

Nursing management of deep sedation in digestive endoscopy: a narrative review

La gestione infermieristica della sedazione profonda in endoscopia digestiva: una revisione narrativa della letteratura

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ABSTRACT

Background: The "Italian Society of Digestive Endoscopy" (SIED) has published a document in which it reports the possibility of administering Propofol by gastroenterologists and endoscopy nurses adequately trained. In order to ensure the quality and safety of sedation when performed by non-anaesthetist personnel, specific and adequate training is needed to facilitate its correct implementation which must comply with the latest recommendations.

The purpose of this study is to verify the effectiveness and safety of deep sedation in endoscopy managed by nurses.

Methods: A narrative review of the literature was performed within the main biomedical databases such as MEDLINE, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Scopus, PsycINFO and Cochrane Central Register of Controlled Trials.

Results: The review process resulted in a total of 17 articles being eligible: all meeting the inclusion criteria. In the literature, nurse-managed deep sedation appears to be a widespread practice with a considerably high level of safety. For this to be possible, it is necessary for the nurse to be adequately trained and work according to specific protocols.

Conclusion: Deep sedation managed by a nurse with advanced skills in digestive endoscopy seems to be a practice that offers a satisfying level of safety, efficacy and efficiency for patients with mild-moderate anaesthetic risk.

Keywords: Sedation; Endoscopy; Nurse; Anaesthesia.



RIASSUNTO

Introduzione: La "Società Italiana di Endoscopia Digestiva" (SIED) ha pubblicato un documento in cui riporta la possibilità di somministrare il Propofol da parte di gastroenterologi e infermieri di endoscopia adeguatamente formati. Al fine di garantire la qualità e la sicurezza della sedazione quando eseguita da personale non anestesista, è necessaria una formazione specifica e adeguata a facilitarne la corretta attuazione che deve essere conforme alle ultime raccomandazioni.

Lo scopo di questo studio è verificare l'efficacia e la sicurezza della sedazione profonda in endoscopia gestita da infermieri.

Materiali e Metodi: È stata eseguita una revisione narrativa della letteratura all'interno dei principali database biomedici come MEDLINE, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Scopus, PsycINFO e Cochrane Central Register of Controlled Trials.

Risultati: Il processo di revisione ha portato a un totale di 17 articoli idonei: tutti conformi ai criteri di inclusione. In letteratura, la sedazione profonda gestita dall'infermiere sembra essere una pratica diffusa con un buon livello di sicurezza. Perché ciò sia possibile è necessario che l'infermiere sia adeguatamente formato e lavori secondo protocolli specifici.

Conclusioni: La sedazione profonda, gestita da un infermiere con competenze avanzate in endoscopia digestiva, sembra essere una pratica che offre un buon livello di sicurezza, efficacia ed efficienza per i pazienti con rischio anestetico lieve-moderato.

Parole chiave: Sedation; Endoscopy; Nurse; Anaesthesia.

REVISIONE DELLA LETTERATURA

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INTRODUCTION

Endoscopic procedures are often perceived by patients as invasive, annoying and painful procedures^[1]. To improve their acceptability and tolerability, it is possible to adopt different types of sedation^[2].

The most commonly used methods for endoscopic procedures are moderate sedation with Midazolam and Fentanyl and deep sedation with Propofol^[3].

Moderate sedation is often inadequate and can result in poor quality procedures^[4,5]. In turn, Propofol combines the properties of rapid action and short effect duration resulting in an ideal sedative for procedures such as those performed in endoscopy^[6]. Propofol appears to be the preferred type of sedation both by endoscopists^[7] and by patients compared to the use of Midazolam^[8,9].

The most described complications of deep sedation are apnoea, hypotension and short periods of hypoxia easily reversible in most cases^[10]. Serious adverse events are very rare^[11].

Propofol does not have an antidote like those available for narcotics and benzodiazepines therefore, several guidelines recommend it to be administered in the presence of anaesthetists^[12].

Over the past 20 years there has been an increase in the use of deep sedation in endoscopic procedures from almost 25% in 2007 to over 50% in 2015^[13] and an increase in endoscopic procedures of 200%-400%^[14]. Colonoscopy is the procedure that has seen the greatest increase in performing, due to colorectal cancer screening campaigns^[15,16]. In Italy too, the activity of endoscopies is constantly expanding, in 2017 alone 97,173 colonoscopies were performed^[16].

The available data about the administration of Propofol by an anaesthetist are highly variable between countries with 31% of cases in Switzerland^[17], 66% in Italy^[18], and 70% in the United States^[14].

In addition, its use is influenced by the reluctance of patients to undergo these procedures under moderate sedation^[19,20] with the effect that the assistance of the anaesthetist increases the costs^[21].

Given the associated economic burden, other options were explored, including Non-Anaesthesiologist Administered Propofol (NAAP)^[22].

To encourage NAAP, in 2010 and 2015 the European Society of Gastrointestinal Endoscopy (ESGE), the European Society of Gastroenterology and Endoscopy Nurses and

Associates (ESGENA) and the European Society of Anaesthesia (ESA) jointly published the first NAAP guidelines for gastrointestinal endoscopy^[23]. Also in Italy the "Italian Society of Digestive Endoscopy" (SIED) has published a document in which it reports the possibility of administering Propofol by gastroenterologists and endoscopy nurses adequately trained^[24].

The role of the anaesthesia nurse appears to be booming over the last 20 years^[25]. Nurse Administered Propofol Sedation (NAPS) was described for the first time in 2003^[26]. In 2011, 73% of Dutch nurses were responsible of administering Propofol during endoscopic procedures^[7] whereas in Italy this was limited to only a few centers^[27].

The practices of the NAAP and NAPS are still severely limited worldwide because at least 21 scientific societies disagree^[28].

The common objection made by anaesthetists and organizations representing them, is that the use of Propofol should be the prerogative of the anaesthetist^[29,30], despite evidence showing that deep sedation is safer than moderate sedation with benzodiazepines and opioids^[11].

In order to ensure the quality and safety of sedation when performed by non-anaesthetist personnel, specific and adequate training is needed to facilitate its correct implementation^[31,32] which must comply with the latest recommendations.

The purpose of this study is to verify the effectiveness and benefits of deep sedation in endoscopy managed by nurses.

METHODS

A narrative review of the literature was performed^[33]. The authors decided to base the research question on the acronym PIOM: population, intervention, outcome, method.

The research question, therefore, turned out to be: "Is deep sedation in patients undergoing digestive endoscopy safe and effective when managed by a specifically trained nurse?"

A literature review was carried out within the main biomedical databases such as MED-

LINE, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Scopus, PsycINFO and Cochrane Central Register of Controlled Trials.

The search string used included the following words combined with the Boolean operators AND and OR: (sedation OR Propofol OR anaesthesia) and (nurse-administered OR nurse anaesthetist OR nurs*) and (endoscopy).

Inclusion criteria

- primary, experimental studies;
- studies concerning the human species;
- studies with a publication date of less than ten years;
- studies in English and Italian.

Exclusion Criteria

- conference proceedings and literature reviews;
- studies that did not present nurses in the population;
- studies that did not have deep sedation as their main object;
- studies not related to digestive endoscopy.

After completing the literature search, four authors independently examined the list of works using an Excel database. In a first phase the titles and abstracts were read based on the previously established eligibility criteria, excluding the unsuitable articles. In case of disagreement, another author from the research group was asked to express their opinion.

In a second phase, the four authors read the full text of the relevant articles. In this way they were able to exclude those studies that did not agree with the study aim.

The following data were collected for each paper: title, authors, publication year, study design, objectives and summary of results. The main information of the relevant articles was organized in a data extraction table (**Table 1**).

Population	Patients undergoing digestive endoscopy with deep sedation administered by nurses
Intervention	Administration of deep sedation
Outcome	The administration of deep sedation by the nurse is safe and effective
Method	Narrative review

Table 1 - Studies in which deep sedation was administered by a nurse

ARTICLE TITLE, AUTHORS, YEAR	DESIGN OF THE STUDY	DESCRIPTION AND SAMPLE	OBJECTIVES	RESULTS
A randomized double-blind trial of anesthesia provided for colonoscopy by university degreed anesthesia nurses in Greece. Bostaki, M. et al. (2012)	Randomized, double-blind prospective study	n. 100 patients	Determine whether anaesthesia provided by a nurse during an endoscopic procedure is comparable in terms of safety and efficacy with moderate sedation.	Sedation during endoscopic procedures by a qualified anaesthesia nurse is a safe and effective practice as demonstrated by the low incidence of patients awakening during surgery and the absence of any pain memories, together with the high satisfaction level of gastroenterologists and nurses.
A retrospective study of nurse-assisted Propofol sedation in patients with amyotrophic lateral sclerosis undergoing percutaneous endoscopic gastrostomy. Kawa, C. et al. (2012)	Retrospective comparative study	n. 60 patients	Retrospectively compare PEG (Percutaneous endoscopic gastrostomy) placement via deep sedation and moderate sedation with NAPS.	There were significantly fewer desaturation events when using NAPS than with standard conscious sedation.
Incidence of sedation-related complications with Propofol use during advanced endoscopic procedures. Cofé, G. et al. (2010)	Prospective study	n. 799 patients	Verify the incidence of complications related to sedation with Propofol used by nurses, for advanced endoscopic procedures.	Propofol can be safely administered to patients undergoing advanced endoscopic procedures by properly trained nurses.
Moderate and deep nurse-administered Propofol sedation is safe. Jensen, J.T. et al. (2015)	Retrospective case-control study	n. 6.840 patients for 7.364 procedures	To evaluate the safety of deep sedation administered by nurses in selected patients undergoing endoscopic procedures.	The use of deep sedation practiced by NAPS is a safe method. The frequency of adverse events during intermittent deep sedation was comparable to that of moderate sedation.
Nurse-administered Propofol sedation for gastrointestinal endoscopic procedures: first Nordic results from implementation of a structured training program. Slagelse C. et al. (2011)	Descriptive, comparative study	n. 2.656 patients	Describe the NAPS training experience, evaluating differences in the protocols.	Sedation with propofol provided by properly trained nurses for selected patients is safe and associated with only a lower risk.
Nurse-administered Propofol sedation is safe for patients with obstructive sleep apnoea undergoing routine endoscopy: a pilot study. Adler, D.G. et al. (2010)	Retrospective study	n. 215 patients	Evaluate whether the use of NAPS with patients with documented obstructive apnoea is as safe as in moderate sedation.	Routine endoscopic procedures using sedation with propofol administered by nurses are safe in patients with obstructive apnoea with complication rates comparable to the use of moderate sedation.
Quality of sedation with Propofol administered by non-anaesthetists in a digestive endoscopy unit: the results of a one-year experience. López-Muñoz, C. et al. (2018)	Prospective study	n. 507 patients	Assess the quality, incidence and types of adverse events of sedation administered by non-anaesthetist personnel in an endoscopy unit.	Administration of Propofol by non-anaesthetist personnel is safe, if it is administered to appropriately selected patients.

ARTICLE TITLE, AUTHORS, YEAR	DESIGN OF THE STUDY	DESCRIPTION AND SAMPLE	OBJECTIVES	RESULTS
Safety Profile and Patient Satisfaction of the Routine use of Propofol in Gastrointestinal Endoscopy. Gurung, R.B. et al. (2014)	Prospective observational study	n. 203 patients	Evaluate customer satisfaction and safety profile in patients undergoing endoscopic examination with nurse-managed sedation under the supervision of an endoscopist.	Deep sedation for upper endoscopy can be safely administered by a trained nurse under the supervision of an endoscopist.
Sedation during endoscopic retrograde cholangiopancreatography: a randomized controlled study of patient-controlled Propofol sedation and that given by a nurse anaesthetist. Nilsson, A. et al. (2014)	RCT	n. 281 patients for 301 procedures	Evaluate the safety of Propofol administered by an anaesthesia nurse for ERCP, comparing it with moderate sedation.	Propofol sedation treated by anaesthesia nurses is superior in quality and adverse events to moderate sedation.
No increased risk of perforation during colonoscopy in patients undergoing Nurse Administered Propofol Sedation. Okholm, C. et al. (2013)	Retrospective study	n. 6.371 colonoscopies	Assess the risk of colorectal perforation in patients undergoing colonoscopy with NAPS deep sedation versus moderate sedation.	The risk of colonic perforation during colonoscopy was not significantly higher in patients undergoing NAPS than in patients undergoing moderate sedation. NAPS has reduced costs by improving efficiency.
Nurse administered Propofol sedation (NAPS) is more efficient than anaesthetologist administered sedation with Propofol (AAP) for endoscopic procedures in patients at low-intermediate anaesthetic risk. Riesco Lopez, J.M. et al. (2017)	Prospective cohort study	n. 1.165 procedures in 1.026 patients	Compare the cost-effectiveness of NAPS and anaesthetologist administered Propofol (AAP) in patients at medium-low anaesthetic risk (ASA I-III).	NAPS in endoscopic digestive procedures is as safe as AAP for patients with low to medium anaesthetic risk and is more efficient than AAP.
Propofol Sedation by the Nurse Under the Endoscopist's Supervision for Outpatient Colonoscopy: Impact on Safety and Endoscopic Unit Utilization. Aumpansub, P. et al. (2017)	RCT	n. 196 procedures	Evaluate the safety of Propofol versus traditional sedation (Midazolam and Meperidine) for outpatient colonoscopy (OC), by the nurse under the endoscopist supervision.	Sedation with propofol by a nurse under the supervision of the endoscopist is safe, particularly with a lower risk of cardiopulmonary adverse events.
Role of Endoscopic Ultrasound for Evaluating Gastrointestinal Tract Disorders in Pediatrics: A Tertiary Care Center Experience. Al-Rashdan, A. et al. (2010)	Retrospective study	n. 58 procedures in 56 patients	To report the safety and the impact of EUS and EUS-FNA (endoscopic ultrasound - fine needle aspiration) on the management of gastrointestinal tract disorders in children. A secondary objective was to evaluate the safety of NAPS sedation in this age group.	Using NAPS for procedures in adults offered faster sedation induction and greater patient satisfaction than conscious sedation with Midazolam and Meperidine. Furthermore, it reports about the safety and feasibility of NAPS for procedures in children.

ARTICLE TITLE, AUTHORS, YEAR	DESIGN OF THE STUDY	DESCRIPTION AND SAMPLE	OBJECTIVES	RESULTS
<p>Safety of Propofol administered by gastroenterologists and trained nurses in an endoscopy unit. A single center prospective study. García Aguilera, X. et al. (2015)</p>	<p>Prospective study</p>	<p>n.7707 procedures</p>	<p>Describe the experience on the safety and efficacy of Propofol administered by the medical and nursing staff in an endoscopy unit.</p>	<p>The use of Propofol administered by the endoscopist and assisted by the nurse is an effective and safe method of sedation that allows for a more comfortable exploration for both the doctor and the patient.</p>
<p>Sedation with Propofol controlled by endoscopists during percutaneous endoscopic gastrostomy. García-Suárez, C. et al. (2014)</p>	<p>Prospective study</p>	<p>n. 47 patients</p>	<p>To evaluate the efficacy and safety of propofol sedation administered by endoscopists for the percutaneous endoscopic gastrostomy procedure.</p>	<p>The results of this study seem to support the use of Propofol by non-anaesthetist personnel as a viable, safe and reliable option when performing advanced endoscopic procedures.</p>
<p>Safety of applying Midazolam-ketamine-Propofol sedation combination under the supervision of endoscopy nurse with patient-controlled analgesia pump in colonoscopy. Kayaalti, S. et al. (2018)</p>	<p>RCT</p>	<p>n. 60 patients</p>	<p>Compare the results of sedation with Midazolam-Ketamine-Propofol performed by a nurse and an anaesthetist during colonoscopy in terms of patient satisfaction and safety.</p>	<p>Sedation in patients with ASA II can be safely performed by an endoscopy nurse using the Patient Controlled Analgesia (PCA) pump under the supervision of an anaesthetist.</p>
<p>Endoscopist-directed Propofol administration versus anaesthesiologist assistance for colorectal cancer screening: a cost-effectiveness analysis. Hassan, C. et al. (2012)</p>	<p>Prospective study</p>	<p>/</p>	<p>Evaluate the potential benefit and drawbacks of an Endoscopist directed Propofol (EDP) policy for colonoscopy in a simulated colorectal cancer screening cohort.</p>	<p>The efficiency and convenience of training nurses for the administration of Propofol has been demonstrated.</p>

RESULTS

Initially, 400 studies were selected. Specifically, 266 in MEDLINE, 72 in CINAHL, 57 in Scopus, 2 in PsycINFO and 1 in Cochrane Central Register of Controlled Trials (**Table 2**). The review process resulted in a total of 17 articles being eligible: all meeting the inclusion criteria.

In the literature, nurse-managed deep sedation appears to be a widespread practice with a good level of safety^[34-40]. For this to be possible, it is necessary for the nurse to be adequately trained and work according to specific protocols^[35,40-42].

Several scientific papers have highlighted that with this practice it is possible to provide Propofol-based sedation to a good percentage of the population who performs screening endoscopies, particularly to patients who are in good health and can be classified according to the anaesthetic risk American Society of Anaesthesiologists (ASA) as I-III (mild-moderate)^[34,37,40,43].

The analysis also shows that it is possible to extend this practice to advanced procedures such as endoscopic retrograde cholangiopancreatography (ERCP) and endoscopic ultrasound (EUS), as the work of Gregory A. Coté et al. of 2010 proved. The study, which assessed the incidence of complications related to deep sedation by nurses during endoscopic procedures, found that in a sample of 799 patients, 12.8% had an episode of desaturation below 90%, 6% of cases required oxygen mask support but in no case oral-tracheal intubation^[41].

The 2010 study by Al-Rashdan A. et al not only confirmed the possibility of managing advanced procedures with NAPS, but also proposed it in the paediatric setting. In fact, all 58 endoscopies performed had been completed without any related complications to sedation^[44].

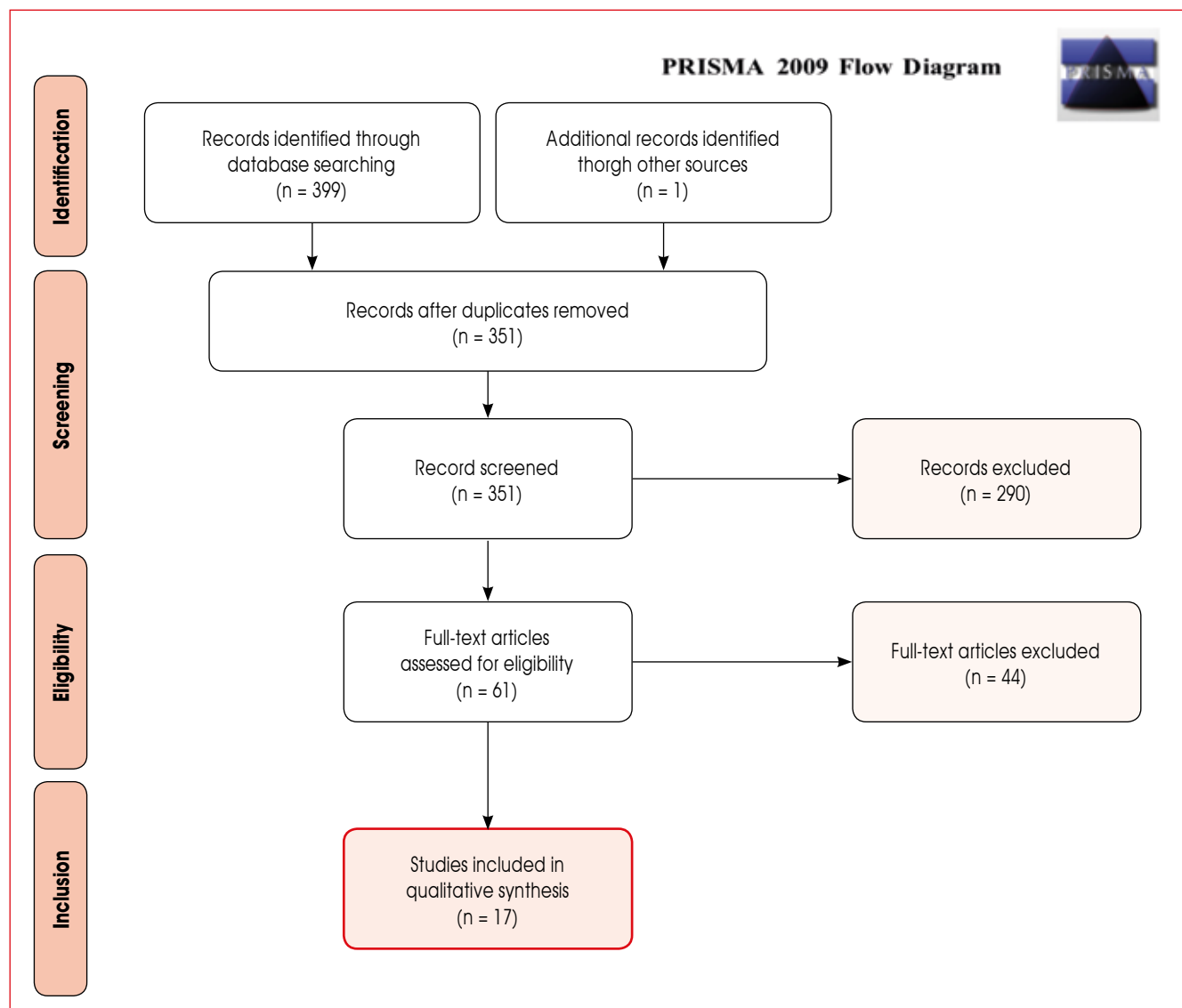
In the work of López-Muñoz, C. et al. in 2018 the quality, incidence, and type of adverse events related to sedation administered

by non-anaesthetist personnel were assessed in 507 patients who underwent an endoscopy. Twelve patients (2.4%) had hypoxemia events, resolved with subluxation of the jaw and increased oxygen flow with the use of nasal cannula without ever needing artificial respirator support or orotracheal intubation^[43].

In a retrospective study by Jensen J. T. et al. of 2015, with a sample of 7,364 endoscopic procedures, the safety of deep sedation administered by nurses in patients undergoing gastroscopies and colonoscopies was evaluated, comparing it with moderate sedation. The frequency of adverse events during intermittent deep sedation was comparable to that of moderate sedation with desaturation in 2.1% of cases. Respiratory failure occurred 6 times in all cases except one which was resolved by the endoscopy team before the arrival of the anaesthetist and therefore was not deemed serious^[34].

A cross-sectional study by Slagelse C. et al. of 2011 on 2,527 patients showed that 34

Table 2 - Study selection.



(2.8%) of those undergoing deep sedation managed by a nurse experienced a 30% reduction of blood pressure lasting less than 2 minutes. A total of 119 patients desaturated below 92%, manual ventilation was initiated in 22 patients and the help of an anaesthetist was required in 11 procedures^[40].

In a retrospective study by Adler, D.G. et al. of 2010 with a sample of 215 patients, of which 105 suffering from obstructive sleep apnoea (OSA), the desaturation rates below 90% were compared using deep and moderate sedation administered by a nurse concluding that no statistically significant differences emerged^[45].

When packing a percutaneous endoscopic gastrostomy (PEG) with NAPS and moderate sedation were compared, fewer desaturation events below 90% were detected when using Propofol^[39,46].

Deep sedation was also more effective in advanced procedures such as ERCP as demonstrated in an RCT by Nilsson, A. et al. of 2015 where nursing managed sedation with Midazolam and Propofol was compared. The work highlighted that the use of Propofol did not generate serious adverse events; in fact, desaturation over 90% has happened in 10 cases for a short period of time and it was promptly resolved by the nurse, whereas the use of Midazolam resulted in the patient having insufficient sedation in 20 procedures which reduced comfort during the exam and lengthened the duration.

In a study carried out in Greece in 2013 on 100 patients undergoing colonoscopy, nurse led deep sedation and moderate sedation were compared. The results conclude that sedation is a safe and effective practice as demonstrated by the low incidence of patient awakening during surgery along with the absence of pain memory compared to that recorded with moderate sedation; in addition, a higher degree of satisfaction was noticed among gastroenterologists and nurses when using deep sedation^[46].

Cost-effectiveness of utilizing NAPS was proven in a Danish retrospective study investigating the possible increase in the incidence of perforations during colonoscopy with NAPS compared to those performed with moderate sedation.

In a study by J. Lopez et al, which made a cost-effectiveness comparison in ASA I-III patients between NAPS and the anaesthetist's management of deep sedation, it was found that nurse-managed deep sedation is cheaper than that of the anaesthetist with the result of making the service offered more efficient^[37].

The efficiency of the NAAP was also described by the work of Hassan, C. et al. of 2012 in which the author hypothesized that the implementation of this policy would result in a

net saving of about 3 billion dollars in 10 years in the United States and about 1 billion in 10 years in France^[50].

The study by Kayaalti S. et al. of 2018 aimed to verify customer satisfaction and adverse events in a population of 60 patients sedated during a colonoscopy procedure by an adequately trained airway support nurse, using a "patient controlled analgesia" (PCA) pump, or by an anaesthetist. Both groups showed high satisfaction from patients with heart rate, blood pressure and spO_2 values that do not show significant differences ($P > 0.05$)^[51].

DISCUSSIONS

This narrative review of the literature suggests the efficacy and safety of deep sedation managed by nurses with advanced skills^[34,41].

These advanced skills could be achieved through several methods: to possess a recognized qualification of specialization in anaesthesia^[42,48,49] (e.g. be a Certified Registered Nurse Anesthetist); to be theoretically and practically trained for a period of 4-6 weeks (under supervision before the nurse could work more independently)^[35,41,49,50]; to take part in a short course where, in the end, you are proctored during the first procedures^[47]; to have a CD-ROM-based training course and an interactive educational session with a written and practical exam, once they pass it, they will be supervised by staff with experience in the use of propofol for the first 10-20 NAPS procedures^[46]; to take part in a 100-hour course divided into 80 hours administered through a virtual platform and 20 hours with theoretical and practical training^[44].

The studies show that standardization of deep sedation using protocols based on the most recent evidence allows the non-medical operator a procedural autonomy without additional risks but with adverse events that can be superimposed on usual care^[51,52,53].

Although Propofol appears to be a drug that can present even serious cardiopulmonary complications, no significant differences associated with administration by the non-medical operator (Registered Nurse, Advanced Practice Nurse) have been recorded^[36,38,43,45,54].

In addition, sedation with propofol managed by the nurse does not show changes in terms of the incidence of colon perforation during the colonoscopy procedure compared to the procedure administered by medical staff or in a moderate sedation regime^[49,55].

In support of the principal aim of this review, it is otherwise relevant that the operators employed in the perioperative phase are mainly the endoscopist and the nurse. Therefore, the administration of deep sedation

from a figure usually present in the operative phase allows a reduction of costs. In addition, there is a reduction of the time spent in the procedure room in the post-operative period in patients treated with Propofol allowing for a greater number of daily procedures^[48,56]. The reduction of healthcare budget is significant in the United States where the practice is consolidated with a decrease in costs with a range of 1 - 3 billion in 10 years^[50]. A day-surgery clinic recorded an average residence time of 18 minutes on 9.152 endoscopies if management of sedation is administered by the nursing staff over a procedural average of 30 minutes^[57].

Patients are also satisfied with the perceived quality of the anaesthesia procedure managed by the nurse given the reduction in post-operative admission time, resumption of basal functions and discharge in a day surgery setting^[43,44,48,54,58].

CONCLUSIONS

In conclusion, deep sedation managed by a nurse with advanced skills in digestive endoscopy appears to be a widely used practice that offers a good level of safety, efficacy and efficiency proven by the literature available to date. However, it is evident that the assistance to patients with high anaesthetic risk necessarily remains a competence of the anaesthetist.

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