Original Article


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Running Title: Variability of sedation practices in Europe

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Conflict of Interest

The authors declared no conflict of interest pertaining to this paper.
ORIGINAL ARTICLE


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ABSTRACT

Background / Aim: The use of moderate to deep sedation, being risky medical procedures, for gastrointestinal endoscopic procedures has increased in Europe considerably. A number of international guidelines have been developed. This survey aims to review if, and if so which quality aspects have been included in new sedation practices, when compared to traditional uncontrolled sedation practices.

Methods: A questionnaire was sent to the National Associations of Nurse Anaesthetists in Europe and the National Delegates of the European Section and Board of Anaesthesiology from January 2012 to August 2012.

Results: Huge variation in practices for moderate to deep sedation were identified between and within European countries in terms of safety, type of practitioners, responsibilities, monitoring, informed consent, patient satisfaction, complication registration and training requirements. 75% of respondents were not familiar with international sedation guidelines. Safe sedation practices (mainly propofol based moderate to deep sedation) are gaining popularity rapidly.

Conclusions: Moderate to deep sedation, being a risky medical procedure, has become common practise for gastrointestinal endoscopy. Safe sedation practices requiring adequate selection of patients, adequate monitoring, training of sedation practitioners and adequate after care, are gaining in a field which is in transition from uncontrolled sedation care to controlled sedation care.

Key Words
Moderate to deep Sedation, Gastrointestinal Endoscopy, Guidelines, Patient Safety
INTRODUCTION

Since Basil Hirschowitz\textsuperscript{1-2} invented a useful flexible endoscope in 1958, which was further developed later\textsuperscript{3}, gastrointestinal (GI) endoscopy has grown from a simple diagnostic procedure to complex time consuming diagnostic and therapeutic invasive interventions. These procedures may be painful and unpleasant to undergo. Although sedation for these procedures is traditionally part of the quality and safety domain of the specialty of anaesthesia, the capacity of anaesthesiologists is too limited to meet the increasing demand for sedation care in most countries, causing the development of solutions where quality and patient safety have not been the primary drivers.

Moderate to deep Procedural Sedation and Analgesia (PSA) by long acting sedative drugs has been more and more replaced by a combination of propofol or benzodiazepines (midazolam) and/or a short acting opioids for use in patients undergoing gastrointestinal endoscopic procedures outside the operation room area. High quality sedation reduces anxiety and discomfort for the patient and improves the quality of the examination or therapy during these procedures. Moderate to deep sedation procedures are potentially risky and have to be carried out by trained professionals under specific safety conditions to achieve a high level of quality, safety and comfort.

The present study was conducted to evaluate, in how far Controlled Sedation Care (CSC) practices have been implemented when compared to traditional Uncontrolled Sedation Care (USC) practices, during gastrointestinal endoscopy (Endoscopic Retrograde Cholangio Pancreatography, colonoscopy and esophago-gastro-duodenoscopy), following the publication of the European\textsuperscript{4-5} guidelines, issued in 2010 for moderate and deep sedation.

Therefore we carried out an online survey (Appendix A), under the National Associations of Nurse Anaesthetists in Europe and the National Delegates of the European Section and Board of Anaesthesiology.

MATERIALS AND METHODS

Definitions

In contrast to light sedation using small doses of midazolam (1-3 mg) traditional Uncontrolled Sedation Care (USC) is defined as moderate to deep sedation procedure\textsuperscript{6-7-8} (usually benzodiazepines with or without opioids) carried out by a person\textsuperscript{9} who may have other responsibilities during the
procedure at the same time. Characteristic is the use of more or less fixed dose protocols for sedatives and/or opioids and a variety of patient monitoring.

Controlled Sedation Care (CSC) is defined as moderate to deep sedation (usually using propofol with or without opioids). CSC is characterized by formal screening of the health status of the patient and is carried out by a trained and certified (MD or nurse) sedation practitioner, whose sole responsibility is, the execution of the sedation procedure and personal observation and standardized monitoring (pulse oximetry, ECG, NIBP) of the patient during the procedure, the recovery and discharge according to formal discharge criteria and after care.

Survey design.

Light, moderate and deep sedation guidelines were defined according to international definitions\textsuperscript{10-11-12} and a 5 chapter, 21-items questionnaire (Appendix A) was developed for the study in accordance with a collaborative effort from representatives of the European Society of Gastrointestinal Endoscopy (ESGE), the European Society of Gastroenterology and Endoscopy Nurses and Associates (ESGENA) and the European Society of Anaesthesiology (ESA). Participants were asked to answer questions pertaining to compare USC versus CSC during gastrointestinal endoscopy against the background of the implementation of recent sedation guidelines. Questions were formulated about demographics, sedation technique, the sedation practitioner, patient monitoring, complications, training, informed consent and patient satisfaction. Patient satisfaction quality indicators have been described as: amnesia, the patient’s opinion, no-pain after the procedure, quick recovery and patient comfort. Respondents were requested to indicate the content of skills training program for the sedation officer for USC and CSC. The international online linked survey was performed from January 2012 until August 2012. The electronic mail addresses of the National Associations of Nurse Anaesthetists in Europe\textsuperscript{13} and the European Section and Board of Anaesthesiology\textsuperscript{14} were provided by both organizations. Efforts to increase the response rate were carried out by sending reminders twice by electronic mail by the investigator.
RESULTS

Demographics

A total of sixty eight surveys (Appendix A) were sent to multiple addresses in Europe by electronic mail: 18 surveys to the National Associations of Nurse Anaesthetists in Europe (Austria, Bulgaria, Czech Republic, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, The Netherlands, Norway, Poland, Slovak Republic, Spain, Sweden, Switzerland, UK) and 50 surveys to the national delegates of the European Section and Board of Anaesthesiology. Our data were basically retrieved from anaesthesiology-associated respondents. Thirty-three (response rate 48.5%) contributors completed the survey. Respondents were from Spain, Italy, The Netherlands, Germany, Austria, Poland, France, Switzerland, Belgium, Bulgaria, Czech Republic, England, Luxembourg, Norway, Portugal, and Sweden. Two contributions did not mention their country of origin.

Patients served by Uncontrolled Sedation Care and Controlled Sedation Care

Seven countries (Belgium, Czech Republic, England, Italy, Norway, The Netherlands and Sweden) indicated that 50% and more patients were served by USC for gastrointestinal endoscopy procedures, usually a combination of midazolam and a short acting opioid. Eight countries (Austria, Bulgaria, France, Germany, Poland, Portugal, Spain and Switzerland) indicated that more than half of the patients were served by CSC care, usually a combination of propofol and/or a short acting opioid, for a GI endoscopy procedure (Table 1).

The sedation practitioner

The person who performed the sedation procedure differed from country to country, within countries and within hospitals. Both, anaesthesiologists (MD), nurse anaesthetists, endoscopists (MD), endoscopy assistants being supported or supervised by endoscopists (MD), physician assistants and other health care personnel, being trained in the art of sedation or not formally trained, provided moderate to deep sedation. The anaesthesiology department is finally medical responsible for moderate to deep sedation and as Sweden an exception. Sedation is confined to anesthesiologist in Bulgaria, Czech Republic, Luxembourg and Portugal (Table 2).
Patient monitoring

Survey respondents providing CSC during GI endoscopy indicated that routinely one or more vital signs in all patients were monitored. During USC was pulse oximetry frequently monitored. The respondents indicated routine monitoring of pulse oximetry and heart rate (100%), Non-Invasive Blood Pressure (NIBP) (94%), Electrocardiography (ECG) (59%) and capnography (47%) or a combination during CSC procedures (Table 3).

Routine monitoring in the recovery room after a CSC procedure consisted of pulse oximetry (100%), heart rate and NIBP (94%), ECG (53%) and capnography (24%) and combinations in Europe (Table 4).

Informed consent and patient satisfaction

Both, in the USC group and in the CSC group, informed consent for the sedation procedure was obtained in 65% of the patients.

CSC services, adherence to guidelines

Survey respondents were asked about the “24 hours a day, 7 days a week”, sedation service for GI endoscopy. 44% of the respondents reported that such a service was available. In other hospitals urgent endoscopic procedures out of office hours were performed under general anaesthesia. Adherence to the European International guidelines for sedation was variable. About 25% of the respondents indicated to adhere to (inter-) national sedation guidelines for moderate to deep sedation. 75% of respondents indicated not to be familiar with these guidelines.

Complication registration

The majority (60%) of the respondents reported to have organized a patient complication registration data system when CSC was performed. Those who did not register complications cited the following reasons: no database available, no sufficient staff to register complications and no protocol to register complications.

Skills Training Program
In both groups, the responsible sedationists for USC and CSC had been trained in Basic Life Support (BLS) (88%). 53% of sedationists in the USC group had undergone Advance Cardiac Life Support (ACLS) training whereas 80% of the CSC group had done so. Basic Airway Management training (BAM) has been taught to 76% of USC practitioners, in contrast to 88% of the CSC sedation nurses. For further skills training program data see Figure 1.

DISCUSSION

The technical advances in diagnostic and therapeutic procedures particularly in gastroenterology have caused an exponential increase in these procedures in the last few decades. These procedures frequently require cooperation from the patient, are not pleasant to undergo and patients more and more require support and comfort to cooperate. Moderate to deep sedation is able to meet these requirements.

The best methods for moderate to deep sedation during gastrointestinal endoscopy are still a matter of debate, depending on the quality indicators (patient comfort, safety, working conditions for the endoscopist, budget impact) considered. Taking into account the widely known shortages of medical anaesthesia personnel in Europe to provide sedation care, alternative solutions to meet the sharply rising need for adequate sedation have been introduced in many European countries, not always taking quality and safety but efficiency and efficacy as starting points or as primary drivers. This has caused (partly) unnecessary morbidity and mortality related to sedation. Moderate to deep sedation is a risky medical procedure, even when performed by trained and qualified sedation staff.

Therefore considerable attention must be focussed on adequate selection of patients and on close monitoring of vital parameters, particularly when undertaking long-lasting interventions and emergency procedures.

Separate from the endoscopist, at least, a well-trained sedation professional should be responsible for clinical and instrumental monitoring of the patient during gastrointestinal endoscopy as recommended at the international sedation endoscopy workshop in 2009.

In Europe, in particular the debate on propofol-based sedation is strongly influenced by different legislation between countries and reimbursement matters and unfortunately not always by quality arguments.
The use of propofol for moderate to deep sedation by non-anaesthesiologists and by non-medical health care personnel is a matter of debate in many countries and various arguments are used.\textsuperscript{25} The properties of propofol as a hypnotic in anaesthesia are well known and a vast experience has been gained in handling the side effects of propofol overdosing. The use of propofol for moderate to deep sedation, however, is a titration technique, which is essentially different from its use as a hypnotic and requires new and different skills from the sedation practitioner, when compared to propofol when used for general anaesthesia. Fortunately numerous examples are available which show that non-anaesthesiologist sedation practitioners, when properly trained, can handle propofol as a sedative appropriately and safely.\textsuperscript{26-27}

Additional risk factors caused by the co-morbidity of the patients and the nature of the endoscopic procedure play important roles in determining whether the support of an anaesthesia team is needed for moderate to deep sedation. We found in our survey a huge variability in sedation practices, which could not be attributed to differences of pure medical origin. The conclusion must be that other factors than quality or patient safety were responsible for the variation of practices, while especially for moderate to deep sedation as risky procedures for risk patients, quality and safety should be leading.

Our survey among the National Associations of Nurse Anaesthetists in Europe and among the National Delegates of the European Section and Board of Anaesthesiology shows that in particular the debate on propofol-based sedation is strongly influenced by different legislation between countries and reimbursement matters and unfortunately not always by quality arguments.

Our survey clearly shows the wide variability of practice for moderate to deep sedation, of the variable skills of sedation practitioners, of the final medical responsibilities and of quality standards of care for a procedure with an established morbidity and mortality. This situation is typically characteristic for a transition period, where first practical solutions have been devised for a rapidly increasing need for moderate to deep sedation, to be followed by quality measures to make sedation safe. The need for quality in sedation means that more and more health care authorities are taking steps to control implementation processes for sedation and maintain quality standards by law.\textsuperscript{28} Sedation as a risky medical procedure requires adherence to medical protocols aiming at comfort and safety for patients, at the development of training programs for sedation practitioners, at adequate screening of patients, at adequate and safe monitoring and at appropriate after care of patients.
Moreover, it becomes clear that the general public more and more refuses to accept medical procedures to be unnecessarily uncomfortable or painful.\textsuperscript{29-30} Generally, speaking according to the data of our survey, CSC care was slightly more prevalent than the USC in highly complex interventional GI endoscopic procedures such as ERCP and others. The time needed to treat these patients efficiently, tends to be much longer than the time required for conventional GI endoscopy procedures such as colonoscopy. In these complicated cases, sedation is therefore carried out aiming at inducing a state of deep sedation.\textsuperscript{31} At this consciousness level, patients may respond to repeated or painful stimuli, but spontaneous respiration could be unstable and insufficient. The risk to develop serious complications is considerable if strict quality and safety measures are not met. Unfortunately CSC 24/7 service is limitative implemented. The reasons for not providing a “24 hours a day, 7 days a week” CSC care were; no demand for outside of normal working hours, sedation service only available for elective cases and no manpower. Overall, patient satisfaction was monitored in 14% of the cases this according to the findings of Staff et al.\textsuperscript{32}

Taking into account, the variability of medico legal rules and legal restrictions in many European countries, the responsibility for sedation procedures also varies widely and lies with anaesthesiologists, nurse anaesthetists, gastroenterologists, endoscopic assistants, physician assistants, emergency physicians, sedation practitioners and more. Other differences may be caused by factors such as the organisation of health care, as the availability of training programmes for sedation professionals, as the anaesthesiologist work force and as reimbursement. Factors such as available equipment and expectations and demands from the patients might have played a role as well. A European Society of Gastrointestinal Endoscopy (ESGE)\textsuperscript{33} survey amongst its members some 6 years before our study reported that in about 50% of ESGE related countries, still less than 25% of patients were sedated for routine diagnostic upper gastrointestinal endoscopy. Our study, although its methodology was different, conducted in 2012 shows that the application of CSC in gastro endoscopy has increased considerably when compared to the ESGE 2006 data.

An encouraging observation from our survey is that instrumental monitoring seems to be applied more abundantly than in 2006, contributing to patient safety.\textsuperscript{34} This is probably caused by the reflection of the risks associated to moderate to deep sedation.\textsuperscript{35-36-37} It is imperative to develop uniform definitions of sedation and complications. This is important for the discussion to make sedation procedures safe, comfortable and of high quality. The study has some important limitations with restrictive
consequences for our conclusions. Our data were basically retrieved from anaesthesiology-associated respondents. Data gathered from the gastroenterologists may produce a different image. However, true national data on sedation are virtually impossible to uncover, because databases on sedation procedures are lacking in virtually all-European countries.

CONCLUSION

In conclusion, in this survey, conducted in anaesthesia professionals, we showed a considerable variability of the practice of sedation in European countries. Notwithstanding the presence of international guidelines, the lack of formal implementation processes has limited the development of uniform policies of sedation, obstructing comparative scientific research into quality and outcome of sedation.\textsuperscript{38-39} For a risky medical procedure such as moderate to deep sedation further improvement of quality by harmonisation of practices will contribute to quality, patient safety and comfort. The international guidelines were translated into medical practice to a very limited extent. Through this study, it becomes clear that there many changes are taking place in sedation practices in Europe, but much remains to be done to ensure maximum safety of the sedated patient.

Conflicts of Interest
This research was not supported by any funding source

ACKNOWLEDGMENTS
A kind word of thanks, to the European National Associations of Nurse Anaesthetists and the European Section and Board of Anaesthesiology for their willingness to fill in our survey.
ABBREVIATIONS
American Society of Anesthesiologists Score (ASA)
American Association of Nurse Anesthetists (AANA)
Controlled Sedation Care (CSC)
European Society of Anaesthesiology (ESA)
European Society of Gastroenterology and Endoscopy Nurses and Associates (ESGENA)
European Society of Gastrointestinal Endoscopy (ESGE)
Electrocardiography (ECG)
Gastrointestinal (GI)
Non-Invasive Blood Pressure (NIBP)
Procedural Sedation and Analgesia (PSA)
Society of Gastroenterology Nurses and Associates (SGNA)
Uncontrolled Sedation Care (USC)
REFERENCES


14. Personal communication. The European Section and Board of Anesthesiology is the Anesthesiology branch of UEMS (European Union Medical Specialities) dealing primarily with Anesthesia and Resuscitation, as well as Intensive Care, Emergency and Pain Medicine. Available at http://www.eba-uems.eu.


FIGURE LEGENDS

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Table 4: Monitoring during recovery after CSC GI endoscopy

Figures
Figure 1: Skills Training Program
### Table 1: Patients served by USC or CSC care

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### Abbreviations

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<td>Table 2: Sedation Practitioner healthcare professional performing CSC during GI endoscopy</td>
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**Abbreviation:**

★ Sedation: confined to anesthesiologist
CSC Controlled Sedation Care
GI endoscopy Gastro Intestinal endoscopy
### Table 3: Routinely patient CSC monitoring during GI endoscopy

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**Abbreviations**

NIPB: Non-Invasive Blood Pressure  
ECG: Electrocardiography  
CSC: Controlled Sedation Care  
GI endoscopy: Gastrointestinal endoscopy
Table 4: Monitoring during recovery after CSC GI endoscopy

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Abbreviations

NIBP: Non-Invasive Blood Pressure  
ECG: Electrocardiography  
CSC: Controlled Sedation Care  
GI endoscopy: Gastro Intestinal endoscopy
FIGURE

Figure 1:
Skills Training Program

- Basic Life Support
- Advance Cardiovascular Life Support
- Basic airway management
- Treatment respiratory problems
- Pharmacology
- Total endoscopy patient care
- Sedation theoretical and practical course

In percent

0 20 40 60 80 100

Controlled Sedation Care
Uncontrolled Sedation Care
Appendix A

1. What % of patients are served by Uncontrolled Sedation Care (benzodiazepines with opioids) for diagnostic and therapeutic gastrointestinal (ERCP, Colonoscopy, esophagi-gastro-duodeno scope) procedures in your country

< 25 %
25 - 50 %
50 - 75 %
> 75 %
I do not know
Other (please specify)

2. What % of patients are served by Controlled Sedation Care (Propofol with opioids) for diagnostic and therapeutic gastrointestinal (ERCP, colonoscopy, esopha–gastro–duodenoscopie) procedures in your country

< 25 %
25 - 50 %
50 - 75 %
> 75 %
I do not know
Other (please specify)

3. Which DRUGS do you use for sedation during diagnostic and therapeutic gastrointestinal procedures in your country: (More answers are possible)

Midazolam
Diazepam
Meperidine
Fentanyl
Alfentanil
Remifentanil
Propofol
Medication cocktails
Others, (please specify)

4. The most popular drug(s) in your country for diagnostic and therapeutic gastrointestinal procedures is / are:

Remifentanil
Midazolam
Diazepam
Meperidine
Fentanyl
Alfentanil
Propofol
Medication Cocktails
Others, (please specify)
5. Do you follow the sedation guidelines (for non-anesthesiologist administration of Propofol for Gastro Intestinal procedures) during your daily practice?

Yes
No

6. If the answer to the above question is "No", indicates why:

I am not familiar with the guidelines
We use other guidelines in our country
Other reasons, (please specify)

7. Who is responsible for the administration during Controlled Sedation Care (Propofol) diagnostic and therapeutic gastrointestinal endoscopy procedures?

Anesthesiologists (MD)
Endoscopist (MD)
Endoscopist nurse
Endoscopy assistant (MD)
Nurse anesthetist
Sedation Practitioner
Other (please specify)

8. If you are using Controlled Sedation Care in certain patients, how do you select them? (More answers are possible)

Indication by procedure
It is the patient preference
It is the preference of the physician
ASA classification 1 and 2
ASA classification 1, 2 and 3
ASA classification 1, 2, 3 and 4
Previous procedure did not succeed
Other (please specify)

9. Which patient's parameters do you routinely monitoring DURING Controlled Sedation Care (Propofol) based endoscopy sedation?

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>Oxymetry</td>
<td></td>
<td></td>
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<tr>
<td>Heart rate</td>
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<tr>
<td>Blood Pressure</td>
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<td>ECG</td>
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<tr>
<td>Capnography</td>
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<tr>
<td>Others, (please specify)</td>
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</tbody>
</table>
10. Which patient’s parameters do you routinely monitor AFTER Controlled Sedation Care (Propofol) based endoscopy sedation in the recovery room

- Oxymetry
- Heart rate
- Blood pressure
- ECG
- Capnography
- Other (please specify)

11. Do all patients sign an inform consent before undergoing a Uncontrolled Sedation Care for diagnostic and therapeutic gastrointestinal endoscopy?

- Yes
- No

12. Do all patients sign an inform consent before undergoing a Controlled Sedation Care (Propofol) for diagnostic and therapeutic gastrointestinal endoscopy?

- Yes
- No

13. Do you use a 24 / 7 Controlled Sedation Care (Propofol) service?

- Yes
- No

14. If the answer to the above questions is “No”, the reason is:

15. Do you evaluate patient satisfaction, based on quality indicators?

- Yes
- No

16. If the answer to the above questions is “Yes”, your quality indicators are:

17. Is there a complication registration of Controlled Sedation Care (Propofol) in a database?

- Yes
- No

18. If the answer to the above questions is “No”, the reasons is:
19. The responsible person who administer Uncontrolled Sedation Care for digestive endoscopy is trained in: (More answers are possible)

Basic Life Support (BLS)
Advanced cardiac life support (ACLS)
Basic airway management (e.g. jaw thrust, mask ventilation
Treatment of acute respiratory problems
Pharmacology, interactions od sedatives and analgesics
Pre- intra- and post endoscopy patient care concerning sedation
Different sedation concepts
Has followed a theoretical and practical sedation course with certificate

20. The responsible person who administer Controlled Sedation Care (Propofol for digestive endoscopy is trained in: (More answers are possible)

Basic Life Support (BLS)
Advanced cardiac life support (ACLS)
Basic airway management (e.g. jaw thrust, mask ventilation
Treatment of acute respiratory problems
Pharmacology, interactions od sedatives and analgesics
Pre- intra- and post endoscopy patient care concerning sedation
Different sedation concepts
Has followed a theoretical and practical sedation course with certificate

21. Which country are you working (please fill in your country below)