"CONTROLLED HYPOTENSION FOR FUNCTIONAL ENDOSCOPIC SINUS SURGERY WITH TWO DIFFERENT DOSES OF FENTANYL- A RANDOMIZED CONTROL STUDY"

By

Dr. POOJA GIRIYAPUR

DISSERTATION SUBMITTED TO SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH CENTER, KOLAR, KARNATAKA

In partial fulfillment of the requirements for the degree of

DOCTOR OF MEDICINE

IN

ANAESTHESIOLOGY

Under the Guidance of

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Professor & HOD

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JUNE 2023

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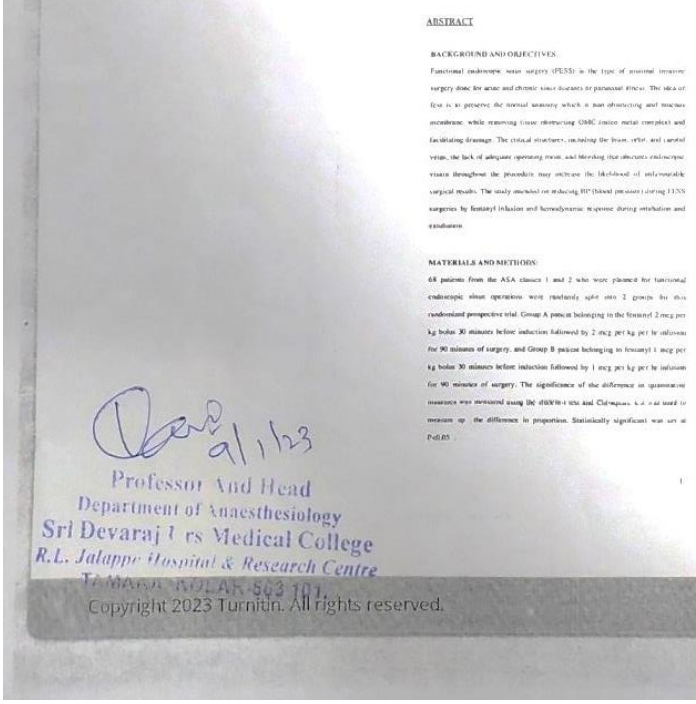

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68 patients from the ASA classes 1 and 2 who were planned for functional endoscopic sinus operations were randomly split into 2 groups for this randomized prospective trial. Group A patient belonging to the fentanyl 2 mcg per kg bolus 30 minutes before induction followed by 2 mcg per kg per hr infusion for 90 minutes of surgery, and Group B patient belonging to fentanyl 1 mcg per kg bolus 30 minutes before induction followed by 1 mcg per kg per hr infusion for 90 minutes of surgery. The significance of the difference in quantitative measures was measured using the student's test and Chi-square test was used to measure up the difference in proportion. Statistically significant was set at P<0.05 .

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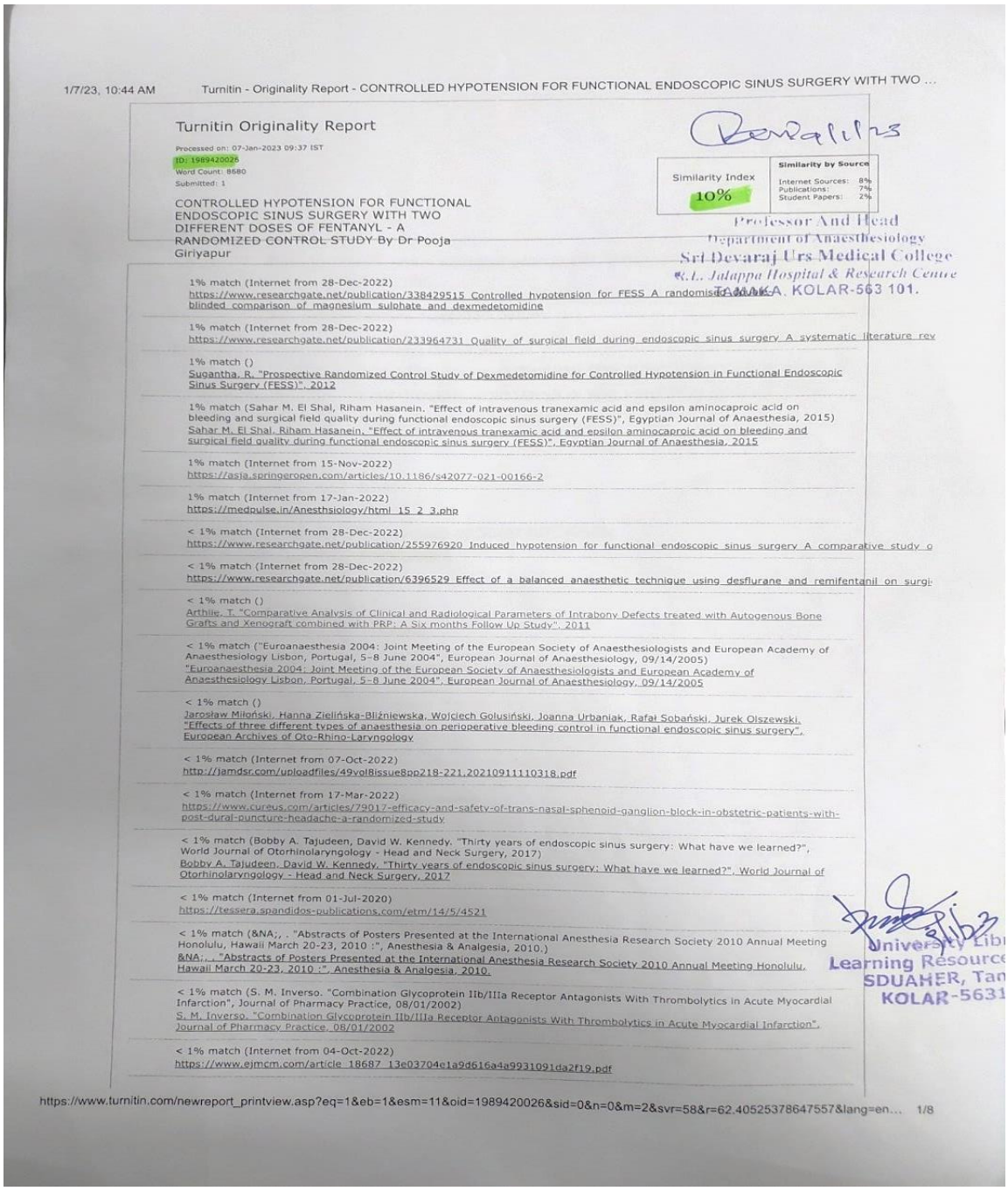

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ACKNOWLEDGEMENT

*First and foremost, I thank my **"Almighty God"** for giving me his endless blessings and mental and physical strength during my post-graduation and for making this dissertation book possible.*

I want to acknowledge all those who have supported me in completing my dissertation and helped me throughout my post-graduation course.

*I wish to express my heart's entire indebtedness. I owe a deep gratitude to my mentor and guide**, Dr. RAVI M,** Professor & Head, Department of Anaesthesiology, for being beneficial throughout the study and offering his invaluable guidance and support to fully understand and complete this study. His vast professional knowledge and expertise ensured that I understood everything before applying the information to my research. With his constant supervision and advice, completing this dissertation was possible.*

*It gives me immense pleasure to extend my sincere thanks to Professor **Dr. SURESH KUMAR.N Dr.KIRAN.N, DR.SUJATHA. MP** and Associate Professors**, Dr.LAVANYA.K and DR. VISHNUVARDHAN.V** for their guidance, motivation and moral support during my entire post-graduation course.*

*I am incredibly thankful to Assistant Professors **DR. SUMANTH T, DR. NAGASESHU KUMARI VASANTHA, DR. SINDHU, Dr. ABHINAYA MANEM** for their constant help and guidance throughout the course. They were a source of encouragement, support, and for patient perusal, to which I am deeply obliged.*

My Heartfelt thanks to senior residents ***Dr. BALAJI, Dr. CHANDRAMOHAN, Dr. ISHITA, Dr. MAHIMA, Dr. SINCHANA, Dr. HUCHAPPA,*** *and my super seniors* ***Dr. MANJULA DEVI, Dr. SRAVANTHI, Dr. SANDEEP, Dr. NAGARAJ S K, Dr. SREENIDI R, and Dr. ARPITHA MARY,*** *for their practical tips, advice, and constant encouragement.*

I express my sincere thanks to my colleagues ***Dr. SMRUTHI N, Dr. PADMASREE M K, Dr. VIDYA C, Dr. YASWANTH P, Dr. ASWIN B, Dr. MATHEW G, Dr. RAHUL K, Dr. YASHASWINI G, Dr. SUNDEEP K, Dr. DHANALAKSHMI M, Dr. MONISHA B*** *and dearest friend* ***Dr. KAVYA,*** *for their co-operation and help in carrying out this study. I thank my* ***JUNIORS*** *for providing valuable tips and clues in completing this work.*

I sincerely thank all the ***SURGEONS*** *who were essential during the study.*

I am also thankful to all the ***O.T.*** *and* ***Paramedical Staff*** *for their valuable help while performing the study.*

I express my profound gratitude to my beloved ***PARENTS, Smt. SHARADA*** *and* ***Sri. ARUN KUMAR GIRIYAPUR and*** *my brother* ***DEEPAK,*** *sister-in-law* ***RAMYA****, and my fiancé* ***Dr. SHARAN PATTANSHETTI*** *for giving me continuous encouragement and unconditional love throughout my life.*

I am also thankful ***to Dr. HARSHINI,*** *statistician, for helping me with the statistical analysis.*

Last but not least, I express my special thanks to all my ***PATIENTS*** *and their families, who in the final conclusion are the best teachers and without whom this study would have been impossible.*

ABSTRACT

CONTROLLED HYPOTENSION FOR FUNCTIONAL ENDOSCOPIC SINUS SURGERY WITH TWO DIFFERENT DOSES OF FENTANYL - A RANDOMIZED CONTROL STUDY

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BACKGROUND AND OBJECTIVES:

Functional endoscopic sinus surgery (FESS) is the type of minimal invasive surgery done for acute and chronic sinus diseases or paranasal illness. The idea of fess is to preserve the normal anatomy which is non obstructing and mucous membrane, while removing tissue obstructing OMC (osteo metal complex) and facilitating drainage. The critical structures, including the brain, orbit, and carotid veins, the lack of adequate operating room, and bleeding that obscures endoscopic vision throughout the procedure may increase the likelihood of unfavourable surgical results. The study intended on reducing BP (blood pressure) during FESS surgeries by fentanyl infusion and hemodynamic response during intubation and extubation.

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68 patients from the ASA classes 1 and 2 who were planned for functional endoscopic sinus operations were randomly split into 2 groups for this randomized prospective trial. Group A patient belonging to the fentanyl 2 mcg per kg bolus 30 minutes before induction followed by 2 mcg per kg per hr infusion for 90 minutes of surgery, and Group B patient belonging to fentanyl 1 mcg per kg bolus 30 minutes before induction followed by 1 mcg per kg per hr infusion for 90 minutes of surgery. The significance of the difference in quantitative measures was measured using the student-t test and Chi-square test was used to measure up the difference in

proportion. Statistically significant was set at $P<0.05$.

RESULTS:

Mean S.B.P. was higher in members of Group B than Group A. In contrast to Group B, Group A had considerably better surgical field conditions, surgeon satisfaction on the AONO'S scale, post operative nausea and vomiting, and a post-operative VAS Score during the first 24 hours.

CONCLUSION:

Pre-induction Fentanyl with infusion can effectively control hypotension during FESS (Functional Endoscopic Sinus Surgery).

KEYWORDS: Fentanyl, Functional endoscopic sinus surgery, General anesthesia, Hemodynamic response, Post-operative pain.

ABBREVIATIONS

FESS	Functional endoscopic sinus surgery
OMC	Osteo metal complex
BP	Blood pressure
ASA	American society of Anesthesiologists
HR	Heart Rate
Bpm	Beats Per Minute
PR	Pulse Rate
NIBP	Non-Invasive Blood Pressure
DBP	Diastolic Blood Pressure
S.B.P	Systolic Blood Pressure
M.A.P.	Mean Arterial Pressure
E.C.G.	Electrocardiogram
SPO_2	Peripheral capillary oxygen saturation
CVS	Cardiovascular system
P.A.	Per Abdominal
R.S.	Respiratory System
C.N.S.	Central Nervous System
VAS	Visual Analogue Scale
Iv	Intravenous
N.S.	Normal Saline
S.S.P.	Surgeon satisfaction profile

SFC	Surgical field condition
C.B.C.	Complete Blood Count
HB	Hemoglobin
CT	Clotting Time
BT	Bleeding Time
WBC	White Blood Count
HS	Hora somni- at bedtime
RFT	Renal function tests
i.e.,	That is
µg/mcg	Microgram
Kg	Kilogram
Mm Hg	Millimeter of Mercury
cm	Centimeter
mg	Milligram
ml	Millilitre
mins	Minutes
Secs	Seconds
SD	Standard Deviation
GABA	Gamma Amino Butyric Acid
PACU	Post-Anaesthesia Care Unit
FIC	Fentanyl induced cough

Tab	Tablet
hr	Hour
$ETCO_2$	Endtidal carbondioxide
No. of	Number of
Approx.	Approximately
Interop	Intraoperative
Postop	Post-operative
cAMP	Cyclic Adenosinemonophosphate
Sr.Cr	Serum creatinine
R.R.	Respiratory rate
R.B.S.	Random blood sugar
Na^+	Sodium
K^+	Potassium
GA	General Anesthesia
LA	Local anesthesia
N_2O	Nitrous oxide
NTG	Nitroglycerin
SVR	Systemic vascular resistance
MOA	Mechanism of action
SE	Side effects
TIVA	Total intravenous anesthesia

MOR	Mu opioid receptor
DOR	Delta opioid receptor
KOR	Kappa opioid receptor
ng	Nanogram
TMT	Trail making test
VFT	Verbal fluency test
GTN	Glyceryl trinitrate

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INTRODUCTION

The common procedure performed for paranasal sinus illness is FESS. The closeness of important structures, such as orbit, brain and carotid vessels, the lack of available operating room, and bleeding that obstructs endoscopic vision during the procedure may increase the likelihood of unfavourable surgical outcomes (like optic nerve trauma, dural puncture, haemorrhage, etc.).[1] These reasons make using induced hypotension during surgery very vital.[1]

A minimally invasive practice called functional endoscopic sinus surgery is used to treat chronic sinusitis. Small bleeding regions can make an operation harder to see and cause the spread of nearby structures. Using a variety of pharmacological drugs during GA, deliberate hypotension that is reducing the MAP between 50 - 65 mmHg in normal blood pressure patients minimises blood loss in various operations.[2,3,4,5]

However, often prescribed hypotensive drugs can have unpleasant side effects, including heart blocks, rebound hypertension, tachyphylaxis, drowsiness, delayed recovery, and vasodilatation (halogenated substances, nitrates, and beta blockers, among others). These drugs are employed to provide a surgical field free of blood by achieving controlled hypotension.[1]

This study is being proposed to find out the impact of predominant sympathoadrenal suppression effects that is lower HR and BP, of two different doses (1mcg per kg and 2mcg per kg) in facilitating controlled hypotension during Functional endoscopic sinus surgery (primary objective). It is also proposed that this study can help control hypotension for patients undergoing FESS, which has not been done before in the institution.

AIMS & OBJECTIVES

OBJECTIVES

The following goals were pursued from January 2021 to June 2022 in this prospective randomized controlled study:

Primary Objective:

- To study the effect of fentanyl infusion on reducing blood pressure during Fess surgeries.

Secondary Objective:

- To study hemodynamic effects during intubation and extubation.

Functional Endoscopic Sinus Surgery

In 1915, Killian wrote a critique of the "History of Endoscopy, from the earliest times to Bozzini," which he recorded all the attempts to inspect the upper airways before the beginning of the 19th century.[6]

Philip Bozzini, in 1806 published on an article describing the 1st "Light Conductor, or description of a simple device and its use for the illumination of the internal cavities and spaces of the live animal body" with this device, it was being able to "see around the corners, inside the cavities of the human body."[6]

In 1902, Hirschmann and Valentin followed shortly by Reichert in 1903, were able to introduce a modified Cystoscope directly into the maxillary sinus through an enlarged Ductal Alveolus.[7] The first endoscopic treatment was then carried out by Reichert, who used a 7 mm endoscope to make crude adjustments to the maxillary

sinuses all the way through an oroantral fistula.[8]

In 1925, Maltz popularised the term "Sinuscopy" and for diagnostic assessment of the Sinonasal cavity, advocated the use of nasal endoscopes.[6] The main paradigm shift in the field of Sinonasal endoscopy occured in the 1960s with the progress of the Hopkins rod system.[9] A pioneering book on diagnostic endoscopy of the nose was written by Messerklinger in 1978 as the outcome of his studies on mucociliary clearance in fresh cadavers.[10,11]

The main method employed to treat persistent sinusitis in modern times is functional endoscopic sinus surgery. FESS is to re-establish the drainage and aeration of the Para nasal sinuses while maintaining typical anatomic architecture by natural Mucociliary clearing process.

Image improvements with improved knowledge of the pathophysiology of chronic sinusitis, its anatomy and the use of image-guided surgery, surgeons can now safely undertake more intricate treatments.[10]

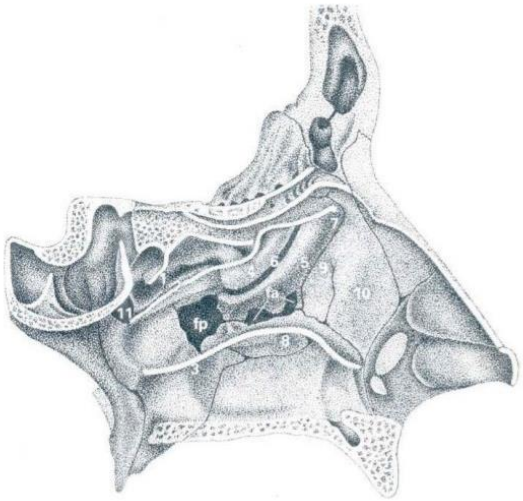


FIGURE 1: BONY STRUCTURES OF LATERAL NASAL WALL

INDICATIONS

The most frequent reasons for endoscopic sinus surgery are inflammatory and infectious sinus conditions. Some of the most typical reason people need endoscopic sinus surgery:

TABLE 1: INDICATIONS FOR FESS

Polyposis	Eustachian tube problems
Obstructed nasal respiration	Postnasal drip
Recurrent and chronic sinusitis	Continuing complaints after the Caldwell-Luc procedure or intranasal fenestration procedures
Epiphora (tearing)	As adjuvant therapy in allergies
Anosmia	Sinubronchial syndrome
Chronic headaches	Bronchial asthma
Mucocele of any paranasal sinus	Recurrent pharyngitis
Retention cysts	Some phonation disturbances
Mycoses (noninvasive)	Special cases of snoring
Orbital complications of acute sinusitis	
Septal spurs	

FESS is a labor-intensive and delicate process. Under general anaesthesia, it is regularly carried done. A local anaesthetic can also be used.

The operating endoscope's image can become obscured by even light bleeding, thus anesthesiologists must prepare the procedure to help the operating teams create a field without blood for better visualisation of the intranasal structures and in order to

lessen intraoperative bleeding. Thus, the function of hypotensive anaesthesia.[1]

COMPLICATIONS OF FESS:

1.Csf leaks

2.Pneumatocephalus

3.Intraorbital bleeding

4.Meningitis

5.Partial loss of vision

6.Diploplia

7.Blindness

8.Stenosis of the nasolacrimal duct

9.Orbital penetration

10.Bleeding

11.Soft tissue inflitration after sinoscopy

PHARMACOLOGY

PHARMACOLOGY OF FENTANYL

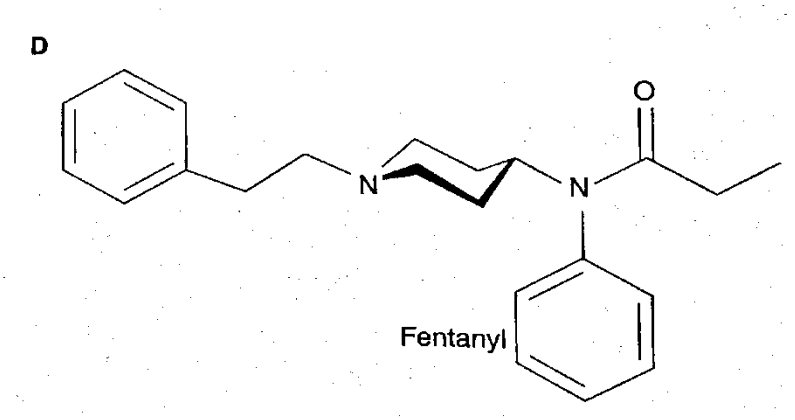


FIGURE 2: CHEMICAL STRUCTURE OF FENTANYL

Fentanyl is a synthetic opioid agonist that is structurally linked to meperidine and a derivative of phenylpiperidine.

It was first created by Janssen Pharmaceutica in 1960 while testing mepheridine derivatives. Sublimaze was the brand name given to the citrate salt..[13,14]

Molecular formula: $C_{22}H_{28}N_2O$; Molecular weight: 336.471 g/mol

MECHANISM OF ACTION

Opioid receptors are present in both C.N.S. and PNS. They are generally stimulated by endogenous peptides released in response to noxious stimuli. These receptors can be broadly classified into mu, kappa, and delta. Fentanyl exerts its pharmacological actions by acting on the MOR (mu-opioid receptor) with less affinity towards DOR(delta opioid receptor) and KOR (kappa opioid receptors). Mu receptors can be again divided into mu1 and mu2 receptors. The mu1 receptor is responsible for analgesia. Bradycardia, respiratory depression, and physical dependence are mediated

by mu2 receptors.[15]

Opioid action is mediated through G protein-coupled receptors. Once Opioid agonists activate this receptor, Voltage-dependent calcium channels are inhibited, thereby decreasing cAMP levels. This blocks the discharge of neurotransmitters from the nociceptive fibers leading to analgesia.

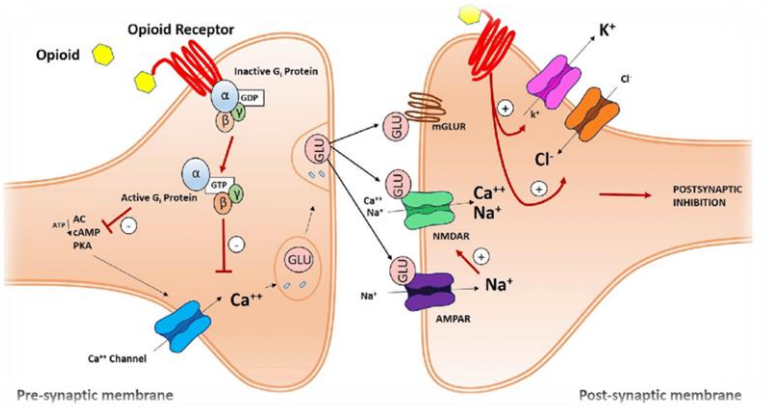


FIGURE 3: MOA OF OPIOID AGONISTS [15]

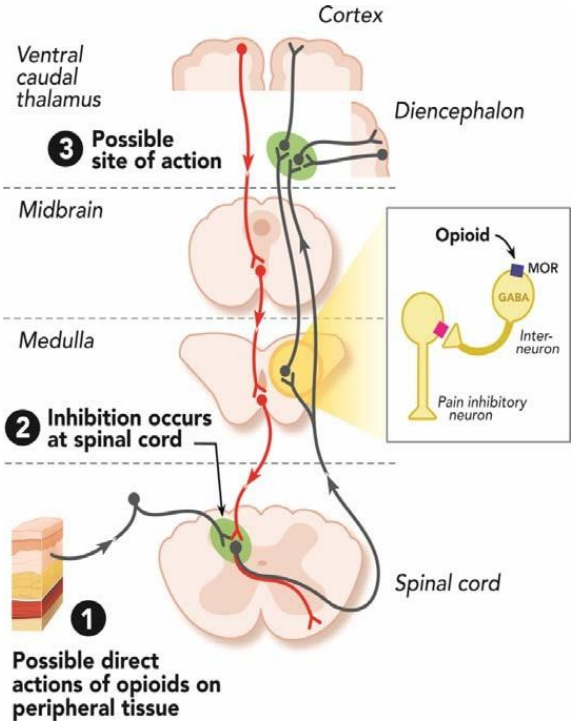


FIGURE 4: GREY PATHWAY SHOWS PAIN CONDUCTANCE FROM PERIPHERY TO CNS. THE RED PATHWAY SHOWS PAIN-MODULATING ZONES IN THE MID-BRAIN AND MEDULLA.[22]

PHARMACOKINETICS OF FENTANYL

The onset of fentanyl is quick, nonetheless, there is a definite delay between its highest plasma concentration and its peak slowing on the EEG. This lag is due to fentanyl's 6.4-minute effect-site equilibration period between the blood and the brain. Fentanyl's quick redistribution to inactive tissue locations, like fat and skeletal muscles, and the resulting drop in the drug's plasma concentration account for the brief duration of action of a single dose.[16]

Progressive saturation of these dormant tissue sites happens when the medication is continuously infused into the patient. the duration of analgesia and depression of breathing may be prolonged as a result, and the plasma concentration of Fentanyl may not fall quickly. [16,23]

ELIMINATION HALF-TIME

Fentanyl quickly spreads from plasma to high vascular tissues following an IV bolus (brain, lungs, heart). In less than 5 minutes, additional than 80% of the injected dose departs the plasma. From the systemic circulation, it gets redistributed into muscle and fat tissues. Elimination half-life varies from 219mins-853mins. Its volume of distribution is 3.5-8l/kg. Its clearance is relatively high (30-72L/hr).[17]

DISTRIBUTION

Plasma proteins are very lipophilic and bind to fentanyl. Patients' dose-adjusted serum fentanyl concentrations were considerably lower in those with less than 3.5g/dl serum albumin. The unionized fraction of the drug is 8.5% at a pH of 7.4.[23]

METABOLISM

In-depth N-demethylation of fentanyl results in the production of norfentanyl, hydroxyproprionyl-fentanyl, and hydroxyproprionyl-norfentanyl. Following a single IV injection of fentanyl, it is eliminated via the kidneys and is detectable in the urine for 72 hours. Fentanyl is eliminated unaltered in urine in less than 10% of cases. It acts as a substrate for the hepatic P450 enzymes (CYP3A), hence it can interact with medications in ways that suggest decreased enzyme function.[16]

PHARMACODYNAMICS OF FENTANYL ANALGESIA

Compared to morphine, it is 75-100 times more potent. Fentanyl mainly exerts its effects on mu1 receptors, primarily responsible for analgesia. A reduction in pain by 50% is seen with a plasma concentration of 1.3 ng per ml.[24]

CARDIOVASCULAR SYSTEM

Myocardial oxygen demand will be reduced due to peripheral vasodilatation, causing preload and afterload drop. Cardiac output entails a small drop in heart rate and arterial pressure. Change in hemodynamics is minimal.[25]

RESPIRATORY SYSTEM

Upper airway reflexes are abolished in a dose-dependent manner. Only with subsequent doses do laryngospasm and apnoea occur.[26,27]

Fentanyl gives rise to respiratory depression. It is shown by elevated $ETCO_2$ levels dose-response curve for carbon dioxide will be declined. Once the end-tidal carbon dioxide reaches 50 mmHg, minute ventilation will increase. When other sedatives like Midazolam accompany Fentanyl, respiratory depression will be enhanced.

Therefore, such patients are monitored and also supplemented with oxygen.[27]

ENDOCRINE SYSTEM

When Fentanyl is administered at a dose of 10mcg/kg, there will be a fall in plasma levels of Epinephrine, Growth hormone, Cortisol, Glucose, and Free fatty acids. On the contrary, when it was given in a dose of less than five mcg/kg, there was no effect on hormones.[28]

FENTANYL-INDUCED COUGH (F.I.C.)

Fentanyl-induced cough can occur somewhere between 18 and 65% of the time48. Numerous theories support F.I.C. The stimulation of vagal C type of fibers in the airway, the disruption of irritant receptors in the tracheobronchial tree, the discharge of histamine from mast cells in the lung, the abrupt adduction of the vocal cords, and the discharge of neuropeptides from prejunctional opioid receptors are a few of these hypotheses.[29,30]

INDICATIONS FOR FENTANYL

1. Analgesic: dose- 1-2 mcg/kg IV.
2. Adjuvant to GA: dose-2-10 mcg/kg [It blunts hemodynamic responses.]
3. Individual anesthetic agent: at 50-150 mcg/kg.
4. As an adjuvant in spinal anesthesia, a dose of 25 mcg of Fentanyl is added to bupivacaine.
5. As an adjuvant in labour analgesia in epidural anesthesia in a dose of 2 mcg/ml.

SIDE EFFECTS

TABLE 2: SIDEEFFECTS OF FENTANYL

SL.NO	SIDE EFFECTS
1	Respiratory depression
2	Cardiovascular effects - hypotension, bradycardia, decrease in cardiac output
3	Seizure activity - seizures, muscle rigidity, myoclonus
4	Increase in Intracranial pressure - head injury patients
5	Nausea and vomiting

CONTRAINDICATIONS FOR FENTANYL

1. Allergic to opioids
2. A patient with a history of COPD and bronchial asthma
3. Patients suffering from head injury and increased intracranial pressure
4. Patients on M.A.O. inhibitors.[31]

HYPOTENSIVE ANESTHESIA

Utilized intraoperatively, hypotensive anaesthesia helps to lessen surgical bleeding and therefore lowers the requirement for blood transfusions. They also shorten the length of the procedure by offering a clear surgical field. Clear vision is the most important requirement in microscopic procedures..[32,33]

DEFINITION:

Either of the following definitions[34]

- SBP (Systolic blood pressure) should be decreased to 80-90 mmHg.
- Mean arterial pressure (MAP) should be decreased to 50-65 mmHg.
- Baseline MAP should be reduced by 30%.

INDICATIONS:

TABLE 3: INDICATIONS FOR HYPOTENSIVE ANESHTHESIA

1.endoscopic sinus surgery	5.middle ear microsurgery
2.oromaxillofacial surgery	6.major orthopaedic surgery
3.spinal surgery	7.prostatectomy
4.neurosurgery	8.liver transplant surgery

CONTRAINDICATIONS:

i. Congenital artery disease
ii. Coronary heart disease
iii. Increased intracranial pressure
iv. Significant cerebrovascular disease
v. Extremes of Age
vi. Hypovolemia
vii. Severe anemia
viii. poorly controlled hypertension
ix. congestive heart failure

TECHNIQUES USED TO CAUSE HYPOTENSION

1. Physiological method

2. Pharmacological method

PHYSIOLOGIC TECHNIQUES

- Body positioning
- Hemodynamic effects of mechanical ventilation
- Changes in heart rate & circulatory volume

PHARMACOLOGIC TECNIQUES:[35,36,37]

Pharmacological agents can generally be divided into two.

1. Inhalational agents

Isoflurane and halothane are two commonly used inhalation agents. A volatile anaesthetic agent concentration results in a dose-dependent reduction in MAP. They also have negative vasodilatory and inotropic property.

2. Peripheral vasodilators

The most often used vasodilators are trimethaphan, nitroglycerin, and SNP.

SNP has a quick onset but a short-lived impact and relaxes vascular smooth muscle. Although it has minimal cardiac effects, it mostly affects venous and arteriolar arteries.

In a manner similar to SNP, NTG lowers blood pressure by relaxing the venous smooth muscle. It also acts quickly but only temporarily. NTG is less harmful than SNP but less effective at lowering blood pressure than SNP.

Through ganglionic blockage and direct vasodilator characteristics, trimethaphan causes hypotension. Additionally, it has a short half-life and offers precise blood pressure management.

Beta-blockers, Hypotension is accomplished by beta-blockers by reducing myocardial contractility. Bronchospasm is the biggest drawback.

Alpha2 agonists (clonidine and dexmedetomidine) are also used for this purpose.

The remifentanil (opioid receptor agonist) is also used to treat controlled hypotension. There is no need for additional hypotensive drugs because of their quick onset and offset.

Controlled hypotension can also be created via spinal and epidural anaesthetic.

REVIEW OF LITERATURE

Jacobi K and Rickauer A J in 1999, 62 patients participated in a trial on preoperative Flupirtine during ambulatory FESS. They were randomised into two groups at random; Group F received preoperative F Flupirtine (100 mg), while Group C received a placebo capsule administered orally 60 minutes before to the start of anaesthesia. They discovered that using flupirtine as a premedication improved the analgesia and hemodynamics of the perioperative period, resulting in reduced nasal bleeding and higher surgeon satisfaction ratings.[40]

Elsharnouby N M et al. 2006;conducted research on the use of $MgSO_4$ as a hypotensive anesthetic method in FESS. The trial involved 60 patients who received magnesium sulphate at doses of 40 mg per kg as a bolus before anesthesia induction and 15 mg per kg per hr as a continuous IV infusion during the procedure. The surgical time was shorter, but the anesthetic period was 10 minutes longer, delaying the anesthetic emergence, according to the results. The amount of blood lost, the amount of anesthesia needed, the MAP and the HR were all dramatically lowered.[41]

Richa F et al., in 2008, compared Dexmedetomidine and Remifentanil in a trial to reduce hypotension during tympanoplasty. Even they came to the conclusion that when compared to the Dexmedetomidine group, the Remifentanil group's MAP and HR were significantly lower. When compared to Dexmedetomidine, the condition of the SFE and the SSS were much higher following Remifentanil.[42]

Dutta A, Choudhary P, et al. from Sir Ganga Ram Hospital, New Delhi, India, conducted a 24-month trial from September 2, 2010, to August 30, 2012, with 120 individuals in a single-center, prospective, randomized-controlled, double-blind, three-

arm dose-finding study. Patients were randomised into one of three groups and received various dosages of fentanyl (2mcg/kg, 3mcg/kg, and 4mcg/kg) before anaesthesia was induced.[1]

The pre-induction results with regard to hemodynamic endpoints, acceptable operating conditions, surgeon satisfaction score, and hypotensive agent sparing, fentanyl appears superior in facilitating regulated hypotension during FESS.[1]

Abdullah A O, Yaman O, Ayten S, et al., 2012, a 50 patient investigation was conducted. Remifentanil was infused into Group R patients at a rate of 0.25 mcg/kg/hr, while dexmedetomidine was infused into Group D patients at a rate of 0.2–0.7 mcg/kg/min. Based on side effect scores, visualisation outcomes of the surgical area, dexmedetomidine and remifentanil provided, safe, regulated hypotensive anaesthesia. [43]

Lee J et al., in 2013, Dexmedetomidine and Remifentanil Hydrochloride's effectiveness was contrasted in intraoperative field conditions and recovery during FESS. Randomly, two patient groups were divided.

According to their findings, there was no discernible difference between the two groups in terms of the surgical field, blood loss, or extubation time. Recuperation was quicker with Remifentanil than with Dexmedetomidine despite the fact that both drugs allowed for hypotensive anaesthesia and acceptable intraoperative fields for endoscopic sinus surgery.[44]

Milonski J, Zielinska H, et al., 2013 studied the impact of functional endoscopic sinus surgery under 3 different forms of anaesthesia on perioperative bleeding control. According to the kind of general anaesthesia that will be used, the three groups of patients were randomly chosen., each with thirty patients. Sevoflurane was used and intravenous

anaesthesia were administered to Groups 1 and 2 respectively (Fentanyl in group 1, Remifentanil in group 2). In group 3, all anaesthesia was administered intravenously, with propofol being used for sedation and remifentanil for analgesia. They came to the conclusion that group 3's use of technologically advanced dosing techniques (T.C.I.) while under fully intravenous general anaesthesia resulted in better control of hypotension, which reduced bleeding in the operating field and cut down on operating time.[46]

Khalifa O S, and Awad O G, compared the efficacy of Dexmedetomidine, $MgSO_4$ or GTN in deliberate hypotension during FESS (functional endoscopic sinus surgery) in 2015. Three groups of 60 patients from ASA 1/2 were assigned at random. The Glyceryl Trinitrate group received an infusion of Glyceryl Trinitrate ranging from 2 to 10 mcg/kg/min (Group G). The dexmedetomidine group (Group DEX) received a bolus of 1 mcg/kg of dexmedetomidine, followed by 0.2-0.7 mcg/kg/hr for maintenance. The magnesium sulphate group (M Group) received a bolus of 50 mg/kg, followed by an infusion of 15 mg per kg per hr for maintenance. According to the findings, Dexmedetomidine caused purposeful hypotension more effectively than Magnesium Sulfate or Glyceryl Trinitrate did.[47]

Nowak S et al., conducted the study on 47 patients who had good preoperative cognitive function scores on the Mini-Mental State Examination. The patients were separated into 3 groups based on the degree of mean intraoperative arterial pressure compared to preoperative blood pressure: mild hypotension, intermediate hypotension, and severe hypotension. Standardized measures such as the Trail Making Test (TMT), the Stroop test and Verbal Fluency Test were used to assess cognitive skills prior to surgery, six hours after surgery, and thirty hours after surgery (V.F.T.).[48]

Results revealed a significant drop in all three groups following Stroop. A test was performed 6 hours after surgery, however it improved 30 hours later with no differences between the groups.[48]

Bharathwaj D K et al., studied the effectiveness of Dexmedetomidine and Propofol infusions when used for Controlled Hypotension during FESS in a research in 2018. HR, MAP, and TBL were statistically significant between Group A and Group B. But Group A being successfully controlled on all 3 parameter throughout FESS. Group B received a continuous infusion of propofol.[49]

Chhabra A et al., 68 patients undergoing endoscopic surgery were the subject of a study in 2020. The patients were randomly assigned to 2 groups, Group D receiving Dexmedetomidine 1 mcg/kg over 10 min followed by an infusion at 0.2 to 0.7 mcg per kg per hr, and Group M receiving $MgS0_4$ (magnesium suplhate) 40 mg per kg over 10 min followed by an infusion at 10 to 15 mg per kg per hr. They came to the conclusion that Dexmedetomidine outperformed MgSO4 in terms of obtaining the target map more quickly and with a lower infusion dose.[50]

Shaheen M D, Chowdhury A K, Sardar K et al. conducted a study in 2020 to compare Dexmedetomidine's effectiveness as a hypotensive drug to Esmolol in FESS. 60 patients were involved; Group D received Dexmedetomidine 1 mcg per kg over 10 min prior to induction of anesthesia and then received 0.4 to 0.8 mcg per kg per hr for maintenance, while Group E received Esmolol loading dosage 1 mcg per kg was infused over 1 min prior to receiving 0.4 to 0.8 mg/kg/hr for maintenance. Results indicated that both medications may be utilised for controlled hypotension and that they had a significant impact on creating the appropriate surgical environment during FESS.[51]

Sahu B P, Nayak I K, et al. A study comparing the effectiveness of two drugs, namely Dexmedetomidine (Group DEX) and Esmolol (Group E), for inducing purposeful hypotension was conducted in May 2021. Each group had thirty people in it. Dexmedetomidine was discovered to be more effective than Esmolol at regulating intraoperative blood pressure while also having favourable effects on anaesthesia and analgesia withdrawal.[52]

MATERIALS AND METHODS

Source of data:

The Study involved 68 patients who were admitted for FESS under GA (general anesthesia) at R L Jalappa Hospital, Anaesthesiology Department, Sri Devaraj Urs Medical College, A Constituent unit of SDUAHER, Tamaka, Kolar, during the Academic year from January 2021-June 2022.

Method of collection of data:

Inclusion criteria:

- Age group between 20 – 60 years
- Either male or female
- A.S.A. status I and II.
- Patients undergoing FESS for sinusitis of nonfungal origin under GA.

Exclusion criteria:

- Patients with uncontrolled hypertension, hyper responsive airway disease from a previous illness, and known opioid hypersensitivity and allergy.
- Patients with hepatorenal dysfunction, cardio-vascular illness, respiratory and endocrine illness.
- Patients with smokers, alcohol abuse, substance abuse, psychiatric disorders.

SAMPLING PROCEDURE:

Ethical clearance was obtained before starting the study.

A thorough pre-anesthetic check-up was carried out, a history was taken, and a systemic examination was done. Vitals were noted, including the weight of the patient.

Investigations asked prior to surgery include.

- ✓ Complete haemogram
- ✓ Serum electrolytes
- ✓ Renal function test
- ✓ Bleeding time (BT) and clotting time (CT)
- ✓ E.C.G.
- ✓ Chest x-ray
- ✓ No other specific investigations were asked.

All patients were examined 1 day before the surgery, investigation reports were checked, the anesthetic procedure was explained, and informed consent was taken.
Fasting was ensured for 8 hours, and Pre-medication for patients included tablets of 0.5 mg alprazolam and 150 mg rantac, which was repeated the morning of surgery. Patients will be divided into two groups randomly.
Group A: Patient belonging to the fentanyl 2mcg/kg bolus 30 min before induction followed by 2mcg/kg/hr infusion for 90 min of surgery.
Group B: Patient belonging to the fentanyl 1mg/kg bolus 30 min before induction followed by 1mcg/kg/hr infusion for 90 min of surgery.

Preparation of drug for infusion:

Fentanyl 2ml containing 100µg was diluted with normal saline till 20cc so that the solution contained 5µg per ml.

The drugs were administered using a syringe pump.

Patients were randomly divided into two groups -

Group A: Patient belonging to the fentanyl 2mcg/kg bolus 30 minutes before induction followed by 2mcg/kg/hr infusion for 90 minutes of surgery.

Group B: Patient belonging to the fentanyl 1mg/kg bolus 30 minutes before induction followed by 1mcg/kg/hr infusion for 90 minutes of surgery.

parameters observed

A)Surgical field condition (S.F.C.)

GRADE	ASSESSMENT
0	No bleeding
1	Slight bleeding -no suctioning required
2	Slight bleeding- occasional suctioning required
3	Slight bleeding-frequent suctioning is required; bleeding threatens the surgical field a few seconds after suction is removed
4	Moderate bleeding -frequent suctioning is required, and bleeding threatens the surgical field directly after suction is removed
5	Severe bleeding -constant suctioning required; bleeding appears faster than can be removed by suction, severely threatening the surgical field.

B)Surgeon satisfaction profile (S.S.P.)

1- Completey satisfied

2-Satisfied

3-Just content

4-Not content

C)Aono's scale (post-operative emergence agitation)

1- Calm

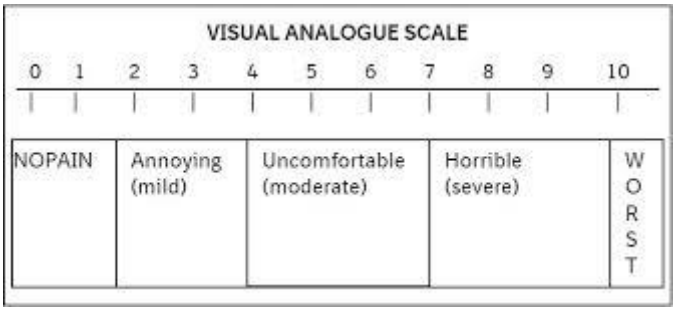
2- Easily consoled

3- Moderate agitation

4- Severe agitation

D) VAS Score

10cm VAS



E) Post-operative nausea and vomiting scoring system

0-No emetic symptoms

1-Nausea

2-Vomiting

F)Ramsay sedation scale

1-Anxious and agitated or restless or both

2-Cooperative, oriented and tranquil

3-Responds to commands only

4-Brisk response to a light glabellar tap or loud auditory stimulus

5-Sluggish response to a light glabellar tap or loud auditory stimulus

6-No response to a light glabellar tap or loud auditory stimulus

Venous access was secured with 18G IVC and fluids were initiated.

After the patient was moved to OT, monitoring of their basal HR, NIBP, and SPO2 began.

Patients were premedicated with Inj. Glycopyrrolate 0.005mg/kg prior to the induction of anaesthesia.

The study drug's loading dose was administered during a 30-minute period at a rate of 1 mcg/kg and 2 mcg/kg according to the group allocation. Prior to the initiation of the infusion, H.R., S.B.P., DBP, M.A.P., R.R., and SPO2 were observed. Preoxygenation was carried out with 100% oxygen for three minutes, then propofol injection at 2 mg/kg was used to produce unconsciousness until verbal commands were lost.

After the loading dose was given, the required monitoring parameters were again recorded.

Tracheal intubation with an appropriate-sized oral endotracheal tube after giving Succinylcholine 2mg/kg muscle relaxant . 60% N_2O in oxygen, isoflurane, and

injectable vecuronium (0.1 mg per kg) are used to maintain anaesthesia. The isoflurane cncentration was adjusted to keep the hemodynamics stable.

The patient was mechanically ventilated to maintain $ETCO_2$ between 30-35mm Hg. H.R., S.B.P., DBP, M.A.P., R.R., and SPO_2 were recorded 1min after intubation, and then at 3min, 5min followed by at every 15 min intervals till extubation.

Bradycardia was treated by IV Atropine at 0.02mg/kg, and hypotension was treated by titrating isoflurane concentration or by the infusion rate of intravenous fluids.

The study drug's infusion was interrupted, and isoflurane was terminated 10 minutes before the reversal.

With injections of 0.05 mg per kg of neostigmine and 0.01 mg per kg of glycopyrrolate, the remaining neuromuscular blockade was reversed.

After careful oral suctioning and observation of the patient's motor recovery and spontaneous breathing efforts, the patient was extubated. Vitals were noted 1, 3,5, and 15min after extubation to check for extubation response.

The surgeon used a preset category scale adapted from the Fromme-Boezzart scale to measure the quality of the surgical field.

The patient was shifted to post op care unit for observation of any nausea or drug-induced side effects.

For the first 24 hrs, the patient was monitored for pain using the VAS score, and the number of analgesics used was noted.

STATISTICAL ANALYSIS

Study design: Randomized Control Study

Statistical analysis:

Data were gathered, coded, and entered into an Excel spreadsheet. All the quantitative measures like H.R., S.B.P., and DBP were presented by mean confidence intervals, qualitative measures like Gender, A.S.A. physical status, Etc, by proportions and confidence interval. The student-t test was used to decide the impact of the difference in the quantitative measurements. The proportional difference was compared using the Chi-square test. Statistics were considered significant if $P < 0.05$.

Sample size:

Based on Prabhat et al., study, the sample size was determined.[1] Mean heart rate at 5min post-intubation was used as prevalence. Group A=85.72±15.28, Group B=77.45±14.30 was taken into consideration.Z_{α}=1.96 at 95% CI, $Z_{1-\beta}$=0.84 for 80% power of the study, assuming 10% of obsolete precision value. Total sample size = 68 out of that 34 in each group will be taken.

FORMULA:

$$n = \frac{2[z_{\dot{\alpha}}+z_{1-ß}]^2\ \sigma^2}{d^2}$$

Where , σ= standard deviation

d=precision

$\dot{\alpha}$ = Significance level

1-ß = Power

RESULTS

Table 4: Distribution of Study participants according to Age and Gender

S.no	Variables	Categories	Group 1 n (%)	Group 2 n (%)
1.	Age	18-24	11 (31.4)	6 (19.4)
		25-34	5 (14.3)	13 (41.9)
		35-44	17 (48.6)	9 (29)
		45-54	2 (5.7)	3 (9.7)
2.	Gender	Male	17 (48.6)	18 (58.1)
		Female	18 (51.4)	13 (41.9)

Table 4 & Figure 5 shows the age distribution of the patients in both groups. It was observed that 48.6% of the patients belonged to35-44 the year's age group, follow by 31.4% in the 18-24 years age group among the group 1 member, and 41.9% of the patients belonged to the 25 to 34 years of age group and 29% in the 35 to 44 years of age group among group 2 members.

Figure 5: Distribution of Study participants according to Age

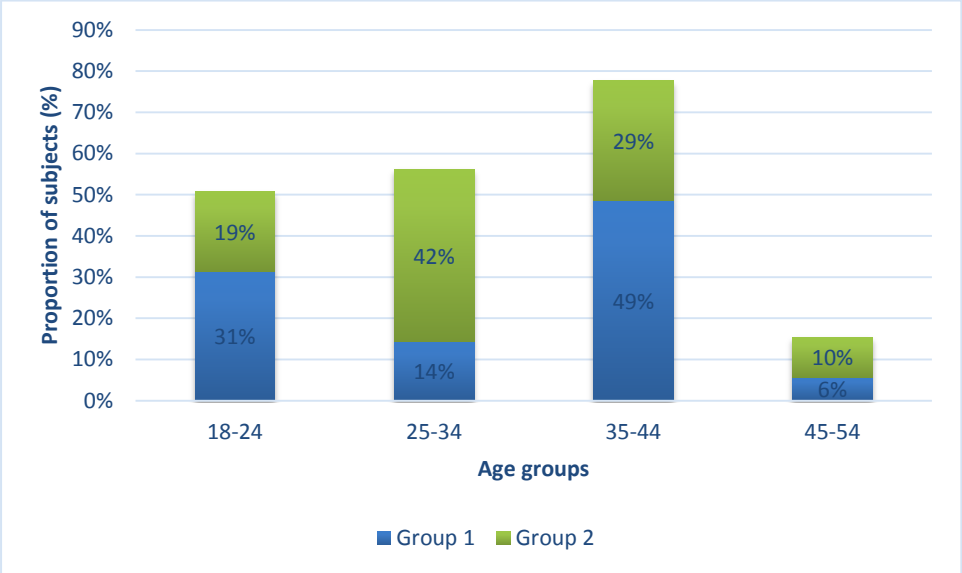


Table 4 & Figure 6 show the gender distribution of the patients in 2 groups. Most patients were females (51.4%) in group 1 and males(58.1%) in group 2.

Figure 6: Distribution of Study participants according to Gender

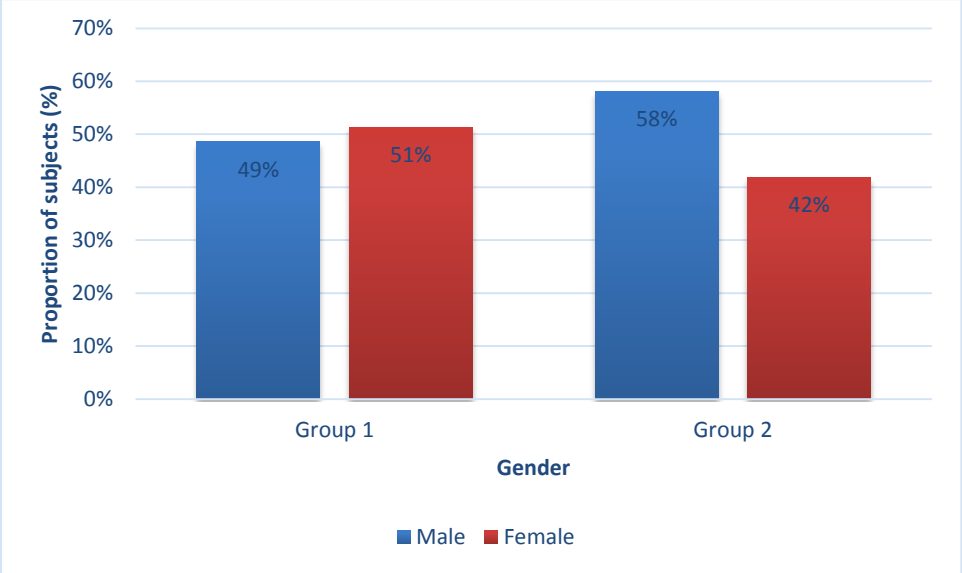


Table 5: Distribution of Study participants according to surgery done for the patients

S.no	Variables	Categories	Group 1 n (%)	Group 2 n (%)
1.	Surgery	FESS	29 (82.8)	24 (77.4)
		FESS & B/L Planectomy	0 (0)	1(3.2)
		FESS & Septoplasty	6 (17.2)	6 (19.4)

Table 5 and Figure 7 show the distribution of the surgery done for the patients. In group 1, 82.8% of the patients underwent FESS, and 17.2% had undergone both FESS and septoplasty. In group 2, 77.4% underwent FESS.

Figure7: Distribution of Study participants according to surgery

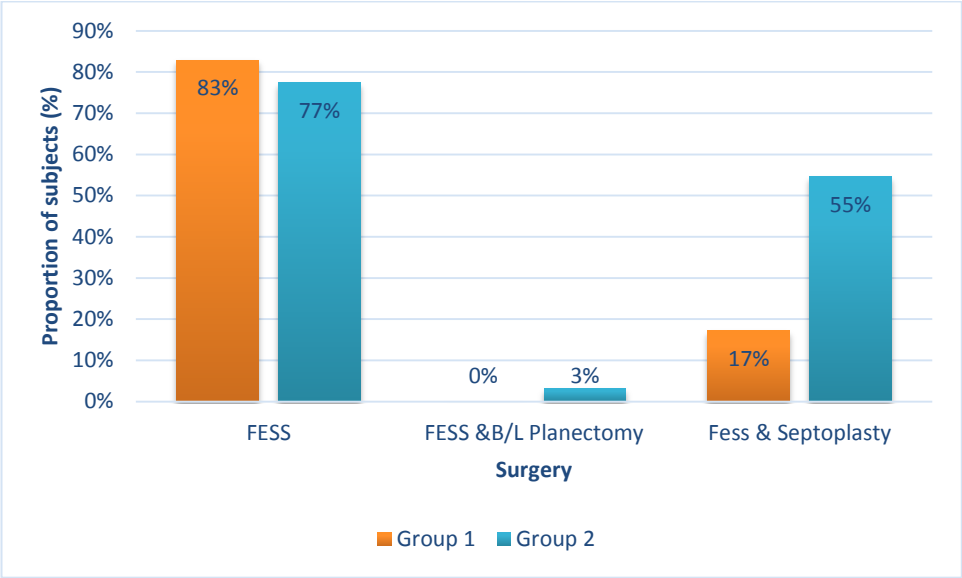


Table 6: Comparison of HR among the patients during the treatment

Heart Rate	Group 1	Group 2	P value
	Mean, SD	Mean, SD	
Baseline	82.6,9.39	82.54, 10.6	0.656
After Infusion	77.88, 9.66	82.03, 7.73	0.078
1 minute after intubation	81.82, 10.93	94.12, 6.92	<0.36
3 minutes after intubation	78.25, 10.13	93.06, 8.71	0.225
5 minutes after intubation	75.25, 9.48	88.48, 9.12	0.976
10 minutes after intubation	73.05, 8.78	86.09, 9.12	<0.896
15 minutes after intubation	70.97, 8.14	82.93, 10.02	0.196
30 minutes after intubation	68.94, 8.11	80.71, 10.99	**0.012**
45 minutes after intubation	66.82, 7.89	76.93, 11.5	**0.002**
60 minutes after intubation	66.14, 7.83	74.87, 11.56	**0.005**
75 minutes after intubation	64.6, 7.73	74.16, 12.75	**<0.001**
90 minutes after intubation	64.8, 7.88	75.16, 12.4	**0.001**
1 minute after extubation	72.17, 8.88	88.77, 8.98	0.294
3 minutes after extubation	69.54, 8.58	85.8, 10.2	0.068
5 minutes after extubation	66.85, 8.65	81.23, 13.15	**0.003**
15 minutes after extubation	65.54, 8.01	79.22, 12.56	**0.001**
30 minutes after extubation	64.34, 7.87	78.8, 12.12	**0.001**

Table 6 compares heart rates among the two groups of patients. The mean heart rate is raised [80.71 (10.99)] among group 2 members than the group 1 member [68.94 (8.11)] after 30 minutes of intubation per minute. The statistical significance of this difference was high (p-value <0.001). likewise, the two groups had significant associations after 45 minutes, 60 minutes, 75, and 90 minutes of intubation ($p < 0.05$). The mean heart rate is raised [81.23 (13.15)] among group 2 members than the group 1 member [66.85 (8.65)] after 5 minutes of extubation per minute. There was a statistical significance between 2 groups (p-value < 0.003). likewise, the two groups had a significant association after 15 minutes and 30 minutes of extubation ($p < 0.001$).

Table 7: Comparison of Systolic Blood Pressure among the patients during the treatment

Systolic Blood Pressure	Group 1	Group 2	P value
	Mean, SD	Mean, SD	
Baseline	129.4, 12.17	128.5, 12.98	0.459
After Infusion	125.4, 12.55	127, 13.5	0.399
1 minute after intubation	124.3, 15.88	138.1, 10.59	**0.042**
3 minutes after intubation	120.1, 15.92	136, 14.01	0.3
5 minutes after intubation	115.1, 16.01	132.4, 15	0.249
10 minutes after intubation	111.7, 14.95	131.7, 10.1	**0.004**
15 minutes after intubation	109.5, 14.6	130.8, 10.53	**0.004**
30 minutes after intubation	108, 14.11	129.3, 10.74	**0.027**
45 minutes after intubation	108.4, 13.17	126.1, 12.55	0.425
60 minutes after intubation	107.2, 12.25	125.9, 11.33	0.726
75 minutes after intubation	106.2, 11.72	125.5, 11.09	0.821
90 minutes after intubation	107, 11.83	128.5, 12.61	0.965
1 minute after extubation	112.1, 14.62	138.2, 10.61	0.087
3 minutes after extubation	110.5, 14.04	137.3, 8.52	**0.009**
5 minutes after extubation	107.6, 13.62	134.1, 8.86	**0.036**
15 minutes after extubation	106.4, 11.64	129.9, 8.02	0.073
30 minutes after extubation	106.4,11.64	129.9, 8.02	0.084

Table 7 compares SBP (systolic blood pressure) among the 2 groups of patients. The mean S.B.P. is raised [138.1 (10.59)] among group 2 members than the group 1 member [124.3 (15.88)] after 1 minute of intubation. There was statistical significance (p-value < 0.05). Similarly, the 2 groups had significant associations after 10 minutes, 15 minutes, and 30 minutes of intubation ($p < 0.05$). The mean S.B.P. is raised [137.3 (8.52)] among group 2 members than the group 1 member [110.5 (14.04)] after 3 minutes of extubation. There was a statistical significance here (p-value < 0.003). Similarly, the two groups had a significant association after 5 minutes of extubation ($p < 0.001$).

Table 8: Comparison of Diastolic Blood Pressure among the patients during the treatment

Diastolic Blood Pressure	Group 1	Group 2	P value
	Mean, SD	Mean, SD	
Baseline	83.2, 6.87	82.41, 8.71	**0.04**
After Infusion	79.25, 7.32	80.74, 8.97	0.06
1 minute after intubation	79.17, 11.43	90.71, 9.46	0.408
3 minutes after intubation	75.22, 12.06	88.64, 10.25	0.369
5 minutes after intubation	70.8, 11.72	85.16, 10.77	0.347
10 minutes after intubation	68.45, 10.9	84.09, 7.36	**0.029**
15 minutes after intubation	66.02, 10.64	81, 8.02	0.110
30 minutes after intubation	64.34, 10.19	79.51, 9.01	0.704
45 minutes after intubation	64.37, 9.86	77.06, 8.4	0.331
60 minutes after intubation	63.82, 9.01	77.45, 8.91	0.705
75 minutes after intubation	62.85, 9.16	76.16, 9.35	0.825
90 minutes after intubation	63.37, 9.39	78.22, 10.49	0.76
1 minute after extubation	68.77, 13.29	86.41, 8.26	**0.002**
3 minutes after extubation	66.71, 12.18	85.25, 9.09	**0.037**
5 minutes after extubation	65.65, 11.26	83.06, 9.13	0.087
15 minutes after extubation	64.25, 9.61	79.35, 7.64	0.075
30 minutes after extubation	65.11, 9.05	76.54, 8.08	0.282

Table 8 compares diastolic BP among the 2 groups of patients. The mean DBP is raised [84.09 (7.36)] among group 2 members than the group 1 member [68.4 (10.9)] after 10 minutes of intubation. Showed statistical significance here (p-value < 0.05). The mean DBP is raised [86.41 (8.26)] among group 2 members than the group 1 member [68.77 (13.29)] after 1 minute of extubation. There was a statistical significance here (p-value <

0.002). Similarly, the two groups had a significant association after 3 minutes of extubation ($p < 0.05$).

Table 9: Comparison of Mean Arterial Blood Pressure among the patients during the treatment

Mean Arterial Blood Pressure	Group 1	Group 2	P value
	Mean, SD	Mean, SD	
Baseline	98.62, 8.13	97.78, 9.36	0.09
After Infusion	94.65, 8.44	96.19, 9.7	0.06
1 minute after intubation	94.23, 12.23	106.5, 9.31	0.247
3 minutes after intubation	90.2, 12.84	104.4, 11.2	0.31
5 minutes after intubation	85.59, 12.72	100.9, 11.89	0.26
10 minutes after intubation	82.87, 11.85	99.98, 7.56	**0.003**
15 minutes after intubation	80.52, 11.44	97.62, 8.02	**0.026**
30 minutes after intubation	78.92, 10.92	96.13, 8.52	0.15
45 minutes after intubation	79.05, 10.11	93.43, 9.04	0.601
60 minutes after intubation	78.3, 9.2	93.62, 9.04	0.798
75 minutes after intubation	77.32, 8.86	92.63, 9.31	0.864
90 minutes after intubation	77.92, 9.13	94.98, 10.61	0.583
1 minute after extubation	83.23, 12.66	103.7, 8.56	**0.01**
3 minutes after extubation	81.32, 11.82	102.6, 8.18	**0.029**
5 minutes after extubation	79.66, 10.93	100, 8.37	0.074
15 minutes after extubation	78.33, 9.46	96.82, 7.23	0.063
30 minutes after extubation	78.9, 8.81	94.34, 7.57	0.356

Table 9 compares MAP among the 2 groups of patients. The MAP is raised [99.98 (7.56)] among group 2 members than the group 1 member [82.87 (11.85)] after 10 minutes of intubation. Showed statistical significance (p-value < 0.05). likewise, the two groups had a significant association after 15 minutes of intubation ($p < 0.05$). The MAP is raised [103.7 (8.56)] among group 2 members than the group 1 member [83.23 (12.66)] after 1

minute of extubation. Statistically significant was this difference (p-value < 0.01). Similarly, the two groups had a significant association after 3 minutes of extubation (p < 0.005).

Table 10: Comparison of Respiratory Rate among the patients during the treatment

Respiratory Rate	Group 1	Group 2	P value
	Mean, SD	Mean, SD	
Baseline	17.02, 2.93	17.09, 2.99	0.742
After Infusion	16.31, 2.44	16.54, 2.91	0.751
1 minute after extubation	18.02, 2.29	17.83, 2.03	0.704
3 minutes after extubation	17.94, 2.15	17.45, 2.85	**0.05**
5 minutes after extubation	18.28, 2.2	17.64, 2.7	0.104
10 minutes after extubation	17.37, 2.87	17.35, 3.3	0.331
15 minutes after extubation	20.05, 13.79	17.41, 3.58	0.323

Table 10 compares Respiratory rates among the two groups of patients. The mean respiratory rate decreased [17.45 (2.85)] among group 2 members more than the group 1 member [17.94 (2.15)] after 3 minutes of extubation. Showed statistical significance (p-value < 0.05).

Table 11: Comparison of SpO2 among the patients during the treatment

SpO2	Group 1	Group 2	P value
	Mean, SD	Mean, SD	
Baseline	98.62, 1.19	98.61, 1.22	0.607
After Infusion	98.4, 1.09	98.51, 1.17	0.543
1 minute after intubation	98.28, 0.98	98.29, 1.13	0.348
3 minutes after intubation	98.68, 1.05	98.67, 0.87	0.506
5 minutes after intubation	98.71, 0.95	98.58, 1.05	0.521
10 minutes after intubation	98.77, 0.87	98.93, 1.12	0.375
15 minutes after intubation	98.85, 1	98.8, 1.10	0.498
30 minutes after intubation	98.82, 0.92	98.87, 0.99	0.865
45 minutes after intubation	99, 0.87	99.03, 0.83	0.993
60 minutes after intubation	98.97, 0.98	98.61, 0.95	0.553
75 minutes after intubation	98.74, 1.06	98.8, 0.94	0.735
90 minutes after intubation	98.97, 0.85	98.93, 0.92	0.453
1 minute after extubation	98.51, 0.85	98.51, 1.12	0.159
3 minutes after extubation	98.54, 1.03	98.48, 1.28	0.355
5 minutes after extubation	98.28, 1.1	98.48, 0.99	0.357
15 minutes after extubation	98.6, 1.06	98.41, 0.92	0.889
30 minutes after extubation	98.57, 1	98.96, 1.04	0.914

Table 11 shows the comparison of SpO2 among the two groups of patients. It was statistically insignificant between 2 groups.

Table 12: Comparison of VAS Score among the patients during the treatment

VAS Score	Group 1	Group 2	P value
	Mean, SD	Mean, SD	
Baseline	1.57, 0.65	2.61, 0.49	**0.033**
6 hours	3.31, 0.79	4.96, 0.31	**0.001**

Table 12 compares VAS scores among the two groups of patients. The mean VAS score is raised [2.61 (0.49)] among group 2 members than the group 1 member [1.57 (0.65)] at baseline. It showed statistically significant difference here (p-value < 0.05). Similarly, the 2 groups had a significant association after 6 hours of treatment (p < 0.001).

Table 13:Comparison of Surgical field condition among the patients during the treatment

Surgical field condition	Group 1	Group 2
	n (%)	n (%)
No bleeding	0 (0)	0 (0)
Slight bleeding-no suctioning required	0 (0)	3 (9.7)
Slight bleeding-occasional suctioning required	23 (74.2)	11 (31.4)
Slight bleeding-frequent suctioning required	5 (16.1)	20 (57.1)
Moderate bleeding-frequent suctioning required	0 (0)	4 (11.4)
Severe bleeding	0 (0)	0 (0)

P value = 0.041

Table 14:Comparison of Surgeon satisfaction profile among the patients during the treatment

Surgeon satisfaction profile	Group 1	Group 2
	n (%)	n (%)
Fully satisfied	4 (12.9)	0 (0)
Satisfied	22 (71)	10 (28.6)
Just satisfied	5 (16.1)	25 (71.4)
Not satisfied	0 (0)	0 (0)

P value = 0.252

Table 15:Comparison of AONO's Scale among the patients during the treatment

AONO's Scale	Group 1	Group 2
	n (%)	n (%)
Calm	30 (85.7)	31 (100)
Not calm but could be easily calmed	5 (14.3)	0 (0)
Moderately agitated or restless	0 (0)	0 (0)
Combative, excited, disoriented	0 (0)	0 (0)

P value = 0.599

Table 16:Comparison of PONVamong, the patients during the treatment

P.O.V.	Group 1	Group 2
	n (%)	n (%)
No emetic symptoms	33 (94.3)	27 (87.1)
Nausea	2 (5.7)	4 (12.9)
Vomiting	0 (0)	0 (0)

P value = <0.005

DISCUSSION

According to the findings of our investigation, controlled hypotension could be started in all participants and maintained effectively. Patients who took fentanyl 2mcg/kg pre-induction showed improved surgical field conditions (S.F.C.) and surgeon satisfaction scores (S.S.S.). Patients who received a 2mcg/kg fentanyl infusion during FESS had better endoscopic images.

There is a tonne of evidence that employing specific hypotensive medications during FESS can effectively achieve and maintain hypotensive anesthesia. However, there is currently only some limited source on Remifentanil research on the use of opioids during FESS hypotensive anaesthesia.[1] While there is little research on usage of pre-induction Fentanyl and infusion , were fentanyl is frequently used and given soon before the induction of anesthesia.[1] The research has not yet looked into how pre-induction fentanyl administration affects the maintenance and onset of controlled hypotension during FESS.

By lowering systemic vascular resistance (S.V.R.) and cardiac output Controlled hypotension can be induced.[1] Any purposeful hypotension approach used during GA (general anesthesia) aims to reduce MAP (Mean arterial pressure) in healthy individuals to levels in between 50 to 65 millimetres of mercury in regard to considerably lessen blood loss. There are pharmacological therapies for Controlled hypotension which can be used both alone and in concert with other forms of care to minimise dosage requirements and, consequently, SE (side effects).

To help with controlled hypotension Inhalation anesthetics like sevoflurane, isoflurane, vasodilators like sodium nitroprusside and NTG , trimethaphan camsilate, alprostadil (prostaglandin E1), alpha 2 adrenergic agonists such as Dexmedetomidine, clonidine, magnesium sulphate ($MgS0_4$), and short-acting opioids, propofol for total intravenous

anesthesia (TIVA) is growing in acceptance.[2]

For FESS, whole intravenous anaesthesia was contrasted with inhalation anaesthesia. Although majority of the individuals did not undergo an intentional hypotensive method, they included seven investigations and reported less blood loss and higher surgical field quality throughout surgery. According to DeConde et al., the body of research supporting complete intravenous anaesthesia consisted primarily of a small number of inconsistently designed and reported trials.[53]

Our study is being suggested to determine the role of the two different doses (1mcg/kg and 2mcg/kg), which have predominant sympathoadrenal suppression effects that is lowering BP and HR, in facilitating controlled hypotension during FESS (primary objective).

Our study shows that preinduction Fentanyl can aid controlled hypotension by establishing favorable hemodynamic state right after the induction of G.A., allowing for the more effective use of commonly used hypotensive medications without developing acute tolerance and side effects.

Dutta A, Choudhary P, et al. completed a 24-month experiment with 120 people. Before induction of anaesthesia , Patients were randomised at random to one of the three groups and given fentanyl in varying doses (2mcg/kg, 3mcg/kg, and 4mcg/kg). Their outcomes Fentanyl appears to be more effective in promoting regulated hypotension during FESS with regard to quantifiable hemodynamic points, surgeon satisfaction, agreeable Surgical conditions.[1]

With the management of adequate doses of pre-induction fentanyl and infusion of fentanyl , it is possible to substitute the unreasonable practice of controlled hypotension

by deepening of anesthesia depth by increasing either inhalational concentration or intravenous dose, which would delay patients emergence from anaesthesia and recuperation in the post-op care room with packed nostrils , in addition to having adverse cardiovascular effects.

STRENGTHS

Fentanyl gives suitable sedation and analgesia, reducing the use of inhalational agents. The side effects of inhalational agents are reduced with the use of Fentanyl.

LIMITATIONS

The sample size could have been more and further studies with reduced doses of Fentanyl may help attain the same outcomes with reduced side effects.

CONCLUSION

Regarding quantifiable hemodynamic endpoints, favorable operating conditions, surgeon satisfaction, and hypotensive agents, pre-induction fentanyl 2mcg/kg dosage appears better than 1mcg/kg dosage in permitting regulated hypotension during FESS.

SUMMARY

The 68 patients who got admitted for FESS under general anesthesia at R L Jalappa Hospital participated in a randomized, single-blinded, prospective control trial, Anesthesiology department, Sri Devaraj Urs Medical College, A Constituent unit of SDUAHER, Tamaka, Kolar, during the Academic year from January 2021-June 2022. It included patients aged between 20-60 years, A.S.A. physical status one or two.

There were two groups of patients assigned after informed consent had been taken. Baseline vitals like H.R., S.B.P., DBP, M.A.P., and SPO_2 were noted before and after a pre-induction dose of Fentanyl. The patient was taken to O.T. Preoxygenation was done for 3mins. The patient was then Premedicated with Inj Glycopyrrolate and induced with propofol.

Group A received Fentanyl 2mcg/kg bolus thirty minutes before to induction, follow by 2mcg per kg per hr infusion for 90 minutes of surgery. Group B received Fentanyl 1mg/kg bolus 30 minutes before to induction, follow by 1mcg per kg per hr infusion for 90 minutes of surgery. Vitals were noted starting from intubation till 15 mins Post Extubation. S.F.C., S.S.S., Vas scores, AONO'S scale, and Ramsay sedation scale were assessed.

SBP, DBP, and MAP significantly decreased in group A, which received fentanyl 2mcg/kg pre-induction and infusion dosage. Fentanyl 1mcg/kg group A had better post-operative analgesia than group B. With regard to quantifiable hemodynamic points, good operating circumstances, surgeon satisfaction, and hypotensive drugs, Group A dosage facilitates regulated hypotension during FESS more effectively than Group B dosage.

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ANNEXURE I

PROFORMA

Investigators: Dr. Ravi M / Dr. Pooja Giriyapur

1. Name of the patient: **2. Age/Sex:** **3. I.P. No. :**

4. Ward: **5. A.S.A. grade:**

- **General physical examination:**

Height: Weight: Pulse rate: B.P.:

Pallor/icterus/cyanosis/clubbing/lymphadenopathy/edema

- **Systemic examination:**

R.S. - **CVS -**

C.N.S. - **P/A -**

- **Investigations :**

Blood group: Hb: WBC: Platelets:

R.B.S.: Blood urea: Sr. Creatinine: Sodium: Potassium:

E.C.G.:

- **Diagnosis :** **Surgery:**
- **Surgery duration:** **Infusion duration:**

- **Group A:** Patient belonging to the Fentanyl 1mcg/kg bolus 30 min before induction followed by 1 mcg/kg/hr infusion till 30 min before the end of surgery.

- **Group B**: Patient belonging to the Fentanyl 2 mcg/kg bolus 30 min before induction followed by 2 mcg/kg infusion till 30 min before the end of surgery.

Baseline vitals:

H.R.: B.P.: M.A.P.: SPO2:

MEAN ARTERIAL PRESSURE AND HEART RATE PROFILE

TIME	Group- A, Fentanyl 2mcg/kg bolus 30 min before induction followed by 2 mcg/kg/hr infusion for 90 mins of surgery	Group-B, Fentanyl 1 mcg/kg bolus 30 min before induction followed by 1mcg/kg/hr infusion for 90 mins of surgery	Heart rate	Blood pressure	MAP	SP02
Bolus dose						
Pre-induction						
Infusion dose						
Pre-intubation						
1 min post - intubation						
3 min post-intubation						
5 min post-intubation						
10 min post - intubation						

15 min post-intubation						
30 min post-intubation						
60 min post-intubation						
120 min post-intubation						
1 min post-extubation						
3 min post-extubation						
5 min post-extubation						
15 min post-extubation						
30 min post-extubation						
30 min interval till shifting from recovery room						

Surgical field condition, surgical satisfaction profile, and post-operative morbid variables (emergence agitation, pain, PONV)

	Group- A, Fentanyl 1mcg/kg bolus 30 min before induction followed by 1 mcg/kg/hr infusion till 30 min before the end of surgery	Group-B, Fentanyl 2 mcg/kg bolus 30 min before induction followed by 2mcg/kg/hr infusion till 30 min before the end of surgery
SFC		
SSP		
Aono's Scale		
VAS at 6 h		
P.O.V.		
Post-operative sedation scores at 30 minutes after extubation		

A)Surgical field condition (S.F.C.)

Grade	**Assessment**
0	No bleeding
1	Slight bleeding -no suctioning required
2	Slight bleeding- occasional suctioning required
3	Slight bleeding-frequent suctioning is required; bleeding threatens the surgical field a few seconds after suction is removed
4	Moderate bleeding -frequent suctioning is required, and bleeding threatens the surgical field directly after suction is removed
5	Severe bleeding -constant suctioning required; bleeding appears faster than can be removed by suction, severely threatening the surgical field.

B)Surgeon satisfaction profile (S.S.P.)

1-Fully satisfied

2-Satisfied

3-Just content

4-Not content

C)Aono's scale for post-operative emergence agitation

1- Calm

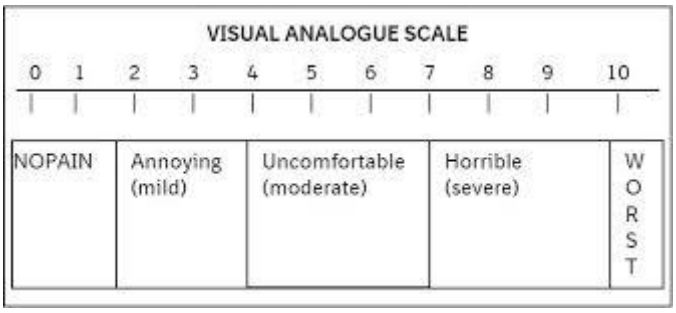
2- Easily consoled

3- Moderate agitation

4- Severe agitation

D) Post-operative pain

10cm visual analogue scale (VAS)



E) Post-operative nausea and vomiting scoring system

0-No emetic symptoms

1-Nausea

2-Vomiting

F)Ramsay sedation scale

1-Anxious and agitated or restless or both

2-Cooperative, oriented and tranquil

3-Responds to commands only

4-Brisk response to a light glabellar tap or loud auditory stimulus

5-Sluggish response to a light glabellar tap or loud auditory stimulus

6-No response to a light glabellar tap or loud auditory stimulus

ANNEXURE II

PATIENT INFORMATION SHEET

TITLE OF THE STUDY: CONTROLLED HYPOTENSION FOR FUNCTIONAL ENDOSCOPIC SINUS SURGERY WITH TWO DIFFERENT DOSES OF FENTANYL- A RANDOMIZED CONTROL STUDY

This study aims to reduce the incidence of intraoperative hypotension in patients undergoing functional endoscopic sinus surgeries under general anesthesia.

Purpose of the research: Fentanyl is used in all patients, but we are using it as an infusion to reduce blood pressure which helps reduce blood loss, produce sedation and give analgesia. Any side effects like hypotension are treated with IV fluid bolus, bradycardia by injection atropine, and sedation is monitored in post-operative with Spo2 and o2 supplements. The patient and the attendees will be wholly explained about the procedure, i.e., the Use of Fentanyl.

Fentanyl will be avoided in patients with uncontrolled hypertension, pre-existing hyper-reactive airway disease, known opioid hypersensitivity /allergy, uncompensated systemic illness(hepatorenal, cardiovascular, respiratory, and endocrine), psychiatric disorders, alcohol/ substance abuse, and smokers.

Procedures and Protocol:

This is a randomized prospective study. 68 patients undergoing elective surgeries under general anesthesia at R L Jalappa Hospital, Tamaka, Kolar, during the Academic year from January 2020-June 2022 will be included in the study.

After obtaining informed consent, 68 patients will randomly be divided into two (2) groups of 34 each. Randomization will be done.

GROUP A: IV FENTANYL 2mcg/kg bolus 30 minutes before induction, followed by 2mcg/kg/hr infusion for 90 minutes of surgery.

GROUP B: IV FENTANYL 1mcg/kg bolus 30 minutes before induction followed by 1mcg/kg/hr infusion for 90 minutes of surgery.

Reimbursements: You will not be given money or gifts to participate in this research. **Confidentiality:** We will not be sharing the identity of the participant. The information we collect from you will be kept confidential, and only researchers involved in this project will have access.

Right to Refuse or Withdraw: You do not have to participate in this research if you do not wish to do so and can refuse to participate.

Whom to Contact: If you have questions, you may ask us now or later. Even after the study has started, you may contact the following person:

For more information:

Dr. Pooja Giriyapur
Post-graduate in Anaesthesiology
Sri Devaraj Urs Medical College, Tamaka, Kolar
Mobile – 9986564916
Email: poojagiriyapur09@gmail.com

Dr. Ravi M
Professor of Anaesthesiology
Sri Devaraj Urs Medical college
Mobile - 9845287591
Email: ravijaggu@gmail.com

ANNEXURE III

INFORMED CONSENT FORM

Name of the institution: Sri Devaraj Urs academy of higher education and research.

TITLE OF THE STUDY

CONTROLLED HYPOTENSION FOR FUNCTIONAL ENDOSCOPIC SINUS SURGERY WITH TWO DIFFERENT DOSES OF FENTANYL- A RANDOMIZED CONTROL STUDY

Name of the principal Investigator: **Dr. POOJA GIRIYAPUR, DR. RAVI MADHUSUDHANA**

I have been explained in a language understandable to me regarding the procedure, i.e., increase in hemodynamic response during intubation and extubation under general anesthesia and the treatment protocol for it.

I have also been explained the need to attenuate hemodynamic responses during intubation and extubation by a combination of drugs like Fentanyl.

The associated side effects of study drugs, such as hypotension and bradycardia, have been enlisted to me as to how they are treated.

Bradycardia: Less than 60 bpm- Inj. Atropine 0.6 mg (I.V.)

and for Hypotension: Less than 30% of baseline systolic blood pressure- Inj.Mephenteramine 6 mg (I.V) will be given.

I have read the information, and I have had the opportunity to ask questions regarding various aspects of the study, and my questions have been answered to my satisfaction. I know I am entitled to refrain/withdraw from the study at any point.

I, the undersigned, agree to participate in this study and authorize collecting and

disclosing my personal information as outlined in this consent form.

Subject's/guardian's name and signature/thumb impression:

Date:

Name and signature of witness:

Date:

Name and signature of principal investigator

Date:

For any clarification, you are free to contact the Investigator:

Principal Investigators

Dr. Pooja Giriyapur (Mobile - 9986564916)

Dr. Ravi Madhusudhana (Mobile - 9845287591)

A copy of this informed consent form has been provided to the participant.

KEY TO MASTER CHART

M	Male
F	Female
KGS	Kilograms
ASA PS	American Society of Anaesthesiologists Physical Status
H.R.	Heart Rate
S.B.P.	Systolic Blood Pressure
DBP	Diastolic Blood Pressure
M.A.P.	Mean Arterial Pressure
mmHg	Millimeter of Mercury
SPO_2	Peripheral Capillary Oxygen Saturation
VAS	Visual Analogue Scale
MINS	Minutes
B/L	Bilateral
FESS	Functional Endoscopic Sinus Surgery
S.F.C.	Surgical field condition
S.S.P.	Surgeon satisfaction profile
P.O.V.	Post-operative nausea and vomiting
R.S.C.	Ramsay sedation score
DNS	Deviated Nasal Septum
D.C.R.	Dacryocystorhinostomy