EJA

Eur J Anaesthesiol 2018; **35**:6–24

GUIDELINES

European Society of Anaesthesiology and European Board of Anaesthesiology guidelines for procedural sedation and analgesia in adults

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Procedural sedation and analgesia (PSA) has become a widespread practice given the increasing demand to relieve anxiety, discomfort and pain during invasive diagnostic and therapeutic procedures. The role of, and credentialing required by, anaesthesiologists and practitioners performing PSA has been debated for years in different guidelines. For this reason, the European Society of Anaesthesiology (ESA) and the European Board of Anaesthesiology have created a taskforce of experts that has been assigned to create an evidence-based guideline and, whenever the evidence was weak, a consensus amongst experts on: the evaluation of adult patients undergoing PSA, the role and competences required for the clinicians to safely perform PSA, the commonly used drugs for PSA, the adverse events that PSA can lead to, the minimum monitoring requirements and post-procedure discharge criteria. A search of the literature from 2003 to 2016 was performed by a professional librarian and the retrieved articles were analysed to allow a critical appraisal according to the Grading of Recommendations Assessment, Development and Evaluation method. The Taskforce selected 2248 articles. Where there was insufficiently clear and concordant evidence on a topic, the Rand Appropriateness Method with three rounds of Delphi voting was used to obtain the highest level of consensus among the taskforce experts.

These guidelines contain recommendations on PSA in the adult population. It does not address sedation performed in the ICU or in children and it does not aim to provide a legal statement on how PSA should be performed and by whom. The National Societies of Anaesthesiology and Ministries of Health should use this evidence-based document to help decision-making on how PSA should be performed in their countries. The final draft of the document was available to ESA members via the website for 4 weeks with the facility for them to upload their comments. Comments and suggestions of individual members and national Societies were considered and the guidelines were amended accordingly. The ESA guidelines Committee and ESA board finally approved and ratified it before publication.

Published online 5 September 2017

This article is accompanied by the following Invited Commentaries:

- De Robertis E, Longrois D, Fuchs-Buder T. Safety and quality of procedural sedation and analgesia practice for adult patients throughout Europe. A step forward. *Eur J Anaesthesiol* 2018; **35**:1–3.
- Prakash A, Webb ST. Procedural sedation and analgesia for adults in Europe. Safety first. *Eur J Anaesthesiol* 2018; **35**:4–5

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DOI:10.1097/EJA.0000000000000683

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Introduction

The current document is organised to facilitate reading by clinicians and anticipate possibly necessary updates as part of the new European Society of Anaesthesiology (ESA) Guidelines doctrine[1] on both article and electronic support. The content facilitates navigation through the article, and it is also the basis of the Executive Summary that will contain only the recommendations. The Full Text of the article contains both the recommendations and the arguments together with the references. Finally, the Table of contents can also be used as a framework of training goals for non-anaesthesia personnel and the acquisition/maintenance of their knowledge and technical skills.

There has been increased interest in procedural sedation and analgesia (PSA) over the last 10 years for many reasons, including higher expectations among patients, availability of short-acting drugs, increased numbers of reported major adverse events associated with PSA and a shortage of anaesthesiologists.

The role of anaesthesiologists in PSA has been stated in several guidelines[2,3] but is still challenged, as some Scientific Societies and Organisations[4,5] have promoted the use of rapid-acting hypnotic drugs, such as propofol for PSA by non-anaesthesiologists who should have acquired the mandatory skills (characteristically held by anaesthesiologists) to avoid and if necessary to manage potentially life-threatening adverse events associated with well conducted PSA or with too deep levels of sedation.

Epidemiological data on the incidence of adverse events during PSA are provided mainly by the publications from the American Society of Anesthesiologists' (ASA) Closed Claims study.[6] However, the analysis of the incidence of adverse events related to PSA [designated as monitored anaesthesia care or monitored anaesthesia care (MAC) in the ASA Closed Claims study] is confounded by the fact that the structure of the ASA Closed Claims process cannot provide either the total number of adverse events or the total number of procedures performed. Furthermore, the ASA Closed Claims study only analysed severe adverse events. Despite these limitations, the weight/percentage of severe adverse events associated with MAC in the Closed Claims database has increased over the last decades from approximately 2% of all anaesthetic claims during 1980 to 1989, to 5% during 1990 to 1999 and 10% during 2000 to 2009. Patient death is the most common severe adverse event in the MAC claims, and significantly more common than mortality associated with general or regional anaesthesia.[7] Most fatal incidents result from inadequate oxygenation and/or ventilation in non-operating room areas with suboptimal monitoring facilities and inability to prevent and appropriately manage over-sedation.

The ESA together with the *European Board of Anaesthesiology* (EBA) has created a taskforce with European experts in PSA. The Taskforce members have defined the objectives of the Guidelines, criteria for the literature search and evidence analysis as well as methods used to provide recommendations. The main objectives of these guidelines are to provide evidence-based recommendations on: the evaluation of adult patients undergoing PSA, the role and competences required for clinicians to safely perform PSA, the minimum monitoring requirements, prevention and management of adverse events from PSA, the commonly used drugs for PSA and post-procedure discharge criteria.

These Guidelines are conceived as an evidence/consensus-based document on which the different European National Societies of Anaesthesiology and the ministries of Health of their respective countries may build their decisions on how professionals can deliver procedural sedation and how PSA can be provided in the safest way according the Helsinki Declaration on Patient Safety in Anaesthesiology.[8] The guidelines may help frame the medicolegal context when considering whether an anaesthesiologist or non-anaesthesiologist performs PSA, and when PSA is to be performed outside an operating room or in an office-based setting. It is however beyond the scope of these Guidelines to provide a focus on light sedation for anxiolytic purposes even if the administration of any sedative drug could cause an unpredicted response, leading to deeper levels of sedation.

Definitions and conceptual frameworks

Procedural sedation and analgesia

The term *procedural sedation and analgesia (PSA)*[9] involves the use of hypnotic and/or analgesic medications to enable effective performance of diagnostic or therapeutic procedures effectively, whilst the patient is closely monitored for potential adverse effects. PSA was previously (and inappropriately) termed *conscious sedation*; indeed, the association of the two terms is contradictory because effective sedation reduces consciousness. Well tolerated PSA results in preservation of airway patency and spontaneous ventilation despite depressed levels of consciousness.

PSA, even when adequately performed, may increase the risk of morbidity and mortality in addition to the diagnostic/therapeutic procedure itself. By recognising the intrinsic risks of PSA, the *Joint Commission on Accreditation of Healthcare Organizations* in the USA mandates that PSA throughout any institution in the United States should be monitored and evaluated by the Department of Anaesthesia. Anaesthesia professionals are not required to be directly responsible for sedation services or their quality assurance, but rather to have an advisory and supportive role.[10] The privileging on who can provide PSA in the United States is regulated by the ASA, which has created a training course that allows the providers to deliver only mild-to-moderate sedation to ASA physical status I and II patients. For high-risk patients (ASA physical status III

and IV), PSA should always be delivered by an anaesthesiologist. The present Guidelines adopt a more detailed definition of the stages of sedation to facilitate correct identification of the patients that must be managed by anaesthesiology professionals.

Stages/levels of sedation

There are several validated ways to define and assess levels of sedation. For example, below is a modified version of the five-level *Ramsay* scale,[11] where level 5 is similar to, or synonymous with, general anaesthesia:

(1) Level 1: Fully awake.
(2) Level 2: Drowsy.
(3) Level 3: Apparently asleep but rousable by normal speech.
(4) Level 4: Apparently asleep but responding to standardised physical stimuli (e.g. glabellar tap).
(5) Level 5: Asleep, but not responding to strong physical stimuli (comatose).

The ASA has defined four levels of sedation,[12] where level 4 corresponds to general anaesthesia (Table 1 – Supplemental Digital File, http://links.lww.com/EJA/A126).

Although differences between the first two levels of sedation are not always clear, whenever a patient reaches a deeper level of sedation (levels 3 or 4), there is also higher risk of life-threatening adverse events that mandate immediate and appropriate management. Importantly, management of transition from levels 3 to 4 may require specific knowledge and technical skills (advanced airway/cardiovascular resuscitation) that are in general only fully mastered by an anaesthesiologist.

Methods

Literature retrieval

A taskforce was created to develop European guidelines on PSA based on the evidence retrieved from the literature and the clinical expertise of each expert in this domain. Members of the taskforce contributed to define the selection of patients based on risk stratification, competences required to provide well tolerated PSA, drugs used for PSA and management of their adverse effects, monitoring, recovery, and criteria for patient discharge. The taskforce formulated a defined number of population, intervention, complication, outcome (PICO) questions and keywords to guide the literature search from the initial proposals from the ESA subcommittees with subsequent validation by the chairmen of the taskforce and literature reviewers. The taskforce also established inclusion/exclusion criteria for the studies. This process was completed by November 2013. The literature search was in January 2014 and updated in June 2016. A broad filter for PSA was applied in conjunction with a study type filter and a specific subgroup filter based on the questions and keywords. The MEDLINE, EMBASE and Cochrane Library databases were searched from 2003 to June 2016 for the normalised and free-text terms '(conscious sedation)', '(deep sedation)', 'procedure*' 'intervention*' or 'exam*' (Appendix 1 – Supplemental Digital File, http://links.lww.com/EJA/A126). A total of 12 263 records were identified (Fig. 2 – flowchart – Supplemental Digital File, http://links.lww.com/EJA/A126). Original articles went through a two-round selection process. First, screening of titles and abstracts was carried out by one reviewer (to remove duplicates and select articles according to inclusion criteria) and, when in doubt, checked by a second reviewer. Systematic reviews, randomised controlled trials, cohort studies, case control studies and cross-sectional surveys were included. Existing guidelines were identified and considered separately. Narrative reviews, editorials, case series or case reports were excluded. Only English language articles were included. A total of 2248 articles were selected.

A second round of selection was carried out by each subcommittee to identify articles concerning adults (older than 18 years of age) receiving PSA for any painful or non-painful diagnostic or therapeutic procedure, but excluding dental surgery and other minor interventions carried out under local anaesthesia. Articles covering long-term sedation in intensive care (other than those for specific procedures that could be considered as PSA) were also excluded. As we wished to include all relevant articles, the ESA subcommittees included any article considered potentially relevant. After this two-round selection, 482 full-text articles were made available for the taskforce members. The articles were individually analysed for risk of bias, applicability, external validity and clinical relevance. Studies where the intervention was obsolete were excluded.

Other methodological considerations

Once the final number of articles was set, evidence was critically appraised using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology.[13–25] As GRADE was used to assess the quality of evidence, the following features were assessed for each outcome:

(1) GRADE was based on limitations of study design (selection, performance, detection, attrition and reporting of bias), effect consistency and size, directness, precision, publication bias, dose–response effect and presence of antagonistic bias.
(2) The transformation of evidence into a recommendation was a function of the panel evaluation of the five factors summarised (Section C, Table 2 – Supplemental Digital File, http://links.lww.com/EJA/A126).
(3) Since the GRADE system could not be used to standardise the decision-making process of the expert panel, the ESA/EBA taskforce selected the Rand Appropriateness Method, published in detail elsewhere,[26,27] for that purpose.

To increase the level of the consensus, especially whenever strong evidence was lacking, a three-round Delphi method was used. The expert panel met in Berlin in June 2015 for a first round of anonymous voting after face-to-face debating. The second and third voting rounds were both internet-based and additional internet-based voting rounds were necessary to establish a consensus between the experts of this ESA/EBA Taskforce whenever there was a lack of evidence in the literature. The experts formulated draft recommendations before each process of voting to serve as a foundation for subsequent discussion and evaluation. The expert panel was updated by short presentations of the literature search results and subsequent interpretation for drafting of the proposed recommendations. The voting process included expert judgments on GRADE factors, such as outcome, importance and evidence-to-recommendation transformers (Tables 3 and 4 – Supplemental Digital File, http://links.lww.com/EJA/A126). An algorithm (Fig. 1 – Supplemental Digital File, http://links.lww.com/EJA/A126) depicted the final rendering of disagreement/agreement graded by the degrees of agreement. This process provided a structured and validated method for expert panel activities. In addition, it standardised statistical methodology for determining the degree of agreement to serve as a foundation for deciding about the grade of recommendation (GoR) (strong versus weak).

Questions

1. What types of co-morbidities and patients require evaluation and management of procedural sedation and analgesia by an anaesthesiologist?

The taskforce provided recommendations that the following groups of patients must be evaluated and managed for PSA by anaesthesiology professionals.

1a. Patients with severe cardiovascular diseases (very good consensus: level of evidence A: grade of recommendation strong)

Patients with cardiovascular diseases should be carefully evaluated and optimised according to a 'first, do no harm' (*primum non nocere*) strategy. This involves full evaluation of physical status and cardiac reserve[28] before PSA. In emergency procedures (e.g. gastroscopy for bleeding), this evaluation might have to be limited. In all other cases, a more complex and systematic approach should be considered, including patient history and co-morbidities, physical examination, including blood pressure (BP) measurement and pulmonary auscultation, biochemical testing, and ECG at rest. Urgency, invasiveness and persistence of those procedures, particularly under suboptimal conditions of PSA, can elicit stress responses with myocardial ischaemia, impairment and failure in cardiac patients.[29,30] Predictive models for preoperative assessment of cardiac risk factors[31,32] may provide objective clinical tools for assessing and predicting individual risks of cardiac events in patients undergoing non-cardiac procedures under PSA. Cardiac patients may also require PSA for minor or major cardiac procedures such as left heart catheterisation or coronary stenting,[33,34] electrical cardioversion[35] and implantation of internal defibrillators,[36] pacemakers or trans-femoral aortic valves.[37] Current practice for these procedures is to provide PSA with benzodiazepine (mainly midazolam) and/or propofol, and low-dose opioid.[34,37] Dexmedetomidine has been proposed as an adjuvant, but it should be used cautiously as its use has been reported mainly in paediatric patients and it is currently off-label in Europe.[38,39] The essential role of an anaesthesiologist has been previously advocated in patients with moderate to severe hypotension (SBP < 90 mmHg) or major cardiac dysfunction.[40,41]

1b. Patients with documented or suspected risk of obstructive sleep apnoea syndrome (very good consensus: level of evidence B: grade of recommendation strong)

Patients with obstructive sleep apnoea syndrome (OSAS) are more vulnerable to drug-induced cardiopulmonary depression during deep sedation.[42] There are different validated instruments to identify patients at risk of OSAS, like the Berlin[43] or STOP-BANG[44] questionnaires. Those are usually performed during the pre-evaluation of the patient in the pre-anaesthesia clinic. Pre-intervention recognition of OSAS is an essential first step in preventing and managing potential complications. A thorough patient history (e.g. snoring, witnessed apnoeas during sleep) and physical examination are important in raising a suspicion of OSAS, but the absence of typical clinical features does not exclude OSAS. Although the use of 'conscious sedation' (in the Guidelines definitions, levels 1 and 2) in OSAS patients did not seem to be related with major and minor cardiopulmonary adverse events[45–48] when the procedure was performed by a non-anaesthesiologist, these data are of limited evidence given their retrospective evaluation and the possible lack of statistical power. The presence of OSAS does not *per se* predict cardiopulmonary complications.[48] However, PSA in OSAS patients may require deeper levels of sedation or even general anaesthesia. Hypoxaemia, arterial hypotension or premature termination of the procedure may occur also with anaesthesiologist providing MAC for patients with OSAS.[49] Fast and adequate management of such complications requires professional skills.

Management of OSAS patients undergoing PSA requires thorough and appropriate understanding of different pharmacological options available, where minimal doses of hypnotics should be used and opioids avoided. Dexmedetomidine has been used with a good safety profile and could be considered as an alternative choice for PSA if OSAS is documented.[50] In patients with severe OSAS, the use of nasal continuous positive airway pressure (CPAP) might reduce risks of post-procedural respiratory

complications but correct management of CPAP usually requires expert skills.[51]

1c. Patients with morbid obesity (BMI greater than 40 kg m^{-2}) (very good consensus: level of evidence A: grade of recommendation strong)

Morbidly obese patients are at higher risk of respiratory complications during PSA for several reasons, including impaired function of respiratory muscles, reduced functional residual capacity, limitation of expiratory flow,[52–54] increased oxygen consumption, increased production of carbon dioxide, increased work of breathing at rest,[52] increased upper airway resistance with propensity for OSAS,[52–55] and the potential for obesity–hypoventilation syndrome, followed by pulmonary hypertension and right heart failure.[56,57] Although BMI is a robust and simple clinical tool for assessment of obesity, it has limitations when analysed alone (e.g. heavily muscled individuals are classified as being overweight). It is now documented that other factors, such as young age and pattern of adipose tissue distribution, may be better predictors of risk of long-term complications; the waist height/hip ratio is also considered to be more predictive of complications.[58] In particular, central obesity is more strongly related to higher risk of impairment of breathing, which often worsens during PSA. As obese patients with OSAS are more prone to airway obstruction, the use of the Berlin[43] or STOP BANG[49,59] questionnaires is proposed to assess the severity of OSAS before providing PSA in obese patients.

Practical recommendations whenever PSA is to be carried out in obese patients are to avoid the supine position and place the patient in a beach chair position, prefer endotracheal intubation as the default choice of airway management, avoid long-acting sedatives, avoid drugs with respiratory depressant effects on the breathing frequency and/or tidal volume, and avoid drugs that induce or reinforce airway obstruction in non-intubated patients. Propofol for sedation seems to be associated with respiratory complications also when used by anaesthetists, so remifentanil and dexmedetomidine (as off-label use in Europe) have been proposed for tailored titration of sedation and analgesia with appropriate monitoring of breathing and depth of anaesthesia despite the fact that both drugs are associated with acute respiratory events and their use should be judiciously evaluated in obese patients where the risk for possible difficult ventilation and intubation can be challenging.[60,61]

1d. Patients with chronic renal failure (glomerular filtration rate below 60 ml min^{-1} 1.73 m^{-2} for more than 3 months or stage 3A) (very good consensus: level of evidence B: grade of recommendation weak)

PSA is required to relieve anxiety and minimise discomfort associated with arteriovenous fistula creation and other procedures in patients with chronic renal failure (CRF). Propofol and alfentanil used to achieve a similar degree of sedation and analgesia have been reported to induce lower SpO_2 values and apnoea/hypoventilation in CRF patients than in control patients.[62] For PSA during procedures of vascular access for haemodialysis, intravenous administration of drugs, such as midazolam and/or fentanyl, are generally preferred for their short onset time, although the maximal effect of midazolam, as estimated by pharmacokinetic and pharmacodynamic models, is about 13 min. No difference has been reported in distribution, elimination or clearance of unbound midazolam between normal patients and CRF patients given intravenous doses of 0.2 mg kg^{-1}.[63] The pharmacokinetics of single-dose fentanyl is not affected in CRF.[64–66] Similar to midazolam,[67] fentanyl is primarily metabolised by the liver.[68] Major, mainly cardiovascular and/or pulmonary, adverse effects associated with the administration of either midazolam or fentanyl have been reported to increase when the two drugs are being combined,[69] particularly in high-risk CRF patients, and there is need for careful intra-procedural and post-procedural respiratory monitoring and management of these patients.

1e. Patients with chronic hepatic disease (model for end-stage liver disease score ≥10) (very good consensus: level of evidence A: grade of recommendation strong)

Patients with chronic liver disease are often exposed to endoscopic procedures requiring PSA for diagnostic assessment of for example oesophageal varices or portal hypertensive gastropathy.[70] Hepatic dysfunction resulting from liver disease can significantly change metabolism and pharmacokinetic properties of hypnotic drugs. The risk of complications related to sedation is increased in these patients.[71,72] Midazolam is preferred in most centres because it has a shorter onset time when compared with diazepam and lorazepam and it has potent amnestic properties. However, prolonged plasma half-life may increase the risks of adverse effects in hepatic dysfunction.[73–76]

In minimal hepatic encephalopathy, procedural sedation with midazolam caused exacerbation of symptoms for up to 2 h after the end of the procedure.[77,78] Propofol used for sedation has a more favourable pharmacokinetic profile requiring no dose adjustment in renal or hepatic failure. Propofol sedation in chronic hepatic failure (including Child C patients) has been reported to be superior to midazolam sedation in terms of safety, efficacy and recovery.[79–86] Propofol-induced hypoxaemia (decreased SpO_2 values) is not common in hepatic failure but can occur, requiring supplemental oxygen and airway support. Measurement of SpO_2 values before PSA can help detecting a hepatopulmonary syndrome.[79,87]

1f. Elderly patients (older than 70 years) (very good consensus: level of evidence A: grade of recommendation strong)

There are many age-related physiological changes in the cardiac, pulmonary, renal, hepatic, endocrine and nervous

systems in elderly patients that need to be evaluated to determine if those patients are at increased risk for complications related to PSA.[88,89] Studies suggest that there are increased risks of arterial hypotension, hypoxaemia, cardiac arrhythmias and aspiration in elderly patients undergoing PSA compared with younger patients.[90–92]

Endoscopic procedures are generally well tolerated in elderly patients, with complication rates similar to those in younger patients.[93–98] An exception is colonoscopy, which is associated with higher perforation rates in patients over 65 years and with higher rates of cardiovascular, pulmonary, and total complications in patients over 80 years compared with younger patients.[99–101] For long procedures, such as endoscopic retrograde cholangiopancreatography, different sedative drugs have been used, and the main concerns seem to be related to reduced doses to avoid over dosage, post-procedural hypoxaemia, and prolonged recovery.[102,103]

It is well known that essential pharmacokinetic and pharmacodynamic changes are associated with the process of ageing. Apparently, the brain becomes more sensitive to hypnotic drugs with age.[104] By evaluating specific effects of propofol by electroencephalography (EEG), Schnider *et al.*[105] have demonstrated increased sensitivity to propofol in elderly patients. An appropriate dose reduction for midazolam and propofol for endoscopies in elderly patients has been extensively studied.[106–108] The onset of action of all anaesthetic drugs used in elderly patients is much slower and the intervals for successive doses (dose-titration) should be adapted accordingly.

1g. Patients with American Society of Anesthesiologists' physical status III to IV (very good consensus: level of evidence B: grade of recommendation strong)

High-risk (ASA status 3 or higher) patients undergoing PSA have a higher risk of hypoxaemia due to hypoventilation,[109–111] calling for adequate clinical observation and monitoring, management of airway patency and ventilation patterns. A new tool to assess potential risk related to PSA called the area under the oxygen saturation curve (AUCDesat) has been advocated as a useful predictive composite index for sedation risk assessment, reflecting individual duration and extent of desaturation over time.[112] Its clinical role still needs to be validated in extensive outcome studies.

2. What are the requirements to provide well tolerated procedural sedation and analgesia?

2a. Adequate upper airways evaluation (very good consensus: level of evidence B: grade of recommendation strong)

The majority of severe complications of PSA are associated with altered upper airway patency and/or respiratory depression, so evaluation of the upper airway before PSA is essential. Documented systematic assessment of the upper airways should be carried out before any PSA. Methods of systematic airway examination have been designed to identify patients where ventilation by face mask[113–115] and/or endotracheal intubation[116–120] might be difficult with standard techniques, but not all difficult airways can be predicted.[118]

Difficult upper airways management is associated with, but not exclusively limited to, individual deviations in general habitus (significant obesity, pregnancy),[121–124] head and neck anatomy (short thyromental distance, limited cervical range of motion, facial or neck trauma, tumour, oedema, abscess, haematoma, tracheal deviation, large neck circumference, dysmorphic facial features, excessive facial hair), mouth opening (small mouth opening, trismus, macroglossia, protruding incisors, small interincisor distance, toothlessness, tonsillar hypertrophy, high arched palate) and jaw anatomy (micrognathia, retrognathia, inability to prognath, that is to advance lower incisors forward beyond upper incisors).[118] For more details, refer to current reference literature in anaesthesia.[118]

2b. Adequate location/monitoring and anaesthesia environment

In addition to environmental factors (e.g. locations of PSA facilities and recovery sites, room sizes, spatial logistics and equipment), human and procedural factors (e.g. staff qualifications, immediate access to emergency support) also influence patient safety. A basic rule for well tolerated PSA is that the clinician performing the sedation should only be responsible for PSA: performing both the invasive procedure and the PSA is unsafe. Ministries of Health should state 'safety first' in their hospitals and private clinics.

2c. All personnel in charge of the procedural sedation and analgesia should be certified for cardiopulmonary resuscitation (very good consensus: level of evidence B: grade of recommendation strong)

The risk of life-threatening complications during or after PSA is increased if staff are inexperienced and less well trained. Complication rates in low-risk patients are considered to be lower than in high-risk patients.

The main problems encountered in patients during and after PSA include hypoxaemia/decreased SpO_2 values (40.2%), vomiting/aspiration (17.4%), arterial hypotension/haemodynamic instability (15.2%), apnoea (12.4%) and cardiac arrest. Although some complications are non-fatal, they can easily lead to cardiac arrest requiring cardiopulmonary resuscitation (CPR).[125] Therefore, proper training in critical emergency medicine of all staff caring for patients during or after PSA is crucial. Training

should include not only management of cardiac arrest but also prevention, recognition of a deteriorating situation and management of deterioration early in the course. Being able to perform CPR immediately in the case of cardiac arrest also requires specific medical material, including a defibrillator, to be immediately available wherever PSA takes place.

Scenario-based and simulation-based training in endoscopic haemostasis may provide opportunities to improve procedural skills and acquire practical experience in managing this medical emergency, which also requires the ability as a team leader to rapidly process, integrate and appropriately respond to complex information under emergency conditions.[126] However, sole manikin training has been shown not to result in sufficient improvement of skills for managing patients.[127] This underlines the importance of specific attention to the science of human factors.

2d. Minimal skills for training for non-anaesthesia providers dedicated to procedural sedation and analgesia

Minimal requirements for provision of PSA include the ability to appropriately perform pre-procedural clinical assessments (including upper airway and co-morbidities assessment); competence at intravenous cannulation; appropriate skills for rapid assessment (by direct clinical observation and monitoring) and management of different levels of sedation; advanced airway management; diagnosis and management of respiratory and haemodynamic depression; detailed knowledge of the pharmacology of drugs used for PSA and for emergency management; certified competence in advanced life support and monitoring of the patient (very good consensus: level of evidence B: GoR strong).

There is consensus in the literature on the needs for certified training of staff directly involved in PSA.[2,128–133] According to the Academy of Royal Colleges in the United Kingdom, individuals who administer drugs for PSA should be aware of their possible adverse events and be prepared and able to rapidly recognise and manage them.[134] Therefore, this taskforce agrees that each provider delivering PSA must be able to evaluate and manage various levels of sedation (see Section 2). The theoretical training should be assessed by a written formal exam with multiple choice questions with a minimal passing score of 75%.[128]

2e. Acquisition/maintenance of minimum technical skills for non-anaesthesia personnel: procedural sedation and analgesia should be carried out only in locations where an anaesthesiologist is immediately available (very good consensus: level of evidence C: grade of recommendation strong)

Technical skills mandatory to acquire and maintain competence in delivering well tolerated PSA include at least bag mask ventilation and placement of a supraglottic airway. Tracheal intubation is not a mandatory requirement but one should be prepared to intubate the patient, for example in case of inhalation of gastric content or any other distress syndrome (anaphylactic shock, bronchospasm). There is evidence that tracheal intubation performed by non-anaesthesiologists is one of the predicting factors for difficult intubation,[135] and there is a need for a certain number of successful intubations before considering the trainee proficient in (advanced) airway management.[136,137] Given the risk of occurrence of major adverse effects during PSA even in healthy patients,[138] a certified competence in advanced life support in all personnel involved in PSA is suggested. Another requirement for well tolerated PSA is the ability to evaluate adequate recovery from PSA. The person responsible for providing PSA should be competent in recognition of full recovery of consciousness[2] using objective tools[139,140] and in case of prolonged or unexpected over sedation, patients should be evaluated according to the Aldrete Score and reach a value of 8 to 10 before allowing discharge from the hospital/office.[141]

Completion of training should be confirmed using a Global Rating Score (GRS) (previously used in other settings[142,143]) that could certify the competence of the trainee dedicated to provide PSA and allow different privileges according to the standard achieved during the final evaluation. This Taskforce suggests that a GRS for evaluating PSA theoretical/technical knowledge should be used before giving privileges for PSA (Appendix 2 – Supplemental Digital File, http://links.lww.com/EJA/A126). It is not the aim of these Guidelines to define the legal/regulatory aspects of PSA practice because they may vary from country to country. The teaching bodies must provide a certificate of proficiency that needs to be endorsed by the national Ministry of Health.

Manikin training alone has been shown not to result in sufficient improvement of skills for care of patients,[124] and a competence maintenance certificate is not currently a requirement in training systems. EBA should support maintenance of skills via every national healthcare body in relationship with the Union of European Medical Societies.

2f. Patient information on procedural sedation and analgesia and the personnel dedicated to provide procedural sedation and analgesia

The clinician has to discuss with the patient the risk, benefits and techniques to deliver PSA before performing the procedure (very good consensus: level of evidence B: GoR strong).

Before performing PSA, the clinician has to complete a full clinical evaluation of the patient to discuss the potential harms and the suggested plan for the scheduled procedure. The clinician should also disclose/present potential alternatives in case of failure that could also

include not having any treatment. The legal concept of the reasonable person is used in obtaining informed consent. The reasonable person doctrine focuses on material risks. A material risk is one that the provider knows or ought to know would be significant to a reasonable person in the patients' position of deciding whether to submit to a particular medication or treatment procedure. However, all conceivable risks do not require disclosure. A printed informed consent form should be used and the informed consent needs to be witnessed. Consent form waivers can be considered acceptable wherever the patient is unable to provide explicit consent due to severe pain or altered mental status.[144–146]

2g. Immediate access to equipment for resuscitation

A difficult airway cart should be readily available wherever PSA is performed (good consensus: level of evidence B: GoR strong).

As airway problems during PSA are quite common and may rapidly lead to severe hypoxaemia, an approved algorithm for difficult airway management should be readily available. If no difficult airway cart is available, specific pre-packed material (e.g. in bags) may be adequate for immediate supply in case of emergency.[147,148]

2h. Location and environment for procedural sedation and analgesia

There should be a dedicated room for PSA inside any facility. Those rooms should have easy access, an easy evacuation system in case of emergency and an elevator large enough to evacuate the patient on a stretcher. A code blue button installed in the PSA room can facilitate an alarm in case of emergency (good consensus – level of evidence C – GoR strong).

A code blue button installed in the PSA room can facilitate alarming in case of emergency as an immediate and appropriate response is vital. However, there are different ways to facilitate alarming of emergency teams for help. Having a code blue button, or at least specific and well known alarm procedures, may save patients' lives in emergency situations.[147]

2i. Presedation fasting

Fasting prior to PSA is not evidence-based. A single protocol as used for preoperative fasting prior to surgery should avoid confusion and mistakes (good consensus: level of evidence C: GoR weak).

The current literature does not provide sufficient evidence to test the hypothesis that pre-procedure fasting results in a decreased incidence of adverse outcomes in patients undergoing PSA.[146–150] Recent guidelines[151] related to preoperative fasting prior to surgery recommend that for adults undergoing elective procedures, the preoperative fasting period is 2 h for clear fluids and 6 h for solid food.

2j. Detailed knowledge of the pharmacology of drugs used for procedural sedation and analgesia

It is beyond the scope of these Guidelines to review in detail the pharmacology of sedative and analgesic drugs commonly used to provide adequate comfort to patients subjected to diagnostic or therapeutic PSA and previously described elsewhere.[149–151] Instead, the main goal of this taskforce in this context is to focus on basic pharmacokinetic and pharmacodynamic aspects of sedative and analgesic drugs. To ensure well tolerated drug administration, clinicians should always be aware of the pharmacological properties of each drug and drug combinations used.[69]

Drug selection for PSA should be based on ease of dosing to reach and maintain the desired level of sedation and analgesia, therefore avoiding adverse events caused by excessive dosage or unexpected reactions to the individual drug or drug combination. As such, the theoretically ideal drug for PSA has a rapid onset, short duration of action and time-independent context-sensitive half-time. In addition, it should have a beneficial haemodynamic and respiratory stability profile. As most of the available drugs for PSA do not cover both the hypnotic and analgesic endpoints, drug combinations are mostly required.[152] Therefore, the clinician should understand the principles of drug interactions to balance between clinical effects and side-effects.[153,154]

For most of the drugs used for PSA, the recommended route of administration is intravenously as the pharmacokinetic effect can be better predicted.[149] Some upcoming evidence exists on intranasal drug administration during PSA, for example for dexmedetomidine.[155]

Propofol remains the most common sedative drug,[156–162] mainly for its short onset time (30 to 60 s), predictable duration of action and short context-sensitive half-time. It induces a dose-dependent amnesia and sedation, leading to unconsciousness and general anaesthesia at higher concentrations.[163] As propofol has no analgesic properties, it is mostly combined with opioids during PSA resulting in a strong synergistic relationship of both sedative and analgesic effects. In addition, these drug combinations can induce significant haemodynamic and respiratory instability requiring fine-tuned titration.[164,165] Alternatively, ketamine and dexmedetomidine have been described as adjuvant drugs with propofol. Pain at the site of injection of propofol is a problem, which can be minimised by reducing the concentration to 0.5% or administering lidocaine or opioids intravenously before its administration.

Benzodiazepines are still used for PSA. The most frequently used benzodiazepine is midazolam for its rapid onset (30 to 60 s) and the maximum effect is reached after 13 min. Its duration of action is longer than propofol (20 to 80 min) and with a prolonged half-life; for this reason, it is used mainly for shorter procedures but with caution in

elderly patients or patients with comorbidities.[166,167] As midazolam has no analgesic properties, it is typically combined with opioids during PSA. Before considering it a sole drug for PSA, its low therapeutic index should be considered.

Ketamine differs from other sedatives in several ways. It possesses analgesic properties and can, therefore, be used as the sole agent for painful procedures. It has a rapid onset of action (30 to 60 s) and a moderate duration of action (10 to 20 min). Because of its cardiovascular stimulating effects, ketamine should be used cautiously in patients with ischaemic heart disease.[168,169]

Two α_2-agonists (clonidine and dexmedetomidine) are used for sedation in clinical practice. Although clonidine has a long duration of action as it is highly lipophilic, dexmedetomidine is more highly bound to plasma proteins.[170] Dexmedetomidine needs to be administered by a slow initial bolus followed by continuous infusion. Its use as 'per se' sedative drug or combined with opioids has recently reached great success in paediatric patients even although the recommended use is for continuous sedation in patients in the ICU.[171] Dexmedetomidine has a beneficial respiratory stability profile, but caution is required as cardiovascular changes related to speed of injection are present.[172]

Different opioids are often used to relieve pain during procedures. Although morphine is the reference drug, synthetic opioids such as fentanyl, alfentanil, sufentanil and remifentanil are more useful to supplement sedatives for short painful procedures.

Most drugs used during PSA are injected as single or repeated boluses or as a continuous infusion. For propofol and remifentanil, pharmacokinetic-based, target-controlled infusion has been introduced into clinical routine and has proven to out-perform manual infusion schemes, resulting in fewer episodes of apnoea, better haemodynamic stability, better patient and clinician satisfaction, better monitoring focus and better patient recovery.[173,174]

2k. Detailed knowledge of the monitoring devices and interpretation of the information provided by the monitors

2k. i. Clinical observation Continuous visual bedside observation of the patient represents the basic level of clinical monitoring during and after any procedural sedation (very good consensus: level of evidence B: grade of recommendation strong)

Standard monitoring parameters [non-invasive BP (NIBP), pulse oximetry, ECG and capnography] are analysed separately in this section but their use during PSA should be considered mandatory. Given the rapid changes caused by the administration of sedative medications combined with analgesic drugs, it is important to have a continuous assessment of the levels of sedation that can vary during the procedure. This requires a combination of clinical observation and monitoring.[175,176] The depth of sedation should be assessed periodically throughout a procedure by using one of these scales or by assessing responsiveness to verbal and tactile stimulation.[177–179] During procedures where a verbal response is not possible (e.g. oral surgery, upper endoscopy), the patient has to demonstrate his/her level of consciousness, such as by squeezing the hand in response to commands or a tactile stimulus. This response suggests that the patient will be able to control his airway and take deep breaths if necessary, corresponding to a state of moderate sedation. Note that a response limited to reflex withdrawal from a painful stimulus is not considered a purposeful response and thus represents a state of deep sedation or general anaesthesia.

2k. ii and iii. Non-invasive blood pressure and ECG: intermittent non-invasive measurements of blood pressure and continuous ECG monitoring are considered mandatory in all patients undergoing procedural sedation (very good consensus: level of evidence B: grade of recommendation strong)

Intermittent frequent measurements of NIBP at least every 5 min although such monitoring could interfere with the procedure[180] and continuous ECG monitoring are both considered mandatory during anaesthetic procedures including PSA. This statement is supported by the ESA/EBA taskforce and non-randomised control trials (non-RCTs) publications.[181] The importance of monitoring these parameters is supported by the fact that significant hypoxia and cardiac arrhythmias have been reported to be associated with upper gastrointestinal endoscopy with or without sedation. These events have been proposed to be associated with age and comorbidity of the patient, the extent and duration of the procedure, and the experience of the endoscopist.[182] Pulse rate and SBP have also both been reported to increase upon pharyngeal introduction of an endoscope.[183]

2k. iv. Pulse oximetry: the most important device for clinical bedside monitoring: should be used in all patients undergoing procedural sedation (very good consensus: level of evidence B: grade of recommendation strong)

As already mentioned above, continuous clinical observation of the patient should be the basic level of clinical monitoring in any patient subjected to PSA. Pulse oximetry, providing transcutaneous values of haemoglobin oxygenation (SpO_2), should be used as a minimum standard for continuous monitoring of all patients undergoing procedural sedation. Not using pulse oximetry during PSA cannot be considered ethically acceptable. Continuous supply of oxygen and monitoring with pulse oximetry are mandatory to minimise the risk of, and rapidly manage, hypoxaemia.[184,185] Today, pulse oximetry is the standard for monitoring of severely ill or injured patients

in perioperative, intensive care and emergency medicine.[186,187] Pulse oximetry enhances patient safety by detecting hypoxaemia earlier and more reliably than other methods.[186,188] The sites most commonly used for detection (finger, toe, ear) have similar accuracy.[187] If available, the variable pitch 'beep,' which gives a continuous audible indication of the oxygen saturation reading, may be helpful. It is recommended to measure SpO_2 before starting PSA, when the patient is breathing room air, to know the patient's baseline SpO_2 and to know which value should be aimed for during the recovery period. However, when using pulse oximetry, it should be taken into account that some influencing factors may lead to false measurements or a delayed display of desaturation or re-saturation. Changes in measurement kinetics or perfusion can lead to aberration of the pulse wave signal with deviations in accuracy and precision,[188,189] for example in hypotension,[189] or when nail polish[190] or acrylic finger nails[191] are used. Pulse oximetry measures oxygenation only but does not allow the evaluation of alveolar ventilation once supplemental oxygen is given to the patient.[184] Therefore, additional monitoring should be used to ensure appropriate respiratory function.

2k. v. Capnography: by facilitating early detection of ventilation problems: should be used in all patients undergoing procedural sedation (very good consensus: level of evidence A: grade of recommendation strong)

In addition to continuous monitoring by visual observation, NIBP, ECG and pulse oximetry, capnography should be used for continuous evaluation of ventilation.[184] It monitors the end-tidal concentration of carbon dioxide, which is in theory more sensitive to alveolar hypoventilation than SpO_2 and is standard monitoring for endotracheal intubation and ventilation in general anaesthesia.[184,192] Sidestream capnography can be measured with special nasal cannulae. Capnography has also been shown to provide earlier indications of apnoea than pulse oximetry.[184,193] Other studies have shown interventions based on capnography compared with standard monitoring with a pulse oximeter result in fewer episodes of apnoea and hypoxaemia.[194–196] Capnography detected 54 episodes of apnoea, and pulse oximetry 27 of them, in 28 of 49 patients subjected to procedural sedation for upper gastrointestinal endoscopy.[193] The addition of capnography to standard monitoring for propofol sedation in adult emergency care reduced, and improved early detection of, hypoxic events.[197] Simultaneous use of other techniques for carbon dioxide measurement (arterial blood gas analysis, transcutaneous measurement) can enhance the validity of capnographic measurements.[198]

A recent meta-analysis[199] supported the use of capnography during PSA concluding that episodes of respiratory depression were 17.6-times more likely to be detected by capnography compared with standard monitoring. Given this evidence in the literature, the ASA and the Academy of Medical Royal Colleges included capnography in the basic monitoring standards whenever the patient has to undergo moderate or deep sedation.[175,200]

2k. vi. Processed electroencephalogram monitors might be considered for monitoring of procedural sedation: particularly when using propofol (good consensus: level of evidence B: grade of recommendation weak)

Some processed electroencephalogram monitors such as bispectral index (BIS) monitoring have been reported to minimise complications during sedation and to evaluate by objective measures the level of sedation.[201,202] In addition, BIS monitoring has been reported not to improve oxygenation or reduce cardiopulmonary complications,[203] and no clinical role of this kind of monitoring has been found during sedation for endoscopic procedures.[204] Nevertheless, BIS monitoring during procedural sedation with propofol has been reported to be associated with higher satisfaction among patients and endoscopists,[204,205] and to enable more effective titration and shorter procedures of sedation.[206] Altogether, available results on the use of BIS monitoring for procedural sedation remain controversial.

Clinical data on other cerebral monitoring methods [e.g. spectral entropy, Narcotrend, MT MonitorTechnik GMBH & CO, Hannover, Germany and Sedline, Masimo, Irvine (CA) USA] are rare. The scarce results indicate that they are utilised as monitors mainly to determine the depth of sedation during a propofol-based sedation.[207] Clinical assessment and Narcotrend-guided sedation using propofol for deep sedation demonstrated comparable propofol dose and recovery time.[208] Both monitoring systems were equally well tolerated and effective. However, the Narcotrend-guided sedation showed less haemodynamic changes and fewer complications compared with the clinical assessment-guided sedation.[208] Evidence supporting the use of these devices during PSA is supported by a limited number of studies.

2l. Knowledge of the major type of complications and their management

Procedural sedation analgesia can be the cause of a wide range of complications that can happen during or after the procedure. These range from mild to life-threatening events that need early and proper recognition and management by the clinician involved in the administration of the PSA (very good consensus – level of evidence B – GoR strong).

Even best practice may result in unavoidable complications. Relevant problems after PSA[92,209–217] include the following:

2l.i. Respiratory depression

Respiratory depression may present because of a decrease in depth and/or rate of ventilation and is attributed to

depression of respiratory control centres, which normally trigger breathing as carbon dioxide levels in the blood rise slightly above the normal threshold. All sedatives, opioids, and potent general anaesthesia inhalation agents have the potential to depress central hypercapnic and/or peripheral hypoxaemic drives, but this risk is minimal with moderate sedation, provided one uses conventional doses and monitors the patient appropriately. Nevertheless, one must be thoroughly skilled in managing respiratory depression in the event it should occur. Management of respiratory depression should commence with standard airway support. Pharmacological reversal of the sedative agents is indicated but requires adequate training.

2l. ii. Airway obstruction

Airway obstruction must be distinguished from respiratory depression. Although obstruction may result in hypoventilation, the patient's actual drive to ventilate (breathe) may or may not be obtunded. Upper airway obstruction may be attributed to anatomical structures or foreign material, both of which are addressed during the initial 'airway patency' portion of the primary assessment. When these procedures fail to establish patency, pathological causes of obstruction must be considered, namely laryngospasm or laryngeal oedema. These events can be distinguished visually by those trained in direct laryngoscopy, but otherwise the distinction is made empirically.

2l. iii. Arterial hypotension

Numerical values that change significantly from baseline should alert the clinician, but evaluation of skin colour changes and patient's consciousness can guide the clinician to maintain an adequate value of blood perfusion. In general, a SBP of 90 mmHg should sustain mean arterial pressure sufficiently to perfuse tissues in the recumbent patient.

2l. iv. Hypertension

'Hypertensive crisis' is the conventional term for sudden elevations in DBP to at least 120 mmHg. A hypertensive crisis is regarded as an 'urgency' if the patient remains asymptomatic and an 'emergency' if signs or symptoms are present, such as chest pain, headache or visual disturbances.

2l. v. Chest pain

Angina/myocardial infarction.

2l. vi. Cardiac arrest

2l. vii. Allergic reactions

The spectrum of allergic reactions can range from a minor local reaction to more severe anaphylactic reactions. The diagnosis of anaphylactic reaction is not always easy to establish. Anaphylactic reactions can present with mild dyspnoea in mild cases or lead to hypotension and shock in severe cases. When a life-threatening anaphylactic reaction does occur, it simulates an acute cardiac, respiratory and metabolic crisis and requires urgent acute critical care. Treatment for anaphylactic reactions includes the discontinuation of the suspected allergen, airway management, fluid resuscitation, antihistamine drugs, hydrocortisone and epinephrine.

2l. viii. Other rare and minor problems include:

(1) Vasovagal reactions
(2) Arrhythmia
(3) Pain and stress in patients
(4) Hallucinations
(5) Nausea and vomiting are common side-effects of opioids. In addition, the over distension of the stomach or colonic loop can produce nausea and vomiting after the endoscopic procedure.
(6) Hypersalivation

2m. Knowledge of the interventions that may be used if required

2m. i. Use of supplemental oxygen

Supplemental oxygen should be available whenever PSA is started and it can be administered to prevent hypoxia, especially in long procedures or whenever a hypoxic period is anticipated (good consensus: level of evidence B: GoR strong).

There is still a debate on the use of supplemental oxygen during PSA[218–220] to reduce the incidence of hypoxaemia. The best evidence supporting the use of oxygen is a double blind, randomised trial of adults undergoing PSA with propofol[218] in which episodes of hypoxia ($SpO_2 < 93\%$) lasting longer than 15 s occurred significantly more often (41%) among the 58 patients given compressed air by face mask compared with the 59 patients given high-flow oxygen (19%) using the same delivery system [difference 23%; (95% confidence interval: 6 to 38%)]. However, the clinical significance of such transient episodes of hypoxaemia remains debatable. Several observational studies have found that supplemental oxygen at lower concentrations does not reliably prevent hypoxaemia during PSA[221,222] and delays the detection of respiratory depression in patients without $EtCO_2$ monitors, as SpO_2 levels may not fall until a prolonged period of hypoventilation or apnoea has occurred.[223,224]

2m. ii. Haemodynamic support (outside cardiopulmonary resuscitation)

Haemodynamic support in case of hypotension/hypertension or any cardiac arrhythmia associated with PSA should be initiated immediately to reduce the risk for a life-threatening condition. In case of major cardiac events, a cardiologist

should be consulted as soon as possible (moderate consensus: level of evidence N/A: GoR weak).

3. How should recovery after procedural sedation and analgesia be managed?

Patients must be monitored in a recovery room for at least 30 min after procedural sedation and analgesia (good consensus: level of evidence B: grade of recommendation strong)

As patients may deteriorate considerably after procedural sedation, sufficient monitoring is essential, but there is no clear evidence on the way they should be monitored after procedural 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 and pulse oximetry) is essential to supplement continuous visual observation by an experienced trained nurse. No clear recommendation can be given on whether recovery should take place in a separate room or in the sedation area, but monitoring for at least 30 min after procedural sedation is considered to be adequate.[225]

The basic criteria for suitability of a patient for discharge after PSA include:

(1) Low-risk procedure with no need to monitor postoperative complications
(2) Mental status and physiological signs should be returned to the baseline values and the patient should be able to take care of him/herself or just with minimal help
(3) Postoperative symptoms such as pain, nausea and dizziness should be well tolerated
(4) A reliable person should be always present with the patient to help him/her in the first hours after discharge.

Discharge criteria should be designed to minimise the risk for cardiorespiratory depression after patients are released from observation by trained personnel. Some discharge scores have been used successfully before to assess the patient after PSA and allow for an earlier discharge after colonoscopy.[226,227] It has also been suggested that patients are ready for discharge when they have reached their 'neuromuscular and cognitive pre-procedure baseline'.[225] To check discharge criteria in patients after PSA, the ALDRETE score seems to be feasible.[228]

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, which problems can arise and how to solve them and when the patient can return to normal activity. A follow-up should be offered to the patient in case he/she could experience problems after having been discharged home.

4. Who should evaluate non-anaesthesia personnel and according to what criteria to establish they are adequately trained to perform procedural sedation and analgesia?

Anaesthesiologists (both anaesthesiologists and anaesthesia nurses in some countries) are the main specialists involved in PSA, and they are able to manage patients at various levels of sedation and general anaesthesia while mastering upper airways, ventilation and circulation. This taskforce suggests that, whenever PSA is provided by non-anaesthesiologists, the different national societies and health authorities have to consider a proper training of these clinicians in delivering well tolerated PSA. The training should be organised and provided by anaesthesia departments. An objective scoring system, for example the Global Rating Scale (Appendix 2 – Supplemental Digital File, http://links.lww.com/EJA/A126) suggested in these guidelines, should be considered to confirm individual proficiency for provision of PSA independently (good consensus – level of evidence N/A – GoR strong).

5. Gaps in evidence and future research

There are still grey areas not supported by strong evidence from RCTs or prospective observational studies. For some topics, such as monitoring, the lack of evidence is balanced by common sense as the advent of advanced monitoring such as peripheral oxygen saturation has dramatically improved safety by earlier detection of episodes of hypoventilation. The use of processed EEGs could lead in the future to the use of automatic closed-loop systems. The real gap in the evidence is represented by the training required to ensure that non-anaesthesiologist clinicians achieve and maintain competence in providing well tolerated PSA.[229] PSA is still associated with both predictable and unpredictable adverse events and complications and so the clinician involved in the management of PSA must have the skills to manage the whole process and its side-effects. Quality control studies are necessary to evaluate safety, complications and risk factors to allow each centre to evaluate its performance (benchmarking) as a basis for quality improvement.

Summary and conclusion

PSA is a frequent practice in hospital and office-based facilities. In the near future, there will be an increasing number of requests for diagnostic/therapeutic interventions requiring PSA. An adequate evaluation of the patient is mandatory to screen for risk factors for possible complications related to the administration of drugs that alter the level of consciousness and can lead to adverse events. The healthcare provider involved in PSA needs a specific training and advanced skills in managing the airway and administering emergency drugs in case this

should be necessary. There is an on-going debate on whether the management of PSA should be centralised in the anaesthesia department. The role of anaesthesiologists should be maintained to coordinate and supervise PSA activities and training to maintain the highest levels of safety.

Acknowledgements relating to this article

Assistance with the guidelines: none.

Financial support and sponsorship: none.

Conflicts of interest: ML received honoraria from Masimo (Irvine, California, USA); EDR received honoraria from Masimo (Irvine, California, USA) and MSD; DL has received grants and funding from LFB (France), Baxter International (USA), and Fresenius Kabi (Germany), and has received speaker's fees of Masimo, Medtronic, Edwards Laboratories, and Orion Pharma; MMRFS has received grants and funding from The Medicines Company (Parsippany, New Jersey, USA), Masimo (Irvine, California, USA), Fresenius (Bad Homburg, Germany), Dräger (Lübeck, Germany), Acacia Design (Maastricht, The Netherlands), and Medtronic (Dublin, Ireland) and honoraria from The Medicines Company (Parsippany, New Jersey, USA), Masimo (Irvine, California, USA), Fresenius (Bad Homburg, Germany), Baxter (Deerfield, Illinois, USA), Medtronic (Dublin, Ireland) and Demed Medical (Temse, Belgium). TFB has received honoraria for lectures from MSD.

Comments from the Editor: this guidelines article was checked by the editors but was not sent for additional, external peer review. FV and TFB are Associate Editors of the *European Journal of Anaesthesiology*.

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EXECUTIVE SUMMARY

Question	Consensus	Level of evidence	Grade of recommendation
1. What types of co-morbidities and patients require evaluation and management of procedural sedation and analgesia by an anaesthesiologist?			
1a. Patients with severe cardiovascular diseases	Very good	A	Strong
1b. Patients with documented or suspected risk of obstructive sleep apnoea syndrome	Very Good	B	Strong
1c. Patients with morbid obesity (BMI greater than 40 kgm^{-2})	Very good	A	Strong
1d. Patients with chronic renal failure (glomerular filtration rate below 60 ml min1 1.73 m^{-2} for more than 3 months or stage 3A)	Very Good	B	Weak
1e. Patients with chronic hepatic disease (model for end-stage liver disease score 10)	Very good	A	Strong
1f. Elderly patients (older than 70 years)	Very good	A	Strong
1g. Patients with American Society of Anesthesiologists' physical status III to IV	Very good	B	Strong
2. What are the requirements to provide well tolerated procedural sedation and analgesia?			
2a. Adequate upper airways evaluation	Very good	B	Strong
2b. Adequate location/monitoring and anaesthesia environment	N/A	N/A	Strong
2c. All personnel in charge of the procedural sedation and analgesia should be certified for cardiopulmonary resuscitation	Very good	B	Strong
2d. Minimal skills for training for non-anaesthesia providers dedicated to procedural sedation and analgesia	Very Good	B	Strong
2e. Acquisition/maintenance of minimum technical skills for non-anaesthesia personnel: procedural sedation and analgesia should be carried out only in locations where an anaesthesiologist is immediately available	Very good	C	Strong
2f. Patient information on procedural sedation and analgesia and the personnel dedicated to provide procedural sedation and analgesia	very good	B	Strong
2g. Immediate access to equipment for resuscitation	Good	B	Strong
2h. Location and environment for procedural sedation and analgesia	Good	C	Strong
2i. Pre-sedation fasting	Good	C	Weak
2j. Detailed knowledge of the pharmacology of drugs used for procedural sedation and analgesia			
2k. Detailed knowledge of the monitoring devices and interpretation of the information provided by the monitors			
2k. i. Clinical observation: Continuous visual bedside observation of the patient represents the basic level of clinical monitoring during and after any procedural sedation	Very good	B	Strong
2k. ii and iii. Non-invasive blood pressure and ECG: intermittent non-invasive measurements of blood pressure and continuous ECG monitoring are considered mandatory in all patients undergoing procedural sedation	Very good	B	Strong
2k. iv. Pulse oximetry: the most important device for clinical bedside monitoring should be used in all patients undergoing procedural sedation	Very good	B	Strong
2k. v. Capnography: by facilitating early detection of ventilation problems should be used in all patients undergoing procedural sedation	Very good	A	Strong
2k. vi. Processed electroencephalogram monitors might be considered for monitoring of procedural sedation particularly when using propofol	Good	B	Weak
2l. Knowledge of the major type of complications and their management	Very good	B	Strong
2m. Knowledge of the interventions that may be used if required			
2m. i. Use of supplemental oxygen	Good	B	Strong
2m. ii. Haemodynamic support (outside cardiopulmonary resuscitation)	Moderate	N/A	Weak
3. How should recovery after procedural sedation and analgesia be managed?			
Patients must be monitored in a recovery room for at least 30 min after procedural sedation and analgesia	Good	B	Strong
4. Who should evaluate non-anaesthesia personnel and according to what criteria to establish they are adequately trained to perform procedural sedation and analgesia?			
Anaesthesiologists (both anaesthesiologists and anaesthesia nurses in some countries) are the main specialists involved in PSA, and they are able to manage patients at various levels of sedation and general anaesthesia while mastering upper airways, ventilation and circulation.	Good	N/A	Strong