

## Review Article

# Italian Digestive Endoscopists and Anesthesiologists Publish a Joint Document of Good Clinical Practice: It was Time!

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## Introduction

The problem of sedation in Digestive Endoscopy (DE) has been a source of debate and controversy both within the world of endoscopists and anesthesiologists and this not only in Italy but in Europe and around the world. Finally the Italian Society of Digestive Endoscopy (SIED) was able to initiate a debate with Italian Society of Anesthesia Analgesia Intensive Care Resuscitation (SIAARTI) and produce a common document of Good Clinical Practice applicable to all Services of national, public and accredited private Digestive Endoscopy Centers, in which the Anesthesiologists Specialist (AS) should be present. Therefore, in this article, a summary of the document is proposed which, starting from the European guidelines of the two disciplines [1-3], wanted to outline appropriate and sustainable clinical-organizational paths, identifying the risks and the necessary skills, as well as the responsibilities, to guarantee the quality and safety of the diagnostic-therapeutic treatments offered in DE.

## Methodology

A Panel of experts was set up, made up of 5 representatives from each of the two Scientific Societies who shared the methodology, defined a series of "clinical questions" to which answers in terms of operative proposals. Then the group proceeded to carry out the Literature Review updated, to elaborate a Survey at the Italian Endoscopy Centers to have "current information" on clinical practices in ED, to prepare a document and submit it to the respective Councils and scientific boards.

## The Document

The document is divided into 7 points:

1. Definition of Sedation-Analgesia-Procedural, in ED.
2. Pre-procedural assessment and risk stratification of patients who are candidates for SAP in ED, defining the precautions to be activated (starting with the withdrawal times of solids and liquids).
3. SAP settings and minimum monitoring standards.
4. Responsibility profiles for SAP in ED. Definition of the role of the doctor of ED.

5. Drugs for sedation and definition of an appropriate use of Propofol for SAP.
6. Post-procedural control of the patient undergoing SAP, and management of possible complications.
7. Definition of the training path and maintenance of the skills of the candidate personnel to perform the SAP in ED.

As part of the document, the authors have introduced and shared some updated and appropriate standard concepts or approaches:

A first concept introduced is included in the definition of Procedural Sedation-Analgesia (PSA) which defines a condition obtained with a hypnotic and/or analgesic to make an effective diagnostic or therapeutic endoscopic procedure possible, ensuring that the patient is closely monitored to prevent potential adverse effects! The "PSA" definitively replaces the ambiguous concept and term of "conscious" or "alert" sedation as sedation always determines a reduction in the level of consciousness and from being conscious it can become deep even without the use of hypnotics. Another important concept is that the figure of the "non-anesthesiologist operator who becomes" Anesthesia provider", or sedo-anesthesia administrator, is also contemplated in the anesthesiological literature [4].

Is absolutely mandatory for the endoscopist who wants to sedate the patient that first of all defines the risk of the patient (ASA score) [5]. Based on this assessment, the endoscopist must decide who to sedate independently and who to submit to anesthesiologist assistance and clearly summarizes the criteria for candidacy for Non-anesthesiologist sedation (NAS).

Are reported and shared the minimum standards that are necessary to perform the SAP in security and also specifies which and how many human resources are required for the correct management of the SAP.

Furthermore, for the first time in the Italian context, the profiles of responsibility in sedation are declared and shared: it is the endoscopist who decides the type of drug/s and the dosage, but administration and monitoring are the responsibility of the nurse in a team that has obviously been trained for the monitoring and management of sedation [1,6,7].

With regard to sedation drugs in particular, the paragraph of the document addresses the problem of the use of Propofol in NAS. This problem which remains very controversial in the world but in particular in Italy where the Italian Drugs Agency (AIFA) has also recently expressed itself restrictively, reiterating that the use of Propofol remains the prerogative of anesthesiologists. Despite this, the panel based on the new knowledge/information and clinical evidence emerging from the current scientific literature [3,7-13] which demonstrates the safety of the drug if used with adequate training states that it is necessary to take into account the effective skills of the endoscopist teams, that if they are prepared for the administration of Propofol, in agreement with the AR of their own hospital they can choose to administer Propofol in the NAS. Particularly valuable then is the part of the document on the management of the possible complications of sedation which are all listed explaining the cause, prevention and possible treatment.

The training and maintenance of the skills of the candidate personnel to perform the SAP in ED is described in the last paragraph. but in reality is the “core” of the Document and of the problem of self-managed sedation by non-anesthesiologist. In fact, if the staff is trained according to the SAP program performed in NAS as proposed by the main scientific societies in the sector [6,14], it increases the safety of sedoanalgesia performed with all available drugs including Propofol.

## Conclusion

The document reports the position of the Panel of experts on some points summarized in a final “Take Home Message”:

- It is not possible to perform diagnostic and therapeutic endoscopic procedures without sedation
- Sedation today is Procedural Sedation-Analgesia (SAP) which defines a condition obtained with a hypnotic and/or an analgesic
- A pre-procedural assessment and risk stratification of the patients to be sedated in Settings appropriate to the recommendations of the Reference Guidelines is essential.

In accordance with the “Profiles of responsibility”, the endoscopy teams can autonomously sedate ASA1 and 2 patients for procedures that are not too long or too complex after adequate training provided by the Departments/Units of RA.

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