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Swiss recommendations for non-anaesthesiologist-administered procedural sedation and analgesia in adults

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Summary

Various specialists use sedation and analgesia for their interventions without the presence of an anaesthesiologist. Therefore, the need for professional recommendations is obvious. The Swiss recommendations were first published in 2016. In contrast to other guidelines, especially those published by the European Society of Anaesthesiology, the Swiss recommendations were developed in close cooperation with other relevant societies that practise procedural sedation and analgesia in adults. The Swiss recommendations were approved by the members of the Swiss Society of Anaesthesiology and Reanimation, the Swiss Society of Gastroenterology and Hepatology, the Swiss Society of Pulmonology, the Swiss Society of Cardiology and the Swiss Society of Vascular and Interventional Radiology. In this way, maximum acceptance and practicability were achieved. Unlike in other recommendations, for example the American Society of Anesthesiology guidelines, the most critical points such as how to deal with deep sedation and who is allowed to perform have been extensively discussed in the Swiss working group and are also addressed in the Swiss recommendations.

The key points of the Swiss recommendations are multidisciplinary acceptance, advanced preoperative evaluation and selection of patients, clear safety recommendations and minimal requirements regarding monitoring, documentation and staff.

Keywords: *practical guidelines, sedation, analgesia, diagnostic procedures, therapeutic procedures*

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Introduction

In the last two decades, minimally invasive diagnostic or therapeutic techniques have emerged and are still gaining importance in modern medicine; these techniques include gastroenterological and respiratory endoscopy, interventional radiology and cardiology. Hence, the number of such procedures is steadily increasing worldwide. For example, by 2024 an estimated number of 11–13 million colonoscopies will be performed in the US annually [1]. Nowadays, an almost indispensable requirement for these interventions is reliable and safe analgesia and sedation to reduce patients' discomfort and pain. Furthermore, an increasing number of patients themselves insist on sedation.

For more than 30 years, intravenous benzodiazepines have been standard agents for moderate sedation in gastroenterology because of their tranquilising, antegrade amnesic and muscle-relaxing properties, and a lack of alternatives [2]. Since 1996, increasing attention has been paid to propofol, a short-acting sedative agent that induces loss of consciousness within minutes, and has a short recovery time that makes it an ideal sedative drug for outpatient procedures [3]. However, because of its narrow therapeutic range, the lack of a specific antidote and the risk of severe side effects, such as respiratory depression, hypotension and bradycardia, initially propofol was used only in the perioperative setting by anaesthesiologists [4]. However, more and more non-anaesthesiologists have used propofol and other drugs for procedural sedation and analgesia safely and successfully. In the last two decades, propofol has been established, at least in Switzerland, as the sedative

Table 1: Sedation depth.

Sedation level	Conscious-ness	Reaction to stim-uli	Spontaneous breathing	Protective reflex	Circulation	Intervention
I minimal	Awake	Normal on call	Normal	Normal	Normal	None
II moderate	Drowsy	Wakeable Normal on call	Adequate	Normal	Generally normal	None
III deep	Sleeping	Not wakeable, re-action to pain	Maybe impaired	Maybe impaired	Generally normal	Maybe secure airway, ventilation
IV anaesthesia	Unconscious	No reaction	Insufficient or missing	Missing	Generally compromised	Secure airway ventilation

drug of choice for endoscopies, mainly in gastroenterology [5, 6]. Despite a great body of evidence demonstrating the safety of non-anaesthesiologist administered sedation with propofol [7–10], this issue remains controversial in many countries [11–14]. Thus, it is imperative and reasonable to evolve practice guidelines that are accepted by all involved specialties, anaesthesiologists and non-anaesthesiologists.

Background of the Swiss recommendations

In many diagnostic and minimally invasive therapeutic procedures, sedation or analgesia is advisable because of the pain and stress the patients experience, in order to offer them good healthcare in the best possible setting. Since not all analgosedation can be managed by anaesthesiologists, the Swiss Society of Anaesthesiology and Reanimation (SGAR) has worked out a consensus paper with representatives of the Swiss Society of Gastroenterology (SGG), the Swiss Society of Cardiology (SGK), the Swiss Society of Vascular and Interventional Radiology (SSVIR) and the Swiss Society of Pneumology (SGP), with binding recommendations and standards for analgosedation managed by non-anaesthesiologists. This first mini-revision is based on the original consensus paper published in the *Swiss Medical Forum* in 2016 [15]. The current article is the English version of the above mentioned mini-revision, which has not been published yet. It was accepted by all the above mentioned societies. The most relevant reason for the revised version was to adequately cover airway procedures such as flexible bronchoscopy.

In the recommendations, the following terms are used: “must” = mandatory standard (minimum requirement); “should” = urgently desired, depending on accompanying diseases of the patient and the type of intervention, “available” = must be available near the workstation and ready for operation in a reasonable time

Recommendations

Prerequisites

In addition to the necessary technical and medical requirements, patient selection is crucial. The risk of an incident arises primarily from a failure to recognise the patient's risk factors and only secondarily from an overdose of analgosedation. However, as a vital hazard to the patient can occur at any time, sufficient precautions must always be taken to detect cardiopulmonary impairment or excessively deep sedation, as well as to successfully manage any complications. For definitions of sedation depth, see table 1.

Basically, the same standards and recommendations for analgosedation by non-anesthetists apply in the practice and in hospital; in the latter, agreements with the in-house anaesthesia service may be of benefit. All general prerequisites of analgosedation performed by non-anaesthesistis are summarised in table 2.

Sedation depth

Depth of sedation is a continuum from moderate sedation (patients can be awakened; stage II) to deep sedation with unconscious patients with insufficient protective reflexes (stage III) and than to general anaesthesia without spontaneous breathing (stage IV) (table 1) [16].

Risk evaluation

The risks of analgosedation depend on the depth of sedation, and the age and relevant accompanying diseases of the patient. Identifying risk factors that promote an incident during analgosedation is therefore of paramount importance. A preliminary risk assessment of the patient, based on the medical records, medical history and a specific physical examination (vital parameters), must be carried out and documented. Medical conditions posing risk factors for unexpected incidents during analgosedation are summarised in table 3 (see also appendix 1). The risks of analgosedation must be weighted differently according to the type of intervention and the competence of the performing physician. Prerequisites for patient safety are sufficient experience and routine of the performing clinician in practising analgosedation and sufficient monitoring, as well as an infrastructure that allows timely detection and treatment of problems. Especially for patients at increased risk, these requirements must be met, otherwise the analgosedation should be carried out by an anaesthesiologist.

Fasting time

For an intervention with analgosedation, all patients must be fasting to prevent aspiration: no solid food whithin 6 hours and clear fluid up to 2 hours before the intervention.

Table 2: General prerequisits for analgosedation performed by non-anaesthesiologists.

Locality	The outpatient analgosedation performed by non-anaesthesiologists in medical practice is limited to a planned light to moderate sedation depth (level I–II according to table 1).
Liability	Instructions (SOP) with sedation and analgesia in the hospital area must be prepared in consultation with the local anaesthesia service.
Ability	The treatment team is able to detect and adequately treat complications such as deep sedation, hypercapnia and apnoea, hypoxia or cardiopulmonary instability.
Quality	The structural and medical quality requirements are to be weighted according to priority and consequence in everyday clinical practice.

SOP = standard operating procedure

Structural quality

Locality

The workplace should be large enough and equipped according to the requirements of the patient and the attending physician (light, monitoring, material, means of summoning assistance). The location should also be equipped for resuscitation. In case of emergency, an evacuation plan to a medical facility that will provide follow-up treatment must be available.

Equipment and technical requirements

Mandatory and recommended equipment and technical requirements for analgosedation are displayed in table 4. Supplementary monitoring such as capnography can be useful for the detection of hypoventilation and apnoea, depending on the procedure. All equipment must be serviced regularly and checked for proper functioning. The drugs must be checked regularly for completeness and expiry date.

Personnel and responsibility

Analgosedation, including monitoring and, if necessary, restoration of vital functions, is the responsibility of a physician. The physician performing the intervention may not perform analgosedation, but a qualified physician or nurse must be available to administer the sedatives and analgesics and to monitor the patient. Furthermore, an additional person familiar with the procedure and location must be immediately available in the vicinity to assist in the case of cardiopulmonary problems or interventional difficulties. In addition, a member of the treatment team must be able to perform bag mask ventilation and maintain oxygen supply.

Table 3: Medical conditions that are risk factors for analgosedation.

Common risk factors	Additional diseases that required hospitalisation
	Coronary heart disease with angina pectoris
	Relevant pulmonary disease with long-term oxygen therapy or O_2 saturation <90% on ambient air
	Heart failure with orthopnoea
	Obesity (body mass index >35 kg/m^2)
	Contraindications for the appropriate sedatives and analgesics
Additional risk factors, which have to be considered according to the intended procedure and the method of analgosedation	Old age (reduced organ reserves)
	Neurological and psychiatric deficits (cooperation and communication)
	Neuromuscular disorders
	Craniofacial anomaly or pathology (“difficult airway”)
	High risk of aspiration (e.g. ileus)
	Severe sleep apnoea syndrome
	Pregnancy

Table 4: Equipment and technical requirements for analgosedation.

Mandatory	Pulse oxymetry
	Venous access
	Oxygen supply
	Resuscitator bag with O_2 connection and reservoir
	Suction device
	Equipment for airway access and management
	Non-invasive blood pressure measurement
	Defibrillator and resuscitation drugs
Recommended	Electrocardiography
	Capnometry
	Inductive breating rate measurement

Process quality

Analgosedation should aim for the lowest possible sedation depth (table 1). Within an institution, only analgosedation procedures and drugs familiar to the personnel involved should be used. Airway management and restoration of other vital functions must be guaranteed at all times; moreover, an emergency algorithm must be available and known. All patients should receive supplemental oxygen. Medication administered (time and dose), beginning and end of the procedure, and vital parameters (including breathing rate, SpO_2, heart rate, blood pressure and pCO_2, if available) should be documented (at a minimum every 10 minutes, recommended blood pressure measurement every 2 minutes). Monitoring after the intervention and the analgosedation, including pain treatment, should be possible. Discharge criteria for outpatients must be defined.

Patient information and consent

Information about the planned measures, including analgesia, and the accompanying risks must be documented on paper or in electronic form. Outpatients, should be warned: no operation of machines, no active participation in traffic, no contracts for an appropriate period after the procedure.

Drugs

The choice of drugs is the responsibility of the attending physician. However, short-acting and easily controllable drugs should be used. Details on drug dosages, indications and side effects are published elsewhere and are not subject of these recommendations [8].

Post-intervention monitoring

The recovery phase of the patient must take place in a suitable room with monitoring (at least pulse oximetry).

Discharge criteria

Discharge from the hospital or institution is possible only when vital parameters are stable and the patient feels subjectively well. The attending physician decides on the time of discharge. It is advisable to recommend that the patient be accompanied on discharge. The patient should be informed about possible complications and given a contact address. This information must be provided in written form.

Training

The specialist societies develop training programmes on the implementation of analgosedation for physicians and trainees in their specialty. The framework conditions and learning objectives of the programmes are defined in cooperation with the SGAR. The SGAR supports the societies in the training of personnel. Physicians and trainees are to be trained periodically in analgosedation and resuscitation.

Limitations

These Swiss recommendations on analgosedation by non-anaesthesiologists are confined to the aforementioned specialities. Thus, they are not transferrable to other specialities which may be involved in analgosedation (e.g., intensivists, surgeons and paediatricians).

Discussion

The ESA recently published European guidelines for procedural sedation and analgesia in adults [17]. The Task Force has done an immense amount of work to identify and analyse 482 full text articles on this topic and to formulate the most comprehensive recommendations in the literature to date. In contrast to the Swiss recommendations [15], the ESA guidelines did not involve experts from other specialities, such as gastroenterology, cardiology, pulmonology and interventional radiology, who have used sedative agents regularly for decades without anaesthesiological support. From our point of view, it is imperative to involve these specialities, because otherwise they would not follow the guidelines. The authors of the European guidelines stated, that "it was not the aim to provide a legal statement on how procedural sedation and analgesia should be performed and by whom", but guidelines are willingly used by lawyers in the case of adverse events. Therefore, guidelines may be used for legal reasons. This is evident, inevitable and reasonable. Some of the task force's recommendations are debatable, such as the recommendation that patients with chronic renal failure, chronic hepatic disease or older than 70 years should be managed only by an anaesthesiologist. Experience in Switzerland is different: with proper preoperative evaluation, these patients can be well and safely treated by an experienced non-anaesthesiologist. Similar comments are made even in the invited commentary on these guidelines [18]. Although it can be assumed that conditions and practices in European countries vary widely, these guidelines focus in principle on safety, without taking into account the need for interdisciplinary cooperation. Current guidelines and studies from other countries are similar [19–22].

The ASA has recently published new guidelines [23] to replace those from 2002 [24]. After 16 years, they have noticed finally that interdisciplinary work is mandatory and formed a task force with physicians from several medical specialty organisations, although the most relevant specialty, the American Society of Gastroenterology, was not included. The ASA guidelines specifically address moderate sedation. They do not address mild or deep sedation and do not address the educational, training, or certification requirements for providers of moderate procedural sedation. Separate practice guidelines, that will address deep procedural sedation are under development. In summary, the most critical points, such as how to deal with deep sedation and who is allowed to perform it, are not defined in these guidelines, in contrast to the Swiss recommendations.

The evolutionary history of the present Swiss recommendations is scarred by mutual scepticism and prejudice. Anaesthesiologists mistrust the ability of other specialists to handle sedation safely and comfortabley; interventionalists are convinced that they have the required skills and experience. In spite of these unfavourable circumstances, optimistic exponents from the executive boards of the Swiss societies of anaesthesiology and gastroenterology have started to jointly develop safety and practice standards. In 2014, a broader working group including other relevant specialties like cardiology, pulmonology and interventional radiology was formed. The aim was to create interdisciplinary Swiss recommendations for sedation and analgesia by non-anaesthesiologists. Convincing the members of the different societies of the need for interdisciplinary collaboration and compromises was laborious. The detailed history was published in 2016 [25]. Finally, in 2016 the recommendations were accepted and published. In 2018 small modifications were made with the acceptance of all specialties. The version presented in this article includes these modifications.

The key points of the Swiss recommendations are multidisciplinary acceptance, advanced preoperative evaluation and selection of patients, clear safety recommendations and minimum requirements regarding monitoring, documentation and staff.

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Appendix 1
Patient questionnaire before interventions with analgosedation

The appendix is available as a separate file for downloading at https://cardiovascmed.ch/en/article/doi/cvm.2019.02035/.