A Comparative study of Oral Ketamine and Oral Midzolam As in Paediatric Patients

By

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I, **Dr.Deepa Allolli** hereby declare that this dissertation entitled **"A Comparative study of Oral Ketamine and Oral Midzolam As in Paediatric Patients"** is a bonafide and genuine research work carried out by me under the guidance of **Dr. Vidya Patil** M.D Professor, Department of Anasthesiology, B.L.D.E.U's Shri B M Patil Medical College Hospital and Research Centre, Bijapur.

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INTRODUCTION

Premedication in children remains a controversial subject. The perfusion of scientific articles relating to premedication and the views expressed in these are testimony for the lack of any one obvious superior regime.

To undergo surgery is a traumatic experience for a child.

Almost all children hospitalized for anesthesia and surgery experience stress. This is due to fear of separation from loved ones, exposure to the strange hospital environment, fear of painful procedures, fear of operation itself or fear of anesthesia. Fear of separation is the main focus of anxiety in preschool age children, whilst older children may equally be worried about the prospect of painful procedures, surgery or anesthesia.

These can leave long lasting unpleasant memories to the child.

Many children are emotionally upset by their experiences in hospital and show bedwetting, nightmares, phobias, tantrums, hostility and rebellion. These problems can be diminished by psychological preparation; however premedication with pharmacological agents is mandatory in paediatric age group because psychological reassurance alone is not sufficient.

The aims of pre medications:

1. To produce sedation, allay anxiety and reduce emotional upset.
2. To prevent excessive secretion in the airway.
3. To block unwanted autonomic reflexes (vagal)
4. To facilitate induction of anesthetic, to supplement anesthesia and reduce the need for general anesthetic drugs.
5. To reduce the volume and acidity of gastric contents and prevent post operative nausea and vomiting.
6. To increase co-operation and permit easy separation from parents.

An ideal pre-medication and permit agent should fulfill the above aims, should be acceptable by the child, route of administration should be atraumatic, rapid and reliable onset of action, minimal side effects and rapid post operative recovery. The various routes of pre-medication include oral, I.V,I.M, rectal and nasal. I.V and I.M routes are associated with risk of fear for needles.

In rectal route, concerns about modesty and association with transient distress are more frequent in older children. Because of its poor tolerance, nasal pre-medication should be reserved for cases where there is no alternative. Thus, oral route remains an acceptable route amongst the available ones. Pre medication with oral ketamine is associated with less hallucinations compared to i.m or i.v because it undergoes high first pass metabolism.

Oral midazolam is considered to be effective as a premedicant without affecting the post operative recovery. Recent reports have indicated that oral pre-medication with ketamine/midazolam is an acceptable, atraumatic route of administration of pre-medication in children with rapid and reliable onset, minimal side effects and rapid post operative recovery.

AIMS AND OBJECTIVES

To compare the efficacy and safety of oral ketamine and oral midazolam as premedicant in paediatric patients aged 1 – 10yrs.

REVIEW OF LITERATURE

In pre-anesthetic days both wine and opium were given to mitigate the terrors of surgery.

The word pre-medication first appeared in print in an article by the American editor anesthetist Frank. H. Mc Mechan in 1920. However the technique of pre-medication was well established for some 40 or 50 years before.

In U.K. the technique of pre-medication was recommended by Dudley Buxton (1909) and Bellamy Gardner (1910). In the late 19^{th} and early 20^{th} century, atropine was used before Choloroform anaesthesia to prevent 'vagal inhibition', erroneously thought to be the cause of death during induction with Choloroform. Morphine had also been used sporadically to reduce the amount of Choloroform required.

In the early 20^{th} century, after ether replaced Choloroform as the predominant anaesthetic agent, preanaesthetic medication with an anticholinergic agent and an opiate rapidly gained general acceptance. The anticholinergic reduced secretions and the opiate was thought to reduce reflex irritability and metabolic rate, rendering the patient "more susceptible to anaesthesia".

Basal narcosis, the practice of rendering the patient unconscious before transfer to the operating room using drug such as paraldehyde or a barbiturate, became popular in the 1930's. The technique to reduce induction trauma and postoperative vomiting by minimizing the amount of ether used. However, the prolonged recovery was very demanding on nursing staff.

The introduction of thiopentone, tubocurarine and halothane in the 1940's and 1950's made smooth induction, light anaesthesia and rapid recovery possible. As side effects of anaesthesia were reduced, those of routine pre-medication with morphine

and atopine or papaverum and scopolamine were noticed. To minimize these pre-medication side effects, new drugs were developed. With the introduction of benzodiazepine in 1960s and modification of the original molecule, a completely new group of drugs with potential as premedicants, came into use.

In 1955 beecher wrote, "It is fair to say that pre-medication has two general purposes (a) To present an quiescent, well – rested, serene patient to the surgeon and (b) To minimize the hazards of anesthesia and surgery." As the cardiovascular and respiratory complications of anesthesia have been reduced, psychological preparation of the patient has gained relative importance.

Thus today, the main aim of pre-medication is to relieve fear and anxiety.

Presenting a calm and quiet patient for induction of anesthesia in the operating room is easy in adult but difficult in a child. It is even more difficult in a child needing repeated anesthesia or in the subnormal child .

The various sedative premedicants that have been and are being used today in pediatric age group include.

A. Up to 15 kgs.

: Trimeprazine elixir forte (vallergan) 4mg/kg 2hrs preop.

: Inj. Pethidine compound 0.06-0.08 ml/kg IM preop.

: Diazepam syrup 0.4 mg/kg orally 2hrs. preop.

B. More than 15kgs:

: Papavaretum – 0.4mg/kg IM 1hour preop.

: Hyoscine – 0.008 mg/kg IM 1hour preop.

C. Newer agents:

Midazolam : Pentobarbital

Ketamine : Methohexitone- IV and Rectal

Fentanyl : Chloral hydrate

Nasal sufentanyl.

Eckenhoff and Helrich (1958) showed that recovery from anesthesia was more prolonged where narcotics have been used and also increased incidence of nausea and vomiting in postoperative period. The opioids might cause respiratory depression in children and most of the time they have to be given in an injectable form.

A survey of preanaesthetic medication U.K.by Mirakhur et al (1978) found that 84% of U.K. anticholinergic used sedative premedication, 56%of them used anticholinergic drugs. Trimeprazine was the most frequently used premedication in children, atropine and hyoscine were the most commonly used anticholinergic drugs.

Thus in paediatric premedication mostly sedatives and hypnotics were used not considering analgesics. As all the commonly used paediatric premedicant drugs lack analgesic effects, wherever there is pre-operative pain, these premedicants are ineffective in producing analgesia and may also fail to induce sedation.

Ketamine a phencyclidine derivative with excellent analgesic property even in subanaesthetic doses was one of the choices. The first description of the clinical use of ketamine as an intravenous and intramuscular anesthetic agent was published in 1966 by ***Corssen*** and ***Domino.***

During the last 30 years, since it was introduced to clinical practice, ketamine has been used for a variety of clinical purposes one of which is preanaesthetic medication in children by intramuscular, rectal, intranasal and oral route.

Sadove and **Shulman** in 1971 experimented on the analgesic effects of ketamine administered in sub anaesthetic doses and found that when given intramuscularly in the dose of 0.44 mg/kg, it provides analgesia lasting for 90 minutes.

Holioster and **burns** (1974) showed that though ketamine appears to be a useful agent for dissociative anesthesia in young children, the intramuscular route is associated with a lower incidence of side effects than the intravenous route.

Grant is et al (1981) reported that following oral ketamine the peak concentration was achieved in around 20-30 minutes and bioavailability was 11-20%. They also found that with the oral dose the concentration of active metabolite norketamine is much higher than that with the intra muscular route.

Morgan and ***Dutkiewiez*** (1983) reported the successful use of ketamine orally in a 3year old girl with 4% partial thickness burns. After administration of 1mg/kg ketamine orally, profound analgesia occurred within 45 minutes with no loss of consciousness. This treatment was repeated successfully 1 hour before change of dressing thereafter[42].

Hain W.R. (1983), advocated that the induction of anesthesia with ketamine orally would require higher dosage. He reported a case of 4 year girl (12kg) with leukemia who required repeated brief anesthesia for procedures, being administered 12.5 mg/kg oral ketmine. By 25 mintes, the girl was reported to be stretching and crying out and had the appearance of a "waking dream". Hain, there by suggested that 'emergence phenomena' occur during induction following oral ketamine in a dosage likely to produce anaesthesia.

Brzustowicz et al (1984) studied the efficacy of oral ketamine pre-medication for paediatric surgery. They concluded that an oral premedicant can be used safely in an outpatient population to decrease perianaesthetic problems without prolongation of recovery time.

Hannalah and ***Patel*** (1989) sought to determine whether intramuscular ketamine would facilitate inhaled induction of anaesthesia in children who are unco-operative. They found low dose IM ketamine to be an acceptable pre-induction drug in young children who are uncooperative for an inhaled induction of anaesthesia.

Vander Bijl and ***Roelofse*** (1991) conquered the rectal route of ketamine administration and showed that good anxiolysis, sedation and cooperation were obtained in children between ages 2 and 9 years who were administered ketamine 5mg/kg rectally for dental extractions.

Rosenburg et al (1991) described a case utilizing the techniques of achieving deep sedation by administration of oral ketamine 6-8 mg/kg combined with oral glycopyrolate in an extremely mentally handicapped female requiring dental treatment.

Rowbottam et al (1991) studied oral ketamine 5mg/kg and 10mg/kg on 40 children and showed the advantages of analgesic and sedative effects but salivation, hypocarbia and dreaming were undesirable side effect on these patients.

Rosen D.A., and Rosen K (1991) used a palatable gelatin vehicle for midazolam and ketamine for oral sedation in children in intensive care units, operation theater and clinics.

Tobias JD., et al (1992) evaluated the efficacy of oral ketamine in alleviating procedure related distress in paediatric oncology patients. Oral ketamine 10 mg/kg administered to 35 children effectively alleviated procedure related distress in these patients.

Neckel W et al (1992) studied oral ketamine as pre-anaesthetic medication for unco-operative patients. They used oral ketamine 5-10mg/kg in water which has bio-availability of approximately 20% was a useful agent for the preinduction of patient who aggressively refused medical treatment.

Donahue and Dineen (1992) reported a severe emergence reaction associated with the use of oral ketamine premedication.

Gutstein HB., et al (1992) used oral ketamine as preanaesthetic medication in 45 children in a dose of 3mg/kg and 6mg/kg mixed with 0.2ml/kg of cola flavoured soft drink. They concluded that an oral dose of 6mg/kg Ketamine is easily administered and well accepted in young children and provides predictable. Satisfactory premedication without significant side effects[33].

Alfanzo Echeverri et al (1993) studied oral ketamine premedication for sedation in paediatric dental surgery out patients. They compared the sedative effectiveness of oral ketamine 6mg/kg and combination of oral meperidine 2mg/kg/promethazine 0.5 mg/kg in two groups of children. They concluded that the quality of sedation was higher in ketamine group and also vomiting was significantly more prevalent among those who received oral ketamine[30].

Lin and Moynihan (1993) compared oral midazolam, oral ketamine and a mixture of the two as preanaesthetic medication for paediatric out patients.

Weksler et al (1993) demonstrated that in a dose of 6mg/kg, nasal ketamine is an alternative to intramuscular preanaestheatic sedation administration in children aged from two to five years[28].

Alderson and Lerman (1994) have compared oral midazolam and oral ketamine for paediatric ambulatory anaesthesia and concluded that midazolam and ketamine offer similar clinical characteristics when used as oral premedicants for children undergoing ambulatory surgery.

Hoffman V et al (1994) treated successfully a patient with post herpetic neuralgia of ophthalmic nerve with subcutaneous and later oral ketamine after classical treatment had failed. They concluded that oral ketamine provides an alternative in the treatment of post herpetic neuralgia. The possible mechanism of action was by its N-methyl-D-Aspartate (NMDA) blocking properties.

Joshi Geetha and Dave C.R. (1994) compared oral ketamine as premedication in paediatric patients in a dose of 5mg/kg and 7mg/kg 45 minutes before surgery mixed with Rasana orange juice 0.2ml/kg to make it palatable. They concluded that ketamine orally in a does of 7mg/kg gives uniform sedation, acceptable induction of anaesthesia and acceptable postoperative period in children[23].

Roy S and Rudra A. (1994) studied oral ketamine as premedicant to find out the optimum dose and efficacy of the drug in pardiatric patients[25].

Qureshi FA et al (1995) conducted a clinical trail on efficacy of oral ketamine and concluded that oral ketamine in a dose of 10mg/kg provides effective sedation and analgesia to young children undergoing laceration wound repair[21].

Francks J.F. et al (1995) reported a case of phantom limb pain, which had not responded to long list of medical therapy or neuro-surgery. After oral ketamine treatment was instituted the patient became free of pain.

Seckerce C et al (1996), studied oral ketamine premedication in children with a dose of 3mg/kg or 6 mg/kg or placebo (cola – 0.2 ml/kg) and concluded that 3 mg/kg ketamine given by mouth to premedicate paediatric patient is as effective as 6 mg/kg but has a decreased incidence of side effects such as nystagmus and vomiting.

Reinemerr HC et al (1996), studied two oral ketamine – diazepam regimes 4 mg/kg and 8 mg/kg ketamine in conjuction with 0.1 mg/kg diazepam and concluded that the 4 mg/kg regimen resulted in more negative behavior and less sleep and the 8 mg/kg regime resulted in less negative behavior and more sleep[17].

Humphries Y et al (1997), Studied oral ketamine as an analgesic and sedative for wound care procedure in the paediatric patient with burns. They used ketamine oral suspension (elixir), compared with that of 300 mg acetaminophen with codein phosphate and diphenhydramine. Nikolajsen L et al(1997) treated a case of post

amputation stump pain treated with ketamine 50mg four times a day dissolved in juice. No side effects or development or tolerance were observed during a 3 month period and concluded that NMDA receptor antagonists may have a potential in the treatment of neuropathic pain, including stump pain.

Eide PK and Stubhaug A. (1997) reported the relief of glossopharyngeal neuralgia pain in case of a 56 year old woman. The pain had lasted for seven years, was localized to the posterior pharynx, tonsillar region and base of the tongue with radiation to the left deep ear structures. Pain was provoked by swallowing. Oral ketamine 60mg, six times a day caused marked pain relief. Pain caused by swallowing was also reduced. Pain relief was associated with some side effects however the treatment was well tolerated by the patient. They concluded that ketamine induced NMDA receptor blockade significantly relieved glossopharyngeal neuralgia[16].

Diaz JH – (1997) Studied intranasal ketamine pre-induction of paediatric out patients. Intranasal ketamine 3mg/kg diluted to 2ml with saline was administered 1 ml per naris, was associated with pleasant and rapid separation of children from their parents, co-operative acceptance of monitoring and of mask inhalation induction and did not cause prolonged post anaesthetic recovery or delayed discharge[14].

K. Balakrishnan ID Panchal and team (1998) studied the efficacy and tolerability of midazolam and diazepam used as preoperative medicants were compared in an open, randomized study of 613 adult patients in ASA class I and II undergoing surgery under general anaesthesia. Midazolam (n=307) was administered by intramuscular injection at a dose of 70 mcg kg-1 body weight one hour before surgery and diazepam (n=306) was administered orally at a dose of 10mg one a half hour before surgery. The degree of anxiety was self assessed by patients on a Visual Analogue Scale and the quality of sedation was rated by the investigator on an ordinal scale; amnesia for

pre-surgical events was assessed by a recall questionnaire. Midazolam produced rapid anxiolytic and sedative effects detectable 15 min post dose. Midazolam produced better sedative anxiolytic and anterograde amnesic effects compared to diazepam. Both drugs were well tolerated in terms of cardiovascular and respiratory parameters.

Beebe DS, Belanki KG, Chang PN et al did a randomized study of 100 children of ASA I & II in four groups with (n=25) in each group. They studied the effectiveness of three types of rectal sedation with midazolam, ketamine or their combination for preoperative sedation. They concluded that rectal route of administration may cause transient distress, but can be useful for co-operative separation of children from their parents and for iv catheter placement prior to induction of general anaesthesia[32].

Funk W, Jakob W, Riedle T and Taeger K.(2000) did a prospective, randomized, double blind study of 120 children of ASA I&II of aged between 2-10 years undergoing surgery of more than 30min.They studied whether addition of low dose of oral ketamine (3mg/kg) to midazlam (0.5mg/kg) was effective compared to oral midazolam 0.5mg/kg or oral ketamine 6mg/kg alone. It was concluded thet significantly better anxiolysis and separation were observed with a combination of ketamine and midazolam[10].

Lt Col Navdeep Sethi, Sqn Ldr LK Dash, Col TP Madhusudanan. (2001) In a prospective, double blind study on 60children (aged between 1-7 years, ASA I&II) Studied the efficacy and safety of two oral premedicants midazolam and ketamine in children, in three separate groups that received either 0.5 mg/kg oral midazolam or 6 mg/kg oral ketamine or a placebo in 5ml of 25% dextrose solution. They found that both drugs were more effective in sedation the children within 30 mins in comparison to a placebo and concluded midazolam is a safe and more efficacious oral premedicant in children with shorter recovery time as compared to ketamine.

Dr. Suranjit Debnath and Dr. Yash Pande (2003) in their randomize control study of 60 children of ASA I&II, aged between 1-10 years, undergoing minor surgery, with 2 groups, n=30 each, compared the efficacy of oral ketamine (6 mg/kg) and oral midazolam (0.5 mg/kg) as premedicants. Their results showed that oral ketamine provides better sedation and anxiolysis with minimal side effects than oral midazolam, both drugs were accepted well by the children[6].

Several clinical trials continue to be conducted on the efficacy of oral ketamine and oral midazolam as premedication in children in various parts of the world today.

All these trials have one goal in common; to find out an ideal premedicant in children.

ROUTES OF DRUG ADMINISTRATION:

Drugs may be given by various routes depending upon:

- Physical and chemical properties of the drug.
- Desired site of action.
- General state of the patient.
- Drug volume and dosage interval.
- Rapidity of response required.
- Other drugs given concomitantly.
- Convenience.

A) Parenteral routes (Intramuscular and Intravenous): These routes are commonly used for premedication in adults. However, these routes cause injection pain and children dislike injections. Very often children remember the premedication needle prick more than surgery. Slight error in dosage by injection can lead to serious consequences in children.

A Danish child who was interviewed by Jacob appeared to be exceptionally afraid of needles. It transported that he believed his skin was a large sac keeping his blood contained and he was convinced that when his skin was punctured, his blood would leak out and he would die. This indicates the misbelieve and fear of needles in children.

B) Oral Route: This route is easy and acceptable by most of the children, provided the taste of the drug is satisfactory. This route is widely used to be absorbed from gastrointestinal tract into the portal system and then pass through the liver before entering the general circulation.

Absorption:

The absorption of the drug from gastrointestinal tract is governed by factors such as surface area of the absorption, physical state of the drug, drug concentration at the site of the absorption. Since most of the drugs are absorbed passively, absorption is favoured when the drug is in the non-ionised and more lipophilic form. Weak acidic drugs are better absorbed in the stomach, and basic drugs are better absorbed in the intestine. Any factor that accelerates gastric emptying will be likely to increase the rate of drug absorption while any factor, that delays gastric emptying will decrease the rate of drug absorption.

First pass metabolism:

This is one more limiting factor in achieving bioavailability of an orally administered drug. The liver can either metabolize this drug into inactive metabolites or can excrete the drug unchanged into the intestine through the biliary system. Both these will limit the bio availability of the drug.

Advantages of oral route of drug administration:

- Convenience of administration.
- Better acceptance.
- Economical.
- More safe.

But oral route requires patient co-operation.

C) Rectal Route: This route is used for drug administration in young children. Drugs like Ketamine, Midazolam, Chloral hydrate are administered by this route. As 50% of the drug bypasses liver, the bio availability is higher.

Disadvantages:

- Absorption is irregular and incomplete.
- Drugs can cause irritation to rectal mucosa.
- Children, more so, older children consider rectum as a most private part and do not like per rectal administration.

D) Intra nasal route: Drugs like Ketamine, Midazolam, have been effectively administered through this route. Drugs will be absorbed across nasal mucosa into the systemic circulation and thus they will not undergo first pass metabolism.

Limitations are:

- Only few drugs are absorbed through this route.
- Large volume of drugs cannot be given.
- Drugs can cause irritation to nasal mucosa.
- Children may not be as co-operative to intranasal as they would be to oral administration.

DRUGS AVAILABLE BY ORAL ROUTE AND THEIR DOSAGES FOR PREMEDICATION:

1. Benzodiazepines:

Diazepam	: 0.1 to 0.2 mg/kg (low dose)
	: 0.5 mg/kg (high dose)
Midazolam	: 0.5 to 1.0 mg/kg
Temezepam	: 1.0 mg/kg
Triazolam	: 0.02 mg/kg

2. Opioids:

Morphine	: 0.1 to 0.4 mg/kg
Triatromorprph	: Morphine + Trimeprazine + Atropine

3. Barbiturates:

Pentobarbitone	: 2 to 4 mg/kg

4. Trimeprazine : 2 to 4 mg/kg

5. Triclofos : 70 to 75 mg/kg

6. Ketamine : 3 to 10 mg/kg

Benzodiazepines: Produce excellent amnesia, unpredictable hypnosis and no analgesia.

Opioids: Produce excellent analgesia no amnesia and poor hypnosis.

Barbiturates: Produce excellent hypnosis, poor amnesia and no analgesia.

Triclofos: Produces good anxiolysis, antisialagogue effect but does not produce analgesia, amnesia and anaesthesia.

Ketamine: Produce excellent analgesia good hypnosis and amnesia but produce hallucinations.

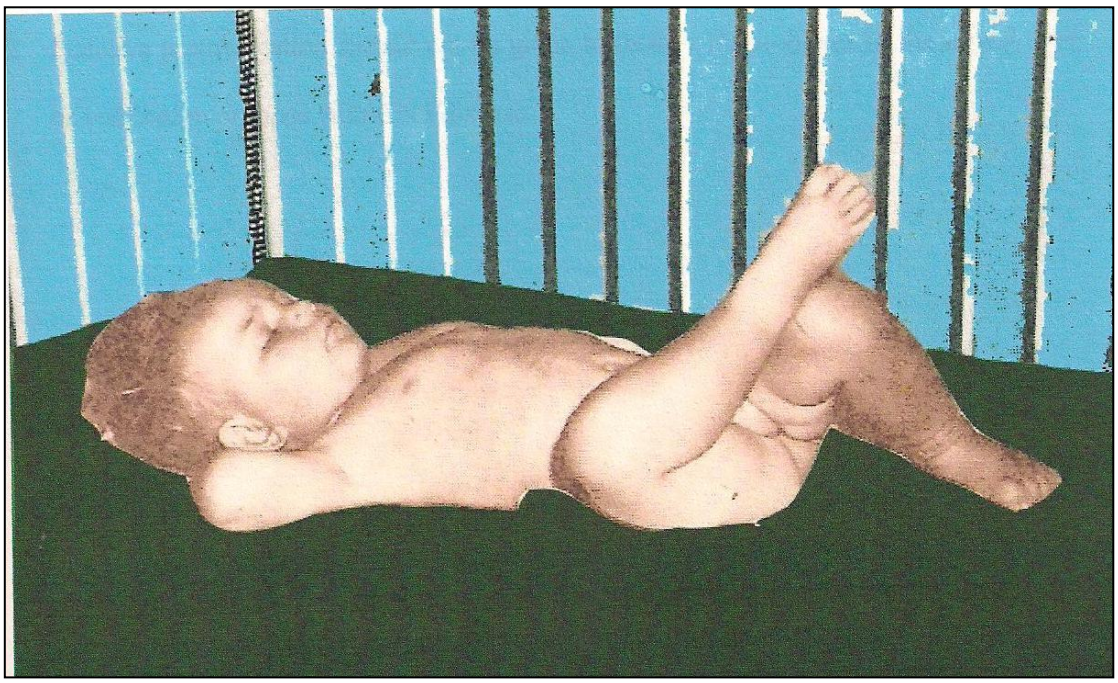


Figure 1. SEDATION WITHOUT DEPRESSION

PHARMACOLOGY OF KETAMINE

Ketamine in a phencyclidine derivative, the only presently available hypnotic agent that also possess analgesic properties and produces “dissociative anaesthesia”, a peculiar state of unconsciousness in which the patient is in a cataleptic state “disconnected” from the surroundings and about to undergo surgery in comfort and without recall.

Chemistry and Physical properties.

Ketamine with a molecular weight of 238 and pKa of 7.5 is a white crystalline salt and soluble in water upto20%. The solution is clear, colourless and stable at room temperature. It forms aqueous solution of Ph 3.5 – 5.5. It is highly lipid soluble. It is supplied as 1%, 5% and 10% solutions for administration either intravenously or intramuscularly.

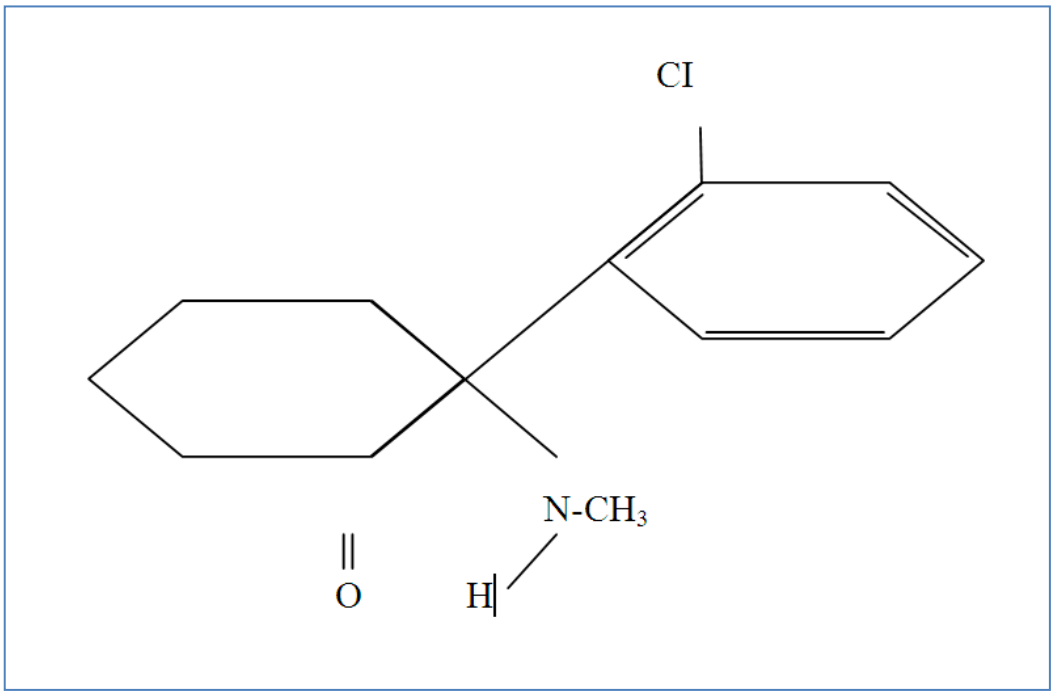


Fig.2 : Ketamine Structure

Pharmacokinetics

Fig 3: Ketamine ampoule

Uptake and distribution:

Peak plasma levels of ketamine are reached immediately after I.V. administration and within 5min of IM injection. Because of its high lipid solubility, ketamine as with thiopentone, initially floods into brain and other highly perfused organs, being distributed more slowly to less well perfused tissues. Redistribution of ketamine from the brain and other vital organs to improve poorly vascularised tissues, as with thiopentone is undoubtedly the key factor in termination of its CNS depression.

Biotransformation:

Ketamine is extensively metabolized by hepatic microsomal enzymes, ketamine is demethylated to Norketamine, hydroxyketmine compounds which are then excreted as glucuronide derivative. Norketamine also has hypnotic and analgesic properties and approximately 1/3 the potency of the parent drug ketamine.

Pharmacodynamics:

Central nervous system:

Ketamine binds non-competitively to the phencyclidine recognition site on N-methy D-aspartate (NMDA) receptors, In addition, ketamine may exert effects at other sites including opioid receptors, monoaminergic, muscarinic receptors and voltage sensitive sodium and L-type calcium channels.

Ketamine produces a state known as dissociative anaesthesia. It increases cerebral oxygen consumption, cerebral blood flow and intracranial pressure. These effects preclude its use in patients with space occupying intracranial lesions. Undesirable psychotomimetic side effects (eg. Illusions, disturbing dreams and delirium) during emergence and recovery are less common in children and in patients premedicated with benzodiazepines.

Cardiovascular system:

In sharp contrast to other anaesthetic agents ketamine increases arterial blood pressure, heart rate and cardiac output. These indirect cardiovascular effects are due to central stimulation of sympathetic system. Accompanying these changes, are increases in pulmonary pressure and myocardial work. For these reasons, it is avoided in patients with coronary artery disease, uncontrolled hypertension, congestive heart failure, and arterial aneurysms. Nonetheless ketamine's indirect stimulatory effects are often beneficial to patients with acute hypovolemic shock.

Respiratory System:

Ventilatory device is minimally affected by the customary induction doses of ketamine, though rapid intravenous bolus administration or pretreatment with opioids occasionally produces apnoea. Ketamine is a potent bronchodilator, making it a good

induction agent for asthmatic patients. Although upper airways reflexes remain largely intact, patients at increased risk of aspiration should be intubated. The increased salivation associated with ketamine can be attenuated by premedication with an anticholinergic agent.

Clinical uses:

Premedication:

Oral ketamine has been used ranging from 6 mg/kg to 10 mg/kg as premedication in children.

Other routes: Intramuscular/ intravenous routes/ per rectal/ intranasal.

Analgesia:

Intense analgesia can be produced with subanesthetic doses of ketamine, 0.2 to 0.5 mg/kg IV. The analgesic effects of ketamine are primarily due to its activity in the thalamic and limbic systems which are responsible for the interpretation of painful signals.

Induction of anaesthesia:

Induction of anaesthesia is produced by administration of ketamine. 1 to2 mg/kg I.V. or 4 to 8 mg/kg IM.

Co-induction:

Small dose of ketamine can be used as co-induction agent to propofol.

Neuraxial analgesia:

The efficacy of epidural ketamine is controversial. Intrathecal administration of ketamine (5 to 50mg in normal saline) produces variable and brief analgesia, unless the ketamine is also combined with epinephrine to slow systemic absorption.

Pharmacology of Midazolam

Midazolam is an imidazobenzodiazepine derivative with an imidazole ring in its structure that accounts for its stability in aqueous solutions and rapid metabolism.

Chemistry and Physical properties.

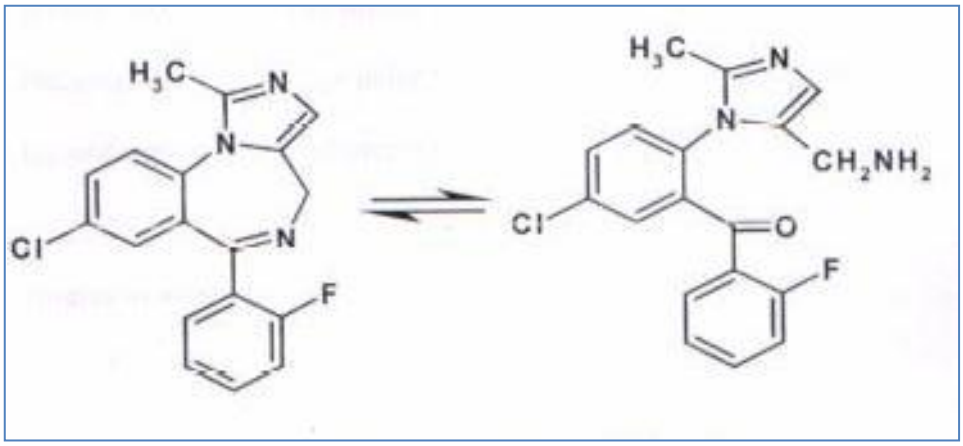


Fig 4: Structure of Midazolam

Midazolam belongs to the benzodiazepine group but unlike most drugs of this group it is water soluble. This is because, its formula includes a ring which opens at pH values below 4.0, imparting water solubility. At the pH of plasma the ring closes and lipid solubility is enhanced.

Pharmacikinetics

Midazolam is highly protein bound (approximately 95percent), though not as highly bound as diazepam. The practical implication of this is that patients with a low plasma albumin from any cause will have an enhanced response to it. The drug follows the usual distribution pattern to vessel-rich tissues and later to the poorly perfused fat. Elimination is then dependent on hepatic biotransformation, which

converts it into 4-hydrixymidazolam, a metabolite almost devoid of pharmacological activity. The initial redistribution is shorter than with diazepam, contribution to the more rapid recovery from the newer drug. The elimination phase ($t_{1/2\beta}$ = 2-3 hours) is also more rapid than with diazepam, though slower than thiopentone or propofol. Eliminating is prolonged in elderly patients and following any major surgery ($t_{1/2\beta}$ = approximately 5 hours), the latter presumably by interfering with liver blood flow. Placental transmission, as judged by the fetal/maternal plasma ratio in animals, is less for midazolam than for diazepam.

Routes of administration and dose

1. Intramuscular – 0.07 – 0.08 mg/kg for sedation.
2. Intravenous – 0.05 - 0.1 mg/kg for sedation.

   When given for conscious sedation, the dose must be titrated. Additional dosages to maintain the desired level of sedation may be given in increments of 25% of initial bolus dose. 0.1 – 0.2 mg/kg for intravenous induction.
3. Oral – 0.5 – 0.75 mg/kg
4. Rectal – 0.75 - 1 mg/kg

   Intranasal – 0.2 mg/kg

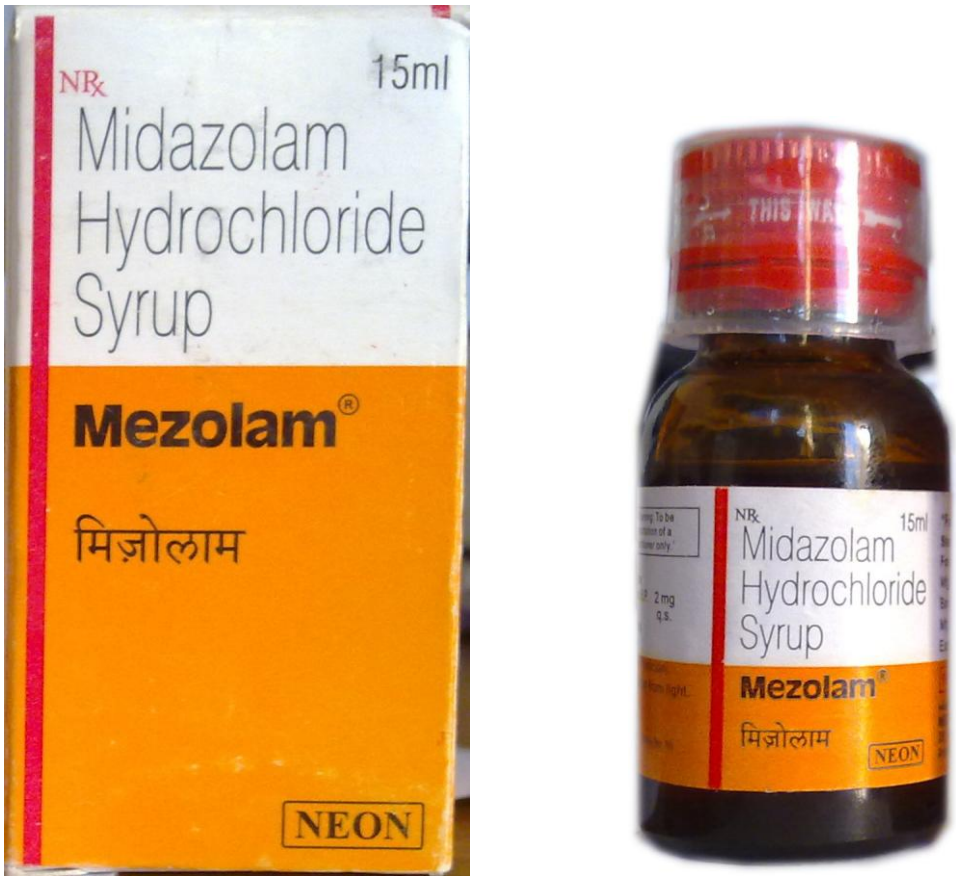


Figure 5: Midazolam Syrup.

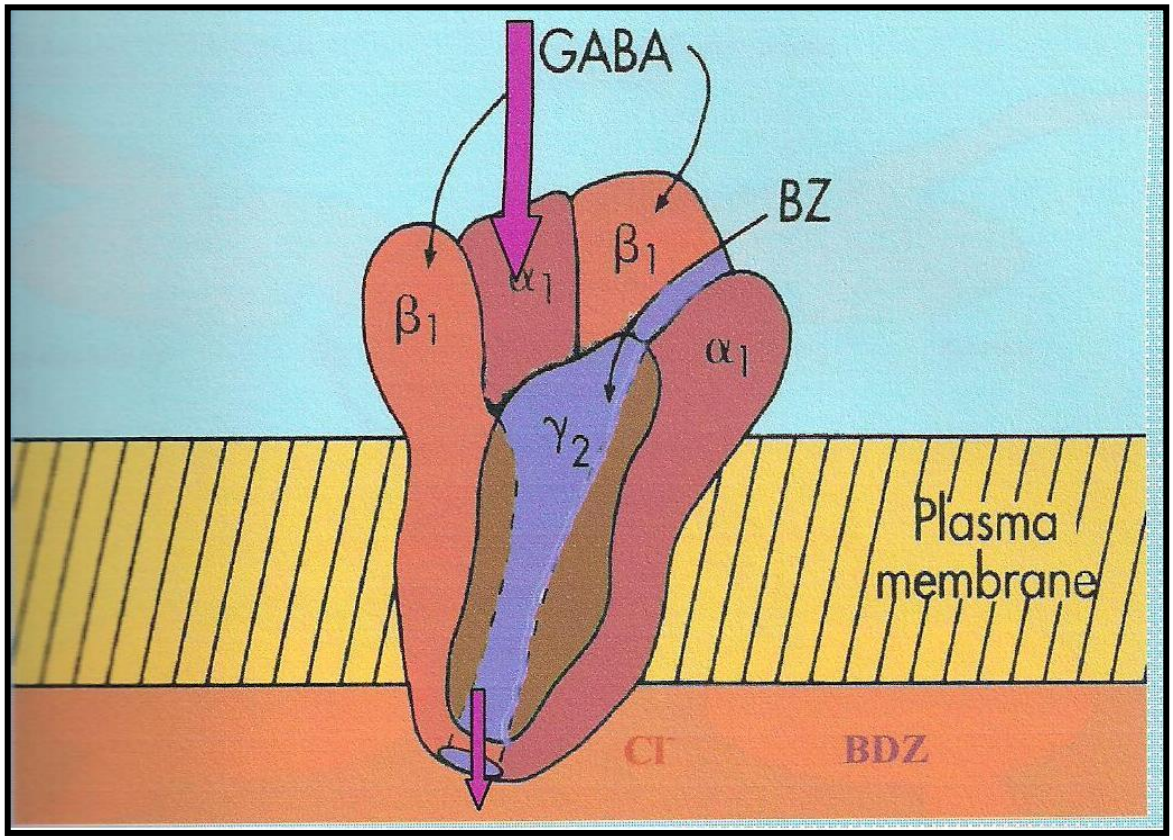


Figure 6: The GABA $_A$ Receptor-Chloride ion channel complex.

Mechanism of action of benzodiazepines: This ion channel is GABA gated. Binding of GABA causes increase in chloride current across the membrane leading to hyperpolarization. Benzodiazepines bind to γ2 subunit of the receptor away from the GABA binding sites of β1 subunits. But they result in sustained binding of GABA, causing prolonged chloride current. Barbiturates are also shown to bind to these receptors.

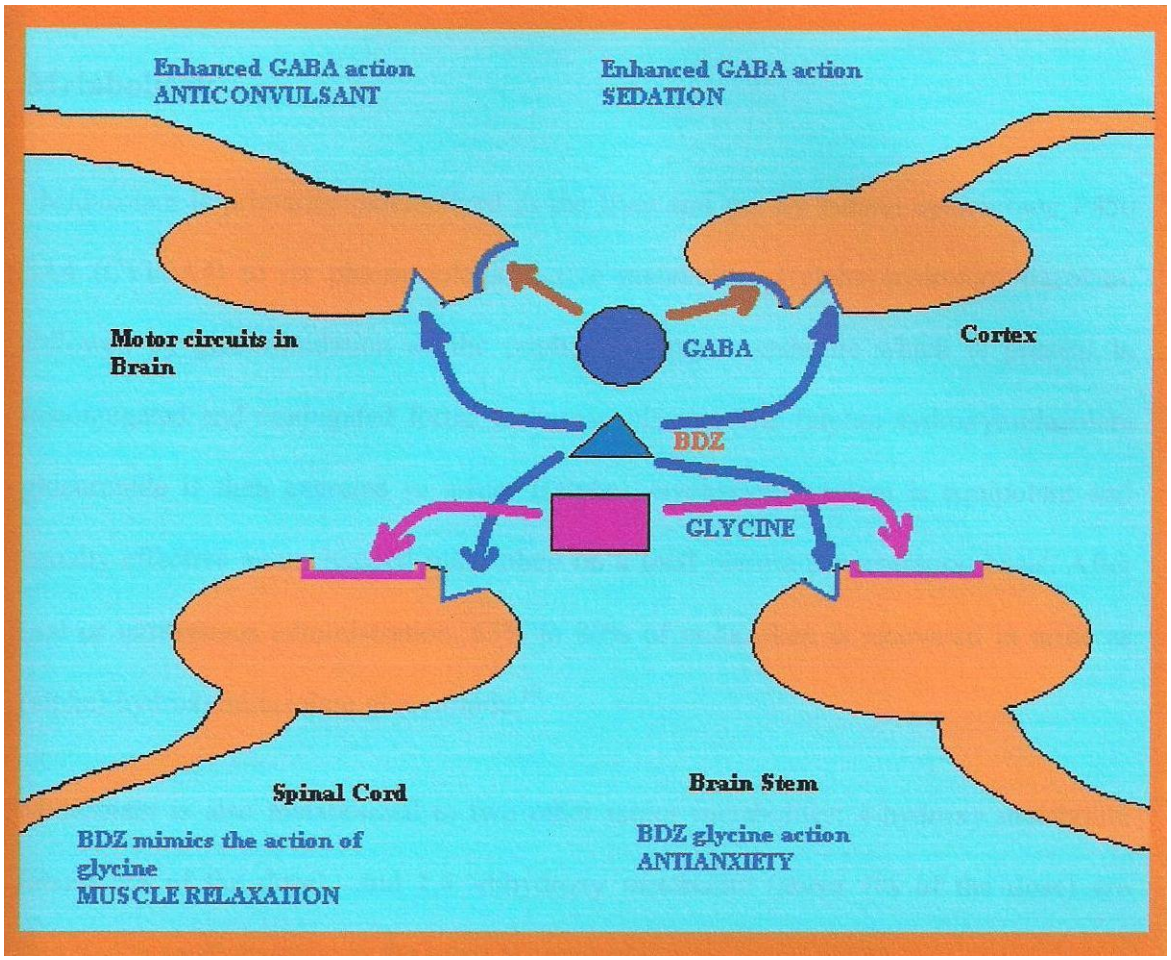


Figure 7: Various sites of action of midazolam. BDZ-benzodiazepine (midazolam), GABA – γ – amino butyric acid.

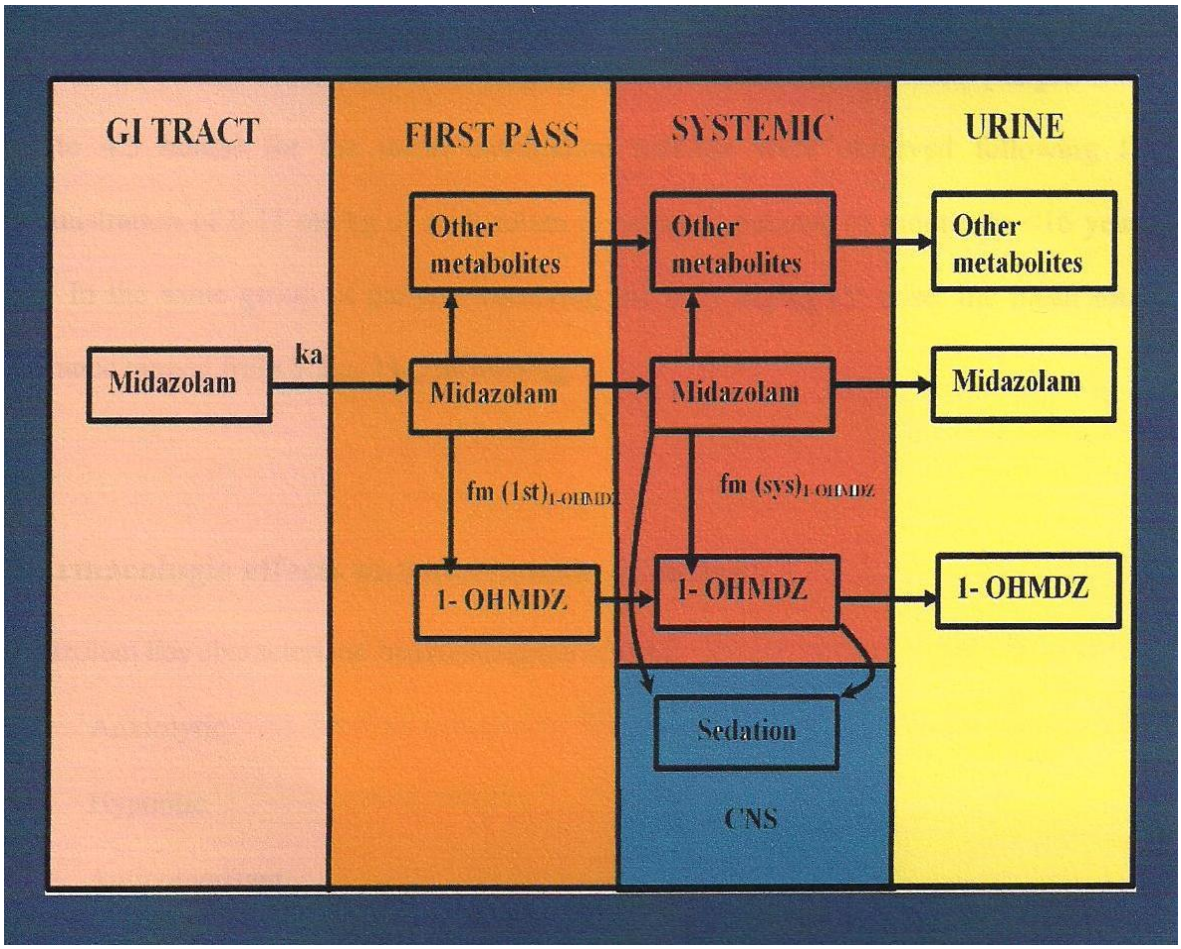


Figure 8: Pharmacodynamic and pharmacokinetic model of midazolam

PHARMACODYNAMICS

Central nervous system

Benzodiazepines act on specific benzodiazepine receptors which are concentrated in the cerebral cortex, hippocampus and cerebellum. Their action is produced by potentiation of specific depressant interneurous which use gamma aminobutyric acid (GABA) as a transmitter. The release of GABA opens the C1 channel, resulting in hyperpolarization of the nerve cell. The specific benzodiazepine antagonist, flumazenil, acts by competitive inhibition of these benzodiazepine receptors, thereby blocking the action of midazolam.

The onset of action is slow and the onset of the sleep takes 2-5 minutes but with wide interpatient variation. Similarly the dose required to induce sleep ranges widely around 0.3mg/kg. However, lower doses (0.05 – 0.1mg/kg) will produce drowsiness and amnesia, which is often all that is required in the clinical situation. Amnesia which is an effect common to all benzodiazepines can be undesirable but in dental practice, for instance, may be a valuable adjunct to therapy. Other CNS effects for which midazolam may be required include an anticonvulsant action (e.g. in status epilepticus) and an antihallucinatory action (e.g. after ketamine or in delirium tremens).

CARDIOVASCULAR SYSTEM

Even in large doses the benzodiazepines have little depressant effect on the heart or circulation. Midazolam causes a fall in systemic vascular resistance rather than the rise as seen with thiopentone, thus reducing pre and after load. While this effect may benefit the patient with a failing heart, it does introduce hazards in hypovolaemic patients. Because of the slow onset of action, any cardiovascular depression with the benzodiazepines is often underestimated, though in clinical

practice, if used in a full general anaesthetic technique, tracheal intubation may counter balance any cardiovascular depression.

RESPIRATORY SYSTEM

Intravenous injection of the benzodiazepines in general can cause respiratory depression and loss of sensitivity to carbon dioxide. Both actions are accentuated by the concomitant use of opioids. These effects in turn are more marked in patients with chronic obstructive airway disease. The use of intravenous benzodiazepines by those not skilled in airway management can lead to unrecognized respiratory obstruction. It is, therefore, highly dangerous to assume that sedation with midazolam is a safe alternative to anaesthesia, permitting the presence of an anaesthetist to be dispensed with.

Local effects

Midazolam, as an aqueous solution, has no irritant effects following intravenous injection.

Clinical uses:

1. Premedication in children and adults.
2. Co-induction agent.
3. Induction of anaesthesia and maintenance.
4. As an adjunct to local anaesthetics.
5. As an antoconvulsant.
6. Treatment of insomnia.
7. As anxiolytic agent.
8. Management of alcohol withdrawal symptoms.
9. As centrally acting muscle relaxant.
10. As an anjunct to ketamine anaesthesia.
11. Sedative for radiological procedures, cardioversion and cardiac catheterization.

MATERIAL AND METHODS

Source and data

This study will be carried out in the department of Anesthesiology, BLDE University Shri B. M. Patil Medical Collage, Hospital & Research Centre, Bijapur from Nov 2009-June2011

METHODS OF COLLECTION OF DATA:

Time bound study. This study will be done during a period of 18 months. All patient in the age group of 1-10 years with inclusion criteria posted for elective surgeries will be included in the study.

Sample Size:

A minimum number of 60 patients, 30 patients in Group I and 30 patients Group II will be allocated by simple random sampling (lottery method).

Inclusion Criteria

Patients of ASA grade I in the age group of 1-10 years undergoing elective surgeries of both sexes will be included.

Exclusion Criteria:

- ✓ Patients of ASA grade II, III, IV and V.
- ✓ Patients with upper respiratory tract infection.
    - Lower respiratory tract infection.
- ✓ History of allergy to any of the study drugs.
- ✓ Any child who did not receive partly or fully the calculated dose of the study drug.
- ✓ Children who are already on other sedative drugs, antiepileptics and anticoagulants.
- ✓ Emergency cases.

Statistical analysis:

At the end of the study all the data will be compiled and analyzed statistically using.

1) Diagrammatic representation

2) Mean $\pm$ SD

3) t or z test

Research Hypothesis

Oral ketamine is an excellent and efficient premedication for pediatric patient undergoing elective surgeries compared to oral midazolam.

PREANAESTHETIC EVALUATION:

During preoperative visit patients detailed history is taken. General physical examinations and systemic examination will be carried out. Basic demographic characters like ages, sex and weight will be recorded.

Investigation like haemoglobin, total count, differential count, ESR, bleeding time, clotting time and complete urine examinations will be carried out. Written information consent will be taken from the patient's guardians/ parents.

PROCEDURE:

Parents are allowed to stay with the child in the preoperative room, where the study drugs are administered. 30 minutes prior to surgery.

Group I patients will receive parenteral formulation of ketamine (50mg/ml) in a dose of 6mg/kg and Group II patients will receive parenteral formulation of midazolam (1mg/ml vial) in a dose of 0.5mg/kg, orally after mixing with equal volume of sugar crystal or dextrose.

Thereafter the child will be constantly observed to see changes in the mood, behavior and appearance.

OBSERVATION AND RESULTS:

After giving oral ketamine or oral midazolam following variable will be compared and assessed.

- ✓ The degree of sedation and anxiolysis.
- ✓ The ease of parents-child separation.
- ✓ The behavior of the child at induction.
- ✓ The reaction of the child to intravenous cannulation.
- ✓ To study the adverse effects if any.

Observations before Premedication

Table 1. Demographic data Showing age, weight and sex distribution

Variable	Group A (n=30)	Group B (n=30)
Age (Yrs) Mean (SD)	6.53 (1.94)	6.08 (2.41)
Sex (M/F)	15/15	14/16
Weight (Yrs) Mean (SD)	17.07 (4.29)	16.04 (5.71)

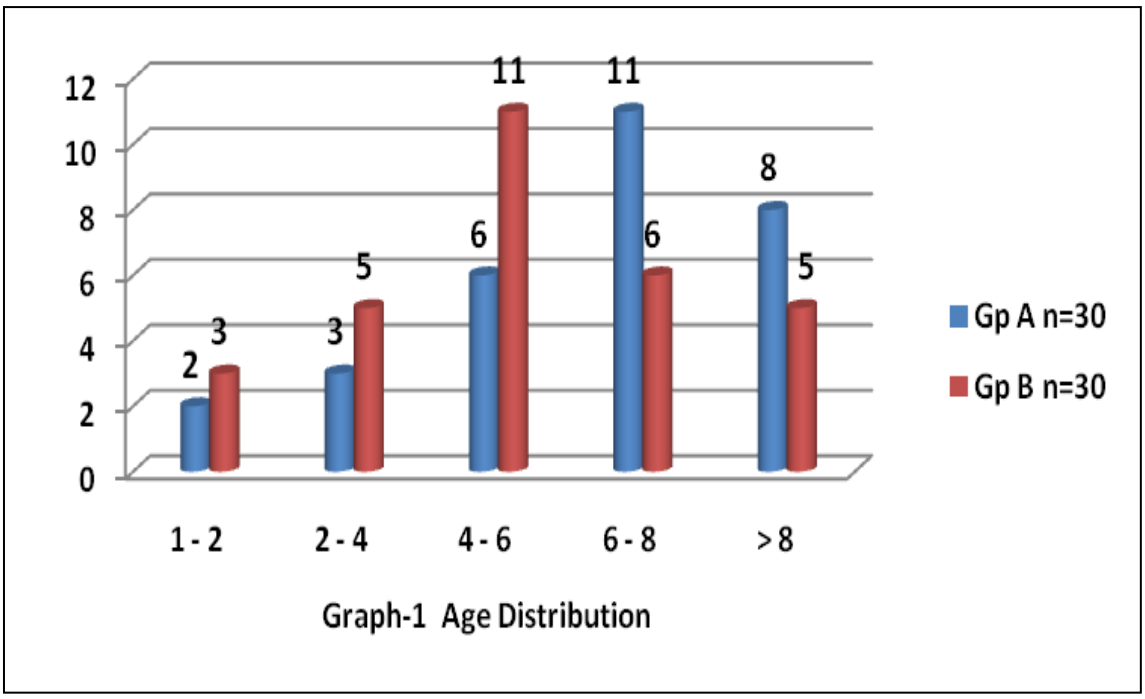
N ≥ number of patients; values are expressed as mean (SD)

The above table reveals the patients demographic date. Two groups were similar in respect of age, sex, weight, ASA physical status. There were no significant differences in the demographic data between the two groups ($p>0.05$), on applying student 't' test.

Table 2: Age wise Distribution

Age in Years	Gp A n=30	Gp B n=30
1 – 2	2	3
2 – 4	3	5
4 – 6	6	11
6 – 8	11	6
> 8	8	5

The age wise distribution of patients in both Gp A and Gp B are shown in the table. The distribution of patients according to age in both groups was not statistically significant (p value is 0.05).

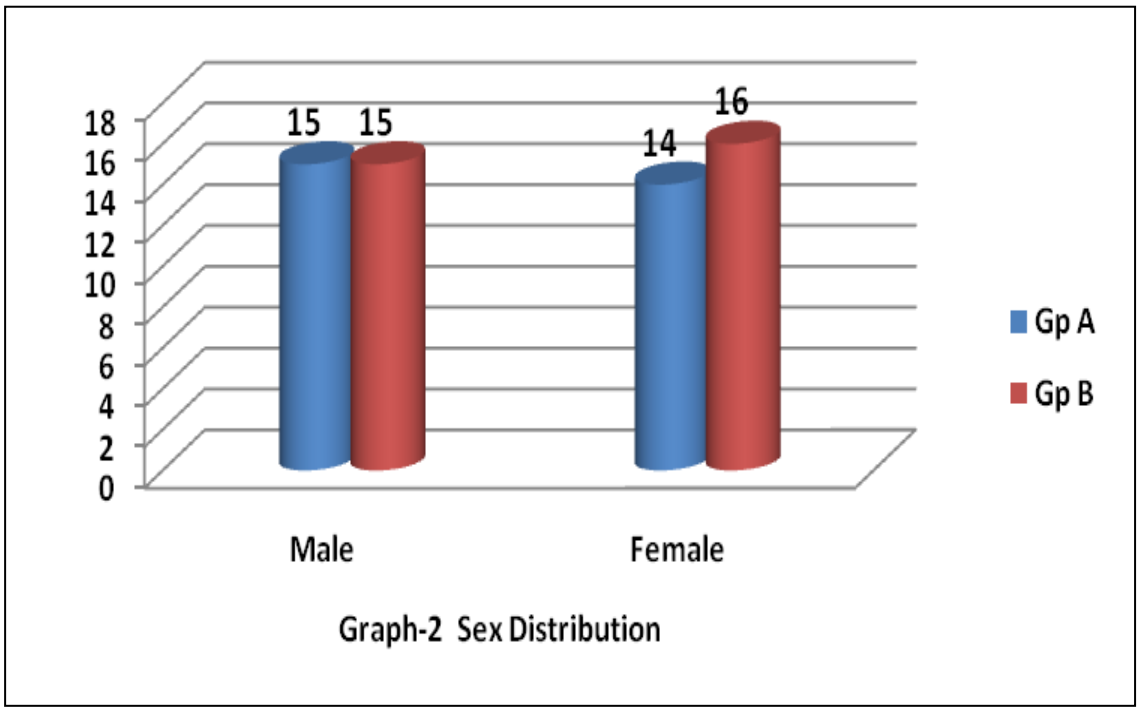


Graph-1 Age Distribution

Table No 3. Sex wise Distribution

Group	Male	Female
A	15	15
B	14	16

The sex wise distribution of patients in both groups A and B are shown. In Gp A there are 15 male and 15 female patients in Gp B 14 male and 16 female. There was no statistically difference between the groups in sex wise distribution.

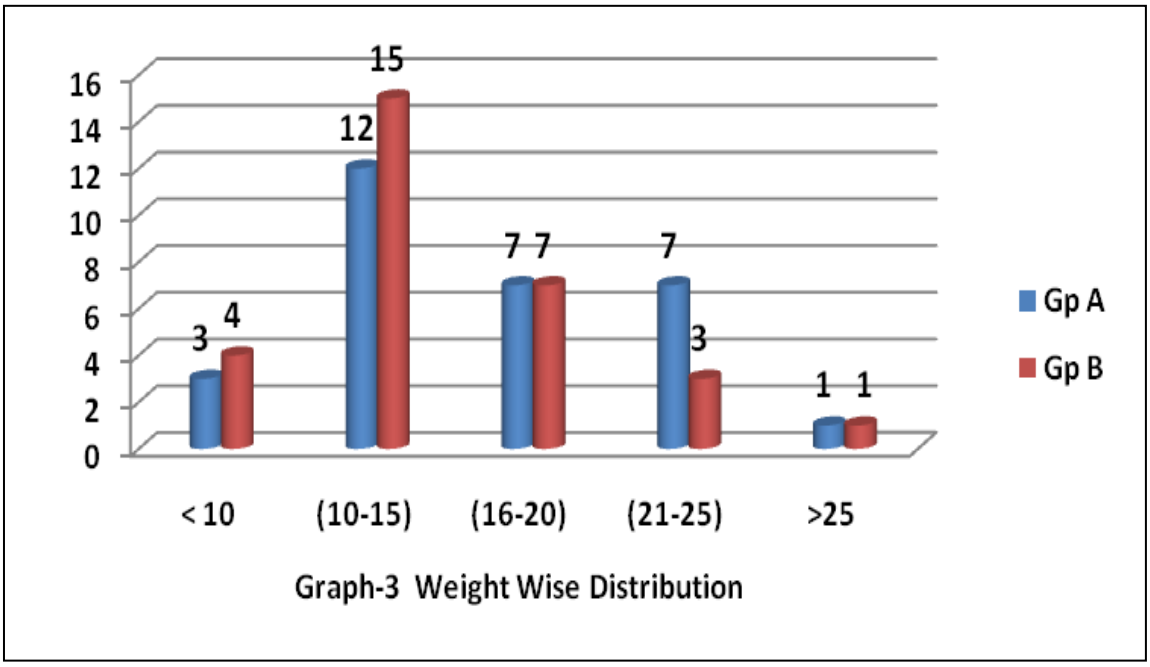


Graph-2 Sex Distribution

Table 4: Weight Distribution

Weight (Kg)	Gp A	Gp B
< 10	3	4
10 – 15	12	15
16 – 20	7	7
21 – 25	7	3
> 25	1	1

The above table shows weight distribution among both groups.



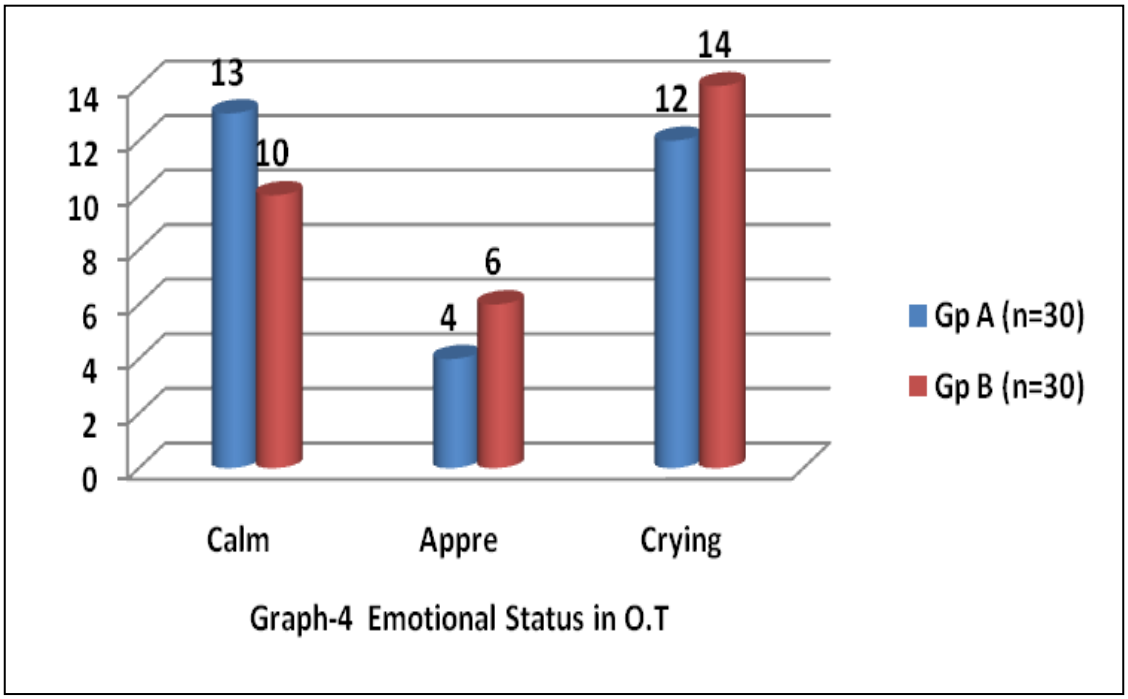
Graph-3 Weight Wise Distribution

Table 5: Showing emotional status of patients before premedication

Emotional Status	Gp A (n=30)	Gp B (n=30)
Calm	13	10
Apprehensive	04	06
Crying	12	14

The above table shows calm (68%) and apprehensive (32%) in group A and calm (84%) and apprehensive (16%) in group B.

The above table shows p value of 0.3205 by chi-square test which is statistically not significant.



Graph-4 Emotional Status in O.T

Table 6: Showing pulse rate before Premedication.

Pulse rate / min	Gp A (n=30)	Gp B (n=30)
Mean	91.5769	99.1200
SD	187.150	9.6104

In this study the p value by students unpaired 't' test was 0.1020 which is statistically not significant. Hence both groups are comparable.

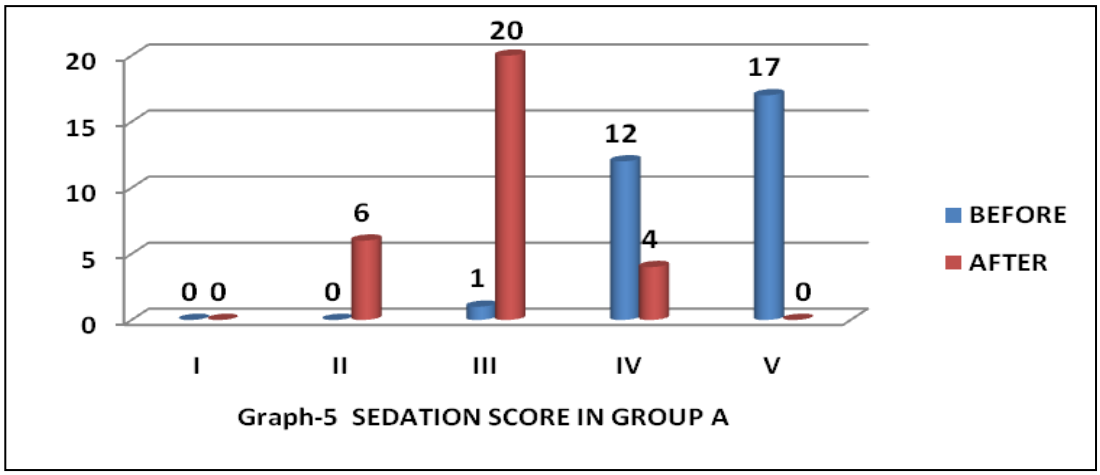
Table 7: Showing onset of sedation after Premedication.

Onset of sedation in mins	Gp A (n=30)	Gp B (n=30)
Mean	17.19	16.24
SD	3.52	2.22

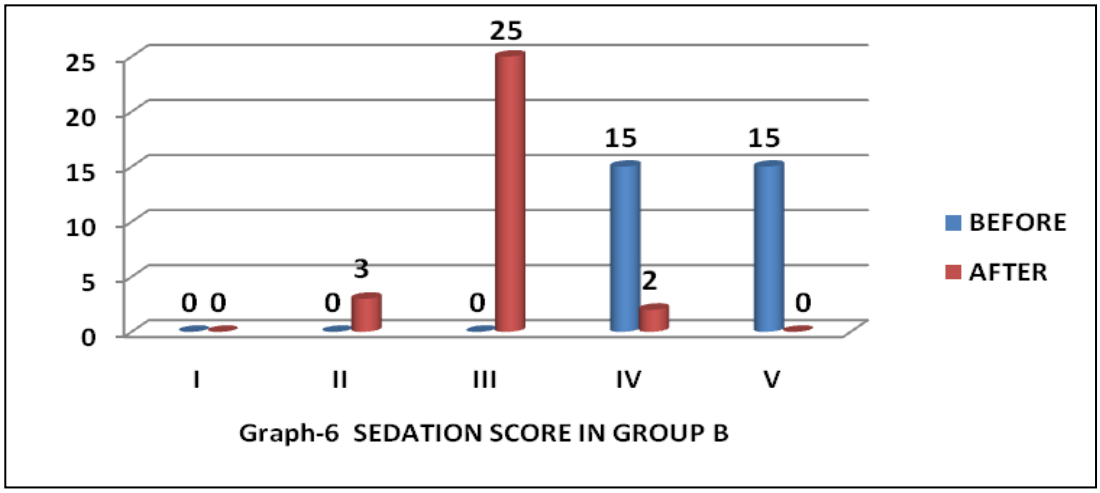
The above table shows p value of 0.1622 by student 't' test which is statistically not significant.

Table 8: Showing sedation score.

Sedation Score	Gp A (n=30)		Gp B (n=30)	
	Before	After	Before	After
I	-	-	-	-
II	-	-	-	3
III	1	20	-	25
IV	12	4	15	2
V	17	-	15	-



Graph-5 SEDATION SCORE IN GROUP A

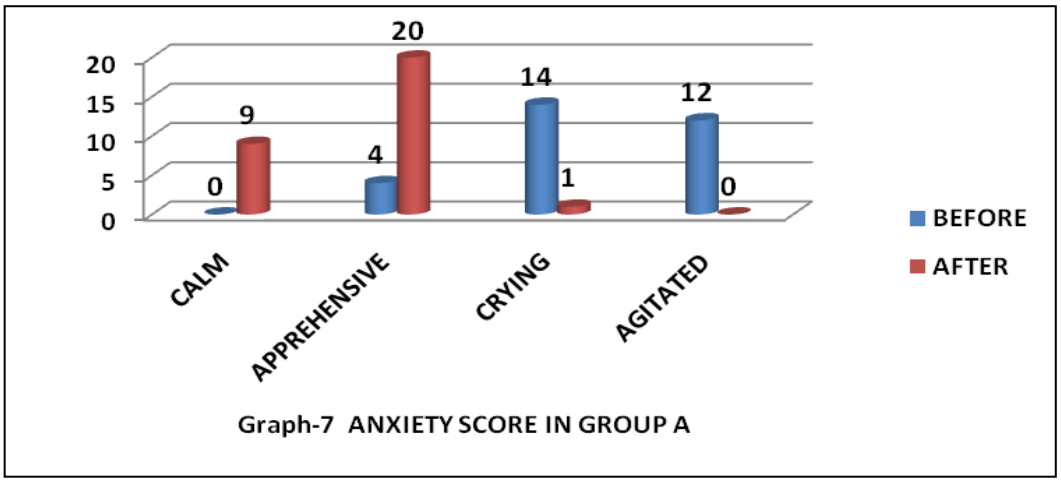


Graph-6 SEDATION SCORE IN GROUP B

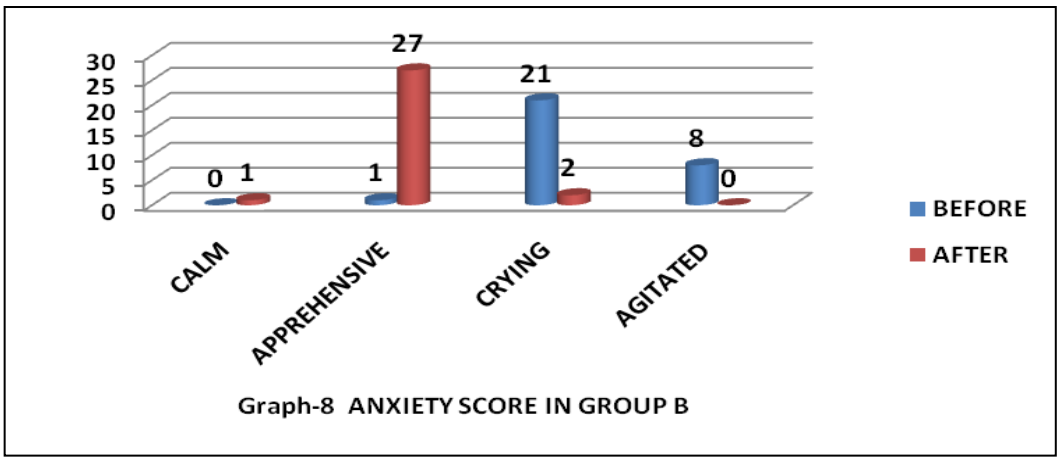
Group A V/s Group B $\chi 2 = 6.00$ $p > 0.05$ there is no significant difference in Sedation score between two groups.

Table 9: Showing Anxiety score.

Anxiety Score	Gp A (n=30)		Gp B (n=30)	
	Before	After	Before	After
I	-	9	-	1
II	4	20	1	27
III	14	1	21	2
IV	12	-	8	-



Graph-7 ANXIETY SCORE IN GROUP A



Graph-8 ANXIETY SCORE IN GROUP B

Group A V/s Group B $\chi 2 = 7.776$ p=0.02 there is significant difference in Anxiety score between two groups.

Table 10: Showing pulse rate after Premedication.

Pulse rate/ mins	Gp A (n=30)	Gp B (n=30)
Mean	101.27 ± 19.39	96.43 ± 5.73
SD	3.54	1.05

Gp A Vs Gp B = 1.31 p=0.199 NS 95% CI=(-12.34 – 2.67)

Table 11: Systolic Blood Pressure after Premedication.

Systolic BP	Gp A (n=30)	Gp B (n=30)
Mean ± SD	98.47 ± 7.09	98.13 ± 6.02
SE	(1.29)	1.09

Gp A Vs Gp B t=0.20 p=0.85 NS 95% CI=(-3.71 – 3.07)

Table 12: Diastolic BP after Premedication.

Diastolic BP	Gp A (n=30)	Gp B (n=30)
Mean ± SD	61.87 ± 3.36	63.07 ± 4.38
SE	(0.614)	(0.801)

Gp A Vs Gp B t=1.19 p=0.239 NS 95% CI=(-0.82 – 3.22)

Table 13: SpO_2 after Premedication.

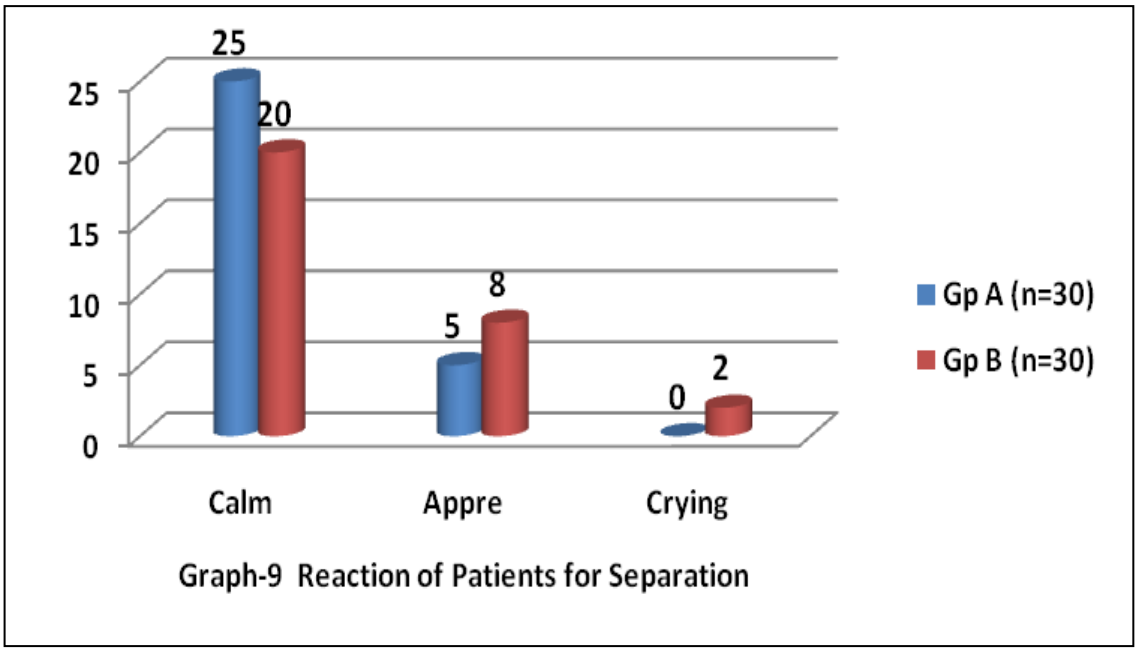
SpO_2	Gp A (n=30)	Gp B (n=30)
Mean ± SD	97.37 ± 2.13	97.63 ± 0.718
SE	(0.39)	(0.131)

Gp A Vs Gp B t=0.65 p=0.519 NS 95% CI=(-0.563 –1.098)

Table 14: Showing emotional reaction of children to separation from parents.

Reaction to separation	Gp A (n=30)	Gp B (n=30)
Calm	25	20
Apprehensive	05	08
Crying	00	02

The reaction of separation calm(88%) appre (12%) in group A. in group B calm (72%) apprehensive (20%) crying (4%). The above table shows p value of 0.2346 by chi-square test which is statistically not significant.

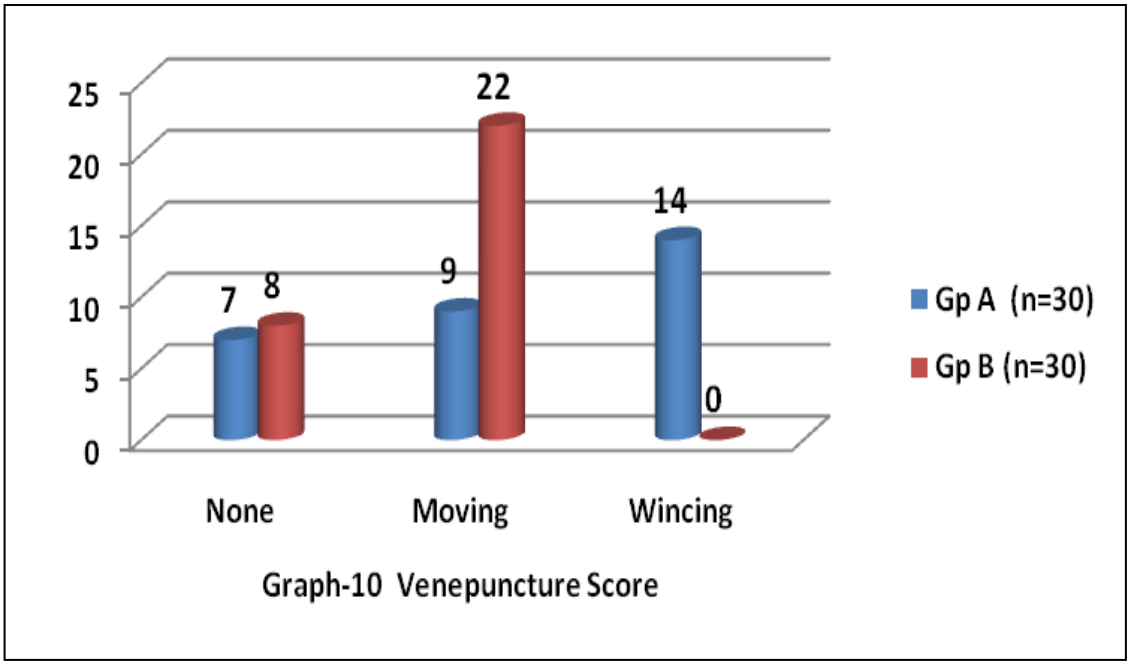


Graph-9 Reaction of Patients for Separation

Table 15: Showing venepuncture score.

Venepuncture Score	Gp A (n=30)	Gp B (n=30)
None	7	8
Moving	9	22
Wincing	14	-

$\chi 2 = 19.518$ $p = 0.00$ highly significant difference between Gp A and Gp B.

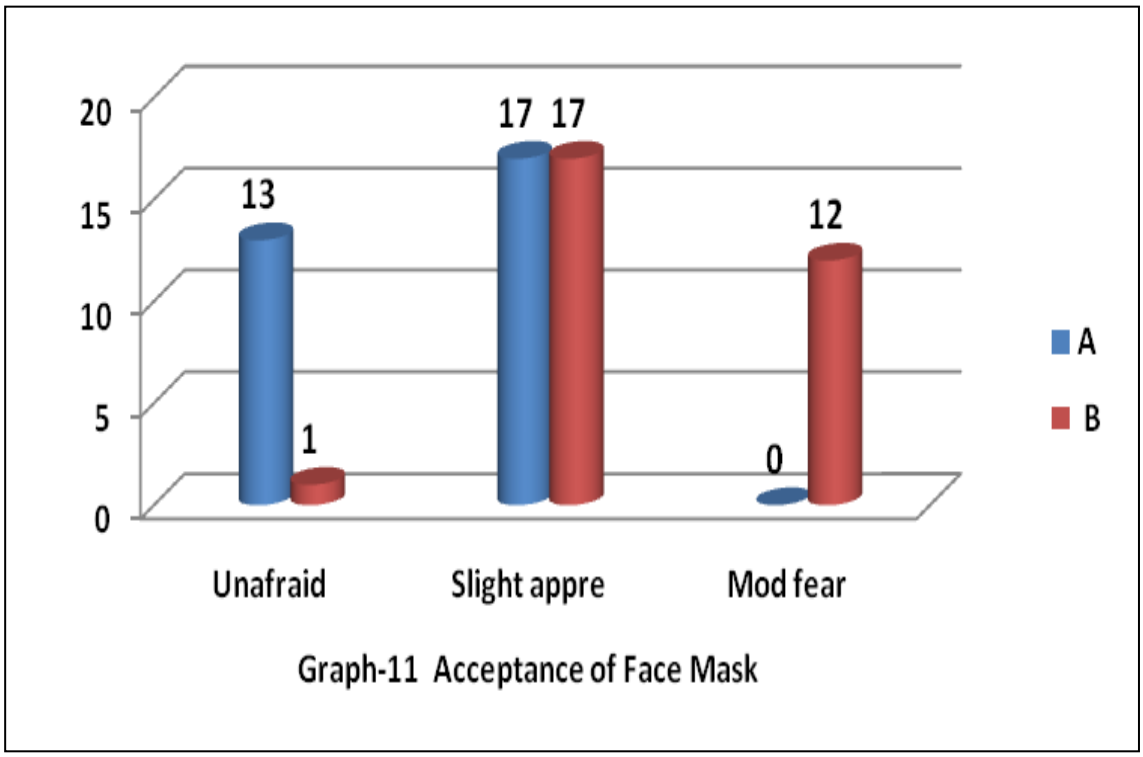


Graph-10 Venepuncture Score

Table 16: Showing the acceptance of face mask by the children.

Group	Gp A	Gp B
Unafraid	13	1
Slight Apprehensive	17	17
Moderate fear	-	12

$\chi 2 = 22.286$ $p = 0.00$ highly significant difference between Gp A and Gp B.



Graph-11 Acceptance of Face Mask

Table 17: Showing types of surgery.

Types of surgery	Gp A (n=30)	Gp B (n=30)
Adenotonsillectomy	8	5
Circumcision	3	3
Closed reduction	1	2
Herniotomy	2	1
Foreign body removal	4	1
Insicion & drainage		5
Kwiring	1	4
Open appendicectomy		1
Brachial Cyst excision	1	2
Ethmoidotomy	2	
Keratosis removal	2	2
Adenoma exicision	1	1
CTEV correction	2	2
STSG	1	1
Myringotomy	1	
Tympanomastoidectomy	1	

DISCUSSION

Under going surgery can be a traumatic experience for the children. Fear of physicians, nurses, foreign environment, fear of needle pricks and forceful separation from parents leave long lasting unpleasant memories to the child. These can be overcome by using pharmacological agents as premedication because psychological reassurance alone is not sufficient. While varied premedications have been advocated to allay anxiety and facilitate smooth separation of children from parents, the ideal premedicant remains elusive. The ideal premedicant in children should be readily acceptable, have rapid, reliable onset of action with minimal side effects. Recent reports suggest that both oral ketamine and oral midazolam, may fulfill many of these criteria.

We therefore under took the following study of compare the efficacy and safety of oral ketamine, and oral midazolam as premedicating agents in paediatric patients undergoing surgeries. A prospective time bound study was undertaken on 60 children of ASA I & II aged between 1-10 years undergoing elective surgeries. This study was conducted in BLDE Hospital, Bijapur : 2009-2011.

The patients were randomly allocated into 2 groups of each.

Group - A = Received oral ketamine (6mg/kg)

Group – B = Received oral midazolam (0.5 mg/kg)

These drugs were mixed with dextrose given to the patients 30 mins prior to the surgery.

Table 1 : Shows the demographics data of the patients. The groups were similar in respect of age, sex, and weight. Hence the groups are comparable

Table 2 : Shows age wise distribution of the patients in the group where the patinas were in the age group 1-10 yrs with mean age in Gp A is 6.53 SD 1.94. and Gp B is 6.08 SD 2.41. the distribution of patients according to age in both groups was not statistically significant. (p value is > 0.05)

Table 3: Shows the sex wise distribution of the patients in both groups, there are 15 male and 15 female in Gp A and 14 male and 16 female in Gp B . There was no statistical difference between the two groups.

Table 4 : Shows weight wise distribution among two groups with mean weight in Gp A is 17.07 SD4.29 and in Gp B mean weight is 16.04 SD 5.71. There was no statistical difference between the two groups.

Table 5 : Showing the emotional status before peremedication calm 68% appre 32%. In group A and calm 84% and appre 16% in group B. here the groups were comparable as there was no statistical difference.

Table 6 : Shows the mean PR and before premedication. The mean pulse rate is 91.57 SD 18.71, and mean RR is 99.12 SD 9.61. There was no statistical difference between two groups.

Table 7: Shows onset of sedation in mins after premedication with the mean time of onset 17.19 SD 3.52 in group A and 16.24 SD 2.22 in group B. there was no statistical difference in the onset of sedation in both groups. Similar findings were observed in the study conducted by ***Lt col Navadeep Sethi, Sqn, Ldr LK Dash, Col TP Madhusudanam.*** In their study on 60 children of ASA I & II aged 1-7yrs and found that both ketamine and midazolam were more effective in sedating the children within 30mins in comparison to a placebo.

In the study conducted by J A Kulkarni on 50 patients of ASA I & II status in the age group 4 – 10 yrs found that Ketamine was well accepted by all the children.

Table 8: Shows sedation score before and after premedication in group A and group B. There was no significant difference in sedation score between two groups. In the study conducted by ***Dr. Suranjit Debnath, Dr. Yash Pande*** in their study on 60children of ASA I aged 1-10yrs found that 77% of children in ketamine group attained sedation score of 3 or less and 36% of children in midazolam group attained sedation score of 3 or less within 30mins.

Table 9: Shows Anxiety score before and after premedication in group A and group B. There was significant difference in Anxiety score between two groups.

Table 10: Showing pulse rate after premedication, inGp A mean pulse rate 101.27± 19.39, in Gp B mean PR 96.43 ± 5.73. there was no statistical difference between two groups in pulse rate after premedication. (P>0.05)

Table 11: Showing BP after premedication in Gp A mean BP was 98.47 ± 7.09 and Gp B mean BP 98.13 ± 6.02. there was no statistical difference between 2 groups.

Table 13: Showing SpO_2 after Premedication in Gp A mean SpO_2 was 97.37 ± 2.13 and Gp B mean SpO_2 was 97.63 ± 0.718. there was no statistical difference between 2 groups.

Table 15 Showing Venepuncture score $\chi 2 = 19.518$ P=0.00 highly significant difference between 2 groups.

Table 16: Showing acceptance of face mask $\chi 2 = 22.286$ P=0.00 highly significant difference between 2 groups.

CONCLUSION

The present study concludes that both oral ketamine and oral midazolam are good premedicating agents in children with minimal side effects, while premedication with 6mg/kg of oral ketamine is better than 0.5mg/kg of oral midazolam in achieving better acceptability, sedation and anxiolysis.

SUMMARY

A study was conducted to evaluate the efficacy of and to compare the effects of oral ketamine and oral midazolam as premedication agents in children and to study the incidence of side effect of the two drugs on 60 patients of each belonging to ASA I & II who were scheduled to under go elective surgeries.

The study was conducted at BLDE Hospital during the period of 2009-2011. The patients were allocated into two groups of 30 each. The drugs given orally 30mins to surgery.

The required parameters observed.

In our study we had the following findings. The demographic data showing age, sex, weight were comparable in both groups.

The acceptance of premedication was good in group A patients with 96% of patients accepting the drug. Where as in Gp B only 76% accepted the drug showing statistically significant difference.

The pulse rate and oxygen saturation before and after premedication showed no statistical significance difference between the two groups.

Onset of sedation showed no statistical difference with mean onset of sedation in minutes of 17.19SD 3.52 in Gp A and in Gp B it is 16.24 SD 2.22.

The sedation score after premedication, which was assessed on 4 point scale showed no significant statistical difference.

The emotional reaction to separation from parents were noted on 3 point scoring scale and found no statistical significant difference.

Venepuncture score was assessed on 4 point scale. Grade I, II and III are considered satisfactory. The groups showed significant difference in venepuncture score.

Acceptance of face mask showed significant difference between two groups.

There was no incidence of laryngospasm and emergence phenomenon in both the groups.

There was presence of increased secretion before induction in 2 patients of Gp A and 1 patient of Gp B.

The presence of side effects like restlessness nausea/vomiting increased secretion in post-op period were observed and noted. These side effects were presents in both groups with no statistical significant difference.

From the study, it was observed that both oral ketamine and oral midazolam are good premedicating agents in children, while acceptability, sedation and anxiolysis were better in ketamine group.

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PROFORMA

Name: Date:

Age: IP. No.:

Sex:

PREPERATIVE EVALUATION

GPE: RR:

Pulse Rate: Weight:

Blood Pressure: Temperature:

Systemic Examination

CVS;

RS;

Others;

Investigation:

Hb: Urine:

BT: HIV:

CT: Hbs Ag

Preoperative diagnosis:

Proposed surgery

ASA Grade

Anesthetic technique

Scoring system

Score	Sedation level
1	Barely arousable
2	Eyes closed (light sleep)
3	Eyes opened but looks drowsy
4	Awake
5	Agitated

Score	Anxiety level
1	Calm and Sleepy
2	Apprehensive but withdrawn from surrounding
3	Crying
4	Agitated and difficult to control

Calculated Dosage:

Drug administered K M

Baseline Scores

Sedation Score – Anxiety Score –

Scores after administration of the drug.

Time	**Sedation**	**Anxiety**	**HR**	**BP**	**SPO_2**
0 Min					
5 Min					
10 Min					
15 Min					
20 Min					
25 Min					
30 Min					

Sedation _____ Anxiety _____

Name any of the following:

Vomiting Respiratory depression:

Separation Score (on separation of child from parents)
1. Easy separation.
2. Whimpers but is easily reassured, not clinging to parents.
3. Cries and cannot be easily reassured but not clinging to parents.
4. Crying and clinging to parents.

Reaction of IV cannulation	
Crying or Struggling	3
Wincing or Vocalizing	2
Moving the hand	1
None	0

Induction Score
1. Unafraid, Co-operative, accepts mask readily.
2. Slight apprehensive of mask, easily reassured.
3. Moderate fear of mask, easily reassured.
4. Terrified, crying, combative.

SAMPLE INFORMED CONSENT FORM:

TITLE OF PROJECT **:** A COMPARATIVE STUDY OF ORAL KETAMINE AND ORAL MIDAZOLAM AS PEMEDICANTS

GUIDE **: Dr. VIDYA PATIL**

PG **: Dr. DEEPA ALLOLI**

PURPOSE OF RESEARCH:

I have been informed that this study will compare the efficiency of premedication between oral ketamine and oral midazolam in paediatric patients undergoing elective surgeries.

PROCEDURE:

I understand that my child /ward will be given either oral ketamine or oral midazolam.

RISKS AND DISCOMFORTS:

I understand that my child/ ward may experience some pain and discomfort during this study period. This is mainly the result of my child's / ward's conditions and the procedure of this study are not expected to exaggerate these feelings which are associated with the usual course of procedure.

BENEFITS:

I understand that my child /ward's participation in the study will help in finding out the efficiency of oral ketamine and oral midazolam for premedication in paediatric patients.

CONFIDENTIALITY:

I understand that the medical information produced by this study will become part of my child/ ward's hospital record and will be subject to the confidentiality. Information of sensitive personal nature will not be a part of the medical record, but will be stored in the investigator's research file.

If the data are used for publication in medical literature or for teaching purpose, no names will be used and other identifiers, such as photographs will be used before giving the permission.

REQUEST FOR MORE INFORMATION:

I understand that I may ask more questions about the study at any time. Dr. Deepa Alloli at the department of anesthesiology is available to answer my questions or concerns. I understand that I will be informed of any significant new findings discovered during the course of this study, which might influence my child's/ ward's continued participation. A copy of this consent from will be given to me to keep for careful reading.

REFUSAL OR WITHDRAWAL OR PARTICIPATION:

I understand that my child's / ward's participation is voluntary and I may refuse his/her participation or may withdraw consent and discontinue my child's / ward's participation in the study at any time without prejudice. I also understand that Dr. Deepa Alloli may terminate my child's / ward's participation in this study at any time after she has explained the reason for doing so.

INJURY STATEMENT:

I understand that in the unlikely event of injury to my child / ward resulting directly from his/her participation in this study, if such injury were reported promptly then appropriate treatment would be available to my child / ward. But no further compensation would be provided by the hospital. I understand that by my agreement of my child's / ward's participation in this study I do not waive any of my legal rights.

I confirm that Dr. Deepa Alloli has explained to me the purpose of research, the study procedures that my child / ward will undergo and the possible risks and discomforts as well as benefits that my child / ward may experience in my own language. I have been explained all the above in details in my own language and I understand the same. Therefore I agree to give my consent for my child's / ward's participation as a subject in this research project.

I have explained to _____ the purpose of the research, the procedures required and the risk and benefits to the best of my ability in patient's own language.

_____ _____

Investigator Date

_____ _____

Participant Date

_____ _____

Witness to signature Date

Group A (Oral Ketamine																		
							Before Premedication		After Premedication									
Sl No	Name	Age	Sex	Ip No	Wt(Kg)	Type of Surgery	Sedation Score	Anxiety Score	PR	BP		Spo2	Sedation Score	Anxiety Score	Separation Score	Reaction to IV cannulation	Ind Score
										Systolic /mmhg	Diastolic /mmhg						
1	Prashant	2 yrs	M	19251	8	pmsr for ctev	5 Agitated	4 Agitated	92	90	60	98	4 Awake	2 Appren	1 Easy sep	2 Wincing	2 Slight Appre
2	Nagesh	6 yrs	M	201	15	circumsicion	5 Agitated	4 Agitated	108	90	64	97	4 Awake	2 Appren	1 Easy sep	2 Wincing	1 Unafraid
3	Gurubai	9 yrs	F	206	26	brachial cyst excision	5 Agitated	3 Crying	110	100	60	98	2 Eyes closed	1 Calm	1 Easy sep	0 None	1 Unafraid
4	Soumya	10 yrs	F	772	24	k wiring	4 Awake	2 Appren	100	100	70	98	3 Eyes opened	2 Appren	1 Easy sep	0 None	1 Unafraid
5	Preethi	4 yrs	F	1120	15	adenotonsillectomy	4 Awake	3 Crying	98	90	62	97	2 Eyes closed	2 Appren	1 Easy sep	1 Moving	2 Slight Appre
6	Bhagya	5 yrs	F	1276	14	adenotonsillectomy	4 Awake	4 Agitated	90	92	64	98	4 Awake	2 Appren	1 Easy sep	2 Wincing	1 Unafraid
7	Channappa	7 yrs	M	1372	18	keratosis removal	4 Awake	3 Crying	98	100	60	91	3 Eyes opened	2 Appren	1 Easy sep	0 None	1 Unafraid
8	nandisha	6 yrs	M	11912	15	lt tympanomastoidectomy	5 Agitated	4 Agitated	104	110	60	97	3 Eyes opened	2 Appren	2 Whimpers	2 Wincing	2 Slight Appre
9	Sachin	1 yr	M	3766	9	ceervical lymph node biopsy	4 Awake	3 Crying	102	90	60	97	2 Eyes closed	2 Appren	2 Whimpers	2 Wincing	2 Slight Appre
10	Jalkavva	10 yrs	F	18978	18	adenotonsillectomy	4 Awake	2 Appren	94	90	60	98	3 Eyes opened	1 Calm	2 Whimpers	1 Moving	2 Slight Appre
11	Bhuvaneshwari	4 yrs	F	59362	12	rt pinna cyst excision	5 Agitated	4 Agitated	196	94	60	97	3 Eyes opened	3 Crying	1 Easy sep	0 None	1 Unafraid
12	Mahesh	5 yrs	M	9036	14	fb ear removal	5 Agitated	3 Crying	96	100	60	97	3 Eyes opened	1 Calm	1 Easy sep	1 Moving	2 Slight Appre
13	Shankarling	5 yrs	M	9555	12	fb ear removal	5 Agitated	3 Crying	110	98	64	98	3 Eyes opened	2 Appren	2 Whimpers	2 Wincing	2 Slight Appre
14	Bharati	8 yrs	F	10518	20	tonsillectomy	4 Awake	3 Crying	102	100	60	97	3 Eyes opened	2 Appren	2 Whimpers	1 Moving	2 Slight Appre
15	Abhijeet	6 yrs	M	10892	14	tonsillectomy	5 Agitated	3 Crying	100	90	68	98	3 Eyes opened	2 Appren	1 Easy sep	2 Wincing	2 Slight Appre
16	panchakshari	6 yrs	F	7419	12	myringotomy	5 Agitated	4 Agitated	103	100	60	99	3 Eyes opened	2 Appren	2 Whimpers	2 Wincing	1 Unafraid
17	Avinash	7 yrs	M	17582	20	ac polyp removal	5 Agitated	3 Crying	76	98	60	97	3 Eyes opened	1 Calm	1 Easy sep	0 None	1 Unafraid
18	baganna	3 yrs	M	17950	10	rt herniotomy	5 Agitated	4 Agitated	94	100	60	98	3 Eyes opened	1 Calm	1 Easy sep	2 Wincing	1 Unafraid
19	sudha	8 yrs	F	263	20	stsg	4 Awake	3 Crying	78	120	70	96	2 Eyes closed	1 Calm	1 Easy sep	1 Moving	2 Slight Appre
20	Siddarth	1 yr	M	1106	8	circumscion	5 Agitated	3 Crying	96	90	60	96	3 Eyes opened	2 Appren	1 Easy sep	1 Moving	2 Slight Appre
21	Nagesh	6 yrs	M	201	15	circumscion	5 Agitated	4 Agitated	106	100	60	97	4 Awake	2 Appren	2 Whimpers	2 Wincing	1 Unafraid
22	vani	6 yrs	F	11369	16	adenotonsillectomy	5 Agitated	4 Agitated	99	110	60	98	3 Eyes opened	1 Calm	2 Whimpers	2 Wincing	1 Unafraid
23	mohan	12 yrs	M	18491	24	adenotonsillectomy	4 Awake	3 Crying	98	108	60	96	3 Eyes opened	2 Appren	2 Whimpers	0 None	2 Slight Appre
24	Akash	8 yrs	M	20773	23	rt ant ethmoidotomy	4 Awake	3 Crying	97	104	70	97	3 Eyes opened	2 Appren	2 Whimpers	2 Wincing	2 Slight Appre
25	Sakhudevi	2 yrs	F	21002	10	granuloma excision	3 Eyes opened	2 Appren	98	100	60	97	2 Eyes closed	1 Calm	1 Easy sep	1 Moving	2 Slight Appre
26	Pooja	10 yrs	F	20625	20	keratosis removal	5 Agitated	4 Agitated	96	98	60	97	3 Eyes opened	2 Appren	2 Whimpers	1 Moving	2 Slight Appre
27	Ashwini	7 yrs	F	2463	11	fb ear removal	5 Agitated	4 Agitated	98	100	60	96	3 Eyes opened	2 Appren	2 Whimpers	2 Wincing	1 Unafraid
28	Pavitra	6 yrs	F	18767	12	adenotonsillectomy	5 Agitated	4 Agitated	97	98	64	97	3 Eyes opened	2 Appren	2 Whimpers	1 Moving	2 Slight Appre
29	Soumya	6 yrs	F	7741	14	closed reduction	4 Awake	2 Appren	98	100	60	98	2 Eyes closed	1 Calm	1 Easy sep	0 None	1 Unafraid
30	Amrit	5 yrs	M	8462	12	rt herniotomy	4 Awake	3 Crying	104	94	60	106	3 Eyes opened	2 Appren	2 Whimpers	2 Wincing	2 Slight Appre

Group B (Oral Midazolam (M)																	
Sl No	Name	Age	Sex	Ip No	Wt(Kg)	Type of Surgery	Before Premedication		After Premedication								
							Sedation Score	Anxiety Score	PR	BP		Spo2	Sedation Score	Anxiety Score	Separation Score	Reaction to IV cannulation	Ind Score
										Systolic/ mmhg	Diastolic /mmhg						
1	Amresh	4 yrs	M	6456	10	k wiring	5 Agitated	4 Agitated	94	98	60	98	4 Awake	3 Crying	3 Cries	2 Wincing	3 Moderate fear
2	Siddarth	1 yr	M	1106	8	circumscion	5 Agitated	3 Crying	96	90	62	99	3 Eyes opened	2 Appren	3 Cries	2 Wincing	2 Slight Appre
3	Sudha	8 yrs	M	263	20	pinna cyst excision	4 Awake	3 Crying	78	100	60	98	3 Eyes opened	2 Appren	2 Whimpers	2 Wincing	2 Slight Appre
4	Mallamma	5 yrs	F	1759	12	orif withdcp	5 Agitated	4 Agitated	90	102	62	99	3 Eyes opened	2 Appren	3 Cries	2 Wincing	3 Moderate fear
5	Basavaraj	6 yrs	M	28698	15	closed reduction	4 Awake	3 Crying	94	104	70	98	4 Awake	2 Appren	2 Whimpers	2 Wincing	3 Moderate fear
6	Sangamesh	5 yrs	M	3252	12	ctevcorrection	5 Agitated	3 Crying	96	94	60	98	3 Eyes opened	3 Crying	2 Whimpers	2 Wincing	3 Moderate fear
7	Guru	4 yrs	M	4021	9	tbw patella	5 Agitated	4 Agitated	94	93	70	99	3 Eyes opened	2 Appren	2 Whimpers	1 Moving	2 Slight Appre
8	Prakash	10 yrs	M	14908	20	l wireremoval	4 Awake	3 Crying	96	100	60	97	3 Eyes opened	2 Appren	2 Whimpers	2 Wincing	3 Moderate fear
9	Vinod	3 yrs	M	829	10	closed reduction	5 Agitated	4 Agitated	103	96	64	98	3 Eyes opened	2 Appren	2 Whimpers	1 Moving	3 Moderate fear
10	Leela	5 yrs	F	10382	14	l andd	5 Agitated	4 Agitated	94	100	62	97	3 Eyes opened	2 Appren	2 Whimpers	2 Wincing	2 Slight Appre
11	Peter	4 yrs	M	9995	14	circumscion	5 Agitated	3 Crying	96	98	60	97	3 Eyes opened	2 Appren	2 Whimpers	1 Moving	2 Slight Appre
12	Sridevi	3 yrs	F	8276	12	adenotonsillectomy	5 Agitated	3 Crying	94	100	60	98	3 Eyes opened	2 Appren	2 Whimpers	2 Wincing	3 Moderate fear
13	Sachin	1 yr	M	3766	8	lymph node biopsy	4 Awake	3 Crying	96	102	62	98	3 Eyes opened	2 Appren	3 Cries	2 Wincing	2 Slight Appre
14	Abhishek	8 yrs	M	621	18	circumscion	4 Awake	3 Crying	98	106	72	97	3 Eyes opened	2 Appren	2 Whimpers	2 Wincing	3 Moderate fear
15	Rachayya	6 yrs	F	27435	16	sinus in ano excision	4 Awake	3 Crying	102	110	62	98	3 Eyes opened	2 Appren	3 Cries	2 Wincing	2 Slight Appre
16	Lakshmi	6 yrs	F	14153	16	appendicectomy	4 Awake	3 Crying	93	103	70	98	3 Eyes opened	2 Appren	2 Whimpers	2 Wincing	2 Slight Appre
17	Bhirappa	5 yrs	M	12864	17	elastic nailing femur	4 Awake	3 Crying	96	100	70	97	3 Eyes opened	2 Appren	3 Cries	2 Wincing	3 Moderate fear
18	Ravi	1 yr	M	12144	8	bonecurretage	5 Agitated	4 Agitated	104	90	58	98	2 Eyes Closed	2 Appren	2 Whimpers	1 Moving	2 Slight Appre
19	Rakshita	3 yrs	F	11344	12	bonecurretage	5 Agitated	3 Crying	98	90	58	97	3 Eyes opened	2 Appren	2 Whimpers	2 Wincing	3 Moderate fear
20	Laxmi	10 yrs	F	4084	22	closed reduction	4 Awake	2 Appren	97	110	68	98	3 Eyes opened	2 Appren	2 Whimpers	2 Wincing	2 Slight Appre
21	Ganesh	6 yrs	M	10620	13	l andd	4 Awake	3 Crying	98	106	70	97	3 Eyes opened	2 Appren	2 Whimpers	1 Moving	2 Slight Appre
22	Bheerlinga	4 yrs	M	13117	12	umbilical denomaexcisio	5 Agitated	3 Crying	94	90	60	98	3 Eyes opened	2 Appren	2 Whimpers	2 Wincing	3 Moderate fear
23	Soumya	6 yrs	F	13073	18	herniotomy	4 Awake	3 Crying	98	100	60	97	2 Eyes Closed	1 Calm	2 Whimpers	1 Moving	3 Moderate fear
24	Kanabai	9 yrs	F	11390	25	adenotonsillectomy	4 Awake	3 Crying	97	94	68	98	3 Eyes opened	2 Appren	2 Whimpers	2 Wincing	2 Slight Appre
25	Anusayabai	4 yrs	F	10884	14	debridement	4 Awake	3 Crying	100	90	60	97	3 Eyes opened	2 Appren	2 Whimpers	1 Moving	2 Slight Appre
26	Borawwa	5 yrs	F	1672	14	stsg	5 Agitated	3 Crying	98	100	60	98	3 Eyes opened	2 Appren	1 Easy sep	2 Wincing	2 Slight Appre
27	Kashibai	3 yrs	F	10953	13	adenotonsillectomy	5 Agitated	4 Agitated	106	90	58	97	2 Eyes Closed	2 Appren	2 Whimpers	2 Wincing	2 Slight Appre
28	Raju	7 yrs	F	11175	18	keratosis removal	4 Awake	3 Crying	87	100	60	97	3 Eyes opened	2 Appren	2 Whimpers	1 Moving	2 Slight Appre
29	Priya	5 yrs	F	1427	13	adenotonsillectomy	4 Awake	3 Crying	110	98	64	96	3 Eyes opened	2 Appren	2 Whimpers	2 Wincing	1 Unafraid
30	Santosh	3 yrs	M	1360	11	fb removal	5 Agitated	4 Agitated	96	90	62	97	3 Eyes opened	2 Appren	2 Whimpers	2 Wincing	2 Slight Appre

KEY TO MASTER CHART

AC polyp	Antro choanal polyp
Appren	Apprehensive
BP	Blood pressure
CTEV	Congenital talipes equino varus
Fb	Foreign body
I & D	Incision and drainage
Ind score	Induction score
PMSR	Postero medial soft tissue release
PR	Pulse rate
Rt herniotomy	Right sided herniotomy
SpO_2	Oxygen saturation
STSG	Split thickens skin grafting
Wt	Weight