Same-day bidirectional endoscopy with nonanesthesiologist administration of propofol: safety and cost-effectiveness compared with separated exams

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Background and aim **The safety and cost-effectiveness of a combination of esophagogastroduodenoscopy (EGD) and colonoscopy [or bidirectional endoscopy (BDE)] versus alternative-day EGD and colonoscopy when using nonanesthesiologist administration of propofol have never been evaluated.**

Patients and methods **This was a single-center prospective registry of consecutive American Society of Anaesthesiology class I–III outpatients undergoing EGD, colonoscopy, and BDE. Propofol was the sole sedative used. Adverse events, recovery time, and procedure-related costs were analyzed.**

Results **Among the 1500 study participants (51.5% women), EGD, colonoscopy, and BDE were carried out on 449, 702, and 349 patients, respectively. All patients were discharged directly from the endoscopy unit. No sex differences were found with respect to age (mean 54.4, range 18–96 years), BMI, or procedure type. Propofol doses for BDE were 25.9% less than when EGD and colonoscopy were performed separately ($P<0.001$). Adverse events, including transient O_2 saturation less than 90%, systolic blood pressure less than 90 mmHg, and bradycardia (<50 bpm), appeared in 10.7% of single EGD and 8.6% of EGD within BDE; for colonoscopies, the figures were 8.6 and 9.5%, respectively ($P=$NS). Recovery time to discharge after BDE was 47.9% shorter than when EGD and colonoscopy were performed separately ($P<0.001$). The cost of same-day BDE was 28.1% lower than that of EGD and colonoscopy performed as separated procedures ($P<0.001$).**

Conclusion **Same-day BDE with nonanesthesiologist administration of propofol resulted in reductions in propofol doses, recovery time, and procedure-related costs as compared with carrying out EGD and colonoscopy separately, without an increase in adverse events.** ***Eur J Gastroenterol Hepatol*** **00:000–000** © **2013 Wolters Kluwer Health | Lippincott Williams & Wilkins.**

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Introduction

The use of sedation in gastrointestinal (GI) endoscopy has experienced an upward trend worldwide over the last decade [1–8]. Initially used only for more complex endoscopic procedures, sedation is now commonly used in esophagogastroduodenoscopy (EGD) and especially in colonoscopy. Both are better tolerated in terms of patient satisfaction and willingness to repeat the examination when sedation is provided [9,10].

Propofol is an ideal agent for relatively short outpatient procedures [11] that combines a rapid onset of action (30–45 s) with a short duration of effect (4–8 min). Although previous meta-analyses comparing propofol-based sedation with traditional sedative agents found that it had similar rates of adverse effects, it was also shown to decrease both time to sedation and recovery time, as well as to increase the quality of endoscopic examination, providing higher patient satisfaction for most endoscopic procedures [9,12,13]. In addition, propofol sedation is cost-effective when administered by a nurse under the supervision of an endoscopist [14], saving the cost of an anesthesiologist involved, which can increase up to 285% [15]. In fact, nonanesthesiologist administration of propofol (NAAP) sedation in clinical practice is supported by a number of studies [16]. Endoscopist-administered propofol sedation for colonoscopy has been found to lead to a better level of satisfaction and fewer side-effects than anesthetist-administered deep sedation in a recent controlled trial [6]. Finally, although some patients report pain on injection of propofol, it can be prevented by administering the drug through the anticubital vein [17].

Same-day EGD and colonoscopy (also called bidirectional endoscopy or BDE) is becoming common in clinical

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practice, with an estimated 10% or more of patients referred for upper or lower endoscopy receiving same-day BDE [18,19]. The diagnostic yield of same-day BDE in identifying potential bleeding sources in patients investigated for nonacute GI bleeding has been shown repeatedly [20–22].

According to four recent studies, three carried out in Asia [23–25] and one in Europe [26], the optimal sequence for same-day BDE is EGD, followed by colonoscopy. All four studies found that in this order, the procedure was better tolerated by both nonsedated patients [23,26] and those sedated by an anesthesiologist, with the latter requiring a lower overall dose of propofol [24]. To date, the use of NAAP in BDE has not been fully evaluated; thus, the safety of endoscopist-controlled sedation when performing two exams in one procedure, its effect on optimizing patient turnover in the endoscopy unit, and the possible cost savings of such a method have not been specifically assessed until now. This study aims to answer questions related to endoscopist-supervised NAAP in outpatients referred to a single Spanish hospital for same-day BDE.

Patients and methods

Patients

From February 2011 to December 2012, all adult (> 18 years) outpatients undergoing sedated EGD, colonoscopy, or same-day BDE in our endoscopy unit were eligible to participate in this study. At the time of referral for endoscopy, each patient's American Society of Anesthesiologists (ASA) class was assessed in our gastroenterology outpatient clinic. Previous allergic reactions to sedative agents as well as contraindications for these agents and concomitant drugs were also assessed. Written informed consent was obtained from each patient.

Exclusion criteria included inability to provide informed consent, head and neck anatomy that could complicate airway rescue (Mallampati score > II [27]), sleep apnea syndrome, ASA class greater than III, a foreseeable duration of the procedure of greater than 1 h, or pregnancy. The registry supporting this study was approved by the local institutional Research Committee.

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) that stipulates which patients can receive sedative agents administered by specially trained physicians without the participation of an anesthesiologist. All endoscopists and nurses in our department had participated in a structured theoretical and practical training program on nonanesthesiologist administration of sedatives.

Propofol was used as the sole sedative agent and was administered by a nurse under the supervision of the endoscopist performing the procedure, who determined dosage frequency and amounts. Oxygen (O_2) was administered through a nasal cannula (2 l/min). ASA class, age, sex, body weight, and height were recorded. Baseline vital signs, including heart rate, blood pressure (BP), and pulse oximetry O_2 saturation were obtained in every patient before induction of sedation.

In patients with a referral for both EGD and colonoscopy in the same sedation procedure, EGD was always carried out first.

NAAP was initiated with a standard 1 mg/kg bolus; in case of patients with ASA class III and older than 65 years of age, the initial dose was 0.5 mg/kg. 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. 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 [28]. Propofol bolus frequency and dose were titrated to patient response, including vital signs and manifestations of restlessness or discomfort. No maximum allowed dosage of propofol was predefined.

Oral intake of clear liquids was allowed until 2 h before the endoscopic procedure, and, in the case of patients undergoing both a colonoscopy and BDE, 4 l of polyethylene glycol solution was used for bowel preparation. 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 oxygen saturation <90% for more than 10 s) requiring supplemental O_2 through a nasal cannula in excess of 2 l/min, transient systolic hypotension (systolic BP < 90 mmHg) not requiring any active medical treatment, or bradycardia (< 50 beats/min) that reversed after the administration of 1 mg of atropine.

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

Discharge criteria included stable vital signs, with the patient alert and oriented with respect to time, place, and person, 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 endoscope to hospital discharge, with the patient completely dressed and conscious.

Cost analyses

To assess the cost savings for the health system when two separate procedures are substituted by BDE, the costs of fungible material (including gloves, materials for placing and maintaining a peripheral venous access, nasal

cannulas, disposable foot covers and smocks, syringes, needles, and endoscopic biopsy forceps), drugs (propofol and atropine ampoules), and personnel costs for the various recovery times (including a three-person team composed of a gastroenterologist, a registered nurse specially trained in endoscopy and sedation, and an auxiliary nurse) were evaluated for each procedure. Individual prices for all endoscopic and disposable materials were obtained from our hospital supply department; personnel costs/h were obtained from salary data provided by the hospital administration. Fixed costs, which included those related with technique-specific items (such as endoscope bite-blocks in gastroscopy), as well as personnel time for scope processing and exploration, were not taken into account as these did not vary between separate procedures and BDE.

Statistical analysis

The required sample size was estimated for a noninferiority contrast between the bidirectional versus separated procedure estimating that the rate of adverse effects would not exceed 5–6% (extracted from preliminary studies) in both groups and estimating a noninferiority limit of 3%. On the basis of these premises and with a power of 80%, between 1106 and 1550 patients needed to be recruited among different groups.

Various indicators were summarized with descriptive statistics. Mean and SD were used for quantitative variables, and 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 a Student's *t*-test (quantitative indicators). The association between propofol doses and independent variables was assessed 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

During the study period, data from 1500 consecutive outpatients (51.5% women) undergoing EGD (449 patients; 29.9%), colonoscopy (702 patients; 46.8%), or BDE (349; 23.4%) in our department were prospectively registered (Table 1). The mean age of the patients was 54.4 years (range: 18–96 years) and the mean BMI was 26.03 kg/m^2 (range: 11.7–47), with no significant differences between sexes for age and BMI. Overall, 45.8% of patients were categorized as ASA class I, 38.6% were ASA class II, and 15.6% were ASA III.

Five different endoscopists assisted by six nurses performed all the procedures; no significant differences were observed among the results of the different explorers.

Some type of therapeutic intervention (including polyp or mucosal resections, tissue coagulations or ablations, and rubber banding of hemorrhoids) was performed in 15.8% of EGD and in 31.6% of colonoscopies independent of whether they were carried out separately or as part of a bidirectional exam.

Propofol dosages

The mean dose of propofol administered was 152.3 ± 63.5 mg/patient in patients undergoing EGD alone, 168.2 ± 71.2 mg in colonoscopies, and 237.6 ± 85.3 mg in patients undergoing BDE. The latter represents a 25.9% reduction in propofol dosage compared with the hypothetical case of performing each exam separately.

Statistically significant relationships were observed between propofol doses and patient age, weight/BMI, and ASA class. The amount of propofol administered was correlated directly with patient weight (Spearman's $\rho = 0.135$; $P < 0.001$) and BMI ($\rho = 0.077$; $P = 0.014$) and correlated inversely with age ($\rho = -0.397$; $P < 0.001$) and ASA class ($\rho = -0.336$; $P < 0.001$) (Fig. 1). After stratification according to the type of exploration, the same significant relationships remained for EGD and BDE; in the case of colonoscopy, significant associations between dose, age, and ASA class persisted, whereas that with body weight did not.

Safety-related events

Mean O_2 saturation, systolic BP, diastolic BP, and heart rate were similar before and during sedation irrespective of the type of endoscopic exam performed (Table 2).

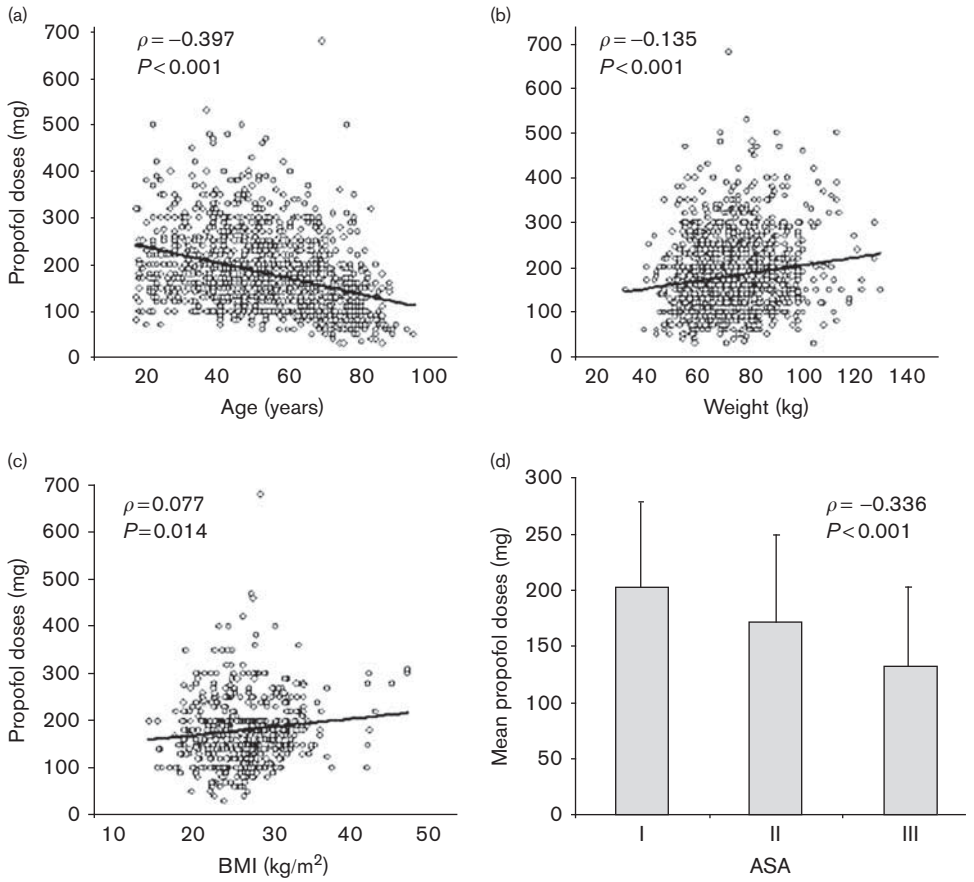
Overall, adverse events occurred in 159 patients (10.6%), and included transient hypoxemia, hypotension, and/or bradycardia. These occurred in 10.7% of patients undergoing EGD versus 8.6% of patients undergoing EGD within a BDE ($P = 0.323$) and in 8.8 versus 9.5% of patients undergoing a colonoscopy alone versus a colonoscopy within a BDE ($P = 0.899$), respectively.

Table 1 Characteristics of the patients included in our study

Characteristics	EGD (*n*=449)	Colonoscopy (*n*=702)	BDE (*n*=349)
Sex [*n* (%)]			
Male	248 (55.2)	351 (50)	129 (37)
Female	201 (44.8)	351 (50)	220 (63)
Age [mean (SD)]	46.5 (18.8)	58 (14.7)	57.4 (15.2)
ASA class [*n* (%)]			
I	267 (59.5)	281 (40)	139 (40.3)
II	118 (26.3)	307 (43.7)	154 (44.1)
III	64 (14.2)	114 (16.2)	56 (16)
BMI [mean (SD)] (kg/m^2)	24.7 (4.1)	27.2 (4.6)	27.1 (4.2)
Weight [mean (SD)] (kg)	72.2 (13.7)	75.2 (14.1)	75.4 (13.8)
Type of procedure [*n* (%)]			
Diagnostic	375 (83.5)	468 (66.7)	218 (62.5)
Therapeutic	74 (16.5)	234 (33.3)	131 (37.5)

In the case of bidirectional endoscopy (BDE), a procedure was considered to be therapeutic when at least one of its components was therapeutic.
ASA, American Society of Anesthesiologists; EGD, esophagogastroduodenoscopy.

Fig. 1



Nonparametric correlation (Spearman's ρ) between age (a), weight (b), BMI (c), and ASA class (d) with propofol doses (mg). ASA, American Society of Anaesthesiology.

O_2 saturation decreased to less than 90% at any given time point during an EGD in 23 (5.1%) single-procedure exams and in 20 (5.7%) EGD exams performed within a BDE. This adverse event was also observed in 13 (1.8%) patients undergoing a colonoscopy alone and in eight (2.3%) patients undergoing the same procedure within a BDE (Table 3). Severe hypoxemia (O_2 saturation <90% for more than 10 s requiring bag-mask ventilation) was only observed in two (0.4%) patients undergoing EGD, one (0.1%) patient undergoing colonoscopy, and one patient (0.3%) undergoing BDE.

The prevalence of hypotension (defined as systolic BP < 90 mmHg) did not differ between EGD and colonoscopies when carried out separately or as part of a BDE (Table 3).

Finally, transient bradycardia (< 50 beats/min) was more frequently documented during EGD performed alone than when carried out as a part of a BDE (4.4 vs. 1.4%; $P = 0.015$) whereas no significant differences were documented for colonoscopies (6.1 vs. 5.2%) (Table 3). The administration of atropine (1 mg) was only needed in 10 (0.7%) patients.

ASA class and age were found to be associated with the prevalence of adverse events, with some kind of adverse event occurring in 56 (8.2%) ASA class I patients, 67 (11.6%) ASA class II patients, and 36 (15.4%) ASA class III patients ($P = 0.005$). Patient age was also associated with the occurrence of adverse events. The mean age of patients with no adverse events was 53.9 ± 16.8 years, compared with 58.9 ± 16.8 years for patients with some type of documented adverse event ($P < 0.001$).

Completeness of exams and recovery time

No endoscopic procedure had to be interrupted because of adverse events. The ratios of cecal intubation or ileal cannulation did not differ between colonoscopies performed alone (93.8%) or carried out as a part of a bidirectional exam (92.8%; $P = 0.563$).

The average recovery time was 13.77 min (5.8): 14.3 min for EGD, 13.2 min for colonoscopy, and 14.3 min for BDE ($P > 0.05$). The overall recovery time did not differ between various ASA classes. Other parameters such as age, sex, or BMI were not associated with a prolonged

Table 2 Sedation-related parameters of 1500 consecutive outpatients undergoing nurse-administered propofol sedation for esophagogastroduodenoscopy, colonoscopy, or same-day bidirectional endoscopy, which consisted of EGD (BDE/EGD) plus colonoscopy (BDE/colonoscopy) carried out consecutively

			BDE ($n=349$)		
	EGD ($n=449$)	Colonoscopies ($n=702$)	Overall	BDE/EGD	BDE/colonoscopy
O_2 saturation % (pulse oximetry) [mean (SD)]					
Baseline	98.6 (1.8)	98.4 (1.9)	98.6 (1.5)	98.4 (1.9)	98.7 (1.7)
During endoscopy	98.1 (3.3)	98.5 (2.4)	98.3 (2.2)	98 (2.9)	98.6 (2.2)
Systolic blood pressure [mean (SD)] (mmHg)					
Baseline	131.4 (19.8)	141.2 (20.4)	133.7 (17.7)	140.3 (21.1)	127 (19.5)
During endoscopy	121.6 (17.8)	125.7 (19.4)	124.3 (16.7)	126.1 (19.7)	122.3 (18.1)
Diastolic blood pressure [mean (SD)] (mmHg)					
Baseline	81.4 (13.4)	85.1 (13.4)	81 (11.2)	84.1 (12.2)	77.9 (14.2)
During endoscopy	77.1 (13.2)	78.6 (12.6)	76.9 (11.2)	77.5 (13.8)	76.1 (12.2)
Heart rate [mean (SD)] (bpm)					
Baseline	74.7 (15)	76.7 (15.5)	77 (12.8)	78.7 (14.5)	75.3 (14)
During endoscopy	72.5 (14.4)	67.3 (12.5)	72.1 (12.3)	75.4 (14)	68.8 (12.5)

BDE, bidirectional endoscopy; bpm, beats/min; EGD, esophagogastroduodenoscopy.

Table 3 Adverse events documented in 1500 consecutive outpatients undergoing esophagogastroduodenoscopy, colonoscopy, and same-day bidirectional endoscopy, which consisted of an EGD (BDE/EGD) and a colonoscopy (BDE/colonoscopy) carried out consecutively

	EGD ($n=449$)	BDE/EGD ($n=349$)	*P*	Colonoscopy ($n=702$)	BDE/Colonoscopy ($n=349$)	*P*
Hypoxemia [*n* (%)]						
Pulse oximetry saturation <90%	23 (5.1)	20 (5.7)	0.719	13 (1.8)	8 (2.3)	0.601
Hypotension [*n* (%)]						
Systolic blood pressure <90 mmHg	5 (1.1)	5 (1.4)	0.759	6 (0.8)	7 (2)	0.134
Bradycardia [*n* (%)]						
Decreased heart rate <50 bpm	20 (4.4)	5 (1.4)	0.015	43 (6.1)	18 (5.2)	0.585
Propofol dosages (mg)	152.3 (63.5)	139.7 (56.3)	0.003	168.2 (71.2)	98.5 (55.5)	<0.001
Duration of the exam [mean (SD)] (min)	9.73 (5.8)	9.53 (4.9)	0.607	25.27 (12.7)	22.98 (10.4)	0.002

BDE, bidirectional endoscopy; bpm, beats/min; EGD, esophagogastroduodenoscopy.

recovery time. No patients needed to be admitted to hospital after colonoscopy; all of them were discharged directly from the endoscopy unit. The overall recovery time after a BDE was 47.9% shorter than if the EGD had been performed separately from the colonoscopy (13.2 min), thus improving patient turnover in the endoscopic unit, that is the number of procedures that can be performed a day.

Healthcare-related costs

On average, same-day BDE cost €68.10/patient (SD 15.40; range €41.50–186.50), which represents a 28.41% reduction in comparison to carrying out a gastroscopy [costing €38.96 (SD 8.2; range 23.8–88.4)/patient] and a colonoscopy [€56.18 (SD 13.7; range 32.5–150.5)/patient] ($P < 0.001$) separately (Table 4).

Discussion

This observational study assesses the advantages in terms of the safety and cost-effectiveness of carrying out same-day BDE in patients referred for both gastroscopy and colonoscopy. We have shown that NAAP for BDE was not associated with an increased risk of hypoxemia, hypotension, or bradycardia in comparison with EGD and colonoscopy carried out separately, despite the longer duration of the exam and increased doses of sedatives.

Propofol is used widely as an anesthetic drug largely because of its rapid onset and offset effects and its relative lack of 'hangover' effects. In the past few years, the use of propofol for GI endoscopy and other interventional procedures [29] has increased worldwide, with clear evidence that NAAP is effective, safe, and cost effective [7], as proved by the establishment of new terms such as 'NAAP' and 'NAPS' (nurse-administered propofol sedation) [30]. Although moderate sedation with midazolam and opioids remains the standard method in many settings [31], propofol is increasingly becoming the preferred sedative agent for routine and advanced endoscopic procedures [32,33]. Published research on its use in BDE is limited to propofol administered by anesthesiologists and a single research exclusively assessing respiratory adverse events (defined as an episode of apnea or airway compromise requiring bag-mask ventilation) in GI endoscopy under NAPS [34]; when administered for EGD plus colonoscopy, the authors reported an event rate of only 0.19%.

Previous research on BDE has indicated that EGD, followed by colonoscopy should be the procedural order of choice [23–26]. This procedural sequence was shown to affect the quality of EGD in same-day BDE significantly, with the quality of scope-tip retroflexion, visualization of the angular fold, and the general

Table 4 Procedure-related costs for esophagogastroduodenoscopy, colonoscopy, and same-day bidirectional endoscopy

Costs (€)	EGD ($n=430$)	Colonoscopy ($n=680$)	BDE ($n=343$)
Fungibles (SD)	9.99 (4.5)	8.26 (4.8)	11.68 (3.5)
Drugs (SD)	0.84 (0.35)	0.93 (0.39)	1.31 (0.47)
Personnel costs (SD)	28.12 (8.04)	46.94 (13.48)	55.13 (13.66)
Overall cost (SD; rank)	38.96 (8.2; 23.8–88.4)	56.18 (13.7; 32.5–150.5)	68.1 (15.4; 41.5–186.5)

Data are expressed as mean (SD) in Euros per procedure.
BDE, bidirectional endoscopy; EGD, esophagogastroduodenoscopy.

assessment of the stomach and upper GI tract being superior when EGD was performed first [23]. This is most likely because of fact that the abdominal bloating caused by insufflation of air during colonoscopy leads to reduced tolerance of a subsequent EGD [25]. In this context, it is possible that colon insufflation with carbon dioxide [35] could improve upon previous results, although this has yet to be assessed for BDE procedures. It is worth noting that the procedural order was consistent in both sedated [24] and nonsedated patients [23–25] in previously developed investigations. After these results, in our study, EGD was performed first in every BDE with NAAP. To the best of our knowledge, this particular strategy had never been fully evaluated before, and after our results, we can reaffirm that the procedure is as safe and efficient as had been shown previously in individual procedures.

It has been shown that the use of propofol as the sole sedative agent shortens the time in the endoscopy unit, leading to a quicker recovery [9,36,37]. Our study has also shown that the recovery and discharge time did not increase for BDE when compared with carrying out both exams separately, but it was reduced by half of what it would have been had both exams been carried out separately. This allows for improvements in patient turnover, which makes additional exams within the same working day possible. Carrying out same-day BDE in those patients referred for EGD and colonoscopy also led to greater cost-effectiveness, not only because the same fungible material (especially material for achieving and maintaining a peripheral venous access, disposable gloves, and endoscopic biopsy forceps) could be used in both exams but also because there was a 25.9% reduction in propofol dosages, mainly during the colonoscopy part of the BDE procedure. In addition, the savings in personnel led to cost reductions of 28.41% compared with carrying out both procedures separately. There are other cost savings not quantified by our study, for example, the fact that patients do not need to travel repeatedly to the hospital avoids the loss of an additional work day. Taking into account that patients undergoing sedation are recommended to come to the hospital accompanied and not to drive after the procedure, the benefits of same-day BDE in economic terms also extend to labor and family environments.

Our study has the strength of prospectively including every consecutive ASA I–III outpatient referred for GI endoscopy under NAAP at our hospital. It is noteworthy that despite documenting significantly more adverse events in ASA III and elderly patients, all 1500 recruited patients were discharged directly from the endoscopic unit with no further sedation-related complications.

However, this study also presents several limitations, which would have been overcome if a randomized-controlled trial had been conducted: the observational nature of the design may have led to selection bias when comparing the various types of procedures. However, we believe that this was irrelevant, especially as the multivariate analysis showed that the differences persisted after adjustment for comorbidity (expressed in terms of ASA class), age, weight, and other factors. In addition, the impact of improved patient turnover because of increased availability of specialized staff to perform additional daily examinations and its effect on the waiting-list for endoscopy and a possible reduction in the time for achieving a diagnosis were not assessed.

Conclusion

NAAP for same-day BDE should be recommended for those patients requiring both EGD and colonoscopy, as it is not only just as safe but also provides additional benefits in terms of propofol dose reductions, procedure-related cost savings, and improvements in patient turnover in the endoscopy unit. Further randomized clinical trials should be carried out to confirm our results.

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Conflicts of interest

There are no conflicts of interest.

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