

RECOMMENDATIONS FOR SEDATION AND ANALGESIA BY NON-ANAESTHESIOLOGISTS



College of Anaesthesiologists
Academy of Medicine of Malaysia



Academy of Medicine of Malaysia

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With the participation of:



College of Dental Specialists
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Academy of Medicine of Malaysia



Malaysian Society of
Gastroenterology & Hepatology

CONTENTS

Committee	2
Preface	3
Foreword from the Master of the Academy of Medicine of Malaysia	4
Message from the President of the College of Anaesthesiologists Academy of Medicine of Malaysia	5
Introduction	6
Definition	7
Clinical Management	8
General Principles	
Pre-procedure Preparation	
Administration of the Sedation	
Patient Support and Monitoring	
Documentation	
Recovery	
Discharge	
Facilities and Equipment	13
References	14
Appendices	15

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COMMITTEE

Dr Lilian Oh Lai Lin

College of Anaesthesiologists

Dr Mary Suma Cardosa

College of Anaesthesiologists

Professor Dr Lian Chin Boon

College of Dental Specialists

Dr Noraini Nun Nahar Yunus

College of Dental Specialists

Dr Wong Foot Meow

College of Dental Specialists

Dr Alzamani Mohd Idrose

College of Emergency Physicians

Associate Professor Dr Ismail Mohd Saiboon

College of Emergency Physicians

Dato' Dr Ravindran Jegasothy

College of Obstetricians & Gynaecologists

Dr Goh Kim Yen

College of Physicians

Dr Tengku Saifudin Tengku Ismail

College of Physicians

Dr Alex Tang

College of Radiology

Dr Ramesh Gurunathan

Malaysian Society of Gastroenterology & Hepatology

Dr Jason Chin

Malaysian Society of Gastroenterology & Hepatology

PREFACE

These recommendations apply to the administration of sedation and analgesia to adult patients by non-anaesthesiologists, whether in the operating theatre or in other locations. The aim of the recommendations is to ensure patient safety and to reduce morbidity and mortality associated with unsafe practices.

These recommendations were initiated by the College of Anaesthesiologists and are the outcome of several meetings and discussions with the committee members listed in this document, representing the Colleges of Dental Specialists, Emergency Physicians, Obstetricians and Gynaecologists, Physicians and Radiologists of the Academy of Medicine of Malaysia and the Malaysian Society of Gastroenterology and Hepatology.

Before finalizing the recommendations, the document was reviewed by Council members of the College of Anaesthesiologists; in addition, committee members from other Colleges obtained feedback from members of their respective Colleges.

The recommendations will be reviewed periodically depending on practices and technological advances.

FOREWORD FROM THE MASTER OF THE ACADEMY OF MEDICINE OF MALAYSIA

First and foremost, I would like to congratulate the College of Anaesthesiologists, Academy of Medicine of Malaysia, for working with all relevant disciplines in coming out with the recommendations for sedation and analgesia for diagnostic, interventional and minor surgical procedures. The main objective of this document is to ensure patient safety and reduce morbidity and mortality.

Sedation to reduce patient discomfort during certain procedures is not to be taken lightly, as any medication which depresses the central nervous system can be potentially dangerous if the patient is not properly monitored for respiratory and cardiovascular system depression. An understanding of dose-effect relationship is also crucial.

This document serves as a useful guide for all doctors carrying out such procedures whether they be doctors-in-training or specialists.

Dr Chang Keng Wee

Master

Academy of Medicine of Malaysia

MESSAGE FROM THE PRESIDENT OF THE COLLEGE OF ANAESTHESIOLOGISTS ACADEMY OF MEDICINE OF MALAYSIA

There is now a widespread practice of administering sedation and analgesia for various diagnostic, interventional and minor surgical procedures by the non-anaesthesia disciplines. We need to ensure that the safety of patients is maintained with accepted standards of care.

I am proud that the College of Anaesthesiologists, Academy of Medicine of Malaysia, initiated these recommendations and I must congratulate the participating disciplines for working together as a team, giving due consideration to the potential risks involved. This document provides a safety guide and outlines the recommended preparation before, during and after such procedures. We are confident it will assist all medical and dental practitioners to be more aware and prepared in the management of such patients.

Assoc Prof Datin Dr Norsidah Abdul Manap

President

College of Anaesthesiologists

Academy of Medicine of Malaysia

INTRODUCTION

Sedation for diagnostic or interventional procedures or minor surgical procedures involves administration of drugs by any route or technique which results in depression of the central nervous system. The objective of sedation is to reduce the discomfort of the patient and to facilitate the performance of the procedure. However, even minor procedures can carry major risks and there have been cases of morbidity and mortality occurring in such patients.

The technique of sedation carries risks because:

1. The patient's protective reflexes are obtunded and airway obstruction and/or aspiration may occur.
2. Depression of respiration may occur, leading to hypoxia.
3. Depression of the cardiovascular system may occur, leading to hypotension, bradycardia and cardiac arrest.

In addition to this, the risk of complications from sedation for endoscopic procedures is also increased by

1. The wide variety of drugs with potential adverse effects, especially in combination, which may be administered to the patient.
2. The possibility of excessive amounts of these drugs being used to compensate for inadequate local analgesia.
3. The difficulty in predicting the response of individual patients to the administered drug, especially in elderly patients and those with co-morbidities.
4. The widely differing standards of monitoring equipment and staffing at different locations.
5. The wide variety of procedures performed under sedation.

It is important to understand the variability of effects which may occur with sedative drugs and that over-sedation or airway obstruction may occur **at any time**. Patient cooperation with maintenance of verbal communication should be the endpoints for procedural sedation.

These recommendations are meant to be a guide on the administration of sedation and analgesia to adult patients by non-anaesthesiologists, whether in the operating theatre or in other locations, in order to ensure patient safety and to reduce morbidity and mortality.

DEFINITION

Sedation is the depression of the central nervous system and/or reflexes by the administration of drugs by any route without loss of consciousness, so that painful and/or uncomfortable procedures can be carried out.

Table 1. Continuum of Depth of Sedation¹

	Minimal Sedation (Anxiolysis)	Moderate Sedation/Analgesia (Conscious Sedation)	Deep Sedation/Analgesia	General Anaesthesia
Responsiveness	Normal response to verbal stimulation	Purposeful response to verbal or tactile stimulation	Purposeful response after repeated or painful stimulation	Unarousable even with painful stimulation
Airway	Unaffected	No intervention required	Intervention may be required	Intervention often required
Spontaneous ventilation	Unaffected	Adequate	May be inadequate	Frequently inadequate
Cardiovascular function	Unaffected	Usually maintained	Usually maintained	May be impaired

When performed by non-anaesthesiologists, the level of sedation should be kept at minimal to moderate. Deep sedation should be avoided unless an anaesthesiologist or a physician with expertise in airway management is present throughout the procedure.

CLINICAL MANAGEMENT

GENERAL PRINCIPLES

1. A registered medical practitioner (RMP) or registered dental practitioner (RDP) must be trained to carry out procedural sedation.
2. All patients planned for procedural sedation must be adequately prepared and given appropriate information.
3. All patients undergoing sedation must be monitored by a trained medical staff throughout the procedure.
4. Post-procedure monitoring must be carried out until patients have fully recovered from the sedation.
5. Appropriate instructions must be given to patients upon discharge after undergoing procedural sedation.

Summary of Steps in the Administration of Procedural Sedation

Pre-procedure

1. Selection of patient for procedure.
2. Patient assessment: Relevant history, physical examination and investigations.
3. Written instructions for patients on pre-procedural preparation (fasting, etc) and post-procedural care (including who to contact in an emergency) in various languages.
4. Consent.

During the procedure

1. IV access.
2. Monitoring - pulse oximeter + NIBP, ECG, with appropriate documentation.
3. Oxygen via appropriate administration device. (e.g. nasal prongs, face mask)
4. Administration of sedation drugs by trained RMP/RDP.
5. Assistant to monitor patient throughout the procedure.

Post-procedure

1. Documentation of procedure, drugs used and vital signs.
2. Recovery - to continue monitoring with pulse oximeter and NIBP.
3. Discharge, accompanied by responsible adult.
4. Repeat post-procedural instructions for home before discharge.

PRE-PROCEDURE PREPARATION

1. Assessment of the Patient

All patients should be assessed properly before procedural sedation/analgesia. This should include:

- a) Relevant medical history, including current problem, co-existing medical problems, past surgical history, history of past sedation and anaesthesia, allergies, current medications, fasting status, presence of false, damaged or loose teeth or other evidence of potential airway problems.
- b) Examination, including that relevant to the current problem, airway, respiratory and cardiovascular status, and other systems indicated by the history.
- c) Results of relevant investigations.

2. Patients who may require an anaesthesiologist to administer sedation

Those patients at increased risk of airway, respiratory or cardiovascular compromise during the procedure may require an anaesthesiologist to care for the patient and administer the sedation. These include patients who:

- a) are elderly, in particular those with significant co-morbidities
- b) have significant cardiovascular, lung, renal or liver disease
- c) are morbidly obese
- d) have significant obstructive sleep apnoea
- e) are known or suspected difficult endotracheal intubation cases
- f) have acute gastrointestinal bleeding with cardiovascular compromise or shock
- g) are at risk of aspiration of stomach contents
- h) have had previous adverse events due to sedation, analgesia or anaesthesia
- i) have a history of substance abuse

The decision to call upon the assistance of an anaesthesiologist will be made by the RMP/RDP after consideration of the risks to the patient.

3. Preparation of the patient for the procedure and sedation

- a) Adequate explanation of the procedure and sedation including risks.
- b) Written consent as appropriate.
- c) The procedure should preferably be performed during office hours when help is more readily available should the need arise.
- d) Adequate instructions for pre-procedural preparation (e.g. fasting) and post-procedural care (e.g. a responsible person to escort and care for the patient after discharge). Ideally, written instructions should be given (Appendix 1 and 2).

ADMINISTRATION OF THE SEDATION

1. The RMP/RDP administering the sedatives should:
 - a) be able to establish intravenous access prior to the procedure,
 - b) have knowledge of the actions of the drug(s) being administered, and be able to adjust dosages of the drugs, especially in those with underlying diseases and concurrent medication, and those with a history of chronic substance abuse,
 - c) monitor the patient's level of consciousness and cardiorespiratory status,
 - d) detect and manage any possible complications that may arise, including cardiopulmonary resuscitation.
2. The prescription of the sedatives is the responsibility of the RMP/RDP.
3. Intravenous anaesthetics such as propofol are to be used only by a RMP/RDP **trained in their use** because of the risk of unintentional loss of consciousness.
4. Sedative drugs should be carefully titrated to effect rather than using a fixed dosage. The use of antagonists to opioids and benzodiazepines should only be during an emergency situation, not as a routine administration at the end of the procedure.

PATIENT SUPPORT AND MONITORING

1. There must be **continuous** monitoring of **pulse rate** and **oxygen saturation** and regular monitoring of **depth of sedation** and **blood pressure** throughout the procedure. Depending on the clinical condition of the patient, monitoring of other parameters such as ECG may also be required.
2. An **appropriately trained** assistant to the RMP/RDP must be present to monitor the cardiorespiratory status of the patient and be able to immediately respond to the patient should the need arise. This person may, if appropriately trained, administer sedatives and/or analgesics under the direct supervision of the RMP/RDP.
3. The patient's oxygen saturation should be monitored continuously with a pulse oximeter, which should be set to alarm when the saturation falls below a preset limit.
4. Supplemental oxygen should be administered during the procedure, especially in patients undergoing airway or gastrointestinal endoscopies.
5. Loss of response to verbal commands or stimulation may indicate loss of airway reflexes, respiratory and/or cardiovascular depression, and sedation should be appropriately lightened.
6. If an adverse event (e.g. airway obstruction or cardiorespiratory insufficiency or allergic reaction to drugs) occurs at any time, **all staff** must devote their entire attention to immediately treating and monitoring the patient until recovery or until such time as another RMP/RDP becomes available to take responsibility for the patient's care.
7. The monitoring must be continued into the recovery phase.

DOCUMENTATION

1. Documentation of the following should be done for all procedures and must be kept as part of the patient's records.
 - a) names of staff involved in the procedure
 - b) history, examination and investigation findings
 - c) dosages of drugs and their timings
 - d) Vital signs: Pulse rate, oxygen saturation and blood pressure: pre, intra and post-procedure

RECOVERY

1. Recovery should be carried out under appropriate supervision in a properly equipped and staffed area for an adequate period of time.
2. Adequate staffing and facilities must be available for monitoring and treating patients who have had complications during or after the procedure.

DISCHARGE

1. Discharge of the patient should be authorised by the RMP/RDP who administered the drugs, or another appropriately qualified RMP/RDP.
2. The patient must be discharged into the care of a responsible adult, who may be given written instructions (Appendix 2).

FACILITIES AND EQUIPMENT

The procedure must be performed in a facility that is adequate in size, and is equipped to deal with a cardiopulmonary emergency. This includes:

- a) an adequate sized room to perform resuscitation if this becomes necessary
- b) adequate lighting
- c) an operating table, trolley or chair which can be tilted head down (preferable but not mandatory)
- d) adequate suction apparatus of operating room standards
- e) a supply of oxygen and suitable devices for administration of oxygen to a spontaneously breathing patient
- f) a means of inflating the lungs with oxygen (e.g. a self-inflating bag and mask) and access to a range of equipment for advanced airway management (e.g. masks, oropharyngeal airways, endotracheal tubes, laryngoscopes, laryngeal mask airways)
- g) availability of resuscitation trolley with appropriate drugs and equipment for cardiopulmonary resuscitation (Appendix 3)
- h) a pulse oximeter
- i) a sphygmomanometer or other blood pressure monitoring device
- j) ready access to an ECG and a defibrillator
- k) a means of summoning emergency assistance

Specialised Equipment for Inhalational Sedation

When inhalational agents such as nitrous oxide are used to provide sedation, risks of chronic exposure should be considered. Special requirements for administration include the following:

- a) The patient breathing circuit must be of lightweight construction, with a reservoir bag for inspired gases and have low resistance to normal gas flows.
- b) The installation and maintenance of any piped gas system must be according to appropriate standards.
- c) There must be regular servicing of equipment and piped gases.
- d) There must be a non-return valve to prevent re-breathing.
- e) Appropriate scavenging system for expired gases is required.
- f) There must be the capacity to administer 100% oxygen.
- g) There must be a low gas flow alarm.
- h) When nitrous oxide is used there must be a minimum oxygen flow of 3 litres/min with a maximum combined flow of 10 litres/min, or, in calibrated machines, a minimum of 30% oxygen. The circuit must include an anti-hypoxic device which cuts off nitrous oxide flow if the oxygen supply fails and opens the system to allow the patient to breathe room air.

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Appendix 1

GUIDELINES FOR PRE-PROCEDURAL FASTING

Age	Substance Ingested	Fasting Time
Children	Clear Fluids*	2 hours
	Breast Milk	4 hours
	Formula Milk, Solids	6 hours
Adults	Clear Fluids*	2 hours
	Milk, Solids	6 hours

*Clear fluids include: water, glucose drink, cordial drinks, clear fruit juices.

Summary: 'the 2-4-6 rule'

- 2 hours clear fluids
- 4 hours breast milk
- 6 hours formula milk and solids

Appendix 3

RESUSCITATION FACILITIES

The list is only a guideline and may be modified according to local circumstances and types of procedures performed.

Emergency Drugs

1. Adrenaline
2. Atropine
3. Frusemide
4. Lignocaine
5. Sodium Bicarbonate 8.4%
6. Hydralazine/Labetalol
7. Nitroglycerine
8. Calcium chloride
9. Naloxone
10. Flumazenil
11. Salbutamol
12. Hydrocortisone
13. Dextrose 50%
14. IV fluids – crystalloids and colloids

Equipment

1. Syringes and needles of various sizes
2. Intravenous cannulae of various sizes
3. IV administration sets
4. Oropharyngeal airways, nasopharyngeal airways of various sizes
5. Laryngoscopes and blades of various sizes
6. Endotracheal tubes of various sizes
7. Self-inflating bags with face masks (e.g. Ambu bag)
8. Oxygen supply and means of delivery via flowmeters
9. Suction equipment
10. Pulse oximeter, Non-invasive blood pressure monitor (NIBP), ECG
11. Defibrillator