

**University of Medicine and Pharmacy of Craiova**

**Doctoral School**

**PhD Thesis**

**Sedation assessment and  
monitoring for patients undergoing  
complex endoscopic procedures**

**Abstract**

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### **Key words**

Sedation, propofol, Non-anesthesiologist (nurse) administered propofol sedation (NAPS), endoscopic ultrasound (EUS), endoscopic retrograde colangiopancreatography (ERCP), advanced endoscopic techniques.

## INTRODUCTION

The types of endoscopic procedures have developed steadily over time, from the diagnostic interventions to complex therapeutic interventions. Advanced procedures include ultrasound endoscopy (EUS), endoscopic cholangiopancreatography (ERCP), endoscopic submucosal dissection (ESD), peroral endoscopic myotomy (POEM), stenting (esophageal, duodenal and colonic), enteroscopy, etc.

Currently, the majority of the endoscopic procedures, diagnostic or therapeutic, are performed under sedation in most centers [1,2]. Consequently, the number and complexity of examinations increased, sedation reducing the patients' anxiety and discomfort, as well as improving the quality of interventions [1-3].

The level of sedation and the drug types depend on a variety of factors, both on the patient's characteristics (age, comorbidities, preferences, ) and on the type of procedure to be performed (standard endoscopy or complex procedures). Sedation varies and includes varying degrees, from minimal and moderate sedation to deep sedation and general anesthesia [4]. Conscious sedation involves intravenous administration of the pharmacological agents that reduce the level of consciousness to a state of drowsiness, relaxation but the patient breathes spontaneously and he does not need intubation or mechanical ventilation. Also, conscious sedation provides adequate heart rate, the possibility of communicating with the medical team and responding to verbal commands [5,6].

The current guidelines support the use of propofol over the use of benzodiazepines and/or opioids, as it offers both patient and doctor safety and satisfaction, reduces the time allocated to the procedure and allows the prompt awakening; therefore propofol becomes the preferred induction agent as it is easy to administer, the patient recovers quickly and has a low rate of occurrence of side effect [2].

The use of intravenous sedation methods on a larger scale has led to an increase in the demand for qualified medical personnel who can correctly evaluate the patient pre-procedural and who can promptly intervene in the patient's benefit, before complications [7].

Thus, propofol administration by another team member, other than the anesthesiologist, "Non-anesthesiologist (nurse) administered propofol sedation" (NAPS) has become a viable option and studies have shown that the procedure is equally safe.

The chief coordinating nurses from endoscopy lab can implement educational programs to train for NAPS techniques.

# PERSONAL CONTRIBUTIONS

## *MATERIAL AND METHOD*

The study was conducted within the Center for Research in Gastroenterology and Hepatology, University of Medicine and Pharmacy of Craiova and the Digestive Endoscopy Department of the Clinical Emergency County Hospital in Craiova and included 2 groups of patients who underwent interventional endoscopic procedures.

Endoscopic procedures (upper digestive endoscopy, colonoscopy, endoscopic ultrasound, retrograde endoscopic cholangiopancreatography) were performed by gastroenterologists. These procedures were performed using standard techniques and followed the routine protocol.

*Study 1* included 192 patients who underwent interventional endoscopic procedures between January 2014 and December 2014 (130 EUS and 62 ERCP). Of the total number of patients, 110 were sedated only with propofol, without any other complementary medication. Adverse events during the procedure were minor. During the procedure we encountered only minor adverse events. Hypoxia and hypotension were recorded to elderly patients who needed assisted ventilation, according to the American Anesthesia Society (ASA) classification and the total dose of propofol.

*Study 2* included 552 patients who underwent both upper and lower digestive endoscopies and endoscopic ultrasound, at the Research Center in Gastroenterology and Hepatology, from September 2015 to February 2016. For all examinations, patients received sedation with propofol. Another group consisting of 552 patients, including both patients admitted to the Craiova County Emergency Clinical Hospital and outpatients who were examined during the same timeframe, represented the control group of the study.

Patients were monitored and supervised for 4-6 hours after the procedure by endoscopy nurse and they remained in the endoscopy unit until they regained consciousness, which was defined as the ability to maintain a lucid conversation. The endoscopy nurse was responsible for the accurate and complete information received by the patients and their family members, both verbally and in written form, regarding the procedure and possible side effects of sedation. At the end of the examination, these sedation-related events were noted by the nurse in a questionnaire [8].

Patients were included in a database that included general identification data, medical history, clinical and paraclinical data, information about treatment and survival. All patients received an informed consent form, the explorations being carried out in accordance with the Declaration of Helsinki on the Ethical Principles of Medical Research involving Human Subjects, mentioned on the World Medical Association website.

#### *Statistical analysis*

Descriptive statistical analysis methods were used to carry out these studies. The distribution of the continuous variables was reproduced using the means and standard deviations. The distribution of categorical variables was described using frequencies and percentages. Fisher's exact test or chi-square was performed to evaluate associations between categorical variables and a P value < 0.05 was considered statistically significant. Statistical analysis was based on the "N-1" Chi-squared test as recommended by Campbell (2007) [11] and Richardson (2011) [12]. Safety intervals were calculated according to the method recommended by Altman et al. (2000) [13]. Moreover, the calculator was used to calculate the proportions, based on Medcalc statistical software (Medcalc Software, Ostend, Belgium).

## **RESULTS**

### *Study I*

The aim of the first study was to evaluate the safety profile of propofol sedation in endoscopy as well as the efficiency and the role of the endoscopy nurse involved in patients care to undergo interventional procedures under propofol sedation and in the same time trained for NAPS techniques in a complex multidisciplinary medical team.

The average age of the 110 patients included in the study was about 60 years, 46 (41.8%) of them being women and 64 (58.2%) men.

During the examinations, several side effects were recorded, including : short-term hypoxia in 4 patients (3.6%), 7 patients (6.4%) required nurses intervention and secretion drainage and 1 patient (0.9%) was ventilated on the mask. A decrease in systolic blood pressure was recorded in 2 patients (1.8%), as was bradycardia (1.8%). Only one procedure (0.9%) was discontinued, the patient requiring orotracheal intubation.

Of the total number, 90 patients (81.8%) had no side effects after the procedure. The other 20 patients (18.2%) had the following problems related to sedation : 5 patients (4.5%) were more drowsy, 3 patients (2.8%) had nausea, 1 (0.9%) patient presented vomiting.

Also, 2 (1.8%) patients had dizziness, 2 (1.8%) headache, 3 (2.8%) coughed, one patient (0.9%) had an allergic reaction at the injection site, one (0.9%) presented with chills and another 2 (1.8%) had mild bradycardia.

## ***Study 2***

The purpose of the second study was to evaluate the quality of endoscopic procedures and to measure patient satisfaction by using a modified version of the GESQ questionnaire. The endoscopy nurse provided the satisfaction questionnaire to all patients, 2 hours after the procedure. Also, the study highlighted the benefit of sedation with propofol, the differences between the group of patients who received sedation and the non sedation group, were significant, with considerable differences between the satisfied and less satisfied patients.

Of the 552 patients who answered the questionnaire, 192 ( 34,7%) performed gastroscopies, 288 (52,1%) colonoscopies and 72 (13,2%) EUS, including endoscopic therapeutic procedures such as polypectomies, mucosectomies (EMR) or EUS guided fine aspiration needle (EUS-FNA).

Regarding the general level of satisfaction, 476 (86,2%) were very satisfied or satisfied, 69 (12,5%) were not satisfied and 7 (1,3%) did not have no answer.

The questionnaire proved to be usefull in receiving patient's feedback, as well as good overall patient satisfaction, regarding the endoscopy unit where they were examined and helped us to overall improve communication, time management and reorganization of the recovery area. Also, propofol sedation seems to be mandatory in order to improve patient satisfaction, differences between the patients who received sedation and those not sedated are significant.

Statistical differences between patients who were sedated with propofol and the group who did not receive sedation were calculated and displayed in Table 1.

	<b>Sedation</b>	<b>No sedation</b>	<b>P-value</b>
<b>Total</b>	<b>552 (100%)</b>	<b>552 (100%)</b>	
- Upper digestive endoscopy	192 (34.7%)	202 (36.6%)	P=0.5101
- Lower digestive endoscopy	288 (52.1%)	285 (51.6%)	P=0.8680
- Ultrasound Endoscopy	72 (13.2%)	65 (11.8%)	P=0.4821
<b>General satisfaction</b>			
- <b>Satisfied</b>	<b>476 (86.2%)</b>	<b>283 (51.3%)</b>	<b>P&lt;0.0001</b>
- <b>Dissatisfied</b>	<b>69 (12.55)</b>	<b>244 (44.2%)</b>	<b>P&lt;0.0001</b>
- <b>Indifferent</b>	7 (1.3%)	25 (4.5%)	P=0.0015
<b>Comunication</b>			
- <b>Satisfied</b>	<b>508 (92%)</b>	<b>433 (78.4%)</b>	<b>P&lt;0.0001</b>
- <b>Dissatisfied</b>	<b>16 (3%)</b>	<b>84 (15.2%)</b>	<b>P&lt;0.0001</b>
- Indifferent	28 (5.1%)	35 (6.3%)	P=0.3901
<b>Procedure</b>			
- Long waiting time	11 (2%)	17 (3.1%)	P=0.2466
- <b>pain / discomfort</b>	<b>29 (5.2%)</b>	<b>78 (14.1%)</b>	<b>P&lt;0.0001</b>
- Long recovery	35 (6.3%)	28 (5.1%)	P=0.3901
<b>The environment</b>			
- <b>Low comfort / intimacy</b>	<b>13 (2.3%)</b>	<b>88 (15.9%)</b>	<b>P&lt;0.0001</b>
- Poor hygiene	17 (3.1%)	32 (5.8%)	P=0.0297
<b>Team skilss</b>			
- <b>Excelent</b>	<b>514 (93.1%)</b>	<b>261 (47.2%)</b>	<b>P&lt;0.0001</b>
- Well	<b>22 (4%)</b>	<b>209 (37.9%)</b>	<b>P&lt;0.0001</b>
- Weak	<b>16 (2.9%)</b>	<b>82 (14.9%)</b>	<b>P&lt;0.0001</b>

Tabel 1. Statistical differences between patients who were sedated with propofol and the group who did not receive sedation

## ***CONCLUSIONS***

- Propofol controlled sedation seems to be the preferred option nowadays, due to the shorter time of action and the rapid awakening, with fewer side effects, respectively, increasing the level of satisfaction of patients and medical staff.
- Sedation in the digestive endoscopy is used more and more, because it determines the quality of the examination. Also, in the case of complex procedures, such as endoscopic ultrasound (EUS) and retrograde endoscopic cholangiopancreatography (ERCP), it contributes to the success of the procedure.
- The endoscopic procedures under sedation are performed after a correct and complete anamnesis of the patient, with standardized monitoring (pulse oximetry, electrocardiogram and blood pressure measurements). However, endoscopy is still performed without sedation in some centers, due to the lack of trained staff and inadequate infrastructure, leading to a decrease in patient satisfaction.
- Our studies revealed that the main complications that appeared in the sedated patients during the endoscopic procedures were insignificant and include the following: hypoxia, decreased systolic blood pressure, bradycardia, drowsiness, nausea.
- Our first study highlighted that a medical team consisting of anesthesiologists and endoscopy nurse can manage the procedures such as EUS and ERCP to be carried out safely. The dedicated endoscopy nurse with experience in both endoscopy and patient's monitoring and surveillance may intervene in time to prevent any complications related to sedation during and after endoscopy, with only one endoscopic procedure that had to be terminated.
- Our second study focused on the efficiency and utility of sedation with propofol, proving significant differences between the group of patients who received sedation and those who did not. The data obtained from the questionnaires, lead to an important feedback which helped us improve the standards in the endoscopy unit, such as communication, better time management and reorganization of the recovery area.
- Despite all the benefits of sedation during endoscopic procedures and implicitly increasing the number of patients who prefer endoscopic intervention under sedation, in the general context of the insufficiency of anesthesiologists, anesthesia given by another medical team member remains a debate.



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