"STUDY OF EFFECT OF INTRANASAL KETAMINE ON POSTOPERATIVE ANALGESIA IN CHILDREN- A ONE YEAR SINGLE BLINDED HOSPITAL BASED RANDOMIZED PLACEBO CONTROLLED CLINICAL TRIAL"

By

REG NO. BA0122002

Dissertation

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Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"STUDY OF EFFECT OF INTRANASAL KETAMINE ON POSTOPERATIVE ANALGESIA IN CHILDREN- A ONE YEAR SINGLE BLINDED HOSPITAL BASED RANDOMIZED PLACEBO CONTROLLED CLINICAL TRIAL"**, is ethical and justifiable.

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LIST OF ABBREVIATIONS

ASA: American Society of Anesthesiologists

CHEOPS: Children's Hospital of Eastern Ontario Pain Scale

CNS: Central Nervous System

ECG: Electrocardiogram

FLACC: Face, Legs, Activity, Cry, and Consolability scale

GABA: Gamma-aminobutyric acid

GA: General Anaesthesia

ICU: Intensive Care Unit

IN: Intranasal

IV: Intravenous

NBM: Nil by mouth

NIBP: Non Invasive Blood Pressure

NMDA: N-Methyl-D-aspartate

OPS: Objective Pain Scale

PONV: Postoperative nausea and vomiting

S.D.: Standard deviation

SpO2: Saturation of peripheral oxygen

TPPPS: Toddler Preschool Postoperative Pain Scale

VAS: Visual analogue scale

ABSTRACT

Title of the article: Study of effect of intranasal ketamine on postoperative analgesia in children- A one-year single blinded hospital based randomized placebo controlled clinical trial.

Background: Postoperative pain management in paediatric patients remains a critical aspect of perioperative care. Intranasal ketamine, a non-opioid analgesic, has shown promising potential in significantly enhancing postoperative analgesia, offering a hopeful outlook for the future of paediatric pain management.

Aims: This study aimed to evaluate the analgesic efficacy of intranasal ketamine in paediatric patients undergoing surgical procedures under general anaesthesia.

Methods: A randomized, placebo-controlled clinical trial was conducted at KLES Prabhakar Kore Hospital and Medical Research Centre. A total of 104 ASA I and II patients, aged 5–18 years, undergoing surgery under general anaesthesia, were randomized into two groups: the Ketamine Group (receiving intranasal ketamine 1 mg/kg) and the Placebo Group (receiving an equivalent volume of placebo). Postoperative parameters assessed included pain intensity, time to first analgesic request, total analgesic consumption in the first 24 hours, sedation levels, and adverse effects. Pain was evaluated using the Children's Hospital of Eastern Ontario Pain Scale (CHEOPS) for children under 7 years and the Visual Analog Scale (VAS) for older patients. Sedation was measured using the Wilson Sedation Score.

Statistical analysis used: Data were analysed using descriptive and inferential statistics, including the Mann-Whitney U test, independent t-test, Chi-square test, and Fisher's exact test. Statistical analyses were performed using open-source software, specifically Python libraries such as Pandas, NumPy, and SciPy.

Results: The Ketamine Group demonstrated significantly lower postoperative pain scores at 1 and 2 hours post-surgery than the Placebo Group. Additionally, the time to the first analgesic request was prolonged, and total analgesic consumption in the first 24 hours was reduced in the Ketamine Group.

Conclusion: Intranasal ketamine, when administered at a low dose, effectively reduces postoperative pain and analgesic requirements in paediatric patients undergoing surgery under general anaesthesia. Its integration into multimodal analgesia protocols not only optimizes pain management but also holds the potential to significantly reduce opioid consumption, offering a promising avenue for enhancing patient outcomes.

Key-words: Paediatrics, Postoperative pain, Visual Analog scale, Ketamine

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INTRODUCTION

Providing patients with timely and effective pain management ensures high-quality care which is essential for enhancing their comfort, recovery, and overall well-being.

Presently, one of the most important duties of all anaesthesiologists is to provide the best possible pain relief.

Utilizing a balanced approach that incorporates both opioid and nonopioid medications for postoperative pain management has emerged as the standard practice.

It is essential to manage patient’s pain after surgery for effective recovery without further postoperative complications. The traditional approach of a single method for pain management will not suffice. Hence multimodal analgesic treatment is required to control postoperative pain effectively.(1)

Opioids are effective analgesics but are linked with depression of the respiratory system, postoperative nausea, vomiting, and sedation in children. Paracetamol is one of the most frequent medications for postoperative pain relief, but administration of it alone can be insufficient for effective analgesia.(2)

In recent studies, it has been demonstrated that Ketamine—a compound that exhibits both analgesic and anti-hyperalgesic properties has a significant decrease in the patient's postoperative pain and opioid requirements.(3)

Ketamine is a derivative of phenycyclidine and is globally known to protect airway reflexes; it has been firmly established as a desired general anesthetic drug-producing sedation.(4)

Ketamine has been utilized effectively for the management of pain and pre-operative sedation at sub-dissociative doses, mainly in children, with limited adverse effects reported.(5)

Adults and children with acute and chronic pain can be managed well with Ketamine since studies have proven its substantial role in pain relief. Studies also confirm its safety and effectiveness in emergency medicine departments and postoperative pain management.(5,6)

Not identifying and addressing pain in children appropriately can result in delayed recovery, emotional distress, and altering the perception of pain.(7)

Some of the previous research has involved intranasal fentanyl, midazolam, or intravenous morphine. (5,8,9)All of them advocated the use of the mentioned drugs in children.

Of various drug delivery systems, the intranasal drug delivery system provides an easy, quick, and needle-free route of drug administration without causing any anguish in children.(10)

By evading the blood-brain barrier and first-pass metabolism, intranasal delivery of medication allows drugs to enter the brain through the nose.(10)

Limited data exist on the analgesic efficacy of the relatively new intranasal administration of Ketamine for pain relief in children. It remains unclear from the available data whether Ketamine is a second-line or adjunct therapy drug or an emerging first-line analgesic.(11)

Few studies have been conducted to determine this element of intranasal Ketamine's effectiveness in children. Hence, this study aims to determine the analgesic efficacy of intranasal Ketamine among pediatric patients following surgical procedures under general anesthesia.

AIM

To determine the analgesic efficacy of intranasal ketamine among paediatric patients following surgical procedures under general anaesthesia.

OBJECTIVES

Primary Objective

1. To determine the effect of intranasal ketamine on postoperative pain in children undergoing surgery under general anaesthesia.

Secondary Objectives

1. To compare the time to the first dose of rescue analgesic drug.
2. To compare the total amount of analgesic drug required in the first 24 hours postoperatively.
3. To determine the adverse effects of the drug, if any.

REVIEW OF LITERATURE

1. A comprehensive meta-analysis was conducted by Dahmani et al. (2011) to examine the analgesic action of Ketamine in intraoperative and postoperative management of children. This research synthesized data from numerous clinical trials, focusing on pain intensity, postoperative analgesic requirements, and the duration of caudal sensory blockade. Their results suggested that Ketamine lowered pain after surgery considerably and, to a lesser degree, reduced the need for nonopioid analgesia in pediatric patients.(3)
2. In 2012, Javid et al. assessed how well a modest dosage of Ketamine relieved pain following tonsillectomy. Seventy-five children between the ages of 3 and 10 were randomly assigned to receive one of three treatments: intravenous Ketamine 0.5 mg/kg, subcutaneous Ketamine 0.5 mg/kg, or a placebo at the end of surgery. They found that pain scores and analgesic usage were significantly lower in both ketamine delivery techniques. The study established that ketamine injections, either intravenously or subcutaneously, were successful in managing post-tonsillectomy pain. Ketamine likewise decreased the demand for analgesics following surgery without enhancing the possibility of complications.(12)
3. In 2015, Bameshki et al. looked into how Ketamine helped with pain control and sedation after surgery. Fifty children aged five to twelve participated, segregated into control and study groups. The study group received IV ketamine-midazolam (ketamine 1 mg/kg, midazolam 0.1 mg/kg) two minutes before the induction of anesthesia. In contrast, the control group received IV midazolam (0.1 mg/kg) before surgery. After surgery, they checked for sedation, agitation, and pain. They found that ketamine addition to midazolam preoperatively reduces agitation and postoperative pain during the first 30 minutes postoperatively, and there was a reduction in pain in the study group at 15 and 30 minutes and agitation at 10 and 15 minutes after extubation. Both groups also had the same mean consumption and duration of the first request for analgesia after surgery and the same incidence of postoperative vomiting.(13)
4. Shrestha et al. (2016) investigated the analgesic potential of intranasal Ketamine for managing moderate to severe pain associated with acute injuries, evaluating its efficacy and safety profile. Thirty-four patients older than 8 years of age with moderateto severe pain were included in the study. Intranasal ketamine 0.7 mg/kg loading dose with an additional dose of 0.3 mg/kg was administered if the visual analogue scale was more than 50 mm after 15 minutes. Vital signs, side effects, sedative level, pain scores, and patient satisfaction were all noted. According to the findings, 27 (80%) patients saw a visual analogue scale drop of more than 20 mm at 15 minutes. At 15, 30, and 60 minutes, the visual analog scale lowered from 80 mm to 40 mm,

20 mm, and 20 mm, respectively. Adverse effects were modest and temporary, and no significant changes in vital signs were seen. They concluded that intranasal Ketamine is a suitable analgesic for patients experiencing moderate to severe pain following an acute injury in an emergency room that is overflowing and underfunded.(14)

5. To establish the effectiveness and safety of intranasal Ketamine for the treatment of acute pain in emergency settings, Seak et al. (2021) conducted a systematic review and meta-analysis. From their findings, intranasal Ketamine is comparable to intravenous analgesics and can be used to treat acute pain in adults in the ER.(15)
6. In 2023, Pakniyat et al. reviewed the literature on intranasal Ketamine as an analgesic for relieving acute pain in emergency rooms. As per their findings, intranasal Ketamine offered remarkably quick, well-tolerated, and clinically significant pain relief in the emergency room.(16)
7. Pandey et al. 2011 compared and evaluated the behavioral reaction, efficacy, and safety of drops and atomized administration of intranasal Ketamine in young, resilient pediatric dental patients. Every child in this two-stage cross-over trial received intranasal Ketamine via both administration methods. In a follow-up visit, thirty-four ASA grade 1 uncooperative children who needed dental care were randomized to receive intranasal Ketamine in drops and atomized spray. Throughout each visit, the vitals were continuously tracked. They concluded that intranasal Ketamine is safe and effective when administered by any method of intranasal drug administration for moderate sedation.(17)
8. The use of intranasal Ketamine and midazolam, delivered using a mucosal atomizer device, as a sedative procedure for reluctant children undergoing stomach aspirates to diagnose tuberculosis was examined by Buonsenso et al. (2014). Intranasal Midazolam (0.5 mg/kg) and Ketamine (2 mg/kg) were administered to 19 children (sedation group) with an average age of 41.5 months, while normal saline solution was delivered twice in each nostril to 17 children (placebo group). They found that intranasal Ketamine with midazolam can cause a specific level of sedation without the requirement of other drugs. They concluded that atomized intranasal Ketamine and Midazolam make stomach aspirations easier and more agreeable for children.(9)
9. In their 2015 study, Riediger et al. examined the effects of intranasal S-ketamine and midazolam sprays in comparison to typical morphine patient-controlled analgesia in patients undergoing spinal surgery. There were twenty-two patients in this study. Following surgery, they noted comparable numerical rating scale scores in the groups receiving morphine-controlled analgesia and S-ketamine-controlled analgesia both at rest and when moving. They discovered that the efficacy of an S-ketamine intranasal spray and intranasal midazolam were comparable to those of conventional intravenous patient-controlled morphine analgesia. In the postoperative context,

S ketamine may be a useful substitute for conventional intravenous morphine patient-controlled analgesia.(18)

10. In 2016, Shimonovich et al. looked into the effectiveness and side effects of intravenous and intramuscular morphine with a sub-dissociative dosage of intranasal Ketamine. A sample of 90 patients aged 18–70 years experiencing moderate to severe acute traumatic pain were randomized to receive either 1.0 mg/kg intranasal ketamine (Group-1), 0.1 mg/kg intravenous morphine (Group-2) or 0.15 mg/kg intramuscular morphine (Group-3). According to the data, intranasal Ketamine had clinically comparable outcomes to intravenous morphine in terms of both time to onset and time to maximal pain reduction, and all three trial groups demonstrated a highly significant, comparable maximal pain reduction. According to the authors, intranasal Ketamine is just as safe and effective as intravenous and intramuscular morphine.(11)
11. Reynolds et al. (2017) compared the efficacy and tolerability of intranasal Ketamine and fentanyl in the treatment of acute traumatic pain in children. Eighty-two children aged four to seventeen years with acute pain resulting from suspected isolated extremity fractures were enrolled in the study and randomized into two groups of forty-one each and treated with 1.5 μg/kg intranasal fentanyl and 1 mg/kg intranasal ketamine. For Ketamine and fentanyl, the mean pain scale score lowered at 20 minutes was 44 ± 36 and 35 ± 29, respectively. The patient's baseline pain scores were similar to those randomly assigned to receive fentanyl and Ketamine: no essential adverse events and no patients in either group required intervention. The common adverse effects of Ketamine were bad taste in the mouth, dizziness, and sleepiness. Sleepiness, a bad taste in the mouth, and an itching nose were the most prevalent manifestations of fentanyl. No respiratory side effects were reported by any subjects.(19)
12. In 2019, Frey et al. conducted a study by contrasting the effects of intranasal Ketamine and fentanyl on pain reduction for pediatric extremity injuries. The study involved 90 children aged 8 to 17 years who presented to the emergency room with moderate to severe pain from a traumatic limb; 45 of the children received intranasal Ketamine (1.5 mg/kg), while the remaining 45 received intranasal fentanyl (2 μg/kg). The visual analogue scale was utilized to gauge pain after the intervention, and the mean VAS reduction was 30.6 mm for Ketamine and 31.9 mm for fentanyl. The outcomes indicated that Ketamine was non-inferior to fentanyl for pain reduction. Although the ketamine group had a greater chance of having side effects, these were transient and mild. The use of rescue analgesia in the cohorts was comparable. The authors concluded that Ketamine had good analgesia that was comparable to fentanyl. They also went on to state that Ketamine could be used in treating children's pain in an emergency condition, particularly where opioids are linked to heightened risk.(20)

13. Murphy et al. (2021) investigated the effect of combined methadone and Ketamine on postoperative opioid requirements in spinal fusion surgery patients. The study randomized 30 patients into two groups: one receiving methadone (0.2 mg/kg) with intraoperative ketamine (0.3 mg/kg/h) followed by 0.1 mg/kg/h for 48 hours, and the other receiving methadone alone with a 48-hour dextrose infusion. Pain ratings, opioid consumption, and patient satisfaction were assessed for three days postoperatively. Results showed that the methadone/ketamine group required less hydromorphone and fewer oral opioids, indicating improved analgesia. The study supports the use of Ketamine as an adjunct to methadone in spinal fusion surgery to enhance pain control and reduce opioid consumption, contributing to multimodal analgesic strategies.(21)
14. In 2022, Osama et al. evaluated the safety and efficacy of intranasal midazolam alone versus midazolam/ketamine combination for preoperative sedation prior to ophthalmic procedures in preschoolers. Participants were given either intranasal midazolam (0.5 mg/kg) or a combination of intranasal midazolam (0.25 mg/kg) and Ketamine (1mg/kg). They found that intranasal Ketamine and midazolam produced better sedation than intranasal midazolam alone in preschoolers before ophthalmic procedures. The ketamine and midazolam combination proved safer, with a lower incidence of bradycardia.(22)
15. The effectiveness of topical ketamine administration via nebulization in lowering the incidence and intensity of postoperative sore throat was investigated by Mehta et al. in 2022. One hundred thirty-four patients with ASA III in the age range of 18-60 years, of either sex, undergoing surgery under GA were selected. They were randomly assigned to one of two groups: Group S received 5.0 ml saline nebulization, while Group K received Ketamine 50 mg (1 ml) in combination with 4.0 ml saline nebulization for 15 minutes. GA was induced 10 minutes after nebulization was completed. After extubating, and at 2, 4, 6, 8, 12, and 24 hours postoperatively, postoperative sore throat monitoring was performed. At 2, 4, 6, 12, and 24 hours postoperatively, ketamine nebulization significantly reduced postoperative sore throat, indicating that preoperative nebulized Ketamine helps reduce the occurrence and severity of postoperative sore throat without causing adverse effects. The results showed that postoperative sore throat occurred in 44% of patients overall, with 41 patients in group S (61%) and 18 patients in group K (26%) experiencing postoperative sore throat throughout the study period.(23)
16. In 2022, Isfahani et al. assessed the impact of intranasal Ketamine versus intranasal fentanyl on pain management in patients with isolated traumatic injuries. The study included two hundred twenty-five patients and was divided into three groups: the control group, the 1 mg/kg intranasal ketamine group, and the 1 μg/kg intranasal fentanyl group. Blood pressure, oxygen saturation, heart rate, respiratory rate, and pain scores were recorded at baseline, 5, 10, 15, 30, and 40 minutes after

the intervention. The authors concluded that because intranasal Ketamine acts within 10 minutes, it can be suggested as a suitable analgesic medication in pain reduction for patients with isolated limb injuries. Additionally, compared to the intranasal fentanyl group, the occurrence rate and severity of side effects were slightly greater in the intranasal ketamine group.(24)

17. In 2020, Sanatkar et al. examined the efficacy of intravenous paracetamol and intranasal Ketamine in treating postoperative pain in children after strabismus surgery. One of two groups—intranasal Ketamine (Group K) or intravenous paracetamol (Group P)—was randomly allocated to 60 young people with strabismus. After general anesthesia was induced, Group K and Group P were given intravenous paracetamol and intranasal Ketamine, respectively. Vital signs, the extent of sedation, the pain scale, and side effects were noted 10, 20, 30, and 60 minutes post-surgery. Researchers demonstrated a statistically significant difference between groups K and P at 10, 20, 30, and 60 minutes after assessing the two groups' pain scores and sedation scales. The two groups had no statistically significant difference in the postoperative adverse events. After strabismus surgery, the authors found that intranasal Ketamine provided more potent analgesia than intravenous paracetamol.(2)
18. In 2018, Yenigun et al. compared the effectiveness of intranasal Ketamine and intranasal fentanyl for postoperative pain relief after tonsillectomy in children. Following tonsillectomy, sixty-three children were randomly assigned to one of three groups: Group I received intravenous paracetamol, Group II received intranasal Ketamine, and Group III received intranasal fentanyl. Scores on the Wilson Sedation Scale and the Children's Hospital of Eastern Ontario Pain Scale (CHEOPS) were taken 15, 30, 60, 2, 6, 12, and 24 hours after the procedure. In order to evaluate bleeding, nausea, vomiting, hallucinations, nightmares, and postoperative discomfort, patients were questioned after surgery. They found that intranasal Ketamine or intranasal fentanyl was superior to paracetamol in postoperative analgesia following pediatric tonsillectomy. Three participants in the intranasal ketamine group exhibited drowsiness. The effectiveness of intranasal Ketamine and intranasal fentanyl for post-tonsillectomy pain did not differ significantly.(25)

BASIC SCIENCES

Nose(26)

Anatomical Structure of the Nose

The nose constitutes the initial segment of the upper respiratory tract and serves critical functions in conditioning inspired air by facilitating its warming, humidification, and filtration. Additionally, it houses the olfactory epithelium, which is responsible for detecting airborne odor molecules and contributing to the sense of smell.

Anatomically, the nose is divided into two primary components: the external nose and the nasal cavity. The external nose comprises several distinct structural elements, including the root, dorsum, apex (tip), anterior nares, nasal septum, and columella. These components collectively provide structural support, maintain airway patency, and contribute to the overall aerodynamic function of nasal airflow.

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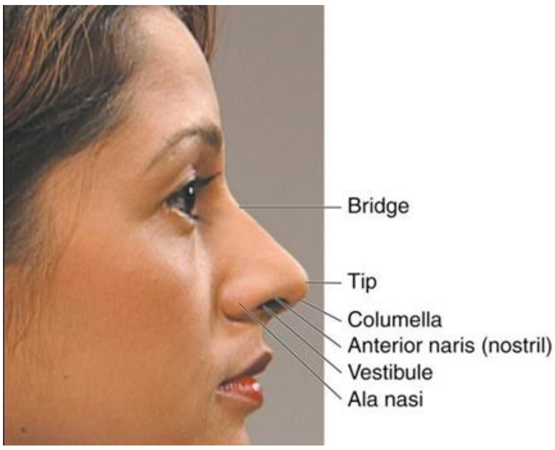


Figure 1: Anatomic structures of the external nose. Seidel's Guide to Physical Examination

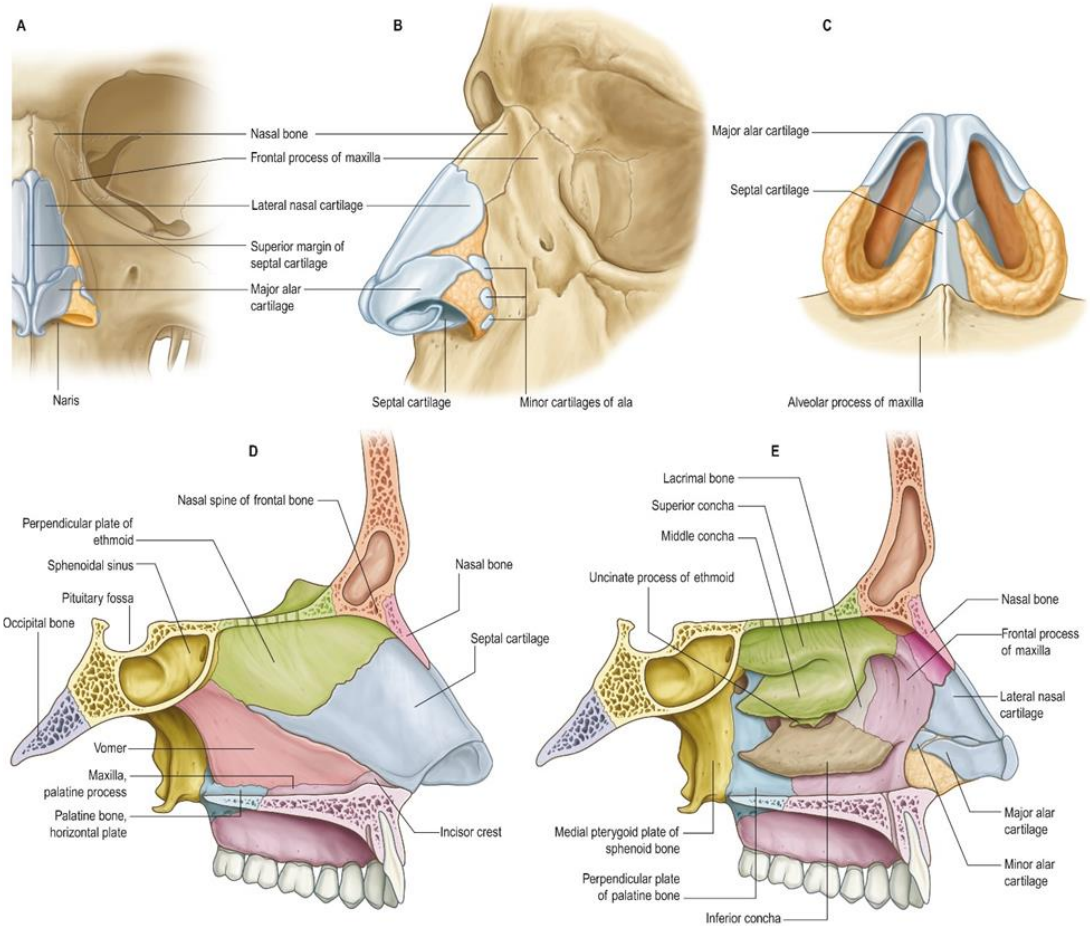


Figure 2: The bony and cartilaginous skeletons of the nose. A, The external nose, frontal view. B, The external nose, lateral view. C, An inferior view of the cartilages. D, The nasal cavity, medial wall. E, The nasal cavity, lateral wall (left side).

Bones and fibroelastic cartilage support the nasal cavities. They open anteriorly through the nostrils and are divided by a septum into right and left cavities. Posteriorly, these cavities connect to the nasopharynx via the choanae. Each nasal cavity features a roof, floor, and medial and lateral walls.

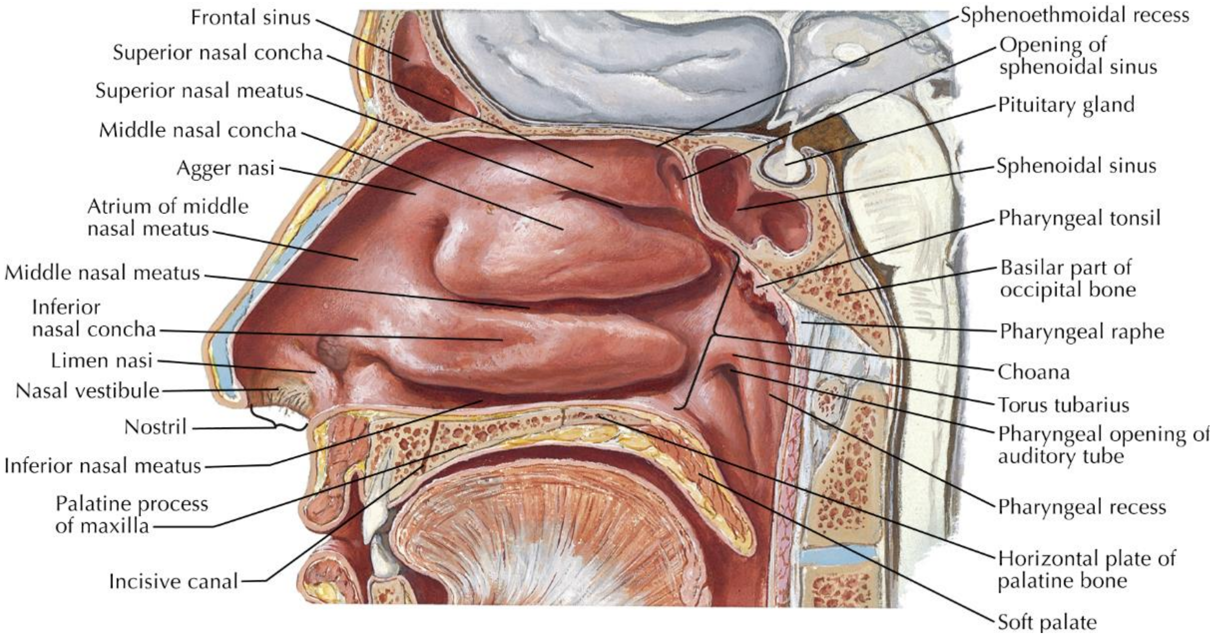


Figure 3: Lateral Wall of Nasal Cavity Netter Atlas of Human Anatomy: Classic Regional Anatomy Approach, Eighth Edition

The turbinates are essential for filtration, heating, and humidifying inspired air. They direct airflow to the olfactory cleft.

Surrounding the nasal cavity are the frontal, maxillary, sphenoid, and ethmoid sinuses. These sinuses and the nasolacrimal ducts drain into the nasal cavity through openings in its lateral walls. The hard palate forms the floor of the nasal cavity.

Vascular Supply of the Nasal Cavity and Paranasal Sinuses

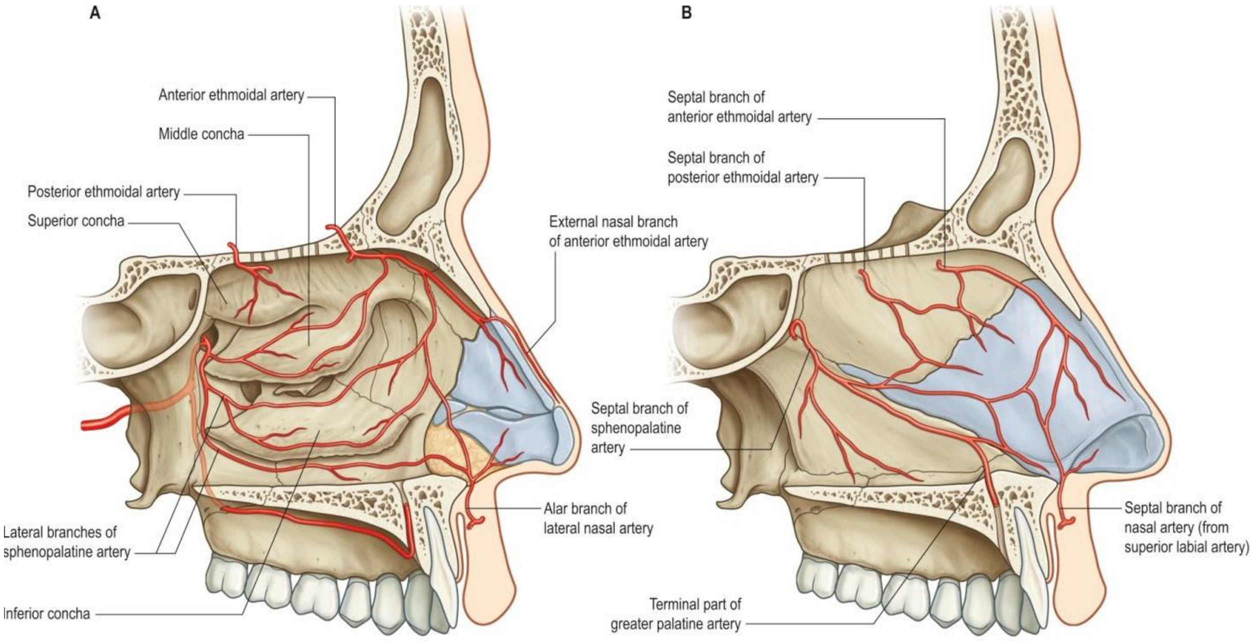


Figure 4: The arterial supply of the nasal cavity. A, The lateral wall of the left nasal cavity. B, The medial wall of the right nasal cavity. With permission from Drake RL, Vogl AW, Mitchell A (eds) Gray's Anatomy for Students, 2nd ed. Elsevier, Churchill Livin

Arterial Supply of the Nasal Cavity and Paranasal Sinuses

The arterial supply to the nasal cavity and paranasal sinuses is derived from branches of the ophthalmic, maxillary, and facial arteries, forming an extensive anastomotic network within the nasal mucosa. These arterial contributions ensure adequate perfusion, support mucosal function and facilitate immune responses within the upper respiratory tract.

The ophthalmic artery, a branch of the internal carotid artery, gives rise to the anterior and posterior ethmoidal arteries, which primarily supply the ethmoidal and frontal sinuses, the roof of the nasal cavity, and the nasal septum. These branches play a crucial role in vascularizing the superior aspects of the nasal cavity.

The maxillary artery, a major branch of the external carotid system, provides extensive vascularization to the nasal mucosa through several key branches:

- Sphenopalatine Artery: As the terminal branch of the maxillary artery, the sphenopalatine artery serves as the principal vascular supply to the nasal mucosa, perfusing the turbinates, meatuses, and the posteroinferior portion of the nasal septum.
- Greater Palatine Artery: This artery supplies the mucosa of the inferior meatus. Its terminal segment ascends through the incisive canal, forming anastomoses on the nasal septum with branches of the sphenopalatine artery, anterior ethmoidal artery, and the septal branch of the superior labial artery. This vascular confluence, known as Little's area (Kiesselbach's plexus), is clinically significant due to its propensity for epistaxis.
- Infraorbital and Alveolar Branches: The infraorbital artery and the superior, anterior, and posterior alveolar branches contribute to the vascularization of the maxillary sinus mucosa.
- Pharyngeal Branch: The pharyngeal branch of the maxillary artery supplies the sphenoidal sinus, further contributing to the interconnected vascular network.

Through its superior labial branch, the facial artery provides additional vascularization to the nasal septum, contributing to the anastomotic network within the nasal mucosa.

Venous Drainage of the Nasal Cavity

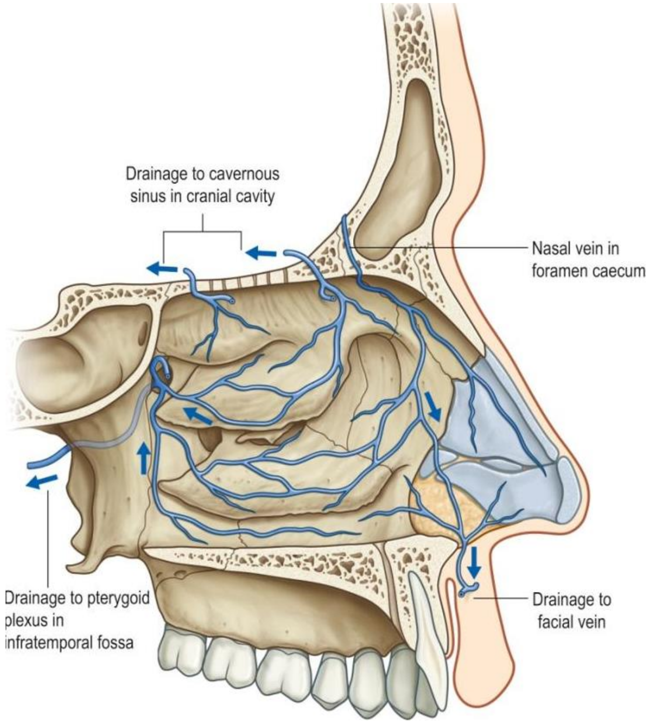


Figure 5: The venous drainage of the nasal cavity: the lateral wall of the left nasal cavity. With permission from Drake RL, Vogl AW, Mitchell A (eds) Gray's Anatomy for Students, 2nd ed. Elsevier, Churchill Livingstone. Copyright 2010.

The venous drainage of the nasal cavity is facilitated by an extensive submucosal cavernous plexus, which plays a crucial role in the thermoregulation and humidification of inspired air. This plexus is particularly dense in the posterior region of the nasal septum and in the middle and inferior turbinates. Numerous arteriovenous anastomoses are present within the deeper layers of the mucosa and in proximity to the mucosal glands, further contributing to these physiological processes.

Venous outflow from the nasal cavity follows distinct pathways depending on the region. The posterior aspect of the nasal cavity predominantly drains into the sphenopalatine vein, which courses posteriorly through the sphenopalatine foramen and ultimately empties into the pterygoid venous plexus. In contrast, the anterior region of the nasal cavity is primarily drained by veins that accompany the anterior ethmoidal arteries, which subsequently discharge into either the ophthalmic or facial veins.

Additionally, a subset of venous channels traverses the cribriform plate, establishing connections with veins on the orbital surface of the frontal lobes of the brain. This complex venous network is of clinical significance due to valveless venous communications, which facilitate the potential spread of infections from the nasal cavity to intracranial structures. Such venous connections highlight the anatomical and pathological importance of the nasal venous system, particularly in the context of rhinogenic intracranial complications.

Nerve Innervation of the Nasal Cavity

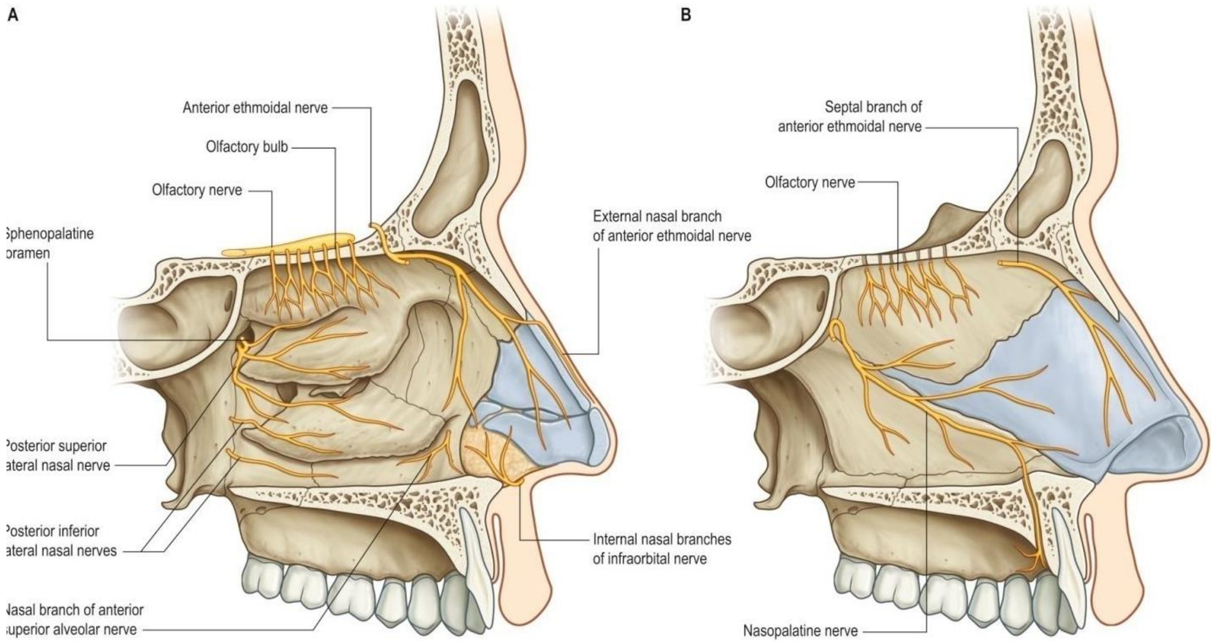


Figure 6: The innervation of the nasal cavity. A, The lateral wall of the left nasal cavity. B, The medial wall of the right nasal cavity. With permission from Drake RL, Vogl AW, Mitchell A (eds) Gray's Anatomy for Students, 2nd ed. Elsevier, Churchill Livingsto

1. Olfactory Innervation

Olfaction is mediated by the olfactory nerves, consisting of multiple small axonal bundles originating from the olfactory receptor neurons in the olfactory mucosa.

2. General Sensory Innervation

General sensory innervation of the nasal mucosa, including touch, pain, and temperature sensation, is provided by branches of the ophthalmic (V1) and maxillary (V2) divisions of the trigeminal nerve.

- Anterior Ethmoidal Nerve (Branch of the Nasociliary Nerve, V1):
    - Supplies the roof of the nasal cavity.
    - Emerges at the inferior margin of the nasal bone as the external nasal nerve.
    - Innervates the skin of the external nose, including the nasal tip.

    - Trauma to this region may result in paresthesia of the nasal tip.
- Infraorbital Nerve (Branch of V2):
    - Innervates the nasal vestibule.
- Anterior Superior Alveolar Nerve (Branch of V2):
    - Provides sensory innervation to:
        - Part of the nasal septum.
        - The floor of the nasal cavity near the anterior nasal spine.
        - The anterior portion of the lateral nasal wall.
- Lateral and Medial Posterior Superior Nasal Nerves (Branches of the Greater Palatine Nerve, V2):
    - Together supply the posterior three-quarters of the lateral nasal wall, roof, and floor.
- Posterior Inferior Nasal Branches (Branches of the Greater Palatine Nerve, V2):
    - Innervate the posterior portion of the lateral nasal wall.
- Nasopalatine Nerve (Branch of V2):
    - Provides sensory input to the inferior portion of the nasal septum.
- Nerve of the Pterygoid Canal (Vidian Nerve):
    - Contributes to the innervation of the upper and posterior regions of the nasal roof and septum.

3. Autonomic Innervation

Autonomic innervation of the nasal cavity regulates mucous gland secretion and vasomotor activity.

- Sympathetic Innervation:
    - Postganglionic sympathetic fibers arise from the deep petrosal nerve.
- Parasympathetic Innervation
    - Preganglionic parasympathetic fibers are conveyed via the greater petrosal nerve.
- Nerve of the Pterygoid Canal (Vidian Nerve):
    - Formed by the convergence of the deep petrosal (sympathetic) and greater petrosal (parasympathetic) nerves.
    - Transmits autonomic fibers to the nasal cavity through the Vidian canal.

Intranasal Administration of Medication

The human nasal cavity is an effective and accessible route for drug administration. Its anatomical and physiological characteristics facilitate rapid drug absorption, making it a valuable alternative to oral and parenteral routes, particularly in emergency and pediatric settings.

The adult nasal cavity has a volume of approximately 15 to 20 mL and a total surface area of around 150 cm^2(27). It consists of highly vascularized respiratory and olfactory regions, which provide efficient drug absorption(28). Notably, blood flow in the nasal mucosa exceeds that of muscle, brain, or liver tissue per cubic centimeter, enhancing drug bioavailability(29).

The olfactory mucosa is theorized to offer a direct pathway to the brain, bypassing first-pass metabolism associated with oral drug administration(10,30). This unique characteristic makes the intranasal (IN) route particularly suitable for delivering central nervous system (CNS)-targeted therapies.

Drugs suitable for nasal mucosal delivery generally exhibit the following properties:

- Low molecular weight for optimal absorption.
- Stability within the nasal environment.
- Solubility in the aqueous mucus lining of the nasal passages (31).

The IN route represents a painless, needle-free, and non-invasive method of drug delivery.

Key advantages include:

- Rapid absorption due to the high vascularity of the nasal mucosa.
- Bypassing of first-pass metabolism, leading to improved bioavailability.
- Ease of administration, particularly in uncooperative or pediatric patients(32).
- Avoidance of injection-related complications, such as nerve injury, inadvertent intravenous or arterial injection, or infection(33).

Clinical Applications

Intranasal drug delivery is widely studied for emergency and paediatric use. Drugs commonly explored for IN administration include:

- Opioid antagonists (e.g., naloxone) for opioid overdose reversal.
- Benzodiazepines (e.g., midazolam) for acute seizure management.
- Analgesics (e.g., fentanyl, sufentanil, ketamine) for pain control.
- Sedatives (e.g., dexmedetomidine) for procedural sedation.

The paediatric population has been a major focus of IN drug research. In paediatric emergency medicine, IN administration is an effective alternative to intravenous or intramuscular routes, particularly for managing pain, sedation, and seizures in uncooperative patients.

Limitations and Contraindications

While intranasal drug delivery is highly effective, certain factors may reduce drug absorption, necessitating dose adjustments or repeated administration(31). These include:

- Abnormal nasal anatomy (e.g., deviated nasal septum, nasal polyps).
- Increased mucous production may impede drug contact with the mucosa.

There are no absolute contraindications to IN drug administration except for allergies to the medication(31).

Intranasal drug delivery presents a promising, non-invasive alternative for medication administration, particularly in emergency and pediatric settings. Its ability to provide rapid drug absorption, avoid first-pass metabolism, and eliminate the need for injections makes it a valuable route of administration. Further research is warranted to optimize dosing strategies, enhance drug formulations, and expand clinical applications.

Ketamine

Ketamine, a phencyclidine derivative, induces "dissociative anaesthesia" by disrupting the thalamocortical and limbic systems(34,35). This results in amnesia and profound analgesia.

Ketamine exists as two optical isomers(35): S (1)-ketamine (left-handed) and R (2)-ketamine (right-handed). S (1)-ketamine is associated with (a) more intense analgesia, (b) faster metabolism and recovery, (c) reduced salivation, and (d) a lower incidence of emergence reactions compared to R (2)-ketamine(36,37). The preservative used in ketamine formulations is benzethonium chloride(38).

Mechanism of action

Ketamine binds non-competitively to N-methyl-D-aspartate (NMDA) receptors, inhibiting their activation and reducing presynaptic glutamate release. It also interacts with μ, δ, and κ opioid receptors and activates descending inhibitory monoaminergic pain pathways by binding to monoaminergic receptors. Additionally, ketamine affects muscarinic receptors, voltage-sensitive sodium and L-type calcium channels, and neuronal nicotinic acetylcholine receptors to produce analgesia(39,40). It has minimal effects on gamma-aminobutyric acid (GABA) -A receptors. Ketamine suppresses neutrophil production of inflammatory mediators and enhances blood flow(41) by preventing neutrophil adherence to blood vessels, which can be impaired by local inflammation from nerve root compression. Its direct inhibition of cytokines in the blood may further contribute to its analgesic effects(38).

Pharmacokinetics

Ketamine exhibits a rapid onset of action, a relatively short duration, and high lipid solubility. With a pKa of 7.5 at physiological pH, peak plasma concentrations are reached within 1 minute after intravenous administration and 5 minutes after intramuscular injection. Due to its high lipid solubility, ketamine quickly crosses the blood-brain barrier and increases cerebral blood flow, enhancing brain concentration. It is then redistributed from highly perfused to less perfused tissues, contributing to delayed psychodynamic effects upon emergence. Ketamine has a high hepatic clearance rate and a large volume of distribution, resulting in an elimination half-life of 2 to 3 hours(38).

Metabolism

Ketamine is metabolized by hepatic microsomal enzymes, with cytochrome P450 enzymes demethylating it to form the active metabolite norketamine(42). This metabolite contributes to the prolonged analgesic effects of ketamine. Norketamine is subsequently hydroxylated and conjugated to form inactive glucuronide metabolites, which are excreted by the kidneys. Chronic ketamine administration induces the enzymes responsible for its metabolism, leading to accelerated clearance and explaining the development of tolerance to its analgesic effects(38).

Clinical Uses

Ketamine is distinctive for providing intense analgesia at sub anaesthetic doses and inducing rapid anaesthesia when administered intravenously at higher doses. To mitigate the risk of coughing and laryngospasm caused by ketamine-induced salivation, the use of an anti-sialagogue in preoperative medication is often advised.

Analgesia

Intense analgesia can be achieved with sub anaesthetic doses of ketamine, ranging from 0.2 to 0.5 mg/kg intravenously(43). Plasma concentrations required for analgesia are lower after oral administration than intramuscular administration, likely due to higher norketamine levels resulting from hepatic first-pass metabolism following oral intake.

Ketamine is believed to provide greater analgesia for somatic pain compared to visceral pain. Its analgesic effects are likely attributed to its activity within the thalamic and limbic systems, crucial for interpreting painful stimuli.

NMDA receptors, excitatory amino acid receptors, are crucial in pain processing and modulation(44). Glutamate, an excitatory amino acid, significantly impacts spinal nociceptive pathways through NMDA receptors. Inhibitors of spinal NMDA receptors, such as ketamine, magnesium, and dextromethorphan, effectively manage postoperative pain and reduce analgesic requirements. Ketamine serves as a valuable analgesic adjunct for patients with chronic pain syndromes undergoing surgery.

Due to its potent analgesic effects, ketamine is widely used for burn dressing changes, debridements, and skin grafting. Its ability to provide excellent analgesia while preserving spontaneous ventilation—particularly in cases complicated by burn scar contractures—represents a significant advantage in these procedures(45).

Induction of Anaesthesia

Anaesthesia is induced with ketamine administered intravenously at 1 to 2 mg/kg or intramuscularly at 4 to 8 mg/kg. Loss of consciousness occurs within 30 to 60 seconds after intravenous administration and 2 to 4 minutes after intramuscular injection. Consciousness typically returns within 10 to 20 minutes following an induction dose, though full orientation may take an additional 60 to 90 minutes.

Amnesia generally lasts 60 to 90 minutes post-recovery, but ketamine does not cause retrograde amnesia. Due to its rapid onset, ketamine is used for induction in children and individuals with intellectual disabilities. In acute hypovolemic patients, ketamine's cardiovascular-stimulating effects are leveraged for induction.

Combining sub anaesthetic doses of ketamine with propofol for total intravenous anaesthesia has been shown to maintain more stable hemodynamics compared to propofol and fentanyl while minimizing the undesirable emergence reactions associated with higher ketamine doses(46). Ketamine's bronchodilatory effects can be advantageous for rapid intravenous induction in patients with asthma(47).

However, ketamine should be used with caution or avoided in patients with systemic or pulmonary hypertension or increased intracranial pressure(38). In small doses, ketamine has been found to alleviate postoperative depressive symptoms in individuals with mental depression(48). Additionally, ketamine has been employed in sub anaesthetic doses to manage bronchospasm in the operating room and Intensive care unit (ICU), with reported success in treating status asthmaticus.

Side Effects

Ketamine is notable among inducing agents for its cardiovascular stimulating effects and its propensity to cause emergence delirium(34). Patients with intracranial pathology are particularly at risk for sustained increases in intracranial pressure following ketamine administration.

Emergence delirium, which may present with visual, auditory, proprioceptive, and confusional illusions, can progress to full delirium in the postoperative period. This condition is likely due to ketamine's effect on the inferior colliculus and medial geniculate nucleus, leading to a distorted perception of sensory stimuli. Factors that increase the likelihood of emergence delirium include (a) age over 15 years, (b) female gender, (c) intravenous doses exceeding 2 mg/kg, and (d) a history of personality disorders or frequent dreaming(42).

To mitigate this phenomenon, administering an intravenous benzodiazepine about 5 minutes before ketamine induction is recommended(49,50).

Postoperative Analgesia(51)

Pain is defined by the International Association for the Study of Pain as: ‘An unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage.’(52)

It consists of sensory, emotional, cognitive, and behavioral components that may be described on the verbal-subjective, motor-behavioral, and physiological levels.

Acute pain serves a useful purpose to protect the body from further harm and allow tissue healing and normally resolves with healing of the underlying injury. Chronic pain is pain that lasts or recurs for longer than 3 months, disrupts sleep and normal living, ceases to serve a protective function, and instead degrades health and function.

Patients at greatest risk of adverse outcomes from undertreated acute postoperative pain include those at the extremes of age or who have concurrent medical illnesses. Inadequately treated acute pain is also a risk factor for poor wound healing, delayed discharge, and the development of chronic pain.

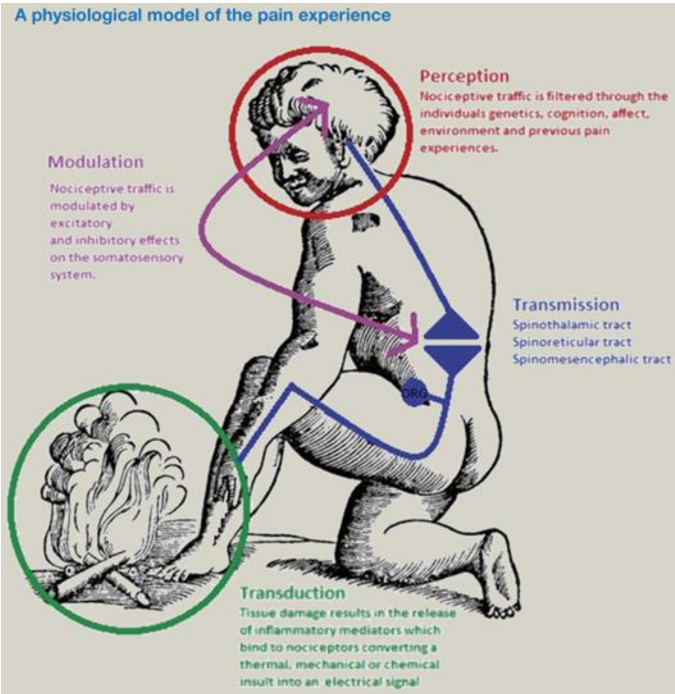


Figure 7: Anaesthesia and Intensive Care Medicine 23:130. 2021 Published by Elsevier Ltd.

Physiology of Postoperative Pain

Postoperative pain development involves complex mechanisms that include both physiological and psychological factors. Understanding these mechanisms is crucial for managing and preventing chronic pain after surgery.

Key Mechanisms of Postoperative Pain Development

- Peripheral and Central Sensitization:

Peripheral sensitization involves the activation of nociceptors at the site of injury, leading to increased pain sensitivity(52,53).

Central sensitization occurs in the spinal cord and brain, where persistent noxious signaling and maladaptive neuroplastic changes enhance pain perception(54–56).

- Neuroinflammation:

Inflammatory mediators, such as interleukin-1β, released by the innate immune system, contribute to the sensitization of sensory neurons(57).

The NLRP3 inflammasome plays a role in this process, and its selective inhibition may reduce postoperative pain without compromising healing (57).

- Neuroplastic Changes:

Long-term synaptic plasticity in the central nervous system, driven by inflammation and nerve injury, maintains pain signaling and contributes to pain sensitization(53,58).

- Psychological Factors:

Psychological elements, including anxiety, depression, and pain catastrophizing, significantly influence the perception and development of postoperative pain(58).

- Genetic and Hormonal Influences:

Genetic predispositions and hormonal changes, such as variations in estrogen levels, can affect pain sensitivity and the development of postoperative pain (58).

Effective management requires a multidisciplinary approach addressing physiological and psychological aspects to improve patient outcomes and prevent chronic pain development.

Principles of Postoperative Pain Management(51,59)

The injury and consequent acute pain trigger complex hemodynamic, metabolic, humoral, immune, and somatosensory responses. Elevated levels of cortisol, catecholamines, and glucagon are seen in experimental studies, with a decrease in insulin sensitivity.

Preoperative and postoperative rehabilitation, including pharmacological, physical, psychological, and nutritional components, has led to enhanced recovery protocols, which should be person and surgery-specific. Multimodal analgesia, compared to mainly opioid-based analgesia, improves pain control and reduces opioid consumption and adverse effects, thereby enhancing recovery.

Effective pain management is a core component of enhanced recovery after surgery.

Assessment of Postoperative Pain(51,60)

The most reliable assessment of postoperative pain is patient self-report, which can give accurate information on the nature, location, intensity, and impact of the pain on function.

Frequent assessment is essential to determine the response to treatment and recognition of adverse side effects.

Careful observation of the patient will reveal behavioral responses to pain, such as grimacing, reduced movement, or splinting of the operative site. There are also physiological responses to acute pain that may indicate that a patient is experiencing pain. Pain can cause tachycardia, hypertension, sweating, pupillary dilatation, and lacrimation.

Assessment of Pain In Paediatric Patients(61–63)

Managing analgesia and sedation in pediatric patients remains a significant clinical challenge, particularly in the postoperative period. Children in these settings experience pain from various sources, including postsurgical, disease-related, device-related, and treatment-related causes. Routine care practices, such as repositioning and mobilization, which were once considered mere triggers of agitation, are now recognized as significant sources of pain.

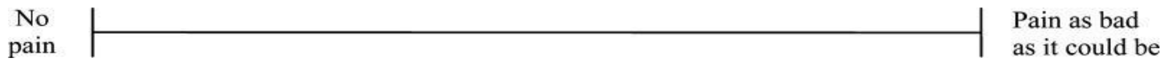
To address these challenges, analgesia must be carefully balanced. Inadequate analgesia can result in excessive pain and anxiety, post-traumatic stress disorder, and aversion to future medical care. Despite these known risks, studies consistently report suboptimal management of both pain and sedation in the pediatric population.

Assessing pain in sedated children is inherently complex, primarily due to age-related variations in pain expression and the inability of many patients to self-report. While self-reporting is the gold standard for pain assessment in children aged six years and older, its reliability can be influenced by factors such as fear of caregiver disapproval, cultural attitudes toward pain, or fear of injections. Validated behavioral pain scales are essential for younger children or those with developmental delays.

Pain expression variation across developmental stages necessitates using age-appropriate and context-specific assessment tools. Clinicians must rely on their judgment to select the most suitable tool, considering the child's verbal and cognitive abilities, clinical status, and the specific type of pain being addressed.

In terms of pharmacological management, ketamine has emerged as a valuable option for pediatric analgesia due to its favorable safety profile. It maintains hemodynamic stability and respiratory function, making it effective as a standalone analgesic for procedural pain or as an adjunct to opioids in the postoperative period. Subanesthetic doses of ketamine have been shown to reduce both pain intensity and opioid requirements. However, further research is needed to determine its optimal dosing, duration, and role within multimodal pain management strategies for children.

Visual Analog Scales



The Visual Analogue Scale (VAS) is a widely used tool for measuring pain intensity, offering a simple and direct method for patients to express their pain levels.

Children older than 5 or 6 years can use a VAS reliably and validly.

To use a VAS, a child must have the cognitive ability to translate the pain experience into an analog format and understand proportionality.

Various forms of VAS exist, including linear horizontal and vertical scales, curvilinear scales, and graded scales. VAS have either a vertical or a horizontal line, usually 10 cm long, with verbal or pictorial anchors indicating a continuum from no pain to severe pain. Children are asked to indicate on the line how much pain they are experiencing. Some have suggested that a vertical scale is more appropriate than a horizontal scale because children may find it easier to conceptualize the notion of greater or lesser intensity of pain with up and down rather than left or right.

VAS has been validated as a ratio scale, meaning it can accurately reflect proportional differences in pain intensity. This property is beneficial for comparing different pain levels and assessing treatment efficacy (64)

VAS has been shown to have excellent psychometric properties, including validity and sensitivity to change, which are essential for tracking pain over time and evaluating the impact of interventions(65). The VAS is generally reliable for measuring acute pain, with high intraclass correlation coefficients indicating consistent results over repeated measures.

VAS remains a valuable tool in research and clinical settings due to its simplicity and ease of use. It is particularly effective in acute pain scenarios where rapid assessment is necessary(66), and its application should be carefully considered based on the context and population.

Visual analogue scales are advantageous for pain measurement due to their sensitivity, reliability, and user preference. They provide a nuanced and accurate assessment of pain intensity, making them a valuable tool in clinical practice and research. Their ability to function as a ratio scale further enhances their utility in evaluating treatment outcomes and comparing pain levels across different contexts.

The Children's Hospital of Eastern Ontario Pain Scale (CHEOPS)

CHEOPS (McGrath et al., 1985) is a widely used behavioral pain assessment tool for pediatric pain management, particularly in postoperative and procedural settings. It is designed to evaluate pain based on observable behaviors such as crying, facial expressions, verbal expressions, torso movement, touch, and leg movement, with each behavior assigned a score. The total score ranges from 4 to 13, with higher scores indicating more severe pain. (67–69)

Children's Hospital of Eastern Ontario Pain Scale (CHEOPS)[a]

Item	Behavioral	Score	Definition
Cry	No cry	1	Child is not crying.
	Moaning	2	Child is moaning or quietly vocalizing silent cry.
	Crying	2	Child is crying, but the cry is gentle or whimpering.
	Scream	3	Child is in full-lunged cry; sobbing: May be scored with complaint or without complaint.
Facial	Composed	1	Child has neutral facial expression.
	Grimace	2	Score only if definite negative facial expression.
	Smiling	0	Score only if definite positive facial expression.
Child verbal	None	1	Child is not talking.
	Other complaints	1	Child complains, but not about pain, e.g., "I want to see mommy" or "I am thirsty."
	Pain complaints	2	Child complains about pain.
	Both complaints	2	Child complains about pain and about other things, e.g., "It hurts; I want my mommy."
	Positive	0	Child makes any positive statement or talks about others things without complaint.
Torso	Neutral	1	Body (not limbs) is at rest; torso is inactive.
	Shifting	2	Body is in motion in a shifting or serpentine fashion.
	Tense	2	Body is arched or rigid.
	Shivering	2	Body is shuddering or shaking involuntarily.
	Upright	2	Child is in a vertical or in upright position.
	Restrained	2	Body is restrained.
Touch	Not touching	1	Child is not touching or grabbing at wound.
	Reach	2	Child is reaching for but not touching wound.
	Touch	2	Child is gently touching wound or wound area.
	Grab	2	Child is grabbing vigorously at wound.
	Restrained	2	Child's arms are restrained.
Legs	Neutral	1	Legs may be in any position but are relaxed; includes gentle swimming or discrete movements.
	Squirming/ kicking	2	Definitive uneasy or restless movements in the legs and/or striking out with foot or feet.
	Drawn up/tensed	2	Legs tensed and/or pulled up tightly to body and kept there.
	Standing	2	Standing, crouching, or kneeling.
	Restrained	2	Child's legs are being held down.

CHEOPS is used in various clinical contexts, including postoperative care, procedural pain assessment, and in guiding pain management decisions. For example, the scale has proven effective in predicting postoperative pain control in children undergoing tonsillectomy, where a score of ≥ 7 correlates with increased complications, underscoring the importance of optimizing pain management to enhance patient outcomes (70). In K-wire removal from the elbow, the CHEOPS score has indicated minimal pain in most children, confirming that the procedure is generally well-tolerated and safe when assessed using the tool (68).

CHEOPS has also been employed to assess procedural distress in children undergoing forearm fracture manipulation, where no significant difference in pain scores was observed between those receiving different types of anesthesia, indicating the tool's reliability across varying anesthesia protocols (71). Furthermore, during laceration repair, using a 50% nitrous oxide/oxygen mixture significantly reduced CHEOPS scores compared to 100% oxygen, highlighting the scale's ability to assess and influence procedural pain management strategies (72).

CHEOPS has been validated for use in a broad age range, from infancy to older childhood, with adaptations available for infants (69,73). Studies show that it has high reliability and validity in infant pain assessment, particularly during procedures such as immunizations (69). Additionally, the scale is effective when used by healthcare professionals and trained parents, with studies reporting strong agreement between parental and nurse ratings, further demonstrating its accessibility and ease of use .

CHEOPS has been cross-validated with other pain scales such as the Objective Pain Scale (OPS), Toddler Preschool Postoperative Pain Scale (TPPPS), and Face, Legs, Activity, Cry, and Consolability scale (FLACC). It showed positive correlations with these scales, supporting its concurrent validity(67).

In some studies, CHEOPS was found to have better agreement with clinical decisions to treat pain compared to other scales, making it a practical choice for pain assessment in clinical settings(70).

CHEOPS remains a reliable, valid, and versatile tool for assessing pain in pediatric patients across various clinical settings. It is particularly useful in guiding postoperative pain management and procedural interventions.

WILSON SEDATION SCALE

Score	Degree of sedation
1	Fully awake, orientated
2	Lethargic
3	Opens eyes with verbal stimulus
4	Opens eyes with moderate pain
5	Does not respond moderate pain

The Wilson Sedation Score is a tool used to assess the level of sedation in patients undergoing various medical procedures. It is particularly useful in settings where sedation needs to be carefully monitored and adjusted, such as during anesthesia or in intensive care units.

The Wilson Sedation Score is a reliable method for assessing sedation levels. Observer-based methods, like the Wilson scale, are preferred over machine-based methods due to their reliability across different levels of sedation. Studies have demonstrated that the modified Wilson scale provides a simple and reliable means to assess and monitor intraoperative sedation, with good interrater reliability when standardized stimuli are used (74).

The Wilson Sedation Score monitors sedation levels in various clinical settings. For instance, it has been used to assess sedation during propofol infusion, where a score of 4 on the Wilson scale was associated with significant suppression of spinal motor neuron excitability (75). Additionally, it has been applied in pediatric settings to evaluate the efficacy of sedation protocols, such as the combination of midazolam and ketamine, which showed optimal sedation in a significant portion of patients (76).

In clinical practice, the Wilson Sedation Score is used to guide sedation protocols and adjustments. For example, in a study involving midazolam, the score was used to determine the appropriate dosing to maintain sedation while allowing for recovery of dynamic balance and psychomotor function within a reasonable timeframe (77). Similarly, in pediatric sedation, the score helps ensure that sedation levels remain within safe limits, avoiding the need for general anesthesia (78).

The Wilson Sedation Score is valuable for assessing and managing sedation in various medical contexts. Its reliability and ease of use make it a preferred choice for clinicians aiming to maintain appropriate sedation levels while minimizing risks and side effects. The score's application across different patient populations and sedation protocols underscores its versatility and importance in clinical practice(74–78).

MATERIALS AND METHODS

Source of Data: Patients aged 5 years - 18 years, of either sex, belonging to ASA grade I and II, undergoing surgical procedures under general anesthesia in KLE's Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehru Nagar, Belagavi 590010.

Study Design: Randomized Control Trial

Study Period: A one-year study

Sample Size:

At a 95 % confidence interval and 85% power sample size is calculated as

$$n = \frac{\left(z_{1-\frac{\alpha}{2}} + z_{1-\beta}\right)^2 \times \ (SD_1^2 + SD_2^2)}{(\bar{x}_1 - \bar{x}_2)^2}$$

$$n = \frac{(1.96 + 1.04)^2 \times (0.36 + 0.16)}{(1.4 - 1.1)^2}$$

$$n = 52\ per\ group$$

So, the minimum required sample size is 2 * n = 2* 52 = 104

The children were randomized into two groups.

Fifty-two children in Group 1 received 1 mg/kg of Intranasal Ketamine with tuberculin syringe and fifty-two children in Group- 2 equal amounts of normal Saline with tuberculin syringe intranasally.

References:

- Yenigun, A., Yilmaz, S., Dogan, R., Goktas, S. S., Calim, M., & Ozturan, O. (2017). Demonstration of analgesic effect of intranasal ketamine and intranasal fentanyl for postoperative pain after pediatric tonsillectomy. International Journal of Pediatric Otorhinolaryngology, 104, 182–185. https://doi.org/10.1016/j.ijporl.2017.11.018 (25)

Sampling technique: Randomized sampling

Inclusion Criteria

1. Children in the age group of 5 to 18 years undergoing surgery under general anesthesia.
2. Children in ASA Grade I – II

Exclusion Criteria

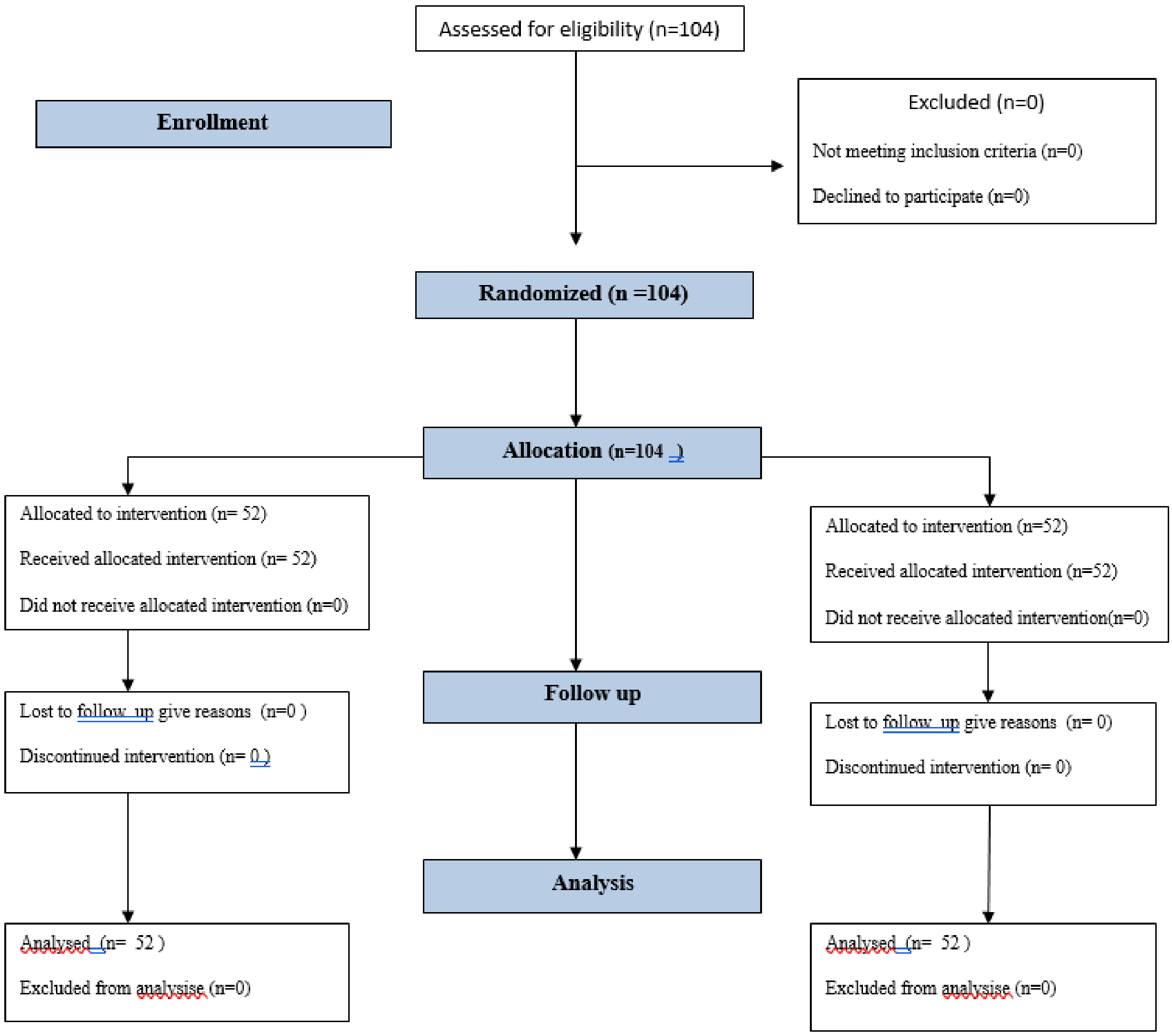
Children with:

1. Allergy to the study drug
2. ASA grade III or >III
3. Aberrant nasal anatomy that precludes intranasal medications.
4. Patients undergoing any nasal surgery

Ethical considerations:

The research protocol was approved by the Institutional Ethics Committee (MDC/JNMCIEC/67) and Clinical Trials Registry- India (CTRI/2023/07/055681), and 104 patients fulfilled the inclusion and exclusion criteria. The study adhered to the ethical principles for medical research as outlined by the World Medical Association's Declaration of Helsinki.

Study protocol: CONSORT flow chart



Randomization and Group Assignment:

Preoperative preparation:

On the day before surgery, the child underwent a thorough pre-anesthetic evaluation to determine the fitness for the surgery under anesthesia. Routine investigations such as complete blood count and coagulation profile were done, and other investigations were performed on a patient-by-patient basis. Parents/legal guardians of the participating children were thoroughly informed about the study's objectives, clinical procedures, treatment outcomes, and the risks and benefits of the procedure. After all their questions had been answered, their informed written consent was obtained. Children aged over

6 years also gave their assent. Each child participant was assigned an identification number to ensure confidentiality. Only the principal investigator had access to their records.

Interventions:

On the day of surgery, after confirming NBM status, the child was administered an IV injection of Glycopyrrolate (0.005 mg/kg) and an IV injection of Ketamine (1 mg/kg) in the preoperative room. The child was shifted to the operating theatre, and baseline ECG, SpO2, and NIBP were recorded. Following this, the child was pre-medicated with an injection of Fentanyl (2 mcg/kg) IV and an injection of Midazolam (0.05 mg/kg) IV. Induction was achieved with titrated doses of injection Propofol (1-2 mg/kg) IV, followed by an injection of Atracurium (0.5 mg/kg) IV to facilitate endotracheal intubation. Intraoperatively, the child was maintained with Oxygen and Nitrous oxide 50:50, Isoflurane, and injection of Atracurium IV at 1/4th the loading dose as a maintenance dose. After the completion of the surgical procedure and once closure began, the patient received the medication, either intranasal Ketamine or intranasal Saline, depending on the Group to which the patient was allocated. The patient was blinded to the drug instilled.

Reversal of the general anesthetic effect was performed with injection of Glycopyrrolate (0.01 mg/kg) IV and injection of Neostigmine (0.05 mg/kg) IV, and the patient was extubated once the criteria for extubation were met.

All children received an injection of paracetamol (15 mg/kg) IV for postoperative analgesia.

After the surgery, the patient was transferred to the post-anesthesia care unit for routine care.

Post operative assessment

All children were assessed for postoperative pain and sedation at 15, 30, 45, and 60 minutes, and at 2, 6, 12, and 24 hours post-operatively using the Children's Hospital of Eastern Ontario Pain Scale (CHEOPS) for children less than and equal to seven years of age, Visual Analog Scale for children more than seven years of age, and Wilson Sedation Scale, respectively. At the end of 24 hours, the patient/parent/guardian was asked about pain, Postoperative nausea and vomiting (PONV), nightmares, and hallucinations. The obtained data were subjected to statistical analysis.

STATISTICAL ANALYSIS

Descriptive Analysis: frequency, percentage, mean and standard deviation.

Inferential Analysis:

Mann-Whitney U test was used to compare the means between the two groups when the data was not normally distributed, such as the mean age of the two groups. Independent t-test was used to compare the means between the two groups when the data was normally distributed, such as mean values of pain intensity between the two groups for the two different pain scales, the mean values of the Wilson Sedation Scale between the two groups, and the mean time taken and amount used of the first rescue analgesia between the two groups. The Chi-square test was used to compare the categorical variables between the two groups, such as the distribution of sex across the two groups. Fisher's exact test was used when the expected frequency was less than 5, such as the distribution of side effects between the two groups. The significance level was set at $p < 0.05$ for all statistical tests.

All statistical analyses were performed using open-source statistical software, which included Python libraries such as Pandas, Numpy , and Scipy.

RESULTS

One hundred four selected patients were divided into 2 groups (Group I and II), each with 52 patients. For the children in Group I - 1mg/kg of Intranasal Ketamine was instilled, and for the children in Group II equal amount of normal saline was instilled.

Table 1 and Graph 1 show the distribution of study participants according to their age. In Group 1, the mean age was 11.31 ± 3.46 years, and in Group 2, the mean age was 11.12 ± 4.27 years. The overall mean age was 11.21 ± 3.87 years. No significant difference was observed in the age distribution between the two Groups.

Table 1 – Distribution of participants according to age in years

Age	Mean ± SD		Total (n=104)
	Group 1 (n=52)	Group 2 (n=52)	
	11.31 ± 3.46	11.12 ± 4.27	11.21 ± 3.87
P value	0.88		
Statistically significant ($p<0.05$) Mann-Whitney U Test. Group 1 = Ketamine, Group 2 = Saline			

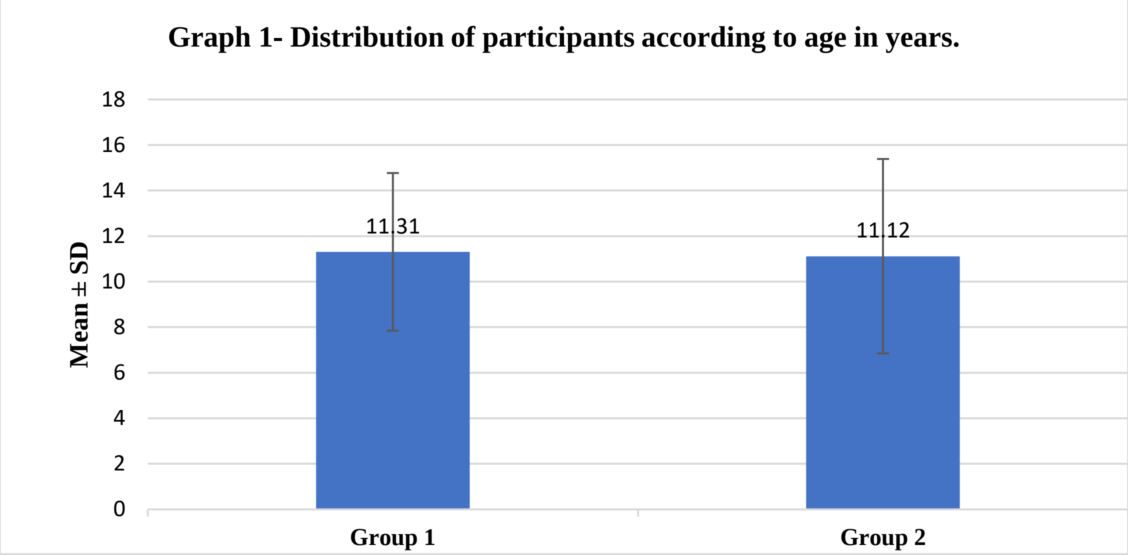


Table 2 and Graph 2 represents the distribution of participants according to sex. In Group 1, 73% were male and 27% were female; in Group 2, 67% were male and 33% were female. There was no significant difference in the sex distribution between the two Groups.

Table 2 – Distribution of participants according to sex

Sex	Group 1 (n=52)	Group 2 (n=52)	Total (n=104)
Male	38 (73%)	35 (67%)	73 (70%)
Female	14 (27%)	17 (33%)	31 (30%)
P value	0.67		
Statistically significant (p<0.05) Chi-Square Test. Group 1 = Ketamine, Group 2 = Saline			

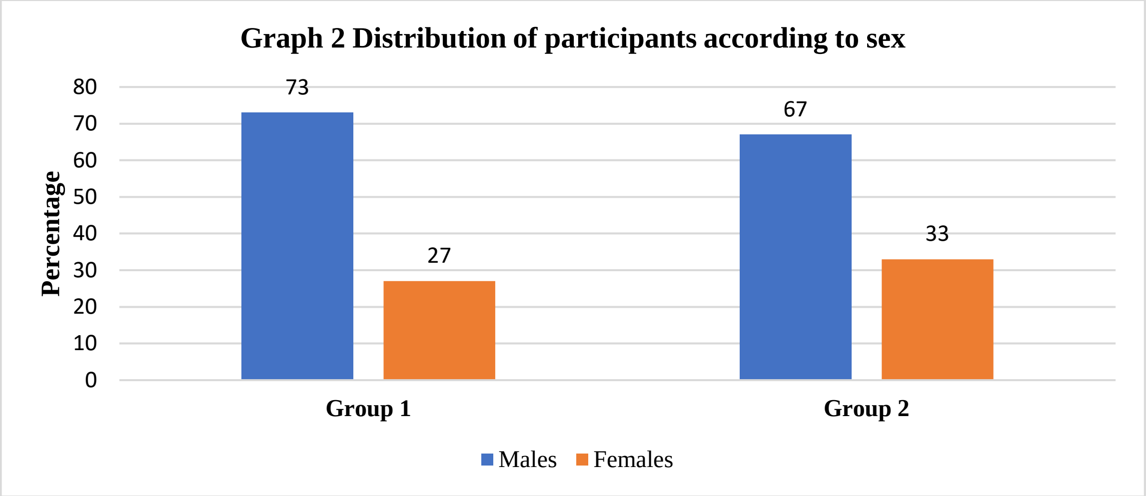


Table 3 and Graph 3 present the mean pain scores at different time intervals for participants under 7 years of age using CHEOPS in Group 1. The mean pain scores were recorded as follows: 15 minutes (5 ± 0), 30 minutes (5 ± 0), 45 minutes (5 ± 0), 60 minutes (5 ± 0), 2 hours (5 ± 0.51), 6 hours (5 ± 0.69), 12 hours (5 ± 0.67), and 24 hours (5 ± 0.69).

Table 3 - Mean value of pain among participants <7 years in Group 1 at different time intervals using CHEOPS.

Time Interval	Group 1 (n=52) Mean ± SD
15 min	5 ± 0
30 min	5 ± 0
45 min	5 ± 0
60 min	5 ± 0
2 hours	5 ± 0.51
6 hours	5 ± 0.69
12 hours	5 ± 0.67
24 hours	5 ± 0.69

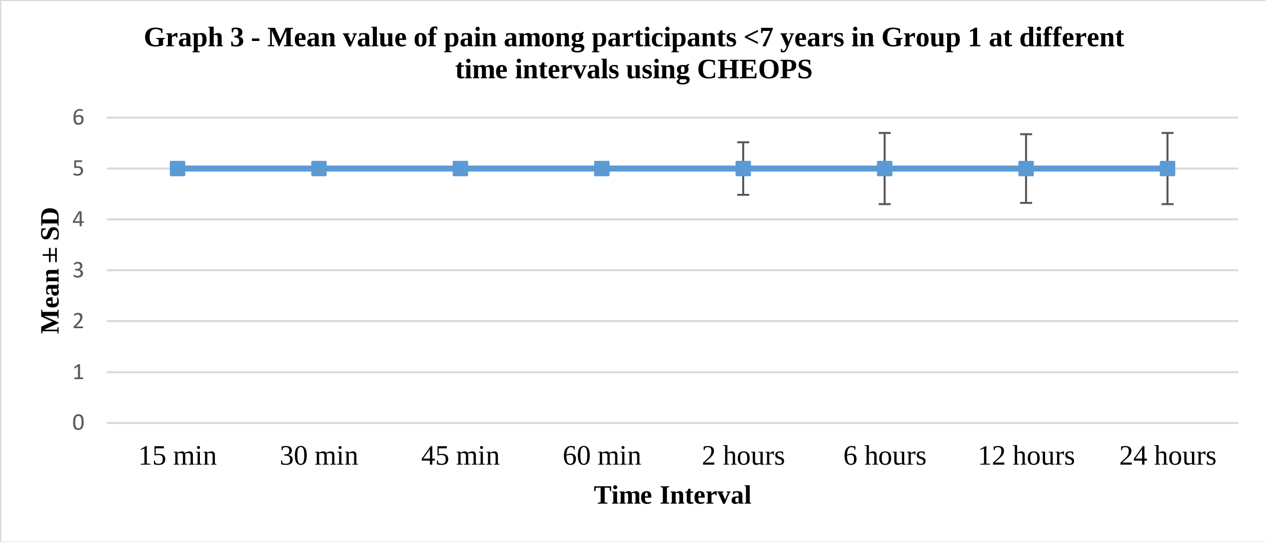


Table 4 and Graph 4 present the mean pain scores at different time intervals for participants under 7 years of age in Group 2 using CHEOPS. The mean scores were: 15 minutes (7.55 ± 0.70), 30 minutes (7.88 ± 0.58), 45 minutes (8.22 ± 0.54), 60 minutes (8.27 ± 0.46), 2 hours (11.33 ± 2.14), 6 hours (5.72 ± 1.40), 12 hours (6.05 ± 0.93), and 24 hours (6 ± 0.97).

Table 4- Mean value of pain among participants <7 years in Group 2 at different time intervals using CHEOPS.

Time Interval	Group 2 (n=52) Mean ± SD
15 min	7.55± 0.70
30 min	7.88± 0.58
45 min	8.22± 0.54
60 min	8.27± 0.46
2 hours	11.33± 2.14
6 hours	5.72 ± 1.40
12 hours	6.05 ± 0.93

24 hours	6 ± 0.97

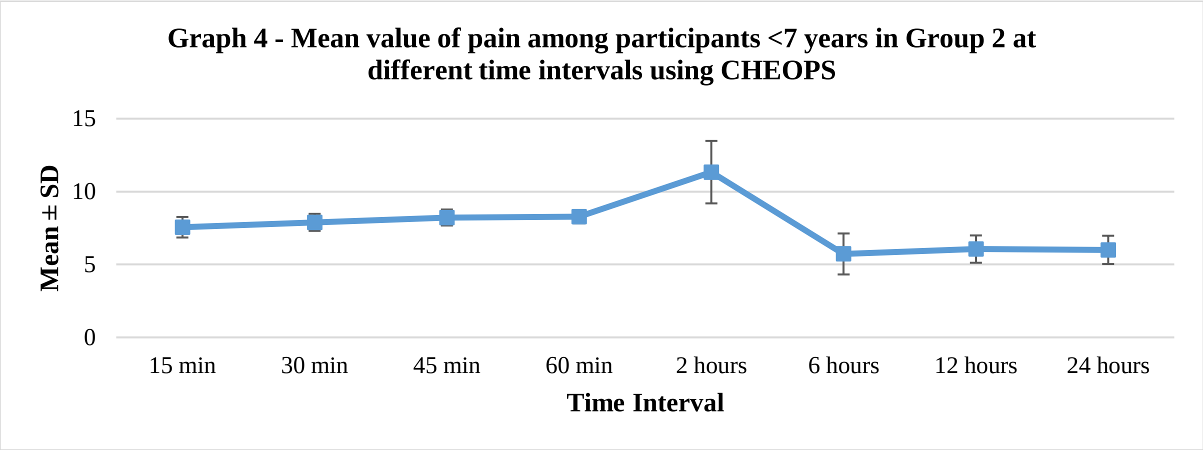


Table 5 and Graph 5 compare the mean pain scores between Group 1 and Group 2 for participants under 7 years of age at different time intervals. Group 1 exhibited significantly lower mean pain scores than Group 2 at 15 minutes, 30 minutes, 45 minutes, 60 minutes, 2 hours, 12 hours, and 24 hours ($p < 0.05$).

Table 5 - Comparison of mean values of pain among participants < 7 years between Group 1 and Group 2 at different interval of time using CHEOPS.

Time interval	Mean ± SD		P value
	Group 1 (n=52)	Group 2 (n=52)	
15 min	5 ± 0	7.55± 0.70	0.0000*
30 min	5 ± 0	7.88± 0.58	0.0000*
45 min	5 ± 0	8.22± 0.54	0.0000*
60 min	5 ± 0	8.27± 0.46	0.0000*
2 hours	5 ± 0.51	11.33± 2.14	0.0040*

6 hours	5 ± 0.69	5.72 ± 1.40	0.7615
12 hours	5 ± 0.67	6.05 ± 0.93	0.0215*
24 hours	5 ± 0.69	6 ± 0.97	0.0714
*Statistically significant (p<0.05) Independent T-Test. Group 1 = Ketamine, Group 2 = Saline			

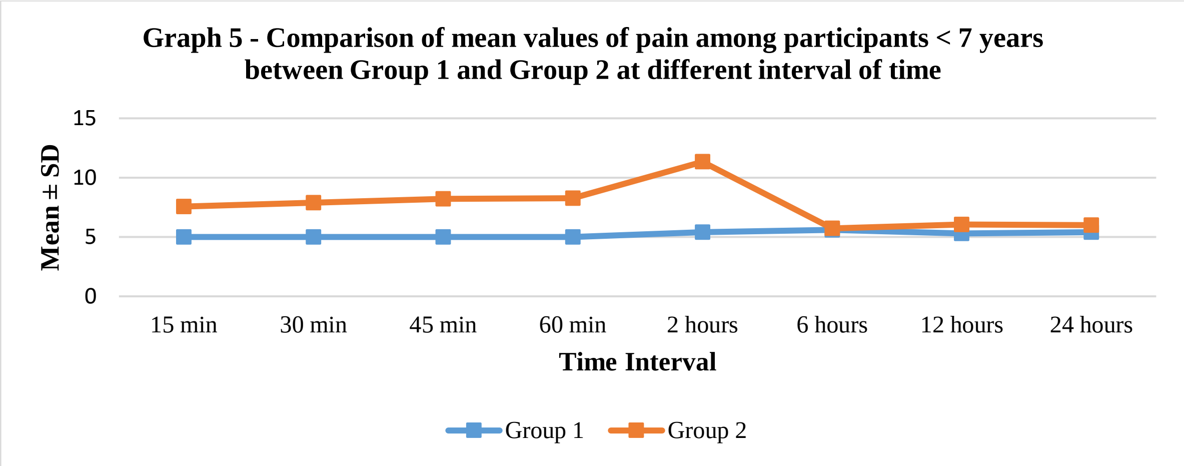


Table 6 and Graph 6 display the mean pain scores at different time intervals for participants over 7 years of age in Group 1 using VAS. The scores were recorded as follows: 15 minutes (0.24 ± 0.43), 30 minutes (0.31 ± 0.47), 45 minutes (0.43 ± 0.5), 60 minutes (0.45 ± 0.5), 2 hours (1.07 ± 0.6), 6 hours (1.1 ± 0.48), 12 hours (0.79 ± 0.42), and 24 hours (0.76 ± 0.43).

Table 6 - Mean value of pain among participants > 7 years in Group 1 at different time intervals using VAS.

Time Interval	Group 1 (n=52) Mean ± SD
15 min	0.24 ± 0.43

30 min	0.31 ± 0.47
45 min	0.43 ± 0.5
60 min	0.45 ± 0.5
2 hours	1.07 ± 0.6
6 hours	1.1 ± 0.48
12 hours	0.79 ± 0.42
24 hours	0.76 ± 0.43

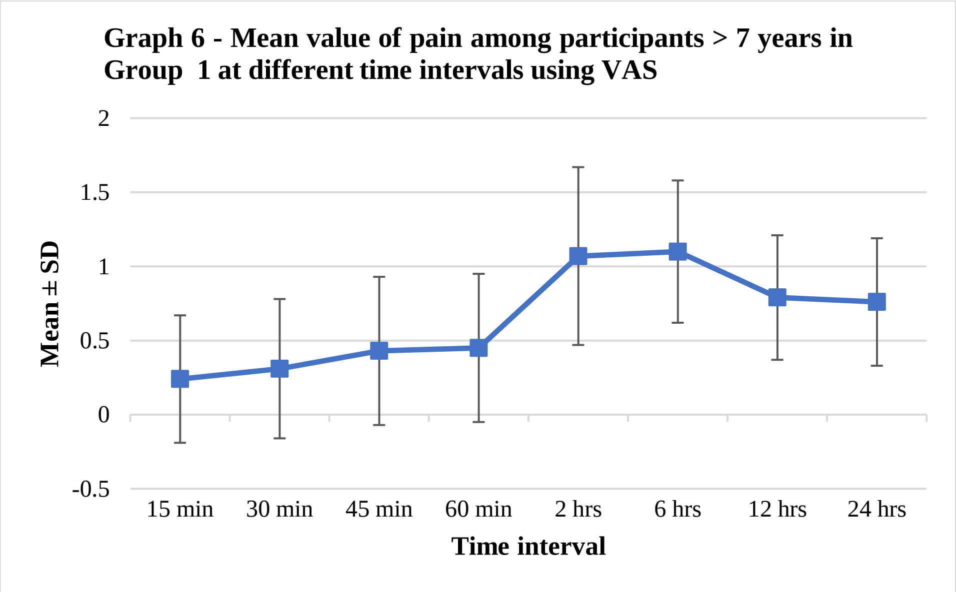


Table 7 and Graph 7 show the mean pain scores at different time intervals for participants over 7 years of age in Group 2. The mean values were: 15 minutes (2.09 ± 0.38), 30 minutes (2.09 ± 0.38), 45 minutes (2.06 ± 0.42), 60 minutes (1.91 ± 0.87), 2 hours (2.65 ± 1.07), 6 hours (1.97 ± 0.94), 12 hours (1.41 ± 0.7), and 24 hours (1.18 ± 0.39).

Table 7 - Mean values of pain among participants > 7 years in Group 2 at different time intervals using VAS.

Time Interval	Group 2 (n=52) Mean ± SD
15 min	2.09 ± 0.38
30 min	2.09 ± 0.38
45 min	2.06 ± 0.42
60 min	1.91 ± 0.87
2 hours	2.65 ± 1.07
6 hours	1.97 ± 0.94
12 hours	1.41 ± 0.7
24 hours	1.18 ± 0.39

Graph 7 - Mean values of pain among participants > 7 years in Group 2 at different time intervals using VAS.

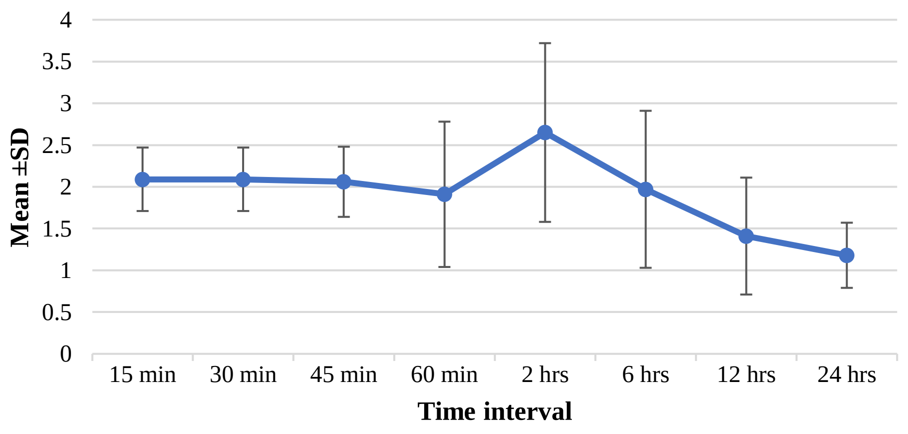


Table 8 and Graph 8 compare the mean pain scores between Group 1 and Group 2 for participants over 7 years of age at different time intervals. Group 1 exhibited significantly lower mean pain scores than Group 2 at all time points ($p < 0.05$).

Table 8 - Comparison of mean values of pain among participants > 7 years between Group 1 and Group 2 at different interval of time using VAS.

Time interval	Mean ± SD		P value
	Group 1 (n=52)	Group 2 (n=52)	
15 min	0.24 ± 0.43	2.09 ± 0.38	0.0000*
30 min	0.31 ± 0.47	2.09 ± 0.38	0.0000*
45 min	0.43 ± 0.5	2.06 ± 0.42	0.0000*
60 min	0.45 ± 0.5	1.91 ± 0.87	0.0000*
2 hours	1.07 ± 0.6	2.65 ± 1.07	0.0000*
6 hours	1.1 ± 0.48	1.97 ± 0.94	0.0000*
12 hours	0.79 ± 0.42	1.41 ± 0.7	0.0000*
24 hours	0.76 ± 0.43	1.18 ± 0.39	0.0000*
*Statistically significant (p<0.05) Independent t- Test. Group 1 = Ketamine, Group 2 = Saline			

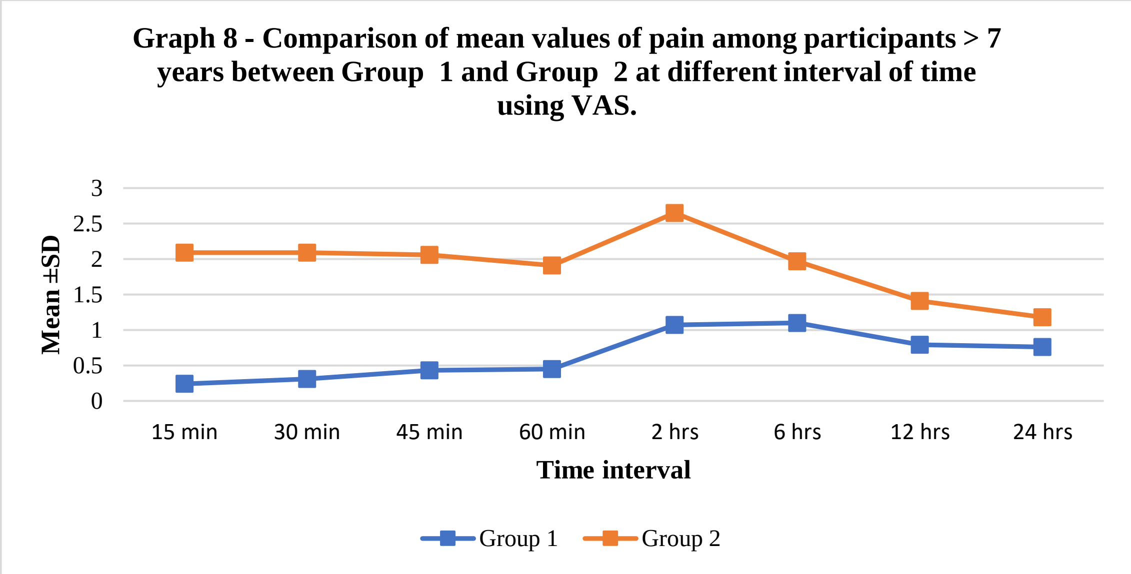


Table 9 and Graph 9 illustrate the mean sedation scores at different time intervals for Group 1 using the Wilson Sedation Score. The mean values were: 15 minutes (2), 30 minutes (1.9 ± 0.3), 45 minutes (1.88 ± 0.32), 60 minutes (1.75 ± 0.44), 2 hours (1), 6 hours (1), 12 hours (1), and 24 hours (1).

Table 9 - Mean values of sedation at different interval of time in Group 1 using Wilson Sedation Score.

Time Interval	Group 1 (n=52) Mean ± SD
15 min	2 ± 0
30 min	1.9 ± 0.3
45 min	1.88 ± 0.32
60 min	1.75 ± 0.44
2 hours	1 ± 0
6 hours	1 ± 0
12 hours	1 ± 0

24 hours	1 ± 0

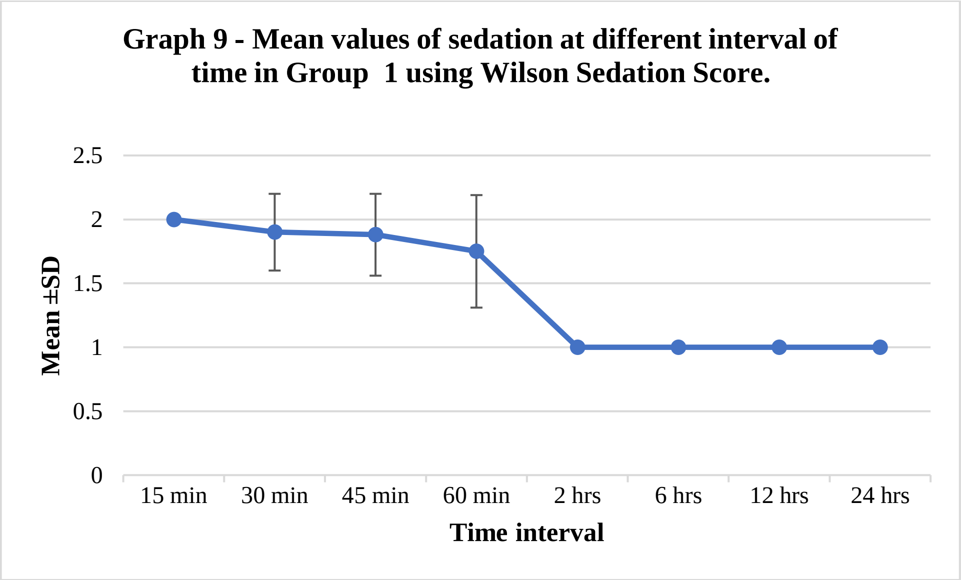


Table 10 and Graph 10 present the mean sedation scores at different time intervals for Group 2 using the Wilson Sedation Score. The mean sedation score remained consistent at 1 across all time points.

Table 10 - Mean values of sedation at different interval of time in Group 2 using the Wilson Sedation Score.

Time Interval	Group 2 (n=52) Mean ± SD
15 min	1 ± 0
30 min	1 ± 0
45 min	1 ± 0
60 min	1 ± 0
2 hours	1 ± 0

6 hours	1 ± 0
12 hours	1 ± 0
24 hours	1 ± 0

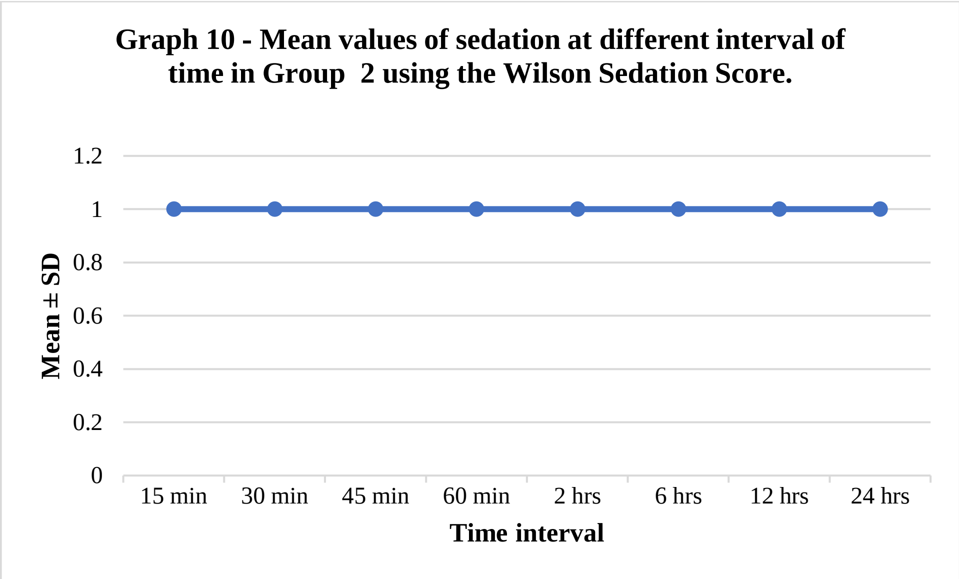


Table 11 and Graph 11 compare the mean Wilson sedation scores between Group 1 and Group 2 at various time intervals. Group 1 exhibited significantly higher sedation scores at 15 minutes, 30 minutes, 45 minutes, and 60 minutes compared to Group 2 ($p < 0.05$).

Table 11 - Comparison of mean values of the Wilson sedation between Group 1 and Group 2 at different time intervals.

Time interval	Mean ± SD		P value
	Group 1 (n=52)	Group 2 (n=52)	
15 min	2 ± 0	1 ± 0	0.0000*
30 min	1.9 ± 0.3	1 ± 0	0.0000*

45 min	1.88 ± 0.32	1 ± 0	0.0000*
60 min	1.75 ± 0.44	1 ± 0	0.0000*
2 hours	1 ± 0	1 ± 0	1.0000
6 hours	1 ± 0	1 ± 0	1.0000
12 hours	1 ± 0	1 ± 0	1.0000
24 hours	1 ± 0	1 ± 0	1.0000
*Statistically significant (p<0.05) Independent t- Test. Group 1 = Ketamine, Group 2 = Saline			

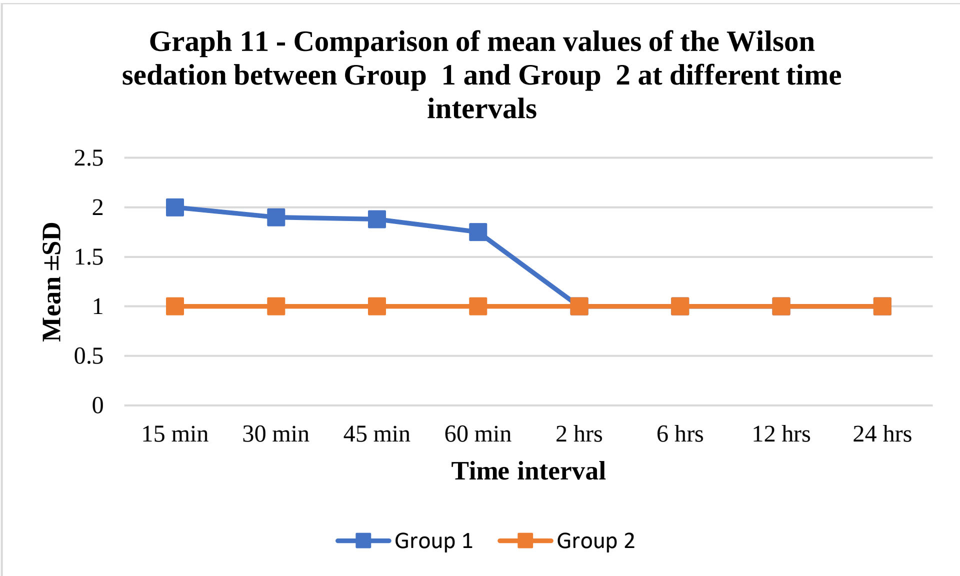


Table 12 and Graph 12 also compare the mean time for the first rescue analgesic dose between Group 1 and Group 2. Group 1 demonstrated a significantly longer duration before requiring the first rescue analgesia than Group 2 ($p < 0.05$).

Table 12 – Mean time for first rescue analgesia in Group 1 and Group 2

Group	Mean ± SD (min)	P value
Group 1	720.00 ± 174.63	0.0000000*
Group 2	160.67 ± 96.44	
*Statistically significant (p<0.05) Independent T-Test. Group 1 = Ketamine, Group 2 = Saline		

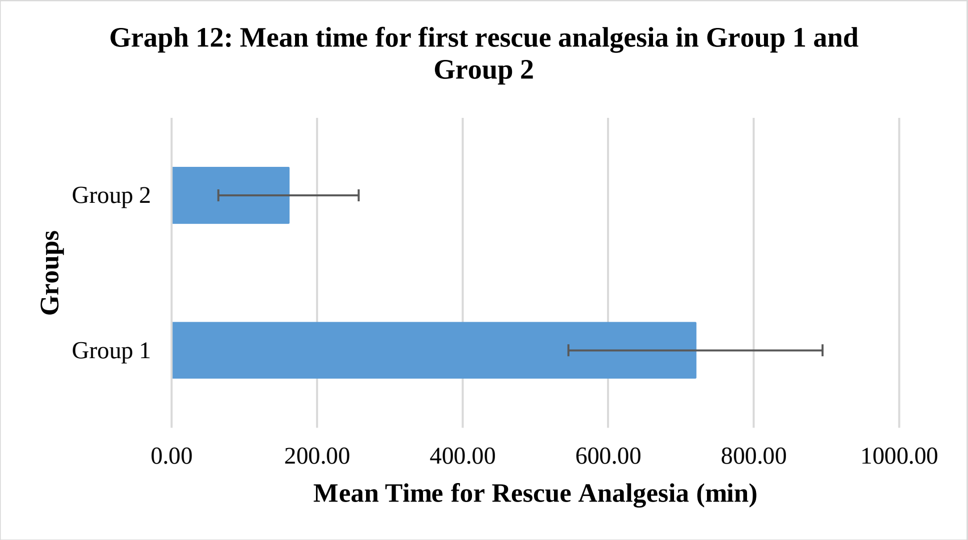


Table 13 and Graph 13 examined the mean amount of analgesic drug required in the first 24 hours between Group 1 and Group 2. Group 1 required a significantly lower amount of analgesic drug compared to Group 2 ($p < 0.05$).

Table 13: Total amount of analgesia required in first 24 hours in mg between Group 1 and Group 2.

Group	Mean ± SD (mg)	P value
Group 1	436.44 ± 168.93	0.0000000*
Group 2	1113.75 ± 544.46	
*Statistically significant (p<0.05) Independent T Test. Group 1 = Ketamine, Group 2 = Saline		

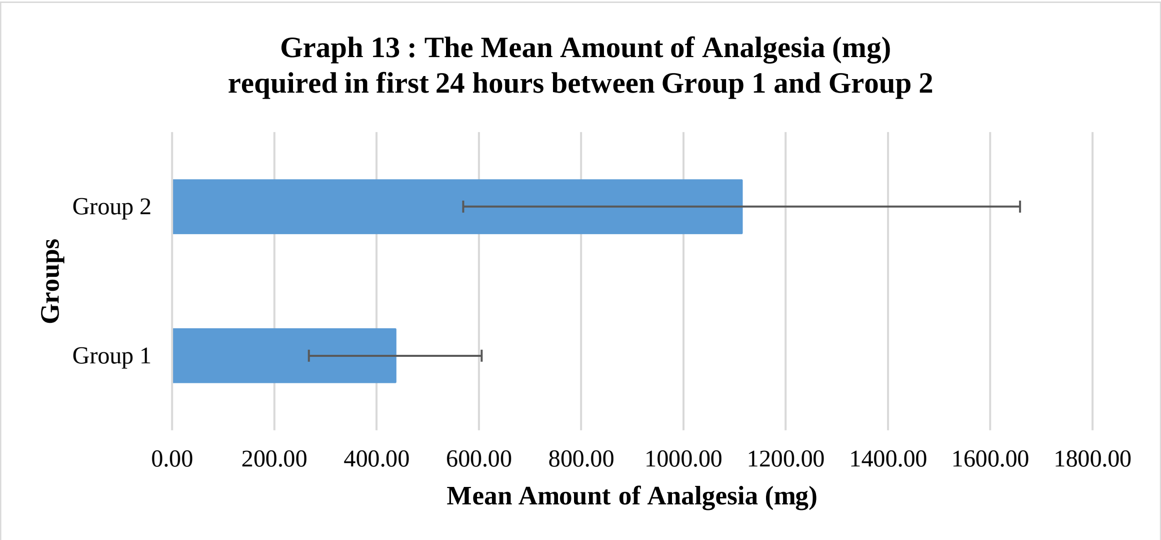
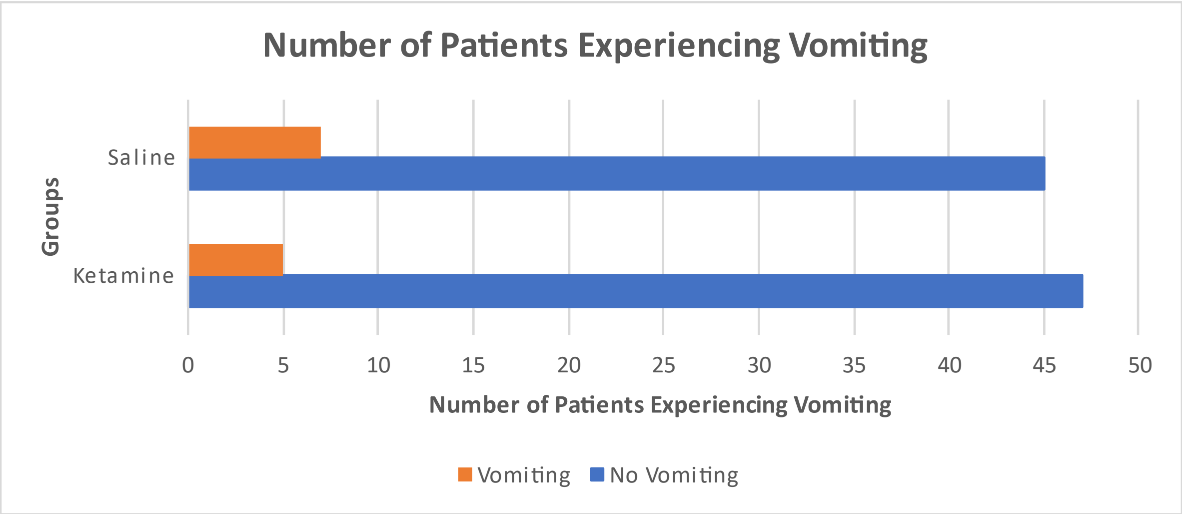


Table 14 and Graph 14 compare the incidence of vomiting between Group 1 and Group 2. No statistically significant difference was observed between the two groups ($p > 0.05$).

Table 14: Side Effects of Vomiting between Group 1 and Group 2

Group	No Vomiting	Vomiting	P value
Group 1	47	5	0.760228
Group 2	45	7	
Statistically significant (p<0.05) Fisher's Exact Test. Group 1 = Ketamine, Group 2 = Saline			

Graph 14



No patients experienced hallucination in either of the group.

DISCUSSION

Effective analgesia and sedation in paediatric patients present a complex and evolving challenge, particularly in the postoperative setting. Pain in this population arises from multiple sources, including surgical trauma, underlying pathology, procedural interventions, and routine care practices such as repositioning and mobilization. Historically, these routine interventions were often dismissed as sources of agitation rather than significant pain contributors. However, a paradigm shift in pain management has led to the recognition of their role in postoperative discomfort, underscoring the necessity of vigilant pain assessment and management in paediatric patients.(79,80)

Accurate pain assessment in paediatric populations remains inherently challenging due to age-related variations in pain perception and expression. While self-reporting is considered the gold standard for children above six years of age, its reliability is often compromised by concerns regarding caregiver disapproval, cultural attitudes towards pain, or apprehension about subsequent interventions, such as injections. In younger children or those with developmental delays, reliance on behavioural and physiological indicators becomes essential, necessitating the use of validated observational pain scales. In this study, the Children's Hospital of Eastern Ontario Pain Scale (CHEOPS) was used for children below seven years, while the Visual Analog Scale (VAS) was employed for those above seven years. In our study, there were 28 patients under 7 years and 76 patients above 7 years.(60,65,70)

Pain management continues to be a central concern in both acute and chronic care settings, with an increasing emphasis on multimodal approaches that enhance analgesic efficacy while mitigating opioid-related risks. One promising pharmacological agent in this context is ketamine, a noncompetitive N-methyl-D-aspartate (NMDA) receptor antagonist. Ketamine has demonstrated efficacy in various pain contexts, including acute postoperative pain and paediatric pain management. Despite initial concerns regarding its psychomimetic effects, recent evidence supports its role in pain management, particularly at sub anaesthetic doses (81) (82). Consistent with previous findings, our study demonstrated ketamine's effectiveness as an analgesic at subanaesthetic doses.

The study population had a mean age of 11.21 ± 3.87 years, with statistical analysis revealing no significant difference in age or sex distribution between the groups. The mean pain scores in the Ketamine group were significantly lower than those in the placebo group at multiple postoperative time points, including 15 minutes, 30 minutes, 45 minutes, 60 minutes, 2 hours, 12 hours, and 24 hours ($p < 0.05$) for participants under seven years of age. Similarly, for participants over seven years of age, the mean pain scores of the Ketamine group remained significantly lower at all measured time intervals

($p < 0.05$). In instances where the CHEOPS score was ≥ 9 or the VAS score was ≥ 4, 15 mg/kg of intravenous paracetamol was administered(83,84).

The perioperative administration of ketamine has been extensively studied as an adjunct to conventional analgesics. A review conducted by Brinck et al. indicated that intravenous ketamine significantly reduces postoperative opioid consumption, enhances analgesic efficacy, and prolongs the time to the first analgesic request. These benefits are particularly pronounced in surgeries associated with high pain intensity, such as thoracotomy and spinal surgery(85,86) .Our findings corroborate this observation. Furthermore, ketamine's opioid-sparing effects contribute to a reduced incidence of PONV, a frequent complication associated with opioid use(85,86).While a few patients in the ketamine group experienced postoperative vomiting, this was not statistically significant and may have been attributable to surgical factors or antibiotic administration rather than ketamine itself.

Multiple studies have established the efficacy of intranasal (IN) ketamine in paediatric analgesia. Frey et al. documented significant pain reduction in children with severe trauma following the administration of sub-dissociative doses of IN ketamine(20). Additionally, a systematic review and meta-analysis found that IN ketamine (1 mg/kg) was non-inferior to IN fentanyl for managing moderate to severe pain, demonstrating comparable pain reduction at 15, 30, and 60 minutes post-administration. Similarly, Umuroglu et al. compared IN ketamine (0.5 mg/kg) with morphine and tramadol for post-tonsillectomy pain, using validated pain assessment tools such as CHEOPS and the Numeric Rating Scale (NRS). Their findings indicated that ketamine provided effective analgesia, although morphine exhibited the most robust pain relief(87). Further studies by Erhan et al. and the PICHFORK trial reinforced the efficacy of IN ketamine, demonstrating its comparable pain relief to fentanyl and its ability to extend the time to the first analgesic request while minimizing opioid consumption.(5)

Our study aligns with these findings, demonstrating that IN ketamine (1 mg/kg) provided significantly greater analgesic efficacy than placebo at all postoperative time points, from 15 minutes to 24 hours. This dose emerged as an optimal balance between analgesic effectiveness and safety, with minimal adverse effects.

Postoperative sedation was assessed using the Wilson sedation scale, revealing that children in the ketamine group exhibited transient drowsiness up to the first postoperative hour. Children in the placebo group remained awake throughout the postoperative period. However, children in the Ketamine group remained drowsy but arousable compared to the Placebo group, who were completely awake. Critically, the rates of vomiting in the ketamine group were comparable to those in the placebo group, reinforcing its clinical feasibility. While mild postoperative vomiting occurred more frequently in the ketamine cohort, these effects were transient and not statistically significant. Our findings are consistent with previous studies by Reynolds et al. and Graudins et al., which reported predominantly mild and self-limiting adverse effects within the first 15 minutes post-administration.(5,88) Importantly, hemodynamic parameters were stable in all patients, and no airway complications or allergic reactions were observed in our study. Additionally, the intranasal administration of ketamine was well accepted by children, and no child complained of hallucinations or nightmares, further supporting its safety and recovery profile in paediatric surgical populations.

Despite these encouraging findings, certain limitations should be acknowledged. Pain assessment in paediatric populations is inherently challenging, although validated pain scales were employed to mitigate subjectivity. The fixed ketamine dose (1 mg/kg) may not fully account for inter-individual variability in analgesic response, warranting further research on dose optimization. Another limitation of our study is the relatively small sample size, which may affect the generalizability of our findings.

Future research should aim to refine IN ketamine protocols and assess long-term outcomes with larger sample sizes in multicentred studies. Large-scale trials comparing IN ketamine with other multimodal analgesic approaches will be crucial in defining its role in paediatric pain management.

CONCLUSIONS

Ketamine in 1 mg/kg dose is optimal for achieving effective analgesia postoperatively while minimizing adverse effects in paediatric patients undergoing surgery under general anaesthesia.

The time to first analgesic request in the postoperative period was significantly prolonged in the ketamine group compared to the placebo group.

Additionally, ketamine administration resulted in a reduced total analgesic consumption within the first 24 hours postoperatively.

Although IN ketamine was associated with mild sedation, especially first hour postoperative, these effects were manageable and did not compromise patient safety and recovery.

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ANNEXURE 1 - INFORMED CONSENT FORM

Study of effect of intranasal ketamine on postoperative analgesia in children-A one year single blinded hospital based randomized placebo controlled clinical trial

Name of the Principal Investigator

Name of Guide/ Co Investigators :

Objective: To determine the effect of Intranasal Ketamine on post-operative pain among children undergoing surgery under general anaesthesia

Introduction: Mr. /Mrs. __________________________ we are requesting you to enroll yourself in the study titled **"Study of effect of intranasal ketamine on postoperative analgesia in children- A one year single blinded hospital based randomized placebo controlled clinical trial"** conducted by , Post Graduate in M.D. Anaesthesiology under the guidance of , Professor, Department of Anaesthesiology, J.N. Medical College, Belagavi under KAHER, Belagavi.

Explanation of Procedure: If you agree to enroll in my study, I will ask you the present and past medical history. Then you will be clinically examined in detail. On the day of surgery, you will receive drug intra nasally in the pre-operative room

Withdrawal from participation in the study: Participation in this study is voluntary. You will be free to decide whether to participate in this study or continue participation once enrolled. In case you decide to withdraw your participation, you are free to do so. However, please convey the decision to the principal investigator.

Possible benefits from participating in the study: You will/will not have nor get any benefits by participating in this study. The data gathered will help the population at large.

Possible risks from participating in the study: There are no risks involved in participating in this study.

Privacy and confidentiality: The information collected from you will be coded, to prevent any person from identifying you. Your identity will never be revealed. The data collected from you will be kept confidential and only processed or aggregated data will be used for publication.

Financial incentives: You will not receive any payment for participating in this study.

Authorization for publication of aggregated data: Results obtained after processing of the aggregated data will be published for scientific purposes and or presented to scientific groups.

However, your identity will never be revealed.

Questions: In case of any questions with regard to this study, you are free to contact: , Department of Anaesthesiology, J.N. Medical College, Belagavi. Phone number: .

If you have any question or complaints with regard to your right as study participant you may contact Dr Harsha Hegde, Chairperson, Ethical committee of JNMC, 08312473777 Extension 4052.

Legal rights: By signing this consent form, we are not waving any of your legal rights

ಮಾಹಿತಿ ಪತ್ರ

ಮಕ್ಕಳಲ್ಲಿ ಶಸ್ತ್ರಚಿಕಿತ್ಸೆಯ ನಂತರದ ನೋವು ನಿವಾರಕದ ಮೇಲೆ ಇಂಟ್ರಾನಾಸಲ್ಕೆಟಮೈನ್ಪರಿಣಾಮಕಾರಿತ್ವ ಒಂದು ವರ್ಷದ ಆಸ್ಪತ್ರೆ ಆಧಾರಿತ ಯಾದೃಚ್ಛಿಕಕ್ಲಿನಿಕಲ್ಪ್ರಯೋಗ

ವಿದ್ಯಾರ್ಥಿ/ಪ್ರಧಾನ ತನಿಖಾಧಿಕಾರಿಯ ಹೆಸರು:
ಮಾರ್ಗದರ್ಶಿ/ಸಹ ತನಿಖಾಧಿಕಾರಿಗಳ ಹೆಸರು:

ಉದ್ದೇಶ: ಸಾಮಾನ್ಯ ಅರಿವಳಿಕೆ ಅಡಿಯಲ್ಲಿ ಶಸ್ತ್ರಚಿಕಿತ್ಸೆಗೆ ಒಳಗಾಗುವ ಮಕ್ಕಳಿಗೆ ಶಸ್ತ್ರಚಿಕಿತ್ಸೆ ನಂತರದ ನೋವಿನ ಮೇಲೆ ಇಂಟ್ರನೇಸಲ್ಕೆಟಾಮೈನ್ಪರಿಣಾಮವನ್ನು ನಿರ್ಧರಿಸಲು.

ಪರಿಚಯ : ಶ್ರೀ/ಶ್ರೀಮತಿ……………..

"ಮಕ್ಕಳಲ್ಲಿ ಶಸ್ತ್ರಚಿಕಿತ್ಸೆಯ ನಂತರದ ನೋವು ನಿವಾರಕಗಳ ಮೇಲೆ ಇಂಟ್ರಾನಾಸಲ್ಕೆಟಮೈನ್ಪರಿಣಾಮಕಾರಿತ್ವ ಒಂದು ವರ್ಷದ ಆಸ್ಪತ್ರೆ ಆಧಾರಿತ ಯಾದೃಚ್ಛಿಕಕ್ಲಿನಿಕಲ್ಪ್ರಯೋಗ" ಎಂಬ ಶೀರ್ಷಿಕೆಯ ಅಧ್ಯಯನದಲ್ಲಿ ನಿಮ್ಮನ್ನು ದಾಖಲಿಸಿಕೊಳ್ಳುವಂತೆ ನಾವು ನಿಮ್ಮನ್ನು ವಿನಂತಿಸುತ್ತೇವೆ

ಕಾರ್ಯವಿಧಾನದ ವಿವರಣೆ: ನನ್ನ ಅಧ್ಯಯನಕ್ಕೆ ಸೇರ್ಪಡೆಗೊಳ್ಳಲು ನೀವು ಒಪ್ಪಿದರೆ, ನಾನು ನಿಮಗೆ ಪ್ರಸ್ತುತ ಮತ್ತು ಹಿಂದಿನ ವೈದ್ಯಕೀಯ ಇತಿಹಾಸವನ್ನು ಕೇಳುತ್ತೇನೆ. ನಂತರ ನೀವು ಪ್ರಾಯೋಗಿಕವಾಗಿ ವಿವರವಾಗಿ ಪರೀಕ್ಷಿಸಲ್ಪಡುತ್ತೀರಿ. ಶಸ್ತ್ರಚಿಕಿತ್ಸೆಯ ದಿನದಂದು,ಶಸ್ತ್ರಚಿಕಿತ್ಸಾ ಪೂರ್ವಕೋಣೆಯಲ್ಲಿ ಔಷಧವನ್ನು ಇಂಟ್ರಾನಾಸಲ್ಆಗಿ ಸ್ವೀಕರಿಸಿ

ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಸುವಿಕೆಯಿಂದ ಹಿಂತೆಗೆದುಕೊಳ್ಳುವಿಕೆ: ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುವಿಕೆಯು ಸ್ವಯಂಪ್ರೇರಿತವಾಗಿದೆ. ಒಮ್ಮೆ ದಾಖಲಾದ ನಂತರ ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಬೇಕೆ ಅಥವಾ ಭಾಗವಹಿಸುವಿಕೆಯನ್ನು ಮುಂದುವರಿಸಬೇಕೆ ಎಂದು ನಿರ್ಧರಿಸಲು ನೀವು ಸ್ವತಂತ್ರರಾಗಿರುತ್ತೀರಿ. ನಿಮ್ಮ ಭಾಗವಹಿಸುವಿಕೆಯನ್ನು ಹಿಂಪಡೆಯಲು ನೀವು ನಿರ್ಧರಿಸಿದರೆ, ನೀವು ಹಾಗೆಮಾಡಲು ಮುಕ್ತರಾಗಿದ್ದೀರಿ. ಆದಾಗ್ಯೂ, ದಯವಿಟ್ಟು ನಿರ್ಧಾರವನ್ನು ಪ್ರಧಾನ ತನಿಖಾಧಿಕಾರಿಗೆ ತಿಳಿಸಿ.

ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುವುದರಿಂದ ಸಂಭವನೀಯ ಪ್ರಯೋಜನಗಳು: ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುವ ಮೂಲಕ ನೀವು ಯಾವುದೇ ಪ್ರಯೋಜನಗಳನ್ನು ಪಡೆಯುವುದಿಲ್ಲ. ಸಂಗ್ರಹಿಸಿದ ಮಾಹಿತಿಯು ಜನಸಂಖ್ಯೆಗೆ ದೊಡ್ಡಪ್ರಮಾಣದಲ್ಲಿ ಸಹಾಯ ಮಾಡುತ್ತದೆ.

ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುವುದರಿಂದ ಸಂಭವನೀಯ ಅಪಾಯಗಳು: ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುವುದರಿಂದ ಯಾವುದೇ ಅಪಾಯಗಳಿಲ್ಲ.

ಗೌಪ್ಯತೆ: ಯಾವುದೇ ವ್ಯಕ್ತಿ ನಿಮ್ಮನ್ನು ಗುರುತಿಸದಂತೆ ತಡೆಯಲು ನಿಮ್ಮಿಂದ ಸಂಗ್ರಹಿಸಿದ ಮಾಹಿತಿಯನ್ನು ಕೋಡ್ಮಾಡಲಾಗುತ್ತದೆ. ನಿಮ್ಮ ಗುರುತನ್ನು ಎಂದಿಗೂ ಬಹಿರಂಗ ಪಡಿಸಲಾಗುವುದಿಲ್ಲ. ನಿಮ್ಮಿಂದ ಸಂಗ್ರಹಿಸಿದ ಡೇಟಾವನ್ನು ಗೌಪ್ಯವಾಗಿ ಇರಿಸಲಾಗುತ್ತದೆ ಮತ್ತು ಪ್ರಕ್ರಿಯೆಗೊಳಿಸಿದ ಅಥವಾ ಒಟ್ಟುಗೂಡಿದ ಡೇಟಾವನ್ನು ಮಾತ್ರ ಪ್ರಕಟಣೆಗಾಗಿ ಬಳಸಲಾಗುತ್ತದೆ.

ಹಣ ಕಾಸಿನ ಪ್ರೋತ್ಸಾಹಗಳು: ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಿದ್ದಕ್ಕಾಗಿ ನೀವು ಯಾವುದೇ ಪಾವತಿಯನ್ನು ಸ್ವೀಕರಿಸುವುದಿಲ್ಲ. ಒಟ್ಟುಗೂಡಿದ ದತ್ತಾಂಶದ ಪ್ರಕಟಣೆಗೆ ಅಧಿಕಾರ: ಒಟ್ಟು ದತ್ತಾಂಶವನ್ನು ಸಂಸ್ಕರಿಸಿದ ನಂತರ ಪಡೆದ ಫಲಿತಾಂಶಗಳನ್ನು ವೈಜ್ಞಾನಿಕ ಉದ್ದೇಶಗಳಿಗಾಗಿ ಪ್ರಕಟಿಸಲಾಗುತ್ತದೆ ಅಥವಾ ವೈಜ್ಞಾನಿಕ ಗುಂಪುಗಳಿಗೆ ಪ್ರಸ್ತುತ ಪಡಿಸಲಾಗುತ್ತದೆ. ಆದಾಗ್ಯೂ, ನಿಮ್ಮ ಗುರುತನ್ನು ಎಂದಿಗೂ ಬಹಿರಂಗ ಪಡಿಸಲಾಗುವುದಿಲ್ಲ.

ಪ್ರಶ್ನೆಗಳು: ಈ ಅಧ್ಯಯನಕ್ಕೆ ಸಂಬಂಧಿಸಿದಂತೆ ಯಾವುದೇ ಪ್ರಶ್ನೆಗಳಿದ್ದಲ್ಲಿ, ನೀವು ಸಂಪರ್ಕಿಸಲು ಮುಕ್ತರಾಗಿದ್ದೀರಿ

ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುವ ನಿಮ್ಮ ಹಕ್ಕಿನ ಕುರಿತು ನೀವು ಯಾವುದೇ ಪ್ರಶ್ನೆ ಅಥವಾ ದೂರುಗಳನ್ನು ಹೊಂದಿದ್ದರೆ ಈವರನ್ನು ಸಂಪರ್ಕಿಸಬಹುದು.

ಡಾ ಹರ್ಷಹೆಗಡೆ,
ಅಧ್ಯಕ್ಷರು,
ಜೆ ಎನ್ ಎಂ ಸಿಯ ನೈತಿಕ ಸಮಿತಿ,
0831-2473777 E xt-4052

ಕಾನೂನು ಹಕ್ಕುಗಳು: ಈ ಸಮ್ಮತಿಯ ನಮೂನೆಗೆ ಸಹಿ ಮಾಡುವ ಮೂಲಕ, ನಿಮ್ಮ ಯಾವುದೇ ಕಾನೂನು ಹಕ್ಕುಗಳನ್ನು ನಾವು ಕಸಿಯುವುದಿಲ್ಲ.

ANNEXURE II - CONSENT/ASSENT STATEMENT

I am making a voluntary decision to participate in the study of effect of intranasal ketamine on post operative analgesia among children- A one year hospital based randomized placebo controlled clinical trial.

My signature below indicates that I have decided to participate and I have read the information provided above or the information provided above has been read to me in the language that I understand best. I was given the opportunity to ask questions and that they have been answered to my satisfaction.

Name of the patient (if age >7 years):

Signature or left thumb impression of the participant (if age >7 years):

Name of the guardian:

Signature or left thumb impression of the guardian:

Name of the investigator:

Signature of the investigator:

ಒಪ್ಪಿಗೆಪತ್ರ

ಮಕ್ಕಳಲ್ಲಿ ಶಸ್ತ್ರಚಿಕಿತ್ಸೆಯ ನಂತರದ ನೋವು ನಿವಾರಕದ ಮೇಲೆ ಇಂಟ್ರಾನಾಸಲ್ಕೆಟಮೈನ್ಪರಿಣಾಮಕಾರಿತ್ವ - ಒಂದು ವರ್ಷದ ಆಸ್ಪತ್ರೆ ಆಧಾರಿತಯಾದೃಚ್ಛಿಕಕ್ಲಿನಿಕಲ್ಪ್ರಯೋಗ ಪರಿಣಾಮದ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ನಾನು ಸ್ವಯಂ ಪ್ರೇರಿತ ನಿರ್ಧಾರವನ್ನು ತೆಗೆದು ಕೊಳ್ಳುತ್ತಿದ್ದೇನೆ. ಕೆಳಗಿನ ನನ್ನ ಸಹಿ ನಾನು ಭಾಗವಹಿಸಲು ನಿರ್ಧರಿಸಿದ್ದೇನೆ ಮತ್ತು ನಾನು ಮೇಲೆ ಒದಗಿಸಿದ ಮಾಹಿತಿಯನ್ನು ಓದಿದ್ದೇನೆ ಅಥವಾ ಮೇಲೆ ಒದಗಿಸಿದ ಮಾಹಿತಿಯನ್ನು ನನಗೆ ಚೆನ್ನಾಗಿ ಅರ್ಥವಾಗುವ ಭಾಷೆಯಲ್ಲಿ ಓದಲಾಗಿದೆ ಎಂದು ಸೂಚಿಸುತ್ತದೆ. ಪ್ರಶ್ನೆಗಳನ್ನು ಕೇಳಲು ನನಗೆ ಅವಕಾಶವನ್ನು ನೀಡಲಾಯಿತು ಮತ್ತು ಅವುಗಳಿಗೆ ನನ್ನ ತೃಪ್ತಿಗೆ ಉತ್ತರಿಸಲಾಗಿದೆ.

ಭಾಗವಹಿಸುವವರ ಹೆಸರು:

ಭಾಗವಹಿಸುವವರ ಸಹಿ ಅಥವಾ ಎಡ ಹೆಬ್ಬೆರಳಿನ ಗುರುತು:

ಸಾಕ್ಷಿಯ ಹೆಸರು:

ಸಾಕ್ಷಿಯ ಸಹಿ ಅಥವಾ ಎಡ ಹೆಬ್ಬೆರಳಿನ ಗುರುತು:

ತನಿಖಾಧಿಕಾರಿಯ ಹೆಸರು:

ANNEXURE II -PROFORM

Title Study of effect of intranasal ketamine on postoperative analgesia in children- A one year single blinded hospital based randomized placebo controlled clinical trial

Patient's Name- I.P. NO.-

Age- Date of Examination-

Gender- Anaesthesiologist-

Address-

Pre-Anaesthetic Evaluation:-

Chief Complaints:

History of Presenting Illness:
Past History:
Family History:

General Physical Examination:

Height: Weight : BMI:

Pallor: Icterus: Cyanosis:

Clubbing: Edema:

PR: RR: SpO_2:

Systemic Examination:

CVS: RS:

CNS: GIT:

Airway Examination:

Teeth:
Jaw Movements:
Airway:

Spine:

Investigations:

ASA GRADE:

Diagnosis:

Proposed Surgery:

Drug/Saline administered once closure starts:

TIME DURATION	**CHEOPS/ VAS**
15 min	
30 min	
45 min	
60 min	
2 hours	
6 hours	
12 hours	
24 hours	

Wilson sedation scale

Score	Degree of sedation
1	Fully awake , oriented
2	Lethargic
3	Open eye with verbal stimulus
4	Open eye with moderate pain
5	Dose not respond moderate pain

The time to first analgesic:

Total analgesic consumption within the first 24 hours postoperatively:

Side effects:

ANNEXURE IV – PHOTOGRAPHS

Photograph 1: Ketamine Ampoules

Photograph 2: Tuberculin Syringe

ANNEXURE V – KEY TO MASTERCHART

ASA: American Society of Anesthesiologists

CHEOPS: Children's Hospital of Eastern Ontario Pain Scale

VAS: Visual analogue scale

ANNEXURE VI – MASTERCHART

Pain Scores

IP No	Age (years)	Sex	ASA	Weight (Kgs)	Diagnosis	Surgery	Pain Scale	Group	Pain (15 min)	Pain (30min)	Pain (45 min)	Pain (60 min)	Pain (120 min)	Pain (360 min)	Pain (720 min)	Pain (1440 min)
10000859	5	Male	1	18	Tonsillitis	Tonsillectomy	CHEOPS	Ketamine	5	5	5	5	5	6	7	5
10002348	6	Male	1	20	Acute Appendicitis	Laparoscopic Appendicectomy	CHEOPS	Ketamine	5	5	5	5	6	6	5	5
10053925	6	Male	1	13	Tonsillitis	Tonsillectomy	CHEOPS	Ketamine	5	5	5	5	5	5	5	6
10054691	5	Male	1	12	Tonsillitis	Tonsillectomy	CHEOPS	Ketamine	5	5	5	5	5	5	5	7
10055989	7	Male	1	17	Tonsillitis	Tonsillectomy	CHEOPS	Ketamine	5	5	5	5	5	6	5	5
10070992	5	Male	1	20	Tonsillitis	Tonsillectomy	CHEOPS	Ketamine	5	5	5	5	6	7	5	5
10072651	5	Male	1	15	Tonsillitis	Tonsillectomy	CHEOPS	Ketamine	5	5	5	5	5	5	6	5
10085431	6	Female	1	18	Lymphnode swelling	Excision	CHEOPS	Ketamine	5	5	5	5	6	5	5	6
10087695	5	Male	1	19	Acute Appendicitis	Laparoscopic Appendicectomy	CHEOPS	Ketamine	5	5	5	5	5	5	5	5
10090813	7	Male	1	18	Tonsillitis	Tonsillectomy	CHEOPS	Ketamine	5	5	5	5	6	6	5	5
10002388	11	Female	1	30	Ranula	Excision	VAS	Ketamine	0	0	0	0	1	1	0	0
10003179	15	Female	1	15	Acute Appendicitis	Laparoscopic Appendicectomy	VAS	Ketamine	0	0	1	1	1	1	0	1

IP No	Age (years)	Sex	ASA	Weight (Kgs)	Diagnosis	Surgery	Pain Scale	Group	Pain (15 min)	Pain (30min)	Pain (45 min)	Pain (60 min)	Pain (120 min)	Pain (360 min)	Pain (720 min)	Pain (1440 min)
10003378	16	Female	1	50	Acute Appendicitis	Laparoscopic Appendicectomy	VAS	Ketamine	0	0	0	0	1	1	1	1
10003968	14	Male	1	33	Ranula	Excision	VAS	Ketamine	0	0	0	0	2	1	0	0
10004229	8	Male	1	12	Acute Appendicitis	Laparoscopic Appendicectomy	VAS	Ketamine	0	0	0	0	0	1	1	1
10005257	12	Male	1	31	Acute Appendicitis	Laparoscopic Appendicectomy	VAS	Ketamine	0	0	0	0	1	1	1	1
10030112	15	Male	1	40	Tonsillitis	Tonsillectomy	VAS	Ketamine	0	0	0	0	1	1	1	1
10030384	10	Male	1	15	Tonsillitis	Tonsillectomy	VAS	Ketamine	0	0	0	0	1	1	1	1
10030410	11	Female	1	27	Tonsillitis	Tonsillectomy	VAS	Ketamine	0	1	1	1	1	1	1	0
10030411	12	Male	1	28	Tonsillitis	Tonsillectomy	VAS	Ketamine	0	0	0	0	1	1	0	1
10031214	10	Male	1	22	Tonsillitis	Tonsillectomy	VAS	Ketamine	1	1	1	1	1	0	1	1
10055797	13	Male	1	27	Tonsillitis	Tonsillectomy	VAS	Ketamine	0	0	1	1	1	1	1	1
10056822	15	Female	1	40	Chronic Suppurative Otitis Media	Tympanoplasty	VAS	Ketamine	0	0	1	1	1	1	1	1
10057455	15	Female	1	40	Acute appendicitis	Laparoscopic Appendicectomy	VAS	Ketamine	0	0	0	0	0	1	1	1
10057587	14	Female	1	40	Tonsillitis	Tonsillectomy	VAS	Ketamine	0	0	0	0	1	1	1	1
10057982	8	Male	1	19	Tonsillitis	Tonsillectomy	VAS	Ketamine	1	1	1	1	1	0	1	1

IP No	Age (years)	Sex	ASA	Weight (Kgs)	Diagnosis	Surgery	Pain Scale	Group	Pain (15 min)	Pain (30min)	Pain (45 min)	Pain (60 min)	Pain (120 min)	Pain (360 min)	Pain (720 min)	Pain (1440 min)
10059643	14	Male	1	38	Tonsillitis	Tonsillectomy	VAS	Ketamine	1	1	1	1	2	0	1	1
10061057	17	Male	1	36	Tonsillitis	Tonsillectomy	VAS	Ketamine	0	0	0	0	1	1	1	0
10061068	9	Female	1	20	Tonsillitis	Tonsillectomy	VAS	Ketamine	0	0	1	1	2	2	1	0
10061316	14	Male	1	40	Tonsillitis	Tonsillectomy	VAS	Ketamine	0	0	0	0	1	2	1	1
10061326	14	Male	1	40	Tonsillitis	Tonsillectomy	VAS	Ketamine	0	0	0	0	1	1	1	1
10061413	13	Female	1	35	Lymph Node Swelling	Excision	VAS	Ketamine	0	0	0	0	1	1	1	0
10061427	15	Male	1	35	Lipoma over chest wall	Excision	VAS	Ketamine	0	0	0	0	1	1	1	1
10061431	11	Female	1	32	Branchial cyst	Excision	VAS	Ketamine	0	0	0	1	0	1	1	1
10061432	13	Male	1	20	CA Urinary bladder	Chemoport insertion	VAS	Ketamine	0	0	0	0	0	1	1	1
10061706	13	Male	1	62	Branchial Cyst	Excision	VAS	Ketamine	0	0	0	0	0	1	1	1
10065503	11	Male	1	25	Tonsillitis	Tonsillectomy	VAS	Ketamine	1	1	1	1	1	2	0	1
10065504	11	Male	1	25	Tonsillitis	Tonsillectomy	VAS	Ketamine	1	1	1	1	1	1	1	1
10066333	9	Female	1	28	Tonsillitis	Tonsillectomy	VAS	Ketamine	1	1	1	1	1	1	1	1
10068463	14	Female	1	48	Fibroadenoma	Excision	VAS	Ketamine	0	0	0	0	0	1	0	0
10070993	10	Male	1	18	Tonsillitis	Tonsillectomy	VAS	Ketamine	0	1	1	1	1	2	1	1
10073550	17	Male	1	50	Tonsillitis	Tonsillectomy	VAS	Ketamine	0	0	1	1	2	1	1	1

IP No	Age (years)	Sex	ASA	Weight (Kgs)	Diagnosis	Surgery	Pain Scale	Group	Pain (15 min)	Pain (30min)	Pain (45 min)	Pain (60 min)	Pain (120 min)	Pain (360 min)	Pain (720 min)	Pain (1440 min)
10075159	13	Male	1	30	Pain abdomen	Laparoscopic Appendicectomy	VAS	Ketamine	0	0	0	0	2	1	1	1
10082550	13	Male	1	40	Tonsillitis	Tonsillectomy	VAS	Ketamine	1	1	1	1	1	2	1	1
10085275	11	Male	1	24	Tonsillitis	Tonsillectomy	VAS	Ketamine	1	1	1	1	2	2	1	1
10085597	15	Female	1	42	Cholecystitis	Laparoscopic cholecystectomy	VAS	Ketamine	0	1	1	1	2	1	1	1
10087668	13	Male	1	31	Pain abdomen	Laparoscopic Appendicectomy	VAS	Ketamine	0	0	0	0	1	1	0	1
10088189	13	Male	1	28	Tonsillitis	Tonsillectomy	VAS	Ketamine	1	1	1	1	2	1	1	0
10088254	11	Male	1	29	Cholecystitis	Laparoscopic cholecystectomy	VAS	Ketamine	0	0	0	0	1	1	1	1
10088352	14	Male	1	35	Tonsillitis	Tonsillectomy	VAS	Ketamine	1	1	1	1	1	2	0	1
10088453	10	Male	1	23	Tonsillitis	Tonsillectomy	VAS	Ketamine	0	0	0	0	2	1	1	0
10088875	14	Male	1	40	Acute Appendicitis	Laparoscopic Appendicectomy	VAS	Ketamine	0	0	0	0	1	1	0	0
10032269	11	Male	1	25	Tonsillitis	Tonsillectomy	VAS	Saline	2	2	2	2	3	3	1	1
10045900	18	Male	1	45	Chronic Suppurative Otitis Media	Tympanoplasty	VAS	Saline	2	2	2	1	2	2	1	1
10047797	14	Male	1	42	Tonsillitis	Tonsillectomy	VAS	Saline	2	2	2	2	3	3	2	2
10057194	8	Male	1	21	Leukemia	Chemoport insertion	VAS	Saline	2	2	2	2	2	2	1	1

IP No	Age (years)	Sex	ASA	Weight (Kgs)	Diagnosis	Surgery	Pain Scale	Group	Pain (15 min)	Pain (30min)	Pain (45 min)	Pain (60 min)	Pain (120 min)	Pain (360 min)	Pain (720 min)	Pain (1440 min)
10057553	13	Male	1	38	Acute appendicitis	Laparoscopic Appendicectomy	VAS	Saline	2	2	2	1	1	1	1	1
10057764	18	Female	1	45	Acute Appendicitis	Laparoscopic Appendicectomy	VAS	Saline	2	2	2	1	2	1	1	1
10058347	13	Female	1	41	Chronic Suppurative Otitis Media	Tympanoplasty	VAS	Saline	2	2	2	2	2	2	1	1
10058391	14	Male	1	50	Tonsillitis	Tonsillectomy	VAS	Saline	2	2	2	2	4	3	3	2
10058637	18	Female	1	49	Chronic Suppurative Otitis Media	Tympanoplasty	VAS	Saline	2	2	2	1	1	2	2	2
10058983	18	Female	1	44	Cervical Lymphadenopathy	Excision	VAS	Saline	2	2	2	1	2	1	2	2
10059270	12	Male	1	18	Tonsillitis	Tonsillectomy	VAS	Saline	2	2	2	3	4	1	1	1
10059274	13	Male	1	22	Tonsillitis	Tonsillectomy	VAS	Saline	2	2	2	2	4	4	1	1
10059519	9	Male	1	22	Tonsillitis	Tonsillectomy	VAS	Saline	2	2	2	2	3	3	2	1
10059638	14	Male	1	38	Tonsillitis	Tonsillectomy	VAS	Saline	2	2	2	3	4	3	2	1
10059756	11	Male	1	50	Chronic Suppurative Otitis Media	Tympanoplasty	VAS	Saline	2	2	2	1	2	2	2	1
10064991	14	Female	1	42	Tonsillitis	Tonsillectomy	VAS	Saline	2	2	2	2	3	2	2	2
10058046	7	Male	1	18	Tonsillitis	Tonsillectomy	CHEOPS	Saline	8	8	8	8	11	11	5	5
10058664	7	Female	1	15	Tonsillitis	Tonsillectomy	CHEOPS	Saline	6	8	8	8	12	6	5	5

IP No	Age (years)	Sex	ASA	Weight (Kgs)	Diagnosis	Surgery	Pain Scale	Group	Pain (15 min)	Pain (30min)	Pain (45 min)	Pain (60 min)	Pain (120 min)	Pain (360 min)	Pain (720 min)	Pain (1440 min)
10068093	14	Female	1	40	Tonsillitis	Tonsillectomy	VAS	Saline	2	2	2	3	4	3	2	2
10068107	18	Female	1	45	Dermoid cyst on scalp	Excision	VAS	Saline	4	4	4	4	1	1	1	1
10068394	14	Female	1	42	Tonsillitis	Tonsillectomy	VAS	Saline	2	2	2	3	4	2	1	1
10069334	17	Male	1	50	Appendicitis	Laparoscopic Appendicectomy	VAS	Saline	2	2	1	1	1	1	0	1
10059050	5	Female	1	12	Hemangioma on arm	Excision	CHEOPS	Saline	8	8	8	9	6	5	6	5
10059556	6	Female	1	12	Tonsillitis	Tonsillectomy	CHEOPS	Saline	7	8	8	8	11	5	5	5
10076521	12	Male	1	22	Tonsillitis	Tonsillectomy	VAS	Saline	2	2	2	3	4	1	1	1
10078922	15	Male	1	30	Tonsillitis	Tonsillectomy	VAS	Saline	2	2	2	2	3	3	2	1
10067146	5	Male	1	11	Tonsillitis	Tonsillectomy	CHEOPS	Saline	7	7	8	8	13	6	6	5
10067574	7	Male	1	12	Tonsillitis	Tonsillectomy	CHEOPS	Saline	8	8	8	8	11	5	6	5
10067575	6	Male	1	9	Tonsillitis	Tonsillectomy	CHEOPS	Saline	7	8	8	8	12	5	6	6
10081441	7	Male	1	14	Leukemia	Chemoport insertion	CHEOPS	Saline	7	7	8	8	11	5	5	7
10082850	5	Male	1	10	Tonsillitis	Tonsillectomy	CHEOPS	Saline	8	8	9	9	13	5	6	6
10087916	5	Male	1	12	Tonsillitis	Tonsillectomy	CHEOPS	Saline	8	8	9	9	13	5	5	6
10089742	7	Male	1	14	Tonsillitis	Tonsillectomy	CHEOPS	Saline	8	8	8	8	12	6	6	7
10091693	15	Male	1	42	Tonsillitis	Tonsillectomy	VAS	Saline	2	2	2	2	3	2	1	1

IP No	Age (years)	Sex	ASA	Weight (Kgs)	Diagnosis	Surgery	Pain Scale	Group	Pain (15 min)	Pain (30min)	Pain (45 min)	Pain (60 min)	Pain (120 min)	Pain (360 min)	Pain (720 min)	Pain (1440 min)
10092084	13	Male	1	37	Acute Appendicitis	Laparoscopic Appendicectomy	VAS	Saline	2	2	2	1	2	1	1	1
10092189	13	Male	1	38	Acute Appendicitis	Laparoscopic Appendicectomy	VAS	Saline	2	2	2	1	3	1	1	1
10092761	7	Male	1	18	CA Urinary bladder	Chemoport insertion	CHEOPS	Saline	7	8	7	8	12	6	6	7
10093224	5	Female	1	12	Tonsillitis	Tonsillectomy	CHEOPS	Saline	9	9	8	8	11	5	7	6
10093431	12	Male	1	30	Cholecystitis	Laparoscopic cholecystectomy	VAS	Saline	2	2	2	1	1	2	2	1
10093591	17	Female	1	40	Tonsillitis	Tonsillectomy	VAS	Saline	2	2	2	2	3	3	2	1
10093842	12	Female	1	36	Tonsillitis	Tonsillectomy	VAS	Saline	2	2	2	3	4	1	2	1
10094006	8	Male	1	15	Appendicitis	Laparoscopic Appendicectomy	VAS	Saline	2	2	2	1	2	1	1	1
10094436	12	Male	1	38	Cholecystitis	Laparoscopic cholecystectomy	VAS	Saline	2	2	2	1	2	1	1	1
10094463	7	Male	1	12	Tonsillitis	Tonsillectomy	CHEOPS	Saline	8	8	9	9	14	6	7	7
10094745	14	Male	1	30	Acute Appendicitis	Laparoscopic Appendicectomy	VAS	Saline	2	2	2	1	3	1	1	1
10166231	15	Male	1	29	Tonsillitis	Tonsillectomy	VAS	Saline	2	2	2	2	3	4	0	1
10776521	7	Female	1	19	Tonsillitis	Tonsillectomy	CHEOPS	Saline	8	9	9	8	11	5	6	7

IP No	Age (years)	Sex	ASA	Weight (Kgs)	Diagnosis	Surgery	Pain Scale	Group	Pain (15 min)	Pain (30min)	Pain (45 min)	Pain (60 min)	Pain (120 min)	Pain (360 min)	Pain (720 min)	Pain (1440 min)
11500128	5	Male	1	10	Acute Appendicitis	Laparoscopic Appendicectomy	CHEOPS	Saline	7	7	8	9	6	6	8	8
11503067	7	Male	1	15	Tonsillitis	Tonsillectomy	CHEOPS	Saline	7	8	9	8	12	6	8	6
10852557	6	Female	1	12	Tonsillitis	Tonsillectomy	CHEOPS	Saline	8	7	8	8	13	5	6	5
10012131	13	Male	1	26	Tonsillitis	Tonsillectomy	VAS	Saline	2	2	2	3	4	2	1	1
10091569	15	Female	1	38	Soft tumor on head	Excision	VAS	Saline	3	3	3	3	1	2	3	1

Wilson Sedation Scores

IP No	Age (years)	Sex	ASA	Weight (Kgs)	Diagnosis	Surgery	Pain Scale	Group	Wilsom Sedation (15 min)	Wilsom Sedation (30 min)	Wilsom Sedation (45 min)	Wilsom Sedation (60 min)	Wilsom Sedation (120 min)	Wilsom Sedation (360 min)	Wilsom Sedation (720 min)	Wilsom Sedation (1440 min)	Time for Rescue Analgesia (min)	Total Amount of Analgesia (mg)	Side effects
10000859	5	Male	1	18	Tonsillitis	Tonsillectomy	CHEOPS	Ketamine	2	2	2	2	1	1	1	1	360	270	-
10002348	6	Male	1	20	Acute Appendicitis	Laparoscopic Appendicectomy	CHEOPS	Ketamine	2	2	2	2	1	1	1	1	720	300	-
10053925	6	Male	1	13	Tonsillitis	Tonsillectomy	CHEOPS	Ketamine	2	2	2	2	1	1	1	1	1440	195	-
10054691	5	Male	1	12	Tonsillitis	Tonsillectomy	CHEOPS	Ketamine	2	2	2	2	1	1	1	1	1440	180	vomitting
10055989	7	Male	1	17	Tonsillitis	Tonsillectomy	CHEOPS	Ketamine	2	2	2	2	1	1	1	1	360	255	-
10070992	5	Male	1	20	Tonsillitis	Tonsillectomy	CHEOPS	Ketamine	2	1	1	1	1	1	1	1	360	300	-
10072651	5	Male	1	15	Tonsillitis	Tonsillectomy	CHEOPS	Ketamine	2	2	2	2	1	1	1	1	720	225	-
10085431	6	Female	1	18	Lymphnode swelling	Excision	CHEOPS	Ketamine	2	2	2	2	1	1	1	1	720	270	-
10087695	5	Male	1	19	Acute Appendicitis	Laparoscopic Appendicectomy	CHEOPS	Ketamine	2	2	2	2	1	1	1	1	720	285	-
10090813	7	Male	1	18	Tonsillitis	Tonsillectomy	CHEOPS	Ketamine	2	2	2	2	1	1	1	1	360	270	-
10002388	11	Female	1	30	Ranula	Excision	VAS	Ketamine	2	2	2	1	1	1	1	1	720	450	-

IP No	Age (years)	Sex	ASA	Weight (Kgs)	Diagnosis	Surgery	Pain Scale	Group	Wilsom Sedation (15 min)	Wilsom Sedation (30 min)	Wilsom Sedation (45 min)	Wilsom Sedation (60 min)	Wilsom Sedation (120 min)	Wilsom Sedation (360 min)	Wilsom Sedation (720 min)	Wilsom Sedation (1440 min)	Time for Rescue Analgesia (min)	Total Amount of Analgesia (mg)	Side effects
10003179	15	Female	1	15	Acute Appendicitis	Laparoscopic Appendicectomy	VAS	Ketamine	2	1	1	1	1	1	1	1	720	225	-
10003378	16	Female	1	50	Acute Appendicitis	Laparoscopic Appendicectomy	VAS	Ketamine	2	2	1	1	1	1	1	1	720	750	-
10003968	14	Male	1	33	Ranula	Excision	VAS	Ketamine	2	2	2	2	1	1	1	1	720	495	-
10004229	8	Male	1	12	Acute Appendicitis	Laparoscopic Appendicectomy	VAS	Ketamine	2	2	2	1	1	1	1	1	720	180	-
10005257	12	Male	1	31	Acute Appendicitis	Laparoscopic Appendicectomy	VAS	Ketamine	2	1	1	1	1	1	1	1	720	465	-
10030112	15	Male	1	40	Tonsillitis	Tonsillectomy	VAS	Ketamine	2	2	2	2	1	1	1	1	720	600	-
10030384	10	Male	1	15	Tonsillitis	Tonsillectomy	VAS	Ketamine	2	2	2	2	1	1	1	1	720	225	-
10030410	11	Female	1	27	Tonsillitis	Tonsillectomy	VAS	Ketamine	2	2	2	2	1	1	1	1	720	405	-
10030411	12	Male	1	28	Tonsillitis	Tonsillectomy	VAS	Ketamine	2	2	2	1	1	1	1	1	720	420	-
10031214	10	Male	1	22	Tonsillitis	Tonsillectomy	VAS	Ketamine	2	2	2	2	1	1	1	1	720	330	-
10055797	13	Male	1	27	Tonsillitis	Tonsillectomy	VAS	Ketamine	2	2	2	2	1	1	1	1	720	405	-

IP No	Age (years)	Sex	ASA	Weight (Kgs)	Diagnosis	Surgery	Pain Scale	Group	Wilsom Sedation (15 min)	Wilsom Sedation (30 min)	Wilsom Sedation (45 min)	Wilsom Sedation (60 min)	Wilsom Sedation (120 min)	Wilsom Sedation (360 min)	Wilsom Sedation (720 min)	Wilsom Sedation (1440 min)	Time for Rescue Analgesia (min)	Total Amount of Analgesia (mg)	Side effects
10056822	15	Female	1	40	Chronic Suppurative Otitis Media	Tympanoplasty	VAS	Ketamine	2	2	2	2	1	1	1	1	720	600	-
10057455	15	Female	1	40	Acute appendicitis	Laparoscopic Appendicectomy	VAS	Ketamine	2	2	2	2	1	1	1	1	720	600	-
10057587	14	Female	1	40	Tonsillitis	Tonsillectomy	VAS	Ketamine	2	2	2	1	1	1	1	1	720	600	-
10057982	8	Male	1	19	Tonsillitis	Tonsillectomy	VAS	Ketamine	2	2	2	2	1	1	1	1	720	285	-
10059643	14	Male	1	38	Tonsillitis	Tonsillectomy	VAS	Ketamine	2	2	2	1	1	1	1	1	720	570	-
10061057	17	Male	1	36	Tonsillitis	Tonsillectomy	VAS	Ketamine	2	2	2	1	1	1	1	1	720	540	-
10061068	9	Female	1	20	Tonsillitis	Tonsillectomy	VAS	Ketamine	2	2	2	2	1	1	1	1	720	300	-
10061316	14	Male	1	40	Tonsillitis	Tonsillectomy	VAS	Ketamine	2	2	2	2	1	1	1	1	720	600	-
10061326	14	Male	1	40	Tonsillitis	Tonsillectomy	VAS	Ketamine	2	2	2	2	1	1	1	1	720	600	vomitting
10061413	13	Female	1	35	Lymph Node Swelling	Excision	VAS	Ketamine	2	2	2	2	1	1	1	1	720	525	-
10061427	15	Male	1	35	Lipoma over chest wall	Excision	VAS	Ketamine	2	2	2	1	1	1	1	1	720	525	-

IP No	Age (years)	Sex	ASA	Weight (Kgs)	Diagnosis	Surgery	Pain Scale	Group	Wilsom Sedation (15 min)	Wilsom Sedation (30 min)	Wilsom Sedation (45 min)	Wilsom Sedation (60 min)	Wilsom Sedation (120 min)	Wilsom Sedation (360 min)	Wilsom Sedation (720 min)	Wilsom Sedation (1440 min)	Time for Rescue Analgesia (min)	Total Amount of Analgesia (mg)	Side effects
10061431	11	Female	1	32	Branchial cyst	Excision	VAS	Ketamine	2	2	2	2	1	1	1	1	720	480	-
10061432	13	Male	1	20	CA Urinary bladder	Chemoport insertion	VAS	Ketamine	2	2	2	2	1	1	1	1	720	300	-
10061706	13	Male	1	62	Branchial Cyst	Excision	VAS	Ketamine	2	2	2	2	1	1	1	1	720	930	-
10065503	11	Male	1	25	Tonsillitis	Tonsillectomy	VAS	Ketamine	2	2	2	2	1	1	1	1	720	375	-
10065504	11	Male	1	25	Tonsillitis	Tonsillectomy	VAS	Ketamine	2	2	2	2	1	1	1	1	720	375	-
10066333	9	Female	1	28	Tonsillitis	Tonsillectomy	VAS	Ketamine	2	2	2	2	1	1	1	1	720	420	-
10068463	14	Female	1	48	Fibroadenoma	Excision	VAS	Ketamine	2	1	1	1	1	1	1	1	720	720	-
10070993	10	Male	1	18	Tonsillitis	Tonsillectomy	VAS	Ketamine	2	2	2	2	1	1	1	1	720	270	-
10073550	17	Male	1	50	Tonsillitis	Tonsillectomy	VAS	Ketamine	2	1	1	1	1	1	1	1	720	750	-
10075159	13	Male	1	30	Pain abdomen	Laparoscopic Appendicectomy	VAS	Ketamine	2	2	2	2	1	1	1	1	720	450	-
10082550	13	Male	1	40	Tonsillitis	Tonsillectomy	VAS	Ketamine	2	2	2	2	1	1	1	1	720	600	vomitting
10085275	11	Male	1	24	Tonsillitis	Tonsillectomy	VAS	Ketamine	2	2	2	2	1	1	1	1	720	360	-

IP No	Age (years)	Sex	ASA	Weight (Kgs)	Diagnosis	Surgery	Pain Scale	Group	Wilsom Sedation (15 min)	Wilsom Sedation (30 min)	Wilsom Sedation (45 min)	Wilsom Sedation (60 min)	Wilsom Sedation (120 min)	Wilsom Sedation (360 min)	Wilsom Sedation (720 min)	Wilsom Sedation (1440 min)	Time for Rescue Analgesia (min)	Total Amount of Analgesia (mg)	Side effects
10085597	15	Female	1	42	Cholecystitis	Laparoscopic cholecystectomy	VAS	Ketamine	2	2	2	2	1	1	1	1	720	630	-
10087668	13	Male	1	31	Pain abdomen	Laparoscopic Appendicectomy	VAS	Ketamine	2	2	2	2	1	1	1	1	720	465	-
10088189	13	Male	1	28	Tonsillitis	Tonsillectomy	VAS	Ketamine	2	2	2	2	1	1	1	1	720	420	-
10088254	11	Male	1	29	Cholecystitis	Laparoscopic cholecystectomy	VAS	Ketamine	2	2	2	2	1	1	1	1	720	435	-
10088352	14	Male	1	35	Tonsillitis	Tonsillectomy	VAS	Ketamine	2	2	2	2	1	1	1	1	720	525	vomitting
10088453	10	Male	1	23	Tonsillitis	Tonsillectomy	VAS	Ketamine	2	2	2	2	1	1	1	1	720	345	vomitting
10088875	14	Male	1	40	Acute Appendicitis	Laparoscopic Appendicectomy	VAS	Ketamine	2	2	2	2	1	1	1	1	720	600	-
10032269	11	Male	1	25	Tonsillitis	Tonsillectomy	VAS	Saline	1	1	1	1	1	1	1	1	130	1125	-
10045900	18	Male	1	45	Chronic Suppurative Otitis Media	Tympanoplasty	VAS	Saline	1	1	1	1	1	1	1	1	360	1350	vomitting
10047797	14	Male	1	42	Tonsillitis	Tonsillectomy	VAS	Saline	1	1	1	1	1	1	1	1	240	1260	-
10057194	8	Male	1	21	Leukemia	Chemoport insertion	VAS	Saline	1	1	1	1	1	1	1	1	240	630	-

IP No	Age (years)	Sex	ASA	Weight (Kgs)	Diagnosis	Surgery	Pain Scale	Group	Wilsom Sedation (15 min)	Wilsom Sedation (30 min)	Wilsom Sedation (45 min)	Wilsom Sedation (60 min)	Wilsom Sedation (120 min)	Wilsom Sedation (360 min)	Wilsom Sedation (720 min)	Wilsom Sedation (1440 min)	Time for Rescue Analgesia (min)	Total Amount of Analgesia (mg)	Side effects
10057553	13	Male	1	38	Acute appendicitis	Laparoscopic Appendicectomy	VAS	Saline	1	1	1	1	1	1	1	1	120	1710	-
10057764	18	Female	1	45	Acute Appendicitis	Laparoscopic Appendicectomy	VAS	Saline	1	1	1	1	1	1	1	1	120	2025	-
10058347	13	Female	1	41	Chronic Suppurative Otitis Media	Tympanoplasty	VAS	Saline	1	1	1	1	1	1	1	1	160	1845	-
10058391	14	Male	1	50	Tonsillitis	Tonsillectomy	VAS	Saline	1	1	1	1	1	1	1	1	120	2250	-
10058637	18	Female	1	49	Chronic Suppurative Otitis Media	Tympanoplasty	VAS	Saline	1	1	1	1	1	1	1	1	240	1470	-
10058983	18	Female	1	44	Cervical Lymphadenopathy	Excision	VAS	Saline	1	1	1	1	1	1	1	1	150	1980	-
10059270	12	Male	1	18	Tonsillitis	Tonsillectomy	VAS	Saline	1	1	1	1	1	1	1	1	120	810	-
10059274	13	Male	1	22	Tonsillitis	Tonsillectomy	VAS	Saline	1	1	1	1	1	1	1	1	120	990	-
10059519	9	Male	1	22	Tonsillitis	Tonsillectomy	VAS	Saline	1	1	1	1	1	1	1	1	360	660	-
10059638	14	Male	1	38	Tonsillitis	Tonsillectomy	VAS	Saline	1	1	1	1	1	1	1	1	120	1710	-
10059756	11	Male	1	50	Chronic Suppurative Otitis Media	Tympanoplasty	VAS	Saline	1	1	1	1	1	1	1	1	360	1500	vomitting

IP No	Age (years)	Sex	ASA	Weight (Kgs)	Diagnosis	Surgery	Pain Scale	Group	Wilsom Sedation (15 min)	Wilsom Sedation (30 min)	Wilsom Sedation (45 min)	Wilsom Sedation (60 min)	Wilsom Sedation (120 min)	Wilsom Sedation (360 min)	Wilsom Sedation (720 min)	Wilsom Sedation (1440 min)	Time for Rescue Analgesia (min)	Total Amount of Analgesia (mg)	Side effects
10064991	14	Female	1	42	Tonsillitis	Tonsillectomy	VAS	Saline	1	1	1	1	1	1	1	1	360	1260	-
10058046	7	Male	1	18	Tonsillitis	Tonsillectomy	CHEOPS	Saline	1	1	1	1	1	1	1	1	120	810	vomitting
10058664	7	Female	1	15	Tonsillitis	Tonsillectomy	CHEOPS	Saline	1	1	1	1	1	1	1	1	120	675	-
10068093	14	Female	1	40	Tonsillitis	Tonsillectomy	VAS	Saline	1	1	1	1	1	1	1	1	120	1800	-
10068107	18	Female	1	45	Dermoid cyst on scalp	Excision	VAS	Saline	1	1	1	1	1	1	1	1	60	2025	-
10068394	14	Female	1	42	Tonsillitis	Tonsillectomy	VAS	Saline	1	1	1	1	1	1	1	1	120	1890	-
10069334	17	Male	1	50	Appendicitis	Laparoscopic Appendicectomy	VAS	Saline	1	1	1	1	1	1	1	1	45	2250	-
10059050	5	Female	1	12	Hemangioma on arm	Excision	CHEOPS	Saline	1	1	1	1	1	1	1	1	60	540	-
10059556	6	Female	1	12	Tonsillitis	Tonsillectomy	CHEOPS	Saline	1	1	1	1	1	1	1	1	120	540	-
10076521	12	Male	1	22	Tonsillitis	Tonsillectomy	VAS	Saline	1	1	1	1	1	1	1	1	120	990	-
10078922	15	Male	1	30	Tonsillitis	Tonsillectomy	VAS	Saline	1	1	1	1	1	1	1	1	140	1350	-

IP No	Age (years)	Sex	ASA	Weight (Kgs)	Diagnosis	Surgery	Pain Scale	Group	Wilsom Sedation (15 min)	Wilsom Sedation (30 min)	Wilsom Sedation (45 min)	Wilsom Sedation (60 min)	Wilsom Sedation (120 min)	Wilsom Sedation (360 min)	Wilsom Sedation (720 min)	Wilsom Sedation (1440 min)	Time for Rescue Analgesia (min)	Total Amount of Analgesia (mg)	Side effects
10067146	5	Male	1	11	Tonsillitis	Tonsillectomy	CHEOPS	Saline	1	1	1	1	1	1	1	1	120	495	-
10067574	7	Male	1	12	Tonsillitis	Tonsillectomy	CHEOPS	Saline	1	1	1	1	1	1	1	1	120	540	-
10067575	6	Male	1	9	Tonsillitis	Tonsillectomy	CHEOPS	Saline	1	1	1	1	1	1	1	1	120	405	-
10081441	7	Male	1	14	Leukemia	Chemoport insertion	CHEOPS	Saline	1	1	1	1	1	1	1	1	120	630	-
10082850	5	Male	1	10	Tonsillitis	Tonsillectomy	CHEOPS	Saline	1	1	1	1	1	1	1	1	60	450	-
10087916	5	Male	1	12	Tonsillitis	Tonsillectomy	CHEOPS	Saline	1	1	1	1	1	1	1	1	60	540	vomitting
10089742	7	Male	1	14	Tonsillitis	Tonsillectomy	CHEOPS	Saline	1	1	1	1	1	1	1	1	120	630	-
10091693	15	Male	1	42	Tonsillitis	Tonsillectomy	VAS	Saline	1	1	1	1	1	1	1	1	140	1890	-
10092084	13	Male	1	37	Acute Appendicitis	Laparoscopic Appendicectomy	VAS	Saline	1	1	1	1	1	1	1	1	120	1665	vomitting
10092189	13	Male	1	38	Acute Appendicitis	Laparoscopic Appendicectomy	VAS	Saline	1	1	1	1	1	1	1	1	180	1140	-
10092761	7	Male	1	18	CA Urinary bladder	Chemoport insertion	CHEOPS	Saline	1	1	1	1	1	1	1	1	120	810	-
10093224	5	Female	1	12	Tonsillitis	Tonsillectomy	CHEOPS	Saline	1	1	1	1	1	1	1	1	120	540	-

IP No	Age (years)	Sex	ASA	Weight (Kgs)	Diagnosis	Surgery	Pain Scale	Group	Wilsom Sedation (15 min)	Wilsom Sedation (30 min)	Wilsom Sedation (45 min)	Wilsom Sedation (60 min)	Wilsom Sedation (120 min)	Wilsom Sedation (360 min)	Wilsom Sedation (720 min)	Wilsom Sedation (1440 min)	Time for Rescue Analgesia (min)	Total Amount of Analgesia (mg)	Side effects
10093431	12	Male	1	30	Cholecystitis	Laparoscopic cholecystectomy	VAS	Saline	1	1	1	1	1	1	1	1	120	1350	-
10093591	17	Female	1	40	Tonsillitis	Tonsillectomy	VAS	Saline	1	1	1	1	1	1	1	1	360	1200	-
10093842	12	Female	1	36	Tonsillitis	Tonsillectomy	VAS	Saline	1	1	1	1	1	1	1	1	120	1620	-
10094006	8	Male	1	15	Appendicitis	Laparoscopic Appendicectomy	VAS	Saline	1	1	1	1	1	1	1	1	120	675	-
10094436	12	Male	1	38	Cholecystitis	Laparoscopic cholecystectomy	VAS	Saline	1	1	1	1	1	1	1	1	380	1140	-
10094463	7	Male	1	12	Tonsillitis	Tonsillectomy	CHEOPS	Saline	1	1	1	1	1	1	1	1	60	540	-
10094745	14	Male	1	30	Acute Appendicitis	Laparoscopic Appendicectomy	VAS	Saline	1	1	1	1	1	1	1	1	190	900	-
10166231	15	Male	1	29	Tonsillitis	Tonsillectomy	VAS	Saline	1	1	1	1	1	1	1	1	360	870	-
10776521	7	Female	1	19	Tonsillitis	Tonsillectomy	CHEOPS	Saline	1	1	1	1	1	1	1	1	120	855	vomitting
11500128	5	Male	1	10	Acute Appendicitis	Laparoscopic Appendicectomy	CHEOPS	Saline	1	1	1	1	1	1	1	1	60	450	-

IP No	Age (years)	Sex	ASA	Weight (Kgs)	Diagnosis	Surgery	Pain Scale	Group	Wilsom Sedation (15 min)	Wilsom Sedation (30 min)	Wilsom Sedation (45 min)	Wilsom Sedation (60 min)	Wilsom Sedation (120 min)	Wilsom Sedation (360 min)	Wilsom Sedation (720 min)	Wilsom Sedation (1440 min)	Time for Rescue Analgesia (min)	Total Amount of Analgesia (mg)	Side effects
11503067	7	Male	1	15	Tonsillitis	Tonsillectomy	CHEOPS	Saline	1	1	1	1	1	1	1	1	120	675	vomitting
10852557	6	Female	1	12	Tonsillitis	Tonsillectomy	CHEOPS	Saline	1	1	1	1	1	1	1	1	60	540	-
10012131	13	Male	1	26	Tonsillitis	Tonsillectomy	VAS	Saline	1	1	1	1	1	1	1	1	360	780	-
10091569	15	Female	1	38	Soft tumor on head	Excision	VAS	Saline	1	1	1	1	1	1	1	1	180	1140	-