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Conscious sedation v. monitored anaesthesia care – 20 years in the South African context

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Sedation of patients for minor procedures is here to stay. However, it is the responsibility of every physician to be aware of the potential complications associated with the combination of drugs administered and to practise in an environment where no risks are taken and no procedures performed outside the circle of safety. Furthermore, as an anaesthetic service, monitored anaesthesia care (MAC) is clearly distinct from

moderate sedation and it is important for patient safety that these differences are recognised and adhered to. In essence, all practitioners must observe the strict distinctions between sedation and MAC to prevent the drift into deeper sedation under inappropriate circumstances.

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A standard definition for 'sedation' is not clear in the local medical literature. Nonetheless, over the past 20 years sedation has become an exciting, valuable practice catering for an expanding array of procedures in and out of hospitals and clinics. It is, by definition, a state of altered or reduced consciousness in which verbal contact with the patient is maintained. However, since its inception the term 'conscious sedation' has been expanded, twisted and manipulated to the extent that it has become a euphemism for GANA (general anaesthesia no airway) or 'anaesthesia lite'. Currently sedation is a poorly controlled practice, often performed in potentially unsafe environments by unqualified personnel who may be unable to deal with complications.

The word 'sedation' and the many terms used (twilight sedation, moderate, conscious sedation) are deceptive. They convey the sense of a safe, pleasant state. There is a perception by the layman and often the physician that this, 'anaesthesia lite' as we have named it, is a safer option than general anaesthesia. In addition, sedation is perceived as a cheap option competing with increased procedural and theatre costs. But at what price?

With the advent of day surgery, ambulatory surgery and 'procedures in rooms', the need for anaesthesia care exceeds the available capacity. Sedation is no longer the sole domain of the anaesthetist. Uniquely, it has become one of the few medical practices performed by a large range of varying practitioners with varying skills and with no certification required. Operating environments are not standardised, even to the extent of equipment, so that any one of a number of complications may arise with potentially catastrophic outcomes.

Sedation has the potential for being abused, with disastrous

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outcomes to patients and practitioners. However, sedation is here to stay and it is therefore crucial to define and therefore quantify the hazards as well as to highlight safeguards for good administration.

The triad of anaesthesia

Anaesthesia is essentially made up of a triangle of analgesia, anaesthesia and relaxation. The ideal approach to anaesthesia is to utilise a balance of the three parameters. If all of these are addressed, this isosceles triangle remains within the circle of safety (Fig. 1a).

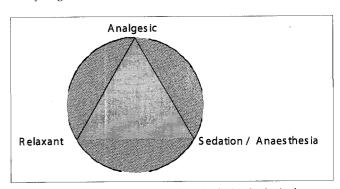


Fig. 1a. The triangle of balanced anaesthesia in the 'circle of safety'.

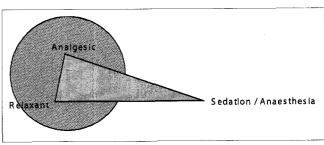


Fig. 1b. The triangle of balanced anaesthesia outside the 'circle of safety'.

However, a common practice with sedation is that the sedative drugs are given in large doses to attempt to achieve a calm, pain-free patient.³ When the standard dose is exceeded

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the patient is drawn out of the circle of safety and exposed to the risk of airway compromise, respiratory depression or cardiac instability (Fig. 1b).

In practice, an inexperienced or unskilled practitioner may easily underestimate the effect of the sedatives administered, miscalculating the time to onset, being caught out by the exponential effect of drug combinations, or s/he may mistreat pain using increasing sedatives, with disastrous periprocedural compromise in potentially non-medical environs. The converse of this is the under-use of sedatives because of a lack of familiarity with particular agents or misconceptions about their use.⁴

History of sedation

Dentistry was one of the frontrunners in utilising sedation – diazepam with local anaesthetic in the early 1970s. However, with the advent of faster-onset, shorter-acting drugs, polypharmacy became a potential problem. In 1972 guidelines were therefore published by the dental fraternity.³ Their aim was to strive for a balance between minimising fear and anxiety and maximising safety.

In 1985 the American Food and Drug Administration approved midazolam and it became available for use in 1986.⁵ Its advantages over diazepam are:⁶ water solubility, short duration of action, potent amnesia, minimal venous irritation, and fast onset

Since the approval of midazolam in the USA in 1986, there has been a 20-year evolution of a practice utilised by almost all medical disciplines, from general practitioners doing simple in-room procedures to interventional radiologists performing complex procedures.⁷ While practitioners have embraced the versatility provided by midazolam, they have also recognised the risk of losing airway control/hypoxia/hypotension. Within a year of its approval, the American Society of Anesthesiologists (ASA) published its first standards for basic intraoperative monitoring, introducing the term monitored anaesthesia care (MAC).⁸

MAC is often perceived as being a stage of sedation that has the patient slightly deeper than just anxiolysis. However, MAC must be supplied by a trained anaesthetist, providing the same level of care as with general anaesthesia and/or regional anaesthesia. As a result, the boundaries need to be clearly laid down and the distinction between MAC and mild sedation needs to be well understood and clarified.^{7,9}

Definitions

For a long time the only anaesthesia states defined by the ASA were either general anaesthesia or sedation and analgesia (conscious sedation). Recognising the restrictions in this, the ASA task force on Sedation and Analgesia for Non-Anesthesiologists then defined four clinical states with different implications for monitoring and manpower. The definitions were presented in a document entitled Continuum of Depth of Sedation.¹⁰

The four stages are: (*i*) anxiolysis (minimal sedation); (*ii*) conscious sedation (moderate sedation analgesia); (*iii*) monitored anaesthesia care or MAC (deep sedation analgesia); and (*iv*) general anaesthesia (GA).

The ASA makes a clear distinction between moderate/twilight sedation and MAC. Sedation is defined as having a 'responsive patient' throughout the procedure, whereas MAC requires pre-sedation assessment and peri-sedation management of the potential physiological and medical derangements.¹¹

Several differences have been identified between these two concepts and the skills required for each, as published in a report by the ASA. The report states: Sedation only should never result in any impairment of the level of consciousness so that the patient is always able to protect their own airway'. On the other hand: The provider of MAC must be prepared and qualified to convert to general anaesthesia when necessary'. In principle, a provider of MAC must be able to intervene and rescue a patient's airway from any sedation-induced compromise.

There is therefore a clear distinction between 'moderate sedation' which is given by an array of personnel such as nurses, surgeons and paramedical assistants, and MAC, an anaesthetic-led service requiring the presence of an independent second physician.

MAC includes an array of pre- and post-procedural responsibilities to return the patient to full consciousness with pain adequately relieved, and management of any potential physiological disturbances, which is by definition beyond the scope of moderate sedation.^{11,12} The use of non-anaesthetic staff, while cost effective in terms of patient expenditure on anaesthetic manpower, can lead to grave cost in patient outcome.

Where does this leave us in South Africa?

In current South African practice there is no licensing requirement for the administration of moderate sedation. In 2002 the *Southern African Journal of Anaesthsia and Analgesia* (*SAJAA*) issued guidelines¹² for the safe use of sedation for adults in response to growing practice as well as concerns for patient safety. There are no absolute figures of complications related to sedation available in South Africa. However, based on the few studies on the subject^{13,14} the majority of deaths occur outside the operating theatre and are mostly related to a cardiopulmonary event. The *SAJAA* guidelines¹² state that the mortality for sedation is very low; however it still exceeds the mortality associated with general anaesthesia for outpatient procedures and therein lies the concern and the need for education outside of the anaesthetic community.





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Table I. Definition of levels of sedation/general anaesthesia (ASA)

	Minimal sedation (anxiolysis)	Moderate sedation/ analgesia (conscious sedation)	Deep sedation/analgesia (MAC)	General anaesthesia
Responsiveness	Normal response to verbal stimulation	Purposeful response to verbal or tactile stimulation	Purposeful response to repeated/painful stimulation	Unarousable even with painful stimulus
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

Table I illustrates the continuum of levels of patient consciousness and the potential risk factors associated with those levels. 14

The original sedation score was pioneered by Ramsay et al. ^{15,16} on ICU patients and still forms the basis on which the current ASA and SAJAA definitions are based (Table II).

Table II. The Ramsay score of sedation

- 1 Patient is anxious and agitated or restless, or both
- 2 Patient is co-operative, orientated, and tranquil
- 3 Patient responds to commands only
- 4 Patient exhibits brisk response to light glabellar tap or loud auditory stimulus
- 5 Patient exhibits a sluggish response to light glabellar tap or loud auditory stimulus
- 6 Patient exhibits no response

The advent of short-acting, rapidly redistributed agents for sedation, hypnosis, analgesia and anaesthesia makes this a rapidly evolving subspecialty. However, the potential misuse of the drugs is becoming a real concern. In order to prevent the drift into MAC, the action and interaction of the various drugs need to be well understood. ^{17,18}

Monitoring

The SAJAA guidelines state that the minimal requirement for conscious sedation is a device for monitoring blood pressure and pulse oximetry. However, since the majority of complications involve airway compromise, we advocate that for all patients undergoing MAC there should be supplemental oxygen as well as the ability to monitor a capnography trace, since merely measuring saturation in patients on face mask

supplemental oxygen will give a very late sign of respiratory failure,¹⁹ whereas the use of capnography will give an early indication of airway obstruction as well as a pattern of respiration.

References

- Consensus Conference. Anesthesia and sedation in the dental office. JAMA 1985; 254: 1073-1076
- Ostermann ME, Keenan SP, Seiferling RA, Sibbald WJ. Sedation in the intensive care unit: a systematic review. JAMA 2000; 283: 1451-1459.
- Council of Dental Education, American Dental Association. Guidelines for teaching the comprehensive control of pain and anxiety in dentistry. J Dent Educ 1972; 36: 62-67.
- 4. Conrad SA. Sedation E Medicine. http://www.emedicine.com/ January 2006.
- Philip BK. Supplemental medication for ambulatory procedures under regional anesthesia. Anesth Analg 1985; 64: 1117-1125.
- 6. Editorial. Midazolam: Is antagonism justified? Lancet 1988; 2: 140-142.
- Epstein BS. The American Society of Anesthesiologist's efforts in developing guidelines for sedation and analgesia for nonanesthesiologists: The 40th Rovenstine Lecture. *Anesthesiology* 2003; 98: 1261-1268.
- 8. American Society of Anesthesiologists. Standards for Basic Intraoperative Monitoring. 1986.
- Novak LC. ASA updates its position on monitored anesthesia care. ASA Newsletter 1998; 62(12). http://www.asahq.org/Newsletters/1998/12_98/ASA updates_1298.html
- Joint Commission on Accreditation of Healthcare Organizations. Standards for moderate and deep sedation and anaesthesia hospital accreditation standards. Oakbrook Terrace, Ill.: JCAHO, 2002: 108-111.
- American Society of Anesthesiologists. Statement of qualifications of anesthesia providers in the office-based setting. Distinguishing anesthesia care (MAC) from moderate sedation/ analgesia (conscious sedation).
- Guidelines for the safe use of sedation for diagnostic, therapeutic and palliative procedures in adults. Southern African Journal of Anaesthesia and Analgesia. 2002; Sept. 1-4
- Bailey PL, Moll JWB, Pace NL, Enst KA, Stanley TH. Respiratory effects of midazolam and fentanyl: Potent interaction producing hypoxemia and apnea. Anesthesiology 1988; 69: A813.
- American Society of Anesthesiologists. Practice guidelines for sedation and analgesia by nonanesthesiologists. Anesthesiology 2002; 96: 1004-1007.
- Ramsay MAE, Savage TM, Simpson BRJ, Goodwin R. Controlled sedation with alpaxalonealphadolone. BMJ 1974; 2: 656-659.
- DeJonghe B, Cook D, Appere-de-Vecchi C, Guyatt G, Meade M, Outin H. Using and understanding sedation scoring systems: a systematic review. *Intensive Care Med* 2000; 26: 275-285.
- Bailey PL, Pace NL, Ashburn MA, Moll JWB, East KA, Stanley TH. Frequent hypotension and apnea after sedation with midazolam and fentanyl. Anesthesiology 1990; 73: 826-830.
- Gastointestinal endoscopy/US Food and Drug Administration collaborative study on complication rates and drug use during gastrointestinal endoscopy. Castrointest Endosc 1991; 37: 471-427
- Ruttmann TG, James MF. Routine postoperative oxygen by facemask is it necessary? S Afr Med J 2001; 91: 444.

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