The Management of a Safe and Cost Effective Conscious Sedation Unit

Hendrik Andries Carstens
Student Number 2383455

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Supervisor
Professor James Roelofse

Abstract

Conscious sedation or moderate sedation and analgesia is an effective and popular alternative option for procedures outside the operating theater. If conscious sedation is a viable alternative to general anaesthesia then we as sedation practitioners must use safe sedation techniques in facilities that meet all the requirements for safe practice.

Three studies were done to determine the safety and efficacy of conscious sedation outside the operating theatre. In the first study post sedation satisfaction in one hundred children aged 3-9 years was evaluated. It was extremely important to determine whether the combination of midazolam, ketamine and propofol, called an advanced sedation technique (SASA, 2015), can be safely used for paediatric sedation outside the operating theatre. The incidence of side-effects after conscious sedation using multiple drugs were documented. It is clear that intravenous sedation with midazolam, ketamine and propofol is safe and effective to use. There may be side effects but they are not long lasting and usually not life-threatening.

In the second study intravenous sedation was administered to 447 adults (aged 18 years and older) using fentanyl (sublimaze^{R}), ketamine (ketalar), midazolam (dormicum) and propofol (Diprivan) (FKMP) called an advanced sedation technique. Post sedation satisfaction, post sedation recovery on arrival home, and the relationship between side effects and different dental procedures were evaluated. The results of the study show that side effects are possible, and can be expected, when we use sedative and analgesic drugs for sedation. However, we report a low incidence of side effects when we compare it with other studies in literature as mentioned. It is known that the use of combinations of drugs may cause unforeseen synergistic pharmacological effects which can be life-threatening. Our results show that the drugs used can be safely used for advanced sedation techniques.

In trying to demonstrate the safety of sedative and analgesic agents used during sedation we looked at the haemodynamic parameters, duration of sedation, pulse

rate and systolic blood pressure, in the third study. The sedation records of 335 patients for dental surgery were assessed for the period 2010 – 2011. Our results show the mean Duration of sedation is substantially and statistically significantly greater with combination FKMP than with the other combinations. The mean duration of sedation is not significantly different between ketamine and propofol (KP) and fentanyl, ketamine and propofol (FKP) (Figure 10).

The use of polypharmacy regarding the combination of drugs, specifically FKMP, will cause a longer duration of sedation. This has implications for safety, as well as the side effect profile during and after sedation. When we use combinations of drugs patients were more comfortable which shows that we do not yet have a single drug that has all the characteristics of an ideal drug for sedation. Different combinations of drugs are used by other practitioners with a higher incidence of side effects. It is difficult to explain the higher values of blood pressures when all four drugs were used. It may have been a ketamine effect, although one would not expect this when using propofol with ketamine. In clinical terms the higher blood pressures are no reason for concern as all our patients were classified as ASA I and II.

Our research study support the view that ketamine can be used safely outside the operating theatre with exciting possibilities for Third World countries for procedures outside the operating theatre. Sedation can be considered a reasonable alternative to general anaesthesia for certain surgical procedures in the Third World. Sedation will be an attractive option not only as far as costs are involved but also the availability of sedation providers. The important lesson from all the results is that sedation providers must be trained in procedural sedation as defined by all international sedation guidelines. We proved in this research study that sedation can be done safely, however we need to make a contribution to train sedation providers.

Sedation will become an attractive alternative to general anaesthesia because of the low side-effect profile and high patient satisfaction. It is interesting that few studies are available that looked at this aspect of sedation. It is clear that a high side-effect profile can contribute to an unsafe sedation technique. Severe nausea

and vomiting can cause numerous haemodynamic disturbances and dehydration. Our research study support the findings of the study by Lapere *et al.,* (2015) that there is a high rate of patient satisfaction, and a low side-effect profile during and after sedation.

This is an extremely important research study and the results are crucial as far as an option for healthcare in developing countries. Sub-Saharan Africa is a densely populated and resource poor subcontinent that provides unique challenges in patient care. These challenges include a lack of facilities and staff for the performance of operative as well as non-operative procedures.

In conclusion, we feel that we are part of Sub-Saharan Africa with all the problems mentioned as far as provision of healthcare is concerned. This research study can make a crucial contribution to safe and cost-effective management of healthcare in Africa for procedures outside the operating theatre.

Declaration

I,

Hendrik Andries Carstens

hereby declare that the work contained in this thesis is my own original work and has not previously, in its entirety, or in part, been submitted at any university for a degree and that all sources I have used or quoted have been indicated and acknowledged as complete references.

Hendrik Andries Carstens

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CHAPTER 1: SCOPE OF THESIS

This thesis evaluates the management of a sedation unit outside the operating theatres with a view to monitor the safety of patients.
The literature review in Chapter 3 gives a broad overview of the safety and cost effectiveness of a sedation unit.

The three studies reported in Chapter 4 look respectively at, the experience of children and parents during the post sedation recovery process, on the journey home and at home. Post sedation satisfaction in adults and haemodynamic effects of drugs were evaluated.

The incidence of adverse events during and after dental procedures done under sedation is evaluated. The safety and efficacy of sedative and analgesic drugs in adults and children during conscious sedation, which is of prime concern for the sedation practitioner, is examined.

Conclusions are reported in Chapter 5

CHAPTER 2: INTRODUCTION

Pain, anxiety and fear are often synonymous in the minds of patients when they go for dentistry. Quite a number of dental procedures can cause pain and pressure, even when local anaesthesia is used. It is claimed that 7-15% of adults (Yagiela, 2001) in the USA are very nervous or terrified about having to receive dental care, in children this incidence is reported as 24%. This may lead to patients ignoring dental care because of the anxiety towards possible dental procedures. This may be detrimental to the health of patients.

Anxiety and fear, and the possibility of pain, towards a sometimes unknown surgical procedure may lead to emotional stress for the patient, varying from suppressed fear of pain, and other stress related symptoms to a phobia which can make dental treatment impossible. Patients may even show physical signs of increased sympathetic stimulation such as sweating, hypertension, tachycardia, and tremors. These symptoms and signs may lead to anxiety-induced cardiac arrhythmias, hypertension, cerebrovascular accidents, and/or vaso-vagal reactions, especially in the medically compromised patient.

In children, studies (Kain *et al*., 1996) indicate that some of the above-mentioned symptoms and signs can lead to an increased incidence of postoperative behavioural symptoms e.g. agitation, restlessness – the frequency may be as high as 60%. It is reasonable to say that any patient has the right to effective pain and anxiety control, and it is the duty of the doctor or dentist to provide this. The benefits of relieving fear, anxiety and pain in a patient are numerous. It ensures a calm, cooperative, understanding patient who is able to tolerate an unpleasant procedure comfortably. It may even lead to better dental care as the patient will visit the dentist for any dental problems.

The question is what can we do to provide pain and anxiety control? Conscious sedation or moderate sedation and analgesia can be an effective method of facilitating dental treatment and is often used as an option with local anaesthesia. Properly provided, by sedation practitioners who are trained to provide this,

sedation is safe, valuable and cost-effective for dental patients. If conscious sedation is a viable option, consideration should be given to develop safe sedation practice in facilities outside the operating theatres.

There are four possible treatment options available for patients undergoing dental surgery

- Local anaesthesia as block / infiltration

  A good option for the non-anxious, reasonably, cooperative patient.
- Local anaesthesia block / infiltration with behaviour management techniques for the moderately anxious patient. It is generally agreed that all anxious and uncooperative patients can and should be managed with behaviour management techniques, but it is not always practically possible. Children are an important group in this regard that should receive special attention.
- General anaesthesia

  This is obviously the easiest way out but the question is, is it always the best option? General anaesthesia is also not always available and the side-effect profile e.g. postoperative nausea and vomiting may be high and unacceptable to patients. It is advisable to ask patients about their preferences. It is known that the need for general anaesthesia for dental surgery in the UK has decreased with sedation techniques becoming available. In the UK and other countries general anaesthesia was an option outside the hospital for dental surgery. (GDC 2005) Since 2012 this practice has been stopped. The health departments in some countries e.g. the UK encourage dental patients to consider having dental procedures under sedation.
- Local anaesthesia block / infiltration with conscious sedation.

  This has become an attractive option as patients can be treated in the dental surgery, and they can go home the same day of the operation. It is also well known that the side effect profile is less than general anaesthesia.

DEFINITIONS, TERMINOLOGY AND SAFETY ASPECTS

Attention must be paid to definitions and certain terminology that form part of quality control in safe sedation practice – giving guidance to those involved in sedation practice (SASA, 2015).

- General anaesthesia is defined as a state of controlled unconsciousness. This is not our goal outside the operating theatre (Sá Rêgo, Watchy and White, 1997).
- Analgesia is defined as the relief of pain without the intention to produce sedation. Some of the analgesic agents for example, the opiates may have sedative effects. An altered mental status may be a secondary effect of medications administered for this purpose (Sá Rêgo, Watchy and White, 1997).
- Local anaesthesia is defined as the elimination of sensation (with or without motor activity) in the body, by topical application, infiltration or local/ regional injection of local anaesthetic agents (Sá Rêgo, Watchy and White, 1997).
- Anxiolysis is a drug-induced state during which patients respond normally to verbal commands, often described as an alternation of mood. Although cognitive function may be impaired, ventilatory and cardiovascular functions are unaffected. The patient is fully conscious, usually calm and alert (Sá Rêgo, Watchy and White, 1997).The level of awareness usually does not change. The state of anxiolysis has very important implications for monitoring, only clinical monitoring is considered necessary.
- Conscious sedation or moderate sedation and analgesia is a pharmacologically induced, controlled, and minimally depressed level of consciousness. Patients usually respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. The patient usually maintains the ability to maintain his airway, and spontaneous breathing is adequate. Cardiovascular function is maintained and vital signs remain stable. If left undisturbed, the patient may fall asleep but is easily roused by auditory or tactile stimuli. Protective reflexes, like coughing and swallowing, are intact (Sacchetti *et al*., 1994). Guidelines exist for the safe

use of sedation for diagnostic, therapeutic and palliative procedures in adults (South African Society of Anaesthesiologists, 2002).

- With conscious sedation or moderate sedation and analgesia the airway is usually maintained.
- It is important to note that the definition of conscious sedation by The General Dental Council's (GDC, 2005) in the UK is somewhat different than other international sedation guidelines – if a patient is not responding to verbal commands, but only to physical stimulation, then the technique is not conscious sedation. It is considered as light general anaesthesia.
- Conscious sedation is defined as a technique in which the use of a drug or drugs produces a state of depression of the central nervous system enabling treatment to be carried out (Wylie Report, 1981), but during which verbal contact with the patient is maintained throughout the period of sedation. The drugs and techniques used to provide conscious sedation for dental treatment should carry a margin of safety wide enough to render loss of consciousness unlikely (General Dental Council, 2005).
- In the rest of the world conscious sedation is seen as a technique whereby the patient will respond to verbal contact and or mild physical stimulation. The GDC further states that it is of fundamental importance that the level of sedation must be such that the patient remains conscious, and is able both to understand and respond to verbal commands. The definition also describes the state of conscious sedation, and does not attempt to prescribe how it should be achieved.
- Procedural Sedation and Analgesia (PSA) is a definition that has become very important in sedation practice, is universally used, and needs to be mentioned. Some organizations believe that older terminology that includes the phrase conscious sedation should be abandoned as it does not really say anything about analgesia which is fundamental to the concept of sedation. Procedural sedation and analgesia (PSA) is a more appropriate and accurate description. PSA should be viewed as a continuum ranging from light to deep sedation, with the depth of sedation easily titrated by selective administration of sedative and analgesic drugs (Evered, 2003). PSA can thus mean either minimal sedation or moderate sedation, or deep sedation.

The problem we have with this definition is that the sedation practitioner has a license to operate at whatever level of sedation, including deep sedation – this could have an impact on the incidence of side effects. The sedation practitioner must monitor his patient closely to prevent the patient slipping into deeper than intended levels of sedation.

- Deep Sedation and Analgesia. The definition needs to be clarified as many guidelines regard this level no different than general anaesthesia. In the UK this level is seen as "light general anaesthesia" and patients should be done in a hospital environment. Deep sedation is defined as a pharmacologically controlled induced state of depressed consciousness. The patient is not easily aroused or roused by repeated stimulation. The protective reflexes for example, coughing and swallowing may be lost. The patient may not be able to respond purposefully to physical stimulation or verbal command. To maintain a patent airway the airway may have to be supported by the sedation practitioner (American Society of Anesthesiologists, 2000; SASA, 2015).

It is important to take note of the approach of the General Dental Council (2005) on procedural sedation,

"The level of sedation must be such that the patient remains conscious, retains protective reflexes, and is able to understand and respond to verbal commands. Deep sedation in which these criteria are not fulfilled must be regarded as light general anaesthesia."

- The GDC regards deep sedation as light general anaesthesia. If deep sedation is planned it must be done in secondary care (in hospital) by an anaesthetist who had sedation training or a medical practitioner with equivalent experience in the administration of sedation.
- General Anaesthesia: A controlled, pharmacologically induced state of unconsciousness accompanied by complete loss of protective reflexes, including the inability to independently maintain an airway, and respond purposefully to physical stimulation or verbal command (American Society of Anesthesiologists, 2000).

The Joint Commission on the Accreditation of Healthcare Organisations (JCAHO) (American Society of Anesthesiologists, 2000) have introduced the new terminology just mentioned:

- minimal sedation (anxiolysis),
- moderate sedation and analgesia,
- deep sedation and analgesia (the patient may require airway interventions)
- General anaesthesia.

The American Society of Anesthesiologists (2000), the updated 2015 South African Society of Anaesthesiologists Guidelines on Procedural Sedation and Analgesia, and almost all professional organizations on guidelines for sedation worldwide, use the following definitions of sedation levels to give clarity to the continuum of sedation;

> *Minimal sedation is a drug-induced state during which patients respond normally to verbal commands. Although cognitive functions and coordination may be impaired, pulmonary and cardiovascular functions are unaffected. Only clinical monitoring is needed to look after the patient during sedation.*

> *Moderate sedation and analgesia, also called conscious sedation, is defined as a drug induced depression of consciousness during which the patient responds purposefully to verbal commands* (General Dental Council, 2005)*, either alone or with light, tactile stimulation. No interventions are usually required to maintain a patent airway and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.*

> *Deep sedation is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated painful stimulation. The ability to maintain pulmonary function independently may be impaired. Patients may*

require assistance in maintaining a patent airway, and spontaneous ventilation may be impaired.

According to UK guidelines on sedation the patient must respond to verbal command to meet the requirements of conscious sedation. When the patient has to be touched, or lightly stimulated to get a response this is not conscious sedation anymore. According to the Wylie report, the drugs and techniques used to provide conscious sedation for dental treatment should carry a margin of safety wide enough to render loss of consciousness unlikely. This definition was originally proposed in the Wylie Report (1981) and the core of it has been adopted by the General Dental Council (UK), the Department of Health (UK), and the Society for the Advancement of Anaesthesia in Dentistry (UK), the Dental Sedation Teachers Group (UK), the South African Dental Association, and the British Society of Gastroenterology.

Several definitions from different professional organizations and interest groups (Berggren and Meynert, 1984; Committee on Drugs of American Academy of Pediatrics. 1992; Coté, 1994; Holzman *et al*., 1994; Oei-Lim, 1997; Whitwam and Mccloy, 1998; Lee, Vann and Roberts, 2001; Jackson and Johnson, 2002; South African Society of Anaesthesiologists, 2002; Scottish Intercollegiate Guidelines Network, 2002; Boidin, Wolff and Doelman, 2002; Department of Health, 2003 and Hallonsten *et al*., 2003;) share the same core elements as described by the term conscious sedation as stated in the Wylie Report's definition of 1981. The core elements are 'maintain a patent airway' and 'respond appropriately to physical stimulation.

In the 2015 SASA guidelines on Procedural Sedation and Analgesia, the term conscious sedation is not used. The term moderate sedation and analgesia, which is more descriptive, has replaced conscious sedation. The term conscious sedation has become more or less obsolete in many countries as it is argued that this is not an accurate description of what sedation is. Whatever the level of sedation it is extremely important for sedation practitioners to be able to recognise it.

A question often asked is, which is the safest: sedation or general anaesthesia? There are very few studies, if any, in literature available that compare the two techniques. Providing high standards are maintained, and suitable trained people are available, both methods are probably equally safe. However, high standards depend upon the quality, training, experience, facilities, guidelines and commitment of those involved. To meet the requirements of safe sedation practice can be found in the 2015 SASA Guidelines on Procedural Sedation and Analgesia, and other international guidelines on safe sedation practice (SASA, 2015).

A question that is more relevant, do we have the manpower to meet the demands of the patient population for surgical procedures? We can offer general anaesthesia in-hospital, and sedation outside the hospital for certain procedures.

Large hospitals may have enough experienced doctors and nurses to run a safe sedation service but smaller hospitals probably do not have this luxury. Safety of conscious sedation outside of the operating theatre (procedural sedation) in South Africa and worldwide is of prime concern for sedation practitioners. At the Faculty of Dentistry, University of the Western Cape, Cape Town no morbidity/mortality has been reported during the last ten years of outside the operating theatre conscious sedation. This is very encouraging in our search for safety and efficacy in sedation practice.

Coplans and Curson (1982) were probably the first practitioners that published on sedation adverse events with parenteral conscious sedation. There were no deaths in over two million sedations from 1970 to 1979. Two fatalities were associated with conscious sedation from 1980 to 1989. This shows that clinicians were worried about the incidence of adverse events even many years in the past, but that the incidence of serious adverse events was very low.

In July 2000, an expert group of dental practitioners was convened by the Society for the Advancement of Anaesthesia in Dentistry (SAAD), the biggest organisation for conscious sedation in dentistry in the U.K. Their aims were to

consider safe standards for conscious sedation in dentistry. This document aimed to identify good clinical practice, which is appropriate and necessary for public and private patients within and outside hospitals. The recommendations help sedation practitioners to attain and maintain high clinical standards. In South Africa, the South African Dental Association (SADA) convened an expert group of representatives from the medical and dental profession to consider standards for safe conscious sedation in South Africa. Guidelines were drawn up concerning safe sedation practice and the need for a dedicated facility where doctors/ dentists could be trained (Ad Hoc Committee of SADA, 2001).

In a newsletter in the year 2000 the American Society of Anesthesiologists (ASA) predicted that by the year 2005, 85% of all operations will be done on an outpatient basis – 25% will be done in the office (Yagiela, 2001). With this expected increase in operations outside the operating theatre there is a need to plan for sedation units that meet the demands for safe sedation practice.

In the year 2010 South African Society of Anaesthesiologists (SASA) published separate sedation guidelines for children and adults. This is a guide for safe sedation practice. The guidelines were updated in 2015 (SASA, 2015). The guidelines give a clear guidance to safe sedation practice.

The growth and popularity of ambulatory anaesthesia and sedation in medicine is probably due to the cost-effectiveness and safety of the procedures (Yagiela, 2001). Although the monetary savings behind this trend are obvious, the same cannot probably be said for dentistry. Most non-invasive medical procedures are not repeated in the same patient. In contrast, many dental procedures such as tooth scaling and operative restorations, which can be uncomfortable, are performed on multiple occasions for the same patient. The choice here is either providing conscious sedation (or other forms of pharmacologic management) repeatedly or equipping the patient with the coping skills necessary to manage fear and apprehension. For the patient, the most cost-effective strategy is to overcome the mental barriers preventing routine dental care. Current procedure-based economics for the dentist strongly favours pharmaco-sedation (Sacchetti *et al*, 1994).

Medical insurance and the government are extremely interested in the option of sedation as economic factors and patient satisfaction begin to play a significant role in medical and dental care. General anaesthesia, when available, is expensive because of the costs of health care in hospitals.

Conscious sedation administered outside a theatre environment, is one important option for patients to get the necessary, safe, and affordable dental care. It is effective in reducing apprehension and pain and can improve patient behaviour without adversely affecting the patient's physiological status. Mortality and serious morbidity are exceedingly rare in modern practice. Although behavioural strategies are clearly more cost–effective for the patient receiving routine dental care, in-office sedation is usually the least expensive alternative for patients requiring pharmacological management (Yagiela, 2001).

Although general anaesthesia is safe, highly effective and reliable, it is becoming less relevant, for various reasons, in especially the dentists' armamentarium – one reason being the cost demands of medical and dental insurance, placing its availability at a premium. This is especially true in areas without traditional operating theatres. With the previous as background, it would make sense to look at an option other than general anaesthesia. Such an option has to be safe, acceptable to the patient, cost-effective, with preferably fewer side effects.

It is believed that conscious sedation for dental surgical procedures, as an alternative for general anaesthesia, will become more and more important as many dental procedures can be done under conscious sedation outside the hospital environment. This makes it a very attractive option for patients. The therapeutic goal of sedation is to provide a calm, comfortable patient without pain, and cooperation when undergoing a procedure that often evokes anxiety, discomfort, and pain, but which may require full patient cooperation. This is possible with conscious sedation.

CHAPTER 3: LITERATURE REVIEW

3.1 Historical aspects of Procedural Sedation and Inhalation Sedation

The beginning of sedation from a historical point of view is not very clear. There is a reference to opiates on a Sumerian tablet about 4000 before Christ. The Egyptian Papyrus Ebers (1500BC) quotes a remedy for "excessive crying in children" and the use of alcohol as a narcoleptic is mentioned in the old testament of the Bible (Cornwell and Cornwell, 1993). Modern sedation, has developed over the last hundred years.

In the preceding century the practice of anaesthesia was established and popularized. This followed the discovery of nitrous oxide by Joseph Priestley in 1776 who himself described the effects as "a highly pleasurable thrilling" (Edmund and Boyle, 1934). Twenty years later Humphry Davy (Fujita, 1998) noted the analgesic properties of nitrous oxide and suggested that it would be suitable for use as an analgesic in surgical procedures. His proposal was largely ignored until Horace Wells (Haridas, 2013), a dental surgeon used nitrous oxide inhalation to extract a tooth.

The incremental technique of Drummond-Jackson using (Gopakumar and Gopakumar, 2011) intravenous hexobarbitone was probably, a controversial way of controlling pain in dentistry. He pioneered the technique to produce a controlled level of consciousness by using increments of hexobarbitone via the intravenous route (Holden, 1983).

Niels Bjorn Jorgensen (1966) is often considered as the father of intravenous sedation in dentistry. In 1945, he and Leffingwell, anaesthesiologist at Loma Linda University, researched possible ways of relieving fear and anxiety in ambulatory patients receiving dental care under local anaesthesia. Jorgensen became probably the first person to use the intravenous route for administration of a combination of intravenous pentobarbitone, pethidine and hyocine as

premedication in patients prior to undergoing long dental procedures (Holden, 1983). Jorgensen demonstrated the safety of this approach for pain and anxiety control, and this technique became known as the Loma Linda technique (Dionne et al., 2001).

During the mid-1950s many different techniques were used to produce varying states of central nervous system depression, from conscious sedation to light general anaesthesia.

Davidau (Gelfman and Driscoll, 1977) first used diazepam (Valium) in 1965 as a sedative agent in dentistry. O'Neil and Verrill (1969) used diazepam as the sole sedative agent for patients undergoing oral surgical procedures. The Verrill sign, is today well-known and used as an indicator of the level of sedation.

During the mid 1960s the ultra–light anaesthetic technique of Drummond-Jackson and the Jorgensen's technique spread rapidly throughout many parts of the world as a way to make patients comfortable during surgical procedures.

In 1965 Foreman (Dionne & Phero, 1991) offered a modification of the Drummond Jackson's technique. He used methohexital, an intravenous anaesthetic agent, to achieve sedation by using small doses of the drug. Patients were maintained at a level where verbal contact was possible with the patient. The margin between sedation and anaesthesia was so close that adverse events were inevitable. The practice of intermittent methohexitone for sedation was largely discontinued in the early 1970s. Accidental anaesthesia did occur with intermittent methohexitone. Intravenous sedative and anaesthetic drugs in current use have narrow margins of safety and therefore require professionals who are trained to administer them. (Yagiela, 2001).

In 1981, the first report on sedation in the UK was under the chairmanship of Dr John Wylie (Wylie Report, 1981). A definition for conscious sedation was suggested which is still in use today. Conscious sedation was defined as:

"A technique in which the use of a drug or drugs produces a state of depression of the central nervous system enabling treatment to be carried

out, but during which verbal contact is maintained with the patient at all times. The margin of safety of the drugs must be wide enough to render the unintended loss of consciousness unlikely".

Poswillo in his report (cited in Hawgood, 2014) suggested the following definition for conscious sedation:

"A carefully controlled technique in which a single intravenous drug, or a combination of oxygen and nitrous oxide, is used to reinforce hypnotic suggestion and reassurance in a way which allows dental treatment to be performed with minimal physiological and psychological stress, but which allows verbal contact with the patient to be maintained at all times. The technique must carry a margin of safety wide enough to render the unintended loss of consciousness unlikely. Any technique of sedation other than as defined above should be regarded as coming within the meaning of dental general anaesthesia."

The General Dental Council (England) (2005) still today endorse the need for conscious sedation for dental procedures as a safe alternative to general anaesthesia.

3.2 Safety of Sedation

3.2.1 Introduction

Ambulatory anaesthesia, also known as outpatient or day–case anaesthesia, refers to the delivery of anaesthetic care where the patient is discharged home on the day of treatment. Patient assessment, monitoring, drugs with wide safety margins, and recovery care remain important components of safe conscious sedation. Our main objective with conscious sedation remains guarding the safety and well-being of our patients.

To relieve anxiety, apprehension and distress in order to improve the patients's coping resources, thereby enabling treatment to be carried out also remains a goal.

The question remains how can we make sedation safe for the patient?

3.2.2 Procedural Sedation and Analgesia (PSA) Guidelines

3.2.2.1 Introduction

The practice of sedation showed a lot of progress over the past 20 years. The development of sedation guidelines and training in sedation played a significant role in ensuring the safety of patients. Sedation practitioners also realized the importance of monitoring of patients. The question still is how many sedation practitioners follow sedation guidelines?

The need for sedation guidelines arose in 1990 after a report of Poswillo (cited in Hawgood, 2014) of severe adverse reactions related to administration of a sedative agent (a brand of alphaprodine). The pharmaceutical company recalled the drug and stopped production. It seemed that misuse of drugs by practitioners, who were not well trained was the big reason for concern.

After years of intense research and discussions the original "Guidelines for the Elective use of Conscious Sedation, Deep Sedation and General Anesthesia in Pediatrics" were published in 1986 (Creedon, 1986). These guidelines were originally developed for use in the dental office and made a big contribution to sedation safety.

Despite the publication of a number of guidelines on pain and anxiety control for dentistry it has become evident that there remain areas of confusion and lack of consensus (Department of Health, 2003). Different opinions regarding definitions, doses, techniques of administration and suitable drugs, lead to the development of minimum requirements regarding the expected level of care required to promote the safety, and welfare of each patient.

The General Dental Council (GDC) states in Maintaining Standards (Lowry, 2000; Department of Health, 2003) in a guidance to dentists on professional and

personal conduct, *"Dentists have a duty to provide and patients have a right to expect adequate and appropriate pain and anxiety control"* A very effective way of providing pain and anxiety control is by the use of conscious sedation. But they highlight that training of sedation practitioners must be part of this approach.

As new information on monitoring and research are disclosed, and the use for conscious sedation for a variety of different procedures increase, so will the guidelines and safety aspects and recommendations be updated, to fulfill the broadening expectations of physicians and patients.

On the issue of guidelines the American Academy of Pediatrics said, "Guidelines are systematically developed recommendations to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances" (American Academy of Pediatrics. Committee on Drugs. 1992; Coté, 1994; Wilson, 1996; American Academy of Pediatrics *et al.*, 2006). These recommendations may be adapted, modified or rejected according to clinical needs and constraints. Guidelines are not intended as standards or absolute requirements and their use cannot guarantee any specific outcome. The guidelines establish a format for focusing attention to details, which should act to protect and promote the welfare of the patient who requires sedation. This will lead to a decrease in adverse events (American Academy of Pediatrics. Committee on Drugs. 1992; Coté, 1994; Wilson, 1996; American Academy of Pediatrics *et al.*, 2006). Guidelines are therefore not a recipe of a sedation technique but a guidance to patient safety.

Paediatric sedation is an area of concern regarding safety, therefore sedation guidelines for children and adults. Because children are sedated in a variety of settings, outside the hospital environment, by individuals with varying degrees of expertise, the above guidelines were re-evaluated and rewritten in 2002 to serve as a guidance to safety of children under sedation (American Academy of Pediatrics. Committee on Drugs. 1992; Coté, 1994; Wilson, 1996; American Academy of Pediatrics *et al*., 2006). This was a huge step forward in ensuring quality control in sedation practice.

It was recognized that there has been considerable variation in the level of care provided to patients under sedation. This was influenced by the facility used for the procedures, availability of monitoring equipment, levels of sedation and expertise of the sedation practitioner. It was then decided that the standard of care for all sedated patients should be uniform. Furthermore, the same standards were applied for both deep sedation and general anaesthesia, emphasizing that with deep sedation there was always the potential for loss of protective reflexes, unconsciousness and possible complications. It may be unsafe for the patient.

The major emphasis of all guidelines remain training and monitoring - this is supported by all professional societies involved in sedation practice and a crucial part of quality control. The pulse oximeter, is now considered a valuable and possibly mandatory monitor to be used continuously with all levels of sedation, with the possible exception of anxiolysis, and specifically nitrous oxide sedation (American Academy of Pediatrics. Committee on Drugs. 1992; Coté, 1994; Wilson, 1996; American Academy of Pediatrics *et al.*, 2006).

> *"The development and implementation of guidelines probably elicits more controversy and emotional discomfort than any other activity professional organizations undertake. Sedation guidelines, both among and within professional organizations, are a prime example. Yet, guidelines offer a sense of accountability, direction, and integrity that would seem both demanded and appreciated by most elements of society" (Wilson, 1996).*

Any professional guideline on sedation should make a clear distinction on the roles of the operator-sedationist, and the independent sedationist, dedicated to providing and supervising only the sedation. This is all about the safety of the patient. In both instances specific training in all aspects of safe sedation practice should be mandatory, especially supervised clinical training.

Where any other level of sedation other than anxiolysis is required, it is strongly recommended that the same medical practitioner does not act as both operator and sedationist. It is however acknowledged that there is a role for the trained operator-sedationist in sedation practice. When a multiple-drug technique is

practiced, it is advisable that an independent sedationist and an observer be involved in the sedation process, as in this research study.

The value of training is not only highlighted in sedation guidelines. Professional organizations also support it. The GDC states, "dentists have a duty of care - to administer conscious sedation only within the limits of their knowledge, training, skills and experience" and that dentists should "have completed relevant postgraduate education and training", and "have clinical experience of the particular conscious sedation technique employed". The guidelines in the document are applicable to both dental and medical practitioners who are practicing conscious sedation in all clinical settings:

> *"Where a second dental or medical practitioner is providing conscious sedation for a patient, the treating dentist must ensure that the person acting as the sedationist has undertaken relevant postgraduate training, accepts the definition of conscious sedation and the principle of minimum intervention and has specific experience of the use of conscious sedation in dentistry ---"*(General Dental Council, 2005).

This is a very important statement by the GDC on the importance of training for practitioners involved in sedation practice and should be supported. This is about patient safety.

The UK Academy of Medical Royal Colleges and their Faculties (Royal College of Anaesthetists, 2001), under the chairmanship of the Royal College of Anaesthetists, wrote in, "Implementing and ensuring Safe Sedation Practice for healthcare procedures in adults" "The key point is that safety will be optimized only if practitioners use defined methods of sedation for which they have received formal training".

The Standing Dental Advisory Committee in the UK has it right when they say, "the key to safe practice is the high level of competence based on a solid foundation of theoretical and practical supervised training, progressive updating of skills and continuing experience" (Department of Health, 2003).

For safety patient sedation practitioners must understand what the sedation continuum means; it is all about the level of consciousness (Appendix 1). The deeper the patient becomes, the higher the possibility of adverse events.

Table 1. The continuum of sedation and sedation end points (SASA, 2015)

	Minimal sedation/ anxiolysis	Moderate sedation/ analgesia *"conscious sedation"*	Deep sedation /analgesia	General anaesthesia
Responsiveness	Responds to verbal stimuli	Purposeful response to verbal or tactile stimuli	Purposeful response only after repeated or painful stimuli	Unable to rouse
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

In South Africa we have Guidelines for Procedural Sedation and Analgesia for both adults and children. They serve as a guide for safe sedation practice and are also acknowledged at international level.

The following is a very important statement in the guidelines,*"all health care professionals participating in the assessment, administration, monitoring and recovery of patients requiring sedation are accountable for safe practice. The patient is entitled to the same standard of care, whether the procedure is undertaken in a physician's office, a remote facility, or in an operating theatre. These guidelines are for use by all medical practitioners and their teams, in order*

to provide safe sedation, analgesia and anxiolysis for adult patients and children" (SASA, 2010, SASA, 2015).

SASA guidelines emphasise the role to provide a reference that will enable all practitioners to act within a framework to ensure patient safety and the successful performance of procedures and include the following (SASA, 2010, SASA, 2015):

- Patient selection and assessment
- Informed consent
- Environmental and clinical setting
- Personnel
- Fasting guidelines
- Standards of monitoring
- Education and training
- Recovery and discharge
- Documentation required during PSA
- Behaviour management

The sedation of children is different from the sedation of adults, therefore we have specific guidelines for children. Children differ anatomically and physiologically from adults, therefore it is necessary to highlight some safety aspects. A child's ability to control his or her own behaviour to cooperate for a procedure depends both on chronologic and developmental age (American Academy of Pediatrics. Committee on Drugs. 1992; Coté, 1994; Wilson, 1996; American Academy of Pediatrics *et al.*, 2006). Studies have shown that it is common for children to pass from the intended level of sedation to a deeper, unintended level of sedation (American Academy of Pediatrics. Committee on Drugs. 1992; Coté, 1994; Wilson, 1996; American Academy of Pediatrics *et al.*, 2006). Therefore children must be closely monitored.

The goals of paediatric sedation in the paediatric patient for diagnostic and therapeutic procedures are to

- guard the patients's safety and welfare;

- minimize physical discomfort and pain;
- control anxiety, minimize psychological trauma, and maximize the potential for amnesia;
- control behaviour and/or movement to allow the safe completion of the procedure;
- return the patient to a state in which safe discharge from medical supervision is possible (American Academy of Pediatrics. Committee on Drugs. 1992; Coté, 1994; Wilson, 1996; American Academy of Pediatrics *et al*., 2006). Although written in 2006 we still accept those goals important for safe paediatric sedation.

Looking at all the guidelines mentioned it is clear that the safety and well-being of the patient must take precedence over all other consideration. The main factors governing safety are the knowledge and skill of the sedation practitioner, who should therefore take his/her responsibilities in this regard very seriously. The drugs and techniques used for conscious sedation should have a margin of safety sufficient to render unintended loss of consciousness or loss of protective reflexes unlikely. All necessary equipment and drugs (Appendix 2) to protect the patient from the effects of unintended oversedation, to rapidly reverse such oversedation, or to deal with emergencies must be immediately available (Ad Hoc Committee of SADA, 2001).

> *"The safe sedation of children requires a protective net composed of skilled personnel, vigilance, monitoring equipment, common sense in selecting patients suitable for sedation, appropriate selection of drugs and drug dosage, age and size appropriate airway management equipment, and drugs to sustain life. Seizures, respiratory arrests, and deaths in a variety of practice settings have occurred when any one of these was deficient."* (American Academy of Pediatrics. Committee on Drugs. 1992; Coté, 1994; Wilson, 1996; American Academy of Pediatrics *et al*., 2006).

Part of the safety net of sedation is to have a sedation plan. A commonly used acronym that is useful in planning and preparation for a sedation procedure is SOAPME (American Academy of Pediatrics. Committee on Drugs, (1992):

S (suction) – size-appropriate suction catheters and a functioning suction apparatus

O (oxygen) – adequate oxygen supply and functioning flow meters/other devices to allow its delivery

A (airway) – size-appropriate airway equipment

P (pharmacy) – all the drugs needed as well as antagonists

M (monitors) – as stipulated in SASA sedation guidelines

E (equipment) – emergency equipment for example, defibrillator (American Academy of Pediatrics. Committee on Drugs. 1992; Coté, 1994; Wilson, 1996; American Academy of Pediatrics *et al.,* 2006).

3.2.2.2 Patient Selection and Assessment

Careful pre-operative assessment will ensure that correct decisions are made regarding suitability of a patient for conscious sedation for the proposed operative procedure (Ad Hoc Committee of SADA, 2001). Patients should be assessed in accordance with the American Society of Anesthesiologists (ASA) Physical Status Classification System (Table 2).

Table 2. (ASA) Physical Status Classification System. (SASA, 2015)

Class I	A normally healthy patient
Class II	A patient with mild systemic disease
Class III	A patient with severe systemic disease that limits activity, but is not incapacitating
Class IV	A patient with severe systemic disease that is a constant threat to life
Class V	A moribund patient not expected to survive 24 hours with or without an operation
"E"	An emergency procedure is denoted by the letter E following the class number

All sedation guidelines recommend that only ASA I and II patients be considered for sedation outside the operating room. (Coté, 1994; Wilson, 1996; Scottish Intercollegiate Guidelines Network, 2002; Hallonsten et *al.,* 2003; American Academy of Pediatrics; American Academy of Pediatric Dentistry, 2004; American College of Radiology, 2005; American Academy of Pediatrics *et al*., 2006 and SASA guidelines, 2015).

Although the ASA classification is not a risk classification, it is used worldwide. Patients assessed as ASA class III, IV or V require higher levels of monitoring and care and should be done in-hospital in a fully equipped operating theatre, with a full range of emergency drugs and resuscitation equipment available.

No patient should be considered for sedation without a focused airway assessment. Various tools are available to assess the airway (SASA, 2015).

The patient should fill in a medical history questionnaire designed to disclose any risk factors, or whether he/she is taking any drugs that may necessitate modification of technique or drug dosage, or the use of special equipment. It may also be decided that the patient does not qualify for sedation outside the operating

theatre. Ability to communicate with the child is essential, and identification of those children unsuitable for sedation is crucial. It is useful to record the pre-sedation assessment on the pre-sedation medical history checklist. An example of the medical history questionnaire is included in Appendix 3 (SASA, 2015). It is useful to also record the pre-sedation assessment on the Sedation Monitoring Chart (Appendix 4).

In order to look after safe sedation practice SASA guidelines recommend that no children under 5 years of age should be sedated by practitioners who do not have the necessary training, and extensive experience in paediatric sedation.

Sedation of children below the age of 1 year is said to be contraindicated because of the possibility of unsafe practice, it is never really relevant in the dental setting. Certain children are at increased risk for complications and should be assessed by a specialist anaesthetist trained in sedation or a highly experienced trained sedation practitioner.

3.2.2.3 Informed consent

Written and verbal informed consent must be obtained and documented prior to the administration of drugs for sedation. Informed consent must never be obtained after administration of sedative drugs. The nature of the procedure to be performed may not be changed after the administration of a sedative drug. Informed consent should include an explanation of the procedure, the proposed sedation technique, other options available, and an explanation of the risks and benefits of appropriate alternatives. Patients must be informed of the possibility that the sedation may fail and that the procedure may have to be abandoned or performed under general anaesthesia at a later date. Consent must be obtained for both the procedure and the sedation (Appendix 5). The patient must be given the opportunity to ask questions (SASA, 2015).

3.2.2.4 Environment and clinical setting

Sedation in children should only be performed in an environment meeting all the criteria for safe practice for example, the facilities, personnel and equipment to manage paediatric emergency situations must be immediately available (Scottish Intercollegiate Guidelines Network, February 2002).

A protocol for access to back-up emergency services shall be clearly identified with an outline of the procedures necessary for immediate use (Wilson, 1996 and American Academy of Pediatrics, *et al.,* 2006).

It is critical that a complete range of sizes of emergency and monitoring equipment be available. The complete list of equipment could be found in Appendix 2.

SADA guidelines say premises suitable for the safe practice of conscious sedation must have an oxygen supply, suction, an emergency electricity supply, a pulse-oximeter, all necessary drugs, including emergency drugs, a chair or table which can be tilted to the Trendelenburg position, a fail-safe relative analgesia machine which cannot deliver a hypoxic gas mixture, and resuscitation equipment (Ad Hoc Committee of SADA, 2001).

3.2.2.5 Personnel

The availability of trained personnel is crucial for safe sedation practice. They "are called" the team for sedation procedures and accepted by all international guidelines.

The team should be,

- An operator-sedationist where applicable for short procedures where the operator-sedationist is both the operator and sedation practitioner, and standard sedation techniques are used. For procedures lasting less than 20 minutes the operator's assistant, can also be the observer. If more than 20

minutes a separate observer is required, with airway certification, to help with monitoring and rescue when necessary

- An observer as described above
- When advanced sedation techniques are used a dedicated sedation practitioner must be present. An observer is required to help with monitoring and rescue when necessary (SASA, 2015).

Some sedation guidelines claim that there must be a minimum of three appropriately trained staff present: the operator, the practitioner administering sedation and monitoring the patient, and at least one additional staff member to provide assistance and rescue if necessary (American College of Radiology, 2005 and Smith, 2009).

The ability to rescue means that practitioners must be able to recognize the various levels of the sedation and have the skills necessary to rescue a patient from a deeper than intended level of sedation (Cote, 1994; Wilson, 1996 and American Academy of Pediatrics *et al*., 2006).

The team must demonstrate evidence of continuing education in sedation (Scottish Intercollegiate Guidelines Network, 2002).

3.2.2.6 Fasting Guidelines

Preoperative fasting is a very controversial issue. It is thought that fasting reduces the risk of aspiration.

Fasting guidelines have been in a state of flux in recent years due to studies which indicate that small amounts of clear fluids taken 2 hours prior to surgery may in fact increase gastric emptying (Sandhar et al., 1989).

Not all sedation practitioners agree on the need for fasting. Dental societies in the UK feel that fasting is not normally required, however some authorities recommend the same fasting requirements as for general anaesthesia (Department

of Health, 2003). Guidelines for fasting periods before elective sedation should generally follow those used for elective general anaesthesia (Scottish Intercollegiate Guidelines Network, 2002).

When a simple sedation or standard technique for example, nitrous oxide sedation is planned, no fasting is necessary (SASA, 2015).

Where advanced techniques (including dissociative and non-dissociative techniques) and/or deep sedation are planned, anaesthetic fasting guidelines should be used (SASA, 2015). The patient is allowed to take before sedation,

- Clear fluids 2 hours
- Breast milk 4 hours
- Formula feed and solid food 6 hours

For the emergency patient, where proper fasting has not been assured, the increased risk of sedation must be weighted against the benefits of the treatment, and the lightest effective sedation should be used (Hallonsten *et al.,* 2003*).*

3.2.2.7 Monitoring

Monitoring in sedation means,

- Clinical monitoring and
- Electronic monitoring

All patients undergoing intravenous sedation must be monitored continuously by clinical (Hallonsten *et al.,* 2003), and electronic means.

Pulse oximetry plays an important role in monitoring. A pulse-oximeter is the minimum monitoring equipment for almost all sedation cases done under procedural sedation, with the possible exception of nitrous oxide sedation. (Ad Hoc Committee of SADA, 2001; American Academy of Pediatrics *et al.,* 2006 and SASA, 2015). There must be regular monitoring and recording of pulse rate,

oxygen saturation and blood pressure. This must be recorded on a sedation flow sheet.

Depending on the clinical status of the patient for example, the obese patient, other monitors such as an ECG or capnography may be required (ANZCA, 2003; Smith, 2009; SASA, 2015). Automated blood pressure apparatus are available; the oxygen saturation levels, pulse rate, and end-carbon dioxide levels can also be evaluated with the same apparatus.

For simple sedation techniques, pulse oximetry and blood pressure measurements must be used.

For advanced sedation techniques pulse oximetry, ECG and non-invasive blood pressure (NIBP) monitoring must be used, capnography is recommended, especially in situations where continuous airway monitoring is difficult. A precordial stethoscope is a useful monitoring device.

Pulse-, and respiration rates, blood pressure, and oxygen saturation levels must be taken at regular intervals during the procedure, usually at 10 minute intervals. Clinical monitoring includes (Hallonsten *et al.,* 2003, SASA, 2015) response by the patient to mild physical stimulation and verbal command. This indicates moderate sedation and analgesia, the level that we recommend for procedures outside the operating theatre. Clinical monitoring also includes level of consciousness (L.O.C) (Appendix 1), colour of mucosae, breathing rate and pattern, and body language (signs of pain or anxiety).

Monitoring of the airway, respiratory rate and pattern, heart rate, oxygen saturation levels and the patient's LOC should continue in the recovery area (Appendix 1) until discharge criteria are met (Appendix 6).

In order to avoid the potential complications of both excessive and inadequate sedation, it is necessary to regularly assess and document the level of conscious sedation (LOC) using a sedation assessment scale. Various sedation scales are available. The COMFORT scale is a subjective physiological and behavioural

scoring system. Eight variables – mean arterial blood pressure, heart rate, muscle tone, facial tension, alertness, calmness/agitation, respiratory behaviour and physical movement – are scored after 2 min period of observation (Smith, 2009).

Newer scales like the Wilson sedation scale and University of Michigan sedation scale (UMSS) (SASA, 2015) are available and more practical than older scales Sedation practitioners choose a sedation that they are familiar with.

3.2.2.8 Education and Training

Sedation practice is in an evolution and revolution. Education and training of all sedation practitioners are supported by all international guidelines and sedation societies. Only in this way we can be certain that sedation can be done safely (SASA, 2015).

Both theoretical and practical training are necessary. Supervised clinical training in sedation techniques are mandatory to ensure safe practice.

A sound knowledge of the pharmacology of drugs is essential for any intending sedation practitioner.

Education and training in the theory, methods and techniques of sedation can be provided in academic institutions where sedation is practised and taught; or in formal short or more extended courses regularly offered.

Knowledge and skills must be updated regularly (SASA, 2015).

3.2.2.9 Recovery and discharge criteria

The ideal is that patients must recover in an appropriate and suitably equipped recovery room, with a health care professional trained in basic life support monitoring him or her. It is also accepted that patients recover in the procedure room. All the necessary monitoring equipment as mentioned previously must be

available to monitor the patient. The sedation practitioner must assume overall responsibility for patients in the recovery area and may not leave the premises until discharge criteria are met. Recovery from sedation is a progressive step-down from completion of treatment through to discharge. A member of the dental team for example, nursing sister must supervise and monitor the patient throughout this period until discharge criteria are met (Department of Health, 2003). To decide whether a patient can be discharged home the sedation practitioner can use a validated tool such as the modified Aldrete scoring system (Table 3), or the Modified Post Anesthesic Discharge Scoring System (MPADSS) (Table 4) (SASA, 2015).

Table 3. Modified Aldrete scoring system (SASA, 2015**)**

Modified Aldrete scoring system	Score
Level of consciousness	
Fully awake	2
Arousable on calling	1
No response	0
Oxygen saturation (%)	
> 90% breathing room air	2
Oxygen required to maintain saturation > 90%	1
< 90% even when breathing oxygen	0
Circulation/blood pressure	
Systolic BP within 20 mmHg of presedation level	2
Systolic BP within 20-50 mmHg of presedation level	1
Systolic BP > 50 mmHg of presedation level	0
Movement/activity	
Able to move all extremities on command	2
2 extremities	1
Doesn't move extremities	0
Respiration	
Able to breathe and cough freely	2
Dyspnoea, shallow or limited breathing	1
Apnoea	0

Table 4. Modified Post Anaesthetic Discharge Scoring System (SASA, 2015**)**

Modified Post Anesthetic Discharge Scoring System (MPADSS)	Score
Vital Signs	
The vital signs must be stable and consistent with age and preoperative baseline	
BP and pulse within 20% of preoperative baseline	2
BP and pulse within 20-40% of preoperative baseline	1
BP and pulse > 40% of preoperative baseline	0
Activity level	
The patient must be able to ambulate at preoperative level	
Steady gait, no dizziness, or meets preoperative level	2
Requires assistance	1
Unable to ambulate	0
Nausea and vomiting	
The patient should have minimal nausea and vomiting before discharge	
Minimal: successfully treated with oral medication	2
Moderate: successfully treated with intramuscular medication	1
Severe: continues after repeated treatment	0
Pain	
The patient should have minimal or no pain before discharge The level of pain should be acceptable to the patient The pain should be controlled by oral analgesics The location, type and intensity of the pain should be consistent with anticipated postoperative discomfort	
Acceptability:	
Yes	2
No	1
Surgical bleeding	
Postoperative bleeding should be consistent with expected blood loss from the patient	
Minimal: does not require dressing changes	2
Moderate: up to two dressing changes required	1
Severe: more than three dressing changes required	0

Although the Aldrete score was not originally designed for use in ambulatory patients after sedation, it is today commonly used to determine when patients are

ready for discharge home. The MPADSS was designed to determine whether patients can go home after ambulatory surgery, and not specifically for assessing patients undergoing PSA. Vital signs (blood pressure, heart rate, respiratory rate, oxygen saturation level, level of consciousness, temperature, and pain levels) must be measured and documented at regular intervals (Appendix 6).

Although still widely used, the modified Aldrete scoring system has been largely superseded by the MPADSS as a tool to determine home readiness (Table 4). When using the MPADSS, patients are judged as fit for discharge when the score is ≥ 9 out of a maximum of 10. It is no longer necessary to ensure that the patient is able to take in fluids orally, or that he or she has passed urine prior to discharge home.

A responsible adult must accompany the patient home. Written and verbal instructions, including the contact details of a physician in the event of complications, must be given to both the patient and the carer. The physician must be satisfied that aftercare is optimal before the patient is discharged. Following the procedure, the patient is not permitted to do any of the following for 24 hours (SASA, 2015):

- Drive a motor vehicle.
- Operate machinery.
- Drink alcohol.
- Sign any legal documents.

Carers are advised to seek immediate help in case of vomiting, strange and unusual behaviour, or any other symptom or sign that does not seem normal for the patient. Carers should also be instructed to look for any breathing difficulties. Medication must be administered as prescribed by the physician. The intake of food or fluids must be introduced slowly. The patient must stay at home and rest quietly.

Patients residing in rural areas must spend the first 24 hours post procedure within

a reasonable distance of medical assistance, or must guarantee that they have access to a telephone or medical care in case of complications.

The Discharge Scoring System (Table 5, Appendix 6) is recommended to establish readiness for discharge from the recovery area to the ward in-hospital. The child should score 12 prior to discharge. In addition there should be no procedural or surgical complication e.g. bleeding.

Table 5. Discharge Scoring System (SASA, 2015)

PHYSICAL SIGN	**CLINICAL LEVEL**	**SCORE**
Level of consciousness	Fully awake/alert/answer questions	2
	Rousable to verbal command	1
	No response	0
Respiration	Able to take deep breaths and cough adequately	2
	Shallow breathing with poor cough	1
	Apnoeic periods	0
Oxygen saturation	>96% on room air	2
	Requires oxygen to maintain saturations >90%	1
	Saturation <90% with oxygen	0
Movement	Able to move all 4 extremities on command	2
	Able to move 2 extremities on command	1
	Not able to move extremities on command	0
Temperature	36 – 38° C	2
	35.5 – 35.9° C or 38.1 – 38.5° C	1
	<35.5° C or > 38.5° C	0
Pain	Minimal discomfort or pain	2
	Significant pain	0

A discharge questionnaire (Appendix 6) can aid in determining if the patient is ready for discharge home. All patients receiving sedation shall be monitored until appropriate discharge criteria are satisfied.

3.2.2.10 Documentation during Procedural Sedation and Analgesia

All the necessary documents are available in the guidelines of SASA for Procedural Sedation and Analgesia (SASA, 2015).

Documentation for sedation must include details of:

- Documentation before sedation
  - Medical questionnaire (Appendix 3).
  - Informed Consent: the patient record must document that appropriate informed consent was obtained according to local, state and institutional requirements (American Academy of Pediatrics *et al.,* 2006) (Appendix 5).
  - Basic equipment and drugs for procedural sedation and analgesia (Appendix 2)
  - Pre- and post sedation instructions (Appendix 7)
- Documentation immediately before the sedation process
  - Pre-procedure checklist (Appendix 8)
- Documentation during sedation
  - Sedation monitoring chart, including practical clinical monitoring (Appendix 4)
  - Sedation scoring system (Appendix 1)
- Documentation after sedation
  - Post-operative record and discharge criteria questionnaire (Appendix 6).

It is good to remember that if we have not written down what we did, it never happened! (Hallonsten *et al.,* 2003).

Pre- and post operative instructions in writing must be given preferably in advance of the procedure to the child and the parent or guardian (Appendix 7).

3.2.2.11 Psychological preparation of children for Procedural Sedation and Analgesia

Preparing children and their families for procedures and medical events can significantly increase their confidence and their ability to cope with health care experiences. Preparation should include all sensory information, a description of the sequence of events, and the expected duration of the procedure. When preparing the child, let him/her smell, feel, and touch the items that may be used for example, smell the alcohol preptic swab, touch the wetness of the swab, and feel how cool it is to the touch (SASA, 2010).

Talking to children is different from talking to adults. In order to provide helpful information, the child's developmental level, age, culture, and education should be taken into consideration. Young children have no sense of reason; "you will feel better after this medicine has been given" is of no apparent benefit to them. They remain fearful.

Medical terminology should be avoided, and further explanation to both child and parents is usually necessary. The use of pictures or actual equipment is strongly recommended.

Communication with the children and parents is extremely important. This is especially the case when the child is expected to undergo on-going or repeated treatment. Looking down, or talking over a child, should be avoided. Children are much more receptive to information when one is at their level.

The caregiver of each child plays a vital role in the hospitalisation of young children. They have an understanding of the child's needs, and are best equipped to interpret the child's behaviors and reactions to, and in, the hospital environment. Frequent conversations with caregivers are crucial to success, and sufficient time should be made available for asking and answering questions.

By providing accurate and developmentally appropriate information, a family's level of uncertainty can be reduced, and their sense of control and involvement increased. This can lead to less emotional distress, and result in the continuation of accurate information processing and the development of positive coping strategies. This behavioural management strategy is important for patients.

3.2.3 Drugs for PSA

Drugs and dosages for PSA in children and adults are available in Appendix 9.

3.2.3.1 Introduction

Practitioners should have an in-depth knowledge of the pharmacology of the drugs they intend to use and their potential complications. Knowledge of each drug's time of onset, peak response, and duration of action is essential (American Academy of Pediatrics *et al.,* 2006; SASA, 2015).

Intravenous anaesthetic agents must only be used by an appropriately trained medical or dental practitioner, and titrated to response. Continuous monitoring of the LOC is mandatory.

Drugs for sedation should have the following general characteristics:

- large margin of safety,
- painless route of administration,
- rapid onset and rapid recovery,
- easy reversibility,
- no side-effects.

Unfortunately no drug or combination of drugs meets the requirements of an ideal drug.

Drugs used for PSA can be synergistic when used in combination and it is mandatory that the doses be reduced accordingly, and titrated to effect in divided doses. The sum of the incremental doses must not exceed the recommended maximum dose. In general, the drugs selected for PSA should have duration of

action in keeping with the duration of the procedure. Sufficient time for peak brain effect (the target site) must be allowed, to prevent accumulation of sedatives.

SASA (2015) recommend that general anaesthetic induction agents (propofol, ketamine, etomidate) and the short-acting opioids (fentanyl, alfentanil, sufentanil) only be used by those formally trained in anaesthesia, or by experienced sedation practitioners with anaesthetic experience who are trained in specific sedation techniques. Sedation practitioners using these drugs must have at least a qualification in ALS/APLS.

Thus, the choice to use IV sedation in clinical practice requires,

- judicious selection of drugs,
- administration at the recommended rate,
- limiting the dose to the maximum recommended by the manufacturer,
- only employing drug combinations when greater efficacy can be demonstrated in comparison to a full therapeutic dose of a single agent, and
- decreasing the dose of the individual agents when a combination is used (Giovannitti and Trapp, 1991).

3.2.3.2 Drugs used for Procedural Sedation and Analgesia

Drugs are comprehensively covered in the SASA Guidelines on PSA (SASA, 2015). The following is a basic summary of drugs used in the study (see Appendix 9).

- **Midazolam**

  Midazolam is the most commonly used benzodiazepine (BZD) for sedation. (SASA, 2015).

  It is a short-acting benzodiazepine with sedative, anxiolytic, amnestic, anticonvulsant, and muscle relaxant effects. It has no analgesic effect but is

the most commonly used sedative in sedation practice. The drug can cause respiratory depression and must be titrated to effect. It must be used with care in elderly patients.

Paradoxical reactions for example agitation occur in up to 15% of patients. This can be especially in uncomfortable in children.

The high lipid solubility of midazolam produces a rapid onset, a more profound sedation and better amnesia according to some clinicians (Ochs et al., 1986).

The clinical effects after intravenous administration is usually seen after 2-3 min (Nordt and Clark, 1997). It usually "gets to the brain" in 10-12 min.

Sedatives like midazolam do not produce analgesia and must not be used alone for painful procedures. If sedatives are used, analgesics are usually administered first.

Midazolam is used extensively as a primary agent, sometimes together with opioids, for intravenous sedation. Caution must be exercised when combining benzodiazepines, or other sedatives, with opioids as the drugs work synergistically.

Although benzodiazepines used for intravenous sedation are seen as safe agents it must be remembered that their clinical effects are highly variable. They must be carefully titrated to clinical effect rather than administered as a bolus injection. When midazolam is slowly titrated intravenously to a clinical endpoint, no clinically significant ventilatory changes occur (Giovannitti, 1987).

The distribution half-life for midazolam is 6-15 min. The short duration of action of midazolam is attributed to its very high rate of metabolic clearance and rapid rate of elimination. The elimination half-life for midazolam is 1-4 hours, which is faster than that of other benzodiazepines. This makes it an

attractive option to use for sedation outside the hospital setting. In addition, the metabolites of midazolam are mostly inactive (Arendt, Greenblatt and De Jong, 1983).

The elimination half-life for midazolam is prolonged in the elderly patient. The dose requirements is lower in the elderly patient.

- **Propofol**

Is a non-opioid, non-barbiturate, sedative/hypnotic intravenous anaesthetic agent used for general anaesthesia and procedural sedation?

What make this drug so attractive for PSA is the rapid onset and short duration of action (half life of 4.4 minutes in adults, children 9 minutes) due to rapid equilibration between the blood and the brain. There is quick redistribution of the drug to peripheral tissues and a rapid metabolic clearance from the blood. It is unfortunately not an analgesic drug.

Propofol is associated with a dose-dependent risk of respiratory depression. This risk is heightened with concomitant opioid use, can be problematic for the clinician wishing to provide analgesia with opioids, as propofol has no intrinsic analgesic properties. It is claimed that when we combine ketamine and propofol (ketofol) we need less propofol and then a lower incidence of respiratory-related adverse events.

Because of the few side effects and smooth recovery characteristics, propofol has proven to be quite useful in paediatrics (Hansen et al., 1997), geriatric, (Chan *et al.,* 1996; Ganapthy *et al.,* 1997) and mentally and/or physically handicapped patients (Roelofse and Van der Bijl, 1994).

Propofol can be used for PSA in children and adults, as boluses and/or continuous infusion (SASA 2010 and 2015).

- **Ketamine**

This drug has withstood the test of time. Ketamine is not the ideal drug for single drug administration because of the side effect profile for example,

nausea and vomiting, but can be combined with other drugs for example, propofol. It may not be so popular for general anaesthesia anymore but the drug still occupies a unique position in the armamentarium of the sedation practitioner.

Ketamine is one of the most significant drugs available for PSA and we discover more are more about this drug. A problem with significant drugs is that you may find people that may use it for other purposes; one of our biggest problems at the moment centers around the recreational use of the drug. The drug is classified as a N-methyl –D-aspartate glutamate receptor antagonist (NMDA).

Ketamine dissociates the thalamo-neocortical and limbic systems (emotional brain). The CNS is in effect dissociated from outside stimuli for example, pain, sight, sound (unpleasant experiences).

The dissociative state is characterized by,

- sedation
- intense analgesia
- amnesia
- intact protective reflexes for example, coughing and swallowing and stabile cardiovascular and respiratory systems. All the characteristics that we want when using ketamine for procedural sedation.

Ketamine, a dissociative drug, is a remarkably versatile compound. It can be administered orally, rectally, intranasally, intravenously, or intramuscularly (SASA, 2015). Ketamine is pharmacologically reasonably predictable: its onset is within 1-2 min after intravenous use, and 5 min after intramuscular administration, and duration of action is about 45 min.

Parenteral ketamine can be used for sedation as boluses, in an infusion, or combined with other drugs for example, propofol.

The analgesic properties of ketamine are evaluated. A number of suggestions for ketamine pain therapy in the perioperative period and for patients with chronic pain are being evaluated (Himmelseher and Durieux, 2005).

Ketamine is used extensively for paediatric procedures in and outside of the operating room (SASA, 2015). It is often combined with propofol for PSA. The reasons for the popularity of ketamine are clear: it provides effective analgesia and sedation with a low incidence of complications, such as the cardiorespiratory depression that can be seen after use of benzodiazepines or narcotics.

As with the use of all sedative drugs side effects do occur. It is possible to see nausea and vomiting, hallucinations, and dissociation. This however dose dependent, and less often seen in the doses that we use for PSA.

- **Fentanyl**

Opioids such as fentanyl are used for analgesia and sedation, although sedation is a secondary effect (Smith, 2009). Fentanyl is an extremely potent analgesic which is 80100 times as potent as morphine. It is especially popular to use in children for various procedures (Jaffe and Martin, 1985).

Fentanyl is an analgesic agent and produces little if any euphoria or mood alteration. Fentanyl has been associated with respiratory depression, chest-wall rigidity, or stiff-chest syndrome. The drug should also be used with caution in patients with restrictive or obstructive pulmonary diseases. Caution should be used with asthmatic patients as well.

Practitioners administering fentanyl intravenously should be experienced sedation-practitioners with airway management skills. The drug should be titrated to effect when used for sedation.

Fentanyl should not be used as the sole analgesic agent for PSA, but rather to augment the effects of other analgesics. When used in combination with other respiratory depressant drugs (such as midazolam), doses should be decreased and titrated to effect. Extreme care should be exercised in the postprocedural period, when the stimulus of the procedure has passed but the drug is still active and more likely to cause respiratory depression (SASA, 2015).

Tables 6 and 7 show the pharmacokinetic and pharmacodynamic parameters of the drugs used in the research study.

Table 6. Pharmacokinetic parameters of drugs used (Colson, 2005).

Drug	pKa	Partition Coefficient	Elimination Half-Life (hours)	Volume of distribution (Liters/kg)	Context-Sensitive Half-Life (minutes)
Midazolam	6.15		1-4	1-1.5	180
Propofol	11.0	5012	0.5-1.5	1.8-5.3	55
Ketamine	7.5		2-3	2.5-3.5	
Fentanyl	8.4	955	3.1-6.6	3-5	260

Table 7. Pharmacodynamics of drugs used (Colson, 2005).

Drug	Anxiolysis*	Sedation	Hypnosis	Analgesia	Amnesia	Anesthesia	Dependency
Midazolam	+	+	+	0	+	+	+
Propofol	0	+	+	0	+		+
Ketamine	0	0	0	+	+	+/D	0
Fentanyl	0	+	+	+	0	+	+

3.2.3.3 Drug interactions

As sedation practitioners we often use combinations of drugs. We must therefore be aware of possible drug interactions between the different drugs.

Some practitioners also mix different drugs in the same syringe. The sedation practitioner must be extremely careful when mixing drugs in the same syringe because of possible precipitation. Independent dosing of drugs is possibly a safer option.

During concomitant use of these drugs, patients should be monitored for potential CNS and respiratory depression, which are common drug interactions if we do not titrate drugs to effect, and know the pharmacodynamics and pharmacokinetics of drug used.

The choice of techniques and drugs used for sedation in ambulatory surgery should be governed by the principle of minimum intervention. The dose of any drug administered should be the minimum dose necessary to achieve the desired effect (Venchard, Thomson and Boys, 2006). When two or more drugs are combined, it is important to be aware of any unforeseen synergistic effects that may cause respiratory and/or cardiovascular depression (Myers *et al.,* 2004).

The following is a summary of possible adverse effects when combining drugs for procedural sedation.

- **Midazolam and ketamine**

  Parker *et al.,* (1997) found that the combination of midazolam and ketamine used independently provides safe and effective sedation for surgical procedures in children. Midazolam provides good anxiolysis and sedation, while ketamine provides both sedation and analgesia. The combination of midazolam and ketamine result in a rapid onset of sedation and analgesia, less severe dysphoric reactions, and reduce or eliminate cardiovascular depressant effects.

  A study performed by Luhmann et al., (2006) shows that larger doses of both drugs would lead to deeper levels of sedation. Ketamine would induce deeper levels of sedation, good analgesia, and less recall but would cause

longer recovery times. Midazolam was administered intravenously in a fixed dose of 2 mg to reduce patient anxiety before ketamine sedation and may have contributed to deeper levels of sedation. Recovery may have been slightly longer because of the addition of midazolam.

Adverse events such as ataxia, nightmares, and hallucinations were seen with the combination although the administration of midazolam may have contributed to a lower incidence. Vomiting, headaches, and crying were also reported before discharge. A greater incidence of post-operative nausea and vomiting (PONV), reported as 34% in children aged 6 to 10 years old, and 32% in children over 11 years old (Luhmann et al., 2006).

This is probably one of the highest reported incidences of PONV in literature when midazolam and ketamine are combined in children. It is well reported and accepted that higher doses of the two drugs give a higher incidence of PONV.

The incidence of PONV was significantly lower in our research study. An oxygen saturation of <93% occurred transiently in 11% of patients who received the ketamine and midazolam combination. This is not a significant finding as an oxygen saturation of 93% or above in children is an acceptable limit during sedation.

In a study by Roelofse, Joubert and Roelofse (1996), 100 children between the ages of 2 and 7 years received either a combination of midazolam (0.35 mg/kg) and ketamine (5 mg/kg) or midazolam alone (1 mg/kg) rectally. Both groups had good sedation and anxiolysis at the time of separation from the parents, and immediately before the procedure. Post-sedation recovery was however more rapid after midazolam alone.

Excessive salivation occurred in 26% of children who received ketamine and midazolam; 14% in the children who received midazolam alone. This study also found a 14% incidence of hallucinations in children in the group that received midazolam alone.

Roelofse, Joubert and Roelofse (1996) reported that there may be a correlation between the incidence of hallucinations, and the dose of rectal midazolam administered in children.

A later study by Roelofse *et al.,* (2004) demonstrated the safety and efficacy of a combination of intranasal ketamine/midazolam. Key features in this study were the ease of administration of drugs, and the rapid onset of action.

It must be realised that the combination of ketamine and midazolam may potentially still induce deeper levels of sedation. The drugs should not be used in combination by sedation practitioners not trained in advanced sedation techniques.

Cheuk *et al.,* (2005) also demonstrated that the combination of intravenous midazolam and ketamine can provide rapid, effective, and safe sedation for children who undergo minor operations. No serious adverse effects were seen in the study. Increased salivation was the most common adverse effect. The median recovery time of 87 min is however quite long since adverse effects are usually dose-related, high doses of drugs should be avoided.

Titration of intravenous drugs remain the best option to prevent overdose and the possibility of respiratory depression. With procedural sedation there is no fixed dose, only a maximum.

In a study done by Roback *et al.,* (2005), respiratory adverse events occurred in 10%, vomiting in 5.4% of the patients.

It is well known that the sedative effects of ketamine are synergistic with those of benzodiazepines. It is believed by some clinicians that the combination of midazolam reduces the occurrence of hallucinations and enhances the quality of ketamine sedation (Oei-Lim, 1997).

- **Ketamine and propofol (ketofol)**

The combination of ketamine and propofol has received interest since the early 1990's as a PSA regimen that allows for the provision of PSA using drug doses lower than typically required for each agent alone. The combination, mixed in the same syringe is in use for long time without any serious adverse events, when used by skilled sedation practitioners.

Ketofol is a combination of two drugs, ketamine a sedative and analgesic drug, propofol a sedative drug, initially used for general anaesthesia.

The two drugs can be administered as a combination in the same syringe, or independently in two separate syringes, the one following the other one. The way the combination is used depends on the individual preferences of the sedation practitioners.

Ketofol can be used as boluses for sedation and analgesia, or as an intravenous infusion with different ratios in both adults and children.

Ketamine is known to preserve respiratory drive (protects against hypoventilation which is excellent for protecting the airway), and its sympathomimetic properties result in an increase in blood pressure. The addition of ketamine provides analgesia that is lacking in a propofol-only regimen.

The use of propofol is associated with a dose-dependent risk of respiratory depression, a risk that is heightened with concomitant opioid use. This can be problematic for the sedation practitioner wishing to provide analgesia with opioids. It is claimed that when we combine ketamine and propofol (ketofol) we need less propofol, and then a lower incidence of respiratory-related adverse events. This is what we see in sedation practice.

Central nervous system and cardiorespiratory depressant effects may occur when propofol is administered with other depressants such as sedative-hypnotic agents, and narcotic analgesics. Patients should be monitored closely for excessive sedation, and cardiorespiratory depression by the sedation practitioner. Titration of drugs to effect remain the best way to prevent adverse events with the administration of drugs.

Literature supports the safe use of ketofol (Willman and Andolfatto, 2007). Ketofol is a very effective and safe combination for PSA in the emergency department.

Patients recover quickly after ketofol administration. The median recovery time of 15 minutes in the study by Willman and Andolfatto, (2007) is an example of the excellent recovery characteristics of ketofol.

One can conclude by saying,

- There is no standard dosing regimen. Sedation practitioners use different ratios and different doses for different procedures.
- Drugs may be safely premixed in the same syringe or dosed sequentially with ketamine administered first to prevent the risk of injection-site pain.
- For short painful procedures usually boluses of ketofol can be used.
- For longer procedures it is advisable that boluses and a maintenance infusion be used.

In children an independent dosing technique is probably better as the level of consciousness may change rapidly. Separating the administration of ketamine and propofol may provide the sedation consistency of ketamine with the rapid recovery time inherent with propofol boluses.

- **Midazolam and propofol**

It is well known that sedative drugs like midazolam and propofol can depress the respiratory system during sedation. The sedation practitioner must understand that the two drugs may cause a synergistic effect. This may even lead to loss of airway control. It is therefore necessary to titrate drugs to effect. Patients should be monitored closely for respiratory depression and possible loss of airway control.

Another possibility to prevent respiratory complications is to use low doses of midazolam and propofol as we used in our research study. Cho, Seo and Youn, (2012) report in their study on the combined use of low dose midazolam and propofol. They feel the combination gives a better sedative effect compared to midazolam single treatment.

- **Midazolam and fentanyl**

Drug interactions between opioid analgesics and other drugs are possible for example, antidepressants. The use of fentanyl with selective-serotonin-reuptake inhibitors may lead to the development of the serotonin syndrome.

Nordt and Clark (1997) report that deaths occurred during the combined use of midazolam, and an opioid such as fentanyl. Midazolam alone produced no significant respiratory effects, but when fentanyl is used significant respiratory depression can occur. The combination of midazolam and fentanyl was associated with hypoventilation in more than 90% of patients.

In a study done by Roback *et al* (2005), respiratory adverse events occurred in 19.3% of the patients.

Pershad and Godambe, (2004) report that 25% of the patients developed hypoxaemia after the administration of midazolam and fentanyl in the

emergency department. Deitch, Chudnofsky and Dominici, (2007) reported hypoxemia in 20% of patients.

The study by Khan, Kaul and Neelakanthan, (2010) highlights the possibility that midazolam and fentanyl for minor surgical procedures, under local infiltration anaesthesia, may produce profound central nervous system and respiratory depression with resultant loss of consciousness. It may even be necessary to resuscitate those patients.

Whether one can classify the above adverse events as drug interactions, is debatable. What is seen is in effect abnormal responses when we combine different drugs. Sedation practitioners need to be very careful when they combine different drugs. Patients must be monitored closely.

In this research study the adverse events as described above were not seen. This may be because of careful patient selection, skills of the sedation practitioner, and titration of drugs used.

3.2.3.4 Adverse events and side effects with the use of single drugs

The question is what is an adverse event with sedation. This is a significant issue for sedation practitioners as it may compromise safety. The World Health Organization defines an adverse event (AE) as *"any untoward medical occurrence that may present during treatment with a pharmaceutical product which does not necessarily have a causal relationship with this treatment"* (Wikipedia, 2014). An adverse drug reaction is a *"response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease"*.

Malviya *et al.,* (2000a) looked at adverse events after patients were discharged home. Patients can be at risk when they return home to an unmonitored setting with no person to look after them. They found a

significant incidence of motor imbalance, agitation, and restlessness after discharge. The issue is can we say this is an adverse effect or a side effect. It is clear we as sedation practitioners need to know more about the pharmacokinetics and pharmacodynamics of sedative and analgesic drugs.

Motor imbalance was the most frequently reported side effect (Malviya *et al.,* 2000b). This shows that we need to inform patients/guardians about this side effect as it can last for a few hours. Agitation or aggressive behaviour occurred in 19% of children, and lasted for more than 6 hours in 36% of patients. This is a reasonably common side effect, we are not yet certain of the causative factors. Drugs may play a role here.

Restlessness was significantly related to younger age which is also not uncommon. Other side effects reported include nausea and vomiting and diarrhoea (Malviya *et al.,* 2000b).

Maybe we can also classify complications as adverse events as they may compromise the safety of the patient. Ceravolo et al., (1986) published a study of 10,000 patients receiving intravenous sedation in which there were no major complications (Giovannitti and Trapp, 1991).

Coplans estimated the mortality rate for parenteral sedation to be around one in a million (Giovannitti and Trapp, 1991). Mortality has been reported in 0,05% of patients, with 60% of this due to hypoxaemia (Quine *et al.,* 1995).

D'Eramo (1999) reported an incidence of 1/6119 patients diagnosed with dysrhythmias during conscious sedation. Phlebitis was relatively common, probably caused by intravenous cannulation, occurring in 1/666 patients who received parenteral sedation.

- **Midazolam**

Although this research study is not about single drug administration one has to look at the possible side effects of single drugs.

The safe use of midazolam is questioned for a long time. Quine et al., (1995) published a study where an operator-sedationist administered incremental doses of midazolam intravenously; 13% of patients had oxygen saturation levels below 80% in the recovery room following sedation. Whether this is a side effect or adverse event is not important. We know we can see this with intravenous midazolam.

The incidence of adverse reactions with the benzodiazepines is usually low. Nausea and vomiting, coughing, and hiccoughs have occasionally been noted. Respiratory depression may also occur with midazolam but this is dose-related in the healthy patients we usually see for sedation. These effects can be reversed with physostigmine administration and with the specific benzodiazepine antagonist, flumazenil (Coulthard *et al.,* 2000). One must just be very careful if you give the antagonist as you also reverse sedation.

When administered in combination with other synergistic drugs or used in higher doses, midazolam is likely to result in the loss of upper airway muscle tone with possible obstruction. Children are particularly vulnerable to the effect of midazolam and may get respiratory depression with a drop in oxygen saturation levels.

Paradoxical reactions have been reported with the use of midazolam. This can be very frustrating for the sedation practitioner. The patient usually becomes agitated, confused, aggressive, and sometimes untreatable. This can occur in 1-7% of patients (Oei-Lim, 1997). Giving additional doses of midazolam in an attempt to control the child or adult usually does not work.

It may even be necessary to reverse the action of midazolam with flumazenil.

Doyle and Perrin (1994) reported symptoms of emergence delirium after the use of intravenous midazolam for conscious sedation.

Wenzel *et al.,* (2002) in a study of 104 patients reported clinically significant adverse events with midazolam in six of the patients. The adverse reactions included aggressiveness, euphoria, depression and intense hiccups. It was successfully treated with a titrated dose of flumazenil 0.25 – 0.5 mg. intravenously.

- **Propofol**

Propofol rarely causes adverse events when titrated in sedation practice. The drug rarely causes postoperative nausea and vomiting.

Propofol is however a controversial drug for use outside the operating theatre for those not skilled in airway management. Deep sedation, airway obstruction and respiratory depression can occur rapidly especially with bolus doses with resultant hypoxaemia.

Prolonged infusions (longer than 18 hours at more than 4 mg/kg/hour) have been associated with fatal metabolic acidosis. The use of propofol infusions in children have been linked with unexplained lactic acidosis, hyperlipidaemia, brady arrhythmias, myocardial failure, and even death (Wheeler et al., 2003). This is called the propofol infusion syndrome which is not really relevant to procedural sedation. Sedation practitioners however need to be aware of this, especially with a slow pulse for an unexpected reason during sedation.

The most common side effect caused by propofol is pain on intravenous injection. It is claimed that it can happen in 31% of patients when using the

dorsum of the hand. Leitch, Sutcliffe and Kenny, (2003) claimed an incidence of 20% in patients. When using the vein in the antecubital fossa the incidence of pain was 8% (Marinella, 1997). Pain because of intravenous administration of propofol can be very uncomfortable for both the patient and sedation practitioner. It can change the sedation levels of the patient and make the procedure uncomfortable.

Several drugs are available to prevent the pain because of propofol administration. 10 mg of 1% lidocaine is usually mixed in propofol when used for bolus administration or an infusion (Bocian and French, 1992; Bryson, Fulton and Faulds, 1995). It is possible that injection into larger proximal veins would prevent this problem (Smith et al., 1994; Leitch, Sutcliffe and Kenny, 2003 and Rodrigo et al., 2003). It is claimed that ketamine 2mg or tramadol 5mg mixed with propofol can also be used to prevent pain.

As previously noted, hypotension can be a side effect. This is usually transient in the healthy patient. Carefully titrated doses will minimize the cardiovascular depression, which is commonly associated with bolus injections of propofol (Parworth *et al.,* 1998).

It is postulated that patients talk a lot when they receive propofol for sedation. This is not really a problem in oral surgery, because the nature of oral surgery makes it difficult for the patient when the dental procedure is being done (Rodrigo and Jonsson., 1989; Rodrigo *et al.,* 2003). We sometimes do see talking after propofol before the dentist start doing the procedure. This sometimes happens when patients are taking antidepressants.

Rodrigo *et al.,* (2003) and Girdler et al., (2000) reported an incidence of 75% of anterograde amnesia in patients that receive propofol. This is hard to believe. Although propofol can cause amnesia we usually see this with

high doses after general anaesthesia. Not much is published on the amnesia effect of propofol.

Neuroexcitatory events, such as tremors, twitching, and hiccups, have been reported (Cockshott *et al.,* 1987). This is not something we see with procedural sedation, but is possible with general anaesthesia in the period before the patient becomes unconscious.

Hallucinations have been described with propofol use (Nelson, 1988). We do not see this with procedural sedation.

Anaphylaxis has been reported during use with propofol. It is however difficult to say whether this hypersensitivity is due to the drug propofol or to the lipid vehicle (Laxenaire *et al.,* 1988; Laxenaire *et al.,* 1992; McHale and Konieczko, 1992).

It is advised in sedation practice that if there is an allergic reaction to propofol it should not be used in those with a history of egg allergy.

- **Ketamine**

Ketamine has become one of the most significant drugs in sedation practice as it a sedative and analgesic.

Side effects because of ketamine administration are of concern. This usually happens when large doses of ketamine are used, not with smaller doses.

The most common side effect is probably hallucinations, which can be uncomfortable. It is interesting to note that this is usually not a serious complication in children (2% incidence) as the hallucinations are not of an aggressive character. This is more often (up to 30% incidence) seen in adults. Risk factors for emergence reactions have been described as:

- age over 15 years,
- female gender,
- a history of vivid dreams, and
- personality or psychiatric problems.

Midazolam can be co-administered (0.05–0.2 mg/kg orally) to reduce the incidence of hallucinations.

Roback *et al*., (2006) reported an incidence of vomiting of 26.3% when ketamine was administered via the intramuscular route as to an 11.9% incidence with the intravenous ketamine route.

Other side effects reported are increased salivation, purposeless movements, and agitation (Hollister and Burn, 1974). Whether this is important in sedation practice can be debated. It is generally accepted that with low doses of ketamine there is a low incidence of side effects.

- **Fentanyl**

Fentanyl can cause respiratory and cardiac depression, particularly in combination with other respiratory depressant drugs. Van Leeuwen, Deen, and Helmers, (1981) reported that respiratory depression had to be reversed in 51% of the fentanyl group who received sedation. This incidence is indeed high, and not seen during our study. One probably has to accept that this is a side effect, and that fentanyl should be titrated to effect.

Fentanyl can cause muscle rigidity which is probably dose-dependent (Koska, Romagnoli and Kramer, 1981). We rarely see this in sedation practice with the small doses we use.

The most common adverse effect of fentanyl is probably nausea, also rarely seen in sedation practice with small doses of the drug used (Mayes and Ferrone, 2006).

3.3 COST-EFFECTIVENESS OF SEDATION

Previously the only option available to the dentist was the use of general anaesthesia in order to perform especially difficult or lengthy dental procedures. This mode of treatment has been proven to be costly, and conscious sedation has become a viable choice as an alternative to general anaesthesia for sedation procedures. The challenge to the dentist with conscious sedation is to find effective ways of behavioural management when a child is not made unconscious as with general anaesthesia (Naidoo, 2004).

Various studies assessed the aspect of cost and tried to relate it to an assessment criteria formula. One asks oneself whether this would be practical. The following is a business definition of cost-effectiveness:

"It involves the offering of the maximum benefit for a given level of expenditure. When limited resources are available to meet specific objectives, the cost-effective solution is the best that can be achieved for that level of expenditure, and the one that provides good value for money" (BNET Business Dictionary, 2010).

Whether the above is so easy to use as a tool for cost-effectiveness is difficult to answer. It is probably not practical.

Society is confronted with many difficult choices in the provision of health care services, and public health programs. To make informed choices, we need information about the impact of services and programs, their costs, and the consequences of choosing one option over another. One tool available for this objective is called the cost-effectiveness analysis (Edejer et al., 2003). Naidoo (2004) did a retrospective study on patients aged 12 months to 12 years treated for dental procedures under general anaesthesia or conscious sedation. He analysed the results of 140 patients treated under general anaesthesia, and 140 patients treated under conscious sedation. Only healthy patients with an ASA I or ASA II classification were included in this study to compare the cost-effectiveness of sedation and general anaesthesia. The overall costs of the procedures were lower in the conscious sedation group.

Smith (2004) did a comparative study of the costs involved in general anaesthesia versus conscious sedation in dental surgery. Twenty-six patients were done under general anaesthesia, 24 patients had conscious sedation for dental surgery. The costs of drugs, disposable items, as well as theatre fees were evaluated. The costs involved for each individual case one was calculated separately. The average age of the patients receiving general anaesthesia in the study was 12.2 years, the average age of the patients receiving conscious sedation was 30.1 years. The average duration of the procedure for general anaesthesia was 45.88 mins/patient which translate to a cost of R5.74/min/patient.

In the conscious sedation group the average time for sedation was 28.70 mins/patient which translate to a cost of R2.37/min/patient. The results of this study, although a small number of patients, show that the costs for conscious sedation are considerably less than those for general anaesthesia.

Lee, Vann and Roberts, (2001) did an interesting study. They compared the cost of general anaesthesia with that of oral conscious sedation for paediatric sedation. This was done in 22 children aged 24 – 60 months.

The results show that if ~~a~~ children need more than three sessions under conscious sedation for dental procedures, then general anaesthesia is possibly a more cost-effective option.

Ashley *et al.,* (2009) reviewed the literature as to cost effectiveness of sedation versus general anaesthesia. Their findings show that general anaesthesia was 46.6% more expensive than conscious sedation.

Dental treatment under sedation may require several visits especially with lengthy procedures. Patients may become uncomfortable to be in the dental chair for long procedures. This is usually not the case for dental treatment under general anaesthesia as there is not really a time limit. It happens rarely that sedation may fail but it is a possibility. In that case a patient may need general anaesthesia which will lead to an escalation in costs. Van Sickels and Tiner, (1992) reported that it was twice as expensive to undergo genioplasty in an outpatient surgical suite under general anaesthesia than in a private office under intravenous sedation.

The following research studies were not done under sedation for dental procedures. They however do highlight the fact that sedation is a cost-effective alternative for general anaesthesia also for medical procedures.

Squires *et al.,* (1995) compared intravenous sedation and general anaesthesia with regard to efficacy, safety and cost in young patients undergoing endoscopic procedures. The average charges were $768.52 in the intravenous sedation group, versus $1,965.42 in the general anaesthesia group.

Jameson *et al.,* (2007) reported that the average cost per child treated with combinations of drugs, as in our research study for example, midazolam and fentanyl was £245.47, whereas the average cost of general anaesthesia was 46.6% more. From the above information on studies done by different researchers it is clear that the cost for sedation is significantly less than the cost of general anaesthesia for procedures outside the operating theater.

It must however be emphasized that not all procedures qualify for sedation outside the operating theater.

CHAPTER 4: STUDIES TO DETERMINE THE SAFETY AND EFFICACY OF CONSCIOUS SEDATION OUTSIDE THE OPERATING THEATER

4.1 An evaluation of Post Sedation Satisfaction in children.

4.1.1 Introduction

Intravenous sedation was used to control pain and anxiety for dental procedures on children during this study. Sedation was preferred to general anaesthesia as theatre capacity is limited with long waiting lists, cost-effectiveness, and the lower incidence of side-effects in sedation.

To choose the right drugs in children is extremely important. Drugs influence the level of consciousness which may influence morbidity and adverse events during and after sedation. Children often slip inadvertently into deeper levels of sedation during conscious sedation and the sedation practitioner must be aware of this.

According to the 2015 SASA guidelines on Procedural Sedation and Analgesia (SASA, 2010; SASA, 2015) the level of consciousness must meet the demands for safe practice; children must be able to communicate and respond to verbal command or light tactile stimulation, and the protective reflexes coughing and swallowing must be intact.

As sedation practitioners we use subjective rating scales to determine the level of consciousness (sedation) as objective monitors for example, the BIS (Bispectral Index Monitor) are extremely expensive and not readily available in developing countries in the world. For subjective monitoring we use either the UMSS (University of Michigan Sedation scale) or the Wilson scale (SASA, 2015) as they are easy to use and understand. The level of consciousness must be documented on a sedation flow sheet during and after sedation (Appendix 1).

Parents received a post-sedation questionnaire to fill in at home as to patient satisfaction and the incidence of side-effects, and to rate the sedation technique.

The parents gave valid informed consent for the procedure and sedation, and to supply this information.

4.1.2 Aims of the study

The aims of this study were

to determine whether the combination of midazolam, ketamine and propofol, that is called an advanced sedation technique (SASA, 2010), can be safely used for paediatric sedation during dental procedures outside the operating theatre

to evaluate the side-effect profile after conscious sedation using multiple drugs. Here we had to rely on the parents to give us most of the information.

It is known that there is a high incidence of side-effects for example, PONV, after general anaesthesia. It is postulated that there is a low incidence of side – effects after conscious sedation (PSA).

4.1.3 Objectives of the study

This study was designed with the following specific objectives:

To assess safety of discharge by measuring the state of mind (recovery) on departure

To assess state of mind on arrival home, and after 4, 8, 12 and 24 hours post-operatively

To evaluate side-effects during the journey home (after discharge) as this may lead to morbidity and anxiety of the children and parents, and a negative attitude towards future use of conscious sedation

To evaluate side effects on arrival home, and after 4, 8, 12 and 24 hours post-operatively

To evaluate the level of consciousness (LOC) during the journey. This is an extremely important point as children may slip into deeper levels of sedation and airway obstruction is a real possibility.

To evaluate the level of consciousness (LOC) on arrival home, and after 4, 8, 12 and 24 hours post-operatively

To evaluate recollection of children of the dental procedures during sedation on arrival home, and after 4, 8, 12 and 24 hours post-operatively.

To assess satisfaction of patients after sedation with a visual analogue rating scale. Post-sedation satisfaction is an important aspect of evaluation of the acceptability of patients of conscious sedation as an alternative to general anaesthesia. It is also expected that sedation practices must undergo a regular, robust audit as part of clinical governance.

4.1.4 Materials and methods

One hundred children aged 3-9 years were entered into this study (≤12 years old as this age group is defined as children) done at the Faculty of Dentistry, University of the Western Cape, Cape Town. Written valid informed consent (Appendix 5) was routinely obtained from a parent for the procedure and sedation, and to fill in the post sedation questionnaires (Appendix 10). Only ASA I and II children were accepted for the study. Children were examined for any disease, especially upper respiratory signs and symptoms, before administration of any drugs. A focused airway examination was done in all children.

Children also received an EMLA® patch on the dorsum of the hand to anaesthetize the skin for cannulation of a vein. A 24-gauge cannula was used in all children and kept *in situ* for the duration of the procedure, and until discharge.

A professional nurse with airway certification, and part of the sedation team, helped with continuous monitoring of blood pressure, ECG, O_2 saturation, respiratory rate, and pulse rate for the duration of sedation and the recovery period.

In this study three intravenous drugs midazolam, ketamine and propofol, were used in separate syringes. Doses and tables of individual drugs were discussed in Chapter 3 (Appendix 9).

Midazolam in children has a rapid onset administered intravenously and should be titrated to response. The drug has anxiolytic, sedative, amnestic and anticonvulsant properties, but unfortunately no analgesic effects.

Ketamine is a dissociative anaesthetic agent used for conscious sedation. It has become a very popular drug administered as independent dosing or in combination with other drugs for example, ketofol, who is a combination of ketamine and propofol. It has unique properties and provides sedation, analgesia, a stable cardiovascular and respiratory systems, and the protective reflexes are intact.

Propofol is an anaesthetic drug used for intravenous sedation. It has a rapid onset of action, provides rapid recovery but has no analgesic properties. There is also no antagonist available to reverse its action.

A combination of ketamine and propofol (Ketofol) used in the same syringe for sedation has become very popular. It is believed that the combination allows us to use reduced doses of both drugs with a lower incidence of side effects.

A sedation flow chart was used to record all information regarding drug administration, doses, vital signs, and discharge readiness as per SASA Guidelines on Procedural Sedation for Children (SASA, 2010). The starting time of starting sedation, length of the procedure duration, and end time of the procedure till the patient discharge were recorded.

Children were only discharged from the sedation facility when they met the discharge criteria according to the Aldrete recovery scale (SASA, 2015) and accompanied by a responsible adult.

Before discharge, parents/escorts received a post sedation questionnaire (PSQ) (Appendix 10) to fill in at home. The form was explained to them. The purpose of the PSQ was to gather information regarding recovery, possible side-effects,

behaviour of the children, and an evaluation of the sedation technique by the parent/escort **(**Appendix 10).

The information (Appendix 10) gathered included the following:

- the state of the mind on departure for example, happy, indifferent, weeping or agitated;
- drug side-effects during the journey for example, nausea, vomiting, a combination of nausea and vomiting, headaches, blurred vision and restlessness;
- the state of mind, level of consciousness, drug-side effects and memory of the procedures on arrival home, and after 4, 8, 12, 24 hours.
- parents were also asked to rate their overall satisfaction with the sedation experience using a 1 to 10 visual analogue scale (Poor to Excellent) (Appendix 10).

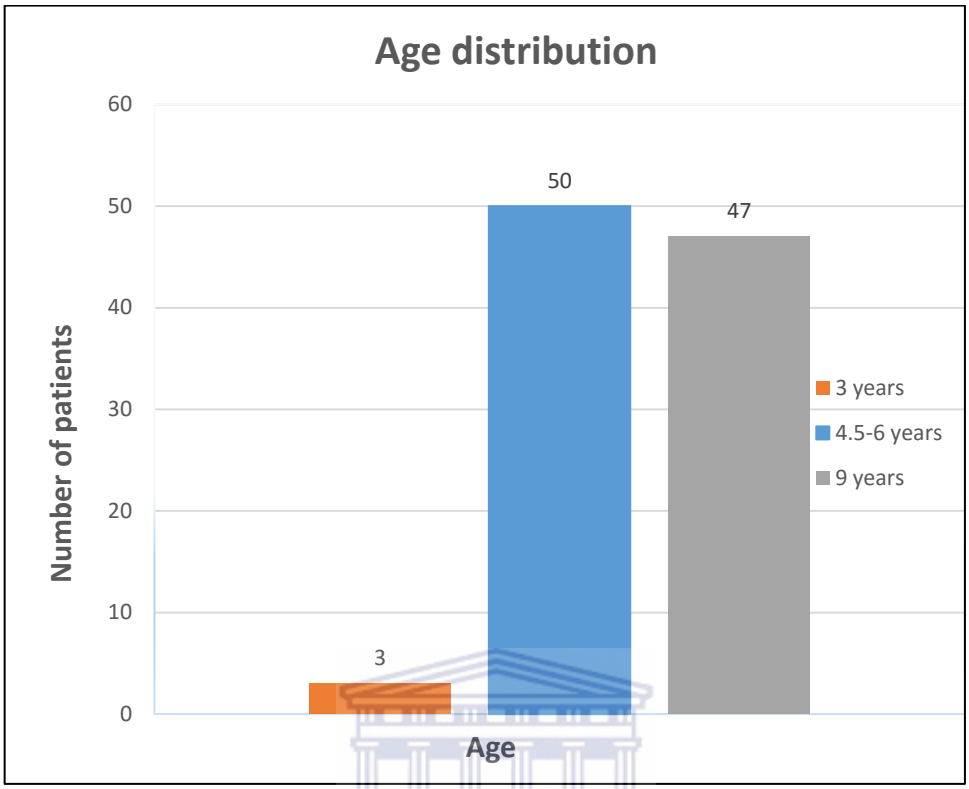
4.1.5 Statistical analysis of results

The data were captured and stored in an Excel ® spreadsheet. Certain basic statistics were calculated and the data were also used for various graphical representations as summaries. Tests of association between class variables were performed by obtaining contingency tables and applying the chi-squared test; where the frequencies in the tables were small the Fisher exact test was used to verify the results indicated by the chi-squared test.

4.1.6 Results

One hundred children aged 3-9 years, and their parents were approached to consider participation in this study. Data from one hundred children were included in the final analysis. A combination of midazolam, propofol and ketamine was used in all the patients. Figure 1 shows the age distribution of the children.

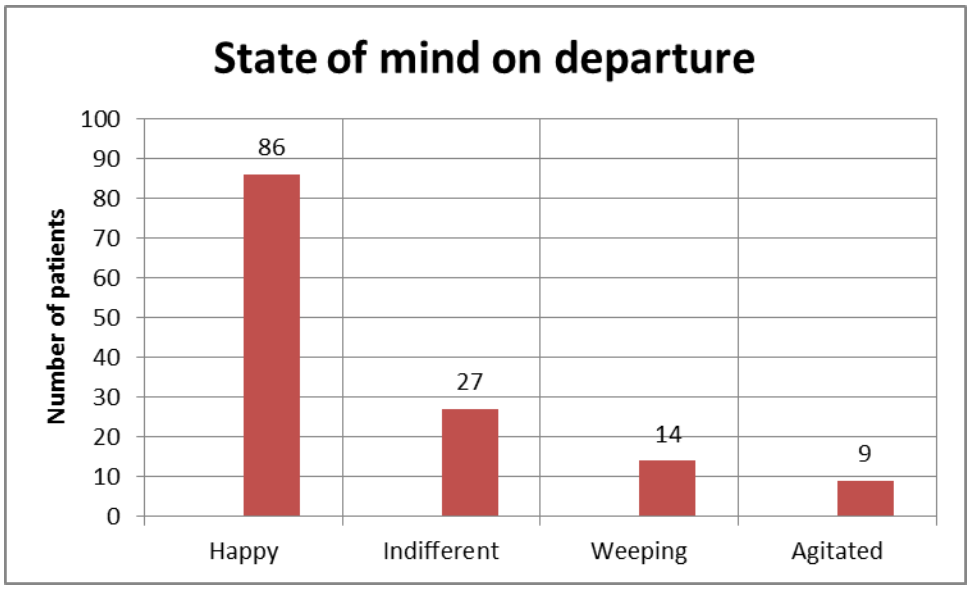
Figure 1. Age distribution



4.1.6.1 The state of mind on departure

Figure 2 shows that the majority of the patients (86%) were happy on departure. The percentages of patients in the different categories evaluated are shown in Figure 2, 95% confidence limits are in brackets: Happy = 86% (78-92), Indifferent = 27% (19-37), Weeping = 14% (8-22), Agitated = 9% (5-16).

Figure 2. State of mind on departure

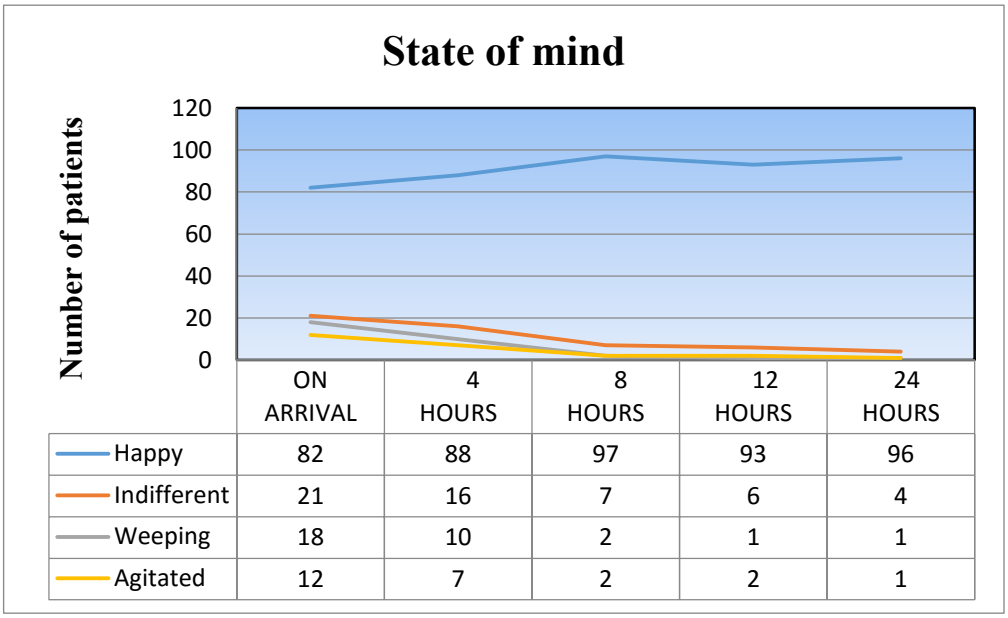


4.1.6.2 State of mind on arrival home, and after 4, 8, 12 and 24 hours

Assessments of children being indifferent, weeping and agitated after 8 hours are shown in Figure 3. A high percentage of children were happy on arrival 24 hours after the sedation experience.

This is a significant finding as to the safety and efficacy of the sedation technique and the way children were treated during their stay at the clinic.

Figure 3. State of mind on arrival home, and after 4, 8, 12 and 24 hours



	ON ARRIVAL	4 HOURS	8 HOURS	12 HOURS	24 HOURS
Happy	82	88	97	93	96
Indifferent	21	16	7	6	4
Weeping	18	10	2	1	1
Agitated	12	7	2	2	1

4.1.6.3 Monitoring of side-effects during the journey, on arrival home, and after 4, 8, 12 and 24 hours

All the side effects that occurred are presented in Figures 4 and 5. Restlessness and blurred vision were present in 29% and 16% respectively. After 8 and 12 hours the number of patients with restlessness came down to 5 and 2. After 24 hours only one patient presented with restlessness, blurred vision and headache.

Figure 4. Drug side effects during journey (after discharge)

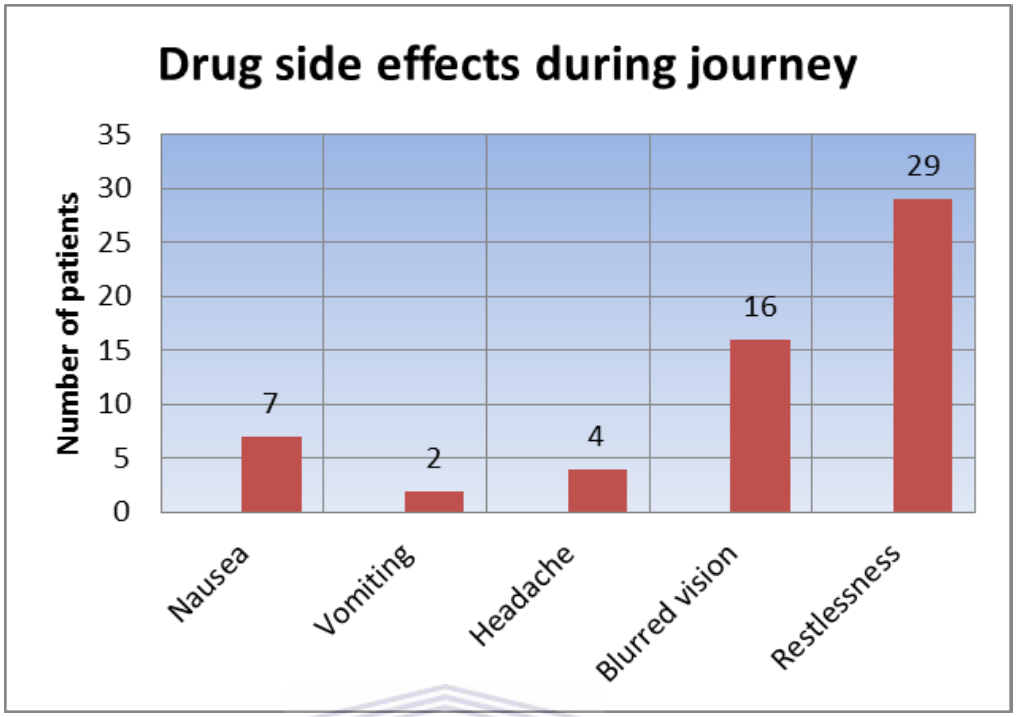
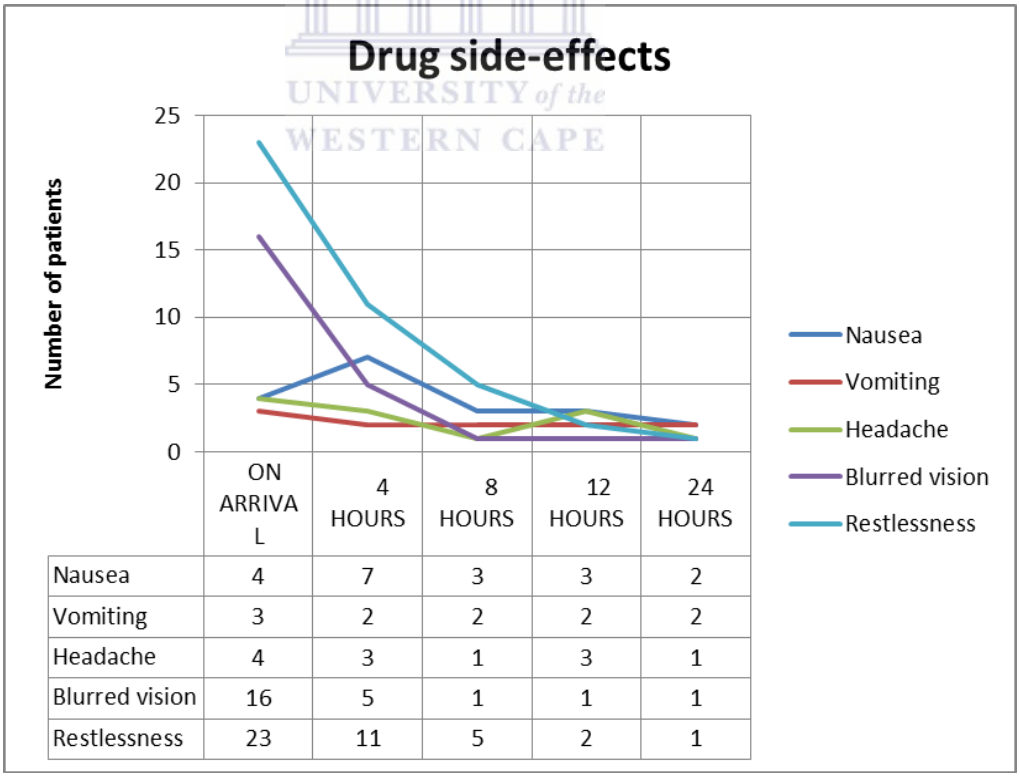


Figure 5. Side effects on arrival home, and after 4, 8, 12 and 24 hours



	ON ARRIVAL	4 HOURS	8 HOURS	12 HOURS	24 HOURS
Nausea	4	7	3	3	2
Vomiting	3	2	2	2	2
Headache	4	3	1	3	1
Blurred vision	16	5	1	1	1
Restlessness	23	11	5	2	1

4.1.6.4 To monitor the level of sedation during the journey, on arrival home and after 4, 8, 12 and 24 hours

Figure 6 shows that 69 people felt awake and orientated during the journey home, 84 felt awake and orientated on arrival (Figure 7) and a high percentage of respondents were awake and orientated 24 hours after arriving home. The number of patients experiencing drowsiness show a downward trend from arrival home to 24 hours after arrival home.

Figure 6. Level of sedation during journey

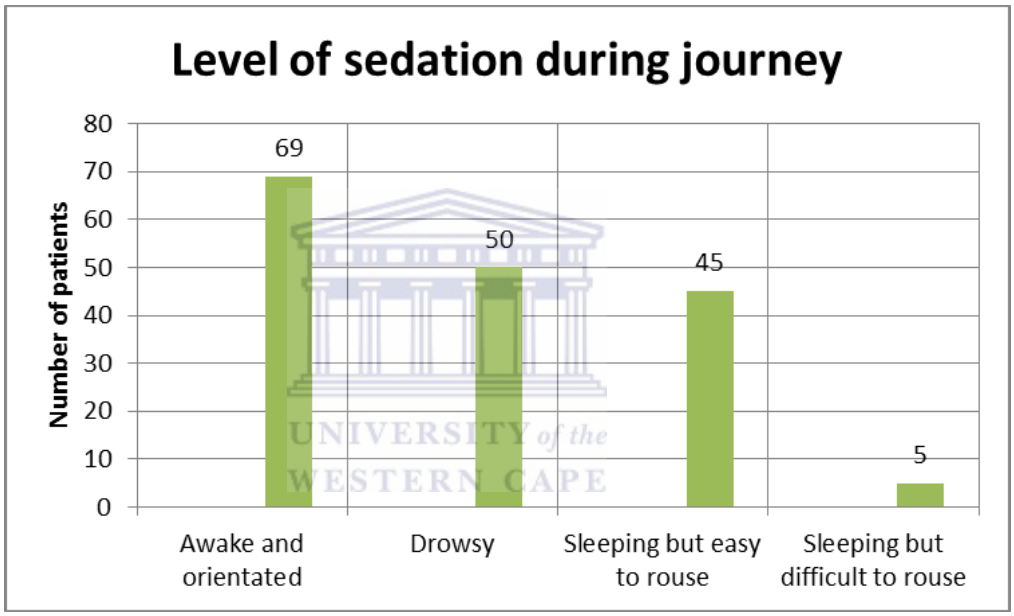
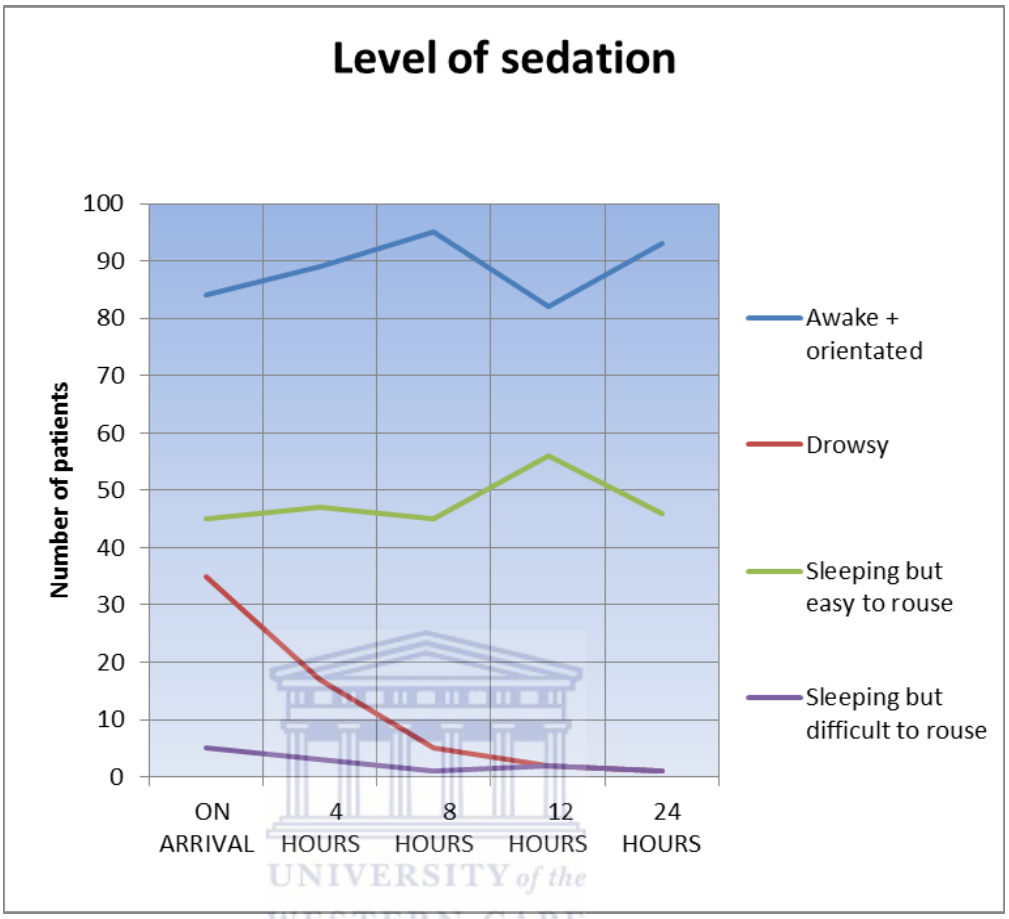


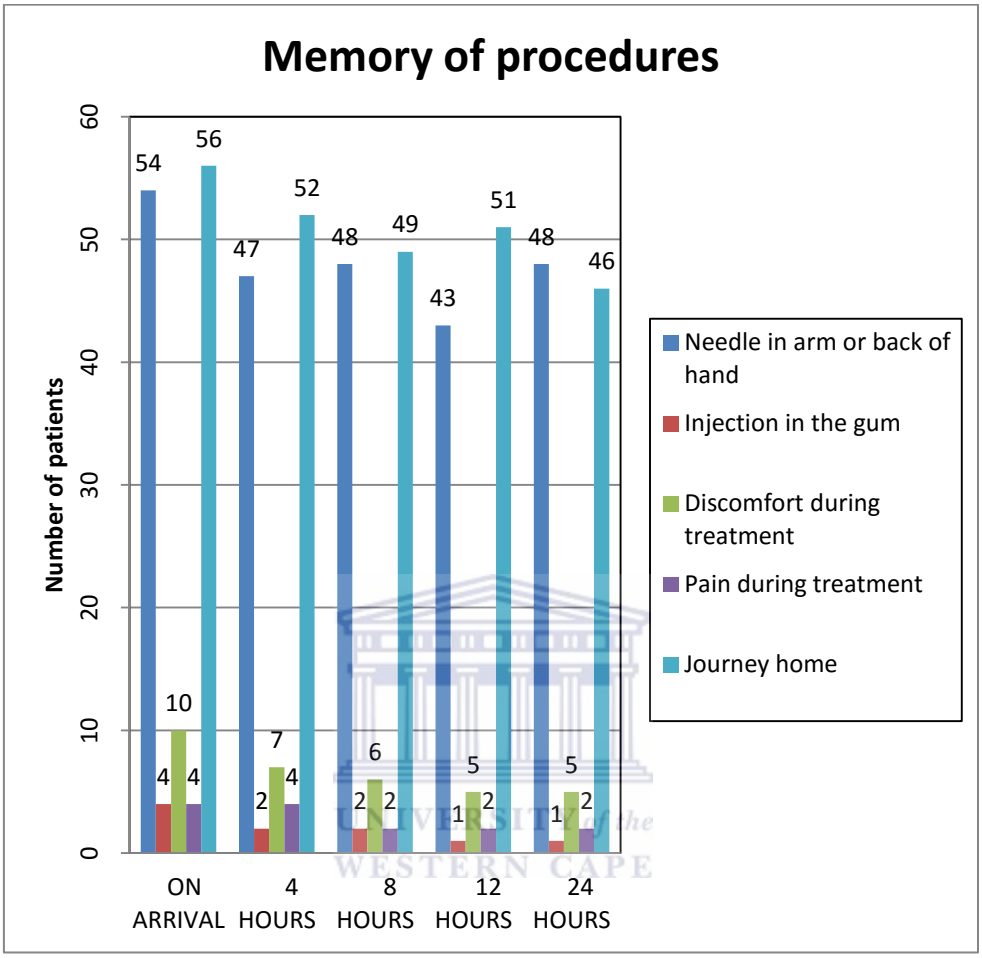
Figure 7. Level of sedation on arrival home and after 4, 8, 12 and 24 hours



4.1.6.5 To test memory of procedures on arrival home, and after 4, 8, 12 and 24 hours

The memory of the procedures on arrival home in Figure 8, for example, injection in the gum, discomfort and pain during treatment, were noted in a small number of patients. This showed that the sedation procedure was comfortable and successful as far as patient satisfaction is concerned. A significant number of patients remembered the cannulation experience on the back of hand. This was expected as some children do remember experiences like this even when an amnesic sedative is administered.

Figure 8. Memory of procedures on arrival home and during the 24 hour period after arrival home



4.1.6.6 Assessment of patient satisfaction after sedation with the visual analogue rating scale

The majority of patients (90%) gave a satisfaction rating of 7-10 on the visual analogue scale of 1 to 10 where 1= poor and 10 equals excellent (Figure 9).

Figure 9. Satisfactory rating of satisfaction of children after sedation

The following tables represent the side-effect profile of the children during the journey home, and at home. The 2x2 tables and chi-square test were used to evaluate the association between the level of sedation state of mind, (Table 8 to Table 10) and drug side effects (Table 11 and Table 12).

The proportion of patients who were not drowsy during the journey and happy on arrival (46/50=0.92) is significantly greater than the proportion who were drowsy during the journey, and happy on arrival home (36/50=0.72): chi squared = 5.488, df = 1, p-value <0.05 (Table 8).

Table 8. Drowsy during journey and happy on arrival home

		Happy on arrival home		
		No	**Yes**	**Total**
Drowsy during journey	**No**	4	46	50
	Yes	14	36	50
	Total	18	82	100

The proportion of patients who were not drowsy during the journey, and indifferent on arrival (5/50=0.10) is significantly than the proportion who were

drowsy during the journey, and indifferent on arrival home (16/50=0.32): chi-squared = 6.0277, df = 1, p-value <0.05 (Table 9).

Table 9. Drowsy during journey and indifferent on arrival home

		Indifferent on arrival home		
		No	**Yes**	**Total**
Drowsy during journey	**No**	45	5	50
	Yes	34	16	50
	Total	79	21	100

The proportion of patients who were not drowsy during the journey and agitated on arrival home (48/50=0.96) is significantly greater than the proportion who were drowsy during the journey and not agitated on arrival home (40/50=0.80): chi-squared = 4.6402, df = 1, p-value <0.05 (Table 10)

Table 10. Drowsy during journey and agitated on arrival home

		Agitated on arrival home		
		No	**Yes**	**Total**
Drowsy during journey	**No**	48	2	50
	Yes	40	10	50
	Total	88	12	100

The proportion of patients who were not nauseous during the journey and not nauseous on arrival home (93/95=0.98) is significantly greater than the proportion who were nauseous during the journey and not nauseous on arrival home (3/5=0.60): chi-squared = 9.2654, df = 1, p-value = <0.05.) (Table 11).

Table 11. Nausea during the journey and nausea on arrival home

		Nausea on arrival home		
		No	**Yes**	**Total**
Nausea during the journey	**No**	93	2	95
	Yes	3	2	5
	Total	96	4	100

The proportion of patients who were not nauseous during the journey and not nauseous at 8 hours after arrival (94/95=0.99) is significantly greater than the

proportion who were nauseous during the journey and not nauseous at 8 hours after arrival home (3/5=0.60): chi-squared = 13.185, df = 1, p-value = <0.05 (Table 12)

Table 12. Nausea during the journey and nausea after 8 hours

		Nausea after 8 hours		
		No	**Yes**	**Total**
Nausea during the journey	**No**	94	1	95
	Yes	3	2	5
	Total	97	3	100

The gender distribution is f=49, m=50(one missing value)

The analyses reported in Tables 8-12 were repeated separately for Males and Females. It turned out that the results for Females were almost exactly like those for the whole group, that is, so far as statistical significance went, but all tests of association gave non-significant results for Males. So it appears that the differences seen in Tables 8-12 are due to differences in the Female responses.

4.1.7 Discussion

The three drugs midazolam, ketamine and propofol were used as a combination in all the children. Our data showed that the common side effects on arrival home were restlessness (29%), blurred vision (16%), nausea (7%), vomiting (2%) and headaches (4%).

The incidence of drowsiness was 45% which can be seen as a side-effect but this is usually expected with administration of sedative drugs to cause anxiolysis. The numbers 50 and 50 in the last columns of Tables 8, 9, 10 are marginal totals in every case referring to the classificatory variable Drowsy during journey. Drowsiness is seen as an indication that patients are starting to relax and that we may proceed with the procedure.

After 8 to 12 hours the incidence of restlessness (5%) and blurred vision (2%) decreased. The number of patients with restlessness came down to 5 and 2 respectively and blurred vision to 1% after 8 and 12 hours.

Fifty percent of the children were drowsy during their journey home. On arrival at home 35% of children were still drowsy, and only 1% at 24 hours.

Wood (2013) reported the incidence of nausea in 5 to 10% of patients after ketamine administration. The combination of midazolam and ketamine showed an incidence of vomiting in 9%, and agitation in 5.4% of children. (Ozdemir *et al.,* 2004).

Wathen *et al.,* (2000) reported agitation in 5.7% of patients after ketamine administration for sedation, and 35.7% in patients after the administration of a combination of ketamine and midazolam. Vomiting occurred in 10.1% of children after ketamine administration, and 5.4 % after a combination of ketamine and midazolam.

The literature (Table 13) shows that the incidence of side effects after the administration of a single drug during sedation is almost the same as when drugs are combined. Our research study shows the same incidence of side effects when using the combination of midazolam, ketamine and propofol (Table 14).

Table 13. Drug administration and side effects during procedures			
Reference	Drugs	Side effects	
		Nausea	Vomiting
Wood, (2013)	Ketamine	5-10%	
Roback et al., (2005)	Midazolam		0.8%
	Ketamine		10.1%
Ozdemir *et al*., (2004)	Midazolam		5.4%
	Ketamine		9.0%
Wathen et al., (2000)	Midazolam		9.6%
	Ketamine		
Kennedy et al., (1998)	Midazolam		7.7%
	Ketamine		
Wathen et al., (2000)	Ketamine		19.4%

The 2X2 tables showed significant associations between levels of sedation, state of mind, and drug side effects during the journey and on the way home.

Table 14. Drug administration and side effects during the journey, on arrival home and 24 hours after arrival home						
Side effects	During the journey	On arrival home	After 4 hours	After 8 hours	After 12 hours	After 24 hours
Nausea	7%	4%	7%	3%	3%	2%
Vomiting	2%	3%	2%	2%	2%	2%
Drowsiness	50%	35%	15%	4%	2%	2%

4.1.8 Conclusion

The research study shows that side effects are present after using sedative drugs for procedural sedation. The sedation practitioner must be aware of this and also inform the parents of this possibility.

It is evident that intravenous sedation with midazolam, ketamine and propofol is safe and effective to use during sedation procedures. There may be side effects but they are not long lasting.

4.2 An evaluation of Post Sedation Satisfaction in adults

4.2.1 Introduction

Side effects after sedation procedures in a hospital setting have been reported in previous studies. Data referring to side effects after discharge home are limited (Malviya *et al.,* 2000a). This is concerning as adverse events may occur when patients are going home. Patients may be at risk on the way home because of lack of monitoring, but also because patients are not informed of this possibility.

Delayed recovery, a possible side effect, can be caused by excessive doses of drugs not titrated to effect, and using the wrong combination of drugs.
Nausea and vomiting can be caused by the administration of certain drugs for example, the opioids, and ketamine.

The purpose of this study, was to determine post sedation recovery on arrival home, as well as the relationship between side effects and dental procedures sedation.

While conscious sedation is generally well-tolerated, certain side effects may be noticed for several hours after the procedure. This is very important to understand as it is possible that the deeper the level of sedation the higher the incidence of side effects (Coplans and Curson, 1982).

Luhmann et al., (2006) reported side effects such as ataxia, nightmares, hallucinations, vomiting, headaches and crying after sedation before discharge.

Oxygen saturation levels of <93% occurred in 11% of patients who received the ketamine and midazolam combination.

Luhman et al., (2006) reported a higher incidence of post-operative nausea and vomiting (PONV) in paediatric patients. The incidence of PONV was reported as 34% in children aged 6 to 10 years, and 32% in children older than 11 years.

The sedative effects of ketamine are synergistic with those of the benzodiazepines. Titration still remains the best option to combine the two drugs. It is reported that the use of midazolam with ketamine reduces the incidence of hallucinations, and enhances the quality of ketamine sedation (Oei-Lim, 1997). Roback *et al*., (2005) reported an incidence of PONV of 5.4% in their study.

Hypoxaemia can be an adverse event, or even called a side effect, during sedation, this usually due to the drugs that depress the respiratory centre. This is the reason why we advise sedation practitioners to titrate sedative drugs to effect.

Mortality is rare during sedation when all the requirements of safe practice are met. Nordt and Clark (1997) reported that deaths occurred during sedation with the combined use of midazolam and an opioid fentanyl. This should not happen when drugs are titrated during sedation. Midazolam alone in their study did not produce significant respiratory depression. Fentanyl alone caused significant drops in oxygen saturation levels.

Pershad and Godambe (2004) reported a 25% incidence of drop in saturation levels after the administration of midazolam and fentanyl for orthopaedic procedures in the emergency department. The American College of Emergency Physicians (2005) reported a 20% incidence of drop in saturation levels in patients receiving midazolam and fentanyl.

The incidence of drops in oxygen saturation levels, as reported above, are high. One would expect the figures to be lower. However it illustrates a very important point, and that is that drugs can cause respiratory depression. Patients need to be monitored continuously.

The level of consciousness should be carefully monitored and documented continuously on a Sedation Scoring System (Appendix 1). The level of sedation can have a direct influence on recovery characteristics. The deeper the sedation level the longer it may take for the patient to recover. This is not an ideal situation for out of hospital sedation.

Four sedative/analgesic drugs namely midazolam, propofol, fentanyl and ketamine were used in this research study. The synergistic effects of the drugs may lead to deeper levels of sedation and prolonged recovery. There may also be a higher incidence of adverse events. The ideal is to titrate drugs to effect.

4.2.2 Aims of the study

The purpose of this study was to evaluate the safety and efficacy and side effect profile of an advanced sedation technique (combining different drugs) in adult patients.

4.2.3 Objectives of the study

This research study was designed with the following objectives in mind:

- To evaluate the incidence of sedation-related side effects on arrival home after administration of combinations of drugs.
- To assess the possible association between the incidence of side effects and specific dental procedures.

4.2.4 Materials and methods

Sedation was administered to 447 ASA I and II male and female adult patients (aged 18 years and older) by the sedation practitioner on duty in the sedation facility of the Faculty of Dentistry. Valid written informed consent was obtained from all sedation patients.

All the patients had an intravenous cannula in placed in a vein on the dorsum of the hand for the duration of the procedure and recovery.

In addition to the dedicated sedation practitioner a nurse helped with monitoring of the haemodynamic parameters.

The following drugs were used in this study, midazolam, propofol, fentanyl, and ketamine. A Sedation Monitoring Chart (Appendix 4) was used to document all the information. The time of onset of sedation, length of the procedure and sedation and time from the end of the procedure to patient discharge were recorded. The patients were discharged from the sedation facility only when they met the discharge criteria (Appendix 6).

Before discharge, the patient, and escort received a questionnaire (Appendix 11) to fill in which consisted of 37 questions related to the patient's experience of the sedation procedure as well as experience of the patient after reaching home. The questionnaire was to be completed at home over the next 24 hours. This questionnaire had to be returned at the follow-up of the patient.

Of particular importance to us was the experience of the patient during and after sedation, especially the side-effect profile, and how they rated the whole process of sedation and surgery.

4.2.5 Statistical analysis of results

The data were recorded in an EXCEL spreadsheet manner suitable for statistical analysis, and the analyses were performed using the program R (R Core Team (2014). The incidence of various side effects was estimated in the usual way by the sample proportions, and associated 95% confidence limits were obtained. Associations between side effects and dental procedures were examined by drawing up appropriate contingency tables and applying the chi-squared test procedure.

4.2.6 Results

Four hundred and fourty seven (447) patients participated in this study. A summary of all side effects, as well as the results of the side effects related to the different dental procedures, and the results of the chi-squared tests can be seen in Table 15. The number of patients with vomiting and described as "other" in the table were insignificant and were not statistically evaluated.

Interesting results were the statistical significance related to drowsiness and the dental procedure ($p<0.006$). There was also a statistical significance between swelling and certain dental procedures ($p<0.002$) (Tables 15). The association is difficult to explain.

- **Incidence of side effects**

Results are summarized in Table 15. The first column of the table gives a list of dental procedures, the first row a list of recorded side effects. The row labelled Overall gives the percentage of patients who experienced the side effect listed in the relevant column, for example, an estimate of the prevalence (incidence?) of Drowsy. The rows labelled Low and High give the lower and upper limits of a 95% confidence interval for the prevalence. For example, of the 447 patients 245 recorded Yes for Drowsy, for example, 54.8%, and this is taken as the estimate of the prevalence (incidence?) of this side effect in the

population. In summary, the estimate of prevalence of Drowsiness is 54.8% with 95% confidence limits (50.5%, 59.5%).

The same explanation applies to the other side effects.

Table 15. Summary of side effects related to dental procedures and results of chi-squared tests

		Drowsy	Dizzy	Nausea	Vomiting	Headache	Muscle	Swelling	Pain	Other pain	Sleep	Emotional	Other
Procedure	**Number**												
None	9	44.4	11.1	0	0	11.1	0	22.2	11.1	22.2	11.1	22.2	0
Peri Gum	45	51.1	17.8	2.2	0	11.1	11.1	17.8	24.4	24.4	8.9	22.2	22.2
Prost	87	59.8	25.3	4.6	0	5.7	8.0	6.9	10.3	11.5	14.9	16.1	0
Implant	137	42.3	19.0	5.8	1.5	8.8	8.8	23.4	10.9	26.3	19.0	23.4	3.6
Endo	29	62.1	24.1	0	0	0	0	0	10.3	20.7	6.9	17.2	3.4
Extract	58	65.5	24.1	3.4	1.7	10.3	12.1	25.9	22.4	22.4	13.8	15.5	1.7
Oral Surgery	7	28.6	28.6	14.3	0	14.3	0	42.9	28.6	0	28.6	14.3	0
Multiple	75	66.7	28.0	8.0	2.7	9.3	12.0	22.7	14.7	24.0	17.3	30.7	1.3
Overall		54.8	22.6	5.2	1.1	8.3	8.9	18.6	14.5	21.5	15.4	21.5	2
Low		50.1	18.8	3.3	0.4	5.9	6.5	15.1	11.4	17.8	12.2	17.8	0.9
High		59.5	26.8	7.6	2.6	11.2	12.0	22.5	18.2	25.6	19.1	25.6	3.8
Chisq		19.61	4.18	6.03		4.73	6.32	22.23	10.71	9.49	5.81	7.3	
P		0.006	0.759	0.534		0.693	0.503	0.002	0.152	0.219	0.562	0.398	

The incidence of side effects in Table 15 is the experience of patients over a 24 hour period. An interesting side effect is the disturbances of sleep pattern (15.4%) which may be related to their pain experience, which is reported as 14.5% by the patients. The high incidence of drowsiness (54.8%) is important for us as sedation practitioners.

There is a low incidence of nausea (5.2%). The term “emotional fragility” (felt down) is difficult to define; it looks like patients may be depressed after the operation but this was not investigated further.

- **Association between the incidence of side effects and specific dental procedures**

Table 16 shows a cross tabulation of patients according to Drowsiness and Procedure. For example, there were 137 patients with procedure=Implant, of these 58 recorded Drowsiness=Yes.

The hypothesis under test here is H_0=the probability of Drowsiness=Yes is identical for all of the Dental Procedures. The chi-squared test applied to the 8×2 contingency table represented by the second and third columns of Table 16 is suitable for testing H_0. The result is: observed chi-squared = 19.61, df.=7, P=0.006, indicating rejection of H_0. Inspection of differences between observed frequencies and expected frequencies under H_0 shows that the incidence of Drowsiness at Procedure=Implant is significantly low, at Procedure=Multiple it is significantly high.

In Table 15 the column headed Drowsy is a brief summary of the results discussed above. It contains Percent Yes, and in the rows labelled chi-squared and P the values 19.61 and 0.006 for observed chi-squared and P.

Examination of Table 15 shows that the results of only one other side effect, namely Swelling, produced a statistically significant observed chi-squared=22.23, P=0.002. Further examination of observed and expected frequencies shows that the percentage Yes is significantly low for Dental Procedure= Prost and Endo.

Table 16. Incidence of drowsiness and individual procedures

PROCEDURES	DROWSINESS			
	None	Yes	Total	Percent Yes
None	5	4	9	44.4
Peri Gum	22	23	45	51.1
Prost	35	52	87	59.8
Implant	79	58	137	42.3
Endo	11	18	29	62.1
Extract	20	38	58	65.5
Oral Surgery	5	2	7	28.6
Multiple	25	50	75	66.7

The incidence of swelling and individual procedures performed are shown in Table 17.

Table 17. Swelling and individual procedures

PROCEDURES	SWELLING			
	No	Yes	Total	Percent Yes
None	7	2	9	22.2
Peri Gum	37	8	45	17.8
Prost	81	6	87	6.9
Implant	105	32	137	23.4
Endo	29	0	29	0.0
Extract	43	15	58	25.9
Oral Surgery	4	3	7	42.9
Multiple	58	17	75	22.7

The above is just an interesting observation but not really significantly relevant to safety of conscious sedation

4.2.7 Discussion

The drugs midazolam, propofol, fentanyl and ketamine were used in all the patients. Muhammad and Siddiqui (2011) reported a 11% incidence of drowsiness in the recovery room one hour after surgery when midazolam was used for sedation.

Our data demonstrates that drowsiness (54.8%) was a significant side effect in patients on arrival home after sedation. This may not be such an important side effect, but it shows that patients be cautioned about for example, driving a motor car within 24 hours after sedation.

What is very significant is that only 5.2% of patients experienced nausea/sick feeling after sedation. This is a significant finding as patient satisfaction is an important component of sedation practice, and will become more so in future as sedation is a fast growing option for patient care.

McGlone, Howes and Joshi, (2004) reported that 70% of patients vomited in recovery or at home following the administration of intramuscular ketamine to 310 children. This is an expected finding as it is well known that intramuscular ketamine can cause a high incidence of PONV.

Roback *et al.,* in 2006 reported that vomiting in the emergency department was more common in the intramuscular ketamine group (26.3%), versus 11.9% in the intravenous ketamine group.

In a study performed by Barr and Wynn (1992) 22% of children were nauseous and 15% vomited after procedural sedation with a combination of ketamine and fentanyl. These findings highlight the importance side effects when using drugs for sedation.

As sedation practitioners we need to use small doses of drugs, and titrate it to effect of applying discharge criteria. The chi-squared results in Table 15 showed significant lack of homogeneity of the percentages for both drowsiness and severe swelling at the operation site.

Our findings show the frequency and quality of side effects when using advanced sedation technique. We however report a low incidence of side effects when we compare it with other studies in literature. We therefore feel that the drugs that we used are safe for sedation practice.

4.3 Haemodynamic Effects of Drugs used in a Clinical Study

4.3.1 Introduction

It is common knowledge that the use of combinations of drugs may cause unforeseen synergistic pharmacological effects. This may cause respiratory and/or cardiovascular depression.

The sedation guidelines of the Scottish Intercollegiate Guidelines Network (2002) claim that sedative drug combinations should be avoided in children as they are often associated with deeper levels of sedation and with more adverse effects. This is not entirely correct as sedative combinations are often used (SASA, 2010). When sedative combinations are used carefully in children, titrated to effect, and administered by a trained sedation practitioner, we do not often see adverse events. This was done in our study with no haemodynamically related adverse events.

Propofol, a drug used for advanced sedation techniques, can cause a decrease in the following haemodynamic parameters, the following effects,

- systolic and diastolic blood pressures,
- respiratory rates,
- oxygen saturation levels and
- pulse rates (Bassett *et al.,* 2003).

The question is did we see this in our study? A study by Roelofse, Joubert and Roelofse, (1996) showed a significant increase in blood pressures and pulse rates in children receiving ketamine and midazolam for sedation. This may have been related to the level of anxiety and/or intrinsic sympathomimetic effects of ketamine.

4.3.2 Objectives of the study

In trying to demonstrate the safety of sedative agents used during sedation we need to look at the haemodynamic parameters; what do drugs do to the blood pressure and pulse rates? The purpose of this study was to evaluate haemodynamic parameters such as pulse rates, systolic blood pressures when using an advanced sedation technique in patients for dental procedures.

4.3.3 Materials and Methods

The sedation records of 335 patients for dental surgery were assessed for the period 2010 – 2011. From 335 sedation records, only 183 records were actually chosen and from this number 158 records were used for further analyses. The following vital signs were continuously recorded on the sedation flow sheet during sedation and recovery; oxygen saturation levels, pulse rates and systolic blood pressure.

A combination of four sedative/hypnotic, and analgesic drugs fentanyl (F), ketamine (K), midazolam (M) and propofol (P) were used. Doses were administered intravenously according to the age and weight of the patients. Patients were selected and examined by the sedation practitioner.

Patients were only discharged from the sedation facility when haemodynamically stable. The following discharge criteria were used:

- blood pressures and pulse rates
- able to swallow and cough,
- can walk without feeling faint,
- no nausea and vomiting,
- breathing unobstructed,
- fully awake and aware,
- no complications of the operation

4.3.4 Statistical analysis of results

Data was recorded in an EXCEL spreadsheet and statistical analysis was performed with statistical package R (R Core Team, 2014). Means and standard deviations were obtained for the subgroups of patients defined by the drug combinations employed for them. The statistical significance of group differences was examined using analysis of variance techniques and the Kruskal-Wallis rank test. Graphs of means, with lower and upper limits useful for judging the significance of mean differences were constructed.

4.3.5 Results

The following codes are used for the drugs: F = fentanyl, K = ketamine, M = midazolam, P = propofol.
The drug combinations used for the 183 patients are listed in Table 18; y=Yes, n=No.

Table 18 gives the number of patients receiving the different drug combinations. For example the table shows that 35 patients received all four drugs during sedation, 58 patients received the two drugs ketamine and propofol.

Table 18. Number of patients receiving the different drug combinations

F	K	M	P	Frequency
n	n	n	n	2
n	y	n	n	1
y	y	n	n	1
n	n	y	n	5
y	n	y	n	2
n	y	y	n	2
y	y	y	n	1
n	n	n	y	4
n	y	n	y	58
y	y	n	y	51
n	n	y	y	1
y	n	y	y	6
n	y	y	y	14
y	y	y	y	35

Because of the low frequencies at many of the drug combinations only those with frequencies greater than or equal to 10 were considered for further analysis; there were four such groups, namely, KP (n=58), FKP (n=51), KMP (n=14), FKMP (n=35).

The variables with respect to which the four groups were compared are: Duration of sedation, Pulse rate and Systolic blood pressure.

- **Duration of sedation**

Table 19 gives summary statistics of variable duration of sedation times for the four groups with the greatest numbers of patients.

The columns labelled lower and upper aremean±1.4(SE), where SE is the standard error of the mean; the factor 1.4 is chosen such that non overlapping of the intervals demarcated by lower and upper indicate statistical significance at level approximately 0.05. The lower limit at (nyyy)(20.74) is greater than the upper limit at (nyny)(10.22), showing that the mean at (nyyy) is statistically significantly greater than the mean at (nyny).

Table 19: Duration of sedation summary statistics

Drug combination								
F	K	M	P	Number	Mean	SD	Lower	Upper
n	y	n	y	58	9.45	4.20	8.68	10.22
y	y	n	y	51	14.73	14.03	11.97	17.48
n	y	y	y	14	27.50	18.05	20.74	34.26
y	y	y	y	35	51.71	25.52	45.67	57.75

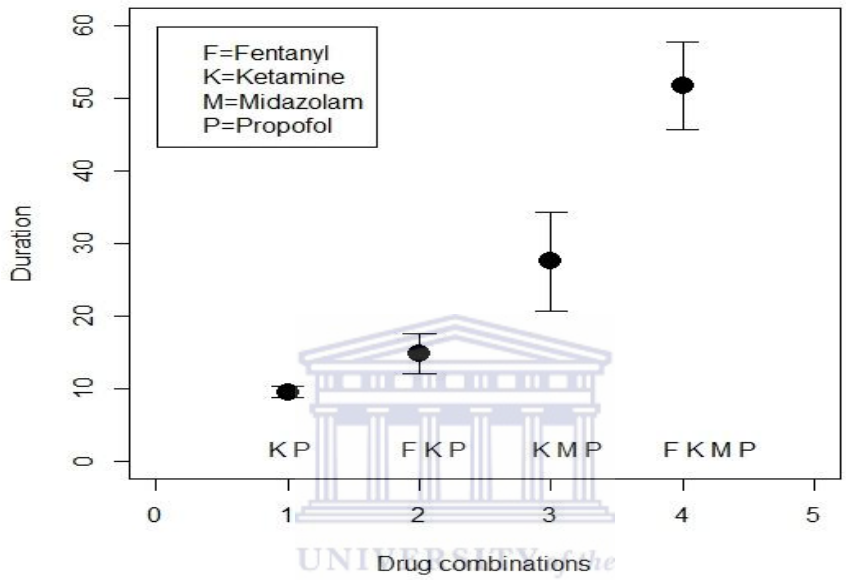
According to a Kruskal-Wallis test there are statistically significant differences between the four group locations (indicated by their means); Kruskal-Wallis chi-squared = 78.737, df = 3, p-value <0.0001.

The data in Table 19 are represented graphically in Figure 10 showing mean values as dots with associated Lower and Upper limits. The limit lower=mean-1.4×SE, Upper=Mean +1.4×SE where SE is the standard error of the mean, $SD/N^{1/2}$; the factor 1.4 in the definition of the limits is chosen so that non-overlap of two independent intervals indicates statistically significant difference of means at level approximately 0.05.

Figure 10 shows some clear trends, for example, the mean Duration of sedation is substantially and statistically significantly greater with combination FKMP than with the other combinations. The mean Duration of sedation is not significantly different between KP and FKP.

This is a significant finding for sedation practitioners. The use of polypharmacy regarding the combination of drugs, specifically FKMP, will cause a longer duration of sedation. This has implications for safety, as well as the side effects profile during and after sedation.

Figure 10. Duration of sedation for certain drug combinations



- **Pulse rate**

Table 20. Pulse rate summary statistics

Fentanyl	Ketamine	Midazolam	Propofol	Number	Mean	SD	Lower	Upper
n	y	y	y	6	85.17	24.88	70.95	99.39
y	y	y	y	10	85.44	15.92	78.01	92.87
n	y	n	y	46	106.33	16.59	102.90	109.75
y	y	n	y	38	108.11	15.92	104.48	111.72

According to a Kruskal-Wallis test there are statistically significant differences between the four group locations (indicated by their means); Kruskal-Wallis chi-squared = 15.427, df = 3, p-value = 0.001.

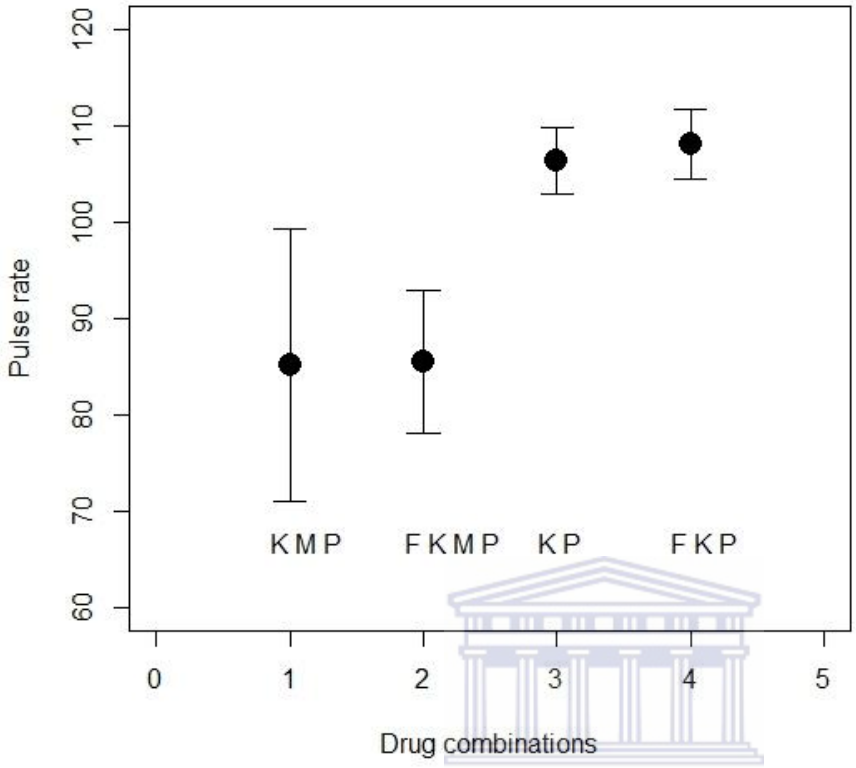
The data in table 20 are presented graphically in Figure 11, which shows mean values as dots with associated lower and upper ±1.4 (SE) limits. The graph shows that the mean pulse rates at (nyyy) (KMP) is significantly smaller than the means at (nyny) (KP) and (yyny) (FKP).

It is noted that there was no tachycardia during sedation (pulse rates > 120/min). The results of the statistical analysis show that all patients were sedated at an acceptable level of consciousness where they were comfortable with no pain or side effects. Combinations of a greater number of drugs clearly show that patients were more comfortable than when fewer drugs were used.

Different combinations of drugs are used by other practitioners with a higher incidence of side effects. The combinations of drugs we used look like an ideal combination for procedural sedation as our side-effect profile was very low.

The important lesson from all the results is that sedation providers must be trained in procedural sedation as expected by all international sedation guidelines.

Figure 11. Drug combinations and pulse rate



- **Systolic blood pressures end of procedure**

Table 21. Systolic End blood pressure summary statistics

Fentanyl	Ketamine	Midazolam	Propofol	Number	Mean	SD	SystEnd.lo	SystEnd.hi
n	y	y	y	13	101.92	14.06	96.46	107.38
y	y	n	y	49	107.47	16.11	104.25	110.69
n	y	n	y	57	109.09	16.72	105.99	112.19
y	y	y	y	35	118.03	19.13	113.50	122.55

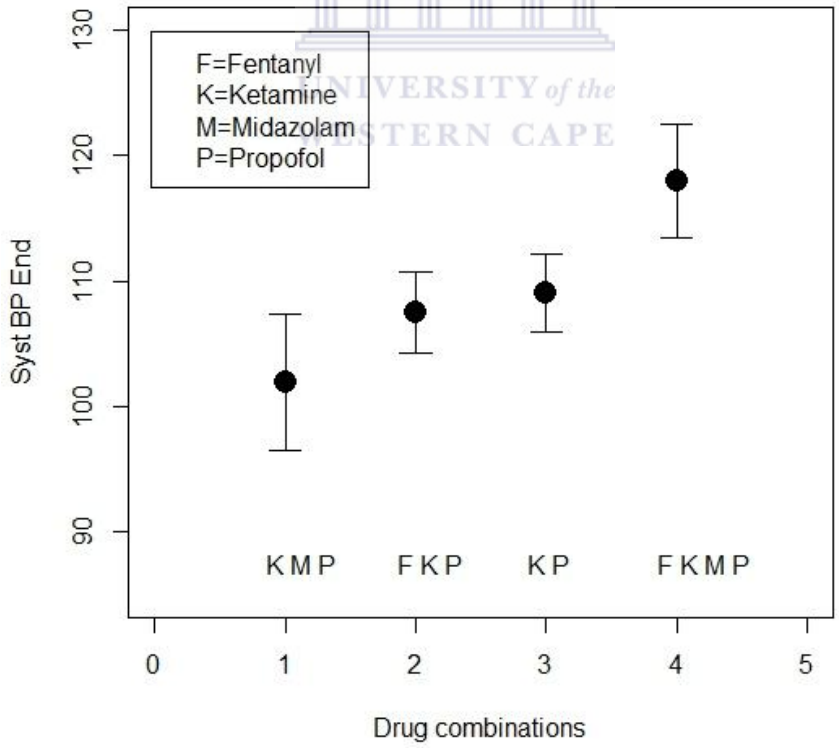
A Kruskal-Wallis test gives results:Kruskal-Wallis chi-squared = 10.253, df = 3, p-value = 0.017, indicating statistically significant differences between group means.

The mean systolic blood pressure end at (yyyy) (FKMP) is significantly higher than the other three means (Table 21). The data in Table 21 are represented graphically in Figure 12, which shows mean values as dots with associated confidence limits.

It is difficult to explain the higher values of blood pressures when all four drugs were used. It may have been a ketamine effect, although one would not expect this when using propofol with ketamine.

In clinical terms the higher blood pressures are no reason for concerns about the safety of the patients.

Figure 12. Drug combinations and systolic blood pressure end of procedure



4.3.6. Discussion

It is reasonably safe to say that, with haemodynamic parameters so stable in this study, combinations of drugs can be safely used for procedural sedation. No incidences of hypotension or bradycardia or other complications were seen.

As sedation practitioners we should be extremely careful when we use multiple drugs. Drug interactions always remain a possibility, which can be a threat to patient safety. Combining different drugs can easily lead to deeper levels of consciousness and even unconsciousness bordering on general anaesthesia.

This study is a significant contribution to current knowledge on the use of combinations of drugs for procedural sedation. Very few studies in the literature report on combinations of drugs for procedural sedation in children and adults.

CHAPTER 5: CONCLUSIONS

This study shows conclusively that procedural sedation can be managed and safely done outside the hospital environment, as an alternative for general anaesthesia for certain dental procedures.

All international guidelines say that ASA I and II patients can be done outside the hospital setting in dental or medical rooms, facilities, and clinics. This study was done in a clinic that is attached to the hospital, outside the hospital theaters.

Paediatric sedation remains a controversial issue, in some countries. There are clinicians that feel that small children must at least be done in a dedicated clinic, or in hospital near operating theaters. There are also clinicians that are uncomfortable about the use of multiple drugs for paediatric sedation. Many of them feel that nitrous oxide sedation is the best option. It is however not an option for longer and more invasive procedures in children.

This research study shows that children can in fact be done safely outside the operating theater when multiple drugs are used. It must however be done in premises that meet all the requirements for safe practice. The sedation practitioner must also have the necessary postgraduate qualification in sedation.

This is an extremely important research study and the results are crucial as far as an option for healthcare in developing countries. Sub-Saharan Africa is a densely populated and resource poor subcontinent that provides unique challenges in patient care. These challenges include a lack of facilities and staff for the performance of operative as well as non-operative procedures.

In a survey on anaesthesia services in developing countries, the authors used a questionnaire to evaluate the difficulties in providing anaesthesia services in Africa. This survey provides us with insight of the availability of anaesthesia services in other developing countries in Africa. The survey results show that 23 % of anaesthetists have the facilities to deliver safe anaesthesia to adults but only 13 % have facilities to deliver safe anaesthesia to children. The questionnaire identified shortages of personnel, drugs, equipment, and training as major factors influencing service delivery. These factors had neither been quantified nor

accurately described before. Training was also highlighted as problematic, with few qualified physician anaesthetists amongst the anaesthesia providers. Most of the non-anaesthetists had previously attended a training course with little supervised clinical training.

Anaesthesia for procedures in children according to the results of the survey appears to be largely ketamine-based, mainly due to a "lack of disposable airway equipment such as tracheal tubes, facemasks and breathing circuits."

Ketamine is available in the majority of countries in Sub-Saharan Africa. It is an extremely important and safe drug as it can provide anaesthesia, sedation, and analgesia. Ketamine's inherent safety profile allows it to be used safely for procedures outside the operating room, provided that standard safety requirements are adhered to. Ketamine, used intramuscularly and intravenously, is regarded by many as the "standard of care for the sedation of children in many developing countries". It can be used by both anaesthetists as well as "untrained personnel" for induction and maintenance of anaesthesia.

Our research study support the view that ketamine can be used safely outside the operating theatre with exciting possibilities for Third World countries for procedures outside the operating theatre. Sedation can be considered a reasonable alternative to general anaesthesia for certain surgical procedures in the Third World.

Bearing in mind the common surgical conditions of childhood in developing countries in Africa, it becomes clear that there is a large potential market for sedation services, not only for dental procedures. Common surgical conditions are encountered. There are often not enough theater capacity, anaesthetists, and other healthcare personnel to provide general anaesthesia.

Sedation will be an attractive option not only as far as costs are involved but also the availability of sedation providers. We proved in this research study that sedation can be done safely, we however need to make a contribution to train sedation providers.

The cost issue and safety still remains a problem as some clinicians feel children must get sedation in-hospital. The alternative would be to negotiate with private hospitals for a reduced fee under general anaesthesia or for that matter sedation in-hospital. This could lead to increased costs which will not be possible to all patients.

We negotiated a reduced fee with a private hospital to look at the costs involved for dental procedures in children under general anaesthesia (Yasin-Harnekar, Carstens and Moola, 2012). One hundred and four children aged 2 - 12 years were entered for this study, 9.2% were younger than 6yrs. This is the age group that clinicians are worried about when combinations of drugs are being used. We proved that children in this age group can be safely done under sedation outside the traditional operating theater.

The objectives were to determine also the

- the cost of dental treatment under general anaesthesia in a private facility where a reduced fee was negotiated.
- The costs involved when only exodontia or restorations were done. The assumption here was that the duration of anaesthesia will be shorter with exodontia, and the fee will be less than when restorations will be done, who usually take a longer time under general anaesthesia.

The average time that children spent under general anaesthesia was 43.3 minutes. In this study 82% of children required both restorations and exodontia.

The costs of general anaesthesia per patient for a 40-minute procedure were R4963.23. This amount includes a negotiated fee of R74.67/min, usually R150/min, for use of the theatre. The current theatre fees in private practice are about 2- 2.5 times the above negotiated fee.

The above shows that doing cases in-hospital are extremely costly. It is not practical to go and negotiate reduced fees with hospital providers. We need another safe option.

It is important to understand that not all procedures can be done under sedation outside the hospital environment. Two possible examples are the complexity of procedures, and the health status of the patients. Sedation has however become an attractive alternative to general anesthesia for certain procedures in healthy patients.

Two issues that make sedation an attractive alternative are the side-effect profile and patient satisfaction. It is interesting that few studies are available that looked at this aspect of sedation. One may ask why a reference to the side-effect profile? Has this got anything to do with safety? It is clear that a high side-effect profile can contribute to an unsafe sedation technique for example, severe nausea and vomiting can cause numerous haemodynamic disturbances and dehydration.

Patient satisfaction during and after sedation remains a very important component of safe sedation. We are going to be judged by the patient.

Patient preferences were evaluated in a study done after general anaesthesia in adult patients (Hill *et al.,* 2002). The results are quite interesting. Forty-nine percent of patients did not want nausea and vomiting, 27% wanted no pain, 13% wanted to be alert soon after the procedure, and 11% were concerned about additional costs under general anaesthesia.

The reality concerning side-effects is much different after general anaesthesia as published in this study. The incidence of severe post-operative pain was 66%, post-operative nausea and vomiting 51%, and headaches 38%.

Erasmus and Roelofse (2008) compared the side–effect profile of three different techniques often used for dental procedures, local anaesthesia, general anaesthesia and procedural sedation in 600 adult patients.

This study also looked at the cost-effectiveness of general anaesthesia and sedation. This study showed conclusively a lower side-effect profile during and after sedation compared to general anaesthesia. It was evident that more patients would prefer sedation in future if they had a choice; 99% of patients would prefer sedation as an option.

As far as costs are concerned 42% of patients complained that the anaesthetic fee was too high during general anaesthesia; only 3% of patients were uncomfortable about the sedation fee.

The costs per time unit for the procedures were,

- Sedation: R15.00 per minute
- General anaesthesia: R75.00 per minute

Lapere *et al.,* (2015) looked at patient satisfaction in a study of 500 patients having sedation for dental procedures. They feel that the clinician's perspective of a good outcome and the patient's experience of a satisfactory service are often two different end–points.

The primary aim of their study was to assess the peri-operative experience of patients undergoing procedural sedation. A secondary aim was to create a post-operative questionnaire which could be used as a measurement tool. The questions could also be used as an audit to assist with adherence to quality assurance and clinical governance.

The method used was to compile a questionnaire to assess the peri-operative aspect of procedural sedation. Five hundred consecutive patients undergoing procedural sedation for dental-related procedures were asked to complete a questionnaire. Patients who did not complete it were excluded. Ninety-eight per cent of the patients return the questionnaire and 489 questionnaires were evaluated.

The results showed that ninety-three per cent of the patients expressed a good (7plus/10) overall experience of procedural sedation, and 92.6% indicated that they would recommend it to others.

The study population showed a high level of satisfaction with their sedation experience. One of the questions was "did you feel safe" during sedation. Very few patients felt unsafe. The low side-effect profile, as in our study, must have contributed significantly to this very positive experience of sedation outside the operating theatre.

Our research study support the findings of the study by Lapere *et al.,* (2015) that there is a high rate of patient satisfaction, and a low side-effect profile during and after sedation.

In conclusion, we feel that we are part of Sub-Saharan Africa with all problems mentioned as far as provision of healthcare is concerned. This research study can make a crucial contribution to safe and cost-effective management of healthcare in Africa for procedures outside the operating theatre.

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Appendix 1: Sedation Scoring System (SASA, 2015).

Wilson Sedation Scale

The level of consciousness can be assessed by using tools such as the Wilson Sedation Scale or the University of Michigan Sedation Scale

Sc	Description
1	Fully awake and oriented
2	Drowsy
3	Eyes closed but rousable to command
4	Eyes closed but rousable to mild physical stimulation (earlobe tug)
5	Eyes closed but unrousable to mild physical stimulation

University of Michigan Sedation Scale (UMMS)

University of Michigan Sedation Scale (UMMS)		
0	Awake and alert	
1	Minimally sedated	Patient drowsy, sleepy but rousable to verbal command
2	Moderately sedated	Patient may be sleeping, can be easily aroused by light tactile stimulation
3	Deeply sedated	Patient asleep, only rousable by significant physical stimulation, or repeated painful stimuli
4	Unrousable	No response with significant physical stimulation

Appendix 2: Basic equipment and drugs for procedural sedation and analgesia (SASA, 2015).

Devices to administer oxygen and assist with ventilation	
Oxygen and oxygen tubing	Oxygen source must be reliable and able to provide at least 90% oxygen via a self-inflating positive pressure delivery system at 15 L/min for at least 60 minutes
Oxygen flow regulator	
Nasal prongs	
Venturi masks	To deliver 40% oxygen
Nebuliser and mask	
Self-inflating resuscitation bag with	
PEEP valve	
Catheter mount	

Airway devices and equipment	
Face masks	Selection of sizes
Laryngeal mask airways or similar supraglottic devices	Sizes 3–5
Range of cuffed endotracheal tubes	Sizes 5–8
Laryngoscope set	Two handles with long and standard blades, and spare batteries and bulbs
Water-soluble lubricant	
10 ml syringe for inflation of pilot balloon	
Tape or equivalent to secure endotracheal tube	
Oropharyngeal airways	Sizes 3–5
Nasopharyngeal airways	Sizes 6 mm and 7 mm
Stylets/introducers	Appropriately sized for endotracheal tubes
Magill forceps	

Monitoring equipment	
ECG monitor and cardiac defibrillator	With conductive paste, chest paddles and razor
Pulse oximeter	
Blood pressure monitoring device	Non-invasive, with appropriately sized cuffs
Stethoscope	
Thermometer	
Blood glucose testing device	
Selection of test tubes for blood biochemistry and full blood count	
Capnograph	Nasal prongs with capnography line strongly recommended, but not compulsory

Equipment with which to gain intravenous access	
Gloves	
Tourniquet	
Sterile gauze pads	
Alcohol skin wipes	
Intravenous cannulae	18–22 gauge
Sterile needles	
Assortment of syringes	1 ml – 50 ml
Sharps container	

Tape or equivalent to secure intravenous cannulae	

Equipment for the accurate infusion of drugs and fluids	
Infusion pumps	Intravenous fluid administration for simple sedation
Syringe drivers	Drug administration in advanced sedation
Intravenous administration sets	Must be compatible with infusion pumps
Stickers for labelling syringes	
Drip stands	
Intravenous fluids	Crystalloids and colloids

Hardware and miscellaneous equipment	
Source of suction	Including connection tubing
Suction catheters	Including catheters for suctioning endotracheal tubes, and Yankauer-type suction nozzles
Therapeutic heat source	
Cardiac arrest board	
Appropriate lighting	
Operating surface that can be tilted	
Urinary catheters	
Nasogastric tubes	
Means of summoning emergency assistance	
South African Resuscitation Council algorithms	Basic and advanced life support
Procedural documentation	

Recommended emergency drugs
Naloxone
Flumazenil
Adrenaline (at least 10 ampoules)
Atropine or glycopyrrolate
Ephedrine or phenylephrine (or other alpha-agonist)
Lignocaine
Glucose 50%
Hydrocortisone, methylprednisolone or dexamethosone
Promethazine (or other H1-antagonist)
Nitroglycerine spray
Aspirin
Salbutamol
Suxamethonium
Intralipid
Calcium-channel blocker e.g. nifedipine
Beta blocker e.g. esmolol
Selective alpha 1 adrenergic and non-selective beta-adrenergic receptor blocker e.g. labetalol

Appendix 3: Medical History Questionnaire (SASA, 2015).

Name			
Sex	Age	Height	Weight

Do you suffer from, or is there a history of, the following? Tick either "yes" or "no" and, if any answer is "yes", provide a detailed explanation.

	YES	NO
1. Cardiovascular disease		
• High blood pressure, that is controlled		
• Heart failure		
• Heart valve lesion, rheumatic fever, or congenital heart disease		
• Dysrhythmia, palpitations (without exertion), or blackouts		
• Shortness of breath when lying down, or walking on a level surface		
If any answer is "yes", please provide a detailed explanation:		
2. Central nervous system disorders		
• Epilepsy, fits (convulsions), or dizziness		
• Depression or psychosis		
If any answer is "yes", please provide a detailed explanation:		
3. Blood disorders		
• Anaemia, sickle cell disorder, or thalassaemia		
• Abnormal bleeding associated with previous dental extractions, surgery or trauma, or do you bruise easily?		
If any answer is "yes", please provide a detailed explanation:		
4. Blood clots		
• Episodes of thrombosis, or embolism of the legs or lungs		
If any answer is "yes", please provide a detailed explanation:		
5. Respiratory disease		
• Do you smoke?		
• History of snoring		
• Lung disease, e.g. asthma, emphysema, or tuberculosis		
If any answer is "yes", please provide a detailed explanation:		
6. Endocrine disorders		
• Diabetes mellitus		
If "yes", please give details of medication and degree of control of blood sugar:		
• Thyroid		
• Porphyria, or other metabolic disorders		
If any answer is "yes", please provide a detailed explanation:		
7. Liver disease		
• Hepatitis, or jaundice		
• Other liver disease		
If any answer is "yes", please provide a detailed explanation:		

	Yes	No
8. Kidney disease		
• Renal disease or disorders, or renal failure		
If the answer is "yes", please provide a detailed explanation:		
9. Muscle disorders		
• Myopathy, dystrophy or progressive weakness, or malignant hyperthermia		
If the answer is "yes", please provide a detailed explanation:		
10. Arthritis and orthopaedic problems		
If the answer is "yes", please provide a detailed explanation:		
11. Stomach problems		
• Indigestion, heartburn, hernia, or ulcer		
If the answer is "yes", please provide a detailed explanation:		
12. Hereditary disease		
If the answer is "yes", please provide a detailed explanation:		
13. History of allergy in general, or allergic reactions to medications		
If the answer is "yes", please provide a detailed explanation:		
14. Previous admission to hospital		
If the answer is "yes", please provide a detailed explanation:		
15. Previous operations		
If the answer is "yes", please provide a detailed explanation:		
16. History of taking medication or drugs, including herbal remedies and recreational drugs		
If the answer is "yes", please provide a detailed explanation:		
17. Previous adverse or unpleasant reaction to anaesthesia		
If the answer is "yes", please provide a detailed explanation:		
18. Infectious diseases		
If the answer is "yes", please provide a detailed explanation:		
19. Airway problems		
If the answer is "yes", please provide a detailed explanation:		
20. Failed sedation		
If the answer is "yes", please provide a detailed explanation:		
21. Is there anything you would like to discuss, but would prefer not to write down?		
If the answer is "yes", please contact your sedationist and discuss this with him/her before the date of your procedure		

…… ……..

Signature (Patient/Parent/Guardian) **Date**

Appendix 4: Sedation Monitoring Chart (SASA, 2015).

DAYCARE SEDATION RECORD		
Date:	Time in:	Time out:
Patient name:	File No:	ASA I II III IV V E
DOB:	Age:	Weight:
Procedure:	Operator:	
	Sedation list:	
	Recovery nurse:	
Previous operations/sedation /GA: Complications: Allergies:	Medical history:	
	Medication:	
Last oral intake: Fluids:	Solids:	
Premedication:	Given at:	
IV cannula size: 24G/22G/20G IV fluids:	Site: Total fluids given:	

TIME																
O_2 %																
RR																
$EtCO_2$																
SpO_2																
190																
180																
170																
160																
150																
140																
130																
120																
110																
90																
80																
70																
60																
50																
Heart																
Drugs:																
1																
2																
3																
4																
5																

Appendix 5: Valid Consent To Sedation And Analgesia For Medical/Dental Procedures (SASA, 2015).

I have been fully informed and I declare the following:
1. I understand the nature of procedural sedation and analgesia, the purpose of the procedure and the risks involved. I understand that no guarantee can be given with regard to the results obtained.

Procedural sedation and analgesia entails the administration of sedative and/or analgesic drugs to induce a reduced level of consciousness to such an extent that normal protective airway reflexes and spontaneous respiration are maintained, and cardiovascular function is unaffected. Procedural sedation and analgesia, together with regional/local anaesthesia, will put me/the patient in a relaxed state to make minor surgery possible. I understand that it is not a general anaesthetic and that I/the patient will not be unconscious, as I/the patient may have to respond to commands from the surgeon and/or the sedation practitioner.

2. Unforeseen adverse events may arise during/after sedation that may require additional or different medications or treatment. I authorise the sedation practitioner to treat such adverse events according to his/her professional judgement:
Possible adverse events include:
- Unintended loss of consciousness
- Drowsiness/dizziness
- Shivering (4%)
- Headaches (4%)
- Post-sedation nausea and vomiting (0.7%)

3. I give consent to the administration of such sedative and/or analgesic drugs as may be considered necessary or advisable by the sedation practitioner responsible for this service.
4. I accept full and complete responsibility for actual and potential costs associated with procedural sedation and analgesia, and I accept full responsibility for the costs that have been explained to me. I agree to comply with the terms and conditions of payment.
5. I have had the opportunity to ask questions and I have been given the opportunity to choose alternative methods of treatment e.g. general anaesthesia, or local anaesthesia without sedation, or the use of local anaesthesia with behaviour management techniques, to my satisfaction.
6. I confirm that I have received written/oral instructions regarding the sedation, which I understand. I will abide by the pre- and postoperative instructions. I have completed a medical history questionnaire and have declared all drugs that I have taken during the last 6 months.

I,…….……(patient/parent/guardian), of address

……...hereby authorise the following

procedure/s to be performed on (name of patient) ……

utilising procedural sedation and analgesia/local anaesthesia techniques under direction of Dr ……..….

Patient/parent/guardian signature ……

Witnesses: 1. ……... 2.……..

Practitioner's declaration: I have explained the procedure of procedural sedation and analgesia, risks, alternatives and expectations to the patient/parent/guardian, and believe that he/she has been adequately informed and have consented.

……..……. ……
Practitioner's signature **Date**

Appendix 6: Post-operative Record and Discharge Criteria Questionnaire (SASA, 2015).

Name of patient:	**Date:**	
	Yes	**No**
Are the blood pressure and heart rate stable?		
Can the patient swallow and cough?		
Can the patient walk without feeling dizzy or faint?		
Is the patient nauseous?		
Is the patient breathing comfortably and of normal colour?		
Is the patient awake and appropriate?		
Has the operative site been checked and is bleeding controlled?		
Have written postoperative instructions been given and explained to both patient and carer?		
Is the patient pain free?		
Have possible complications been explained?		
Has a prescription been given or medication dispensed?		
Is there a responsible adult to accompany the patient?		
Monitoring		

TIME															
O_2 given															
RR															
SpO_2															
Heart rate:															
Temperature:															
BP 190															
180															
170															
160															
150															
140															
130															
120															
110															
90															
80															
70															
60															
50															
40															
30															

Patient has been assessed and is deemed fit for discharge at: (time and date)	
Mode of transport home is:	
Signature of recovery nurse:	

Appendix 7: Pre- and post-sedation instructions for patients and carers (SASA, 2015).

(Please read the instructions carefully, and then fill in your details.)

Dear Patient/Parent/Guardian,

You need to undergo a procedure/operation, and your doctor/dentist has chosen to do this under sedation. Please read the following information and instructions carefully. If anything is unclear, please contact your doctor/dentist at the following telephone numbers:
Tel:……

Pre-sedation instructions

- If you suffer from any medical condition or take any acute or chronic medicine, you will need to inform your doctor/dentist before the procedure/operation. A medical history questionnaire has been included; please complete this and return it to your doctor/dentist before the procedure/operation. This is an important document, as it will help us to decide whether you qualify for the sedation that will have to be given for the procedure/operation. If you feel sick or unwell, please call your doctor/dentist so that he/she can decide whether it is necessary to postpone the treatment.
- Please wear comfortable clothes with loose-fitting sleeves.
- Do not eat anything for at least 6 hours before the procedure/operation. Clear fluids may be taken up to 2 hours before.
- If you take **chronic medication, please do so** on the day of the procedure/operation, after discussing this with your doctor/dentist.
- Please arrive in good time for your appointment, at least 30 minutes beforehand. In some cases, your doctor/dentist may feel that you will benefit from premedication to reduce your anxiety and make you feel relaxed. If this is the case, your doctor/dentist may request that you come earlier for your appointment so you can take the premedication.
- Please empty your bladder before the procedure/operation.
- You must have an adult escort to accompany you home. The escort may remain with you until the sedation is underway and the procedure/operation is about to start. The escort will then be requested to leave the procedure/operation room.
- There must be arrangements in place for you and the responsible escort to travel home by private car or taxi rather than public transport.
- It may be necessary to put a drip/cannula in a vein in your hand or arm.

Post-sedation instructions (aftercare of the patient)

- A responsible adult must take you home after the sedation, and you must remain in the company of a responsible adult for the remainder of the day. Sedation **will not** be given if you arrive without an escort.
- You must not be in charge of other people.
- You may not drive, operate equipment or participate in any other activities that require alertness or coordination (e.g. swimming, cycling, etc.) for at least 12 hours following the procedure/operation.
- You must not climb heights (e.g. ladders, scaffolding).
- If you are taking any regular medication, ask your doctor/dentist when you should take your next dose after the sedation.
- You should not experience nausea or vomiting after sedation. If you do vomit, and this happens more than once, please contact your doctor/dentist.
- Do not eat or drink if you are nauseous. Introduce any fluids or foods slowly after sedation. If you tolerate clear fluids, you may then progress onto solids.
- If you have not passed urine within 6-8 hours of being discharged, please contact the doctor/dentist at the telephone numbers provided.
- The sedation may result in amnesia (loss of memory). This is temporary, sometimes lasting for a few hours.

I, …….. , the undersigned, have read and understood these pre- and post-sedation instructions, and agree to contact the doctor/dentist if there is anything more that is not clear to me.

…… ……..
Signature Date

We do not anticipate that you will have any adverse events or complications. Should you become concerned about anything, please contact:

Dr …… Telephone: ……

Appendix 8: Pre-procedural Checklist (SASA, 2015).

To be completed and signed by sedation practitioner

Name:			Date of birth:		
Age:			Weight:		
Responsible doctor:			Sedation practitioner:		
Procedure: Elective/Emergency/Urgent			Name of accompanying adult:		
Has the patient completed a medical questionnaire? Yes / No					
Has the patient been fully evaluated? Yes / No			Has the patient been physically examined and evaluated? Yes / No		
Sedation contraindication checklist					
Past sedation history Yes / No Details:			Previous sedation satisfactory Yes / No Details:		
Airway problems Yes / No Details:			Previous failed sedation Yes / No Reason:		
Raised intracranial pressure Yes / No Details:			Previous complications of sedation Yes / No Details:		
Sleep apnoea Yes / No			Depressed level of consciousness Yes / No		
Respiratory failure Yes / No			Serious illness Yes / No Details:		
Fasting time checklist					
Fasted for solids (including milk)			From: (minimum 6 hours)		
Fasted for clear juice/water			From: (minimum 2 hours)		
Significant underlying conditions (see medical questionnaire)					
Renal dysfunction Yes / No			Cardiac dysfunction Yes / No		
Hepatic dysfunction Yes / No			Gastro-oesophageal reflux Yes / No		
Respiratory dysfunction Yes / No			Known allergies/drug reactions Yes / No		
Chronic medication Yes / No If yes, have they been taken today? Yes / No			Specify chronic medication:		
Premedication and monitoring					
Premedication prescribed and by whom:			Drug: Dose: Time: D		
Premedication administered: Yes / No			Name of person who administered premedication:		
Name of sedation practitioner: Qualification:			Name of qualified attendant:		
Equipment checklist (tick if present)					
Pulse oximeter		NIBP		ECG	
Airway equipment		Oxygen		Drugs	
Resuscitation equipment		Temperature probe		Circulatory support equipment	

Signature of sedation practitioner: ……..……...Date: ……

Name of sedation practitioner (block letters): ……

Qualification: .....

Appendix 9: Drug dosing schedule for adults (SASA, 2015) and children (SASA, 2010).

Dosing schedule of midazolam (Adults) (SASA guidelines, 2015).

Route of administration	Dose	Recommended maximum dose	Time to peak effect	Duration of action
Oral	0.25-0.5 mg/kg	7.5 mg	10-30 minutes	60 minutes*
Buccal/sublingual	0.25mg-0.3mg	7.5 mg	10-15 minutes	20-60 minutes*
Intravenous	0.05-0.1mg/kg to a maximum bolus of 2mg**	3 mg	3-5 minutes	20-60 minutes*
Rectal	0.5-0.75mg/kg		10-20 minutes	60 minutes*
Intranasal	0.2-0.3 mg/kg	7.5mg	10-15 minutes	20-60 minutes

*Dose-related
**Titrate to effect and repeat dose every 10 minutes until desired level of sedation is achieved, or recommended maximum dose is reached,.
***With elderly patients, it is advised that smaller intravenous doses must be titrated to effect (SASA guidelines, adults, 2015).

Single agent dosing schedule of midazolam (Children) (SASA guidelines, 2010).

Route of administration	Dose	Recommended maximum dose	Time to peak effect	Duration of action
Oral	0.25–0.5 mg/kg	7.5 mg	10–30 minutes	60 minutes*
Sublingual	0.25–0.3 mg/kg	0.3 mg/kg	10–15 minutes	20-60 minutes*
Intravenous	0.025–0.1 mg/kg**	1 mg	3–5 minutes	20-60 minutes*
Rectal	0.5–0.75 mg/kg	1 mg/kg	10–20 minutes	60 minutes*
Intranasal	0.2–0.3 mg/kg	0.3 mg/kg	10–15 minutes	60–120 minutes*

When used in combination with other drugs, doses should be decreased and titrated to effect
* Dose-related
** Titrate to effect, repeat dose every five minutes until desired level of sedation achieved (SASA guidelines, children, 2010).

Dosing schedule for bolus doses of propofol (Adults) (SASA guidelines, 2015).

Dose	Titration	Onset of action	Repeat dose	Duration of action*
Bolus 0.5 mg/kg over 3-5 minutes*	1 minute	45-90 seconds	0.5 mg/kg	5-8 minutes

Dosing schedule for infusion of propofol for PSA (Adults) (SASA guidelines, 2015).

Intravenous infusion	Target controlled infusion
2–4 mg/kg/hour titrated to clinical effect	Effect site concentration 1-2 μg/ml
In elderly patients, commence infusion at 1–2 mg/kg/hour	In elderly patients, recommended effect site concentration is0.6-0.8 μg/ml

Single agent dosing schedule of propofol (Children) (SASA guidelines, 2010).

Dose	Onset of action	Duration of action	Repeat dose	Titration interval
0.3-0.5 mg/kg	45-90 seconds	5-8 minutes	0.5 mg/kg	1 minute

Dosing schedule of ketofol, consisting of ketamine 5mg/ml and propofol 9 mg/ml (Children) (SASA guidelines, 2010).

Route of administration	Dose	Onset of action	Duration of action	Repeat dose	Titration interval
Intravenous	0.05 ml/kg*	30 – 90 seconds	5-10 minutes	0.05 ml/kg	1-5 minutes

*Ketamine 0.25 mg/kg and propofol 0.45 mg/kg.

Dosing schedule of ketamine (Adult) (SASA guidelines, 2015).

Route of administration	Dose	Onset of action	Time to peak effect	Duration of action*
Oral	4–6 mg/kg as single agent, 2 mg/kg if used with other sedatives/ analgesics	> 5 minutes	30 minutes**	4–6 hours
Intravenous	0.5–1 mg/kg***	1.5 minute	3–5 minutes	5-10 minutes
Intramuscular	2–4 mg/kg	2–5 minutes	20 minutes	30 minutes**
Rectal	4–6 mg/kg	> 5 minutes	30 minutes**	30–120 minutes**
Nasal	5 mg/kg	10 minutes	20 minutes	1 hour

*Duration of action is prolonged if ketamine is administered with other sedatives/analgesics
**Dose-related
***Titrate to effect and repeat dose every 10 minutes if necessary, until desired level of sedation achieved

Dosing schedule of ketamine (Children) (SASA guidelines, 2010).

Route of administration	Dose	Onset of action	Time to peak effect	Duration of action
Sedation				
Oral	6-10 mg/kg	>5 minutes	30 minutes*	4-6 hours
Intravenous (bolus)	0.25-1 mg/kg**	<1 minute	3-5 minutes	10-15 minutes
Intravenous (infusion)	0.5-1 mg/kg/hr***	<1 minute	3-5 minutes	10-15 minutes
Intramuscular	2-4 mg/kg	2-5 minutes	20 minutes	30-120 minutes*
Rectal	4-6 mg/kg	>5 minutes	30 minutes*	30-120 minutes*
Analgesia				
Oral	4-6 mg/kg	>5 minutes	30 minutes*	4-6 hours
Intravenous	0.15-0.3 mg/kg/hr	<1 minute	3-5 minutes	15 minutes

* Dose-related

** Titrate to effect, repeating dose every three minutes until desired level of sedation achieved

*** Infusion following bolus dose of 0.25-1 mg/kg

Dosing schedule of fentanyl (Adult) (SASA guidelines, 2015).

Route of administration	Dose	Onset of action	Time to peak effect	Maximum dose	Duration of action
Oral/transmucosal	5-15µ/kg	15-30 minutes	30-45 minutes		1 hour*
Intravenous	0.25µ/kg**	3-6 minutes	2-3 minutes	2µ/kg	30 minutes*

* Dose-related
** Titrate to effect and repeat dose every 5 minutes, until desired level of analgesia is achieved

Single agent dosing schedule of fentanyl (children) (SASA guidelines, 2010).

Route of administration	Dose	Onset of action	Time to peak effect	Maximum dose	Duration of action
Oral/transmucosal	1-5µ/kg	15-30 minutes	30-45 minutes	5µ/kg	1 hour*
Intravenous	0.25µ/kg**	Immediate	3-8 minutes	2µ/kg	30 minutes*

When used in combination with other drugs, doses should be decreased and titrated to effect

* Dose-related

** Titrate to effect, repeating dose every 3 minutes until desired level of analgesia achieved or maximum dose reached

Appendix 10: Post Conscious Sedation Recovery Audit Questionnaire (At home).

POST CONSCIOUS SEDATION (CS) RECOVERY AUDIT QUESTIONNAIRE (AT HOME)

DATE:		**NAME:**		**DoB:**		**GENDE**	**M** / **F**

QUESTIONNAIRE DETAILS:			**STATE OF MIND ON DEPARTURE:**		
Explained to escort	Yes	No	Happy	Yes	No
Escort agrees to complete questionnaire	Yes	No	Indifferent	Yes	No
			Weeping	Yes	No
Signature of parent/guardian/escort:			Agitated	Yes	No

TIME OF DEPARTURE:		**MODE OF TRANSPORT HOME:**	
DURATION OF JOURNEY HOME:		**TIME OF ARRIVAL AT HOME:**	

DRUG SIDE-EFFECTS DURING JOURNEY:			**LEVEL OF SEDATION DURING JOURNEY**		
Nausea	Yes	No	Awake + orlentated	Yes	No
Vomiting	Yes	No	Drowsy	Yes	No
Headache	Yes	No	Sleeping but easy to rouse	Yes	No
Blurred vision	Yes	No	Sleeping but difficult to rouse	Yes	No
Restlessness	Yes	No			

STATE OF MIND:	**ON ARRIVAL**		**4 HOURS**		**8 HOURS**		**12 HOURS**		**24 HOURS**	
Happy	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
Indifferent	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
Weeping	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
Agitated	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No

LEVEL OF SEDATION	**ON ARRIVAL**		**4 HOURS**		**8 HOURS**		**12 HOURS**		**24 HOURS**	
Awake + orientated	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
Drowsy	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
Sleeping but easy to rouse	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
Sleeping but difficult to rouse	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No

DRUG SIDE - EFFECTS	**ON ARRIVAL**		**4 HOURS**		**8 HOURS**		**12 HOURS**		**24 HOURS**	
Nausea	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
Vomiting	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
Headache	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
Blurred vision	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
Restlessness	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No

MEMORY OF PROCEDURES	**ON ARRIVAL**		**4 HOURS**		**8 HOURS**		**12 HOURS**		**24 HOURS**	
Needle in arm or back of hand	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
Injection in the gum	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
Discomfort during treatment	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
Pain during treatment	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
Journey home	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No

SATISFACTORY RATING SCALE: **[POOR]** **1 2 3 4 5 6 7 8 9 10** **[EXCELLENT]**

WILL YOU OR YOUR CHILD CONSIDER HAVING CONSCIOUS SEDATION AGAIN IN FUTURE:

YES OR NO (WHY?) _____

PLEASE FAX TO: (021) 931 2287

ATTENTION: DR HA CARSTENS / PROF J ROELOFSE

Appendix 11. Post Conscious Sedation Questionnaire (At home).

POST CONSCIOUS SEDATION QUESTIONNAIRE

(Conscious Sedation = CS) Please tick applicable box/es

Although there are some 37 questions to be answered, the contents of this questionnaire is original, and will be of great benefit to health care professionals that administer Conscious Sedation. Your cooperation in this regard will be greatly appreciated.

1 What was the nature of your surgery

	1	Periodontal (gum) surgery
	2	Fillings, bridge work or crowns
	3	Implant surgery (any stage)
	4	Endodontics (root fillings)
	5	Extractions
	6	Sinus work or other oral surgery

2 Person performing the surgery

	1	Specialist
	2	General dentist

3 For how long was your operation scheduled

	1	1hr
	2	2hr
	3	3hr
	4	4hr

4 Why did you choose to have your procedure done under local anaesthetic with sedation

	1	Anxiety / previous bad experience
	2	Advised by dentist
	3	Given choice of this combination vs general anaesthetic
	4	Length of operation
	5	Had prevoius CS - was a pleasant experience - wanted CS again
	6	Other: Please state:

	yes=1	no=2
5 Did you feel comfortable with the idea of having a procedure done under CS?		
6 Did your dentist explain CS to you?		
7 Did the anaesthetist explain CS to you?		
8 Did you receive documentation from the anaesthetist's office beforehand		
9 With hind sight, do you feel that you were well prepared for the CS		
10 Anything more that you would have liked to know before the operation		

If you answered "yes" to the above question 10 - please give details:

	yes=1	no=2
11 Was this graph easy to understand?		
12 Did you find that this graph was useful in helping to understand the CS?		
13 Was this graph an accurate refelection of how you remember the CS ?		

14 Did you feel safe during the procedure?

If you answered "no" to the above question 14, please state the reasons/s below.

	yes=1	no=2
15 Have you before had dental treatment with the benefit of local anaesthetic only?		

16 The procedure, done under CS, proved to be:

1	Very bad
2	Bad
3	Average
4	Good
5	Excellent

	yes=1	no=2
17 Have you had a previous bad experience with work done with local anaesthetic?		

If "yes", how old were you , and give a few details about that experience:

18 During the conscious sedation, did you:	yes=1	no=2
Feel uncomfortable at all?		
Have any problems with breathing?		
Feel like choking?		
Experience any pain?		
Experience any other unpleasant sensations?		
(Please give datails)		

	yes=1	no=2
19 Did you feel cold at any stage during the procedure?		

20 The nature of CS allows for communication between the surgeon/anaesthetist and patient. Throughout the procedure the patient is frequently re-assured.

	yes=1	no=2
Can you remember any of this?		

21 If you can, what was the nature of this?	verbal =1	touch=2

	yes=1	no=2
22 Do you think that this made any difference to you?		
23 Were you happy with the level of monitoring?		

24 What do you remember feeling?	none=1	little=2	all=3
Anaesthetist's IV injection			
Dentist's local anaesthetic injection			
Subsequent/follow-up local anaesthetic injections by the dentist			
Operation itself			

25 Your procedure was performed outside a hospital setting.

Your anaesthetist was dressed in a shirt and tie/business suit.
Did you expect him to be dressed in theatre greens?

yes=1	no=2

26 What period of time elapsed between the conclusion of the surgery and leaving for home?

minutes

27 Immediately following your surgery, both the dentist and anaesthetist spoke to you. How much of that conversation do you think that you remembered?

1	nothing
2	a little
3	everything

yes=1	no=2

28 Would you have preferred to stay longer (to recover) before leaving for home?

29 How much of your journey home can you remember?

1	nothing
2	a little
3	everything

30 You arranged for someone to accompany you home.
For how long did this person stay?

31 Did you experience any of the following after you reached home?

	Yes= 1	No= 2	If yes, for how long? 0-30 min=3	30-60=4	60-90=5	90-100=6
Drowsiness						
Dizziness/unsteadiness						
Nausea/sick feeling						
Vomiting						
Headache						
Muscle aches/ stiffness						
Severe swelling at operation site						
Severe pain from dental operation						
Any other pain/discomfort						
Disturbance of sleep pattern						
Emotional fragility/felt "down"						
Other - please give details						

yes=1	no=2

32 Did you feel fit to return to your work on the following day?

If not - why?

33 How long did it take before you could perform your normal duties, or felt as if you could have done so?

1	< 6 hrs
2	6 - 12 hrs
3	12 - 24 hrs
4	> 24 hrs

34 If you had to have the same procedure again, what will your choice be:

	yes=1	no=2
local anaesthetic only		
local anaesthetic with conscious sedation		
general anaesthetic (performed in hospital)		

35 Please state why you will choose above option?

36 You received a bill from the anaesthetist for the CS. Do you feel that the amount charged was

1	modest
2	fair
3	too expensive
4	not applicable

yes=1	no=2

37 Do you feel that you can recommend conscious sedation to others?

Thank you for taking time out to complete this questionnaire

Please supply the following details:

Name:	
Age:	Telephone: