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Procedural sedation in Belgium : guideline for safe patient care

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Abstract : Guideline produced by the Society for Anesthesia and Resuscitation of Belgium Working Group on Procedural Sedation (SARB-WG-PS).

Keywords : procedural sedation ; patient safety ; guidelines.

Introduction

More and more procedures are performed under superficial or more profound sedation. The number of diagnostic and therapeutic interventions, for which procedural sedation is used is increasing every day (1, 2). This is due to the growth of minimally invasive procedures performed at remote locations (remote from the main Operating Room) and the increasingly frail, older and sick patient population. Also, more novel drugs with a short acting profile and a profile ideally suited for sedation facilitate the growth of procedural sedation in many situations. Additionally, in some areas, a shortage of trained anesthesiologists generates the need for procedural sedation performed by non-anesthesiologists.

However, procedural sedation carries many risks and therefore adequate support, training and monitoring are required to safely execute sedation (1, 2). The current document is produced by the Society for Anesthesia and Resuscitation of Belgium (SARB) Working Group on Procedural Sedation and endorsed by the Belgian College of Emergency Physicians, the Belgian Society of Disaster Medicine, and the Belgian University Professors of Emergency Medicine, and the Interventional Radiology Section of the Belgian Society of Radiology. The goal of the guideline is to enhance the quality and safety of procedural sedation in adults performed by anesthesiologists and non-anesthesiologists. The document translates various recent international guidelines into a guidance document suited for the Belgian situation (1-3). Most importantly, it will not focus on the pediatric population, nor will it address sedation in

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the intensive care unit, the emergency department, and out of hospital emergency interventions. It could serve as a framework for hospitals and anesthesiology departments.

In particular, SARB believes that healthcare professionals delivering procedural sedation must not only be cognizant of the potential complications but must also be able to diagnose the complications, manage them clinically, and provide or request alternative therapies, such as resuscitation and the necessity of general anesthesia to a physiologically unstable patient who may have multiple comorbidities.

For high-risk patient groups or high-risk procedures or more profound levels of sedation, patient safety is best served when sedation is delivered by medically qualified healthcare professionals who are enrolled in or have completed an accredited full training program in anesthesiology.

Definition of procedural sedation

The administration of anxiolytic, sedative, hypnotic, analgesic, and/or dissociative medication(s) to attenuate anxiety, pain, unwanted reflexes and/or motion during a diagnostic or therapeutic procedure. These agents are administered in order to facilitate amnesia, decrease awareness, improve patient comfort and/or safety during a diagnostic or therapeutic procedure (2).

Complications and risks associated with procedural sedation

Practitioners who administer procedural sedation and/or analgesia should be aware that the transition from complete consciousness through the various depths of sedation to general anesthesia is a continuum and not a set of discrete, well-defined stages. The margin of safety of drugs used to achieve sedation and/or analgesia varies widely between patients and loss of consciousness with its attendant risk of loss of protective reflexes may occur rapidly and unexpectedly. Procedural sedation is associated with adverse events (AE's) and mortality, which occur much more frequently with procedural sedation than with general anesthesia or regional anesthesia (2). Too deep sedation, airway obstruction, respiratory or cardiovascular complications may occur insidiously at any time. Therefore, practitioners who administer sedative, analgesic or other drugs that alter the conscious state of a patient, and those who supervise recovery from sedation, must be prepared to identify and manage the potential risks such as :

1. Depression of protective airway reflexes, airway obstruction and loss of airway patency ;
2. Depression of respiration in frequency and depth ;
3. Depression of the cardiovascular system ;
4. Drug interactions or adverse reactions, including anaphylaxis ;
5. Unexpectedly high sensitivity to the drugs used for procedural sedation and/or analgesia which may result in unintentional loss of consciousness, and respiratory or cardiovascular depression ;
6. Individual variations in response to the drugs used, particularly in the extremes of age, and those with pre-existing disease ;
7. The possibility of unintended deeper levels of sedation ; risks inherent in the wide variety of procedures performed under procedural sedation and/or analgesia.

According to Agostino et al. various factors can predict the occurrence of a complication : age, ASA (American Society of Anesthesiologists) score, Mallampati score, emergency and length of the procedure (4). Although various complications can occur, they are rare. Bellolio et al reported on serious complications (5). The most common adverse event is hypoxia, with an incidence of 40.2/1,000 sedations, followed by vomiting with 16.4 to 170/1,000 sedations and hypotension with 15.2/1,000 sedations. Severe adverse events requiring emergent medical intervention were rare, with one case of aspiration in 2,370 sedations (1.2/1,000), one case of laryngospasm in 883 sedations (4.2/1,000), and two intubations in 3,636 sedations (1.6/1,000). Apnea was estimated to occur in 51.4/1,000.

Recently, two tools have been described to record and evaluate in a standardized way the complications and adverse events associated with procedural sedation (6, 7). In 2012, the world SIVA (World Society for Intravenous Anesthesia) international sedation task force described a standardized set of definitions for adverse events occurring during procedural sedation (6). They integrated various international definitions of adverse events into one comprehensive definition of adverse events that is sedation specific : *'Unexpected and undesirable response(s) to medication(s) and medical intervention used to facilitate procedural sedation and analgesia that threaten or cause patient injury or discomfort'*. A tool was then synthetized and published for standardized reporting of adverse events which can be found on the world SIVA website. Minimal, minor and sentinel adverse events were defined as well as the

strategy to manage the adverse events. Outcome is also reported in the tool.

Roback et al. in 2018 reported on the tracking and reporting outcomes of procedural sedation (TROOPS) tool (7). The International Committee for the Advancement of Procedural Sedation (ICAPS, www. ProceduralSedation.org) developed a multidisciplinary, consensus-based, standardized quality-improvement tool intended to be applicable for all types of sedation providers in all locations worldwide. This tool is suitable for inclusion in either a paper or an electronic medical record. It is founded upon the premise that adverse events are best defined by their associated interventions and patient-centered outcomes. An additional, parallel research tool is presented to promote consistency and standardized data collection for procedural sedation investigations.

The SARB Working Group on Procedural Sedation suggests to use a standardized tool such as the SIVA tool or TROOPS tool.

Levels of Sedation

The ASA has defined four levels of sedation where level 4 corresponds to general anesthesia. The four defined levels of sedation are : minimal sedation (anxiolysis), moderate sedation/analgesia, deep sedation/analgesia and general anesthesia. These four levels of sedation can be defined as :

Level 1 : Minimal sedation/anxiolysis : patient has eyes open spontaneously.

Level 2 : Moderate sedation/analgesia : patient responds to verbal commands.

Level 3 : Deep sedation/analgesia : patient reacts only to tactile stimulation.

Level 4 : General anesthesia : patient does not react to stimulation.

This terminology with a subdivision into four clearly defined levels of sedation still stands today as it is incorporated in the latest and recent versions of American (ASA, American Society of Anesthesiology) and European (ESA, European Society of Anaesthesiology) guidelines for procedural sedation (1, 2). In its recommendations on patient safety in anesthesia, the SARB adds a supplementary level (which here would be level 0) defined as “awake and oriented” (8). It must be emphasized that the various levels of sedation are a continuum and evolution to a more profound level of sedation is always possible. Therefore, continuous vigilance, monitoring of the patient and the actual depth of sedation are required.

Governance of procedural sedation

Although sedation is performed by different health care providers worldwide, the Joint Commission on Accreditation of Healthcare Organizations mandates that procedural sedation throughout any accredited institution should be monitored and evaluated by the Department of Anesthesia [2]. In level 1 or 2, anesthesia professionals are not required to be directly responsible for doing sedation, but rather to have an advisory and supportive role and should evaluate safety and quality. In level 1 and 2, the physician performing the procedure for which sedation is requested and administered is responsible for the sedation. The sedation however is performed by another health care provider.

The SARB (Society of Anesthesia and Resuscitation of Belgium) Working Group on Procedural Sedation advises that for level 1 and 2 sedation in ASA 1 and 2 patients, sedation can be performed by or delegated to health care providers that are non-anesthesiologists but that are trained by the Anesthesiology Department. For level 3 sedation or higher and in patients with ASA class 3 or higher, sedation should always be performed by an anesthesiologist. It must be emphasized that the health care professional performing procedural sedation should NOT be involved in the execution of the actual intervention for which procedural sedation is administered. However, in level 1 and 2 sedation, the provider performing sedation can assist the physician doing the procedure. For level 3 or 4, sedation is a task which excludes any other task performed at the same time.

Patient evaluation and preparation

Currently, there is insufficient evidence that pre-procedural evaluation of a patient prior to sedation reduces mortality and morbidity. Observational studies indicate that some adverse outcomes (*e.g.*, unintended deep sedation, hypoxemia or hypotension) may occur in patients with some preexisting medical conditions when procedural sedation is administered. These conditions include : extremes of age, ASA status III or higher, obstructive sleep apnea, respiratory distress syndrome, chronic renal and hepatic impairment, morbid obesity (BMI>40), allergies, psychotropic drug use, history of gastric bypass surgery, pediatric patients who are uncooperative or who have behavior or attention disorders, cardiovascular disorders, and history of long-term benzodiazepine use. Case reports indicate similar adverse outcomes for newborns,

patients with mitochondrial disease, epilepsy with tonic-clonic seizures, and patients with a history of benzodiazepine use (9). The SARB Working Group on Procedural Sedation also warn practitioners on the possibility of more frequent adverse outcomes after procedural sedation in patients with neuromuscular disorders such as amyotrophic lateral sclerosis, and myasthenia. Due to their motor weaknesses, those patients are particularly sensitive to the effects of sedation medications, and are particularly at risk of ventilation problems. Special caution should also be paid to patients with a history, familial or personal, of malignant hyperthermia. Therefore, it is advised that ALL patients undergoing procedural sedation are screened and evaluated prior to sedation. The recommendations are to review previous medical records and interview the patient or family, conduct a focused physical examination of the patient, and review available laboratory test results. The Working Group recommends, if possible, to perform the pre-procedure evaluation well enough in advance (days to weeks). In case of any doubt regarding an eventual increased risk for the patient to undergo level 1 and 2 sedation with regard to his/her past medical history, including neuromuscular disorders and malignant hyperthermia, the advice of an anesthesiologist should be sought at. The pre-procedure evaluation files of patients scheduled to undergo level 3 or higher sedation should be reviewed by an anesthesiologist.

Additionally, pre-procedure preparation is essential. Patients should receive all necessary information on procedural sedation and the alternatives. Information about potential side-effects and the required precautions (such as the need for a third party to assist in the hours after sedation and the prohibition to manage a motorized vehicle) should be made available. Patients should be informed about the correct fasting times (and they should strictly adhere to them). Currently, there is no clear evidence-based fasting protocol for procedural sedation that results in a decreased incidence of adverse effects. Guidelines related to preoperative fasting prior to surgery have become more liberal and allow clear liquids until 2 hours and solid food until 6 hours prior to surgery.

For all patients undergoing procedural sedation it is recommended to have a secure intravenous access, which is open and accessible. However, there might be situations in which an IV access is not absolutely mandatory and actually might induce more problems.

Monitoring and location

Monitoring should be established according to safety first guidelines (8). This should include standard electrocardiographic monitoring (ECG), non-invasive blood pressure monitoring (NIBP), saturation monitoring by pulse oximetry and capnography. Even in spontaneously breathing patients that are not intubated, capnography is essential. Pulse oximetry is not a substitute for ventilation monitoring (1, 2). Parker and co-workers performed a systematic review of the use of capnography during moderate levels of procedural sedation and concluded that capnography reduced the risk of hypoxemia (by 31%), increased the detection of adverse respiratory events, and was not associated with additional harm (10). Capnography will detect respiratory depression at an earlier stage than any other type of monitoring. Each sedated patient in a level 2 state of sedation or higher deserves capnography. Visual evaluation of the patient is necessary at all times and vital signs should be meticulously recorded in a sedation record. A record on regular time points of the actual level of depth of sedation should be performed.

Administration of additional oxygen is debatable since high oxygen concentrations can induce respiratory depression by reducing respiratory drive and can mask respiratory depression. The working group advises to administer supplementary oxygen when oxygen saturation drops below 93% together with other measures. When oxygen saturation is higher than 93% no additional oxygen is absolutely indicated.

Locations in which sedation is performed should have adequate lighting, electrical outlets, oxygen supply, suction equipment, and the rooms should have sufficient size. We refer to the recently published updated Safety First Guidelines in this respect (8). An emergency call system and a clear route for evacuation of a patient on a stretcher in case of emergency should be available.

In each location where procedural sedation is performed, immediate availability to resuscitation equipment must be guaranteed. This includes equipment for advanced airway management in case of difficult airway. Also, equipment for advanced cardiac life support such as a defibrillator must be closely available.

Sedative agents

It is beyond the scope of these recommendations to review in detail the pharmacology of sedative and analgesic drugs commonly used for procedural

sedation. They have been previously described elsewhere in detail (11-13). The attending physician, responsible for sedation, should make a drug selection based on the protocols written by the Anesthesiology Department. To ensure well tolerated, effective and safe drug administration, the health care provider performing sedation should always be aware of the pharmacological properties of each drug and drug combination used. Drug selection should be based on ease of dosing to reach and maintain the desired level of sedation, avoiding adverse events due to excessive dosage, or unexpected reactions to individual drugs or drug combinations. As such, theoretically, the ideal drug for procedural sedation has a rapid onset, short duration of action and time-independent context-sensitive half-time. In addition, it should have an advantageous hemodynamic and respiratory profile. Most of the time, drug combinations are required. Therefore, the clinician should understand the principles of drug interactions to balance between clinical effects and side-effects. The recommended route of administration is the intravenous one, insofar as, in that case, the pharmacokinetics and pharmacodynamics can be better predicted.

Antidotes should be readily available at the location where sedation is performed.

Sedation by non-anesthesiologists can only be performed using standard doses of benzodiazepines in monotherapy and nitrous oxide in monotherapy up to a 50% concentration. Combination therapy or the use of sedative agents such as propofol, ketamine, opioids, or IV dexmedetomidine is reserved to anesthesiologists.

Minimal personnel requirements

Anesthesiologists are adequately trained to perform all levels of procedural sedation. Non-anesthesiology care providers that perform sedation (see above for what is allowed) and the responsible physician should be adequately trained by the Anesthesiology Department to monitor and manage the whole process and associated adverse effects. This includes at least :

– Training to perform pre-sedation assessment as described above.
– Knowledge of fasting guidelines.
– Knowledge of sedative drugs and monitoring devices.
– Knowledge and management of hemodynamic complications.
– Skills of basic airway management.
– Skills on the use of additional oxygen.
– Skills of defibrillation.
– Knowledge of the most common and the most serious complications.

Training of non-anesthesiologists to provide procedural sedation should be controlled and performed by the Anesthesiology Department and by anesthesiologists (1, 2). The treating physician is responsible for the patient and the sedation executed by health care providers when the targeted level of sedation is level 1 or 2. A rescue emergency protocol needs to be available at all times.

Recovery from sedation

All facilities and areas in which procedural sedation is performed should have clear possibilities to monitor patients following sedation. Although there is no clear evidence on who should monitor patients and how long patients should be monitored, from a practical point of view, post-sedation monitoring (with at least NIBP, ECG, capnography and pulse oximetry) is essential to supplement visual observation by a trained nurse. Monitoring for at least 30 minutes after procedural sedation is mandatory and until full patient recovery has occurred.

Discharge criteria should be designed to minimize the risk for cardiorespiratory depression after patients are released from observation by trained personnel. Some discharge scores have been used successfully to assess the patient after sedation. The ALDRETE (14) score is easily feasible and is proposed by the Working Group as a valuable tool. An alternative might be the PADSS score (15). Clear written discharge instructions should be given to the patient and to the patient's caregiver who needs to accompany the patient after discharge. The clinician discharging the patient needs to explain the postoperative plan, the problems that can arise and how to solve them, what is allowed or not allowed during the first 24 hours, including not driving motorized vehicles, and when the patient can return to normal activity. A follow-up should be offered to the patient in case he/she experiences problems after having been discharged home.

Summary of recommendations

1. Procedural sedation is performed with an increasing frequency.
2. Procedural sedation is defined as the use of anxiolytic, sedative, hypnotic, analgesic, and/or dissociative medication(s) to attenuate anxiety, pain, unwanted reflexes and/or motion during

a procedure. These agents are administered in order to facilitate amnesia, decreased awareness, patient comfort and/or safety during a diagnostic or therapeutic procedure.

3. Procedural sedation is associated with ad-verse events usually related to obstructive breathing, hypoxemia or cardiovascular instability.
4. Identification of risk factors for complica-tions is essential for health care providers performing sedation.
5. The SARB Working Group on Procedural Sedation suggests to use a standardized tool such as the SIVA tool or TROOPS tool to record complications.
6. The SARB Working Group on Procedural Sedation advises that superficial levels of sedation in ASA 1 and 2 patients can be performed by non-anesthesiologists which are trained by the Anesthesiology Department. Deeper levels of sedation and sedation in ASA class 3 or higher should always be performed by an anesthesiologist. Sedation by non-anesthesiologists can only be performed using standard doses of benzodiazepines in monotherapy and nitrous oxide in monotherapy up to a 50% concentration or by intranasal dexmedetomidine. Combination therapy or the use of sedative agents such as propofol, ketamine, opioids or IV dexmedetomidine is reserved to anesthesiologists.
7. Procedural sedation is an exclusive task. The person in charge of sedation cannot perform the intervention. Only in case of level 1 or 2 sedation, the person performing sedation is allowed to assist the physician.
8. Four levels of sedation as defined by the ASA and SARB should be adopted : Minimal sedation (anxiolysis) ; moderate sedation/ analgesia, deep sedation/analgesia and general anesthesia.
9. All patients should receive in depth pre-procedural and pre-sedation screening, which is performed preferably well in advance of the procedure and sedation.
10. Fasting guidelines should be adhered to, informed consent should be given, and an IV access should be established.
11. Monitoring of sedation should be done according to the SARB Safety First guidelines [8] and should include ECG, NIBP, pulse oximetry and capnography monitoring.
12. Locations should be safe and accessible, and resuscitation equipment should be immediately available.
13. Drugs for procedural sedation should have a rapid onset and short duration of action.
14. Personnel should have knowledge about the sedative drugs used.
15. Non anesthesiology personnel performing sedation should have received adequate training from anesthesiologists.
16. Recovery from sedation is done in a specific area and patients are discharged according to an established discharge score.

Conflicts of interest

MVDV, during the last three years (2018-2019-2020), received honoraria for consultancy, lectures and research from Aguettant, Aspen, CLS Behring, Ever Pharma, Ferrer, Flatmedical, Grunenthal, HeronTx, Janssen Pharmaceuticals, Medtronic, MSD, Nordic Pharma, Sintetica and Viforpharma. MVDV received research grants in the last three years from the Belgian Association of Regional Anesthesia (BARA), European Society of Regional Anesthesia and Pain Therapy (ESRA), Belgian Society of Anesthesia and Resuscitation (BSAR) and the Obstetric Anesthetists Association (OAA).

LB during the last three years (2018-2019-2020), received honoraria for consultancy, lectures and research from Medtronic.

MC during the last three years (2018-2019-2020), received honoraria for consultancy, from Medtronic and a research grant from Teleflex Medical Incorporated.

PF during the last three years (2018-2019-2020), received honoraria for consultancy, lectures and research from Medtronic. PF received no research grants in the last three years.

JJ has no conflicts of interest to disclose.

JM during the last three years (2018-2019-2020), received honoraria for consultancy, lectures and research from Medtronic, Merck, Johnson & Johnson and GE Healthcare. JM received research grants in the last three years from Merck.

BR during the last three years (2018-2019-2020), received honoraria for consultancy, lectures and research from Medtronic.

DvB during the last three years (2018-2019-2020), received honoraria for consultancy, lectures and research from Baxter and Medtronic

VvR during the last three years (2018-2019-2020), received honoraria for consultancy, lectures and research from Medtronic. VvR received no research grants in the last three years.

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