Propofol, administered by a nurse under an endoscopist's supervision, was the sole sedative agent used.**

Results **Of the 1000 patients (563 women/437 men, mean age 57, range 8–89 years) included in the study, 57.4% showed ASA I and 42.6% ASA II characteristics. The cecal intubation rate was 96.9%. 48.2% of the procedures were for therapeutic purposes. The mean propofol dose was 177 mg (range 50–590 mg). Doses correlated inversely with patient age ($r = -0.38$; $P < 0.001$) and were lower in ASA II patients ($P < 0.001$) and in diagnostic (rather than therapeutic) exams ($P < 0.001$). The average recovery time (from extracting the colonoscope to patient discharge) was 18.6 min (range 4–75) and longer in ASA II patients ($P = 0.05$). A pulse oximetry saturation of less than 90% and a decrease in systolic blood pressure of more than 20 mmHg were observed in 24 (2.4%) and 385 (35.8%) patients, respectively. Both events were more frequent in patients older than 65 years ($P < 0.05$); the latter was more common in ASA II patients.**

Conclusion **Colonoscopy under endoscopist-controlled propofol sedation in low-risk patients is safe and effective, allowing for a complete exploration, although patients at least 65 years old and/or classified as ASA II are more likely to present a decrease in blood pressure and have a prolonged recovery time.** ***Eur J Gastroenterol Hepatol*** **24:787–792** © **2012 Wolters Kluwer Health | Lippincott Williams & Wilkins.**

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Introduction

Technological developments in recent years have augmented the diagnostic and therapeutic potential of digestive endoscopy, leading to a notable increase in this procedure to the point that it is now almost considered to be a routine exam. Initially used only for more complex endoscopic procedures such as endoscopic retrograde cholangiopancreatography or endoscopic ultrasonography [1], sedation is increasingly being utilized in more frequently performed endoscopic procedures such as gastroscopy and colonoscopy. As both these techniques can be carried out without sedation [2,3], they are better tolerated in terms of patient satisfaction and willingness to repeat the examination when sedation is administered [4,5]. In fact, many patients do not accept unsedated colonoscopy, especially when suggested as an elective procedure for the purposes of colorectal cancer screening, even when it does not affect the number of patients in whom lesions are detected [6]. Sedation is also essential in pediatric explorations [7]. The availability of safe sedative agents with fast-working and short-lived effects that are easy to use in patients undergoing colonoscopy has thus played an important role in improving both the acceptability and the tolerance of the procedure.

Propofol is an intravenous sedative agent that is used widely for the induction of general anesthesia and for the sedation of ventilated patients in ICUs. An increasing body of evidence indicates that propofol can be administered safely by specially trained registered nurses and gastroenterologists [8].

Compared with traditional sedative agents such as benzodiazepines or narcotics, propofol leads to fewer post-procedure residual effects, requires a shorter hospital stay, increases post-procedure patient satisfaction [9], and provides the highest endoscopist satisfaction [10]. To provide nonanesthesiologists with a comprehensive

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framework for administering propofol during digestive endoscopy, several consensus-based guidelines have been published recently in Europe [9] and the USA [11]. However, the use of sedation in colonoscopy varies considerably between countries more than any other aspect of endoscopic practice. Thus, although sedation is routine in the USA [5,12] and Canada [13], it is used in less than half of all screening colonoscopies in Europe [2,10]. These differences can be explained by cultural variations in the expectations of patients and the beliefs and preferences of endoscopists [12], but differences in specific regulations on the use of sedative drugs by nonanesthesiologists or ICU physicians from region to region must also be taken into account.

Because information on the use of propofol by nonanesthesiologists in colonoscopies performed in Europe, and particularly in Spain, is scarce, procedure-related information in our field has only been addressed in a limited manner [14,15].

This study, which represents the largest registry of consecutive outpatients sedated with propofol in Spain and one of the largest in Europe, aims to prospectively assess the safety and effectiveness of nurse-administered propofol sedation (NAPS) under an endoscopist's supervision in low-risk outpatients referred to a single Spanish hospital for colonoscopy.

Patients and methods

Patients

From February 2010, all outpatients undergoing a colonoscopy in our endoscopy unit were eligible to be a part of this study, until we reached 1000 consecutive procedures. Each patient's American Society of Anaesthesiology (ASA) class had been assessed in our gastroenterology outpatient clinics at the time the patients were referred for colonoscopy. Previous allergic reactions to sedative agents and contraindications for them and the use of concomitant drugs were also assessed. Written informed consent was obtained from each patient.

Exclusion criteria included inability to provide informed consent, high-risk head and neck anatomy (Mallampati score > 2) that could complicate airway rescue, sleep apnea syndrome, ASA class greater than II, a referral for both gastroscopy and colonoscopy in the same sedation procedure (to avoid confounding factors), a foreseeable duration of the procedure of more than 1 h, or pregnancy. This study was approved by the Institutional Research Committee at our hospital (19 September 2009).

Endoscopic and sedation procedures

Endoscopic exams were carried out in accordance with the current regional law (disposition 1/2007 of The Castilla-La Mancha Health Service or SESCAM), which stipulates that sedative agents can be administered by specially trained physicians in low-risk patients, whereas it must be controlled by an anesthesiologist only in high-risk patients (ASA III with no additional risks and ASA IV). To prepare our staff for this study and before starting the registry, all the certified endoscopists and nurses in our department participated in a structured theoretical and practical training program on nonanesthesiologist administration of sedatives, including pharmacology properties and interactions of sedative agents, the principles and concepts of sedation and monitoring, recovery, discharge criteria, and the management of complications, legal aspects, basic airway management, treatment of acute respiratory problems, and basic and advance cardiopulmonary resuscitation.

Propofol was used as the sole sedative agent and was administered by a nurse under the supervision of the endoscopist conducting the procedure, who determined the frequency and the amount of dosages. Oxygen (O_2) was administered through a nasal cannula (2 l/min). ASA class, age, sex, and body weight were recorded. Baseline vital signs, including heart rate, blood pressure (BP), and pulse oximetry O_2 saturation, were obtained in all patients before induction of sedation. All the attendant nurses were trained in endoscopic procedures.

The level of sedation was designed to maintain the patient between a score of 2 and 4 in the Modified Observer's Assessment of Alertness/Sedation score [16] (Table 1).

NAPS was initiated with a 0.5–1 mg/kg bolus (depending on the age and the ASA class of the patient and the decision of the endoscopist). Repeated boluses of 10–20 mg of propofol were then administered on demand at 30–60-s intervals for the entire duration of the procedure.

Propofol bolus frequency and dose were titrated to the patient response, including vital signs and manifestations of restlessness or discomfort. No maximum allowed dosage of propofol was predefined.

Liquid oral intake was allowed until 2 h before the colonoscopic procedure. Continuous heart rate and pulse oximetry O_2 saturation were monitored throughout the endoscopic procedure, with BP being assessed at 5-min intervals.

Adverse events were defined as hypoxemia (reduction in O_2 saturation <90% for more than 10 s) requiring supplemental O_2 through a nasal cannula in excess of 2 l/min, transient hypotension (< 90 mmHg or a decrease of >20 mmHg over basal values) not requiring any active

Table 1 Modified observer's assessment of alertness/sedation scale [16]

Responsiveness	Score
Responds readily to name spoken in normal tone	5
Lethargic response to name spoken in normal tone	4
Responds only after name is called loudly and/or repeatedly	3
Responds only after mild prodding or shaking	2
Responds only after painful trapezius squeeze	1
Does not respond to painful trapezius squeeze	0

medical treatment, or bradycardia (< 50 bpm) that reversed after the administration of 1 mg of atropine.

Serious adverse events were defined as hypoxemia requiring bag-mask ventilation, hypotension (< 90 mmHg), or persistent bradycardia requiring liquid infusion and specific medical treatment.

Discharging criteria included stable vital signs, patient alert and oriented to time, place, and individuals, with no pain or bleeding, and able to dress and walk without assistance. Recovery time was defined as the period from the extraction of the colonoscope to the patient's discharge from the hospital, completely dressed and conscious.

A quarter of the recruited patients were randomized to receive 1 mg of atropine at the beginning of the exploration, to analyze whether this strategy avoided bradycardia and/or the occurrence of hypotension. Randomization was performed by a computer at the time of the reception of each patient. A 1 mg dose of atropine was also administered during the procedure in cases in which heart frequency decreased below 50 bpm.

Statistical analysis

Various indicators were summarized with descriptive statistics. Mean and SD were used for quantitative variables, and the absolute and relative frequencies for qualitative variables. The contrast between the different indicators for efficacy and safety was determined using the χ^2-test (categorical indicators) or using a Student's *t*-test (quantitative indicators). We explored confounding between independent variables by multivariable analysis (logistic regression) with odds ratio (OR) and 95% confidence intervals (CI 95%). Recovery time was analyzed by multiple linear regression.

All calculations were carried out using the PASW statistical package, version 18.0 (SPSS Inc., Chicago, Illinois, USA).

Results

Patient characteristics

Between February and November, 2010, data from 1000 consecutive outpatients (563 women and 437 men) undergoing colonoscopy in our department were prospectively registered (Table 2). No differences between sexes were observed in the parameters analyzed. The mean age was 57 years (range 8–98 years). Overall, 57.4% of patients were categorized as ASA class I and 42.6% were ASA class II. In 48.2% of the exams, a therapeutic intervention was performed (including polyp or mucosal resections, tissue coagulations or ablations, and rubber banding of hemorrhoids). Five different endoscopists and six nurses carried out all the exams; no differences were observed in the results between different explorers.

Propofol dosages

The mean dose of propofol administered was 177 mg/patient (range 50–590 mg).

A negative and significant correlation existed between the amount of propofol administered and the age of the patient (Spearman's $\rho = -0.38$; $P < 0.001$): Those patients aged 65 years and older received an average dose of 148 (SD 61) mg, compared with an average dose of 192 (SD 79) mg in younger patients ($P < 0.001$).

Propofol dosages also varied depending on the ASA class: ASA I patients received a significantly higher dose than ASA II patients (187±76 vs. 163±73 mg, respectively; $P < 0.001$). Finally, a significantly higher dose of propofol was required for sedation in therapeutic colonoscopies compared with diagnostic procedures (184±79 vs. 170±73 mg, respectively; $P < 0.001$).

Completeness of exams

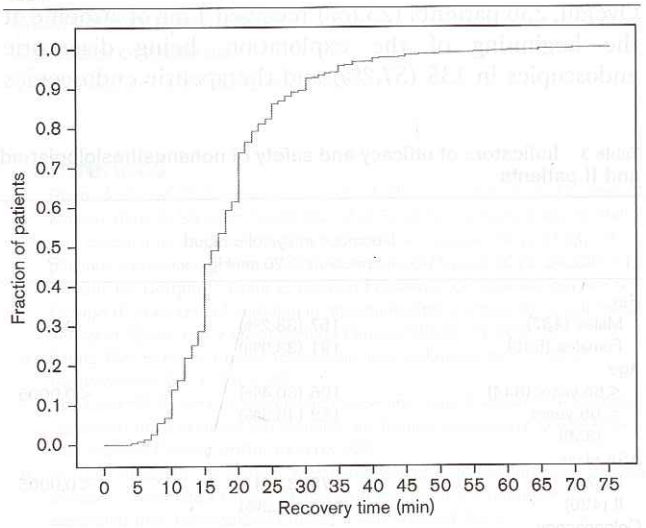
Overall, 96.9% of the colonoscopies performed (969) reached to the cecum or the terminal ileum. Overall, 99.9% of the examinations were able to explore the intended segment of

Table 2 Characteristics of patients and sedative endoscopic procedures in American Society of Anesthetics class I and II patients

	ASA class I (*n*=574)	ASA class II (*n*=426)	*P*
Sex [*n* (%)]			
Males	253 (44.1%)	184 (43.2%)	0.80
Females	321 (55.4%)	242 (56.8%)	
Age [years (mean±SD)]	50.8±15.3	65.6±13.7	<0.001
Dose of propofol [mg (mean±SD)]	187±76	163±73	<0.001
Recovery time [min (mean±SD)]	18.1±8.1	19.3±9.8	0.05
Endoscopy [*n* (%)]			
Diagnostic endoscopy	336 (58.5%)	182 (42.7%)	<0.001
Therapeutic endoscopy	238 (41.5%)	244 (57.3%)	

ASA, American Society of Anesthetics.

Fig. 1



Cumulative fraction of patients and recovery times after colonoscopy (estimated from the time the colonoscope was removed to the time of hospital discharge).

the colon (in therapeutic re-explorations in which a previous complete exam made cecum intubation unnecessary). The average recovery time was 18.6 min (SD 8.8, range 4–75 min) (Fig. 1); it was somewhat longer in ASA class II patients ($P = 0.05$). Other parameters, such as age, sex, or purpose of colonoscopy (therapeutic or diagnostic), were not associated with a prolonged recovery time (Table 3). No patients needed to remain at hospital after the colonoscopy, and all of them were discharged.

Safety-related events

Adverse events occurred in 39 patients (3.9%), with hypoxemia in 25 cases and hypotension in 14 cases. Serious adverse events were observed in 0.1% of the patients. Thus, although a decrease in systolic BP of more than 20 mmHg was observed in 358 patients (35.8%) after initiating the procedure, only 1.4% of patients showed a BP below 90 mmHg. Such decreases in BP were more frequent in ASA class II patients ($P < 0.0005$). In 24 cases (2.4%), O_2 saturation decreased to less than 90% at any given moment during the procedure, with spontaneous recovery. Only one patient required bag-mask ventilation to restore the pulse oximetry saturation to above 90%. Both hypotension and hypoxemia were more frequently observed in patients aged 65 years or older ($P < 0.05$). In general, however, the O_2 saturation presedation baseline and the minimum during sedation did not differ significantly (mean: 97%, SD: 3). No colonoscopy procedure had to be interrupted because of adverse events. Multivariable analysis showed similar results; a decrease in systolic BP of more than 20 mmHg was mainly associated with age (being the OR for $\geq$ 65-year-old vs. <65-year-old patients 1.70; CI 95% 1.27–2.28; $P < 0.001$) and ASA class (OR for ASA class II vs. ASA class I patients 1.32; CI 95% 0.99–1.78; $P = 0.06$).

Need for atropine during colonoscopy

Overall, 236 patients (23.6%) received 1 mg of atropine at the beginning of the exploration, being diagnostic endoscopies in 135 (57.2%) and therapeutic endoscopies in 101 (42.8%). Forty-six patients (4.6%) received the same dose of this drug during the procedure because their heart frequencies decreased below 50 bpm, out of which 29 were therapeutic procedures (6.6%) and only 17 (3.3%) were diagnostic exams ($P = 0.039$). Overall, only 5.8% of the 764 patients who did not receive atropine at the beginning of the exploration required it during the procedure; for patients who had received it before colonoscopy, a second dose was necessary only in two patients (0.8%).

Discussion

This pioneer single-center registry in Europe shows that NAPS is safe and efficient in ASA class I and II patients, facilitating a complete colonic exploration in almost all cases.

Our results are in agreement with those of previous studies on the safety and efficacy of nonanesthesiologist-administered sedation in selected low-risk patients. In addition, sedation allowed us to reach the targeted colonic segment in most cases, allowing a high cecal intubation rate of 96.9%, superior to previously reported figures for procedures performed without sedation, which range from 80.7 to 93.9% [17–20]. Our results support the previously reported conclusion that the use of propofol sedation appears to be the critical factor in achieving successful, complete colonoscopies in patients receiving referrals because of previous incomplete explorations [21].

Propofol has proved to be a very safe drug in sedated endoscopy, with hypoxemia and hypotension being its most frequently reported adverse effects. Other adverse effects include punctually reported idiosyncratic reactions [22] and the scarcely reported development of propofol infusion syndrome, a rare severe complication mainly appearing in patients undergoing long-term sedation with high doses of propofol [23]. We observed an O_2 saturation of less than 90% in 2.5% of our series and a decrease of more than 20 mmHg with respect to the basal line in 35.8%; this was

Table 3 Indicators of efficacy and safety of nonanesthesiologist-administered propofol sedation in American Society of Anesthetics class I and II patients

	Decrease in systolic blood pressure > 20 mmHg	P	Pulse oximetry saturation < 90%	P	During-colonoscopy atropine administration	P	Recovery time (min)	P
Sex								
Males (437)	167 (38.2%)	0.16	12 (2.7%)	0.53	20 (4.6%)	0.98	18.1±8.5	0.09
Females (536)	191 (33.9%)		12 (2.1%)		26 (4.6%)		19.0±9.1	
Age								
<65 years (644)	196 (30.4%)	<0.0005	11 (1.7%)	0.054	26 (4%)	0.25	18.6±8.3	0.93
≥ 65 years (356)	162 (45.5%)		13 (3.7%)		20 (5.6%)		18.6±9.8	
ASA class								
I (574)	178 (31%)	<0.0005	10 (1.7%)	0.12	31 (5.4%)	0.16	18.1±8.1	0.05
II (426)	180 (42.3%)		14 (3.3%)		15 (3.5%)		19.3±9.8	
Colonoscopy								
Diagnostic (518)	175 (33.8%)	0.17	12 (2.3%)	0.86	17 (3.3%)	0.04	19.1±8.8	0.07
Therapeutic (482)	183 (38%)		12 (2.5%)		29 (6.6%)		18.1±8.9	

ASA, American Society of Anesthetics.

significantly more frequent in patients aged 65 years and older and in ASA class II patients. A reduced glucuronidation of propofol in the liver or oxidation by enzymes of the cytochrome P-450 family in elder patients could be hypothesized [22]. However, hypotension defined as systolic BP less than 90 mmHg was only observed in 1.4% of the patients. Our figures are lower than those reported previously for hypoxemia (11%) and hypotension (5%) in a meta-analysis on propofol-based sedation [4], probably because of the low-risk status of the patients included in our study; in fact, ASA class I classification has been identified recently as a protective factor for the appearance of complications in endoscopist-guided sedation in endoscopic ultrasonography [1]. In any case, the rate of serious complications did not increase with patient age in our series, which is in good agreement with previously reported experiences using propofol sedation in patients older than 80 years of age [14]. This is probably because the dose of propofol used was significantly lower in elderly patients.

Colonic insufflations can produce bradycardia through vagal nerve stimulation, with the preventive use of atropine remaining controversial. Our results showed that the systematic administration of atropine is unnecessary in colonoscopy, as only 5.8% of our patients reached a heart frequency (< 50 bpm) that required a single 1 mg dose of atropine to recover the baseline value. It is interesting to note that therapeutic interventions were significantly more likely to require atropine administration, probably because colonic insufflations are more intense in this group.

Some of our results warrant further discussion. For example, all of our examinations were carried out on outpatients, all of whom were discharged from the hospital after a short (< 20 min) recovery time and provided with written instructions recommending direct patient observation by another individual during the following hours. Serious post-procedure adverse effects are less frequent with propofol than with a combination of benzodiazepines and opioids [24], and when they occur, they may appear up to 30 min after the administration of these drugs, representing less than 10% of procedure-related adverse effects [25]. An average recovery time of nearly 20 min thus seems sufficient to safely discharge patients, thereby minimizing the consumption of hospital resources. Moreover, our results clearly indicate that although the recovery time was slightly longer (about 1 min) in ASA class II patients, it was not significantly different for older patients or in cases of therapeutic procedures. In any case, the recovery time in our patients was significantly shorter than the 70 min reported when using midazolam alone [26] or the average 23 min reported when combining midazolam with propofol [27]. Propofol metabolizes much faster than benzodiazepines, which may reduce recovery and discharging time and improve the turnover of the endoscopic system [27].

The use of propofol in gastrointestinal endoscopy has experienced an upward trend in the USA [28] and Europe over the last decade; recent nationwide surveys conducted in Germany [29] and Greece [30] have shown that sedation is becoming the standard practice during endoscopic procedures. However, sedation remains uncommon in Italy [27] and Spain [1], even though one Spanish survey concluded that sedation should be administered in most colonoscopy procedures and called for improvements in anesthesiology resources [31]. Differences in drugs and protocols exist; although propofol is widely used in the USA, Canada, and Germany, its use appears to be restricted in Spain, Italy, and Greece. In a recently published international survey, endoscopists cited medicolegal issues and cost as the main reasons for not considering the implementation of nonanesthesiologist-administered propofol [10]. Rex *et al.* [8] estimated that substituting anesthesia specialists with gastroenterologists in low-risk explorations would represent huge economic savings, and we have shown that sedation prevents the need to repeat incomplete exams, thus saving on hospitalization expenses and reducing costs.

Our regional law clearly regulates the use of propofol under the supervision of specially trained physicians and odontologists in low-risk patients, which represents an advantage in providing both comfort to patients and savings to our health system. Other Spanish regions lack a similar regulation, creating a legal gap when applying this strategy, even within the same country. European Guidelines issued for nonanesthesiologists are a first step in improving endoscopists' knowledge of sedated endoscopy and broadening its routine use, but they also represent an opportunity for professional societies and regulatory agents to develop common regulations for reducing healthcare costs while providing more satisfactory care for our patients.

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Conflicts of interest

There are no conflicts of interest.

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