

# Rethink analgo-sedation in digestive endoscopy: the role of scientific societies in tracing training path

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**Abstract. – OBJECTIVE:** The Italian Society of Anesthesia, Analgesia, Reanimation and Intensive Care Medicine (SIAARTI) and the Italian Society of Digestive Endoscopy (SIED) worked together to produce a joint Good Clinical Practice (GCP) on analgo-sedation in digestive endoscopy and launched a survey to support the document. The aim was to identify and describe the actual clinical practice of sedation in Italian digestive endoscopy units and offer material for a wider and more widespread discussion among anesthetists and endoscopists.

**SUBJECTS AND METHODS:** A national survey was planned, in order to support the statements of the GCP. Twelve thousand and five hundred questionnaires were sent to the members of SIAARTI and SIED in June 2020.

**RESULTS:** A total of 662 forms (5.3%) returned completed. Highly complex procedures are performed according to 70% of respondents; daily anesthesiologist's assistance is guaranteed in 26%, for scheduled sessions in 14.5% and as needed in 8%. 69% of respondents declared not to have a dedicated team of anesthesiologists, while just 5% reported an anesthesiologist in charge.

A complete monitoring system was assured by 70% of respondents. Dedicated pathways for COVID-19-positive patients were confirmed in <40% of the answers. With regard to moderate/deep sedation, 90% of respondents stated that an anesthetist decides timing and doses. Propofol was exclusively administered by anesthetists according to 94% of answers, and for 6% of re-

spondents the endoscopist is allowed to administer propofol in presence of a dedicated nurse, but with a readily available anesthetist. Only 32.8% of respondents reported institutional training courses on procedural analgo-sedation.

**CONCLUSIONS:** The need to provide patients scheduled for endoscopy procedures with an adequate analgo-sedation is becoming an increasing concern, well-known in almost all countries, but many factors compromise the quality of patient care. Results of a national survey would give strength to the need for a shared GCP in gastrointestinal endoscopy. Training and certification of non-anesthetist professionals should be one of the main ways to center the objective.

*Key Words:*

Endoscopy, Sedation, Survey, Analgesia, Anesthesia.

## Introduction

Endoscopy has developed a lot in the last years for interventional procedures as well as for screening of colon cancers. As a consequence, the need to provide patients with adequate analgo-sedation is becoming a topical issue for anesthetists<sup>1</sup> and endoscopists<sup>2</sup>. The increasingly number of high-risk patients and procedures, and the aware-

ness of the possible physical and psychological sequelae due to an insufficient and unsatisfactory sedation, claim for a dedicated effort<sup>3</sup>. The search for a guaranteed consensus among specialties and scientific societies, along with the quality of the procedures and the maximum patient safety, is desirable.

Several analysis<sup>1,2,4</sup> have been produced on this topic, arising from different starting points, which have led to divergent attitudes among scientific societies and even to retractions of previous shared documents<sup>4</sup>. The propofol administration's responsibility profile has been the main field of fight; the statements of national medicines agencies have not helped to solve the question, confirming an exclusive use by anesthesiologists<sup>5</sup>.

In 2017, the European Society of Anesthesiology and the European Board of Anesthesiology produced a comprehensive guideline<sup>6</sup> for procedural sedation and analgesia in adults. The main purpose was to provide recommendations applicable to all European National Societies, keeping in mind the strong pressure from the non-anesthesiology world to perform procedural sedation without the direct support of anesthesia services. As written in an accompanying Editorial, "it remains the responsibility of each Non-Anesthesiologist Societies and other national regulatory bodies to consider their adoption, in whole or in part"<sup>7</sup>.

A non-negligible issue is the cost-benefit ratio and the shortage of anesthesiologists, especially in times when events such as the COVID-19 pandemic, have put the system under stress and diverted a vast number of professional resources towards Critical Emergency Care<sup>8</sup> to the detriment of elective activities.

Moving from these heterogeneous scenarios, the Italian Society of Anesthesia, Analgesia, Resuscitation and Intensive Care Medicine (SIAARTI) and the Italian Society of Digestive Endoscopy (SIED) have decided to share an intersocietal Good Clinical Practice (GCP) on analgo-sedation in digestive endoscopy in order to improve the safety, quality, and efficiency of the activities carried out in that area, and at the same time to find a reasonable and feasible starting point for future documents based on updated evidence<sup>9</sup>.

The primary purpose of the Document was to establish clear rules and provide the basis for organizational models that can be applied to any local reality, with the hope of raising in-

terest even out the national borders. A national survey was launched by the board, aiming at giving a picture of the current situation and supporting the statements proposed in the GCP. The main findings of this survey are shown and discussed in the present paper. They are food for thought and provide an opportunity for discussion on the potentiality offered by European guidelines and national documents, as well as the importance of the correct implementation by Scientific Societies.

## Subjects and Methods

In June 2020, an e-mail with the survey link (available at: <http://www.surveymonkey.com>) was sent to all the Italian anesthesiologists affiliated to SIAARTI, and to the endoscopists members of SIED, with a time frame of 4 weeks. Subjects were anonymous but an indication about geographical area of emplacement was required. In case of homonyms, a match control was provided to prevent multiple participation.

The survey was composed of 7 sections and 16 queries (Table I), which in order concerned the setting of the Endoscopy Center; the organization of anesthetic assistance; aspects related to logistics and patient monitoring; the drugs used and the methods of administration, including responsibility profiles; the criteria for discharging the patient undergoing procedural analgo-sedation; training and certification; finally a last section concerning personal opinion on the usefulness of a survey conducted on this topic.

The majority of the items were multiple choice questions, or in some cases had a binary answer (YES/NO). In the logistics section, a specific question was proposed regarding the implementation of specific COVID-19 pathways for positive patients scheduled for an endoscopic procedure. In the section dedicated to sedation drugs, a specific question has been proposed about the propofol administration's responsibility. The Survey was supported by SIAARTI and SIED (Scientific subcommittee of data May 12, 2020)

The survey was conducted following the ethical principles outlined in the Declaration of Helsinki, even no Institutional Review Board-is required. Data is presented as absolute number and percentage (Q13 allows a multiple choice). Data were analyzed using MEDcalc version 18.6 (available at: <https://www.medcalc.org>).

**Table I.** The survey.

Queery	Question
<b>Setting - Endoscopy Center</b>	
Q1	In the ED center where you work, what procedures are performed?
Q2	How often does endoscopic activity require anesthetic presence?
<b>Human resources</b>	
Q3	How is the anesthetic assistance organized in your ED center?
Q4	In case of urgency, what could anesthetist do?
<b>Logistics</b>	
Q5	Is there a monitoring system for the procedures in your ED Center?
Q6	In your ED Center is there an observation area (recovery room) to monitor patients at the end of the procedures?
Q7	Is there a dedicated nurse in the observation area (recovery room)?
Q8	Has a specific COVID-19 pathway for digestive endoscopy been outlined in your hospital?
<b>Medicines</b>	
Q9	What kinds of drugs for analgo-sedation are available in your ED center?
Q10	Who decides the timing and doses of the administration of sedative drugs for mild sedation?
Q11	Who decides the timing and doses of the administration of sedative drugs for moderate / deep sedation?
Q12	Who administers propofol?
<b>Discharge</b>	
Q13	Who discharge the patient underwent to procedural sedation?
<b>Privileges, training and maintenance of skills</b>	
Q14	Is there a specific procedure in your hospital for assigning privileges to no-anesthesia specialists for the management of procedural sedation?
Q15	Have training courses for analgo-sedation for non-anesthetists or nurses been organized by your hospital?
<b>Opinions</b>	
Q16	Do you think the topic of the Survey would be useful in contributing to the improvement of current standards in ED?

ED: Endoscopy Digestive.

## Results

Twelve thousand and five hundred questionnaires were sent, 662 (5.3%) completed forms were returned. The largest percentage of responses came from the Northern Italy (251), while 195 completed forms were received from Central Italy, and 203 from the Southern Italy. Twelve forms were returned without indication of the region of origin, and only one from abroad. The overall data are reported in Table II. Approximately 70% of respondents declared to perform highly complex procedures in their center, while only a small percentage (8.4%) limited their activities to upper gastrointestinal endoscopies and diagnostic colonoscopies. Regarding the daily coverage of endoscopic activities by anesthesia services, this would be guaranteed just for 26% of the answers, while for 14.5% only for scheduled sessions and for 8% as needed. Sixty-nine percent of the respondents reported that the anesthesiologists turn in Endoscopy Unit within the service without a dedicated team, and only 5% reported that there

is a referred figure as responsible. In case of urgency, almost one-third of the respondents (28%) declared to receive support by the internal emergency team.

Seventy percent of responses showed that a comprehensive noninvasive monitoring system is available for patients undergoing endoscopic procedures, compared with a quarter of respondents using only partial monitoring (usually pulse oximetry). Seventy-six percent of respondents have a dedicated recovery room, but only 50% reported the presence of a dedicated nurse. More than 60% of the answers showed that there are no dedicated pathways for COVID-19 positive patients in digestive endoscopy.

Almost 60% of the respondents declared that they use various drugs for analgo-sedation. In the case of light sedation, the responsibility for deciding timing and doses of drug administration seems equally shared between the anesthetist and endoscopist. Instead, almost 90% replied that moderate/deep sedations are under the exclusive responsibility of the anesthetist.

**Table II.** Endoscopy center questions.

QueryOptions	Responses		
Q1 617 answers	Upper GI Endoscopies and diagnostic colonoscopies only	8.43%	n=52
	Upper GI Endoscopies and operative colonoscopies	35.33%	n=218
	Even high complexity procedures [ERCP, Enteroscopies]	69.53%	n=429
Q2 617 answers	on daily basis	26.26%	n=162
	>2 times a week	32.25%	n=199
	1 time a week	18.80%	n=116
	only for scheduled sessions	14.59%	n=90
	as needed, without scheduling	8.1%	n=50
Q3 617 answers	anesthetist in charge of the service	5.19%	n=32
	mainly dedicated staff	14.91%	n=92
	turning personnel	69.04%	n=426
	all the previous	10.86%	n=67
Q4 615 answers	can address to colleagues working in the ED area	9.11%	n=56
	can request help from colleagues present in the Hospital	62.93%	n=387
	call the Emergency Team of the hospital	27.97%	n=172
Q5 617 answers	yes, with full monitoring	70.5%	n= 435
	yes, but only with partial monitoring	26.09%	n= 161
	no, but it is available as needed	3.4%	n=218
Q6 617 answers	Yes	76.34%	n=471
	No	16.86%	n=104
	No, but the Recovery Room of the operating block is available	6.81%	n=42
Q7 616 answers	yes	50.32%	n=310
	no	49.68%	n=306
Q8 611 answers	Yes	62.68%	n=383
	No	37.32%	n=228
Q9 616 answers	benzodiazepines	16.07%	n=99
	propofol	20.62%	n=127
	opioids	1.95%	n=12
	ketamine - dexmedetomidine	0.81%	n=5
	halogenated agents	0.00%	n=0
	neuromuscular blocking drugs	0.00%	n=0
	all of the above	58.77%	n=362
none (they are taken on demand)	1.79%	n=11	
Q10 617 answers	only the anesthetist	33.39%	n=206
	the endoscopist supported by a nurse	32.90%	n=203
	both (case by case evaluation)	33.71%	n=208
Q11 616 answers	only the anesthetist	87.82%	n=541
	the endoscopist supported by a nurse	1.95%	n=12
	both (case by case evaluation)	10.23%	n=63
Q12 618 answers	always the anesthetist	94.01%	n=581
	also the endoscopist supported by a nurse, but with a readily recruitable anesthetist	5.99%	n=37
Q13 617 answers	the endoscopist	27.23%	n=168
	the anesthetist	22.53%	n=139
	the nursing staff	9.24%	n=57
	the anesthetist or the endoscopist, depending on who has carried out the sedation	45.71%	n=282
Q14 617 answers	Yes	11.99%	n=74
	No	50.89%	n=314
	I do not know	37.12%	n=229
Q15 616 answers	Yes	13.47%	n=83
	No	67.21%	n=414
	I do not know	19.32%	n=119
Q16 617 answers	Yes	87.20%	n=538
	No	2.11%	n=13
	I still don't have an opinion on the matter	10.7%	n=66

GI: Gastrointestinal; ED: Endoscopy Digestive; ERCP: Endoscopic Retrograde Cholangiopancreatography.

The endoscopist assisted by a nurse only seems to intervene in just less than 2%. This data was confirmed by the fact that almost always (94%) it is the anesthetist who administers propofol. For 6% of respondents, the endoscopist is used to administering propofol but if assisted by a dedicated nurse and with readily available assistance from the anesthetist.

Only 12% of the sample confirmed the existence of an institutional procedure for assigning privileges to the various specialists for the management of procedural sedation, while 37% are not aware of it. Accordingly, just over two-thirds of the respondents (67.2%) confirmed the absence of institutional training courses on procedural analgo-sedation, dedicated to non-anesthetists and nurses.

The survey was welcomed by almost all respondents, in fact 87.2% of the sample believe that the topic might be useful for the improvement of current clinical standards.

## Discussion

The national survey launched jointly by SIAARTI and SIED, allowed to focus on open and still unresolved issues in daily practice, which would give strength and rational foundations for the drafting of GCP on procedural analgo-sedation in endoscopy<sup>9</sup>. The document arose from the acknowledgment of an increased request for procedural analgo-sedation in digestive endoscopy and from awareness of an issue of accountability, clinical safety, and availability of dedicated professional resources. Undoubtedly, the growing activities in digestive endoscopy probably represent the most complex and critical area of non-operating room anesthesia for anesthesia services. At the same time, a review of the organizational models is required in terms of quality, efficiency, and safety<sup>10-12</sup>.

The sample analyzed accounts for just over 5% of all forms sent and may seem small at first glance. However, considering that not all anesthetists are involved in endoscopy activities, 662 respondents can be considered representative enough.

On average, the anesthetists are called to support digestive endoscopy services that perform highly complex procedures, which should require deep sedation or even general anesthesia, but the anesthesia services seem not to answer adequately these needs. The main deficiencies are scheduled daily coverage, dedicated teams, and referred professionals. For 40% of the sample analyzed, the anesthesia services do not have a programmed

daily schedule and almost a quarter offer a limited programmed support or according to need. The high turnover of anesthesiologists, associated with the almost total absence of reference figures, would expose inevitably the activities to a lack of coordination and shared procedural protocols. Furthermore, this widespread precarious model would limit the correct and orderly execution of endoscopic activities during the week.

Thus, it is not surprising that endoscopic scientific societies have promoted in the last years the practice of “procedural sedation by non-anesthesiologists”, sustaining equal or if even better performances<sup>3,13</sup>.

In addition to the common lack of dedicated anesthetists, the findings about the absence of a dedicated nurse who oversees the recovery room reported by 50% of respondents worsen safety levels and quality of care provided to patients undergoing procedural sedation. These data partly confirm the results of a survey<sup>14</sup> launched in 2015 by the Italian Association of Endoscopy Nurses, which highlighted the lack of recovery rooms and a different logistic flow to preserve sanitization respectively in 15% and 45% of centers. That survey showed more frequent deficiencies in the endoscopy centers of Central-Southern Italy.

Probably similar scenarios are present worldwide.

Despite all these limitations and deficiencies, the present survey outlines a picture of Italian endoscopy services in which the widespread dependence on anesthesiologic support, even for light sedations, aggravates the well-known lack of a dedicated team available daily. In fact, it is foreseeable that in a non-marginal part of cases, patients are not offered any form of sedation, or that endoscopic activities may suffer important limitations due to the lack of assistance. Again, it is conceivable that similar problems are encountered not only in Italy, but according to our knowledge this is the first structured survey on this field.

According to the results of our survey, the practice of the propofol administration by the endoscopist, assisted by a dedicated nurse and with a readily recruitable anesthetist, is very limited if not absent. Anyway, national experiences<sup>15</sup> of non-anesthetist propofol administration were published in the last years, in analogy with similar experiences worldwide<sup>16</sup>. However, it happens outside of any shared national procedure and in disagreement with regulatory statements of national and European medicines agencies, which clearly affirm that “in order to ensure patient safety and reduce the clinical risk



of moderate analgo-sedation with propofol, it is necessary that these procedures continue to be followed and managed by specialized anesthetists<sup>17</sup>. Actually, the debate is longstanding and has shown deep controversies among societies<sup>18</sup>. The practice of non-anesthesiologist-administered propofol sedation (NAAPS) is irregularly distributed and limited in the different countries<sup>19-20</sup>. Several studies<sup>21-23</sup> showed as NAAPS offers shorter recovery times and not significant higher adverse effects in comparison with other sedation regimens. However, NAAP sedations came at the cost of decreased patient and endoscopist satisfaction<sup>13</sup>, and its role in non-trial settings (in terms of improved patient satisfaction, increased patient turnover, improved safety of the procedures) should be demonstrated. In the setting of advanced endoscopic procedures and/or high-risk patients, anesthesia provider-administered sedation would indeed offer improved safety and efficacy, and there are not controversies among societies about this issue<sup>24</sup>. The GCP launched by SIAARTI and SIED, unique in the international panorama, raised a hard debate among endoscopists, some of them claiming the restrictive impact of the recommendations<sup>25-26</sup>. Data from the survey support the need to give clear rules and offer viable solutions in this growing field of activities.

It is unanimously recognized that NAAPS requires a specific training of the personnel involved, under the supervision of the anesthesia team<sup>6</sup>. Addressing this issue, in 2013, the European Society of Gastrointestinal Endoscopy (ESGE) and the European Society of Gastroenterology and Endoscopy Nurses and Associates (ESGENA) issued a joint position statement presenting the “European Curriculum for Sedation Training in Gastrointestinal Endoscopy”, aimed to organize training in gastrointestinal endoscopy sedation for non-anaesthesiologists<sup>27</sup>.

Despite this, the risk of a scarce awareness is quite high according to the results of our survey. In fact, only 12% of the sample recognized the existence of an institutional procedure for assigning privileges to the various non-anesthesia specialists for the management of procedural sedation, while 37% are not aware of it. Over two thirds of the respondents (67.2%) declared that no local institutional training courses have been organized for procedural analgo-sedation for non-anesthetists and nurses. As a consequence, NAAPS is still performed according to local experiences, and Propofol has continued to be the core of the discussion between societies at a scientific and regulatory level over the past 10 years<sup>28</sup>. Consequently, the defi-

nition of training course and maintenance of the skills, is one of the purpose of intersocietary GCP<sup>9</sup>. We think important to remind the words of Christian Werner, Andrew Smith and Hugo Van Aken on an invited commentary published on EJA in 2011: “anesthesiologists in every European nation have a unique opportunity to show leadership in shaping the practice of procedural sedation and in training sedation practitioners. Using our influence and expertise to create the right conditions for skilled sedation can only enhance the quality and safety of sedation practice throughout Europe. It would be unfortunate if fundamentalism and populism were to weaken our position as a profession<sup>16</sup>”.

### **Limitations**

A limitation of the study is that anesthesiologists and endoscopists has been separately contacted. We have the whole data but the respective percentages are not available. Therefore, a possible double response from the same center could have been reported, emphasizing the content of the answers. Nonetheless, 662 respondents in our opinion should show a realistic picture of the present situation.

### **Conclusions**

In conclusion, the survey is a useful tool because it outlines a reality that sees anesthesia as having important prerogatives, but probably not sufficiently structured to support the growing development of digestive endoscopy, and to meet the patient needs. In our opinion national surveys overcome the national borders if they deal with widespread issues, and offer worldwide valuable arguments of discussion among professionals, stimulating the proactive role of the anesthetists. It is essential to address the problem of procedural analgo-sedation in digestive endoscopy, especially from the organizational and training perspectives. Awareness and efforts of scientific societies and supervisory authorities are fundamental. We think that nowadays the exclusivity in propofol administration is probably anachronistic, but openness to others than anesthesiologists should be always guided according to patient safety. The argument of analgo-sedation in digestive endoscopy is felt strongly, as evidenced by the highly satisfactory feedback recorded by the respondents and should stimulate the search for cultural and educational models that go beyond guidelines and consensus not applicable in all circumstances and represent a starting point for future upgrades.

### Ethics Approval

This research accomplishes with all the international requirements for ethics in research. This article does not contain any studies with human participants or animals performed by any of the authors.

### Informed Consent

All subject involved in this survey expressed a previous consent to participate.

### Availability of Data and Materials

The data that support the findings of this study are available from the corresponding author upon reasonable request.

### Conflict of Interest

The authors declare no competing interests.

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