# "COMPARISON OF POSTOPERATIVE ANALGESIC EFFICACY OF TOPICAL ANAESTHESIA AND COMBINED TOPICAL ANAESTHESIA WITH NERVE BLOCK [ANTERIOR ETHMOIDAL NERVE AND INFRAORBITAL NERVE] IN PATIENTS UNDERGOING SEPTAL AND ENDOSCOPIC SINUS SURGERIES UNDER GENERAL ANAESTHESIA"

Dissertation submitted to THE TAMILNADU DR.M.G.R.MEDICAL UNIVERSITY in partial fulfillment for the award of the degree of

**DOCTOR OF MEDICINE** 

IN

ANAESTHESIOLOGY



# INSTITUTE OF ANAESTHESIOLOGY AND CRITICAL CARE

# MADRAS MEDICAL COLLEGE

CHENNAI - 600 003

**APRIL 2016** 

#### CERTIFICATE

This is to certify that the dissertation entitled "Comparison of postoperative analgesic efficacy of Topical anaesthesia and combined Topical anaesthesia with Nerve block [Anterior Ethmoidal nerve and Infraorbital nerve] in patients undergoing septal and endoscopic sinus surgeries under General anaesthesia" submitted by DR.C.CHITRA in partial fulfillment for the award of the degree of Doctor of Medicine in Anaesthesiology by The Tamilnadu Dr.M.G.R. Medical University, Chennai and it is a bonafide record of work done by her in the Institute of Anaesthesiology and Critical Care, Madras Medical College and Rajiv Gandhi Government General Hospital, during the academic year 2014-2016.

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# **DECLARATION BY THE GUIDE**

This work was done by Dr.C.CHITRA on the topic "Comparison of postoperative analgesic efficacy of Topical anaesthesia and combined Topical anaesthesia with Nerve block [Anterior Ethmoidal nerve and Infraorbital nerve] in patients undergoing septal and endoscopic sinus surgeries under General anaesthesia" under my supervision and I ensure that the candidate has abided by the rules of the ethical committee.

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PLACE:

#### **DECLARATION**

I, Dr.C.Chitra, solemnly declare that this dissertation entitled "Comparison of postoperative analgesic efficacy of Topical anaesthesia and combined Topical anaesthesia with Nerve block [Anterior Ethmoida] nerve and Infraorbital nerve] in patients undergoing septal and endoscopic sinus surgeries under General anaesthesia" is a bonafide work done by me in the Institute of Anaesthesiology and Critical Care, Madras Medical College and Rajiv Gandhi Government General Hospital, Chennai, during the period 2014-2016 under the guidance of Professor Dr.V.Pankajavalli, M.D., D.A., Institute of Anaesthesiology and Critical care, Madras Medical College and Rajiv Gandhi Government General Hospital, Chennai-3 and submitted to The Tamilnadu Dr.M.G.R.Medical University, Guindy, Chennai-32, in partial fulfillment for the award of the degree of MD Anaesthesiology (Branch X). I have not submitted this dissertation previously to any university or journal for the award of any degree or diploma.

DATE: PLACE:

(Dr.C.Chitra)

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#### ABSTRACT

# COMPARISON OF POSTOPERATIVE ANALGESIC EFFICACY OF TOPICAL ANAESTHESIA AND COMBINED TOPICAL ANAESTHESIA WITH NERVE BLOCK [ANTERIOR ETHMOIDAL NERVE AND INFRAORBITAL NERVE] IN PATIENTS UNDERGOING SEPTAL AND ENDOSCOPIC SINUS SURGERIES UNDER GENERAL ANAESTHESIA

#### **BACKGROUND AND OBJECTIVES:**

Functional Endoscopic Sinus Surgery (FESS), septoplasty, submucosal resection of nasal septum, polypectomy are the commonly performed nasal surgeries. Peripheral nerve blocks provide superior pain control during surgery and post operative period and devoid of side effects like somnolence, nausea and vomiting. They also attenuate the stress response following surgery.

#### **MATERIALS AND METHODS:**

A total of sixty patients were taken up for the study. They were randomly divided into two groups, Group A received topical anaesthesia followed by General anaesthesia and Group B received Topical anaesthesia followed by General anaesthesia and then bilateral nerve block of Anterior Ethmoidal nerve and Infraorbital nerve prior to surgery. The comparison of analgesic efficacy was done based on the intraoperative and post operative haemodynamics, postoperative pain scoring by Visual Analogue Scale (VAS) and need for rescue analgesia.

#### **RESULTS:**

Patients who received topical anaesthesia combined with the nerve block (Group B) were found to have good perioperative haemodynamic stability, reduced post operative pain and reduced need for rescue analgesia when compared to the patients who received topical anaesthesia alone (Group A).There was a statistically significant difference between both the groups with p<0.05 in the postoperative haemodynamics, post operative pain (visual analogue scale) and need for rescue analgesia.

#### **CONCLUSION:**

The Anterior ethmoidal nerve block and Infraorbital nerve block with Bupivacaine given preoperatively in combination with the topical anaesthesia provided more haemodynamic stability in perioperative period, reduce the postoperative pain and the need for rescue analgesia when compared to topical anaesthesia alone in nasal surgeries done under General anaesthesia.

#### **KEY WORDS:**

Topical anaesthesia, Anterior ethmoidal nerve block, Infraorbital nerve block, Nasal surgeries.

#### **INTRODUCTION**

# "For all the happiness that mankind can gain It is not in pleasure but in relief from pain"

#### John Dyrden.

Pain is a fundamental protective biological phenomenon. The International Association for the Study of Pain has defined pain as an unpleasant sensory and emotional experience associated with actual or potential tissue damage. Adequate pain relief during the perioperative period is the main part of balanced anaesthesia.

Functional Endoscopic Sinus Surgery (FESS), septoplasty, submucosal resection of nasal septum, polypectomy are the commonly performed nasal surgeries. Anaesthesia for the nasal surgeries has evolved from topical local anaesthesia, local anaesthesia with intravenous sedation, local anaesthesia with General anaesthesia, Regional nerve blocks, combined nerve blocks with General anaesthesia.

Local anaesthetics were used topically and the major limitations of topical anaesthesia are inadequate blocks and patient discomfort.

Intravenous sedation with topical anaesthesia has increased the patient comfort but at the same time increases the risk of aspiration as it may abolish the airway reflexes.

General anaesthesia is popularly used in nasal surgeries. The use of cuffed oral tracheal tube and posterior pharyngeal pack prevent aspiration, controlled hypotension to decrease the blood loss, adequate muscle relaxation and smooth emergence and extubation are the main protocols followed in General anaesthesia in such surgeries.

1

Regional nerve block techniques like blockade of anterior and posterior Ethmoidal nerve, Greater palatine nerve, Glossopharygeal nerve, Infraorbital nerve have gained importance nowadays and become a well accepted component of comprehensive anaesthetic care. Its role as expanded from the operating room into the arena of post operative pain management.

Peripheral nerve blocks have definite advantages of high degree of patient and surgeon satisfaction because of superior pain control during surgery and post operative period and devoid of side effects like somnolence, nausea and vomiting. These techniques also have found to attenuate the stress response following surgery.

Opiods are the drugs which are commonly used for post operative pain relief but these drugs have certain limitations like respiratory depression, sedation, nausea and vomiting.

The regional nerve blocks can provide better post operative pain relief comparable to opiods without much side effects.

#### **ANATOMY OF THE NOSE**

The nose consists of the external nose and the nasal cavity.

#### **External nose:**

It is pyramidal in shape which consists of osteocartilaginous framework covered by muscles and skin.

#### **Osteocartilaginous framework:**

Upper one third is bony which consists of two nasal bones, and lower two thirds is cartilaginous which consists of upper lateral cartilages, lower lateral cartilages, lesser alar cartilages, and septal cartilage.

#### Nasal musculature:

The nasal muscles help to provide movement of nasal tip, and the overlying skin. Procerus nasalis, Levetaor labii superioris alaque nasi, depressor septi, anterior and posterior dilator nares are the nasal muscles.

#### Nasal skin:

The skin over the nasal bones is thin and freely mobile. The skin over the nasal cartilages is thick and adherent and contains plenty of sebaceous glands.

#### Internal nose:

It is divided into right and left nasal cavities by the nasal septum. Anterior nasal aperture is called the naris /nostril. Posterior nasal aperture is called choana.

#### Nasal cavity consists of two portions-

Vestibule: [Skin lined portion] in the anterior and inferior part of the nasal cavity.
It contains sebaceous glands, hair follicles, and hair is called as vibrissae.

2. Nasal cavity proper: It consists of lateral wall, medial wall, roof and floor.

#### Lateral wall:

It contains three projections called turbinates [Inferior, Middle, Superior]. Below each turbinate is the corresponding meatus. [Inferior, Middle, Superior meatus].

#### Medial wall:

It consists of three parts: Columellar septum, Membranous septum, Septum proper.

Septum proper consists of 1.The vomer 2. The perpendicular plate of the ethmoid, 3. Large septal cartilage.

#### **Roof:**

Anterior part -formed by nasal bones, middle part by cribriform plate of ethmoid bone, posterior part by the body of sphenoid bone.

#### Floor:

Anterior three-fourths is formed by the palatine process of the maxilla, posterior one-fourths is formed by the horizontal plate of the palatine bone.

#### NERVE SUPPLY OF THE NOSE:

#### 1. Olfactory nerves-

12-20 nerves pass through the cribiform plate and end in the olfactory bulb. They supply the olfactory region of the nose and carry the sense of smell.

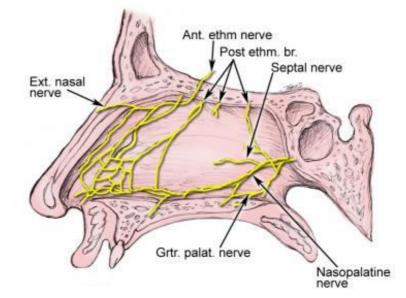
#### 2. Autonomic nerves-

Parasympathetic nerve fibres -from Greater superficial Petrosal nerve (vasodilatation and nasal secretion). Sympathetic nerve fibres-from Deep Petrosal nerve (vasoconstriction)

#### 3. Nerves of general sensation-

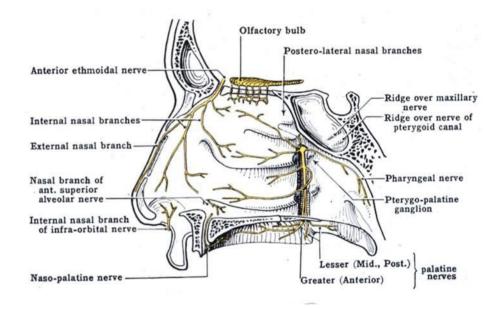
They are derived from ophthalmic and maxillary divisions of the Trigeminal nerve (cranial nerve-V).

- 1. Anterior Ethmoidal nerve-anterior parts of nasal cavity- both the lateral wall and the septum is supplied by this nerve.
- 2. Infraorbital nerve-supply the vestibule of the nose both the lateral and medial side.
- 3. Branches of Sphenopalatine ganglion (Nasopalatine, Greater palatine nerves) supply posterior part of nasal cavity, both the lateral and medial side.



NERVE SUPPLY OF THE NASAL SEPTUM

#### NERVE SUPPLY OF THE LATERAL WALL OF NOSE



#### LYMPHATIC DRAINAGE OF THE NOSE:

Anterior part and external nose - Submandibular nodes

Posterior part - Retropharygeal nodes and upper deep cervical nodes.

#### **BLOOD SUPPLY OF THE NOSE:**

The nose is supplied richly by the External and Internal Carotid systems.

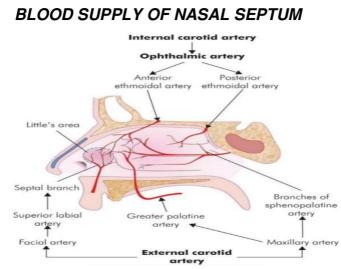
Nasal septum: -

#### Internal carotid system:

Anterior ethmoidal and posterior ethmoidal artery (branches of Ophthalmic artery)

#### **External carotid system:**

Sphenopalatine artery and Greater palatine artery (branch of maxillary artery), septal branch of superior labial artery (branch of facial artery).



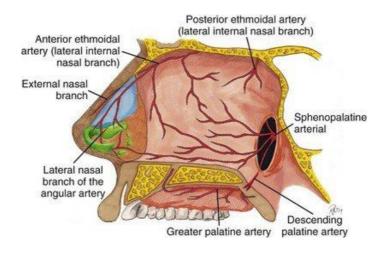
#### Lateral wall: -

#### Internal carotid system:

Anterior ethmoidal and Posterior ethmoidal artery(branches of Ophthalmic artery).

#### External carotid system:

Posterior lateral nasal branches (from Spheno palatine A.), Greater palatine artery( From maxillary A.), Anterior superior dental branches( from the infra orbital branch of maxillary A.), vestibular branches from Facial A.



## **BLOOD SUPPLY OF THE LATERAL WALL OF NOSE**

# ANATOMY OF PARANASAL SINUSES

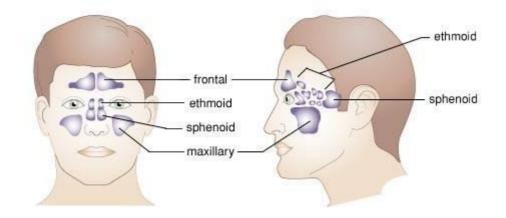
The Paranasal sinuses are air-containing cavities around the nasal cavity. They are lined by Pseudo stratified ciliated columnar epithelium. They four sinuses are,

Frontal air sinuses in the frontal bone

Ethmoidal air sinuses in the ethmoidal bone

Maxillary air sinuses in the maxillary bone

Sphenoidal air sinuses in the sphenoidal bone



#### FUNCTION OF PARANASAL SINUSES:

- Add humidity and temperature to the inspired air
- Resonance to the voice
- Aid to make the skull lighter
- Aid for the growth of facial skeleton

# **NERVE SUPPLY:**

Frontal Sinus :	Supraorbital nerve
Maxillary sinus :	Infraorbital nerve, Anterior, Middle and Posterior superior
	alveolar from Maxillary nerve
Ethmoidal sinus :	Anterior and Posterior Ethmoidal nerve
Sphenoidal sinus :	Branches From Sphenopalatine Ganglion

# DRAINAGE OF PARANASAL SINUSES:

Frontal sinus	:	Infundibulum of middle meatus
Anterior ethmoidal sinus	:	Infundibulum of middle meatus
Middle ethmoidal sinus	:	Middle smeatus on or above the bulla ethmoidalis
Posterior ethmoidal sinus	:	Superior meatus
Maxillary sinus	:	posterior part of the infundibulum of middle meatus
Sphenoidal sinus	:	Sphenoethmoidal recess

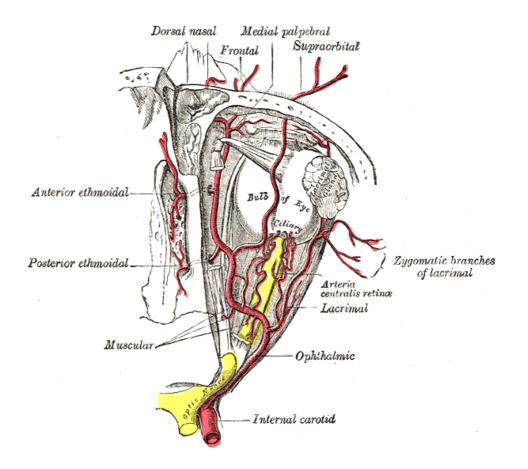
#### NEUROANATOMY OF ANTERIOR ETHMOIDAL NERVE

The ophthalmic division is the first division of the Trigeminal nerve.

It gives rise to the nasociliary nerve.

The nasociliary nerve has given off its four branches -

1. Ramus communicans to ciliary ganglion, 2.Long ciliary nerves, 3. infratrochlear nerve, 4. Posterior ethmoidal nerve and after crossing the Optic nerve it run below the superior rectus and superior oblique muscle and then continues as the anterior ethmoidal nerve near the medial orbital wall.

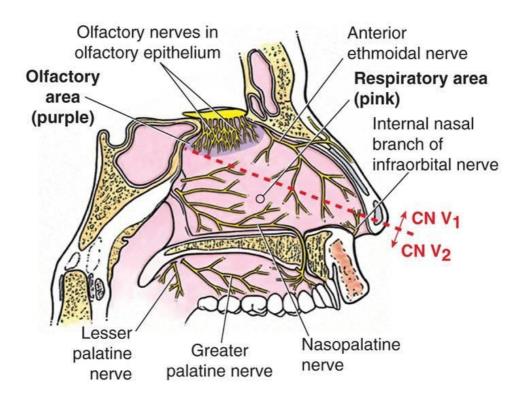


The anterior ethmoidal nerve gives sensory branches to the meninges and it transverses through the anterior ethmoidal foramen and the canal and run along the cribriform plate to enter the nasal cavity through the slit lateral to the crista galli.

The anterior ethmoidal nerve provides sensory branches to the nasal cavity. It divides into internal and external nasal branches.

**The external nasal branch** passes deep to nasalis and the superficial musculo aponeurotic layer, deep fatty layer till the alar cartilages, and supplies sensation to the skin of the nasal ala, distal aspect of the dorsum of the nose and tip of the nose.

**The internal nasal branch** divides into the medial and lateral nasal branches which supplies the mucosa of the nasal septum and the lateral nasal wall, respectively.



#### NEURO ANATOMY OF INFRAORBITAL NERVE

The Trigeminal nerve gives rise to second division, the maxillary nerve. The maxillary nerve enter via the foramen rotundum and then enter the pterygopalatine fossa. It gives branches to the pterygopalatine ganglion .It continues anteriorly to give sensory branches that innervate the midface.

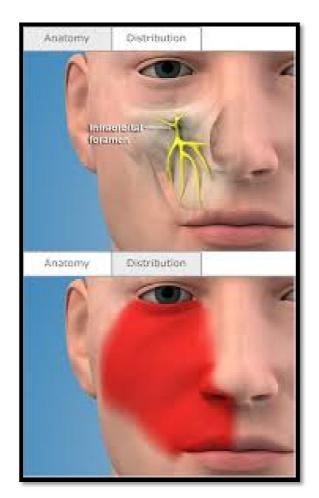
The sensory nerves from the maxillary nerve are the anterior superior alveolar nerve and the infraorbital nerve.

The anterior superior alveolar nerve arise in the infraorbital canal and pass below the infraorbital foramen, and it turns inferolaterally to supply the sensation to the incisors, center of the lip, columella, and tip of the nose.

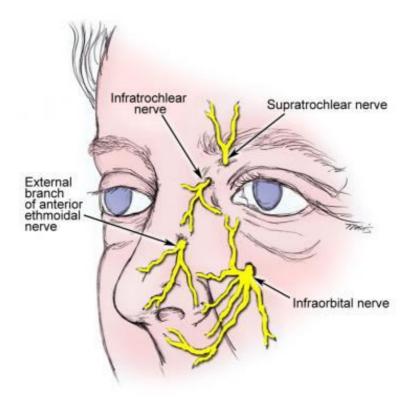
The infraorbital nerve in the floor of the orbit traverses the infraorbital canal. The infraorbital foramen lies 6-8 mm below the infraorbital rim on the mid pupillary line.

The sensory nerves from the maxillary nerve are the anterior superior alveolar nerve and the infraorbital nerve.

The anterior superior alveolar nerve arise in the infraorbital canal and pass below the infraorbital foramen, and it turns inferolaterally to supply the sensation to the incisors, center of the lip, columella, and tip of the nose.



#### DISTRIBUTION OF INFRAORBITAL NERVE



Branches of Infraorbital nerve:

- 1. Inferior palpebral branch,
- 2. External nasal branch,
- 3. Internal nasal branch,
- 4. Superior labial branch,
- 5. Lateral and medial sub branches of the superior labial branch.

The external nasal branch supplies sensory innervations to the lateral part of the nose and the ala. The internal nasal branch supplies sensory innervation to the nasal septum and the vestibule of the nose.

#### ANATOMY AND PHYSIOLOGY OF PAIN

The International Association for the Study of Pain (**IASP**) has defined Pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage"

Sensations are usually described as epicritic (non-noxious) or protopathic (noxious).

Epicritic sensations are temperature discrimination, proprioception, pressure and light touch, are sensed by low threshold receptors and are conducted by large myelinated nerve fibres.

Protopathic sensations are any type of painful stimulus, and they are sensed by high threshold receptors and conducted by unmyelinated **C** fibres and lightly myelinated **A delta** fibres.

#### **CLASSIFICATION OF PAIN:**

- Based on pathophysiology nociceptive, neuropathic or mixed
- Based on duration acute, chronic
- Based on etiology postoperative pain, cancer pain
- Based on affected area headache, low back ache

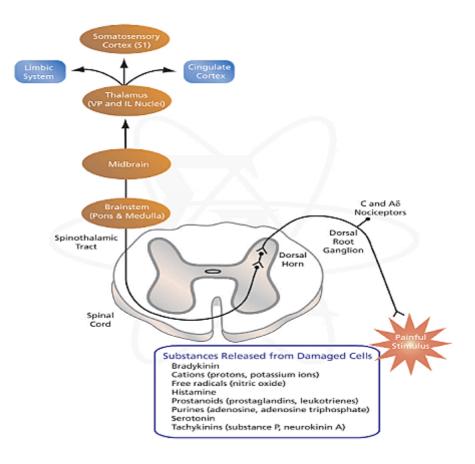
Nociceptive pain is caused by activation of specialized receptors, the nociceptors which is present in almost all tissues of the body. The stimuli may be mechanical, thermal or chemical.

Neuropathic pain is caused by injury or acquired abnormalities of peripheral nerves, dorsal root ganglia, nerve roots or central neural structures.

Acute pain is mostly caused by nociceptive stimulus and chronic pain is caused by nociceptive, neuropathic or mixed type of pain.

#### ANATOMY OF PAIN PATHWAY

Pain is conducted along three neuronal pathways, which transmit nociceptive stimuli from periphery to the cerebral cortex.



#### FIRST ORDER NEURONS:

They are the cell bodies of the primary afferent neurons located in the dorsal root ganglia. Each neuron has a single axon that divides into two, one to the peripheral tissue, and other one to the dorsal horn of spinal cord.

#### **SECOND ORDER NEURONS:**

Dorsal horn of spinal cord contain the second order neurons that synapse with the primary afferent neurons and then the axon of the second order neurons crosses the midline and via the contralateral spinothalamic tract to reach the thalamus.

Pain fibres originating from the head are carried by the trigeminal, facial, glossopharygeal and vagal nerves.

First order neurons are located in the cell bodies of gasserian ganglia for the Trigeminal nerve, geniculate ganglia for the Facial nerve, petrosal ganglia for the Glossopharygeal nerve, jugular (somatic) and ganglion nodossum (visceral) for the Vagus nerve. The axonal process from these ganglia reach the respective brain stem nuclei via their cranial nerves. The second order neurons are present in the brain stem nuclei. The spinal cord gray matter was divided by Rexed into 10 laminae. The first six laminae make up the dorsal horn which is the principle site of pain modulation through ascending and descending pathways.

C-fibres mostly have second order neuron in Lamina 1, 2, 5.

A delta fibres have second order neurons in Lamina 1, 5, 10.

Lamina 1 receives nociceptive inputs from cutaneous and deep somatic tissues.

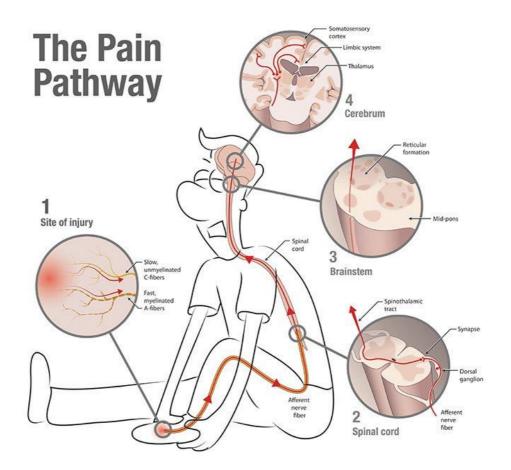
Lamina 2 otherwise called as substantia gelatinosa plays vital role in processing the cutaneous nociceptive inputs and also modulate them.

#### **SPINOTHALAMIC TRACT:**

It is divides into lateral (neospinothalamic), medial (paleospinothalamic) tracts.

The lateral spinothalamic tracts goes to the ventral and postero lateral nucleus of the thalamus and discriminate the location, duration and intensity of pain.

The medial spinothalamic tract goes to the medial part the thalamus and responsible for the emotional and autonomic features of pain.



#### **THIRD ORDER NEURONS:**

The thalamus contain the third order neuron.

Lateral thalamic nuclei project to the somato sensory cortex in the post central gyrus. Pain perception and localization occur in these areas.

Medial thalamic nuclei project to the anterior cingulated gyrus which mediate the emotional aspect of pain.

#### ALTERNATE PAIN PATHWAY:

- SPINORETICULAR TRACT(arousal, autonomic response)
- SPINOMESENCEPHALIC TRACT(antinociceptive response)
- SPINOHYPOTHALAMIC TRACT(emotional response)
- SPINOTELENCEPHALIC TRACT(emotional response)

### INTEGRATION WITH MOTOR SYSTEM:

Afferent dorsal horn synapse with the motor neurons in the anterior horn of spinal cord, that is responsible for reflex muscle activity to the pain.

#### INTEGRATION WITH SYMPATHETIC SYSTEM:

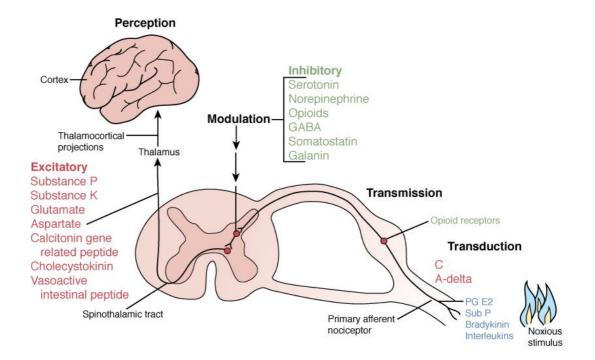
The afferent nociceptive neurons synapse with the sympathetic system in the intermedio-lateral column (Lamina 7) and that is responsible for the vasoconstriction, spasm of smooth muscles, and release of catecholamines.

#### **PHYSIOLOGY OF NOCICEPTION:**

Nociceptors are free nerve endings sensitive to heat, mechanical and thermal stimuli. The two main nociceptors are C fibres and A delta fibres.

**C fibres:** They are unmyelinated fibres, with conduction velocity of < 2 m/second. They evoke slow response burning and dull aching pain. They are mostly polymodal which respond to heat, mechanical and thermal stimuli.

A delta fibres: They are myelinated fibres, with conduction velocity of 15 to 55 m/second. They evoke sharp fast response pain like pinprick, stabbing pain.



#### **EXCITATORY NEUROTRANSMITTERS:**

Substance-P,CRGP, Glutamate, Aspartate, ATP.

#### **INHIBITORY NEUROTRANSMITTERS:**

GABA, Glycine, Acetylcholine, Adenosine, Serotonin, Norepinephrine, Encephalins and Endorphins.

#### **PERIPHERAL MODULATION OF PAIN:**

Nociceptors display sensitization following repeated stimuli, manifested by enhanced response to noxious and non noxious stimuli.

#### **PRIMARY HYPERALGESIA:**

The mediators are Histamine, Serotonin, Bradykinin, Prostaglandins.

#### **SECONDARY HYPERALGESIA:**

This produces the triple response of Lewis- Redness, edema and flare and severe pain.

The mediators are Substance –P and CGRP (Calcitonin Gene Related Peptide).

#### **CENTRAL MODULATION OF PAIN:**

#### **FACILITATION:**

They are produced by the wind up phenomenon, receptor field expansion, hyperexcitability of flexion reflexes. The main mediators are Glutamate, Aspartate, Substance-P, CRGP, VIP and CCK.

#### **INHIBITION:**

#### **1. SPINAL INHIBITION:**

Glycine, and GABA are the mediators.

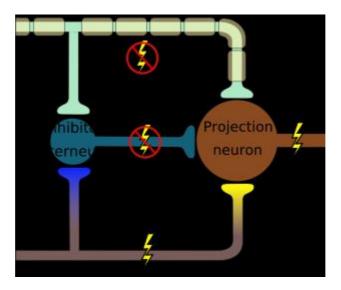
# 2. SUPRASPINALINHIBITION:

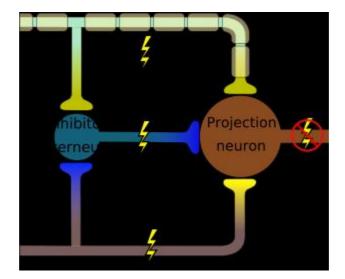
Norepinephrine, serotonin, encephalins and endorphin.

The major sites of origin are peri aqueductal gray matter, nucleus raphe magnus and the ascending reticular activating system.

# GATE CONTROL THEORY OF PAIN:

It was first proposed by Wall and Melzack in 1965. The inhibitory interneurons present in the substantia gelatinosa can inhibit the presynaptic pathway of the afferent neurons and produce post synaptic inhibition of secondary neurons and closing the "gate", thereby decrease the pain response to the nociceptive stimuli.





# PHARMOCOLOGY OF LIGNOCAINE AND BUPIVACAINE

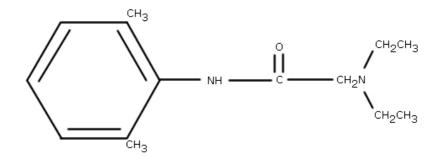
Local anaesthetics provide analgesia for surgical procedures. They provide reversible conduction blockade along the peripheral and central nervous pathways.

#### **MOLECULAR STRUCTURE:**

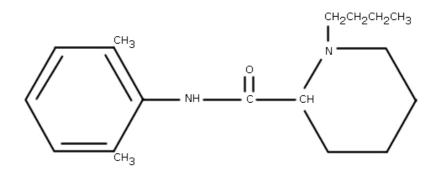
Lipophilic aromatic ring, Hydrophilic tertiary amine, both connected by the aromatic chain.

In amide local anaesthetics (-NHC-) links the hydrocarbon to the lipophilic aromatic ring.

#### STRUCTURE OF LIGNOCAINE



#### STRUCTURE OF BUPIVACAINE



#### **MECHANISM OF ACTION**

Local anaesthetics bind to the specific inner portion of the voltage gated Na channel alpha subunit and block the permeability of the Na ion and slows the rate of depolarisation, and hence threshold potential is not reached and thus action potential is not propagated.

Peripheral nerve is composed of unmyelinated C fibres and myelinated A fibres.

Atleast two to three nodes of Ranvier (1cm) has to be exposed by the local anaesthetic concentration for conduction block to occur.

# PHARMACOKINETICS

Local anaesthetics are weak bases.If pK value is very close to the physiological pH those drugs will have optimal ratio of ionised and unionised drug and hence show a rapid onset of action.

DRUG	LIGNOCAINE	BUPIVACAINE
POTENCY	1	4
ONSET	RAPID	SLOW
TOXIC PLASMA CONCENTRATION	>5 µg/ml	>3 µg/ml
рК	7.9	8.1
PROTEIN BINDING	70%	95%
LIPID SOLUBILITY	3%	97%
<b>VOLUME OF DISTRIBUTION(L)</b>	91	73
CLEARANCE IN L/MINUTE	0.95	0.47
ELIMINATION HALF TIME	96 MINUTES	21 MINUTES

Both lignocaine and Bupivacaine have vasodilator property and great systemic absorbtion.

Peripheral nerve is composed of unmyelinated c fibres and myelinated A fibres.

Atleast two to three nodes of Ranvier (1cm) has to be exposed by the local anaesthetic concentration for conduction block to occur.

### **Concentration minimum (Cm)**

It is the minimum concentration of local anaesthetic necessary to produce conduction blockade of nerve impulse. Cm is decreased in high frequency stimulation and it is increased for a larger nerve fiber and during fall in pH. Cm for motor fibres is twice the Cm of sensory fibres.

#### **ABSORBTION AND DISTRIBUTION:**

It has a high uptake in the lungs from the venous circulation. It distributes to the highly perfused tissues first(BRAIN,HEART,KIDNEYS) and slowly to the less perfused structures like musle and fat. Lipid solubility is important in redistribution, and it is the primary determinant of the anaesthetic potency. Amides are widely distributed in tissues when compared to ester local anesthetics.

Placental transfer is influenced by the plasma protein binding.

### Metabolism:

It occurs in the liver by the microsomal enzymes.

### **Clearance:**

The poor water solubility of the local anaesthetic limits the renal excretion of the unchanged drug to <5%.

# Useof vasoconstrictors:

Epinephrine 1:200000 or  $5\mu$ g/ml will produce vasoconstriction and decrease the systemic absorbtion and maintain the drug concentration in the vicinity of the nerve fibre.

#### Maximum dose :

Lignocaine:4.5 mg/kg and Lignocaine with adrenaline 7mg/kg

Bupivacaine 3 mg/kg

#### Adverse effects :

- 1. Allergy- due to methyl paraben preservative..
- 2. LAST (Local Anaesthetic Systemic Toxicity)
- 2a. Central nervous system effects:

Perioral numbness, restlessness, vertigo, tinnitus, skeletal twitching, seizures, unconsiousness, coma.. Threshold will decrease during hypercarbia and hyperkalemia.

2b. Cardiovascular system effects:

Systemic hypotension, myocardial depression, depressed conduction and automaticity (prolonged P-R interval and QRS), arythmias (premature ventricular contractions, ventricular tachycardia), and atrio ventricular heart blocks.

Threshold for the cardiovascular side effects will decrease with drugs like Digitalis, Calcium channel blockers, Beta blockers and during hypoxia, hypercarbia and acidosis.

# ASA GUIDELINES - MANAGEMENT OF LOCAL ANAESTHETIC SYSTEMIC TOXICITY

- 1. Airway management
- 2. Seizures- Benzodiazepines, Small doses of Thiopental or Propofol.
- 3. Succinylcholine is considered if seizures persist after Benzodiazepines.
- Cardiac arrest-(Epinephrine 10-100 μg bolus), ventricular arythmias (Amiodarone)
- Lipid emulsion therapy-1.5 ml/kg 20% lipid emulsion for thirty minutes, followed by 0.25 ml/kg/minute infusion
- 6. Propofol is not a sustitute for lipid emulsion.
- 7. Cardio pulmonary bypass

# **CLINICAL USES**

# LIGNOCAINE :

Topical

Infiltration

Intravenous Regional Anaesthesia (Bier's Block)

Peripheral nerve block

Epidural

Spinal

# **BUPIVACAINE :**

Peripheral nerve block

Infiltration

Epidural

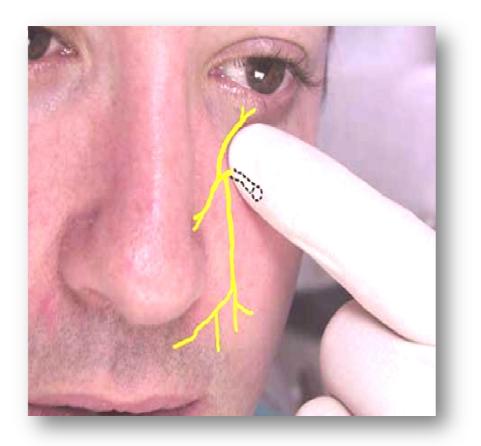
Spinal

### **TECHNIQUE OF INFRAORBITAL NERVE BLOCK**

The infraorbital nerve is blocked by two approaches. 1. Percutaneous approach, 2.Intraoral approach. In this study I used the intraoral approach.

# 1. Percutaneous approach:

The infraorbital foramen is palpated 6-8mm below the inferior orbital rim in the mid pupillary line. 3cm 25 gauge needle is inserted over the infraorbital foramen, after hitching the bone needle is slightly withdrawn and 2ml of 0.25% of bupivacaine can be given adjacent to the foramen. Pressure is applied immediately after the injection.



#### 2. Intraoral approach:

The infraorbital foramen is located and palpated from the buccal mucosa of the inner side of the upper lip superior to the ipsilateral first premolar teeth of the desired side.The upper lip is retracted with the non-dominant thumb, without occluding the infraorbital foramen.25 gauge needle is advanced into the mucolabial fold just anterior to the apex of the first premolar teeth. The needle is slowly advanced along the axis of the premolar towards the infraorbital foramen, approximately 5-10 mm.2 ml of 0.25% of bupivacaine is injected after careful aspiration.



### **Complications:**

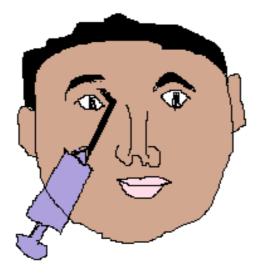
Local tissue edema, Accidental intravascular, intraneural injection.

Injury to the orbital structures if needle is advanced more deeply.

# **TECHNIQUE OF ANTERIOR ETHMOIDAL NERVE BLOCK**

Under strict aseptic precautions, the anterior ethmoidal nerve is blocked by using 3cm 25 gauge needle inserted 1cm above the medical canthus and redirected posterolaterally along the bone to a depth of 1.5cm. 2ml of 0.25% bupivacaine is given after careful aspiration. Pressure is applied immediately after withdrawing the needle.

This block provide sensory anaesthesia to the anterior part of the septum and the anterior part of the lateral wall of the nose and the ethmoidal sinuses.



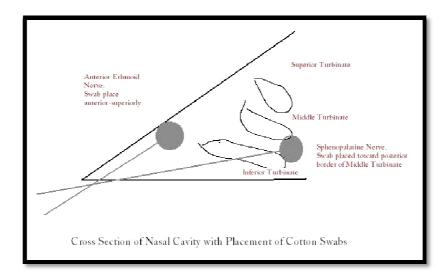
### **Complications:**

#### Ecchymosis

Accidental intravascular injection

Injury to the orbital structures

### TOPICAL ANAESTHESIA OF THE NOSE



4% Lignocaine combined with nasal decongestant like oxymetazoline or

4% lignocaine with 1:100000 adrenaline are the commonly used drugs for topical anaesthesia of the nose

The patient is placed in sitting position.

The cotton gauze is grasped by the forceps and rolled around it to form a cylindrical shaped pledget.

The pledget or cotton swab is soaked with the anaesthetic agent.

The first pledget is placed between the middle and inferior turbinate posteriorly (for the blockage of sphenopalatine nerves).

The second pledget is placed antero-superiorly (for the blockage of ethmoidal nerves).

Anaesthesia is typically obtained in 5-10 minutes. If not, the pledgets can be replaced with new ones.

# HISTORY

In 1784, James Moore used mechanical compression of nerve compression as a method to provide surgical anaesthesia.

In 1857, Gadecke isolated an alkaloid from leaves of Erythroxylon coca.

In 1860, Albert Niemann isolated pure white crystals of this alkaloid and named it as cocaine.

Cocaine was first used for eye surgeries by Carl koller.

Cocaine was later used popularly in nasal surgeries duo to its anaesthetic and vasoconstrictive properties.

In 1884, William Halsted and Richard Hall introduced the concept of peripheral nerve block by the injection of cocaine in the vicinity of the nerve to produce nerve block.

In 1904, Einhorn discovered Procaine.

In 1905, Heinrich F Braun used adrenaline with the local anaesthetic drugs to prolong the effect and decrease the toxicity.

In 1943, Nils Lofgren synthesized Lignocaine. Lofgrens layed foundation for discovery of other derivatives such as mepivacaine, prilocaine, bupivacaine and etidocaine.

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### **REVIEW OF LITERATURE**

**Lynch MT<sup>5</sup> etal** compared the intraoral and percutaneous approach of infra orbital nerve block. They studied 12 patients. All the patients received percutaneous block on one side and intra oral block on the otherside. They concluded that the pain during the injection was less, duration was longer, intensity of anaesthesia in upper lip is more in intraoral approach when compared to percutaneous approach.

**Molliex and Navez<sup>6</sup> et al** studied the role of nasociliary and infraorbital nerve block in twenty four patients undergoing nasal surgery. The blocks were given under mild sedation of Midazolam 0.03 mg/kg. They used equal mixture of 0.25% bupivacaine and 1% lignocaine for the blocks. The nasociliary blocks were given without adrenaline to eliminate retinal artery spasm. In addition the branches of pterygopalatine nerves were anaesthetized using a piece of gauze soaked with local anesthetic placed along the posterior aspect of middle turbinate. Operative conditions were judged as good in 20 out of 24 patients. The main limiting factor using regional anesthesia alone was long duration surgery and unpleasant feeling of patients due to bleeding in nasopharynx. Risk of aspiration avoided in regional anaesthesia.

**Prabhu KP<sup>11</sup> et al** compared the infraorbital nerve block and peri-incisional infiltration of 0.125% of bupivacaine in 30 children [4-20 months age group] who have undergone cleft lip repair. All the children received standardized General anaesthesia, then the nerve block in one group and peri-incisional infiltration in other group followed by surgery. The heart rate, blood pressure was recorded intraoperatively and post operatively every two hours for the first 12 hours. Behavioural pain score was used for the post operative assessment of pain. They

concluded that bilateral Infraorbital nerve block provided more prolonged analgesia when compared to the peri-incisional infiltration.

**Higashizawa**  $T^{13}$  et al studied the efficacy of Infraorbital nerve block in patients undergoing endoscopic endonasal maxillary sinus surgery under General anaesthesia pertained to the Isoflurane consumption and post operative pain score.He studied 50 patients. They were divided into two groups.One group received 1ml of 0.5% of Bupivacaine othergroup received 1ml of normal saline for Infraorbital nerve block.Isoflurane inspired concentration was adjusted to maintain systolic blood pressure during surgery at 85-90 mmHg, and pain intensity at 15minutes after end of anaesthesia was evaluated on five-point pain scale.Results concluded as statistically significant difference in infraorbital nerve with bupivacaine when compared with other group with respect to reduced consumption of Isofurane and reduced postoperative pain score.

McAdam D<sup>9</sup> et al studied the post operative analgesic efficacy of Infraorbital nerve block in patients of Trans-sphenoidal Hypophysectomy. They used intraoral approach for the Infraorbital nerve block after the intubation. They found that patients were pain free in the postoperative period for long hours and avoidance of opiods allow better neurological examination following such major neurosurgical procedures.

**Budac and Stefan<sup>1</sup> et al** studied the post operative analgesic efficacy of infraorbital block in children undergoing emergency repair of facial lacerations involving upper lip and inframaxillary area, elective cleft lip repair, rhinoplasty and endoscopic endonasal surgeries. They found that post operatively, patients who received the infraorbital nerve block with 1ml of 0.25% Bupivacaine were comfortable and pain free and didn't require rescue opiod analgesia. So they

concluded that bilateral Infraorbital nerve block as an excellent option for the above said surgeries.

**Rajamani** A<sup>12</sup> et al compared the post operative analgesic efficacy of bilateral Infraorbital nerve block and intravenous Fentanyl following cleft lip repair. They studied 80 children equally divided into two groups. One group received 1ml of 0.25% bupivacaine for infraorbital nerve block and other group received 2 microgram/kg of intravenous Fentanyl soon after intubation using standard General anaesthesia. The heart rate, blood pressure, time of awakening, time of first cry, time of first post operative feed noted. They concluded that nerve block group children had more profound analgesia, and awakened and feed early when compared to Fentanyl group.

Edward R.Mariano<sup>3</sup> et al studied the analgesic efficacy of infraorbital nerve block combined with standardized General anaesthesia.He studied 40 patients.20 patients received bilateral infraorbital nerve block with 0.5% Bupivacaine 3ml and other 20 patients received 3ml preservative free normal saline. All patints received General anaesthesia before the blocks.In addition all patients received 10ml of 1% lignocaine with adrenaline for local infiltration. Rescue analgesic used post operatively was Hydromorphone 0.2-0.4 mg IV, if VAS pain score>=4.He concluded that subjects those who receive bupivacaine for the Infraorbital nerve block show reduced post operative pain score and decreased requirement of opiod rescue analgesic.

Mortimer  $NJ^8$  et al investigated the effectiveness of infraorbital nerve block for alar anaesthesia. He studied 100 patients. All patients received topical mucosal anaesthesia, followed by intraoral infraorbital nerve block .10 minutes later sharp stimulus was given over the nasal ala.66 patients the block is adequate.34 patients the block was inadequate.these 34 patients received anterior ethmoidal nerve block of external nasal branch as adjunct,after which the block provide adequate and complete anaesthesia. So they recommended using infraorbital nerve block(anterior ethmoidalnerveblock if additionally required) prior to direct infiltration of local anaesthetic into the ala of the nose to reduce the discomfort of the patient.

**Kim HS<sup>4</sup> et al** studied the postoperative analgesic efficacy of Anterior ethmoidal nerve block for reduction of fractured nasal bones under general anaesthesia. The use of Anterior Ethmoidal nerve block as preemptive analgesia for management of post operative pain. 80 patients were enrolled 40 patients received Anterior Ethmoidal nerve block with 2% Lignocaine with Adrenaline and other 40 patients were the control group. They concluded that the reduction of post operative pain was statistically significant in patients of Anterior Ethmoidal nerve block group.

# AIM OF THE STUDY

The aim of this study is to compare the post operative analgesic efficacy of the Topical anaesthesia and combined Topical anaesthesia with Anterior Ethmoidal nerve block and Intraorbital nerve block in patients undergoing septal and endoscopic sinus surgeries under General anaesthesia.

The comparison is with respect to,

### Primary objective-

Postoperative pain score by Visual Analogue Scale

# Secondary objectives:

Intraoperative Fentanyl consumption

Postoperative need for rescue analgesia

# **MATERIALS AND METHODS**

### **DURATION OF THIS STUDY - 3 months**

After approval from the Institutional ethical committee and informed consent from patients, they were randomly allocated into two groups.

### Group A

30 patients received pre operative topical anaesthesia with 4% lignocaine nasal pack followed by General anaesthesia and surgery.

### **Group B**

30 patients received pre operative topical anaesthesia with 4% lignocaine nasal pack followed by General anaesthesia., and then bilateral Anterior Ethmoidal nerve block and Infra orbital nerve block with 2ml of 0.25% of bupivacaine each side and surgery proceeded.

### **INCLUSION CRITERIA:**

- Age:18-75 Years
- Gender : Both male and female
- ASA Class : 1 and 2
- Surgery : Elective septal and endoscopic sinus surgeries
- Informed Consent : Obtained patients

# **EXCLUSION CRITERIA :**

- Patients refusal
- Known allergy to local anaesthetic
- Local sepsis at injection site
- Psychiatric diseases
- Coagulopathy
- Inability to comprehend or adhere to study protocol
- Not satisfying Inclusion criteria

# **MATERIALS REQUIRED:**

- 4%Lignocaine, Oxymetazoline
- 0.25% Bupivacaine
- 3 cm 25 gauge needle, 22 gauge spinal needle
- 2ml,5ml syringes
- Monitors: ECG, NIBP, SPO<sub>2</sub>
- Generalanaesthesia Drugs:
- Inj.Glycopyrrolate, Inj.Fentanyl
- Inj.Thiopentone, Inj.Succinylcholine, Inj.Atracurium. Isoflurane
- Inj.Dexamethasone
- Emergency Drugs
- Endotracheal tubes, bougie, suction apparatus
- Intravenous fluids
- Betadinesolution, Sterile gauzes.

## **METHODOLOGY**

After the approval of the Institutional Ethical Committee, and patient satisfying inclusion criteria, informed consent was obtained.

Topical anaesthesia with nasal pack 4% lignocaine (1.5ml each side) with Oxymetazoline done preoperatively 30 minutes before surgery.

Randomization by closed envelope method into Group A and Group B.

Pre operative baseline Heart Rate, BP, SPO2 Measurement

General Anaesthesia Planned

Inj.Glycopyrrolate-0.2mg IV

Inj.Fentanyl 50µg IV

Preoxygenation was done and Induction done with Inj.Thiopentone 5 mg/kg and

Muscle relaxant:Inj.succinyl choline 2 mg/kg and intubation was done.

Moistened gauze throat pack under direct vision by laryngoscope

Anaesthesia maintained with Isoflurane., N<sub>2</sub>0:O<sub>2</sub> 2:1 and Inj. Atracurium.

# **GROUP A :** Surgery started after General anaesthesia

# **GROUP B** : After General Anaesthesia, Nerve Block was given prior to surgery

S:no	Name of block	Needle used	Method	Drug
1.	ANTERIOR	3cm 25	Needle inserted 1cm	2ml of
	ETHMOIDAL	gauge	above the inner	0.25% Bupivacaine
	NERVE	needle	canthus and directed	given after careful
	BLOCK		posterolaterally	aspiration
			keeping needle tip in	
			contact with the	
			bone 1.5cm deep.	
2.	INFRA	22	Infraorbital foramen	2mlof
	ORBITAL	gauge	palpated externally	0.25% Bupivacaine
	NERVE	spinal	and the cheek	given after careful
	BLOCK	needle	retracted with the	aspiration
			thumb.Needle	
			inserted parallel to	
			long axis of upper	
			first premolar teeth	
			into mucobuccal	
			foldso that needle	
			contact the bone at	
			the entrance of the	
			foramen.	

Surgery started and completed. Patient extubated .The following parameters were observed and statistically analysed and results were compiled.

# **PARAMETERS OBSERVED:**

### 1. PULSE RATE AND BLOOD PRESSURE:

### Baseline

Intraoperatively -every 10 minutes till end of surgery

Postoperatively- Immediate (10 min after extubation), and thereafter hourly once for 6 hours.

# 2. INTRAOPERATIVE ADDITIONAL FENTANYL CONSUMPTION-

Injection fentanyl (20  $\mu$ g) repeated if pulse rate and blood pressure rises 20% from the baseline value.

# 3. PAIN ASSESSMENT BY USING THE VISUAL ANALOGUE SCALE (VAS)

Immediate postoperative period (10 minutes after extubation)

Thereafter hourly once for six hours.

# 4. POSTOPERATIVE NEED FOR RESCUE ANALGESIA

# (INJ.DICLOFENAC):

It is given if the VAS pain score is more than 4cm, if given the time is noted.

# 5. COMPLICATIONS

# DATA ANALYSIS

The patients were divided into two groups - Topical Anesthesia and Topical Anesthesia + Nerve Block. Descriptive statistics was done for all data and were reported in terms of mean values and percentages. Suitable statistical tests of comparison were done. Continuous variables were analysed with the unpaired t test and paired t test. Categorical variables were analysed with the Chi-Square Test and Fisher Exact Test. Statistical significance was taken as P < 0.05. The data was analysed using SPSS version 16 and Microsoft Excel 2007.

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#### SAMPLE SIZE CALCULATION

Sample size was determined based on

#### Study

Bilateral infraorbital nerve blocks decrease postoperative pain but do not reduce time to discharge following outpatient nasal surgery

#### Authored by

Edward R. Mariano et al

## **Published in**

Can J Anaesth. 2009 Aug; 56(8): 584–589.

In this study it has been observed that In the first 24 h, there were trends for subjects in Group IOB to report lower NRS scores (mean [SD]) for worst pain (29 [27]) than subjects in Group NS (43 [23], P = 0.114) with a difference of 33%.

### **Description:**

The confidence level is estimated at 95%

with a z value of 1.96

the confidence interval or margin of error is estimated at +/-12

Assuming p% =39 and q%=61

 $n = p\% \ x \ q\% \ x \ [z/e\%]^2$ 

n= 33 x 67 x [1.96/12]<sup>2</sup>

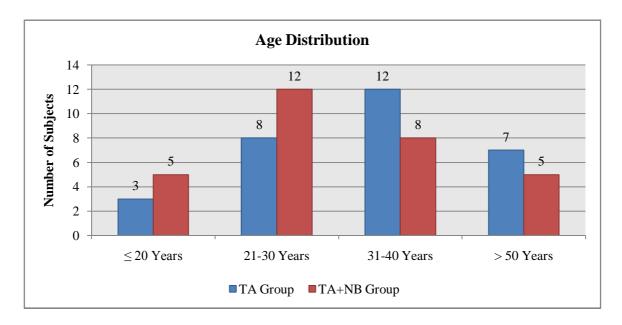
# n= 58.32

Therefore 58 is the minimum sample size required for the study (n=30 in TA Group arm and n=30 in TA+NB Group arm)

#### **ABBREVIATIONS**

- TA Topical Anaesthesia
- TA+NB Topical Anaesthesia + Nerve Block
- **SBP** Systolic Blood Pressure
- **DBP** Diastolic Blood Pressure
- MAP Mean Arterial Pressure
- **PR** Pulse Rate
- VAS Visual Analogue Score
- ASA American Society of Anaesthesiologist classification
- **Group A** = TA = Topical Anaesthesia Group
- **Group B** = TA + NB = Topical Anaesthesia + Nerve Block Group

# AGE DISTRIBUTION



Majority of the Topical Anesthesia Group patients belonged to the 31-40 years age class interval (n=12, 40%) with a mean age of 33.80 years.

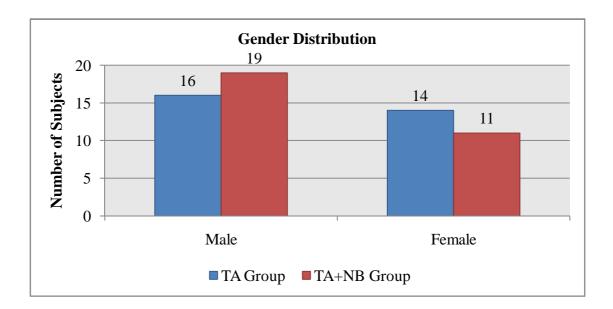
Age	TA Group	%	TA+NB Group	<del>%</del>
$\leq 20$ Years	3	10.00	5	16.67
21-30 Years	8	26.67	12	40.00
31-40 Years	12	40.00	8	26.67
> 50 Years	7	23.33	5	16.67
Total	30	100	30	100

Age Distribution	TA Group	TA+NB Group
Ν	30	30
Mean	33.80	31.23
SD	9.37	10.53
P value - Unpaired t test	0.3228	

In the Topical Anesthesia + Nerve Block group patients, majority belonged to the 21-30 years age class interval (n=12, 40%) with a mean age of 31.23 years.

The association between both the groups in terms of age distribution was found to have no statistically significant difference since p > 0.05 as per 2 tail unpaired t test. Hence both the groups are comparable in age distribution.

#### **GENDER DISTRIBUTION**

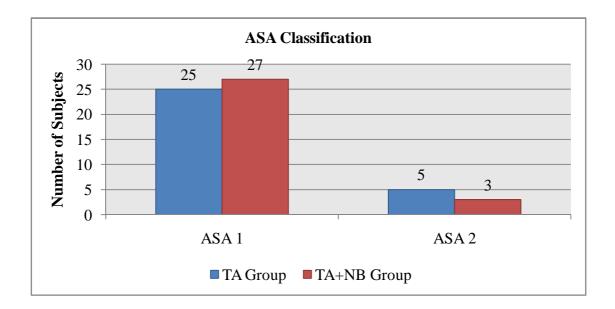


Gender Distribution	TA Group	%	TA+NB Group	<del>0/0</del>
Male	16	53.33	19	63.33
Female	14	46.67	11	36.67
Total	30	100	30	100
P value - Chi Squared	0.601	0		

Majority of the Topical Anesthesia Group patients belonged to the male gender group (n=16, 53.33%). In the Topical Anesthesia + Nerve Block group patients, majority belonged to the male gender group (n=19, 63.33%).

The association between both the groups in terms of gender distribution was found to have no statistically significant difference since p > 0.05 as per 2 tail unpaired t test. Hence both the groups are comparable in gender distribution.

# ASA CLASSIFICATION



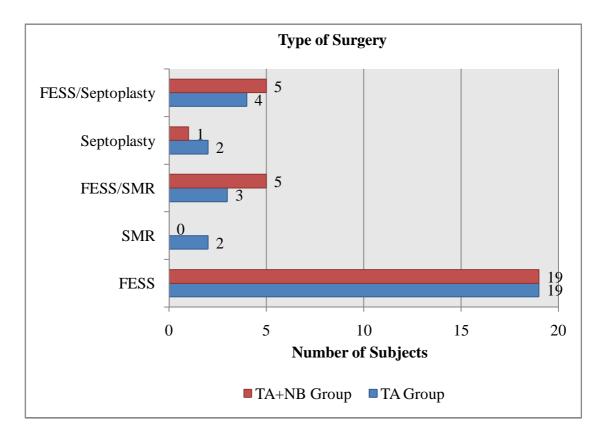
ASA Classification	TA Group	%	TA+NB Group	<u>%</u>
ASA I	25	83.33	27	90.00
ASA II	5	16.67	3	10.00
Total	30	100	30	100
P value – Fishers Exa	act Test	0.706	5	

Majority of the Topical Anesthesia Group patients belonged to the ASA I class (n=25, 83.33%).

In the Topical Anesthesia + Nerve Block group patients, majority belonged to ASA I class (n=27, 90%).

There was no statistically significant difference between both the groups since p > 0.05 as per fishers exact test .Hence both the groups are comparable in ASA classification.

### **TYPE OF SURGERY**



Majority of the Topical Anesthesia Group patients belonged to the FESS surgery class interval (n=19, 63.33%). In the Topical Anesthesia + Nerve Block group patients, majority belonged to FESS surgery class interval (n=19, 63.33%).

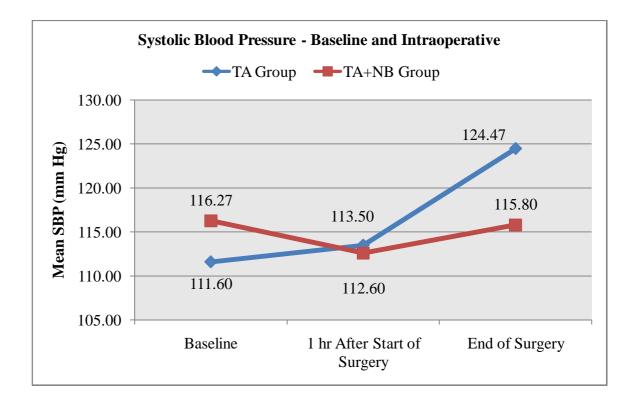
Type of Surgery	TA Group	%	TA+NB Group	<u>⁰⁄₀</u>	P value Fishers Exact Test
FESS	19	63.33	19	63.33	1.0000
SMR	2	6.67	0	0.00	0.4915
FESS/SMR	3	10.00	5	16.67	0.7065
Septoplasty	2	6.67	1	3.33	>0.9999
FESS/Septoplasty	4	13.33	5	16.67	>0.9999
Total	30	100	30	100	

The association between the intervention groups and Type of Surgery was not statistically significant since p > 0.05 as per Fishers exact test.

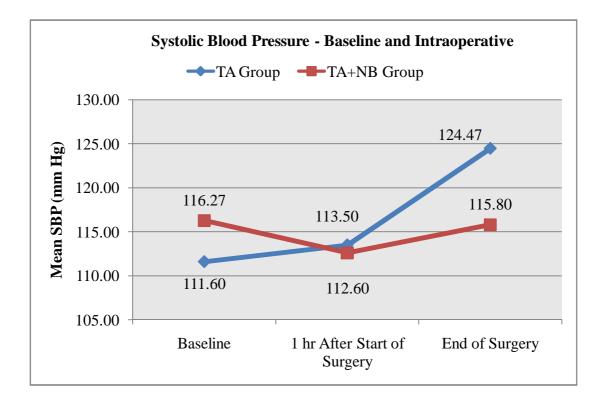
# SYSTOLIC BLOOD PRESSURE

The Systolic Blood Pressure in both the groups were compared intraoperatively and postoperatively and the results are as follows:

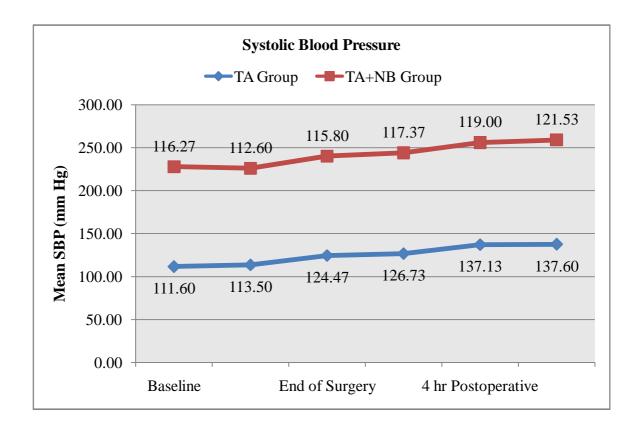
Systolic blood pressure		Baseline	1 hour After Start of Surgery	End of Surgery	Immediate Postoperative	4hours Postoperative	6hours Postoperative
	N	30	30	30	30	30	30
TA Group	Mean	111.60	113.50	124.47	126.73	137.13	137.60
	SD	5.76	10.35	8.41	8.41	8.01	6.07
	N	30	30	30	30	30	30
TA+NB Group	Mean	116.27	112.60	115.80	117.37	119.00	121.53
	SD	8.72	9.86	11.84	11.22	12.03	11.38
P value Unpaired t test		<mark>0.0180</mark>	0.7315	<mark>0.0019</mark>	<mark>0.0006</mark>	<mark>0.0000</mark>	<mark>0.0000</mark>



In patients belonging to Topical Anesthesia group, the mean systolic blood pressure intraoperatively increased to an average of 116.52 mm Hg in comparison with patients belonging to Topical Anesthesia + Nerve Block group in whom the mean systolic blood pressure increased to an average of 114.89 mm Hg with a p-value of 0.0180 and 0.0019 according to unpaired t-test. The mean systolic blood pressure baseline - intraoperatively was meaningfully more in Topical Anesthesia group compared to Topical Anesthesia + Nerve Block intervention group by 1.63 mm Hg. This significant difference of 1.01 times increase in mean systolic blood pressure intraoperatively in Topical Anesthesia group compared to Topical Anesthesia + Nerve Block intervention group is true and has not occurred by chance. In this study we can safely conclude that Topical Anesthesia group showed rise in systolic blood pressure intraoperatively compared to Topical Anesthesia + Nerve Block in patients undergoing septal and endoscopic sinus surgeries under General Anesthesia.



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In patients belonging to Topical Anesthesia group, the mean systolic blood pressure postoperatively increased to an average of 133.82 mm Hg in comparison to 116.52 mm Hg in the intraoperative period with a p-value of 0.0329 according to paired t-test. The mean systolic blood pressure postoperatively was meaningfully more in Topical Anesthesia group compared to intraoperative period by 17.30 mm Hg. This significant difference of 1.14 times increase in mean systolic blood pressure postoperatively in Topical Anesthesia group is true and has not occurred by chance. In this study we can safely conclude that Topical Anesthesia group showed an increase in systolic blood pressure postoperatively compared to intraoperative period in patients undergoing septal and endoscopic sinus surgeries under General Anesthesia.

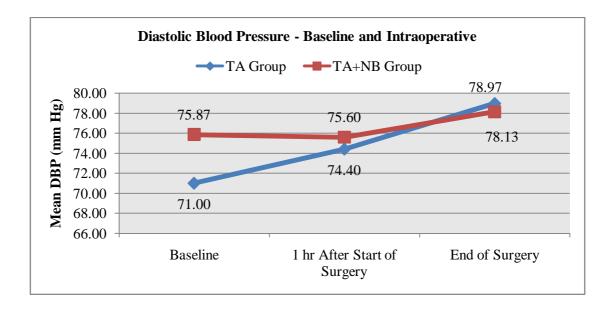
Mean Systolic Blood Pressure	TA Group	TA+NB Group
Baseline - Intraoperative	116.52	114.89
Postoperative	133.82	119.30
P value Paired t test	0.0329	0.1180

In patients belonging to Topical Anesthesia + Nerve Block group, the mean systolic blood pressure postoperatively increased to an average of 119.30 mm Hg in comparison to 114.89 mm Hg in baseline – intraoperative period with a p-value of 0.1180 according to paired t-test. The association between the Topical Anesthesia + Nerve Block and increase in mean systolic blood pressure postoperatively compared to intraoperative period in patients undergoing septal and endoscopic sinus surgeries under General Anesthesia was not statistically significant since p > 0.05 as per paired t test.

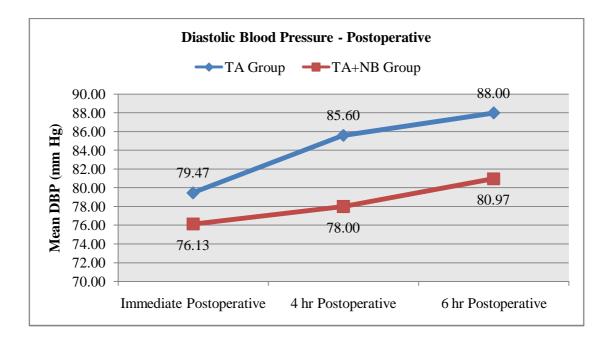
## DIASTOLIC BLOOD PRESSURE

The Diastolic Blood Pressure in both the groups were compared intraoperatively and post operatively and the results are as follows:

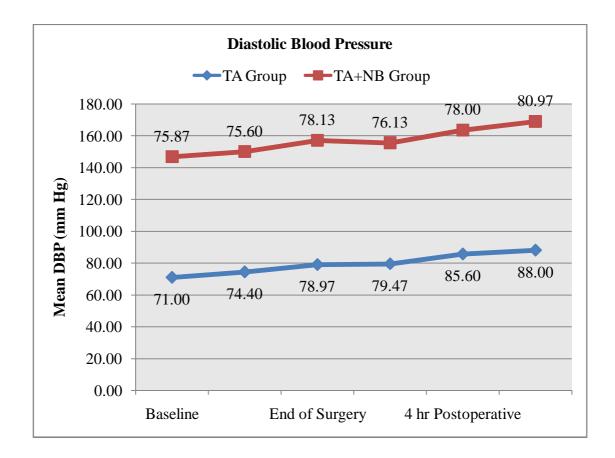
Diastolic Blood Pressure		Baseline	1 hour After Start of Surgery	End of Surgery	Immediate Post- operative	4hours Post- operative	6hours Post- operative
	N	30	30	30	30	30	30
TA Group	Mean	71.00	74.40	78.97	79.47	85.60	88.00
	SD	2.86	5.62	5.39	6.26	7.09	6.24
	N	30	30	30	30	30	30
TA+ NB Group	Mean	75.87	75.60	78.13	76.13	78.00	80.97
1	SD	6.50	6.94	7.50	7.06	8.32	8.64
P value Unpair test		<mark>0.0006</mark>	0.4646	0.6231	<mark>0.0480</mark>	<mark>0.0003</mark>	<mark>0.0007</mark>



In patients belonging to Topical Anesthesia group, the mean diastolic blood pressure in the intraoperative period is decreased to an average of 74.79 mm Hg in comparison with patients belonging to Topical Anesthesia + Nerve Block group in whom the mean diastolic blood pressure is an average of 76.53 mm Hg with a p-value of 0.0006 according to unpaired t-test. The mean diastolic blood pressure in the intraoperative period was less in Topical Anesthesia group compared to Topical Anesthesia + Nerve Block group by 1.74 mm Hg. This significant difference of 2% drop in mean diastolic blood pressure at baseline in Topical Anesthesia group compared to Topical Anesthesia + Nerve Block group is true and has not occurred by chance. In this study we safely conclude that Topical Anesthesia showed decreased diastolic blood pressure during the intraoperative period when compared to Topical Anesthesia + Nerve Block in patients undergoing septal and endoscopic sinus surgeries under General Anesthesia.



In patients belonging to Topical Anesthesia group, the mean diastolic blood pressure postoperatively is increased to an average of 84.36 mm Hg in comparison with patients belonging to Topical Anesthesia + Nerve Block group in whom the mean diastolic blood pressure is an average of 78.37 mm Hg with a p-value of 0.00480, 0.0003 and 0.0007 according to unpaired t-test. The mean diastolic blood pressure postoperatively was meaningfully more in Topical Anesthesia group compared to Topical Anesthesia + Nerve Block group by 5.99 mm Hg. This significant difference of 1.08 times increase in mean diastolic blood pressure postoperatively in Topical Anesthesia group compared to Topical Anesthesia + Nerve Block group is true and has not occurred by chance. In this study we can safely conclude that Topical Anesthesia group showed an increase in diastolic blood pressure postoperatively compared to Topical Anesthesia + Nerve Block in patients undergoing septal and endoscopic sinus surgeries under General Anesthesia.



In patients belonging to Topical Anesthesia group, the mean diastolic blood pressure postoperatively is increased to an average of 84.36 mm Hg in comparison to 74.79 mm Hg in the intraoperative period with a p-value of 0.0075 according to paired t-test. The mean diastolic blood pressure postoperatively was meaningfully more in Topical Anesthesia group with a difference of 9.57 mm Hg. This significant difference of 1.13 times increase in mean diastolic blood pressure postoperatively in Topical Anesthesia group compared to baseline and intraoperative period is true and has not occurred by chance. In this study we can safely conclude that Topical Anesthesia group showed an increase in diastolic blood pressure postoperatively.

Mean Diastolic Pressure	TA Group	TA+NB Group
Baseline Intraoperative	74.79	76.53
Postoperative	84.36	78.37
P value Paired t test	<mark>0.0075</mark>	0.1470

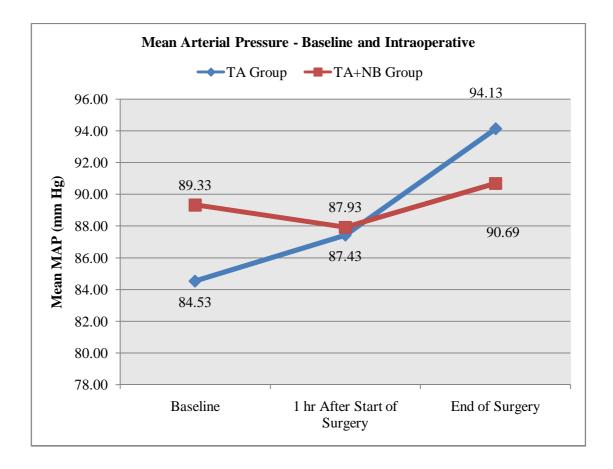
In patients belonging to Topical Anesthesia + Nerve Block group, the mean diastolic blood pressure postoperatively is increased to an average of 78.37 mm Hg in comparison to 76.53 mm Hg baseline and intraoperative period with a p-value of 0.1470 according to paired t-test. The association between the Topical Anesthesia + Nerve Block and increase in mean diastolic blood pressure postoperatively compared to baseline and intraoperative period in patients undergoing septal and endoscopic sinus surgeries under General Anesthesia is considered to be not statistically significant since p > 0.05 as per paired t test.

By conventional criteria the association between the intervention groups and diastolic blood pressure is considered to be statistically significant all through the postoperative period since p < 0.05 as per unpaired t test.

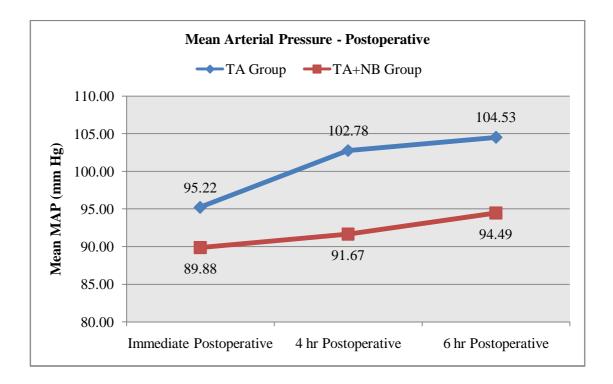
## MEAN ARTERIAL PRESSURE

The Mean Arterial Pressure was compared in both the groups intraoperatively and postoperatively and the results are as follows:

Mean Arterial Pressure		Baseline	1 hour After Start of Surgery	End of Surgery	Immediate Post- operative	4 hours Post- operative	6 hours Post- operative
	N	30	30	30	30	30	30
TA Group	Mean	84.53	87.43	94.13	95.22	102.78	104.53
	SD	3.44	6.64	5.67	5.99	6.83	5.24
	N	30	30	30	30	30	30
TA+ NB Group	Mean	89.33	87.93	90.69	89.88	91.67	94.49
Group	SD	6.58	6.89	8.26	7.78	9.00	9.18
P value Unpaired t test		<mark>0.0010</mark>	0.7757	0.0654	<mark>0.0043</mark>	<mark>0.0000</mark>	<mark>0.0000</mark>

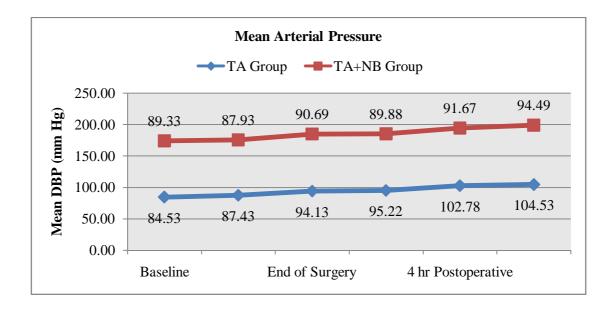


In patients belonging to Topical Anaesthesia group, the mean arterial pressure intraoperatively increased from 84.53 to 94.13 around 10.4mmHg on an average, but in Topical Anaesthesia with Nerve Block group the mean arterial pressure increased from 89.33 to 90.69 on an average of 1.36 mmHg. The Topical Anaesthesia group showed an increase in mean arterial pressure intra operatively when compared to Topical Anaesthesia and Nerve Block group.



In patients belonging to Topical Anesthesia group, the mean arterial pressure postoperatively is increased to an average of 100.84 mm Hg with a p-value of 0.0170 according to paired t-test. The mean arterial pressure postoperatively was meaningfully more in Topical Anesthesia group compared to baseline and intra operative period by 12.14 mm Hg. This significant difference of 1.14 times increase in mean arterial pressure postoperatively in Topical Anesthesia group is true and has not occurred by chance. In this study we can safely conclude that Topical Anesthesia group showed an increase in mean arterial pressure postoperatively.

In patients belonging to Topical Anesthesia + Nerve Block group, the mean arterial pressure postoperatively is increased to an average of 92.01 mm Hg with a p-value of 0.1291 according to paired t-test. The association is considered to be not statistically significant since p > 0.05 as per paired t test.



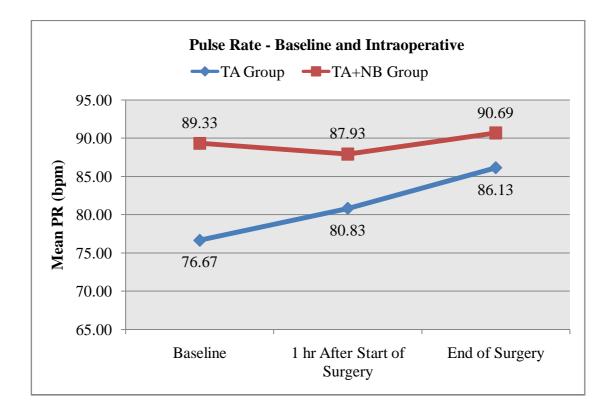
Mean Arterial Pressure	TA Group	TA+NB Group
Baseline- Intraoperative	88.70	89.32
Postoperative	100.84	92.01
P value Paired t test	<mark>0.0170</mark>	0.1291

In this study we can safely conclude that Topical Anesthesia group showed increase in mean arterial pressure postoperatively compared to Topical Anesthesia + Nerve Block in patients undergoing septal and endoscopic sinus surgeries under General Anesthesia.

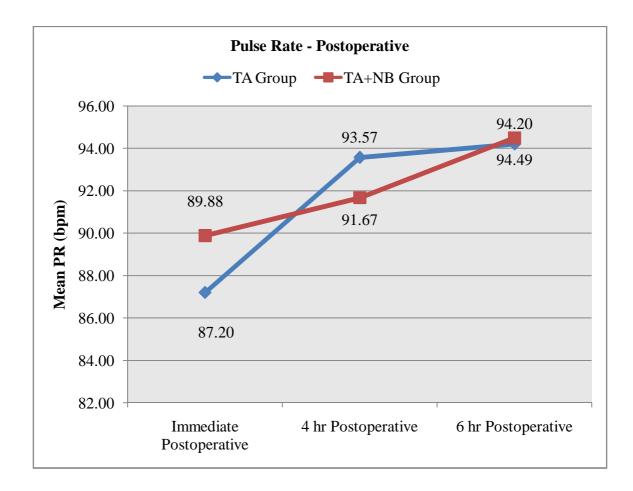
## **PULSE RATE**

The Pulse Rate of both the groups were compared intra operatively and postoperatively and the observations are as follows:

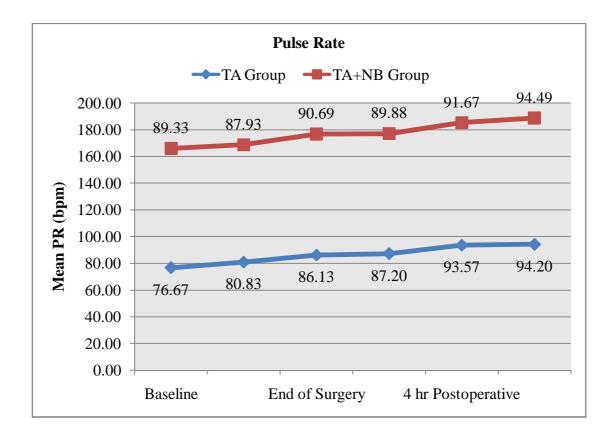
Pulse Rate		Baseline	1 hour After Start of Surgery	End of Surgery	Immediate Post- operative	4 hours Post- operative	6 hours Post- operative
	N	30	30	30	30	30	30
TA Group	Mean	76.67	80.83	86.13	87.20	93.57	94.20
	SD	6.68	6.69	6.44	5.91	6.14	6.46
	N	30	30	30	30	30	30
TA+ NB Group	Mean	89.33	87.93	90.69	89.88	91.67	94.49
Ĩ	SD	6.58	6.89	8.26	7.78	9.00	9.18
P value Unpaired t test		<mark>0.0000</mark>	<mark>0.0002</mark>	<mark>0.0208</mark>	0.1393	0.3441	0.8884



In patients belonging to Topical Anesthesia group, the mean pulse rate at baseline to end of surgery period is decreased to an average of 81.21 bpm in comparison with patients belonging to Topical Anesthesia + Nerve Block group in whom the mean pulse rate is an average of 89.32 bpm with a p-value of 0.0000, 0.0002 and 0.0208 according to unpaired t-test. The mean pulse rate at baseline to end of surgery period was meaningfully less in Topical Anesthesia group compared to Topical Anesthesia + Nerve Block group by 8.11 bpm.. This significant difference of 9% drop in mean pulse rate at baseline to end of surgery period in Topical Anesthesia group compared to Topical Anesthesia + Nerve Block intervention group is true and has not occurred by chance. In this study we can safely conclude that Topical Anesthesia group showed a decrease in pulse rate at baseline to end of surgery period compared to Topical Anesthesia + Nerve Block.



In patients belonging to Topical Anesthesia intervention group, the mean pulse rate postoperatively is decreased to an average of 91.66 bpm in comparison with patients belonging to Topical Anesthesia + Nerve Block intervention group in whom the mean pulse rate is an average of 92.01 bpm with a p-value of 0.1393, 0.3441 and 0.8884 according to unpaired t-test. The association between the Topical Anesthesia intervention and decrease in mean pulse rate postoperatively compared to Topical Anesthesia + Nerve Block intervention group in patients undergoing septal and endoscopic sinus surgeries under General Anaesthesia is considered to be not statistically significant since p > 0.05 as per paired t test.

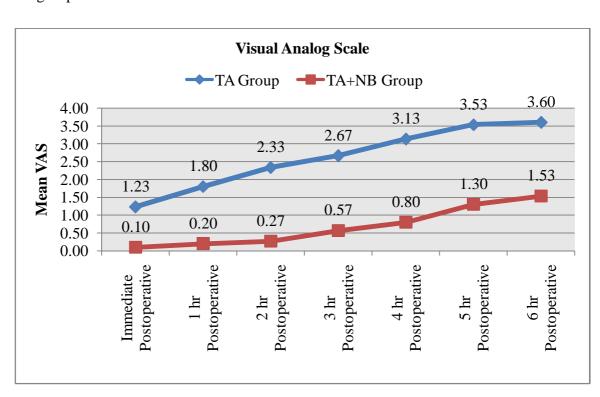


In patients belonging to Topical Anesthesia group, the mean pulse rate postoperatively is increased to an average of 81.21 bpm in comparison to 91.66 bpm baseline – intraoperative period with a p-value of 0.0162 according to paired t-test. The mean pulse rate postoperatively was meaningfully more in Topical Anesthesia group compared to baseline – intraoperative period by 10.44 bpm. This significant difference of 1.13 times increase in mean pulse rate postoperatively in Topical Anesthesia intervention group is true and has not occurred by chance. In this study we can safely conclude that in Topical Anesthesia group there was an increase in mean pulse rate postoperatively compared to baseline – intraoperative period in patients undergoing septal and endoscopic sinus surgeries under General Anesthesia.

Mean Pulse rate	TA Group	TA+NB Group
Baseline- Intraoperative	81.21	89.32
Postoperative	91.66	92.01
P value Paired t test	<mark>0.0162</mark>	0.1291

In patients belonging to Topical Anesthesia + Nerve Block group, the mean pulse rate postoperatively is increased to an average of 92.01 bpm in comparison to 89.32 bpm baseline – intraoperative period with a p-value of 0.1291 according to paired t-test. The association between the Topical Anesthesia + Nerve Block intervention and increase in mean pulse rate postoperatively was not statistically significant since p > 0.05 as per paired t test.

#### VISUAL ANALOGUE SCALE



The Visual Analogue Scale scoring for post operative pain was noted in both the groups and the results are as follows:

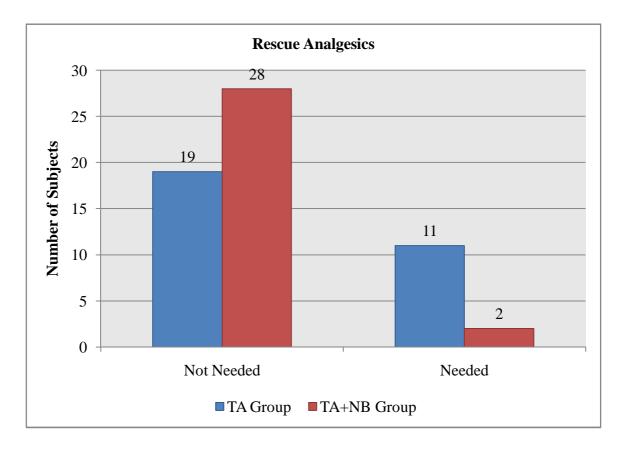
In patients belonging to Topical Anesthesia group, the VAS postoperatively is increased to an average of 2.61 points in comparison with patients belonging to Topical Anesthesia + Nerve Block group in whom the VAS is an average of 0.68 points with a p-value of 0.0000 according to unpaired t-test. The VAS postoperatively was meaningfully more in Topical Anesthesia group compared to Topical Anesthesia + Nerve Block group by 1.93 points. This significant difference of 3.84 times increase in VAS postoperatively in Topical Anesthesia group compared to Topical Anesthesia + Nerve Block group is true and has not occurred by chance. This significant difference of 3.84 times increase in VAS postoperatively in Topical Anesthesia group compared to Topical Anesthesia + Nerve Block group is true and has not occurred by chance.

Visual Analog Scale scoring		Immediate Postoperative	1hour Postoperative	2hours Postoperative	3 hours Postoperative
	Ν	30	30	30	30
TA Group	Mean	1.23	1.80	2.33	2.67
	SD	0.68	0.85	0.88	0.96
	N	30	30	30	30
TA+NB Group	Mean	0.10	0.20	0.27	0.57
	SD	0.31	0.55	0.69	0.94
P value Unpaired t test		<mark>0.0180</mark>	<mark>0.0000</mark>	<mark>0.0000</mark>	<mark>0.0000</mark>

Visual Analog Scale scoring		4hours Postoperative	5 hours Postoperative	6 hours Postoperative
	N	30	30	30
TA Group	Mean	3.13	3.53	3.60
	SD	0.97	1.04	0.86
	N	30	30	30
TA+NB Group	Mean	0.80	1.30	1.53
	SD	1.03	1.15	0.90

We safely conclude that Topical Anesthesia group showed an increase in VAS postoperatively compared to Topical Anesthesia + Nerve Block .There was a statistically significant difference in Visual Analogue Scale scoring.

#### **NEED FOR RESCUE ANALGESIC**



In patients belonging to Topical Anesthesia group, the need for rescue analgesic is increased to 36.67 percentage points in comparison with patients belonging to Topical Anesthesia + Nerve Block group in whom the need for rescue analgesic is 6.67 percentage points with a p-value of 0.0102 according to fishers exact test. The need for rescue analgesic was meaningfully more in Topical Anesthesia group compared to Topical Anesthesia + Nerve Block group by 30.00 percentage points. This significant difference of 5.50 times increase in need for rescue analgesic in Topical Anesthesia intervention group compared to Topical Anesthesia + Nerve Block intervention group is true and has not occurred by chance.

Rescue Analgesics	TA Group	%	TA+NB Group	<u>%</u>	P value Fishers Exact Test
Not Needed	19	63.33	28	93.33	
Needed	11	36.67	2	6.67	<mark>0.0102</mark>
Total	30	100	30	100	

In this study we can safely conclude that Topical Anesthesia group showed statistically significant increase in the need for rescue analgesic compared to Topical Anesthesia + Nerve Block in patients undergoing septal and endoscopic sinus surgeries under General Anesthesia.

### INTRA OPERATIVE ADDITIONAL FENTANYL CONSUMPTION

The intra operative additional Fentanyl consumption was nil in both the groups and there was no statistically significant difference.

Intraoperative Additional Fentanyl Consumption	TA Group	%	TA+NB Group	<del>%</del>
Not Needed	30	100	30	100
Needed	0	0	0	0
Total	30	100	30	100

## COMPLICATIONS

Both the groups had no major complications in the intra operative and post operative period and there was no statistically significant difference in the complications.

Complications	TAGroup	%	TA+NB Group	<del>%</del>
Absent	30	100	30	100
Present	0	0	0	0
Total	30	100	30	100

#### DISCUSSION

A total of sixty patients who were undergoing elective sinus and septal surgeries under General Anaesthesia were randomnly divided into two groups, Group A and Group B. Group A received topical anaesthesia and Group B received combined Topical anaesthesia with bilateral nerve block of Anterior Ethmoidal nerve and Infraorbital nerve.

The comparison of analgesic efficacy of the two groups was done based on the introperative and post operative haemodynamics, postoperative pain assessment by visual analogue scale and need for rescue analgesia.

The demographic profile in both the groups in terms of AGE, GENDER, ASA STATUS TYPE OF SURGERY showed no statistically significant difference and hence both the groups are comparable in the above said four parameters. Duration of surgery was around 2 hours in both the groups.

#### SYSTOLIC BLOOD PRESSURE:

In Group A, there was a statistically significant difference in increase of systolic blood pressure intraoperatively compared to baseline value and much significant increase during postoperative period.

In Group B there was no statistically significant difference in increase of systolic blood pressure both intraoperatively and post operatively.

Hence we infer that Group A patients showed a statistically significant rise in systolic blood pressure when compared to Group B both in the intraoperative and the post operative period.

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#### **DIASTOLIC BLOOD PRESSURE:**

In Group A there was a fall in diastolic blood pressure intraoperatively when compared to the baseline which was not statistically significant, and there was rise in diastolic blood pressure post operatively which was statistically significant. In Group B the increase in diastolic blood pressure was not statistically significant both intraoperatively and postoperatively.

Hence we infer that Group A showed statistically significant rise in diastolic blood pressure in the post operative period when compared to Group B.

#### MEAN ARTERIAL BLOOD PRESSURE:

The Group A showed mild increase in mean arterial pressure intra operatively and also showed a significant rise in mean arterial pressure in post operative period.

In Group B the increase in Mean arterial pressure was not statistically significant both intraoperatively and postoperatively.

Hence we infer that Group A showed statistically significant rise in Mean arterial pressure in the post operative period when compared to Group B.

#### **PULSE RATE:**

In Group A there was a decrease in pulse rate intraoperatively, when compared to the baseline which was statistically significant and there was an increase in pulse rate post operatively which was not statistically significant. In Group B there was an increase in pulse rate both intraoperatively and post operatively but it was not statistically significant.

Hence we infer that decrease in pulse rate in Group A was statistically significant in intraoperative period when compared to Group B.

## <u>FROM THE ABOVE OBSERVATIONS TOPICAL ANAESTHESIA</u> <u>COMBINED WITH THE THE NERVE BLOCK ( GROUP B ) WAS FOUND</u> <u>TO BE HAEMODYNAMICALLY MORE STABLE WHEN COMPARED TO</u> <u>TOPICAL ANAESTHESIA ALONE ( GROUP A ).</u>

#### INTRAOPERATIVE ADDITIONAL FENTANYL CONSUMPTION:

Both Group A and Group B patients did not require any additional doses of Fentanyl intraoperatively.

#### **VISUAL ANALOGUE SCALE:**

In Group A there was an early increase in the VAS scores in the post operative period and in Group B there was a delayed and mild increase in the VAS scores in the post operative period.

Hence we infer that VAS scores was significantly less in Group B compared to Group A as per statistical observations.

VAS pain score was significantly less in the Nerve block Group B in this study .This observation is comparable with the study conducted by Edward R Mariano et al who concluded reduced pain score with infra orbital nerve block in FESS surgeries and also comparable with the study of Kim HS et al who concluded reduced post operative pain score with Anterior Ethmoidal nerve block in fractured nasal bones.

#### POST OPERATIVE NEED FOR RESCUE ANALGESIA:

Rescue analgesia was given with Inj.Diclofenac in whom Visual Analogue Scale score is more than 4 in the post operative period. In Group A 11 patients out of 30 required rescue analgesia .In Group B only 2 patients out of 30 required rescue analgesia.

Hence we infer that there was a statistical significant increase in the need for rescue analgesia in Group A when compared to Group B.

# COMPLICATIONS DURING INTRAOPERATIVE AND POST OPERATIVE PERIOD:

Both Group A and Group B patients had no major complications.

## FROM THE ABOVE OBSERVATIONS TOPICAL ANAESTHESIA COMBINED WITH NERVE BLOCK (GROUP B) WAS FOUND TO HAVE REDUCED POST OPERATIVE PAIN AND REDUCED NEED FOR RESCUE ANALGESIA WHEN COMPARED TO TOPICAL ANAESTHESIA ALONE (GROUP A).

#### SUMMARY

This prospective randomized study was done to compare the post operative analgesic efficacy of the Anterior Ethmoidal nerve block and Infraorbital nerve block in patients undergoing septal and endoscopic sinus surgeries under General anaesthesia. 30 patients in Group A and 30 patients in Group B are allotted randomly. Group A received topical anaesthesia and Group B received combined Topical anaesthesia with bilateral nerve block of Anterior Ethmoidal nerve and Infraorbital nerve with Bupivacaine. The comparison of analgesic efficacy of the two groups was done based on the introperative and post operative haemodynamics, postoperative visual analogue pain scale scoring and need for rescue analgesia.

The results obtained were as follows-

AGE, GENDER, ASA STATUS, TYPE OF SURGERY showed no statistically significant difference and hence both the groups are comparable in the above said four parameters.

**SYSTOLIC BLOOD PRESSURE:** Group A patients showed a statistically significant rise in systolic blood pressure when compared to Group B both in the intraoperative and the post operative period.

**DIASTOLIC BLOOD PRESSURE:** Group A showed statistically significant rise in diastolic blood pressure in the post operative period when compared to Group B.

**MEAN ARTERIAL PRESSURE:** Group A showed statistically significant rise in Mean arterial pressure in the post operative period when compared to Group B.

**PULSE RATE:** There was a decrease in pulse rate in Group A during intraoperative period when compared to Group B.

#### INTRAOPERATIVE ADDITIONAL FENTANYL CONSUMPTION:

Both Group A and Group B patients not required additional doses of Fentanyl Intraoperatively.

**VISUAL ANALOGUE SCALE:** VAS scores was significantly less in Group B compared to Group A as per statistical observations.

**POST OPERATIVE NEED FOR RESCUE ANALGESIA:** There was a statistical significant increase in the need for rescue analgesia in Group A when compared to Group B.

**COMPLICATIONS:** Both Group A and Group B patients had no major complications.

## PATIENTS WHO RECEIVED TOPICAL ANAESTHESIA COMBINED WITH NERVE BLOCK WERE FOUND TO HAVE GOOD PERIOPERATIVE HAEMODYNAMIC STABILITY, REDUCED POST OPERATIVE PAIN AND NEED FOR RESCUE ANALGESIA WHEN COMPARED TO THE PATIENTS WHO RECEIVED TOPICAL ANAESTHESIA ALONE.

#### CONCLUSION

The Anterior ethmoidal nerve block and Infraorbital nerve block with bupivacaine given preoperatively in combination with the topical anaesthesia provided more haemodynamic stability in the perioperative period, reduce the postoperative pain and need for rescue analgesia when compared to topical anaesthesia alone in nasal surgeries done under General anaesthesia.

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### **INFORMATIONS TO PARTICIPANTS**

:

:

Investigator

Dr.C.Chitra

Name of the participant

Title:

"Comparison of postoperative analgesic efficacy of Topical anaesthesia and combined Topical anaesthesia with Nerve block [Anterior Ethmoidal nerve and Infraorbital nerve] in patients undergoingseptal and endoscopic sinus surgeries under General anaesthesia"

You are invited to take part in this research study. We have got approval from the Institutional Ethics Committee. You are asked to participate because you satisfy the eligibility criteria. We want to compare the Topical anaesthesia Group and Combined Topical anaesthesia with Nerve block group on intraoperative Fentanyl consumption and post operative pain score.

#### What is the purpose of the research?

This study is done to compare the Topical anaesthesia Group and Combined Topical anaesthesia with Nerve block group on intraoperative Fentanyl consumption and post operative pain score in the patients operated for elective nasal /panasal sinus surgeries.

#### The study design:

All the 60 patients are divided into two groups randomly.

- Group A Topical anaesthesia given preoperatively
- Group B Combined Topical anaesthesia and Nerve block given preoperatively.

#### **Benefits:**

NERVE BLOCK can provide

Good Pain relief intraoperatively and postoperatively and can delay the postoperative rescue analgesia.

Reduces the Fentanyl consumption intraoperatively thereby reduce the cost of total drugs usage.

Reduces the side effects of Fentanyl like nausea and vomiting.

#### **Discomfort and Risks**

1. Minimal swelling at the injected site.

2. Allergy to local anaesthetics

All emergency drugs and equipments are readily kept available, if any complications occurs it is easily recognizable and treatable.

This type of techniques has been shown well tolerated in previous studies, and if you do not want to participate you will have alternative of setting the standard treatment and your safety is our prime concern.

## Signature/ Thumb impression of Patient Patient Name:

Date : Place :

Signature of the Investigator	:	
Name of the Investigator	:	Dr.C.Chitra

#### PATIENT CONSENT FORM

#### **Study Title:**

"Comparison of postoperative analgesic efficacy of Topical anaesthesia and combined Topical anaesthesia with Nerve block [Anterior Ethmoidal nerve and Infraorbital nerve] in patients undergoingseptal and endoscopic sinus surgeries under General anaesthesia"

Study Center: Institute of Anaesthesiology and Critical Care, Madras Medical College& Rajiv Gandhi Govt. General Hospital, Chennai - 3.

I confirm that I have understood the purpose of procedure for the above study. I have the opportunity to ask the question and all my questions and doubts have been answered to my satisfaction.

I have been explained about the pitfall in the procedure. I have been explained about the safety, advantage and disadvantage of the technique.

I understood that my participation in the study is voluntary and that I am free to withdraw at anytime without giving any reason.

I understand that investigation, regulatory authorities and the ethics committee will not need my permission to look at my health records both in respect to current study and any further research that may be conducted in relation to it, even if I withdraw from the study.

I understand that my identity will not be revealed in any information released to third parties or published, unless as required under the law. I agree not to restrict the use of any data or results that arise from the study.

> Signature / Thumb impression of patient Name of the patient

Signature of the investigator:

Name of the investigator: Dr.C.CHITRA

## PROFORMA

#### DATE :

NAME :		IP NUMBER :	
AGE :		DIAGNOSIS :	
SEX :		SURGERY :	
H/O Comorbid illnes	SS:		
H/O Medications :			
H/O Previous Surger	ry:		
Preoperative Assess	ment :		
CVS :	<b>RS</b> :		
PULSE RATE :	/Min BP :	mmHg	
AIRWAY :		ASA I	
Topical anaesthesia Additional dosage : Inj.Fentanyl given If given :Dose : Time of Intubation : Nerve Block : given	not given Time:	'ime:	
_			
Time of Nerve Block	к:		

Anterior Ethmoidal Nerve block:

Infraorbital nerve block:

Surgery Started Time :

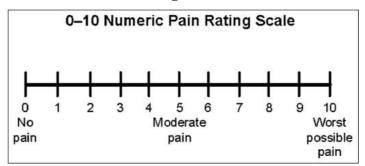
Sl.No	Time (Every 10 Minutes)	Pulse Rate	<b>Blood Pressure</b>

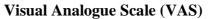
Surgery ended time :

Complication in the Intraoperative period:

Time of Extubation :

## Post Operative Monitoring :





Duration after surgery	VAS PAIN SCORE	Time of Rescue analgesia [if VAS core>4cm]	Pulserate	Blood pressure
Immediate				
Post op				
1 <sup>st</sup> hour				
2 <sup>nd</sup> hour				
3 <sup>rd</sup> hour				
4 <sup>th</sup> hour				
5 <sup>th</sup> hour				
6 <sup>th</sup> hour				

Complication in the post operative period:

## PATIENTS NAME GROUP-A

S.No	Group	Name	Age	Sex	Ip no	Surgery	ASA	Intraoperative additional fentanyl consumption	Complications during intraoperative period
1	А	VASUDEVAN	42	М	31006	FESS/SMR	1	NIL	NIL
2	А	ANISH KUMAR	21	М	31007	SEPTOPLASTY	1	NIL	NIL
3	А	RAMAKRISHNAN	32	М	33212	SEPTOPLASTY	1	NIL	NIL
4	А	RAVI	44	М	33203	FESS	1	NIL	NIL
5	А	PREMA	50	F	28534	FESS	2	NIL	NIL
6	А	RASSOL HYDEEN	28	М	34958	SMR	1	NIL	NIL
7	А	SANGEETHA	28	F	11518	SMR	1	NIL	NIL
8	А	KISHORE	18	М	36144	FESS	1	NIL	NIL
9	А	THAMEEM	29	М	37230	FESS/SMR	1	NIL	NIL
10	А	LAKSHMI	40	F	36275	FESS/SEPTOPLASTY	1	NIL	NIL
11	А	MOHAMMEDRAMATHULLA	43	М	37612	FESS	2	NIL	NIL
12	А	CHITRA	40	F	37937	FESS	1	NIL	NIL
13	А	MUTHULAKSHMI	18	F	38520	FESS	1	NIL	NIL
14	А	SAKTHIVEL	19	М	39082	FESS	1	NIL	NIL
15	А	SHYAMALA	39	F	40631	FESS/SEPTOPLASTY	1	NIL	NIL
16	А	SASAN KUMAR	39	М	40328	FESS	1	NIL	NIL
17	А	MEENA	40	F	41291	FESS	1	NIL	NIL
18	А	BABY	35	F	41558	FESS	1	NIL	NIL
19	А	MARY SUJATHA	29	F	41572	FESS	2	NIL	NIL
20	А	VANILLA	27	F	40811	FESS/SEPTOPLASTY	1	NIL	NIL
21	А	SAKUNTHALA	50	F	41089	FESS	2	NIL	NIL
22	А	RAJESH	31	М	41650	FESS	1	NIL	NIL
23	А	RAVICHANDRA BABU	40	М	49758	FESS	1	NIL	NIL
24	А	RAJESHWARI	21	F	41622	FESS	1	NIL	NIL
25	А	RANJINI	42	F	12783	FESS/SEPTOPLASTY	1	NIL	NIL
26	А	RAMESH	35	М	10622	FESS	1	NIL	NIL
27	А	ARUMUGAM	35	М	33000	FESS/SMR	1	NIL	NIL
28	А	MALAR	22	F	10643	FESS	1	NIL	NIL
29	А	RAJKUMAR	32	М	12184	FESS	1	NIL	NIL
30	А	NATARAJAN	45	М	44655	FESS	2	NIL	NIL

## PATIENTS NAME GROUP-B

S. No	Group	Name	Age	Sex	Ip.no	Surgery	ASA	Intraoperative Additional Fentanyl Consumption	Complications during intra operative Period
1	В	ANUSIYA	34	F	38622	FESS/SEPTOPLASTY	1	NIL	NIL
2	В	NEELAMBAL	65	F	38615	FESS	2	NIL	NIL
3	В	BABU	26	М	44655	FESS	1	NIL	NIL
4	В	POONGOTHAI	25	F	44654	FESS	1	NIL	NIL
5	В	MARI	30	М	10761	FESS/SMR	1	NIL	NIL
6	В	VELU	36	М	11101	FESS/SMR	1	NIL	NIL
7	В	CHINNAPAREDDY	27	М	11402	FESS	1	NIL	NIL
8	В	NARAYADU	45	М	17617	FESS/SMR	2	NIL	NIL
9	В	MOHAN	29	М	10551	FESS	1	NIL	NIL
10	В	PARIMALA	43	F	16521	FESS/SEPTOPLASTY	1	NIL	NIL
11	В	MEENAKSHI	30	F	47211	FESS	1	NIL	NIL
12	В	VIGNESH	18	М	47561	FESS	1	NIL	NIL
13	В	DEVAN	39	М	48312	FESS	1	NIL	NIL
14	В	INDRA	37	F	50259	FESS	1	NIL	NIL
15	В	DEVAN	30	М	48216	FESS/SMR	1	NIL	NIL
16	В	SELVAM	24	М	50222	FESS	1	NIL	NIL
17	В	DHARANI	26	F	57812	FESS/SEPTOPLASTY	1	NIL	NIL
18	В	BALAJI	18	М	53052	FESS	1	NIL	NIL
19	В	GOKUL RAJ	18	М	53050	SEPTOPLASTY	1	NIL	NIL
20	В	VIGNESH	18	М	16133	FESS/SEPTOPLASTY	1	NIL	NIL
21	В	MEENAMBAL	33	F	18469	FESS	1	NIL	NIL
22	В	VEERAMAHADEVAN	34	М	19101	FESS	1	NIL	NIL
23	В	HARIPRIYA	20	F	17104	FESS	1	NIL	NIL
24	В	DANIEL PAUL	24	М	19204	FESS	1	NIL	NIL
25	В	BAKTHAVATCHALAM	47	М	55380	FESS	1	NIL	NIL
26	В	VADIVEL	38	М	52320	FESS	1	NIL	NIL
27	В	KASIAMMAL	42	F	42143	FESS/SMR	2	NIL	NIL
28	В	NIRMAL RAJ	22	М	41663	FESS/SEPTOPLASTY	1	NIL	NIL
29	В	NAGALINGAM	35	М	41662	FESS	1	NIL	NIL
30	В	GOMATHI	24	F	42898	FESS	1	NIL	NIL

S. No	Group	Base line	1hr after start Of surgery	End of Surgery	Imm.post.op	4 hr post op	6hr post op
1	A	72	70	86	90	98	88
2	А	76	70	72	80	88	88
3	А	71	72	74	86	88	89
4	A	68	82	94	94	100	92
5	A	80	81	84	86	92	88
6	A	86	82	82	80	82	86
7	А	88	84	92	90	88	90
8	A	86	82	91	92	94	93
9	А	70	78	76	80	84	85
10	А	84	82	88	84	90	89
11	А	78	80	94	98	102	100
12	А	76	72	86	85	96	98
13	А	78	68	88	88	94	98
14	А	72	90	90	98	108	106
15	А	68	82	86	84	86	89
16	А	68	78	72	74	88	92
17	А	69	88	86	86	100	104
18	А	70	82	82	84	92	92
19	А	64	78	89	86	92	90
20	А	76	84	90	89	96	96
21	А	86	90	94	94	101	105
22	А	74	76	76	76	84	89
23	А	78	89	92	91	96	94
24	А	84	88	89	96	100	106
25	А	76	88	92	92	98	108
26	А	88	81	87	89	96	96
27	А	82	91	92	90	99	96
28	A	76	70	84	84	89	89
29	A	78	79	88	84	92	94
30	А	78	88	88	86	94	96

## PULSE RATE OBSERVATIONS GROUP-A

S. No	Group	Base line	1hr after StartOfsurgery	End of Surgery	Imm.post op	4hr post Op	6hr post Op
1	В	78	76	76	70	76	78
2	В	82	84	84	86	78	80
3	В	84	82	82	82	88	82
4	В	84	82	81	82	85	85
5	В	86	80	82	78	84	88
6	В	88	80	82	84	82	78
7	В	84	82	94	92	104	98
8	В	76	68	76	76	76	72
9	В	78	72	76	78	76	74
10	В	78	76	70	71	72	78
11	В	86	86	86	82	90	88
12	В	88	76	86	88	82	90
13	В	88	78	80	82	84	81
14	В	84	78	82	82	84	88
15	В	84	74	82	82	88	82
16	В	82	82	84	81	86	88
17	В	80	84	84	82	86	84
18	В	68	74	64	68	68	70
19	В	74	74	64	68	68	70
20	В	88	92	84	82	84	82
21	В	68	74	70	76	76	78
22	В	78	72	76	78	76	74
23	В	86	86	96	98	106	100
24	В	84	88	90	92	84	84
25	В	92	86	92	90	89	82
26	В	90	88	94	92	94	88
27	В	80	88	84	88	87	84
28	В	76	85	82	84	84	88
29	В	78	76	79	82	76	78
30	В	78	64	74	80	84	82

## PULSE RATE OBSERVATIONS GROUP-B

S.NO	BL SBP	BL DBP	BL MAP	1 HR SBP	1 HR DBP	1 HR MAP	END SBP	END DBP	END MAP	IPO SBP	IPO DBP	IPO MAP	4HR SBP	4HR DBP	4HRMAP	6HR SBP	6HR DBP	6HR MAP
1	110	70	83	117	70	86	120	86	97	122	84	97	142	94	110	138	86	103
2	110	70	83	138	86	103	138	90	106	140	90	107	158	86	110	158	88	111
3	110	70	83	106	78	87	120	84	96	126	78	94	142	86	105	140	90	107
4	110	70	83	122	78	93	136	84	101	138	80	99	148	92	111	140	86	104
5	110	70	83	108	74	85	116	70	85	108	74	85	128	70	89	130	86	101
6	110	70	83	98	68	78	108	70	83	116	78	91	126	78	94	130	70	90
7	110	70	83	120	80	93	130	90	103	132	90	104	132	94	107	140	86	104
8	110	70	83	120	74	89	120	78	92	126	70	89	134	84	101	138	82	101
9	110	70	83	100	62	75	128	78	95	128	74	92	136	84	101	134	88	103
10	110	70	83	98	68	78	130	74	93	130	76	94	136	78	97	138	88	105
11	110	70	83	106	72	83	132	74	93	136	78	97	138	86	103	138	92	107
12	110	70	83	108	70	83	122	78	93	126	78	94	138	84	102	140	94	109
13	110	70	83	108	78	88	112	78	89	116	78	91	136	84	101	140	90	107
14	110	70	83	126	70	89	138	90	106	136	94	108	150	92	111	148	92	111
15	110	70	83	120	84	96	130	80	97	130	84	99	138	90	106	136	90	105
16	110	70	83	106	74	85	116	77	90	116	74	88	124	70	88	132	74	93
17	110	70	83	118	74	89	128	76	93	130	70	90	142	94	110	138	86	103
18	110	70	83	100	64	76	120	76	91	120	78	92	132	78	96	140	84	103
19	110	70	83	116	78	91	132	82	99	128	86	100	134	86	102	134	90	105
20	110	70	83	118	74	89	132	80	97	132	84	100	140	90	107	136	88	104
21	110	70	83	118	78	91	134	78	97	132	80	97	146	94	111	146	92	110
22	130	70	90	130	76	94	130	82	98	132	86	101	144	92	109	142	94	110
23	108	68	81	116	74	88	122	78	93	138	84	102	132	84	100	136	94	108
24	110	74	86	112	76	88	122	74	90	120	78	92	136	82	100	130	90	103
25	110	68	82	108	74	85	120	74	89	126	70	89	146	90	109	140	90	107
26	116	78	91	114	70	85	120	76	91	122	78	93	130	86	101	136	92	107
27	130	80	97	130	84	99	132	84	100	136	86	103	138	92	107	136	92	107
28	116	74	88	114	78	90	120	74	89	122	76	91	132	90	104	136	96	109
29	118	78	91	116	78	91	120	76	91	130	70	90	136	88	104	132	96	108
30	100	70	80	94	68	77	106	78	87	108	78	88	120	70	87	126	74	91

## **BLOOD PRESSURE OBSERVATIONS GROUP-A**

S.NO	BL SBP	BL DBP	BL MAP	1HR SBP	1HR DBP	1HR MAP	END SBP	END DBP	END MAP	IPO SBP	IPO DBP	IPOMAP	4HR SBP	4HR DBP	4HR MAP	6HR SBP	6HR DBP	6HR MAP
1	120	70	87	116	74	88	116	80	92	122	78	93	110	78	89	108	74	85
2	140	90	107	106	90	95	146	98	114	149	92	111	146	98	114	142	97	112
3	110	70	83	106	70	82	114	78	90	116	74	88	122	76	91	120	78	92
4	120	84	96	106	88	94	116	78	91	118	76	90	122	84	97	126	74	91
5	110	70	83	102	68	79	126	88	101	126	84	98	120	74	89	118	74	89
6	116	70	85	108	74	85	106	78	87	116	70	85	120	76	91	128	86	100
7	110	68	82	100	70	80	106	78	87	106	74	85	100	78	85	106	70	82
8	130	90	103	132	92	105	142	100	114	140	100	113	150	100	117	152	104	120
9	110	70	83	100	70	80	100	78	85	100	68	79	110	70	83	116	74	88
10	116	78	91	100	70	80	102	70	81	116	78	91	120	76	91	120	84	96
11	110	70	83	116	74	88	120	76	91	122	74	90	126	84	98	122	78	93
12	110	78	89	116	78	91	118	80	93	118	84	95	116	84	95	108	78	88
13	106	78	87	120	70	87	112	78	89	110	70	83	122	74	90	126	78	94
14	116	78	91	120	74	89	120	88	99	120	78	92	116	78	91	116	84	95
15	130	70	90	130	70	90	142	74	97	142	72	95	144	80	101	146	88	107
16	118	74	89	126	84	98	102	76	85	100	68	79	118	70	86	120	78	92
17	110	68	82	100	72	81	106	74	85	106	74	85	100	74	83	106	78	87
18	114	70	85	108	70	83	106	72	83	108	70	83	112	78	89	118	78	91
19	110	70	83	108	74	85	110	68	82	112	76	88	112	70	84	116	76	89
20	114	72	86	106	70	82	100	70	80	106	76	86	108	70	83	114	78	90
21	110	76	87	106	70	82	108	70	83	108	68	81	112	72	85	118	76	90
22	112	80	91	106	72	83	112	76	88	112	74	87	108	74	85	118	78	91
23	106	78	87	130	90	103	124	76	92	120	86	97	140	100	113	142	108	119
24	110	78	89	114	74	87	112	74	87	110	72	85	114	72	86	118	78	91
25	114	72	86	118	76	90	118	76	90	118	72	87	118	76	90	118	76	90
26	118	76	90	112	70	84	116	72	87	118	74	89	116	72	87	118	78	91
27	140	90	107	130	80	97	126	88	101	124	76	92	120	82	95	134	88	103
28	120	82	95	120	82	95	118	76	90	120	76	91	116	72	87	116	78	91
29	118	78	91	106	74	85	110	76	87	120	74	89	114	74	87	116	78	91
30	120	78	92	110	78	89	120	78	92	118	76	90	118	74	89	120	82	95

## **BLOOD PRESSURE OBSERVATIONS GROUP-B**

## VAS SCORE GROUP-A

S. No	Group	Imm.post.op	1hr	2hr	3hr	4hr	5hr	6hr	Rescue analgesia/which hour	Complications in post operative period
1	А	1	1	2	4	5	4	3	YES/IN 4 TH HOUR	NIL
2	А	1	3	3	4	4	5	5	YES/IN 5 TH HOUR	NIL
3	А	1	2	3	4	4	5	4	YES/IN 5 TH HOUR	NIL
4	А	2	4	4	4	4	5	4	YES/IN 5 TH HOUR	NIL
5	А	1	1	1	2	2	2	3	NOT NEEDED	NIL
6	А	0	1	2	2	2	2	3	NOT NEEDED	NIL
7	А	2	3	3	3	3	4	4	NOT NEEDED	NIL
8	А	1	2	2	3	3	4	4	NOT NEEDED	NIL
9	А	2	2	3	3	3	4	4	NOT NEEDED	NIL
10	А	2	2	3	3	3	4	4	NOT NEEDED	NIL
11	А	2	2	3	3	4	4	5	YES/IN 6 TH HOUR	NIL
12	А	1	2	3	3	3	4	5	YES/IN 6 TH HOUR	NIL
13	А	0	1	2	3	4	4	5	YES/IN 6 TH HOUR	NIL
14	А	2	3	3	4	4	5	4	YES/IN 5 TH HOUR	NIL
15	А	2	2	2	3	3	3	4	NOT NEEDED	NIL
16	А	0	1	1	1	2	3	3	NOT NEEDED	NIL
17	А	2	3	4	4	5	4	3	YES/IN 4 TH HOUR	NIL
18	А	1	1	2	2	3	4	4	NOT NEEDED	NIL
19	А	2	2	2	2	2	3	3	NOT NEEDED	NIL
20	А	2	2	3	3	3	3	3	NOT NEEDED	NIL
21	А	1	2	3	3	4	5	4	YES/IN 5 TH HOUR	NIL
22	А	1	2	2	2	3	4	4	NOT NEEDED	NIL
23	А	2	2	3	3	3	4	4	NOT NEEDED	NIL
24	А	1	2	2	2	3	3	3	NOT NEEDED	NIL
25	А	1	2	3	3	5	4	4	YES/IN 4 TH HOUR	NIL
26	А	1	1	1	1	2	2	3	NOT NEEDED	NIL
27	А	1	1	1	1	2	2	2	NOT NEEDED	NIL
28	А	1	1	1	1	2	2			NIL
29	А	1	1	2	2	2	2	3	NOT NEEDED	NIL
30	А	0	0	1	2	2	2	2	NOT NEEDED	NIL

## VAS SCORE GROUP-B

S. No	Group	Imm.post.op	1hr	2hr	3hr	4hr	5hr	6hr	Rescue analgesia/ Which hour needed	Complications post op
1	В	0	0	0	0	0	0	1	NOT NEEDED	NIL
2	В	0	0	0	0	0	1	1	NOT NEEDED	NIL
3	В	0	0	0	1	1	1	2	NOT NEEDED	NIL
4	В	0	0	0	0	0	1	1	NOT NEEDED	NIL
5	В	0	0	1	1	1	2	2	NOT NEEDED	NIL
6	В	0	0	0	0	0	0	0	NOT NEEDED	NIL
7	В	1	2	3	4	4	5	4	YES/NEEDED IN 5 <sup>TH</sup> HR	NIL
8	В	0	0	0	0	1	1	1	NOT NEEDED	NIL
9	В	0	0	0	0	1	1	1	NOT NEEDED	NIL
10	В	0	0	0	1	1	2	2	NOT NEEDED	NIL
11	В	0	0	0	1	1	1	2	NOT NEEDED	NIL
12	В	0	0	0	0	0	1	1	NOT NEEDED	NIL
13	В	0	0	0	0	1	1	2	NOT NEEDED	NIL
14	В	0	0	0	0	1	1	1	NOT NEEDED	NIL
15	В	0	1	1	1	1	1	1	NOT NEEDED	NIL
16	В	1	1	1	1	2	2	2	NOT NEEDED	NIL
17	В	0	0	0	0	1	1	1	NOT NEEDED	NIL
18	В	0	0	0	0	0	1	1	NOT NEEDED	NIL
19	В	0	0	0	1	1	1	2	NOT NEEDED	NIL
20	В	0	0	0	1	1	2	2	NOT NEEDED	NIL
21	В	0	0	0	1	1	1	2	NOT NEEDED	NIL
22	В	0	0	0	0	0	0	0	NOT NEEDED	NIL
23	В	1	2	2	3	4	5	4	YES/NEEDED IN 5 <sup>TH</sup> HR	NIL
24	В	0	0	0	0	0	1	1	NOT NEEDED	NIL
25	В	0	0	0	0	0	1	2	NOT NEEDED	NIL
26	В	0	0	0	0	0	1	1	NOT NEEDED	NIL
27	В	0	0	0	0	0	1	2	NOT NEEDED	NIL
28	В	0	0	0	0	0	1	1	NOT NEEDED	NIL
29	В	0	0	0	0	0	0	1	NOT NEEDED	NIL
30	В	0	0	0	1	1	2	2	NOT NEEDED	NIL

#### INSTITUTIONAL ETHICS COMMITTEE MADRAS MEDICAL COLLEGE, CHENNAI-3

EC Reg No. ECR/270/Inst./TN/2013 Telephone No. 044 25305301 Fax: 044 25363970

#### CERTIFICATE OF APPROVAL

To Dr.C.Chitra Postgraduate M.D.(Anaesthesiology) Madras Medical College Chennai 600 003

Dear Dr.C.Chitra,

The Institutional Ethics Committee has considered your request and approved your study titled "Comparison of postoperative analgesic efficacy of Topical anaesthesia and combined Topical anaesthesia with Nerve block (Anterior Ethmoidal nerve and Infraorbital nerve) in patients undergoing septal and endoscopic sinus surgeries under General anaesthesia " No.21042015.

The following members of Ethics Committee were present in the meeting held on 07.04.2015 conducted at Madras Medical College, Chennai-3.

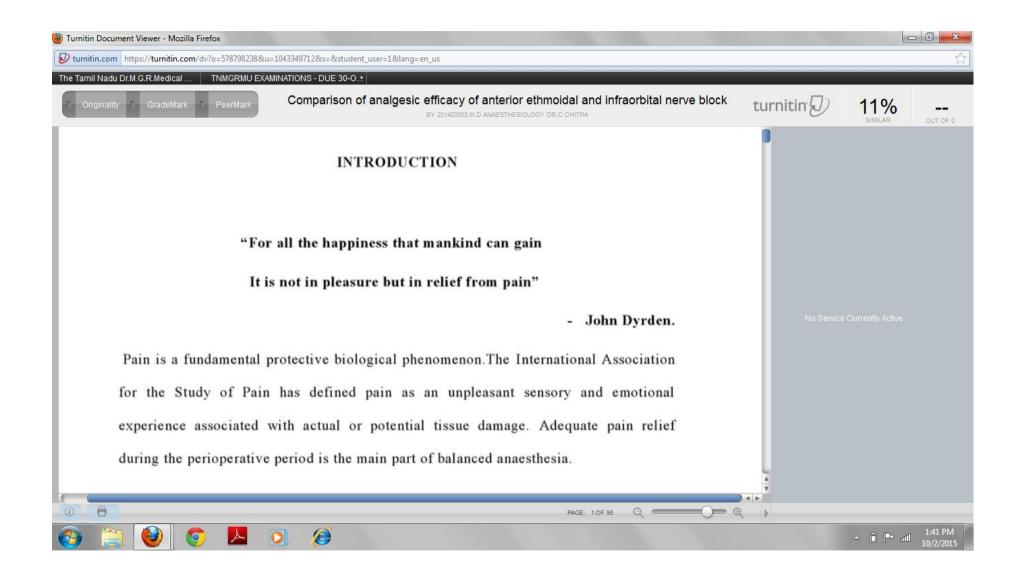
- 1. Prof.C.Rajendran, M.D.,
- 2. Prof.R.Vimala, M.D., Dean, MMC, Ch-3
- 3. Prof.B.Kalaiselvi, M.D., Vice-Principal, MMC, Ch-3
- 1. Prof.B.Vasanthi, M.D., Prof. of Pharmaeology, MMC
- 5. Prof.P.Ragumani, M.S., Professor of Surgery, MMC
- 6. Prof.S.Baby Vasumathi, Director, Inst. Of O&G, MMC
- 7. Prof.K.Ramadevi, Director, Inst.of Biochemistry, MMC
- 8. Prof.Saraswathy, M.D., Director, Pathology, MMC, Ch-3
- 9. Prof.K.Srinivasagalu, M.D., Director, I.I.M. MMC, Ch-3
- 10. Thiru S. Rameshkumar, B. Com., MBA
- 11. Thiru S. Govindasamy, B.A., B.L.,
- 12. Tmt. Arnold Saulina, M.A., MSW.,

- : Chairperson : Deputy Chairperson
- : Member Secretary
- : Member
- : Member
- : Member
- : Member
- : Member : Member
- : Lay Person
- : Lawyer
- : Social Scientist

We approve the proposal to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study and SAE occurring in the course of the study, any changes in the protocol and patients information/informed consent and asks to be provided a copy of the final report.

Momhor Con Ethiop Committee MEMBER SECRETARY INSTITUTIONAL ETHICS COMMITTEE MADRAS MEDICAL COLLEGE CHENNAL-600 003



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