# Implementation of the European Society of Gastrointestinal Endoscopy (ESGE) and European Society of Gastroenterology and Endoscopy Nurses and Associates (ESGENA) sedation training course in a regular endoscopy unit

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## ABSTRACT

**Background** Several scientific societies have endorsed non-anesthesiologist sedation (NAS) during gastrointestinal endoscopy, considering it a safe procedure when administered by adequately trained personnel. This study aimed to evaluate the occurrence of adverse events after implementation of the European Society of Gastrointestinal Endoscopy (ESGE) and European Society of Gastroenterology and Endoscopy Nurses and Associates (ESGENA) sedation training program.

**Methods** From January 2017 to August 2018, data from all consecutive endoscopic procedures in adults (≥18 years) performed at our endoscopy unit were collected using an electronic reporting system.

**Results** All staff (physicians and nurses) completed the ESGE-ESGENA sedation course. In total, 12 132 patients underwent endoscopic procedures, 10 755 (88.6 %) of which were performed in a non-anesthesiological setting. Of these, about 20 % used moderate sedation with midazolam + fentanyl and 80 % used deep sedation with additional propofol. No sentinel, 5 (0.05 %) moderate risk, and 18 (0.17 %) minor risk adverse events occurred, all during moderate or deep sedation, and all managed by endoscopy staff without the need for anesthesiologist assistance.

**Conclusions** After completing the ESGE-ESGENA sedation training program, the rate of adverse events was very low in our institution. The findings support implementation of the program in all digestive endoscopy units and inclusion in the curriculum for physicians and nurses to ensure safe endoscopic procedures.

## Introduction

In modern practice, endoscopy is rarely performed without sedation. However, the definition of standard of care is difficult; clinical scenarios range from low doses of benzodiazepine to general anesthesia, the latter being used especially for therapeutic procedures.

The endoscopic outcomes (i. e. detection of pre-neoplastic and neoplastic lesions, completion rates during esophagogastroduodenoscopy or colonoscopy) achieved with the administration of benzodiazepine alone or combined with opioid are quite optimal, even though patients' experiences are not always adequate [1]. For this reason, many countries have tended

to use propofol, and several scientific societies have approved this practice [2–4].

Compared with traditional sedation, propofol-balanced sedation (PBS) presents similar rates of adverse events, provides higher patient satisfaction, decreases the time to sedation and to recovery, and increases the quality of the endoscopic examination [5, 6]. Nevertheless, PBS performed by non-anesthesiologists, despite generally considered a safe procedure, is still a matter of debate due to the present regulations.

Recently, an Italian position paper clarified that propofol usage is limited to hospital settings but that prescription and administration by anesthesiologist is not required, according to some drug packages, thus overcoming medical legal issues [4]. However, propofol may lead to deep sedation or severe adverse events that require cardiopulmonary support. Specific knowledge and skills are necessary within the endoscopy team (both physicians and nurses) to ensure safe sedation. For this purpose, the European Society of Gastrointestinal Endoscopy (ESGE) and the European Society of Gastroenterology and Endoscopy Nurses and Associates (ESGENA) have recently published a joint position statement on a European curriculum for sedation training in gastrointestinal (GI) endoscopy [7].

Sedation is a continuum of states ranging from minimal sedation through to general anesthesia; it is not always possible to predict how a patient will respond. Irrespective of the drugs used, non-anesthesiologist sedation (NAS) requires appropriate patient selection, use of an established protocol for drug administration, careful patient monitoring during the procedure, and criteria for discharge. Moreover, endoscopy staff should be able to rescue patients whose level of sedation becomes deeper than initially intended.

This study analyzes our experience with NAS for endoscopic procedures in a community hospital after the implementation of a specific training program based on ESGE-ESGENA recommendations. The aim of the study was to evaluate the occurrence of adverse events related to sedation after implementation of the training program.

# Methods

## Study design

This was a single-center, observational, prospective study, conducted in a community hospital and approved by the institutional review board as part of a quality improvement program.

## Training program

Physicians and nurses completed the ESGE-ESGENA sedation training course, which comprises theoretical and practical assignments (▶ **Table 1**). Theoretical training included pre-sedation assessment, use and interpretation of sedation levels, pharmacological properties of drugs (including antagonists), description of monitoring criteria, hypoventilation clinical signs, electrocardiography and heart rate monitoring, as well as cardiopulmonary resuscitation.

Practical training was set on airways assessment and cardiopulmonary resuscitation. Finally, gastroenterologists and nurses performed at least 50 procedures under the direct supervision of an anesthesiologist, with final practical evaluation. In addition, physicians had to obtain an advanced life support certificate and nurses required a basic life support certificate.

▶ **Table 1** Training program details.

| |
|---|
| **Theoretical part** |
| ▪ Pharmacology, pharmacokinetics, and interactions of sedatives, analgesics, and respective antidotes |
| ▪ Principles of sedation and monitoring patients including analysis of ECG monitoring |
| ▪ Different sedation concepts |
| ▪ Pre-, intra-, and post-endoscopy patient care concerning sedation, monitoring, recovery, discharge criteria, management of complications, and documentation |
| ▪ Legal aspects (e. g. delegation, informed consent) |
| **Practical part** |
| ▪ Basic airway management (e. g. freeing of airways, chin lifts, jaw thrust, bag-valve mask ventilation) |
| ▪ Use of different tubes for airway ventilation (e. g. Mayo and Guedel tube, laryngeal tube) |
| ▪ Treatment of acute respiratory problems |
| ▪ BLS and ALS, including the use of defibrillators |

ECG, electrocardiogram; BLS, basic life support; ALS, advanced life support.

## Patients and procedures

From January 2017 to August 2018, data from all consecutive endoscopic procedures in adults (aged ≥ 18 years) performed at our digestive endoscopy unit were collected using an electronic reporting system.

Patients were excluded from the analysis if they refused sedation, were pregnant or breast-feeding, underwent procedures performed with primary involvement of an anesthesiologist (e. g. urgent setting, estimated long-lasting and/or therapeutic procedures such as endoscopic retrograde cholangiopancreatography, endoscopic submucosal dissection, or endoscopic ultrasound-guided drainage), or took regular narcotic analgesics or psychotropic drugs for chronic conditions (▶ **Table 2**).

All endoscopic procedures performed in a non-anesthesiological setting were analyzed. Fentanyl, midazolam, and/or propofol were administered by a team consisting of one endoscopist and two nurses, one of whom was exclusively dedicated to sedation and patient monitoring. According to patients' characteristics, procedures were performed using midazolam + fentanyl to achieve moderate sedation or PBS when deep sedation was intended. Patients with cardiorespiratory American Society of Anesthesiologists (ASA) class 3 or class ≥ 4, Mallampati class 4, and conditions with a risk of airway obstruction such as pharyngolaryngeal tumors, obstructive sleep apnea syndrome requiring continuous positive airway pressure, and extreme obesity (body mass index ≥ 40 kg/m$^2$) are considered at high risk for adverse events during deep sedation, and conse-

▶ **Table 2** Patient selection criteria.

| Exclusion criteria for NAS | Inclusion criteria for PBS | Exclusion criteria for PBS |
|---|---|---|
| Urgent setting | ASA 1 – 2 and non-cardiorespiratory ASA 3 | Cardiorespiratory ASA 3 and ASA ≥ 4 |
| Estimated long-lasting and/or therapeutic procedures (i. e. ERCP, ESD, EUS-drainage) | Mallampati class ≤ 3 | Mallampati class 4 |
| Patients who take narcotic analgesics or psychotropic drugs for chronic conditions | | Conditions with risk of airway obstruction:<br>▪ pharyngolaryngeal tumors<br>▪ OSAS requiring CPAP<br>▪ extreme obesity (BMI ≥ 40) |

NAS, non-anesthesiologist sedation; PBS, propofol-balanced sedation; ASA, American Society of Anesthesiologists; ERCP, endoscopic retrograde cholangiopancreatography; ESD, endoscopic submucosal dissection; EUS, endoscopic ultrasound; OSAS, obstructive sleep apnea syndrome; CPAP, continuous positive airway pressure; BMI, body mass index.

quently, endoscopic procedures were performed under moderate sedation in these patients (▶ **Table 2**) [8].

The protocol dosages have been previously established with anesthesiologists and consisted of: midazolam 0.03 mg/kg (with an adjustment dose of 0.03 mg/kg after 3 – 4 minutes), fentanyl 1 – 1.3 µg/kg (with a second injection of 25 – 50 µg in case of long-lasting procedures, i. e. > 45 minutes); for deep sedation, propofol 0.3 – 0.6 mg/kg (with an adjustment dose of 0.3 – 0.4 mg/kg after 2 minutes) was added.

Supplementary oxygen (4 L/min) and multiparametric monitoring (i. e. continuous pulse oximetry and heart rate, noninvasive arterial blood pressure every 5 minutes, and continuous electrocardiographic tracing) were provided as recommended by European guidelines [2].

### Adverse events

Adverse events related to sedation were defined according to the consensus document from the International Sedation Task Force of the World Society of Intravenous Anaesthesia [9]. This tool is a five-step process that requires the identification and description of the adverse event, the intervention performed, the outcome, and the overall severity of the adverse event.

Sentinel adverse events are defined as any one or more of the following conditions:

- description of adverse events: oxygen desaturation, severe or prolonged (defined as any oxygen saturation < 75 % or an oxygen saturation < 90 % for > 60 seconds); prolonged apnea (defined as cessation of respirations for > 60 seconds); cardiovascular collapse/shock (defined as clinical evidence of inadequate perfusion); or cardiac arrest (defined as an absent pulse);
- interventions performed with the intent of treating the adverse events: chest compressions, tracheal intubation, or the administration of neuromuscular blockers (e. g. succinylcholine), vasopressors including epinephrine, or atropine (with the intent to treat bradycardia rather than hypersalivation);
- outcome of adverse events: permanent neurological deficit, pulmonary aspiration syndrome (defined as known or suspected inhalation of foreign material such as gastric contents into the respiratory tract associated with new or worsening respiratory signs), or death.

Moderate risk adverse events are defined as adverse events that, while not sentinel, are serious enough to quickly endanger the patient if not promptly managed (i. e. oxygen desaturations 75 % – 90 % for < 60 seconds treated with bag-valve mask-assisted ventilation and/or oral/nasal airway insertion), involve alteration in vital signs (i. e. hypotension defined as a change of > 25 % from baseline, treated with rapid intravenous fluids), and require unplanned hospitalization or escalation of care (i. e. transfer to intensive care unit or prolonged hospitalization).

Minor risk adverse events are those encountered periodically in most sedation settings (i. e. oxygen desaturations 75 % – 90 % for < 60 seconds treated with airway repositioning and/or increased oxygen administration), involve transitory alteration in vital signs (bradycardia, tachycardia, hypotension, hypertension) defined as a change of > 25 % from baseline requiring no therapy, and produce no adverse outcome.

Patients experiencing obstructed breathing (initial oxygen desaturation > 90 %) were promptly managed by chin lifts or jaw thrusts by the dedicated nurse. Minor events of this nature were not recorded because they are not considered adverse events by the standardized definitions applied [9].

After the procedure, patients were observed in the recovery room. Finally, a nurse assessed the patient's suitability for discharge based on the Modified Observer's Assessment of Alertness/Sedation scale [10]. Written post-procedural recommendations were given to patients and caregivers.

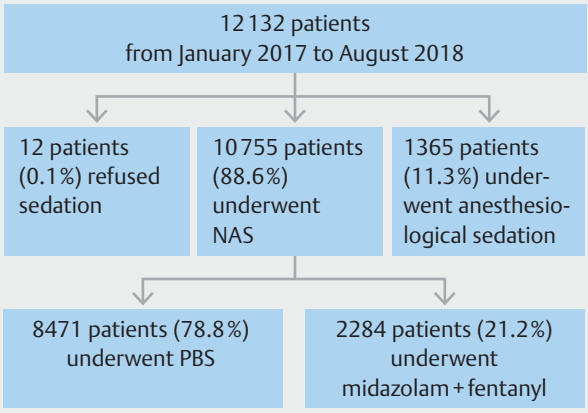
### Statistical analysis

Data were collected using a structured database and analyzed using SPSS software v. 22 (IBM Corp., Armonk, New York, USA). Continuous data are expressed as mean and standard deviation (SD); categorical data are expressed as a percentage.

## Results

All endoscopy staff (physicians and nurses) completed the ESGE-ESGENA-recommended sedation training course, with a final evaluation test.

During the study period, a total of 12 132 patients underwent endoscopic procedures in our unit. Among these, 10 755 procedures (88.6 %) were performed in a non-anesthesiological setting. A total of 1377 patients (11.4 %) were excluded be-




▶ **Fig. 1** Distribution of patients according to sedation status, sedation-administering staff, and type of sedation. NAS, non-anesthesiologist sedation; PBS, propofol-balanced sedation.

cause either anesthesiological assistance was needed (n = 1365, 11.3 %) or they refused sedation (n = 12, 0.1 %) (▶ **Fig. 1**).

A total of 2284 procedures (21.2 %) were performed under moderate sedation using midazolam + fentanyl, and 8471 (78.8 %) were performed under deep sedation using additional propofol (PBS).

Demographic details and clinical features of patients are presented in ▶ **Table 3**.

▶ **Table 3** Demographics details and clinical features of patients.

| | Total procedures (n = 10 755) | Midazolam + fentanyl (n = 2284) | PBS (n = 8471) |
|---|---|---|---|
| Sex, n (%) | | | |
| ▪ Male | 4941 (45.9) | 1119 (49.0) | 3822 (45.1) |
| ▪ Female | 5814 (54.1) | 1165 (51.0) | 4649 (54.9) |
| Age, mean (SD), years | 61.3 (14.8) | 64.3 (15.0) | 60.5 (14.6) |
| Weight, mean (SD), kg | 72.8 (15.1) | 74.7 (7.1) | 72.3 (15.7) |
| BMI, mean (SD), kg/m$^2$ | 25.77 (4.37) | 26.6 (4.9) | 25.7 (4.3) |
| **ASA class, n (%)** | | | |
| ▪ 1 | 5519 (51.3) | 1262 (55.3) | 4257 (50.2) |
| ▪ 2 | 4728 (44.0) | 852 (37.3) | 3876 (45.8) |
| ▪ 3 | 508 (4.7) | 170 (7.4) | 338 (4.0) |
| **Mallampati class** | | | |
| ▪ 1 | 4979 (46.3) | 803 (35.2) | 4159 (49.1) |
| ▪ 2 | 5195 (48.3) | 1187 (52.0) | 4007 (47.3) |
| ▪ 3 | 581 (5.4) | 294 (12.8) | 305 (3.6) |

PBS, propofol-balanced sedation; SD, standard deviation; BMI, body mass index; ASA, American Society of Anesthesiologists.

## Adverse events

A total of 23 adverse events (0.21 %) were registered: 5/2284 (0.22 %) during moderate sedation, and 18/8471 (0.21 %) during deep sedation.

Specifically, we reported no sentinel adverse events, 5 (0.05 %) moderate risk adverse events, and 18 (0.17 %) minor risk adverse events (▶ **Table 4**). All 5 moderate risk adverse events were reported during deep sedation: 3 oxygen desaturations (75 % – 90 % for < 60 seconds treated with oral airway insertion), 2 hypotension treated with rapid intravenous fluids. Of the 18 minor risk adverse events, 5 were reported during moderate sedation (2 oxygen desaturations [75 % – 90 % for < 60 seconds treated with airway repositioning], 2 tachycardia, 1 hypertension), and 13 occurred during deep sedation (7 oxygen desaturations [75 % – 90 % for < 60 seconds treated with airway repositioning], 3 bradycardia, 2 hypertension, 1 tachycardia).

All adverse events were managed by endoscopy staff without the need for anesthesiologist assistance. Moreover, no unplanned of prolonged hospitalization, death, permanent neurological defect or pulmonary aspiration syndrome occurred.

## Adverse events in elderly population

A subanalysis was performed using age of 80 years as a cutoff. A total of 9630 patients were aged < 80 years (89.5 %; mean age 58.7 [SD 13.3] years), and 1125 were ≥ 80 years (10.5 %; mean age 83.6 [SD 3.2] years). A total of 19 adverse events (0.20 %) were reported in patients < 80 years. In patients ≥ 80 years, all 4 adverse events (0.36 %) were defined as minor risk (2 oxygen desaturations during moderate sedation, and 1 oxygen desaturation and 1 bradycardia during deep sedation) (▶ **Table 4**).

## Drug dosages

In patients receiving deep sedation with PBS, midazolam mean dosage was lower than that used in moderate sedation (2.4 [SD 1.0] mg vs. 3.5 [SD 1.1] mg for upper GI endoscopy; 2.3 [SD 0.8] mg vs. 3.0 [SD 1.1] mg for colonoscopy). The fentanyl mean dosage was also lower in PBS during colonoscopy (74.4 [SD 19.8] µg vs. 81.5 [SD 20.2] µg).

In patients aged ≥ 80 years, midazolam, fentanyl, and propofol mean dosages were lower than dosages administered in patients < 80 years (▶ **Table 5**).

# Discussion

Every patient has the right to receive a painless and stress-free endoscopic examination. It appears ethically unjustifiable to withhold sedation from patients or to offer any kind of sedation in an unsafe manner, without adequate knowledge and instruments.

Our experience supports the safety of NAS following the incorporation of a specific ESGE-ESGENA training program into the staff curriculum. Several scientific societies have approved NAS during GI endoscopy, considering it a safe procedure when administered by adequately trained personnel [2, 3, 6].

▶ **Table 4** Adverse events.

| | Total procedures | Midazolam + fentanyl | PBS |
|---|---|---|---|
| **Total population** | | | |
| Total AEs | 23/10755 (0.21 %) | 5/2284 (0.22 %) | 18/8471 (0.21 %) |
| Sentinel AEs | 0 | 0 | 0 |
| Moderate risk AEs | 5 | 0 | 5 |
| ▪ Oxygen desaturation | 3 | 0 | 3 |
| ▪ Hypotension | 2 | 0 | 2 |
| Minor risk AEs | 18 | 5 | 13 |
| ▪ Oxygen desaturation | 9 | 2 | 7 |
| ▪ Bradycardia | 3 | 0 | 3 |
| ▪ Tachycardia | 3 | 2 | 1 |
| ▪ Hypertension | 3 | 1 | 2 |
| **Patients ≥ 80 years** | | | |
| Total adverse events | 4/1125 (0.36 %) | 2 | 2 |
| Sentinel AEs | 0 | 0 | 0 |
| Moderate risk AEs | 0 | 0 | 0 |
| Minor risk AEs | 4 | 2 | 2 |
| ▪ Oxygen desaturation | 3 | 2 | 1 |
| ▪ Bradycardia | 1 | 0 | 1 |

PBS, propofol-balanced sedation; AE, adverse event.

Despite the large body of evidence for NAS in the literature, no specific data have been published on the safety of NAS after implementation of the ESGE-ESGENA training program in daily clinical practice. In a noninferiority randomized controlled trial, authors demonstrated that NAS with propofol is equivalent to anesthesiologist-administered sedation in terms of adverse event rate for colonoscopy in a low-risk population, when carried out by skilled personnel. However, propofol sedation was performed by an endoscopist with experience in emergency medicine, who had also previously trained his nursing staff, with no standardized certified course [11]. Conversely, we prospectively collected data on over 10 000 endoscopic procedures after all staff, both physicians and nurses, had completed the ESGE-ESGENA sedation training program. We registered a global complication rate of 0.21 %. Specifically, no sentinel adverse events were reported, further supporting that NAS, even with propofol, is a safe practice when performed by properly trained personnel. The ESGE-ESGENA sedation training program allowed all professional figures involved in NAS to improve their knowledge of each step of sedation, starting from fundamental steps (i. e. careful selection of patients and subsequent choice of sedation), to adequate monitoring during the procedure and, finally, to interventions performed to avoid adverse events (i. e. airway repositioning).

▶ **Table 5** Mean (standard deviation) dosages of sedation drugs.

| Procedures and drug | Midazolam + fentanyl | PBS |
|---|---|---|
| **Total population** | | |
| Upper GI endoscopy | | |
| ▪ Propofol, mg | | 68.3 (40.0) |
| ▪ Midazolam, mg | 3.5 (1.1) | 2.4 (1.0) |
| ▪ Fentanyl, µg | 61.4 (7.6) | 63.1 (8.1) |
| Colonoscopy | | |
| ▪ Propofol, mg | | 66.5 (49.1) |
| ▪ Midazolam, mg | 3.0 (1.1) | 2.3 (0.8) |
| ▪ Fentanyl, µg | 81.5 (20.2) | 74.4 (19.8) |
| Upper GI endoscopy + colonoscopy | | |
| ▪ Propofol, mg | | 95.6 (54.2) |
| ▪ Midazolam, mg | 3.0 (1.0) | 2.3 (0.8) |
| ▪ Fentanyl, µg | 71.3 (18.6) | 69.4 (21.6) |
| **Patients < 80 years** | | |
| Upper GI endoscopy | | |
| ▪ Propofol, mg | | 71.3 (38.8) |
| ▪ Midazolam, mg | 3.9 (1.0) | 2.4 (0.7) |
| ▪ Fentanyl, µg | 64.1 (22.1) | 57.1 (12.5) |
| Colonoscopy | | |
| ▪ Propofol, mg | | 67.1 (44.4) |
| ▪ Midazolam, mg | 3.1 (0.9) | 2.3 (0.6) |
| ▪ Fentanyl, µg | 84.5 (15.6) | 74.7 (16.5) |
| Upper GI endoscopy + colonoscopy | | |
| ▪ Propofol, mg | | 104.1 (54.7) |
| ▪ Midazolam, mg | 3.1 (0.9) | 2.3 (0.5) |
| ▪ Fentanyl, µg | 82.0 (17.8) | 71.1 (17.9) |
| **Patients ≥ 80 years** | | |
| Upper GI endoscopy | | |
| ▪ Propofol, mg | | 44.6 (3.3) |
| ▪ Midazolam, mg | 2.4 (0.5) | 2.1 (0.5) |
| ▪ Fentanyl, µg | 0 | |
| Colonoscopy | | |
| ▪ Propofol, mg | | 49.6 (40.0) |
| ▪ Midazolam, mg | 2.4 (0.6) | 2.2 (0.5) |
| ▪ Fentanyl, µg | 59.4 (0.7) | 60.6 (13.2) |
| Upper GI endoscopy + colonoscopy | | |
| ▪ Propofol, mg | | 67.1 (49.0) |
| ▪ Midazolam, mg | 2.9 (0.8) | 2.2 (0.5) |
| ▪ Fentanyl, µg | 60.0 (1.1) | 58.8 (14.7) |

PBS, propofol-balanced sedation; GI, gastrointestinal.

The advantages of propofol are well known and have been extensively published [12]. However, propofol is still underused in many countries and is mostly administered by anesthesiologists, which increases costs. Conversely, NAS, even with propofol, represents a unique opportunity to reduce costs (i. e. anesthesiologist reimbursement) without affecting efficacy or safety of the procedure [13]. PBS allows benzodiazepine and opioid dosages to be decreased, thereby reducing the benzodiazepine-related adverse event rate, especially in frail patients (i. e. elderly patients or in patients with renal or liver failure). The availability of benzodiazepine and opioid antagonists may lead physicians to underestimate the risks of over-sedation. Moreover, the different pharmacokinetic characteristics of benzodiazepine, opioids, and their antagonists impose a prolonged recovery time, which is often not observed. Our study showed that lower mean dosages of benzodiazepine and fentanyl were required during PBS, and no reversal agents were needed to reduce the level of sedation or to manage adverse events, reflecting the knowledge acquired during the ESGE-ESGENA training program.

Sedation is a continuum that can range from anxiolysis to deeper grades, often in an unpredictable way. Therefore, endoscopy staff should be qualified in airway management and advanced life support irrespective of the drugs used. In our series, total adverse events were low because professionals had been trained to continuously monitor patients. Once oxygen saturation started to decrease (but was still >90 %), the nurse responsible for monitoring the patient routinely applied airway repositioning (i. e. chin lifts or jaw thrusts), in order to prevent adverse events. Moreover, no sentinel adverse events occurred, and all moderate and minor risk adverse events were managed by endoscopy staff, without the need to call an anesthesiologist for assistance.

In the subanalysis of elderly patients, a limited number of adverse events occurred (4/1125, 0.36 %). We recorded only minor risk adverse events, both during moderate and deep sedation. In this setting, more caution was taken to reduce the mean dosage of each drug.

Our study has some limitations. No detailed digital data are available before 2017; therefore, a comparison between the two eras (i. e. before and after introduction of the ESGE-ESGENA program) was not possible. However, this limitation might be partially overcome by the consistent number of all procedures (over 10 000). Another limitation could be the lack of patient satisfaction feedback. However, our unpublished data collected for internal quality analysis on 500 patients (20 % upper GI endoscopy, 80 % colonoscopy) revealed that 100 % of patients who underwent PBS and who had experienced standard sedation with benzodiazepine + opioid in a previous endoscopic examination, would repeat the next procedure with propofol.

## Conclusions

The time for a cultural change in safe sedation management in GI endoscopy has arrived. After completing the ESGE-ESGENA sedation training program, the rate of adverse events was very low in our institution. Our experience supports implementation of the program in all digestive endoscopy units and inclusion in the curriculum for physicians and nurses in order to ensure safer endoscopic procedures.

## Competing interests

The authors declare that they have no conflicts of interest.

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CORRECTION

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In the above-mentioned article, the name of Alessandro Pignatti has been corrected. This was corrected in the online version on July 22, 2020