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Guidelines

Guidelines for sedation and/or analgesia by non-anaesthesiology doctors

SECTION and BOARD OF ANAESTHESIOLOGY[1], European Union of Medical Specialists

Working Party on Sedation by non-anaesthesiology doctors J. T. A. Knape[*], H. Adriaensen[†], H. van Aken[¶], W. P. Blunnie[‡], C. Carlsson[§], M. Dupont[‖], T. Pasch[**]

[*]*University Medical Center Utrecht, Division of Perioperative Care and Emergency Care, Department of Anaesthesiology, The Netherlands;* [†]*Universitair Ziekenhuis Antwerpen, Department of Anesthesiology, Wilrijkstraat, Edegem, Belgium;* [¶]*Westfälische Wilhelms Universität, Klinik für Anästhesiologie, Albert Schweitzer-strasze, Münster, Germany;* [‡]*Mater Misericordiae Hospital, Division of Anaesthesia, Eccles Street, Dublin, Ireland;* [§]*University Hospital MAS Anesthesi-kliniken, Department of Anaesthesiology, Ingång, Malmö; Sweden;* [‖]*Hôpital St Joseph, Service de Reanimation, Boulevard de Louvain, Marseille, France;* [**]*Universitäts Spital Zürich, Institut für Anästhesiologie, Rämistrasse, Zürich, Switzerland*

Summary

The still ever increasing demand for sedation and/or analgesia for diagnostic and therapeutic procedures puts high pressure on anaesthesia care providers all over Europe. Since the capacity to provide that service by anaesthetists is limited in most European countries, guidelines for non-anaesthetist doctors who want to sedate patients on a high-quality level and especially in a safe way are mandatory. This paper, produced by a working party of the European Board of Anaesthesiology of the European Union of Medical Specialists (EUMS/UEMS), gives direction to those practitioners who feel responsibilities in this area of medicine. Close cooperation with anaesthesiologists seems mandatory to achieve and sustain a high-quality standard for our patients undergoing medical or surgical procedures under sedation.

Introduction

Sedation and/or analgesia techniques are required to treat an ever increasing number patients for medical diagnostic or therapeutic procedures. It is important to establish high-quality guidelines for applying these services by non-anaesthetist doctors, because the capacity of anaesthesiologists to provide this service is insufficient in most European Countries. Clear definitions of sedation goals are mandatory to avoid conflicting discussions on goals and safety. Important prerequisites for quality and safety in sedation and/or analgesia by non-anaesthetist doctors are: the screening for risks and the selection of patients, training of staff, the use of a limited number of short-acting drugs, the establishment of monitoring standards, the description of the procedure of sedation, record keeping, adequate recovery facilities, evaluation of outcome and quality assurance. Implementation of these guidelines should include proposals for training programmes, for quality and efficiency indicators and for clinical outcome research.

The use of techniques to achieve sedation and/or analgesia for diagnostic or therapeutic procedures has increased enormously in the last decade due to

[1]The areas of expertise of anaesthesiology are Perioperative Anaesthesia Care, Emergency Medicine, Intensive Care Medicine, Pain Medicine and Reanimation.

Correspondence to: Johannes T. A. Knape, Department of Anaesthesiology, Division of Perioperative Care and Emergency Care, University Medical Center Utrecht, The Netherlands. E-mail: j.t.a.knape@umcutrecht.nl; Tel: +31302509677; Fax: +31302541828

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the increase in minimally invasive diagnostic and therapeutic surgery and the availability of potent and fast-acting sedative and analgesic drugs.

These drugs are particularly helpful for procedures in which the application of a general anaesthetic is not mandatory or not available but which are unpleasant to undergo or for which a patient is so anxious that the procedure cannot be carried out by the physician or surgeon without some pharmacological anxiolytic support.

Due to the apparent ease of administration of sedative techniques and due to the shortage of anaesthetic staff in many European countries, sedation and/or analgesia is more and more frequently carried out by non-anaesthetist doctors or even by paramedical staff without realizing its risks. Its morbidity and mortality are estimated to be considerably higher than with anaesthetic or sedative techniques in which professional anaesthetic teams are involved and have taken responsibility.

Consensus procedures have been set up in a number of countries, but are not truly evidence-based because of a lack of data of sedation procedures.

At this moment, anaesthetists in many countries unfortunately cannot provide services for all requests of procedures of sedation and/or analgesia for a variety of reasons; on the other hand anaesthetists have to take responsibility in formulating sedation and/or analgesia guidelines by non-anaesthetist doctors with adequate minimum guarantees for safety and quality of care. Since only a few guidelines can be based on hard evidence, regular updates of the guidelines must be foreseen in the light of scientific data on the subject to come in the near future.

Definitions

Sedation is a technique of administering drugs to induce a state that allows patients to tolerate unpleasant procedures while maintaining cardiorespiratory function. A degree of lowering of consciousness is a characteristic consequence of the procedure.

The level of sedation can be assessed and scored using a modified sedation scale, being an adaption from the scale that was originally developed by Ramsay and colleagues [1] (Awake levels: 1. Patient anxious and agitated or restless or both. 2. Patient cooperative, oriented and tranquil. 3. Patient responds to commands only. Asleep levels: dependent on the patient's response to a light glabellar tap or loud auditory stimulus: 4. A brink response. 5. A sluggish response. 6. No response).

- Sedation level 1: Fully awake.
- Sedation level 2: Drowsy.
- Sedation level 3: Apparently asleep but rousable by normal speech.
- Sedation level 4: Apparently asleep but responding to a standardized physical stimulus, such as glabellar tap.
- Sedation level 5: Asleep, but not responding to physical stimuli (comatose). This state is similar or synonymous with anaesthesia.

The term 'conscious sedation' is avoided. This term suggests a well-defined medical entity and a state of consciousness that could easily be established, which is not.

Analgesia is a state of absent perception of pain. This state can be achieved using intravenous (i.v.) or regional analgesic or anaesthetic drugs.

Amnesia is a condition where a patient is not able to recall (unpleasant) events.

Anaesthesia is a pharmacologically mediated condition resulting in loss of consciousness, and in analgesia allowing painful and potentially life-threatening diagnostic and/or operative surgical procedures to be carried out. All or most vital protecting reflexes are lost, requiring medical specialist expertise for support of vital functions to assure an adequate outcome and safety for the patient [2].

Objectives

Sedation and/or analgesia techniques by non-anaesthetist doctors are not reasonably expected to result in such a level of sedation that the vital, protective reflexes are lost. In order to allow patients to undergo unpleasant procedures, the objective of sedation and/or analgesia is to achieve a level of sedation comparable to 'sedation level 2 or 3' using appropriate pharmacological techniques.

In relation to the serious risks associated with 'sedation level 4 (or even 5)', this level of sedation is only to be handled by trained, adequately knowledged and skilled persons such as anaesthetists. It is recognized, however, that short, lasting seconds, periods of sedation level 4 cannot be avoided completely in all cases during a sedation procedure. 'Sedationists', being non-anaesthetists, should therefore be adequately trained to handle these situations. They need skills to keep the airway patent and to support normal breathing. It should be an objective to maintain verbal contact with the patient at all times.

Patient selection

Patients from whom a sedation and/or analgesia procedure is requested must be screened for medical

risk factors before a decision for a sedation procedure is decided upon. If there are risk factors, an anaesthetist must be consulted to decide whether the particular patient is fit to undergo the suggested sedative and surgical procedure or if further diagnostic procedures or pre-treatment may justify the suggested sedative technique in the particular patient. In other cases, the patient has to be evaluated to see whether a general anaesthetic is indicated to allow the procedure to be carried out.

Inclusion and exclusion criteria

Requirements for sedation by non-anaesthetist doctors:

- Patients of ASA Class I and II[2].
- Patients of ASA Class III in a stable condition.
- Diagnostic or surgical procedure compatible with inclusion and exclusion criteria for day case surgery.
- Patients capable of giving informed consent.

Patients not eligible for sedation by non-anaesthetist doctors:

- In cases of a language barrier.
- Old age: people (>70 yr) as judged on the condition of the patient.
- Previous history of adverse events during anaesthesia, including difficulty in tracheal intubation.
- History of allergy to any of the drugs that might be used.
- Patients requiring intensive care treatment.
- Patients who cannot be accompanied home by another responsible person after the procedure or for whom no adequate aftercare can be guaranteed for 24 h.

Training of the staff

Both diagnostic or therapeutic procedure and sedation and/or analgesia are to be considered as separate medical procedures. The physician who carries out the diagnostic or therapeutic procedure is responsible not only for that but also for sedation and/or analgesia. The patient should give his/her informed consent for both procedures separately.

Therefore, additional training in the principles and practice of sedation and/or analgesia is necessary not only for the physician but also for the supporting personnel. When the physician is carrying out the procedure, he cannot supervise the sedation and/or analgesia at the same time. A well-trained, dedicated person, not being the doctor doing the procedure, should be in charge of providing sedation and monitoring vital signs. The physician/surgeon carrying out the procedure must be satisfied that this person is adequately trained and capable of performing his/her task. The physician/surgeon who is finally responsible both for the medical/surgical procedure should receive additional training in:

- Basic cardiopulmonary physiology and skills in airway management.
- Pharmacology of sedatives, analgesics, the respective antagonists, their pharmacokinetics and interactions.
- The theory and practice of sedation procedures.
- Principles and practice of monitoring and their limitations.
- Complications of sedation and/or analgesia.
- Advanced life support skills.
- Recovery and discharge criteria.

The supporting nurse or personnel should have been trained similarly, although basic life support may be sufficient instead of advanced life support training.

A regular training and recertification program should be set up.

Drugs

By all means, efforts should be undertaken to achieve pain relief by adequate methods such as topical, infiltration or regional analgesia, rather than to rely on i.v. sedation or on an i.v. route of pain relief which may be associated with complications. I.v. pain relief should always be additional to an established method of pain relief. If that is not possible, it is wise to switch to a general anaesthetic conducted by a qualified anaesthetic team.

For reasons of control and safety, there is a preference to use monotherapy in sedation and/or analgesia, and to use fast- and short-acting drugs, with which the medical team is familiar. The effect of long acting drugs is unpredictable and the drugs may show unwanted interactions, which are difficult to control. Their use for sedation and/or analgesia by non-anaesthetist doctors should be discouraged. One should try and limit oneself to drugs such as midazolam, alfentanil and their respective antagonists flumazenil and naloxone. I.v. techniques using propofol may also be used after appropriate training. Antagonists such as flumazenil and naloxone must be immediately available.

[2]ASA Physical Status: ASA I: healthy patient; ASA II: mild systemic disease, no functional limitations; ASA III: severe systemic disease, define functional limitations; ASA IV: severe systemic disease that is a constant threat to life; ASA V: moribund patient not expected to survive 24 h with or without operation.

Monitoring

Every patient undergoing sedation and/or analgesia should be monitored by a trained person, whose primary task is the uninterrupted monitoring of the patient. Each patient should be given an i.v. access.

Monitoring should consist of a minimum of pulse oximetry, non-invasive blood pressure measurement and electrocardiogram, and continuous visual observation of breathing and its frequency. Supplemental oxygen should be given only if significant hypoxaemia occurs, as is often the case e.g. in upper gastrointestinal endoscopy. Resuscitation and equipment to administer oxygen should be present in working order; all personnel should be trained to handle these devices.

Procedures of sedation and/or analgesia

After monitoring has been started, the method of analgesia of choice has to be applied to the patient (topical, infiltration of regional analgesia). Consideration should be given to the self-administration of 50% nitrous oxide in oxygen for pain relief. If additional sedation and/or analgesia is required, small doses of the sedative drugs should be administered i.v. Again, enough time should be taken to judge the effects of the drugs given on consciousness and on the vital cardiopulmonary signs and parameters.

As stated before, a sedation level of 2–3 should be the end-point of the procedure. Constant monitoring of the patient is required and close communication between the monitoring person and the physician is mandatory. In order to deepen the level of sedation, if a response to an unpleasant stimulus is observed, small increments of the drugs used may be given and its effect must be observed continuously. Non-anaesthetists frequently interpret restlessness during a procedure as being caused by pain and not by hypoxaemia, which is usually the cause. Therefore, hypoxaemia must be excluded before any further analgesia is given. Sedation can never compensate for an inadequate local anaesthesia block; in that case, repeat the block.

The combination of a sedative and an analgesic will cause important potentiation of the effects of both drugs. The dosage of these drugs should therefore be reduced to 1/4 of the dose without concomitant administration of other depressant drugs. Most serious problems and fatalities during sedation have resulted from drug combinations especially with opioids.

Records

Records should be made not only of the diagnostic or surgical procedure, but also of the sedation and/or analgesia procedure. Vital signs and the level of consciousness should be noted at frequent intervals, especially immediately following the administration of sedative drugs and during the immediate post-procedure period when the external stimuli are removed. Registration of the sedative procedure serves evaluation in terms of a quality audit and medico-legal requirements.

Recovery

Patients who have undergone sedation and/or analgesia procedures have to be observed carefully in the post-procedural period in an adequately equipped recovery facility using the same monitoring as was used during the procedure. This is especially of value in the immediate post-procedural period since these patients are at increased risk directly after the unpleasant or painful stimulus is removed.

Patients should be visually observed at all times for a minimum period of 30 min following the administration of agonist and antagonist drugs. Discharge criteria should include the following:

- The patient should be fully conscious and should respond appropriately. The patient should be able to stand and walk unaided. In the case of a mentally handicapped person, the patient should behave like he/she did before the sedation procedure.
- Vital signs have returned to the normal values of the particular patient and are stable for at least 30 min.
- Pain, discomfort, nausea and vomiting are under control within acceptable limits.

Aftercare

An accompanying person should be responsible for transport home and care for the first 24 h. Detailed instructions should be communicated in writing to deal with complications such as severe pain, bleeding, nausea and vomiting. A first-aid referral address should be supplied. Patients should be contacted by phone the next day for evaluation of the first 24 h. In case of complications requiring more intensive care, a hospital bed should be made available.

Evaluation and quality assurance

Evaluation of the results of sedation and/or analgesia procedures should be done on a regular basis in the form of audits for quality-of-care assurance purposes.

Notes

- Patients with a mental handicap and children may undergo procedures of sedation and/or

analgesia like other patients. Proper selection of patients is mandatory, however, to ensure good outcome. In this subgroup of patients, a general anaesthetic may be the technique of choice more frequently than in other cases.

- Each institution or department where sedation and/or analgesia is performed should set its own standards for these procedures. It is recommended that anaesthetic departments take responsibility in the preparation of the standards.
- It is of importance for the Subcommittee on Sedation to assign the strength of evidence to the various items mentioned in the near future. Standards of care should preferably be based on hard evidence. Clinical studies should be undertaken to provide this evidence.
- Revisions of these guidelines are required at 5 yr intervals.

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