"THE EFFECT OF ULTRASOUND GUIDED ERECTOR SPINAE BLOCK USING ROPIVACAINE WITH FENTANYL, ROPIVACAINE WITH DEXMEDETOMIDINE ON POSTOPERATIVE PAIN AND OPIOID CONSUMPTION IN PATIENTS UNDERGOING LUMBAR SPINAL SURGERIES-A ONE YEAR RANDOMISED CLINICAL TRIAL."

By

REG NO. BA0121006

Dissertation

Submitted to
KAHER, Belagavi, Karnataka,
In partial fulfilment of the requirements for the degree of

M.D.

In

ANAESTHESIOLOGY

DEPARTMENT OF ANAESTHESIOLOGY,
JAWAHARLAL NEHRU MEDICAL COLLEGE,
KAHER, BELAGAVI – 590010
KARNATAKA.

DECEMBER – 2024/JANUARY - 2025

KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH,

BELAGAVI, KARNATAKA.

ENDORSEMENT

This is to certify that the dissertation entitled **"THE EFFECT OF ULTRASOUND GUIDED ERECTOR SPINAE BLOCK USING ROPIVACAINE WITH FENTANYL, ROPIVACAINE WITH DEXMEDETOMIDINE ON POSTOPERATIVE PAIN AND OPIOID CONSUMPTION IN PATIENTS UNDERGOING LUMBAR SPINAL SURGERIES- A ONE YEAR RANDOMISED CLINICAL TRIAL."** is a bonafide research work done by **REG NO.BA0121006.**

Dr. RAJESH. S. MANE M.D
Professor and Head,
Department of Anaesthesiology,
J.N. Medical college,
Nehru Nagar, Belagavi- 590010.

Date: 26/6/24
Place: Belagavi.

KAHER BELAGAVI J.N. MEDICAL COLLEGE

Dr. N.S. MAHANTSHETTI M.D,(PAEDS)
Principal,
J.N. Medical college,
Nehru Nagar, Belagavi- 590010.

PRINCIPAL
J.N. Medical College,
BELAGAVI- 590 010

Date:
Place: Belagavi.

KLE Academy of Higher Education & Research (Deemed to be University), Belagavi, Karnataka

UNDERTAKING

I, **Reg.no., BA0121006** here by declare that the information and the data mentioned in my dissertation **THE EFFECT OF ULTRASOUND GUIDED ERECTOR SPINAE BLOCK USING ROPIVACAINE WITH FENTANYL, ROPIVACAINE WITH DEXMEDETOMIDINE ON POSTOPERATIVE PAIN AND OPIOID CONSUMPTION IN PATIENTS UNDERGOING LUMBAR SPINAL SURGERIES-A ONE YEAR RANDOMISED CLINICAL TRIAL."** belongs to me and is original. I am aware of the definition of *Plagiarism* as detailed below:

- An act or instance of using are closely imitating the language and thoughts of another author without authorization and the representation of that authors work as one's own, as by not crediting the original author.
- A piece of writing or other work reflecting such unauthorised use or imitation.
- The deliberate or reckless representation of another's words, thoughts, or ideas as one's own without attribution in connection with submission of academic work, whether graded or otherwise.

I hereby declare that the dissertation prepared by me is an original one and does not involve plagiarism anywhere. In case at a later stage, it is found that I have indulged in plagiarism, then, I am solely responsible for the same and the institution is at liberty to take any disciplinary action against me including cancellation of dissertation or any other penalties imposed by the university.

DATE: 26-06-2024

PLACE: Belagavi

Registration no.: BA0121006

ANTI-PLAGIARISM CERTIFICATE

JAWAHARLAL NEHRU MEDICAL COLLEGE

(A constituent unit of KLE Academy of Higher Education & Research Deemed-to-be-University)

(Recognized by National Medical Commission, New Delhi)

Accredited 'A+' Grade by NAAC (3rd Cycle) **Placed in Category 'A' by MoE (GoI)**

Nehru Nagar, Belagavi- 590 010, Karnataka, INDIA

0831 - 2471350 0831 - 2470759 www.jnmc.edu incipal@jnmc.edu

Ref No: MDC/PG/ Date: 25-06-2024

"ACCEPTANCE LETTER"

The softcopy of thesis entitled: **"THE EFFECT OF ULTRASOUND GUIDED ERECTOR SPINAE BLOCK USING ROPIVACAINE WITH FENTANYL, ROPIVACAINE WITH DEXMEDETOMIDINE ON POSTOPERATIVE PAIN AND OPIOID CONSUMPTION IN PATIENTS UNDERGOING LUMBAR SPINAL SURGERIES-A ONE YEAR RANDOMISED CLINICAL TRIAL"** has been submitted for anti-plagiarism check through Turnitin software. The scan has been carried out and the scanned output reveals a match percentage of **10%** which is within the acceptable limits of **10%** as per the guidelines given by UGC.

Guide.

KAHER BELAGAVI J.N. MEDICAL COLLEGE

Dr. (Mrs.) N.S. Mahantashetti.
Chairperson-Antiplagiarism Committee &
Principal,
J. N. Medical College, Belagavi.

To,
Reg. No. BA0121006
Postgraduate Student,
2021-22 Batch,
Department of Anaesthesiology
J. N. Medical College, Belagavi.

ETHICAL CLEARANCE

K.L.E. ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Deemed – to- be- University)
Accredited 'A+' Grade by NAAC in (3rd Cycle) Placed in Category 'A' by MHRD (GoI)

JNMC INSTITUTIONAL ETHICS COMMITTEE
JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)

Website: http//www.jnmc.edu
E-Mail : dome@jnmc.edu

Phone: (+ 91-(0)831 Office : 2472550
Principal: 2471701
Fax No. +91 (0)831 – 2470759

Ref No.MDC/JNMCIEC/ 152 **Date: 27/09/2022**

To,
BA0121006
PG Student in Anaesthesiology,
J. N. Medical College,
BELAGAVI.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"THE EFFECT OF ULTRASOUND GUIDED ERECTOR SPINAE BLOCK USING ROPIVACAINE WITH FENTANYL, ROPIVACAINE WITH DEXMEDETOMIDINE ON POSTOPERATIVE PAIN AND OPIOID CONSUMPTION IN PATIENTS UNDERGOING LUMBAR SPINE SURGERIES- A ONE YEAR RANDOMISED CLINICAL TRIAL."** is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee.

(Dr. Smita Sonoli)
Member Secretary
JNMC Institutional Ethics Committee
J.N.Medical College, Belagavi.

(Dr. Harsha Hegde)
Chairman,
JNMC Institutional Ethics Committee
J.N.Medical College, Belagavi

165

ABSTRACT

TITLE- THE EFFECT OF ULTRASOUND GUIDED ERECTOR SPINAE BLOCK USING ROPIVACAINE WITH FENTANYL, ROPIVACAINE WITH DEXMEDETOMIDINE ON POSTOPERATIVE PAIN AND OPIOID CONSUMPTION IN PATIENTS UNDERGOING LUMBAR SPINAL SURGERIES - A ONE YEAR RANDOMISED CLINICAL TRIAL.

CONTEXT – Spine surgeries are associated with severe postoperative pain beyond 24 hours. This study is aimed at evaluating the duration of USG guided ESPB block with two drug combinations i.e. Ropivacaine with Fentanyl and Ropivacaine with Dexmedetomidine. We also evaluated the total 24-hour postoperative opioid consumption in both these groups.

AIMS- To compare the total duration of block of ultrasound guided Erector Spinae block using Ropivacaine with Fentanyl "(GROUP-A)" and Ropivacaine with Dexmedetomidine "(GROUP-B)" in patients posted for lumbar spine surgeries under GA. To evaluate the total 24-hour opioid consumption in the above-mentioned groups.

SETTING AND DESIGN- A ONE YEAR HOSPITAL BASED RANDOMISED CLINICAL TRIAL.

MATERIALS AND METHODS- A total of 60 Patients aged 18- 65 years, of either gender, belonging to ASA grade I-II, undergoing elective lumbar spine surgeries under general anaesthesia were enrolled in the study and randomized into two groups. In GROUP A patients ESPB was performed with Ropivacaine with Fentanyl. In Group B patients ESPB was performed with Ropivacaine with Dexmedetomidine. Total duration of the block and total 24hour postoperative opioid consumption was measured.

RESULT- Group B shows a significantly lengthened duration of analgesia with about 17.8 hours mean time for the first rescue analgesia. Group A exhibits a notably shorter duration of time for the administration of first dose of rescue analgesic, with 4.93 hours mean time. The total twenty-four-hour postoperative consumption of opioids is significantly low in GROUP B AND the postoperative VAS scores were continuously lower.

CONCLUSION- use of Dexmedetomidine as an adjuvant to Ropivacaine in Ultrasound guided Erector Spinae Plane Block, is superior to the use of Fentanyl as an adjuvant in providing longer duration of action of ESPB and reducing the overall twenty-four-hour opioid consumption and in maintaining stable hemodynamic parameters postoperatively with lower VAS scores.

KEYWORDS- ESP block, Lumbar spine surgeries, VAS scores, Opioids, Post-operative pain.

LIST OF ABBREVIATIONS

ASA- American Society of Anaesthesiologists

USG- Ultrasound Guidance

GA- General Anaesthesia

ESPB- Erector Spinae Plane Block

IP- In-plane

VAS- Visual Analogue score

mins- Minutes

kg-Kilogram

mg-Milligrams

L - liters

ml- milliliters

NBM- Nil by mouth

NIBP- Noninvasive blood pressure

PR- Pulse Rate

RR- Respiratory rate

SpO2- Saturation percentage of oxygen

Iv- Intravenous

HS- Highly significant

VS-Very significant

S- Significant

NS-Not Significant

MHz-Megahertz

S.D.-Standard deviation

SBP- Systolic Blood Pressure

DBP- Diastolic Blood Pressure

HR- Heart Rate

TABLE OF CONTENTS

SL.NO	SECTIONS	PAGE NO.
1	INTRODUCTION	1-3
2	OBJECTIVES	4
3	REVIEW OF LITERATURE	5-9
4	BASIC SCIENCES	10-43
5	METHODOLOGY	44-53
6	RESULTS	52-74
7	DISCUSSION	75-79
8	CONCLUSION	80
9	SUMMARY	81-82
10	BIBLIOGRAPHY	83-89
11	ANNEXURES	
	ANNEXURE I-INFORMED CONSENT	90-95
	ANNEXURE II- PROFORMA	96-98
	ANNEXURE III- PHOTOGRAPHS	99-104
	ANNEXURE IV- MASTER CHART	105-106
	ANNEXURE V- KEY TO MASTERCHART	107

LIST OF FIGURES

Sl.No.	Description	Page no.
1.	Anatomy of Erector Spinae Muscles	13
2.	Cross sectional diagram of Erector Spinae Plane	14
3.	Schematic diagram of Erector Spinae Plane block	15
4.	Curvilinear USG probe	18
5.	Beam of Curvilinear USG probe	19
6.	Schematic diagram of In-plane approach	21
7.	USG image of In-plane approach	21
8.	Different positions of USG probe	22
9.	USG-Parasagittal articular process view	23
10.	USG view of interlaminar space	24
11.	USG view of Transverse process	25
12.	Chemical structure of Ropivacaine	26
13.	Chemical structure of Fentanyl	31
14.	Chemical structure of Dexmedetomidine	36
15.	VAS scale	45

LIST OF TABLES

Sl.No.	Description	Pages
1.	Pharmacokinetics of Dexmedetomidine	40
2.	VAS. Value interpretation	45
3.	Comparison of demographic details in two groups	54
4.	Age distribution among both groups	54
5.	Comparison of time for 1st rescue analgesia over group.	57
6.	Comparison of total opioid consumption in 24hours, in two groups.	59
7.	Comparing the use of analgesics in both the groups.	60-61
8.	Comparing VAS over time in both the groups.	63
9.	Comparing (HR) heart rate over time in both the groups.	66
10.	Comparing SBP (systolic blood pressure) over time in both the groups.	69-70
11.	Comparing (DBP) diastolic blood pressure over time in both the groups.	72

LIST OF STASTICAL GRAPHS AND PLOT DIAGRAMS

Sl.No	Description	Pages
1.	Mean plot of age over the groups	56
2.	Bargraph depicting the distribution of sex between both groups	56
3.	Mean plot of total duration of block in two groups	58
4.	Bargraph of distribution of total 24hour opioid usage over time in both groups	60
5.	Bargraph showing distribution of rescue analgesia used over time in both groups	62
6.	Mean plot of VAS over time in both groups	65
7.	Mean plot of HR over time in both groups	68
8.	Mean plot of SBP over time in both groups	71
9.	Mean plot of DBP over time in both groups	74

LIST OF PHOTOGRAPHS

Sl.No.	Description	Page no.
1.	Photograph USG Machine with probe.	99
2.	Photograph Curvilinear Ultrasound probe and local anaesthetic Ropivacaine.	100
3.	Photograph Showing the additives Fentanyl and Dexmedetomidine.	101
4.	Photograph of equipment used to perform the block.	102
5a.	Photograph of Sono anatomy of insertion of needle of ESPB (1).	103
5b.	Photograph Sono anatomy of separation of erector spinae plane after drug injection (1).	103
6a.	Photograph of Sono anatomy of Trajectory of needle of ESPB (2).	104
6b.	Photograph Sono anatomy of separation of erector spinae plane after drug injection (2).	104

INTRODUCTION

Lumbar spinal surgery involves extensive anatomical resection resulting in severe postoperative pain. Postoperative analgesia is usually provided with opioids. Opioids are known to cause undesired effects like "sedation, respiratory depression, nausea, vomiting, bowel disturbances, inadequate analgesia". Poor analgesic control may further lead to increased respiratory and cardiac complications, delayed mobilization, increased period of hospitalization and may even lead to chronic pain syndrome. To overcome these complications multimodal analgesia is preferred.

Several more recent regional anaesthetic procedures like Erector Spinae Plane Block (ESPB), Thoracolumbar Interfacial Plane block have also come into practice.

The ESPB provides excellent pain relief with no impairment of spinal cord functions making it preferred technique of pain management in spine surgeries.

In ESPB, local anaesthetic is deposited in a plane between the transverse process (lumbar or thoracic vertebra) and Erector spinae muscle plane[(1)].

Ultrasound guided ESPB is a novel technique which is easy to perform with very few complications due to absence of any major structures around the site of injection that may be accidentally injured[15,16].

Motor function is preserved, this allows early ambulation of patient and immediate evaluation of postoperative neurological function.

Though there have been several studies on ESP block for lumbar surgeries, there is a gap in knowledge regarding the usage of different additives to the local anesthetic, that will further increase the time of action of the block, potentiating its efficacy and decrease the opioid consumption.

Ropivacaine is an amide local anesthetic with 4-6 hours of duration of action. It is a widely used local anesthetic for neuraxial anesthesia and several regional anesthetic procedures. Though it is related to Bupivacaine structurally it has fewer side effects compared to Bupivacaine, making it the choice of drug for our study [32].

Fentanyl is an opioid which is widely used as an additive to local anesthetic drugs[29]. It is known to increase the duration of action of local anesthetic drugs due to direct agonist effect on opioid receptors present on peripheral nerves[32]. It has higher efficacy and fewer adverse effects

compared to other opioids, when used as an adjuvant to local anesthetic drugs[13] and systemic side effects can be avoided when used locally.

Dexmedetomidine is an agonist of α2 adrenergic receptors. Several evidence-based results claim that it prolongs duration of action of local anaesthetic drugs[9,10,11,12,13] due to its local vasoconstrictive property[14] and by direct inhibition of peripheral nerve conduction. It has additional sedative effect and the property of hemodynamic stability[14]. There are very few studies on the addition of Dexmeditomidine as an adjunct in ESPB.

Hence, this study was carried out to compare the duration of the ESP block with two drug combinations i.e. Ropivacaine with Fentanyl and Ropivacaine with Dexmedetomidine in patients posted for lumbar spine surgeries. We will also be examining the total 24-hour opioid consumption in both the groups.

OBJECTIVES OF STUDY:

PRIMARY OBJECTIVE:

To "compare" the total duration of block of ultrasound guided Erector Spinae block using Ropivacaine with Fentanyl "(GROUP-A)" and Ropivacaine with Dexmedetomidine "(GROUP-B)" in patients posted for lumbar spine surgeries under GA.

SECONDARY OBJECTIVE:

To evaluate the total 24-hour opioid consumption in the above-mentioned groups.

REVIEW OF LITERATURE

Lumbar spine surgeries are associated with extreme postoperative pain, increased usage of intravenous opioids, delayed recovery and poor outcomes. Pain immediately following surgeries is one of the elements that determines an early recovery.

Regional anesthesia techniques are a major part of multimodal analgesic regime and reduce opioids usage[30].

In 2021 a review article published by Ki Jinn Chin, described the evidence based basic mechanism of action involved in ESPB by evaluating several available and existing literatures. They concluded that an optimum volume of local anaesthetic required for the desired effect in ESPB is 10ml and it may range from 20-30 ml[15].

Serkan Tulgar et al. published a review article in 2020. They described the procedure of ESP block, advantages of the block and its indications based on several case and clinical reports[16].

A case control study that is prospective and randomized is done by Vipin kumar goel in 2021 where they compared the efficiency of USG guided bilateral ESPB versus multimodal analgesia. They concluded that the ESP block was superior to plain intravenous opioid based multimodal analgesia in minimizing blood loss, reducing postoperative opioid consumption and had very minimal side effects. They stated that ESP block provides excellent post operative pain relief resulting in increased patient satisfaction[(2)].

A study conducted by Bahadir Ciftci in 2020 compared the two existing interfacial blocks i.e. ESPB and modified Thoracolumbar interfacial block in reduction of pain, post lumbar spine surgeries. They described the techniques of both the blocks and concluded that

both the blocks were excellent in providing analgesia and there was no superiority of a block over the other one[(34)].

A randomized control trial conducted on 40 patients by Swati Singh et al in 2018 concluded that bilateral ultrasound guided ESPB is an excellent intervention in providing postoperative analgesia in patients after lumbar spinal surgery. The ease of performance of the block when compared to other blocks was also discussed and it was also

stated that there were no complications while performing the block making it a safer technique[3].

In 2019 Neha kanojia et al performed ESP block in a series of 15 cases where single shot ESP block was performed with plain 0.375% Ropivacaine. They stated the duration of block was 6-8 hours. It was concluded that the block had exponentially reduced the postoperative pain in the patients[4].

Renee.J.C. van den Broek et al conducted a study retrospectively - on uses of including ESPB to conventional anaesthetic care in patients who underwent posterior lumbar spinal surgeries. It showed a favorable effect on pain reduction and brought about reduction in opioid administration. It was concluded that reduced use of opioids intravenously results in early postoperative ambulation and positive effect outcome on recovery[5].

A retrospective study on patients scheduled for Lumbar spine surgeries by Cedric Cirenei et al. concluded that erector spinae block has good analgesic control postoperatively resulting in reduction of overall 24-hour opioid consumption[6].

A review article published in 2020 by Krishna Prasad G V et al. enlisted the various drugs that can be used as additives to local anesthetics while performing various field and regional blocks. They described the advantages of Fentanyl and Dexmedetomidine when used as additives to local anesthetics was described[8].

In 2017, a prospective study carried out by Farooq N et al. In this study they compared the efficiency of Fentanyl versus Dexmedetomidine as additives to Ropivacaine in Interscalene block (brachial plexus) in relation to using plain Ropivacaine. The parameters that were evaluated were time of onset of motor blockade, time of onset of sensory blockade and duration of action of sensory block in all three groups. Through their observations it was determined that combining Fentanyl with Ropivacaine showed better

outcomes compared to combining Dexmedetomidine with Ropivacaine or using plain Ropivacaine[28].

Gao Z in 2019, conducted a study in patients undergoing VATS lobectomy. They compared the potency of ESPB with Dexmedetomidine and Dexamethasone as additives to Ropivacaine and with that of using plain Ropivacaine. It was found that postoperative pain scores i.e. VAS were lower, longer duration of the block (18 hours), early ambulation of the patients were observed in the group where Dexmedetomidine was used as an additive to Ropivacaine. They concluded that Dexmedetomidine is a better additive[26].

BASIC SCIENCES

ANATOMY:

The erector spinae is a group of muscles and tendons which run the length of the spine on the left and the right, from the sacral region to the base of the skull. They are also known as the Sacro-spinalis group of muscles [19].

The muscular fibers form a large fleshy mass that splits, in the upper lumbar region, into three columns, viz., a lateral (iliocostalis), an intermediate (longissimus), and a medial (spinalis).

Action: It controls the forward flexion of the thorax, which can occur secondary to gravity. The actions of the cervical and capitis groups are unknown. These muscles are small compared to the larger cervical muscle groups and have little force capacity.

Relationships: Covered by thoracolumbar fascia, serratus posterior inferior, rhomboids, and splenii muscle groups.

SPINALIS – medial most group

- Spinalis thoracis
    - Origin: Spinous processes of T11-L2.

- Insertion: Spinous processes of the upper thoracic vertebra.

- Spinalis cervicis
    - Origin: ligamentum nuchae and C7 spinous process
    - Insertion: spinous processes of the axis and C3-C4.

- Spinalis capitis
    - Usually, a few fibers of semispinalis capitis that inserts onto the spinous processes of C7 and T1.

LONGISSIMUS – middle group

- Longissimus capitis
    - Origin: C4-T4 transverse processes.
    - Insertion: Posterior edge of the mastoid process.

- Longissimus cervicis
    - Origin: T1-T4 transverse processes.
    - Insertion: Posterior tubercle of C2-C6 transverse processes.

- Longissimus thoracis
    - It contains lumbar and thoracic sections.
    - Largest of erector spinae group.
    - Origin: Transverse process at inferior vertebral levels.
    - Insertion: Transverse process at superior vertebral levels and mastoid process.

ILIOCOSTALIS - Most lateral group of the erector spinae

- Iliocostalis cervicis
    - Origin: Angle of ribs 3 to 6.
    - Insertion: posterior tubercle of the transverse process of C4-C6.
- Iliocostalis thoracis
    - Origin: Angle of lower six ribs.
    - Insertion: Transverse process of C7 and angles of the upper six ribs.
- Iliocostalis lumborum
    - It contains lumbar and thoracic sections.
    - Origin: Medial end and the dorsal segment of the iliac crest.
    - Insertion: L1-L4 lumbar transverse processes, the angle of ribs 4 to 12, and thoracolumbar fascia.

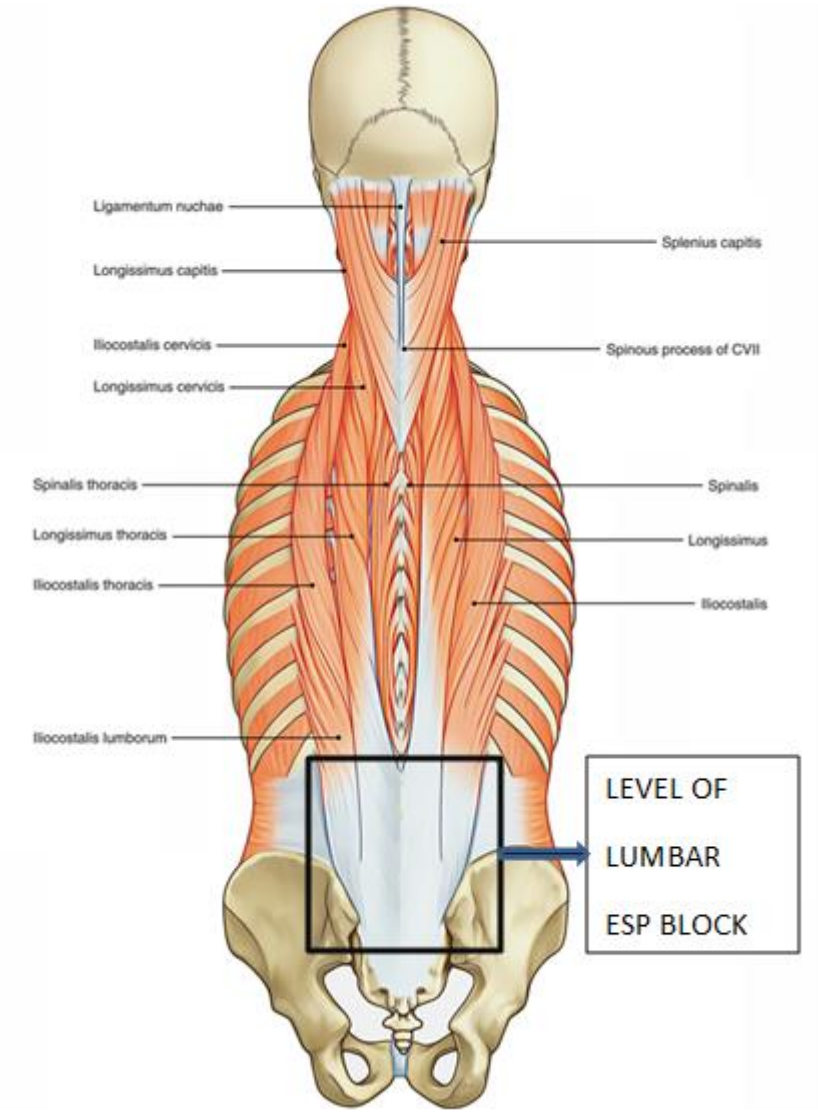

Ligamentum nuchae
Splenius capitis
Longissimus capitis
Iliocostalis cervicis
Spinous process of CVII
Longissimus cervicis
Spinalis thoracis
Spinalis
Longissimus thoracis
Longissimus
Iliocostalis thoracis
Iliocostalis
Iliocostalis lumborum
LEVEL OF
LUMBAR
ESP BLOCK

Figure – 1

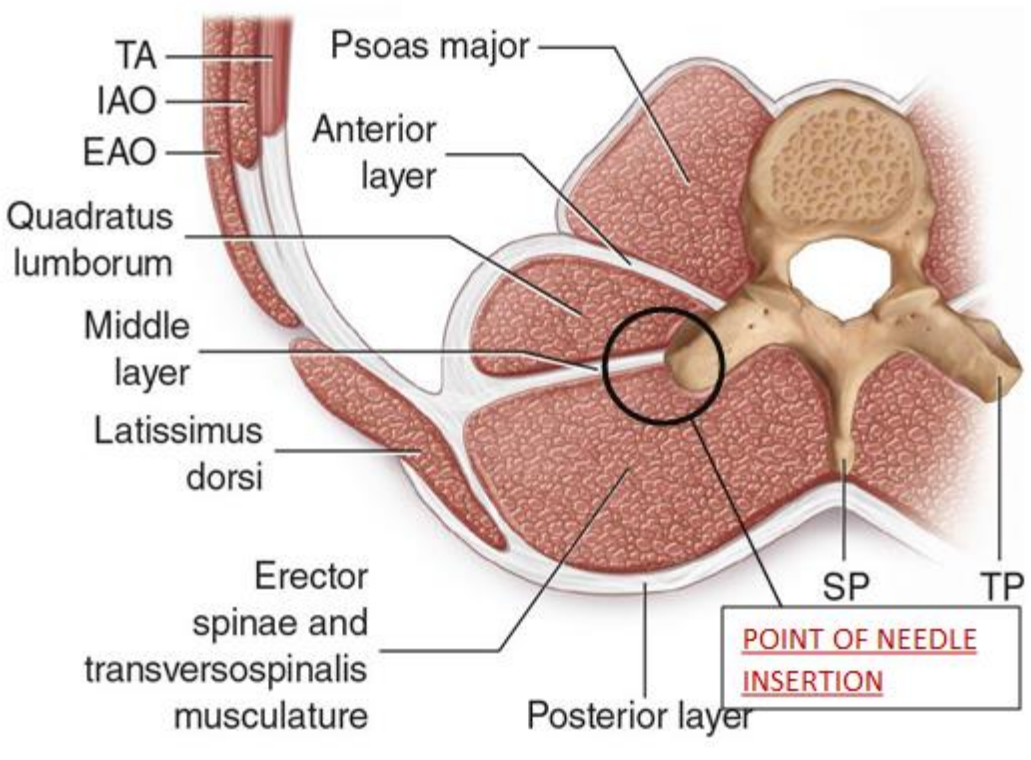


Figure - 2

Erector spinae plane:

It is a paraspinal fascial plane which lies in between the erector spinae muscle group and the transverse processes of the spine[19].

Spinal nerves continue as the dorsal ramus and ventral ramus after leaving the epidural foramen.in the lumbosacral region.

The ventral ramus merges to form the lumbar and sacral plexuses.

The dorsal ramus in the lumbosacral area separates into the medial, intermediate, and lateral branches and supplies sensory innervation to the waist and buttocks.

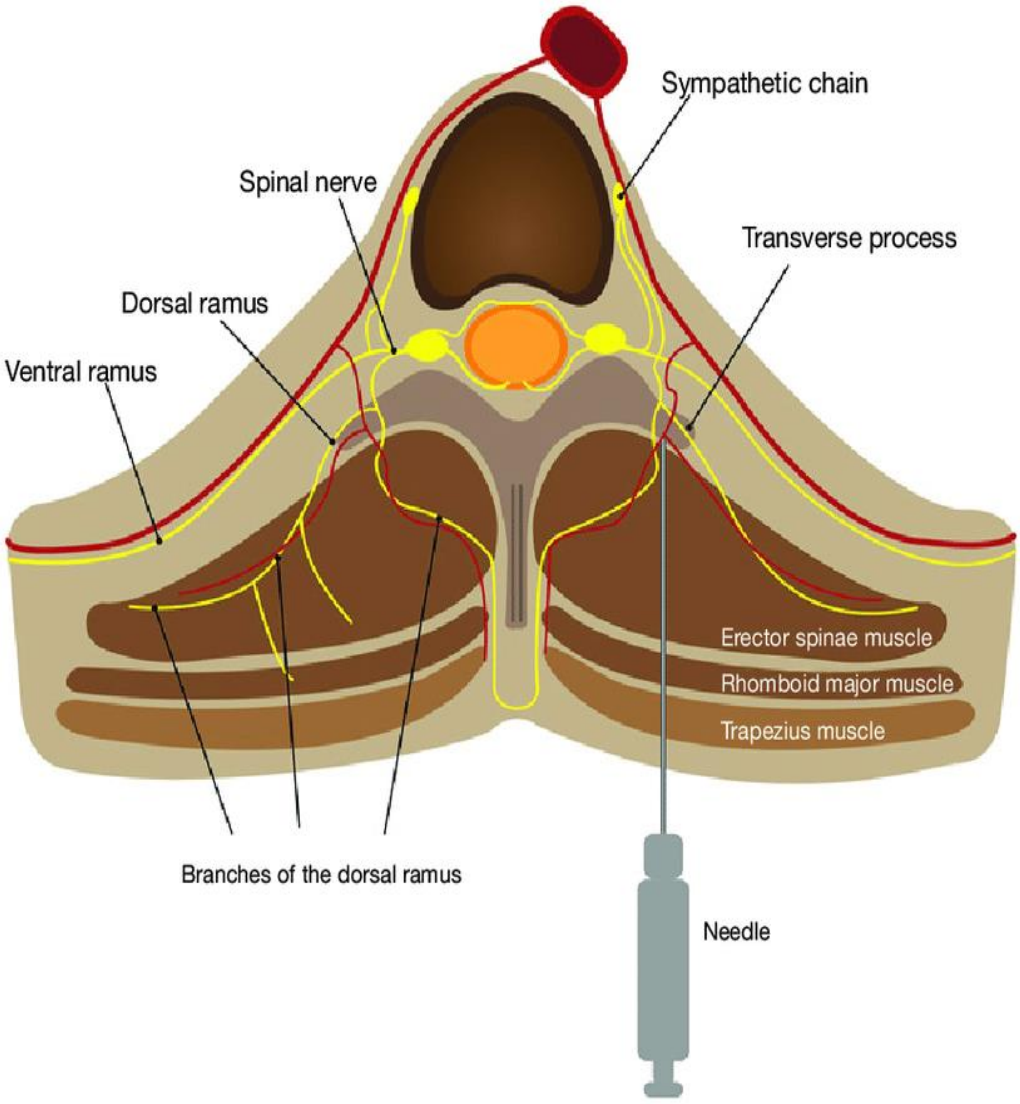


Figure - 3

ULTRASONOGRAPHY:

Ultrasound, which is a sound waves in frequency range of around 2 to 15 megahertz has a wide range of diagnostic and treatment applications in the field of medicine. Ultrasonography[21,22] works on the principle of Piezoelectric effect. This effect converts mechanical / kinetic energy into electrical energy by deformation of crystals. The piezoelectric effect can also be reversed i.e., by electrical energy the crystals can be oscillated to form ultrasound waves (mechanical energy).

The ultrasound transducer has the function of producing the ultrasound by the above said mechanism. This ultrasound produced travels through tissues and gets reflected back. The returned echo waves after reaching the transducer gets changed to electrical energy which is later processed and produce an image. The transducers work in a range of frequencies. Linear transducers with higher frequencies (5 – 7.5 MHz) are used in imaging superficial structures whereas curvilinear probe with lower frequencies (2.5 – 3.5 MHz) produce images of deeper structures.

It is on the surface that lies between tissues of varying density, the ultrasound gets reflected. If the difference in densities is higher, the sound waves that get reflected is also high and the opposite also holds true.

Therefore, with very high difference of densities (bones, air, calculi) the sound will be completely reflected back. This produces acoustic shadowing. If the tissues are homogenous in their densities, then echo-free images are seen (blood, urine, ascites).

TRANSDUCERS:

This is the hand-held part of the ultrasound machine. It has the function of inter-converting the energies (electrical and mechanical) based on piezoelectric effect. They contain lead zirconate titanate crystals commonly. They produce ultrasound waves in either linear(sequential) arrays or phased arrays. It comprises 5 major components:

- Crystals: possessing piezoelectric property. Can be arranged in either a linear or curvilinear manner.
- Electrodes: positive and ground for electrical connection.
- Damping block: to dampen stray sound waves.
- Matching layer: one or multiple. For proper transmission of sound waves to the tissues.
- Housing.
- Tendons and joints,
- During laparoscopic procedures,

- Measuring body fat thickness,
- Peripheral nerve blocks

The block was performed with the help of a curvilinear USG transducer.

CURVILINEAR TRANSDUCER:

- The Piezoelectric crystals – curvilinear arrangement.
- They produce convex ultrasound beam.
- Used to image deeper tissues.
- As depth of imaging increases, image resolution decreases.
- Foot print is wide with central frequency being, 2.5 – 7.5MHz for 2D imaging and 3.5 – 6.5MHz for 3D imaging .

Figure- 4

Figure - 5

APPROACHES AND TECHNIQUES

There are two basic approaches to ultrasound guidance. With the out-of-plane technique, the needle tip crosses the plane of imaging as an echogenic dot. With the in-plane approach, the entire tip and shaft of the advancing needle are visible.

The block was performed by in-plane approach.

In-plane (IP):

In this technique a needle is inserted along the length of ultrasound probe. It aligns the entire length of the beam with the shaft of needle. The image displayed will depict the entire needle shaft and its tip thereby improving the precision of nerve blocks. But the needle visibility depends on angle of insertion and the needle traverses a longer path to reach the target area.

Advantages:

Most direct visualization.

Disadvantages:

1) Partial line-ups (creating a false sense of security when the needle tip is not correctly identified.

2) Some unimaged needle path occurs with IP approach, but typically less than with OOP approach.

3) Longer paths and therefore more structures to cross with the block needle.

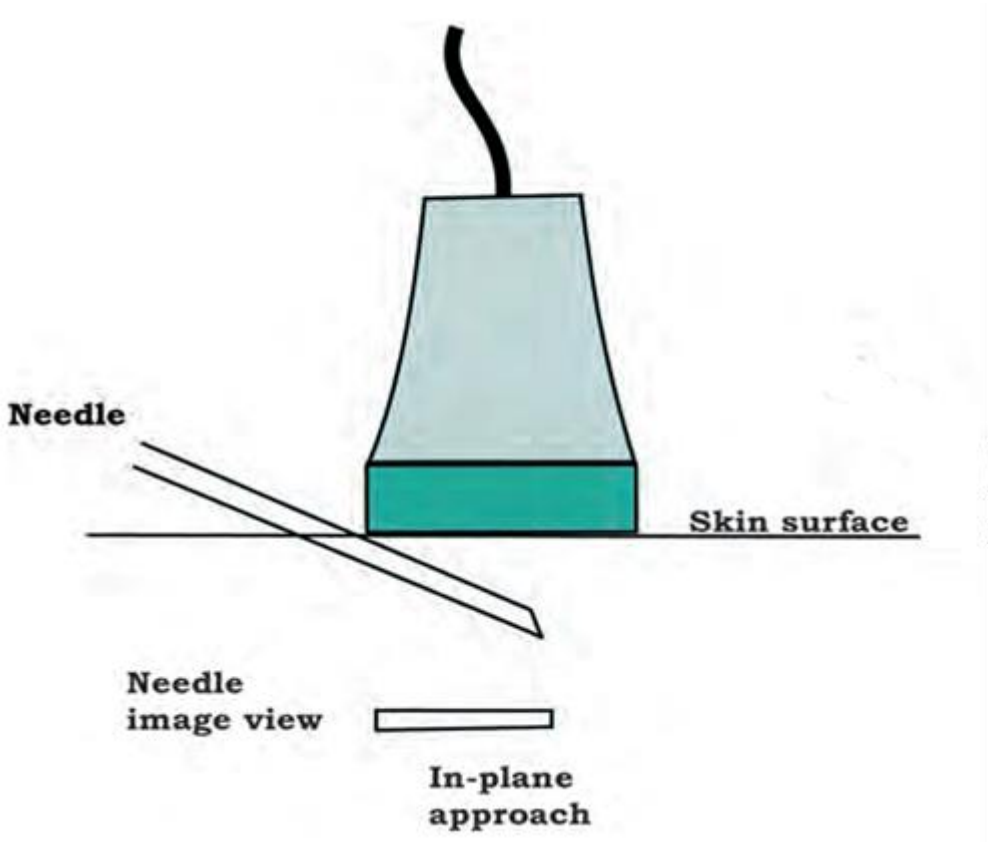


Figure - 6

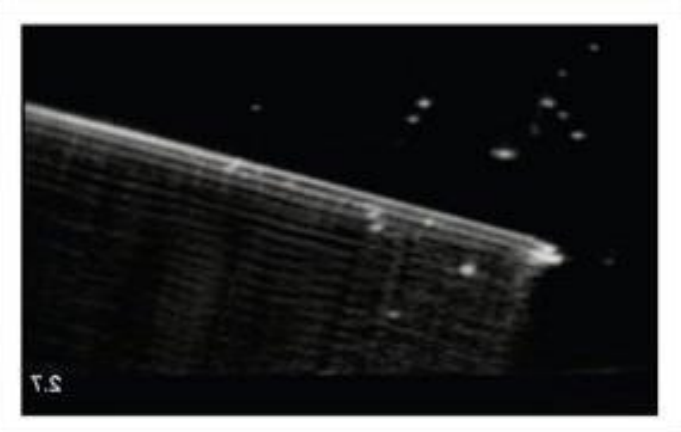
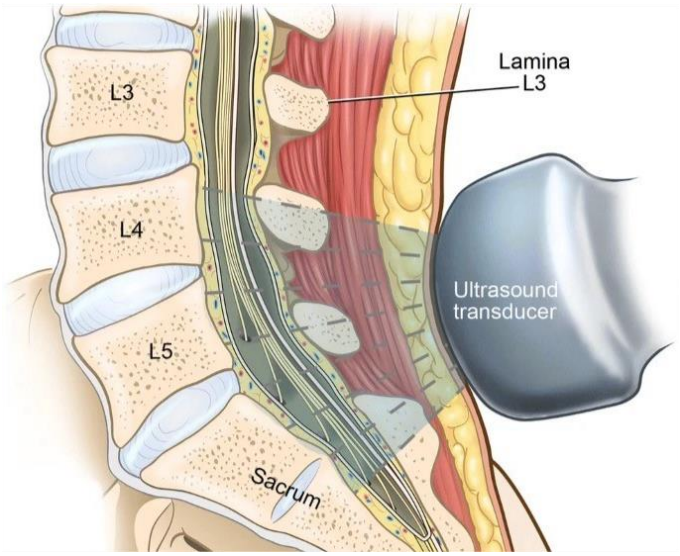


Figure - 7

SONOANATOMY:

Position of the patient: Prone

Position of the probe: midline in sagittal plane.



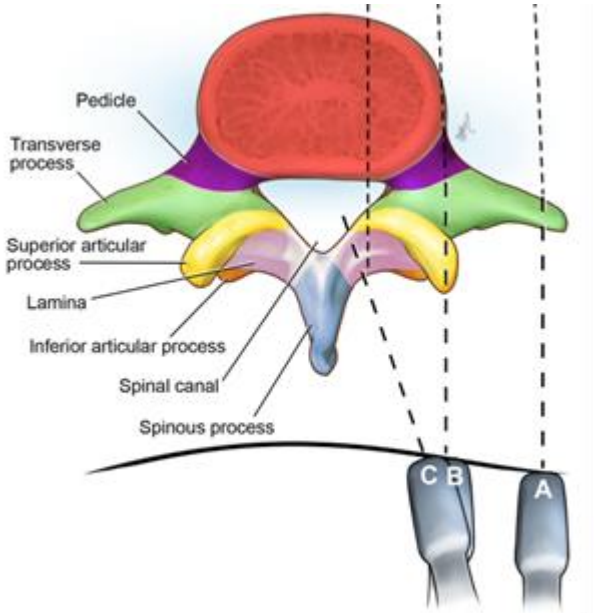


Figure - 8

Spinous processes appear as continuous hyperechoic structures.

As the probe is moved laterally the articular processes start appearing and form a sign called **CAMEL HUMP SIGN** [17,20]**.**

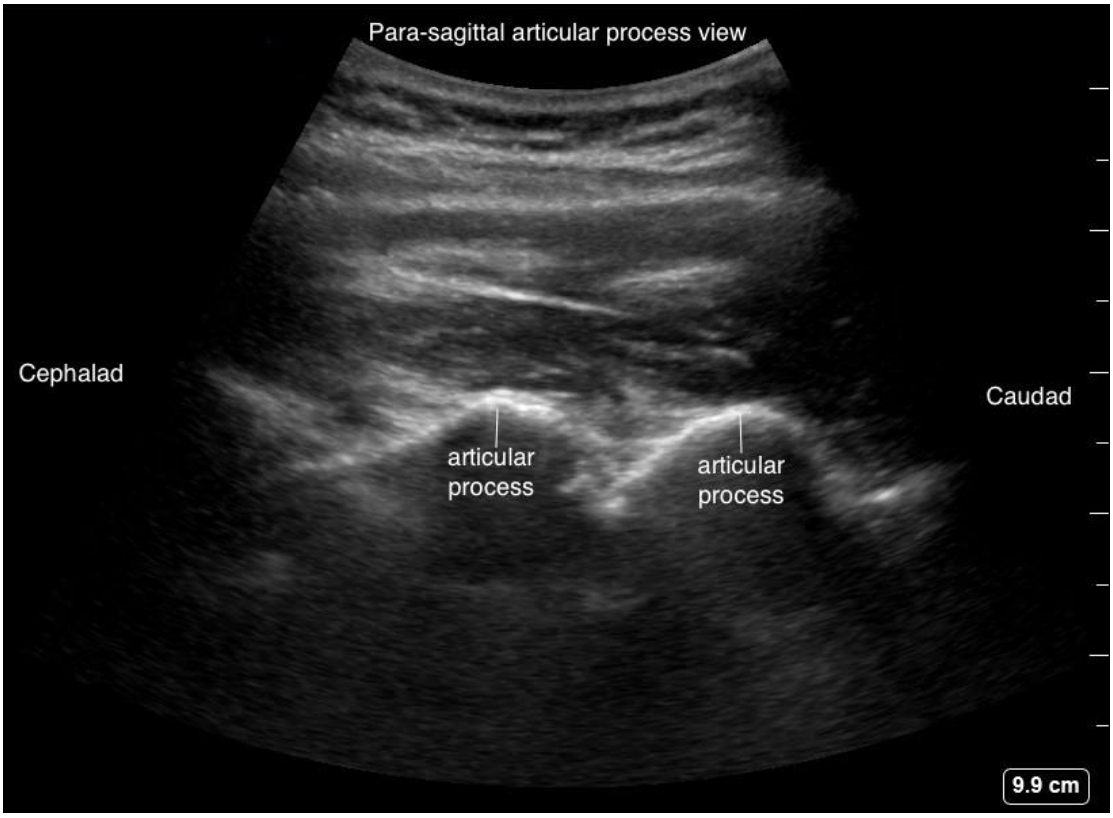


Figure - 9

At this point if the transducer is tilted medially the interlaminar space appears as **SAWTOOTH or HORSE HEAD** appearence [17,20].

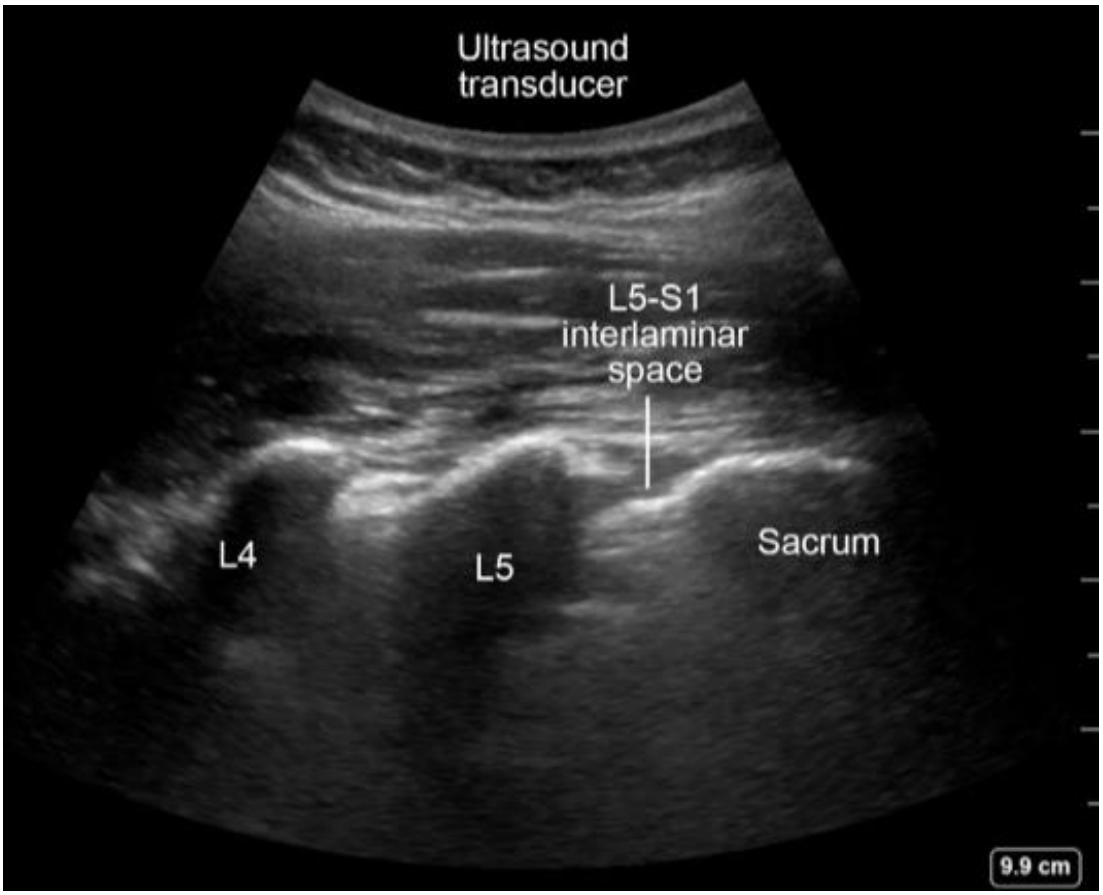


Figure - 10

By continuing to move the probe laterally the transverse processes start appearing and form the **TRIDENT SIGN**[17,20]

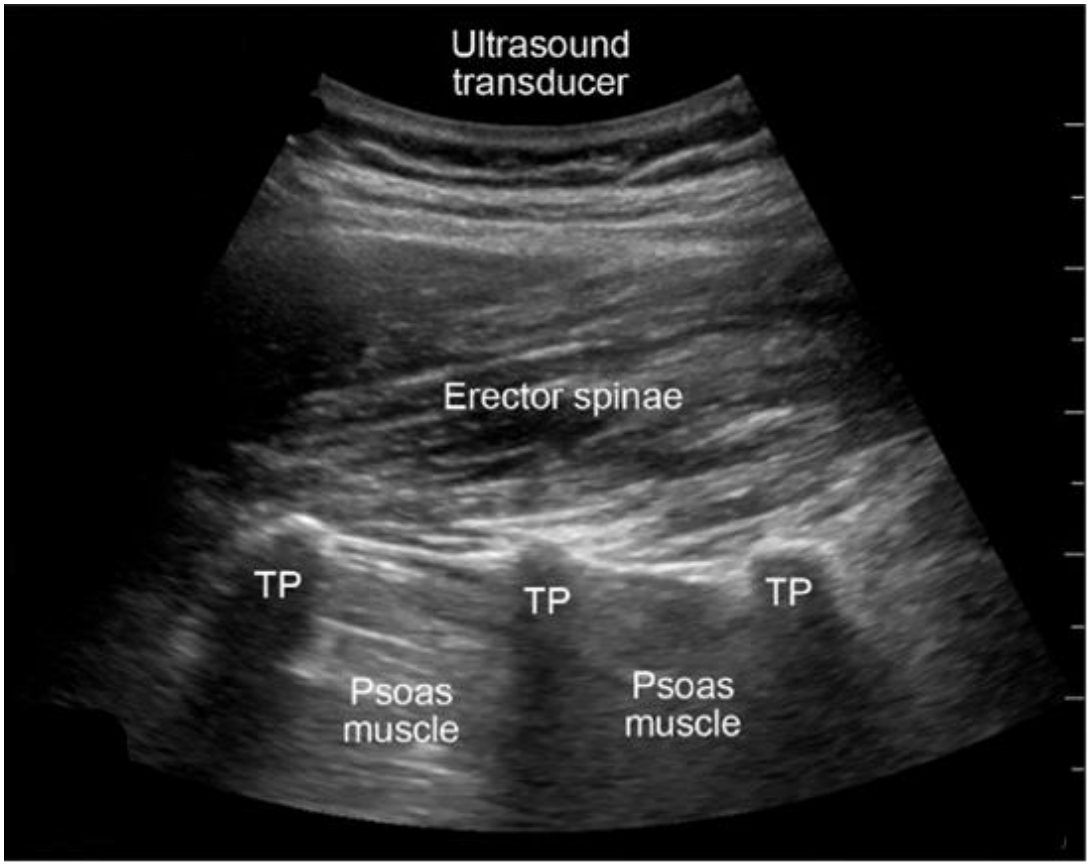


Figure - 11

At this point if the probe is moved further laterally there is abrupt ending of transverse process shadow, which becomes the point of insertion of the needle and deposition of the drug.

ROPIVACAINE

Ropivacaine[32] is a long-acting amide local anesthetic, it is less lipophilic than other local anesthetics like bupivacaine resulting in less systemic absorption. When used at lower doses, the motor block is limited and non-progressive. It is less lipophilic compared to bupivacaine resulting in decreased penetration of myelinated large motor fibers (Aβ fibers) and selectively acts on the pain-transmitting A δ and C nerve fibers. The nature of motor blockade produced by ropivacaine is slow in onset, short in duration, and has less intensity. The clearance of ropivacaine is higher than Bupivacaine. Cardiotoxicity and CNS toxicity are less in ropivacaine compared to bupivacaine.

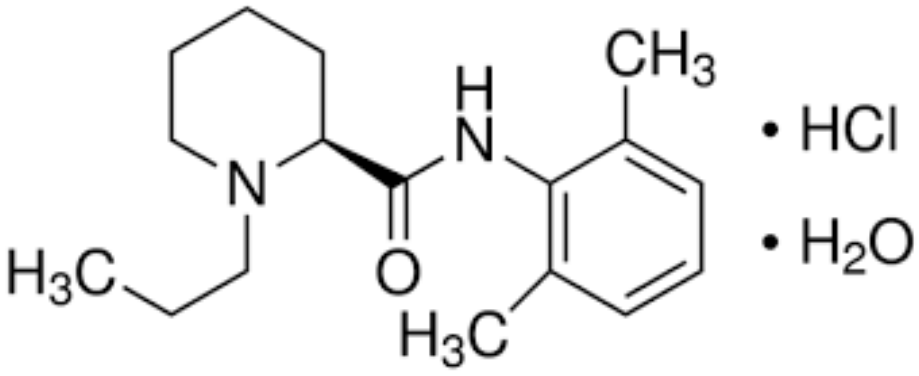


Figure - 12

Mechanism Of Action and Correlation with Structure

Ropivacaine reversibly inhibits the voltage gated sodium channels present on the nerve cell membranes thus preventing the influx of sodium ions into the cells. This:

I. Blocks generation and conductance of nerve impulses.

II. Slows propagation of nerve impulses

III. Reduces the rate of rise of action potential

Almost all local anesthetic agents block the unmyelinated C and myelinated Aδfibres, which transmit pain impulses, at the same rate.

The rate of blockade of motor fibers (Aα and Aβ) however, depends upon the physio chemical properties like pKa and lipid solubility of the individual drug. As ropivacaine is less lipid soluble than bupivacaine, the Aα and Aβ blockade is slower and hence motor blockade is less potent. The motor block produced by ropivacaine is slower in onset, less in intensity and shorter in duration.

Clinically the order of blockade of nerve fibres is autonomic, sensory and motor, while the regression of the block occurs in reverse order.

The order of the loss of nerve function is

1. Pain
2. Temperature

3. Touch

4. Proprioception

5. Skeletal muscle tone.

Pharmacokinetics

Absorption*:*

The systemic concentration of ropivacaine depends on the total dose and concentration of drug given, the route of administration, the patient's hemodynamic state and the vascularity of the site of administration.

Distribution*:*

After intravascular infusion, ropivacaine has a steady state of distribution of 41 ± 7 liters. It is 94% protein bound, mainly to α_1-acid glycoprotein. Ropivacaine can easily cross the placenta.

Metabolism and excretion:

Ropivacaine is extensively metabolized by the liver, predominantly by the cytochrome P_{4501A} mediated aromatic hydroxylation to produce 3 – hydroxyl ropivacaine. After a single IV dose, approximately 37% of the total dose is excreted in the urine as both free and conjugated 3-hydroxy ropivacaine. An additional unquantified amount of 2 – hydroxyl – methyl ropivacaine has also been identified as a metabolite.

Ropivacaine metabolites are mainly excreted via the kidney. After i.v. administration 86% of the dose is excreted in urine of which only 1% is

in unchanged form. Following IV administration, ropivacaine has a mean ± SD total plasma clearance of 387 ± 107 mL/min, an unbound plasma clearance of 7.2 ± 1.6 L/min and a renal clearance of 1 mL/min. The mean ± SD terminal half-life is 1.8 ± 0.7 h and 4.2 ±1.0 h after i.v. and epidural administration respectively.

Pharmacodynamics

Central Nervous System &Cardiovascular System:

Ropivacaine has a higher threshold for both cardiac as well as neuro toxicity as compared to bupivacaine due to its lower lipid solubility and stereo - selective properties. This holds good for both isomers of ropivacaine which have been shown to be less cardio depressant than respective bupivacaine isomers in animal studies.

CNS toxicity occurs earlier than cardiac toxicity on iv infusion in healthy volunteers.

Potency:

Lipid solubility of a local anesthetic correlates well with its potency and toxicity. Compounds which are more lipophilic penetrate the nerve cell membrane more readily. Thus, fewer molecules are required to produce the desired conduction blockade.

Adverse Effects

Excessive plasma levels are due to over dosage, unintentional intravascular injection or slow metabolic degradation. The mean doses at which CNS symptoms of toxicity begin to occur in human beings are 4.3 and 0.6 mcg/mL of total and free plasma concentrations respectively. When prolonged blocks are used the risks of reaching a toxic plasma concentration or inducing local neural injury are increased. Various possible side effects include

a) Injection site pain.

b) **Cardiovascular system toxicity:** Vasovagal reaction, syncope, postural hypotension, non-specific ECG abnormalities which include wide QRS complexes, increased conduction time and reduced contractility.

c) **Gastrointestinal system toxicity:** Faecal incontinence, tenesmus, nausea, vomiting.

d) **Central nervous system toxicity:** Tremor, Horner's syndrome, dyskinesia, neuropathy, vertigo, convulsion and coma. Because of the depressant effect of ropivacaine on medulla, excitatory stage of CNS might not occur.

e) **Liver and Biliary system toxicity:** Jaundice.

f) **Metabolic disorders:** Hypomagnesemia.

FENTANYL

It is an opioid[32].

Molecular Formula: C22H28N2O

Chemical Structure

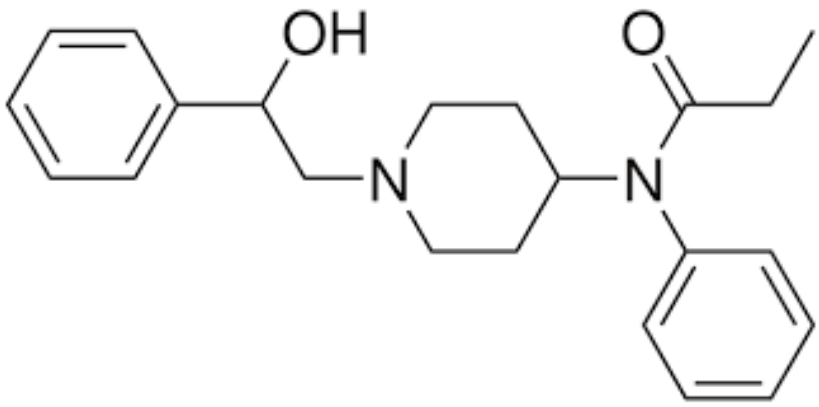


Figure - 13

Route of Administration: Epidural, Intrathecal, IV, Skin Patch, Sublingual.

Pharmacokinetics:

Bioavailability:

- Transdermal – 92%
- Intranasal – 89%

- Buccal – 50%
- Ingestion – 33%
- Intramuscular – 100%.

Protein Binding: 80-85%

Metabolism: Liver primarily by CYP3A4

Onset Of Action: 5 minutes

Duration Of Action: 30-60 minutes

Excretion: Mostly by kidney

USES OF FENTANYL:

Intravenous:

Intravenous fentanyl is often used for anesthesia and analgesia. During anesthesia it is often used along with propofol. It is also administered in combination with midazolam to produce sedation for endoscopy, cardiac catheterization and in emergency rooms. It is also used in the management of chronic pain including cancer pain.

Neuraxial block:

Fentanyl is given intrathecally as a part of spinal anaesthesia or epidurally for epidural anaesthesia and analgesia. The greater potency and rapid onset of action reflect the greater lipid solubility of fentanyl compared with that of morphine which facilitates its passage across the blood brain barrier. In obstetrics the dose must be closely regulated to prevent large amounts of transfer from mother to foetus.

Patches:

Fentanyl transdermal patches are used in chronic pain management. The patches work by slowly releasing fentanyl through the skin into the blood stream over 48-72 hours allowing for long lasting pain management.

Adjuvant:

Fentanyl is being used as an adjuvant to many local anesthetics in regional and field blocks. This is due to the direct actionn of fentanyl on the opioid receptors present on the peripheral nerve fibers.

Intranasal:

The bioavailability of intranasal fentanyl is about 70-90% but with some imprecision due to clotted nostrils pharyngeal swallow and incorrect administration.In children intranasal fentanyl is useful for the treatment of moderate to severe pain and is well tolerated.

Mechanism of action:

As a mu receptor agonist, it binds 50-100 times more strongly than morphine.Fentanyl can also bind to the delta and kappa opioid receptor but with a lower affinity. Its strong potency relative to morphine is largely due to its lipophilicity.

Fentanyl binds to opioid receptors – G-Protein Coupled Receptor which regulates synaptic transmission. Binding of fentanyl activates the GPCR which initiates signaling to result in the inhibition of the release of nociceptive neurotransmitters.

Side Effects of Fentanyl (29):

- Depression of ventilation.
- Hypotension.
- Nervousness.

- Increase in intracranial pressure to head injury patients.
- Seizure activity following rapid IV administration.

DEXMEDETOMIDINE

Dexmedetomidine is a selective α2 agonist which have properties of sedation, analgesia, anxiolysis and sympatholytic effect. Since dexmedetomidine is having all these properties, it is used in perioperative period and in intensive care unit for sedation, analgesia. Few studies have shown that dexmedetomidine have anti-shivering properties.

Physical and Chemical Properties:

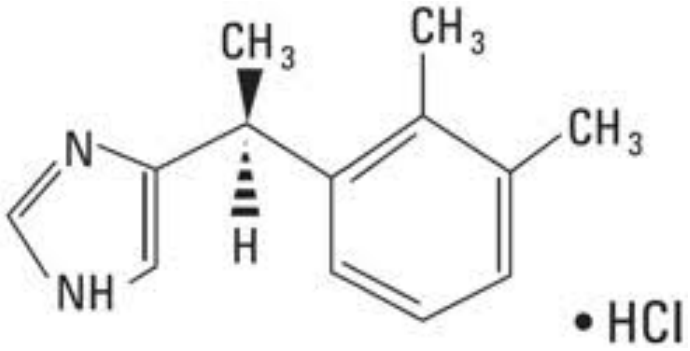


Figure : 14

Dexmedetomidine is a d-enantiomer of medetomidine which belongs to imidazole group of α2 agonists. It has high specificity for α2 receptors than α1 receptors (α2: α1 = 1600:1) when compared to clonidine (α2: α1 = 200:1). Dexmedetomidine is highly water soluble. pKa is about 7.1.

The presynaptic αadreno receptors which regulates the release of Noradrenaline was designated as α2 adrenoreceptors. These α2 adreno receptors are widely distributed in CNS and peripheral tissues, thereby controlling the modules of sympathetic nervous system. The α2 receptors subdivided into α2A , α2B, α2c etc. All these are required for normal regulation of presynaptic neurotransmitter release from the central nor-adrenergic area and from sympathetic nerves in heart.

PHARMACOKINETICS:

Dexmedetomidine is a dextro-isomer of medetomidine. It is administered by intravenous route. It is short acting with linear concentration dependent kinetics.

DOSING AND ADMINISTRATION:

The pharmacodynamic effects of the drug are achieved at a plasma concentration of 0.5-1.2ng/dl. The dose of the drug approved by FDA is a loading dose of 1mcg/kg body weight over a period of 10 minutes followed by a maintenance dose of continuous intravenous infusion of 0.2 to 0.7 mcg/kg/hr.

The rate flow of this infusion is titrated according to required level of sedation and by careful monitoring of hemodynamics of the patient. Dexmedetomidine is used as a good sedative agent in ophthalmic surgeries. In these surgeries the drug is administrated intravenously as a loading dose of 0.5 mcg/kg followed by a maintenance dose of 0.6 mcg/kg/hr.

DISTRIBUTION:

Dexmedetomidine is significantly bound to plasma protein (94%). The pharmacokinetics of this drug is explained as a "two-compartment model". After intravenous injection it is rapidly distributed with a distribution half-life of 6 minutes. The elimination half-life of the drug is 2 to 2.5 hours. The steady state volume of distribution is estimated as approximately 68L to72 L.

METABOLISM AND ELIMINATION:

The dexmedetomidine is mostly metabolized in the liver by the cytochrome P450 enzymes by glucuronidation and biotransformation.

There are various metabolic pathways by which dexmedetomidine is metabolized.

1. N-glucuronidation to inactive metabolites (41%).

2.N-methylation to 3-hydroxyN-methyl dexmedetomidine (21%).

3. Hydroxylation followed by conjugation.

4. Conjugation and N-methylation.

5. Hydroxylation followed by conjugation.

Most of the drug undergoes complete biotransformation which results in minor quantity of drug to be excreted in urine and feces as unconjugated form. The elimination half-life of the drug is approximately 2 hours with an average clearance of 45L/hour in adults. The pharmacokinetics of the drug are impaired in patients with hepatic and renal diseases. In hepatic diseases, there is an increase in half-life, volume of distribution and as well as decrease in clearance and protein binding of the drug. In renal diseases, there is a decrease in terminal elimination half-life, but no change in clearance and volume of distribution.

Table :1 PHARMACOKINETICS OF DEXMEDETOMIDINE

Molecular weight	236.7 Daltons
Lipid solubility	30
Distribution half life	6 min.
Protein binding	94%
Volume of distribution	118 L.
Elimination t1/2	120 – 180 min.
Context sensitive half life	4 – 250 min.

MECHANISM OF ACTION:

Dexmedetomidine[32] is a potent α2 agonist. The α2 receptors are a part of both central nervous system and peripheral nervous system. These receptors are also present in liver, kidney and pancreas. The site of action of these receptors are presynaptic, post synaptic and extra synaptic regions among which presynaptic sites are of major concern. So, depending on site of action of these receptors, various responses are evaluated. The presynaptic site is the region where modulation of release

of Nor-adrenaline and ATP occurs. Since it is a potent α2 agonist; it mainly acts on presynaptic region and causes inhibition of release of nor-adrenaline. Its main action is to inhibit the neuronal firing in the brain and spinal cord by action on the α2 receptors and thus leading to bradycardia, hypotension, sedation and analgesia.

PHARMACODYNAMICS:

Dexmedetomidine after its initial dose administration exerts a brief biphasic pattern of cardiovascular response. This response is seen after a loading dose of 1microgram/kg of body weight. There is an initial

increase in blood pressure followed by reflex bradycardia. This initial increase in blood pressure is because of stimulation of α2b receptors which are present in smooth muscles. This is followed by a decrease in blood pressure which is because of central sympathetic system outflow blockade.

Dexmedetomidine inhibits the release of noradrenaline, thus leading to further hypotension and bradycardia. Postoperative bradycardia is commonly noticed with dexmedetomidine injection. Cautious use of

dexmedetomidine in patients with poor left ventricular function should be considered.

Dexmedetomidine sedative effects are achieved by action on α2 adrenoreceptor located on postsynaptic membrane. It inhibits the G-protein which leads to an increase in conductance through the potassium

channels. The sedative effect of dexmedetomidine is achieved by action on locus coeruleus located in brain stem.

The uses of the drug dexmedetomidine are as follows:

1. Sedation of intubated patients in ICU. (NOTE: it should be used more than 24 hours.)

2. Sedation of surgery patients without being intubated.

3. Reduction of use of opioids and other anesthetic agents.

4. Anxiolytic.

5. Before performing laryngoscopy to reduce intubation response.

6. Anti-shivering property. Dexmedetomidine acts as anti-shivering agent by binding to α2 receptors, thus mediate vasoconstriction and acts as anti-shivering agent. Dexmedetomidine reduces vasoconstriction and shivering threshold by acting on central thermoregulatory mechanisms rather than peripheral neurotransmitter.

7. As an adjuvant to spinal anesthesia and peripheral nerve blocks.

ADVERSE EFFECTS:

1) Bradycardia.

2) Sinus arrest.

3) Hypotension.

4) Transient hypertension.

5) Hypoxia

6) Nausea and vomiting.

7) Anemia

8) Atrial fibrillations

9) Fever, tachycardia.

10) Headache, agitation and nervousness (occurs if the drug is used for more than 24 hours.)

CONTRAINDICATIONS:

1) Drug hypersensitivity.

2) Cardiac dysfunction (mainly left ventricular dysfunction mainly)

3) Advanced cardiac blocks.

4) Shock/ hypovolemia.

VAS SCORE

Figure: 15

The Visual Analogue Scale (VAS) consists of a straight line with the endpoints defining extreme limits such as 'no pain at all' and 'pain as bad as it could be'. The patient is asked to mark his pain level on the line between the two endpoints. The distance between 'no pain at all' and the mark then defines the subject's pain[25].

VAS value	Interpretation of pain
0	No pain
1-3	Mild pain
4-6	Moderate pain
7-10	Severe pain

Table : 2

METHODOLOGY

STUDY DESIGN: Hospital Based, One Year Randomized clinical trial.

STUDY PERIOD: One year (September 2022 to August 2023)

PLACE: "Department of Anesthesiology, K.L.E. Dr. Prabhakar Kore Hospital and Medical Research Centre, KAHER, Belagavi".

DATA SOURCE: 18–65-year-old individuals, posted for lumbar spine surgery electively under GA at Nehru nagar, K.L.E. Dr Prabhakar kore hospital & Research center &, Belagavi, Karnataka.

SAMPLE SIZE: Total of 60 patients were segregated into two groups with thirty patients within each individual group.

CALCULATION OF SIZE OF SAMPLE: Using the mean and the standard deviation the formula of sample size was calculated

$$n = \frac{(z_\alpha + z_\beta)^2 (s_1^2 + s_2^2)}{(\bar{X}_1 - \bar{X}_2)^2}$$

z_α denotes "significance level".

z_β denotes the "power of the test".

z_α =1.96 for "significance level of 5%".

z_β =0.84 for "power of test to be 80%".

Ref: "Effectiveness of bilateral ultrasound guided erector spinae plane block in percutaneous lumbar osteosynthesis for spine trauma – Cedric Cirenei et al"[(6)].

The parameter considered in the calculation was VAS score.

$\bar{X}_1$ denotes mean of the 1st group (1.7)

$\bar{X}_2$ denotes mean of the 2nd group (3.1).

s_1 denotes standard deviation of 1st group (1.7)

s_2 denotes standard deviation of the 2nd group (3.1).

The size of sample obtained with these values is 28. The size of sample was increased to round it off to 30.

Two groups that were allotted are: GROUP A – 30

GROUP B – 30

Sampling technique: After both inclusion and exclusion criteria were met and after procuring informed and written consent patients have been segregated into above-mentioned cohorts based on computer-based randomization.

Inclusion Criteria:

- ASA I & II.
- 18years – 65years.
- Belonging to Either sex.
- Patients posted for lumbar spine surgeries electively, under general anesthesia.
- Provides Consent.

Exclusion Criteria:

- Patient receiving chronic analgesic therapy
- Patient with history of opioid dependence

- Patients with bleeding disorders
- Patients on anticoagulative medication
- Patients who refused to consent

- Complex spine surgeries with longer than three-hour duration.

Ethical Clearance:

Before starting our study, we procured approval from the Ethical and Research Committee of our institution, JNMC, Nehrunagar, Belagavi.

Informed Consent:

After meeting the selection (inclusion) criteria, the patients have been explained about the procedure and course of the study and the type of intervention being done in their own vernacular language. Before enrolment into the clinical trial an informed consent in their vernacular language was obtained from all the patients.

Data Collection Methods:

The clinical trial was carried out in patients posted for elective lumbar spine surgeries, aged between 18 to 65 years, belonging to either sex and American Society of Anaesthesiologists grade I & II

The study period was one year. After clearance and approval from the ethical committee of the institution, written and informed consent has been procured from all the subjects who were included under the study.

Both groups were preoperatively assessed on the day before the surgery and simultaneously the consent was taken. On the day of surgery after confirming nil per mouth status of the patient an intravenous cannula was secured. Standard ASA monitors were attached inside the OT i.e. ECG, Spo2, NIBP.

The premedication was given with intravenous-glycopyrrolate 0.005mg/kilogram, intravenous Midazolam-0.05mg/kilogram, intravenous Fentanyl 2mcg/kilogram. Induction of patients was done with intravenous Propofol 2mg/kilogram, intravenous injection of Vecuronium 1.2mg/kilogram. They were then intubated using Endotracheal tubes that were of appropriate size. For maintenance of anaesthesia Oxygen: N2O:: 50:50, inhalational agent Isoflurane and vecuronium infusion were used.

Once the patient is shifted to prone position, spine level intended for the surgery was marked with the help of C-arm. A curvilinear ultrasound

probe was positioned over the midline oriented vertically and the marked spinous process was identified. The USG transducer slid laterally to locate the transverse process of lumbar vertebra, which was approximately 3cms lateral to the spinous process.

After the targeted transverse process was located a 22 Guage spinal needle was introduced in plane at 30-40^0 angle aiming towards the dorsal surface of the transverse process of interest till resistance was felt. 25ml of 0.5% ROPIVACAINE with 25 mcg FENTANYL on each side (total - 50ml of 0.5% Ropivacaine,50mcg Fentanyl) in GROUP A and 25ml of 0.5% ROPIVACAINE with 25 mcg DEXMEDETOMIDINE was injected on each side following a negative blood aspiration (total - 50ml of 0.5% Ropivacaine, 50mcg Dexmedetomidine) in the GROUP-B.

Post operatively the patients self-reported pain score using Visual Analogue Score for pain was recorded immediately after transfer to postoperative care unit i.e.: VAS-0, second hour VAS-2, fourth hour VAS-4, sixth hour VAS-6, twelfth hour VAS-12 and twenty-fourth hour VAS-24 postoperatively.

Patients whose VAS score was greater than 3 received 100mg Tramadol intravenously in 100ml Normal Saline (maximum of 4 doses i.e. 400mg in 24 hours), as rescue analgesic in addition to 1gram paracetamol i.v.

All the study subjects were routinely given 1gram paracetamol i.v. every 6^{th} hourly.

The time at which rescue analgesia was first administered and the total dosage and time points at which opioids were consumed postoperatively was recorded.

Statistical analysis:

Data is analysed using statistical software R version 4.4.0. and Microsoft Excel.

Frequency tables were used for variables that are categorical.

Mean ± SD /Median (Min, Max) form was used for the variables that were continuous.

"Chi square test" was used to check the association of variables that are categorical with groups. Normality of variable was checked by "Shapiro Wilk test" and "QQ plot".

For data following normal distribution, parametric tests were used. Otherwise, non-parametric tests were used.

The means of variables over groups were compared with "Two sample t test". The distribution of variables over groups was compared with "Mann Whitney U test". Friedman test was used to compare the distribution of variables over time. The comparisons were represented appropriately using different bar graphs and the value of *p* which is less than or equal to 0.05 were considered significant statistically.

RESULTS:

The Data comprises of measurements of 60 subjects which are segregated into 2 groups

"GROUP A" – Ropivacaine with Fentanyl – 30 subjects.

"GROUP B" – Ropivacaine with Dexmedetomidine – 30 subjects.

The following table gives the comparison of demographic details over groups.

Table 3: Comparison of demographic details in two groups.

Variables	Subcategory	Group A	Group B	Total	p-value
Age (years)	Mean ± SD Median (Min, Max)	47.6 ± 11.58 50 (19, 65)	50.34 ± 9.52 50 (31, 65)	48.95 ± 10.62 50 (19, 65)	0.3250[t]
Sex	Female	12 (40%)	12 (40%)	24 (40%)	1[C]
	Male	18 (60%)	18 (60%)	36 (60%)	

Abbreviation: t – Two sample t test, C – Chi square test.

Table 4: Age distribution among both groups.

Age (years)	Group A	Group B
18 - 34	4	3
35 - 49	10	11
50 - 65	16	16

In terms of age, Group A has a mean age of 47.6 years with a standard deviation of 11.58, while Group B has a slightly higher mean age of 50.34 years with a standard deviation of 9.52. However, the difference in mean age between the two groups is not statistically significant (p-value = 0.3250). The median age for both groups is 50 years, with ranges from 19 to 65 years for both.

Regarding gender distribution, both groups have an equal distribution of females and males, with 40% females and 60% males in each group.

There is no significant difference observed from the “Chi-square test” in the distribution of genders between the two groups (p-value = 1).

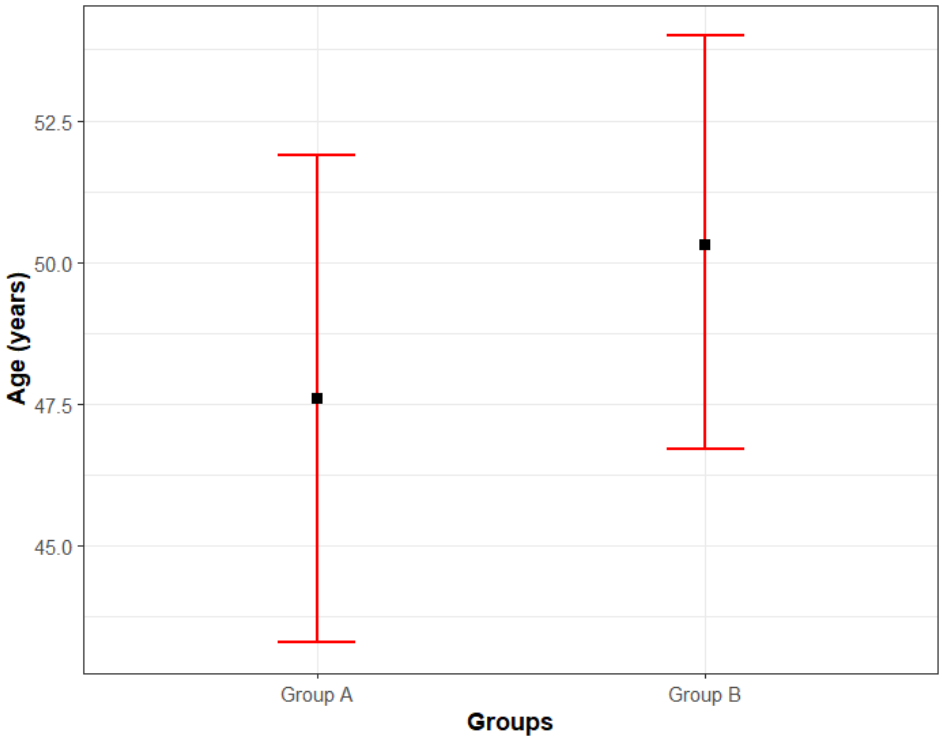


Figure 1: The plot showing mean of age over groups.

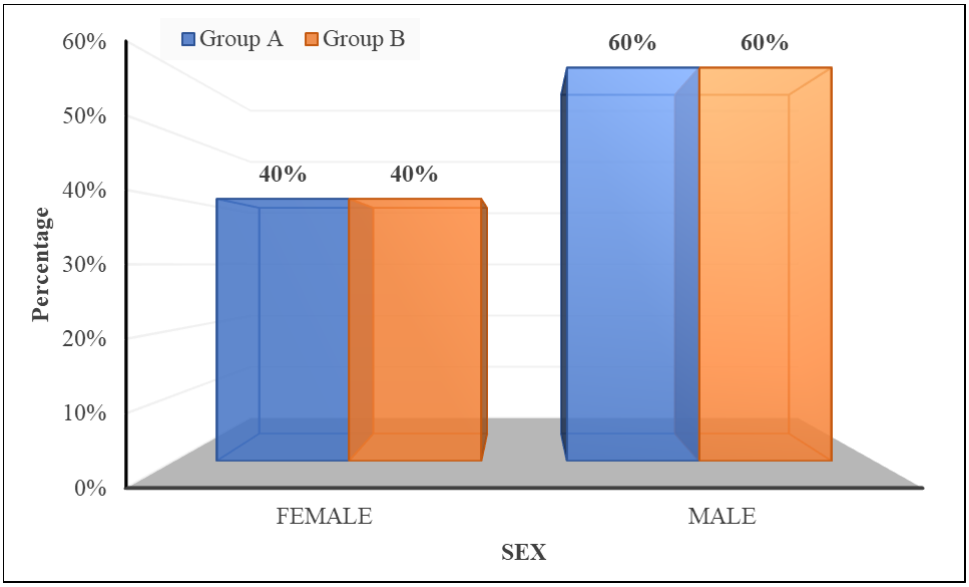


Figure 2 : Distribution of sex between both the groups.

The following table gives the comparison of time for first rescue analgesia over group.

Table 5: Comparison of time for 1st rescue analgesia over group.

Variable	Group A	Group B	Total	p-value
Time for 1st rescue analgesia	4.93 ± 3.29 4 (2, 12)	17.8 ± 7.92 24 (2, 24)	11.59 ± 8.9 6 (2, 24)	**< 0.001^{MW*}**

*Abbreviation: MW – Mann Whitney U test, * indicates statistical significance.*

Group A exhibits a notably shorter time duration for the first rescue analgesia, with a mean time of 4.93 hours (ranging from 2 to 12 hours). In contrast, Group B shows a significantly longer duration, with a mean time of 17.8 hours (ranging from 2 to 24 hours) for the first rescue analgesia. The difference in the time for the first rescue analgesia between the two groups is significant statistically (p-value < 0.001).

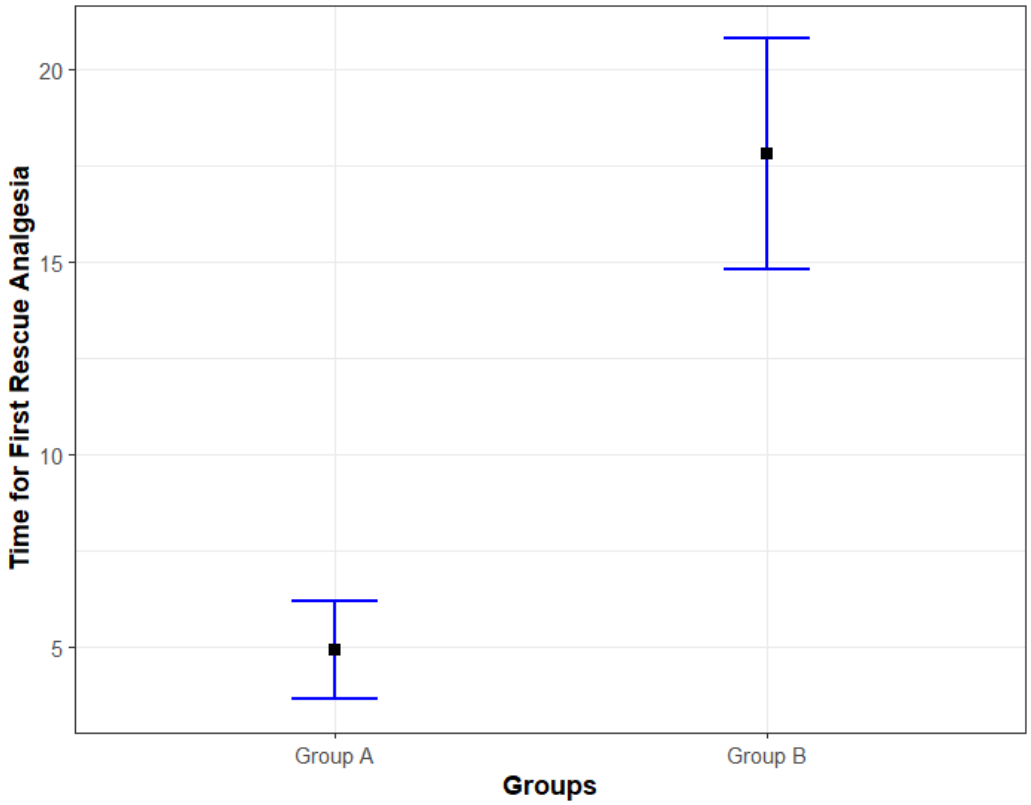


Figure 3 : Mean plot of total time (duration)of analgesia in two groups.

(time point at which the rescue analgesia was administered first)

The following table gives the comparison of total opioid usage in 24hours over group.

Table 6 : Comparison of total opioid consumption in 24hours, in two groups.

Total opioid Usage in 24hours	**Number of patients in Group A**	**Number of patients in Group B**	**Total number of patients**	**p-value**
100mg	8 (26.67%)	9 (30%)	17 (28.33%)	**< 0.001^{MC*}**
200mg	6 (20%)	3 (10%)	9 (15%)	
300mg	8 (26.67%)	1 (3.33%)	9 (15%)	
400mg (maximum dose)	7 (23.33%)	0	7 (11.67%)	
NIL	1 (3.33%)	17 (56.67%)	18 (30%)	

*Abbreviation: MC – Chi square test with Monte Carlo simulation, * indicates statistical significance.*

The difference in total opioid usage between both the groups is significant statistically (p-value < 0.001). Group B has lower opioid consumption compared to Group A.

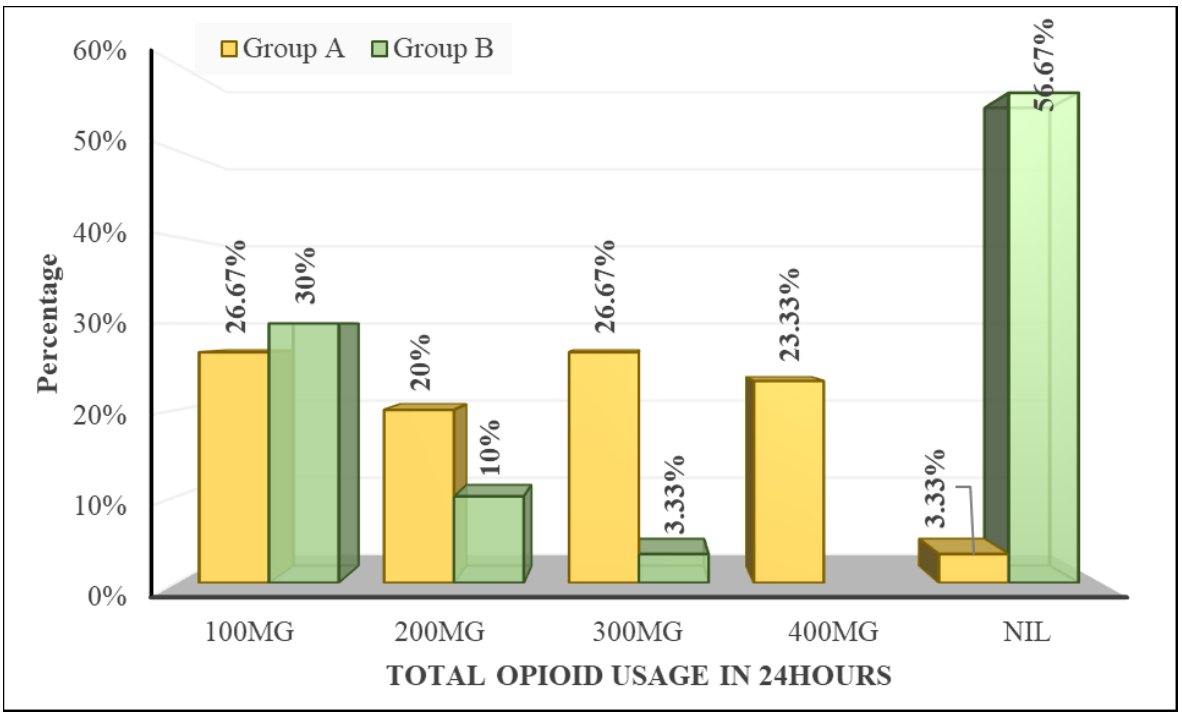


Figure 4 : Distribution of total opioid usage in 24hours over time in two groups.

The following table gives the comparison of analgesics used over group.

Table 7 : Comparing the use of analgesics in both the groups.

Time points	Analgesics used	Group A	Group B	Total	p-value
Post Extubation	NIL	30 (100%)	30 (100%)	60 (100%)	1C
0 min	100mg tramadol	1 (3.33%)	(0%)	1 (1.67%)	0.9999 MC
	NIL	29 (96.67%)	30 (100%)	59 (98.33%)	

2 hours	100mg Tramadol	8 (26.67%)	1 (3.33%)	9 (15%)	**0.0285 MC***
	NIL	22 (73.33%)	29 (96.67%)	51 (85%)	
4 hours	100mg Tramadol	8 (26.67%)	1 (3.33%)	9 (15%)	**0.0285 MC***
	NIL	22 (73.33%)	29 (96.67%)	51 (85%)	
6 hours	100mg Tramadol	17 (56.67%)	5 (16.67%)	22 (36.67%)	**0.0013 C***
	NIL	13 (43.33%)	25 (83.33%)	38 (63.33%)	
12 hours	100mg Tramadol	24 (80%)	7 (23.33%)	31 (51.67%)	**< 0.001 C ***
	NIL	6 (20%)	23 (76.67%)	29 (48.33%)	
24 hours	100mg Tramadol	15 (50%)	5 (16.67%)	20 (33.33%)	**0.0062 C***
	NIL	15 (50%)	25 (83.33%)	40 (66.67%)	

*Abbreviation: C – Chi square test, MC – Chi square test with Monte Carlo simulation, * indicates statistical significance.*

Initially, at post-extubation time point, all subjects in both “Group A” and “Group B” did not receive any analgesics (NIL). Hence statistical significance between the groups at this time point (p-value = 1) is none.

At 0 min, only 1 (3.33%) subject in group A received 100mg tramadol while no one in group B received analgesics. At this time point we observed no statistical significance between the groups (p-value = 0.9999).

As time progresses, significant differences emerge in the analgesics administered between the two groups. At two (2) hours, four (4) hours, six (6) hours, twelve (12) hours, and twenty-four (24) hours, Group A demonstrates a higher percentage of patients receiving 100mg tramadol compared to Group B. These differences showed statistical significance (p-values <0.05).

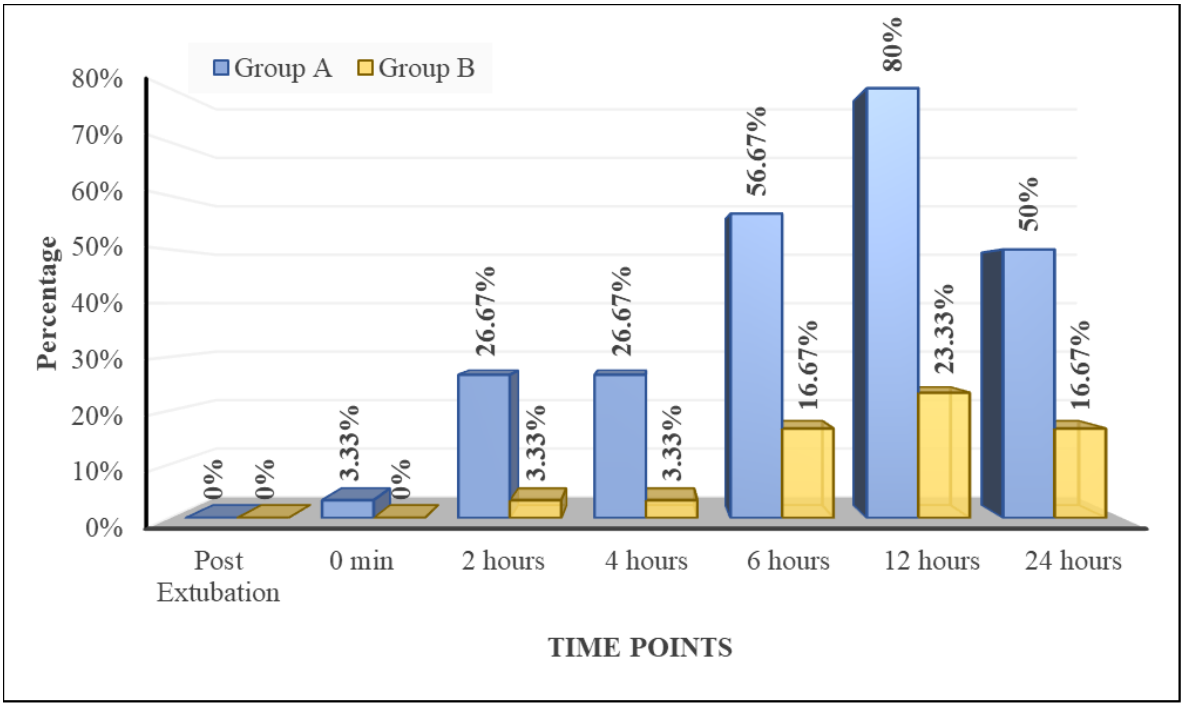


Figure 5 : Bar graph showing the distribution of analgesics used over time in two groups.

The following table gives the comparison of VAS over time and group.

Table 8 : table Comparing VAS over time in both the groups.

VAS	Group A	Group B	Total	p-value
Post extubation	0.27 ± 0.83 0 (0, 3)	0.03 ± 0.18 0 (0, 1)	0.15 ± 0.61 0 (0, 3)	0.2815^{MW}
0 min	0.8 ± 1.21 0 (0, 4)	0.83 ± 0.95 0.5 (0, 3)	0.82 ± 1.08 0 (0, 4)	0.5480^{MW}
2 hours	3.27 ± 1.11 3 (2, 5)	2.1 ± 0.88 2 (0, 4)	2.68 ± 1.16 3 (0, 5)	< **0.001^{MW}***
4 hours	3.8 ± 1.1 4 (2, 6)	2.27 ± 1.05 2 (0, 5)	3.03 ± 1.31 3 (0, 6)	< **0.001^{MW}***
6 hours	3.87 ± 0.94 4 (2, 6)	2.47 ± 1.07 2 (0, 4)	3.17 ± 1.22 3 (0, 6)	< **0.001^{MW}***
12 hours	3.97 ± 0.89 4 (2, 6)	2.83 ± 0.91 3 (1, 5)	3.4 ± 1.06 3.5 (1, 6)	< **0.001^{MW}***
24 hours	3.73 ± 0.87 4 (2, 5)	2.47 ± 1.04 2 (0, 5)	3.1 ± 1.15 3 (0, 5)	< **0.001^{MW}***
p-value	< **0.001^{F}***	< **0.001^{F}***	-	-

*Abbreviation: t – Two sample t test, MW – Mann Whitney U test, F – Friedman's test, * indicates statistical significance.*

Initially, at the post-extubation time point, there is a slight difference in VAS scores between Group A and Group B, but it does not reach statistical significance (p-value = 0.2815). Similarly, at 0 minutes, there is no significant difference (p-value = 0.5480). However, at two (2) hours, four (4) hours, six (6) hours, twelve (12) hours, and twenty-four (24)

hours, Group A consistently demonstrates higher mean VAS scores compared to Group B, with p-value < 0.001 at each time point. This observation is significant statistically.

Additionally, the Friedman test revealed significant increase in VAS over time within group A and group B (p-values < 0.001).

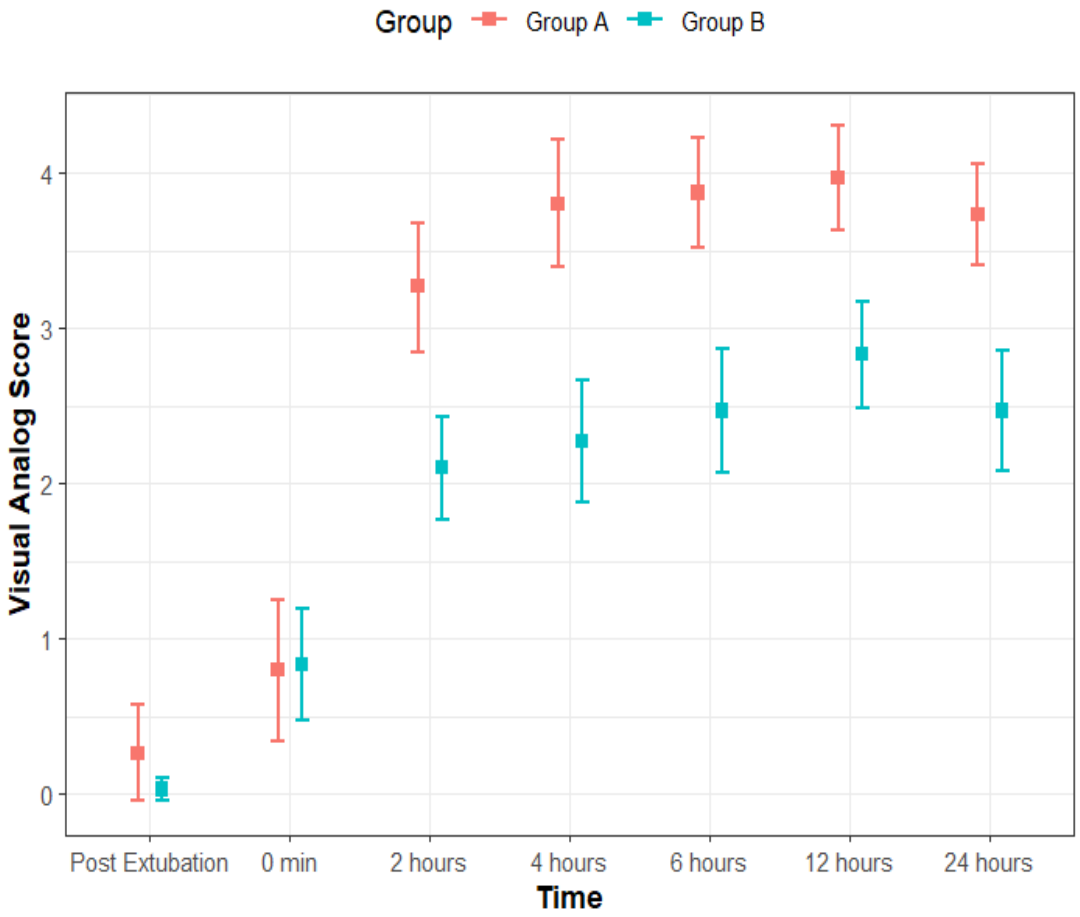


Figure 6 : Mean plot of VAS over time in two groups.

The following table gives the comparison of heart rate over time in two groups.

Table 9 : Comparing (HR) heart rate over time in both the groups.

HR	Group A	Group B	Total	p-value
Post extubation	77.63 ± 8.37 78 (62, 90)	75.17 ± 9.52 76 (58, 96)	76.4 ± 8.98 77 (58, 96)	0.2911^{t}
0 min	79.1 ± 8.02 81 (64, 92)	76.6 ± 9.3 78 (55, 92)	77.85 ± 8.7 78.5 (55, 92)	0.2536^{MW}
2 hours	81.7 ± 7.24 82 (64, 97)	77.03 ± 9.02 78 (60, 99)	79.37 ± 8.45 80 (60, 99)	**0.0311^{t}***
4 hours	82.13 ± 6.33 82 (65, 90)	76.5 ± 8.99 78 (60, 94)	79.32 ± 8.22 82 (60, 94)	**0.0058^{MW}***
6 hours	83.47 ± 7.28 86 (66, 94)	77.33 ± 9.28 78 (58, 96)	80.4 ± 8.83 82 (58, 96)	**0.0046^{MW}***
12 hours	81.9 ± 7.35 83.5 (66, 96)	76.93 ± 7.79 78 (62, 92)	79.42 ± 7.92 80 (62, 96)	**0.0137^{t}***
24 hours	82.63 ± 7.52 84 (68, 98)	77.37 ± 7.12 79.5 (64, 90)	80 ± 7.73 82 (64, 98)	**0.0072^{t}***
p-value	**< 0.001^{F}***	0.2385^{F}	-	-

*Abbreviation: t – Two sample t test, MW – Mann Whitney U test, F – Friedman's test, * indicates statistical significance.*

Initially, at post-extubation, Group A exhibits a slightly higher mean heart rate of 77.63 ± 8.37 bpm compared to Group B's mean heart rate of 75.17 ± 9.52 bpm. This observation is of no statistical significance (p-value = 0.2911). Similarly, at 0 minutes, Group A has a mean heart rate of 79.1 ± 8.02 bpm, whereas Group B has a mean heart rate of 76.6 ± 9.3 bpm, with no significant difference (p-value = 0.2536).

However, as time progresses, significant differences emerge. At two (2) hours, four (4) hours, six (6) hours, twelve (12) hours, and twenty-four (24) hours, Group A consistently exhibits higher mean heart rates compared to Group B, with p-values at each time point < 0.05. This indicates the finding is statistically significant.

Additionally, the Friedman test revealed significant increase in heart rate over time within “Group A” (p-value < 0.001) but not within “Group B” (p-value = 0.2385).

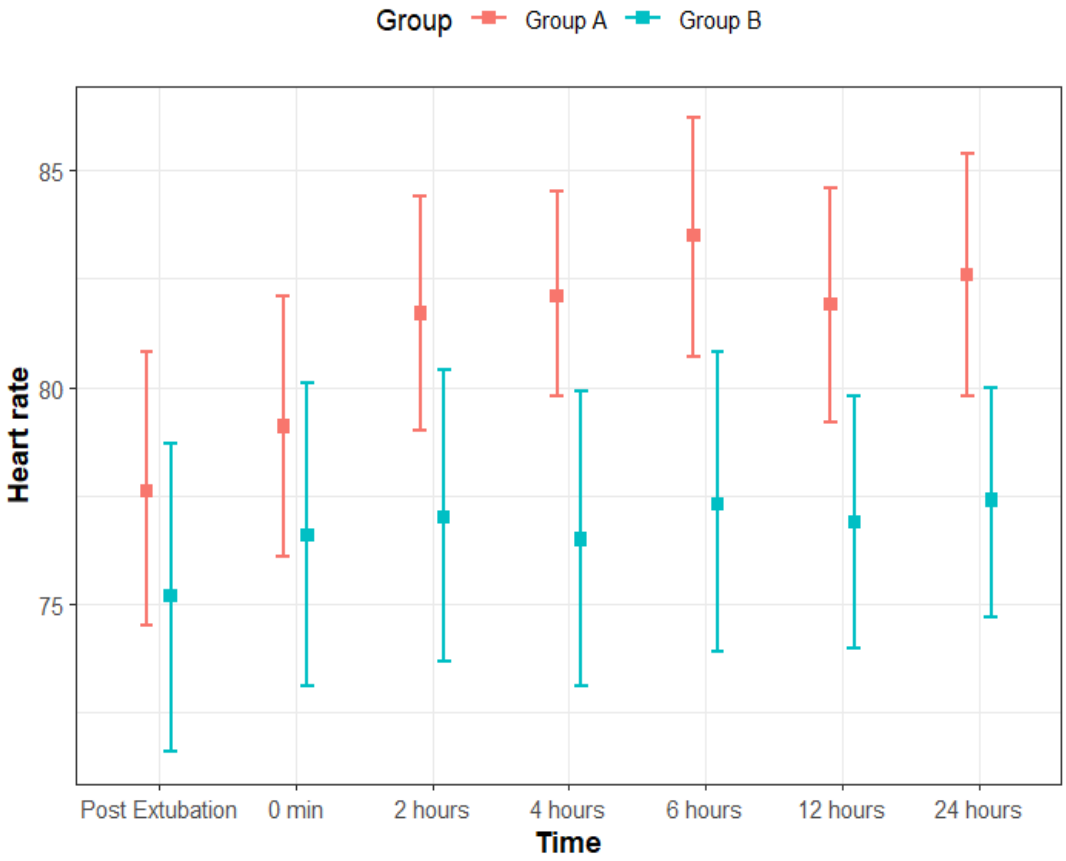


Figure 7 : Plotting the of mean HR over time in both the groups.

The following table compares the SBP (systolic blood pressure) over time in both groups.

Table 10 : Comparing SBP (systolic blood pressure) over time in both the groups.

SBP	Group A	Group B	Total	p-value
Post extubation	123.67 ± 15.2 130 (100, 150)	119.33 ± 12.58 120 (90, 140)	121.5 ± 14 120 (90, 150)	0.2737[MW]
0 min	126.67 ± 12.69 130 (100, 150)	118 ± 11.26 120 (100, 140)	122.33 ± 12.67 120 (100, 150)	**0.0072[MW*]**
2 hours	129.67 ± 15.64 130 (100, 160)	119.67 ± 11.59 120 (100, 140)	124.67 ± 14.55 120 (100, 160)	**0.0105[MW*]**
4 hours	129.67 ± 17.12 130 (100, 170)	121 ± 12.13 120 (100, 140)	125.33 ± 15.35 130 (100, 170)	**0.0349[MW*]**
6 hours	129.33 ± 12.58 130 (110, 150)	120.67 ± 12.58 120 (100, 150)	125 ± 13.21 120 (100, 150)	**0.0124[MW*]**
12 hours	130.53 ±	120.33 ±	125.43 ±	**0.0011[M]**

	11.4 130 (110, 156)	11.29 120 (100, 150)	12.37 130 (100, 156)	**^{W*}**
24 hours	129.67 ± 13.26 130 (100, 160)	120.67 ± 10.81 120 (100, 140)	125.17 ± 12.82 125 (100, 160)	**0.0089^{M}** **^{W*}**
p-value	0.1825^{F}	0.7638^{F}	-	-

*Abbreviation: MW – Mann Whitney U test, F – Friedman's test, * indicates statistical significance.*

Initially, at post-extubation, Group A exhibits a slightly higher SBP compared to Group B. However, this difference is not statistically significant (p-value = 0.2737). However, as time progresses, significant differences emerge. At 0 mins, two (2) hours, four (4) hours, six (6) hours, twelve (12) hours, and twenty-four (24) hours Group A consistently exhibits higher mean SBP compared to Group B, with p-values < 0.05 at each time point. This indicates the observation is significant statistically.

The Friedman test indicates that there is no significant increase in SBP over time within both "Group A" (p-value = 0.1825) and "Group B" (p-value = 0.7638).

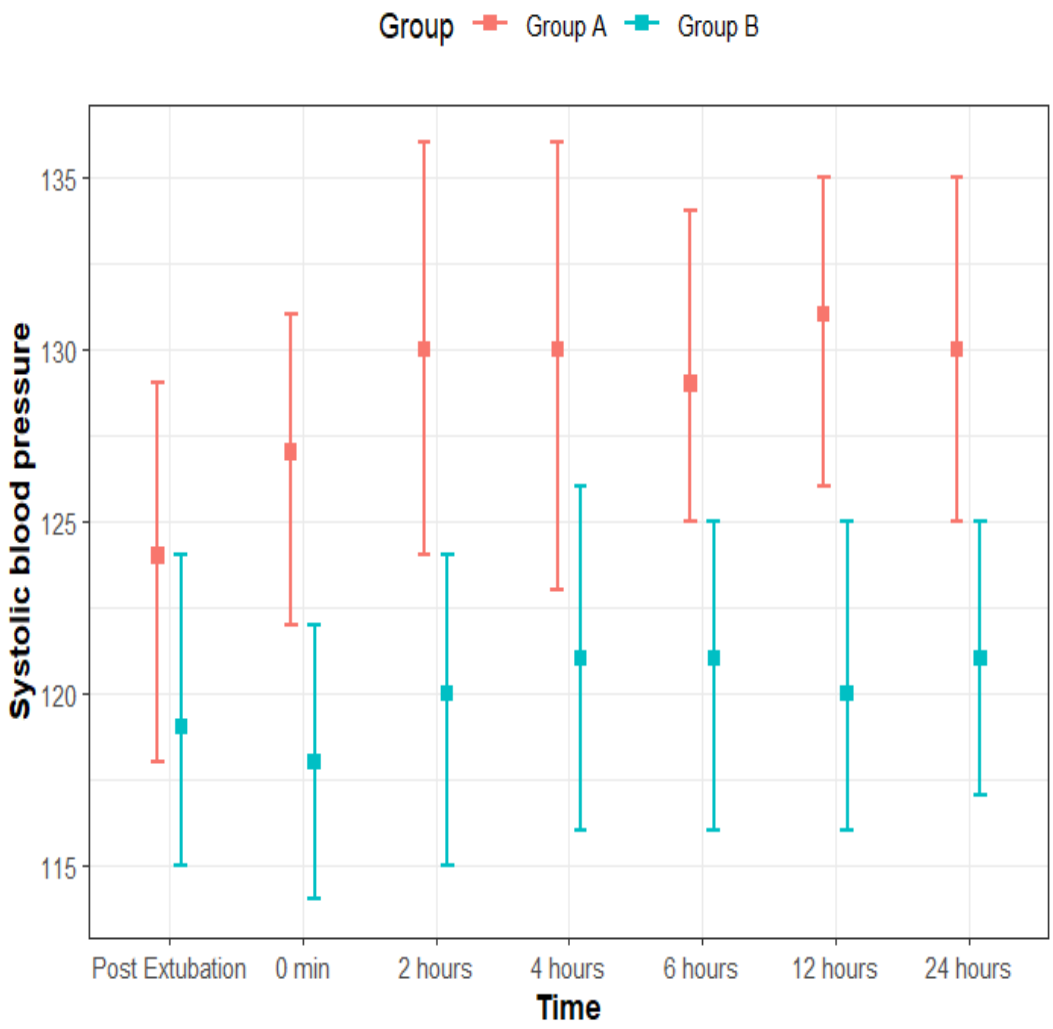


Figure 8 : Mean plot of SBP over time in two groups.

The following table compares (DBP) diastolic blood pressure over time in both the groups.

Table 11: Comparing (DBP) diastolic blood pressure over time in both the groups.

DBP	Group A	Group B	Total	p-value
Post extubation	78.3 ± 10.46 80 (60, 99)	73.67 ± 9.28 70 (60, 90)	75.98 ± 10.08 80 (60, 99)	0.0918^{MW}
0 min	77.33 ± 8.68 80 (60, 90)	73.33 ± 9.59 75 (50, 90)	75.33 ± 9.29 80 (50, 90)	0.1412^{MW}
2 hours	80.33 ± 9.64 80 (60, 90)	74.67 ± 8.6 75 (60, 90)	77.5 ± 9.5 80 (60, 90)	**0.0191^{MW} ***
4 hours	78.33 ± 7.91 80 (70, 90)	74.67 ± 6.81 75 (60, 90)	76.5 ± 7.55 80 (60, 90)	0.1077^{MW}
6 hours	82 ± 8.87 85 (70, 90)	77 ± 10.88 80 (60, 110)	79.5 ± 10.16 80 (60, 110)	**0.0322^{MW} ***
12 hours	80.33 ± 9.28 80 (60, 90)	76.63 ± 10.27 80 (60, 90)	78.48 ± 9.88 80 (60, 90)	0.1407^{MW}
24 hours	80.67 ± 9.44 80 (60, 90)	78.67 ± 8.6 80 (60, 90)	79.67 ± 9.01 80 (60, 90)	0.3189^{MW}
p-value	0.5001^{F}	0.0756^{F}	-	-

*Abbreviation: t – Two sample t test, MW – Mann Whitney U test, F – Friedman's test, * indicates statistical significance.*

Initially. at post-extubation, there is a slight difference in DBP between Group A and Group B, but it does not reach statistical significance (p-value = 0.0918). Similarly, at 0 minutes, there is no significant difference

(p-value = 0.1412). However, as time progresses, distinct patterns emerge. At 2 hours and 6 hours, Group A showed higher mean DBP compared to Group B, with p-values < 0.05 at these time points. This indicates the findings are statistically significant. At four (4) hours, twelve (12) hours and twenty-four (24) hours, the difference in DBP between both the groups is of no significance,

The Friedman test indicates that there is no significant increase in DBP over time within both “Group A” (p-value = 0.5001) and “Group B” (p-value = 0.0756).

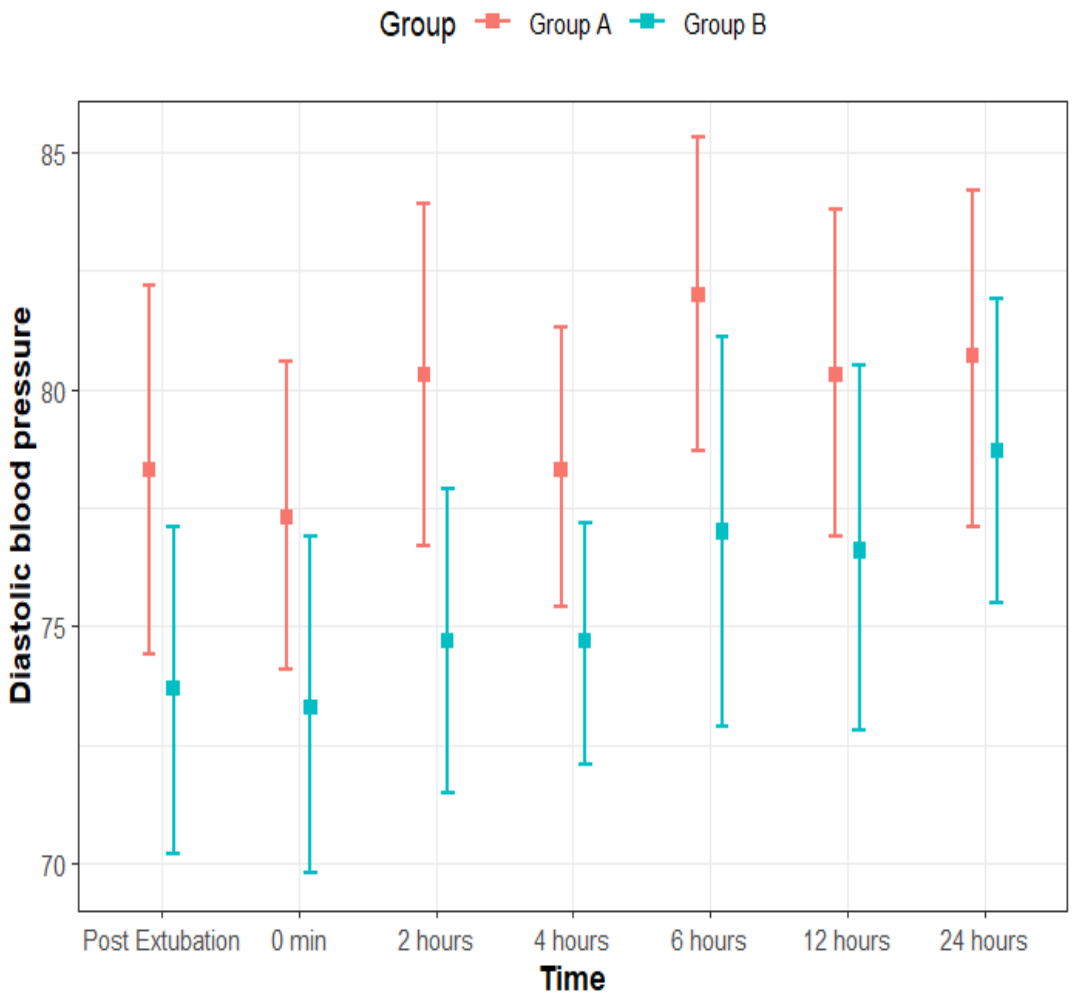


Figure 9 : The plot showing mean DBP over time in two groups.

DISCUSSION

One of the concerning issues with Lumbar spine surgeries is, it is associated with intense pain immediately after the surgical procedure, especially in the first twenty-four-hour postoperative period. This is due to the extensive anatomical dissection involved in the surgery. Inadequate post-operative analgesic control is associated with respiratory and cardiac complications, delay in ambulation of the patient, which is further associated with increased risk of DVT, lengthened hospital admissions and poor patient satisfaction.

Conventionally postoperative pain has been treated with intravenous opioids, but increased use of opioids is known to be associated with undesired effects like sedation, nausea, vomiting, respiratory depression[30].

There is emergence of new regional anesthetic techniques like ultrasound guided ESPB, Thoracolumbar Plane block[34] and other interfacial blocks which are not only easier to perform but are also associated with minimal complications and provide excellent analgesia.

The clinical trial comprised of 60 patients, between the age of Eighteen to Sixty-five years belonging to American Society of Anaesthesiologists Grade I & American Society of Anaesthesiologists Grade II, who were listed for elective lumbar spine surgeries under General Anaesthesia and were randomly segregated equally into two cohorts (Thirty subjects in each group).

Following the administration of General Anaesthesia ESP block was given with 25ml of "0.5% Ropivacaine" and "50mcg Fentanyl" in "GROUP A" and 25ml of "0.5% Ropivacaine" with "50mcg Dexmedetomidine" in "GROUP B". The volume of the drug to be injected was decided in reference to the evidence provided by Yong qiu et al[35]. in their article published in 2020 and from review article published by Serkan Tulgar et al[16].

In the current study both the groups were comparable with respect to the demographic data with no statistical significance.

In this clinical trial we found that Group B shows a significantly lengthened duration of analgesia with about 17.8 hours mean time (ranging from 2 to 24 hours) for the first rescue analgesia. This correlates with observations in the study published by Kathuria et al. where supraclavicular brachial plexus block was performed using Dexmedetomidine as an additive to Ropivacaine[10].

Group A exhibits a notably shorter duration of time for the administration of first dose of rescue analgesic, with 4.93 hours mean time (ranging from 2 to 12 hours).

In our study we compared the difference in amount of opioid consumption in both groups. The total twenty-four-hour postoperative consumption of opioids is significantly low in GROUP B (56.67%) of them did not require any opioids) compared to GROUP A (only 3.33% of the patients in group A did not require any opioids) (p-value < 0.001).

This correlates with the observations found in the trial conducted by Jian C et al. and Kathuria et al. Where addition of dexmedetomidine to ropivacaine has reduced the consumption of opioids[10].

In GROUP B where combination of Ropivacaine with Dexmedetomidine was used, the postoperative VAS scores were continuously lower. These findings were similar to the observations found in the clinical study done by Gao Z et al. where dexmedetomidine was used as an adjuvant for ESP block for VATS lobectomy[27].

Whereas Group A consistently demonstrated significantly higher mean VAS scores compared to Group B (p-value < 0.001).

In clinical study we also observed that the patients receiving Dexmedetomidine as adjuvant in ESP block showed more stable hemodynamic parameters postoperatively when compared to that of the group receiving fentanyl.

The strengths of the study are:

1. The ease of performance of the block.
2. No complications in relation to the procedure or drugs were observed.
3. Excellent analgesia resulting in early mobilization of the patient.
4. Good patient satisfaction.

The limitations of our study are:

1. The dose of Dexmedetomidine and Fentanyl were fixed and were not adjusted according to the weight which might have led to some bias in duration of the block.
2. Though mean duration of surgeries did not exceed more than 3 hours the duration of surgery in each case was not taken into consideration.

CONCLUSION

In our clinical trial titled, "THE EFFECT OF ULTRASOUND GUIDED ERECTOR SPINAE BLOCK USING ROPIVACAINE WITH FENTANYL, ROPIVACAINE WITH DEXMEDETOMIDINE ON POSTOPERATIVE PAIN AND OPIOID CONSUMPTION IN PATIENTS UNDERGOING LUMBAR SPINE SURGERIES"

Based on the above discussed findings we conclude that, use of Dexmedetomidine as an adjuvant to Ropivacaine in Ultrasound guided Erector Spinae Plane Block, is superior to the use of Fentanyl as an adjuvant in providing longer duration of action of ESPB and reducing the overall twenty-four-hour opioid consumption and in maintaining stable hemodynamic parameters postoperatively with lower VAS scores.

SUMMARY

In this clinical trial 60 patients of either sex belonging to ASA I & II posted for elective lumbar spine surgery under general anesthesia were divided into two groups, GROUP A and GROUP B via computer generated randomization.

After the induction of general anesthesia, USG guided Erector Spinae Plane Block was given with respective drug combinations i.e. Ropivacaine with "Fentanyl" (GROUP-A) and Ropivacaine with "Dexmedetomidine" (GROUP-B). The duration of block and total 24hour opioid consumption in both the groups was compared.

We observed that:

1. The age and gender distribution were comparable between the two groups.
2. ESPB using Ropivacaine with Dexmedetomidine (GROUP-B) shows a significantly longer duration, with a mean time of 17.8 hours (ranging from 2 to 24 hours) for the first rescue analgesia.
3. Whereas the ESP block using Ropivacaine with Fentanyl (GROUP-A) exhibits a notably shorter time duration for the first

rescue analgesia, with a mean time of 4.93 hours (ranging from 2 to 12 hours).

4. It was observed that the total 24 opioid consumption in “GROUP A” was significantly higher when compared with “GROUP B”.
5. Group A demonstrates consistently higher mean VAS scores compared to Group B, with p-values indicating statistical significance at each time point.
6. We further observed that postoperatively the mean HR values and mean SBP values over time are significantly lower within “GROUP B” when compared to that of “GROUP A”.

Therefore, based on observations discussed throughout our trial we conclude that adding Dexmedetomidine to Ropivacaine has increased duration of action of ESPB, significantly brought down the opioid dosage requirement while providing excellent analgesia for 24 hours postoperatively after lumbar spine surgeries with better postoperative hemodynamic control as well.

BIBLIOGRAPHY

1. Forero M, Adhikary SD, Lopez H, Tsui C, Chin KJ. The erector spinae plane block: A novel analgesic technique in thoracic neuropathic pain. Reg Anesth Pain Med. 2016;41:621–7.
2. Goel VK, " Clinical efficacy of ultrasound guided bilateral erector spinae block for single-level lumbar fusion surgery: a prospective, randomized, case-control study.," The Spine Journal. 2021 Nov 1;21(11):1873-80.
3. Singh S and 31(3):354., "Bilateral ultasound guided erector spinae plane block for postoperative pain management in lumbar spine surgery: a case series.," Journal of neurosurgical anesthesiology. 2019 Jul 1;31(3):354.
4. Kanojia N and 34(3):202., "Efficacy of ultrasound guided bilateral single shot erector spinae plane block for post-operative analgesia in patients undergoing lumbar spine surgery.," Indian Journal of Pain. 2020 Sep 1;34(3):202.
5. Van den Broek RJ and 11, " Evaluation of adding the Erector spinae plane block to standard anesthetic care in patients undergoing posterior lumbar interbody fusion surgery.," Scientific Reports. 2021 Apr 7;11(1):1-6.

6. Cirenei C and 150:e585-90., "Effectiveness of Bilateral Ultrasound-Guided Erector Spinae Plane Block in Percutaneous Lumbar Osteosynthesis for Spine Trauma: A Retrospective Study," World Neurosurgery. 2021 Jun 1;150:e585-90.
7. Zhang S and 21(1):1-8., "The effects of erector spinae plane block on perioperative opioid consumption and rehabilitation in video assisted thoracic surgery.," BMC anesthesiology. 2021 Dec;21(1):1-8.
8. Krishna Prasad GV, Khanna S, Jaishree S, Vipin S. Review of adjuvants to local anesthetics in peripheral nerve blocks: Current and future trends.
9. Yoshitomi T, Kohjitani A, Maeda S, Higuchi H, Shimada M, Miyawaki T. Dexmedetomidine enhances the local anesthetic action of lidocaine via an α-2A adrenoceptor. Anesth Analg. 2008;107(1):96-101.
10. Kathuria S, Gupta S, Dhawan I. Dexmedetomidine as an adjuvant to ropivacaine in supraclavicular brachial plexus block. Saudi J Anaesth. 2015 Apr-Jun;9(2):148-54.

11. Esmaoglu A, Yegenoglu F, Akin A, Turk CY. Dexmedetomidine added to levobupivacaine prolongs axillary brachial plexus block. Anesth Analg. 2010;111(6):1548-51.
12. Gandhi R, Shah A, Patel I. Use of dexmedetomidine along with bupivacaine for brachial plexus block. Natl J Med Res. 2012;2(1):67-69.
13. Kirksey MA, Haskins SC, Cheng J, Liu SS. Local anesthetic peripheral nerve block adjuvants for prolongation of analgesia: A systematic qualitative review. PLoS One. 2015;10(9).
14. Chotani MA, Mitra S, Su BY, Flavahan S, Eid AH, Clark KR, et al. Regulation of alpha(2)-adrenoceptors in human vascular smooth muscle cells. Am J Physiol Heart Circ Physiol. 2004;286(1).
15. Chin KJ, El-Boghdadly K. Mechanisms of action of the erector spinae plane (ESP) block: a narrative review. Can J Anaesth. 2021 Mar;68(3):387-408.
16. Tulgar S, Aydin ME, Ahiskalioglu A, De Cassai A, Gurkan Y. Anesthetic techniques: Focus on lumbar erector spinae plane block. Local Reg Anesth. 2020;13:121-33.

17. Kolli S, Narouze S, Kalagara H. How I do it: Neuraxial ultrasound. ASRA News. 2021;46:10.52211/asra110121.068.
18. Sethuraman RM. Erector spinae plane block in spine surgeries: Single-level versus bi-level, single-shot versus continuous catheter technique. Saudi J Anaesth. 2024;18(1):105-7.
19. Philo R. Gray's Anatomy for Students, 2nd Ed. by Richard L. Drake, A. Wayne Vogl, and Adam W. M. Mitchell. Clin Anat. 2009;22(7):846-7.
20. Sinnatamby CS. Last's anatomy: regional and applied, 12th edn. Ann R Coll Surg Engl. 2013;95(3):230.
21. Bushberg JT, Boone JM. The Essential Physics of Medical Imaging. Wolters Kluwer Health; 2011.
22. Heggie JCP, Liddell NA, Maher KP, St.Vincent's Hospital (Melbourne Vic). Applied Imaging Technology. St.Vincent's Hospital; 2001.
23. Goyal A, Kalgudi P, Sriganesh K. Ultrasound-guided erector spinae plane block for perioperative analgesia in cervical and thoracic spine surgeries: A case series. Neurol India. 2021;69(2):487-9.

24. Lawrence JT, London N, Bohlman HH, et al. Preoperative narcotic use as a predictor of clinical outcome: Results following anterior cervical arthrodesis. Spine (Phila Pa 1976). 2008;33:2074-8.
25. Wang X, Ran G, Chen X, Xie C, Wang J, Liu X, et al. The effect of ultrasound-guided erector spinae plane block combined with dexmedetomidine on postoperative analgesia in patients undergoing modified radical mastectomy: A randomized controlled trial. Pain Ther. 2021;10(1):475–84.
26. Clinton JD, McGirt MJ. Best evidence in multimodal pain management in spine surgery and means of assessing postoperative pain and functional outcomes. J Clin Neurosci. 2015;22(6):930-8.
27. Gao Z, Xiao Y, Wang Q, Li Y. Comparison of dexmedetomidine and dexamethasone as adjuvant for ropivacaine in ultrasound-guided erector spinae plane block for video-assisted thoracoscopic lobectomy surgery: A randomized, double-blind, placebo-controlled trial. Ann Transl Med. 2019;7(22):668.
28. Jian C, Shen Y, Fu H, Yu L. Effects of ultrasound-guided erector spinae plane block with dexmedetomidine combined with ropivacaine of the same dose and different concentrations on analgesic effect and rehabilitation quality of patients undergoing thoracoscopic wedge

resection of the lung: A prospective, randomized, controlled trial. BMC Anesthesiol. 2022;22(1):225.

29. Farooq N, Singh RB, Sarkar A, Rasheed MA, Choubey S. To evaluate the efficacy of fentanyl and dexmedetomidine as adjuvant to ropivacaine in brachial plexus block: A double-blind,prospective, randomized study. Anesth Essays Res. 2017;11(3):730-9.
30. Devin CJ, McGirt MJ. Best evidence in multimodal pain management in spine surgery and means of assessing postoperative pain and functional outcomes. J Clin Neurosci. 2015;22(6):930-8.
31. Haefeli M, Elfering A. Pain assessment. Eur Spine J. 2006 Jan;15 Suppl 1(Suppl 1):S17-24.
32. Stoeltings physiology and pharmacology-5th edition.
33. Gabriella Iohom, Clinical assessement of postoperative pain, Postoperative pain management,W.B.Saunders,2006.
34. Ciftci B, Ekinci M, Celik EC, Yayik AM, Aydin ME, Ahiskalioglu A.Ultrasound-Guided Erector Spinae Plane Block versus Modified-Thoracolumbar Interfascial Plane Block for Lumbar Discectomy Surgery: A Randomized, Controlled Study. World Neurosurgery. 2020 Dec;144:e849–55.

35. Qiu Y, Zhang TJ, Hua Z. Erector Spinae Plane Block for Lumbar Spinal Surgery: A Systematic Review. J Pain Res. 2020 Jul 1;13:1611-1619.

ANNEXURES

ANNEXURE 1 –

INFORMED CONSENT FOR PARTICIPATION IN RESEARCH STUDY

Mr. /Mrs. /Miss._____we are requesting you to enroll you in the study titled **"THE EFFECT OF ULTRASOUND GUIDED ERECTOR SPINAE BLOCK USING ROPIVACAINE WITH FENTANYL, ROPIVACAINE WITH DEXMEDETOMIDINE ON POSTOPERATIVE PAIN AND OPIOID CONSUMPTION IN PATIENTS UNDERGOING LUMBAR SPINAL SURGERIES A ONE YEAR RANDOMISED CLINICAL TRIAL.**

Respected Sir/Madam, we request you to participate in our study as you are eligible for it. During the study you will be asked some questions regarding your medical history and you are supposed to answer to the best of your knowledge.Your participation in this research is voluntary. Your decision whether or not to participate in the study will not affect your relationship with J.N. Medical College. If you decide to participate you are free to withdraw at any time.

Purpose of the study:

The purpose of research is to **compare the duration of analgesia and** the total 24-hour opioid consumption **in ultrasound guided Erector Spinae block using Ropivacaine with Fentanyl (GROUP-A) and Ropivacaine with Dexmedetomidine (GROUP-B) in patients undergoing lumbar spine surgeries under general** anesthesia.

Procedure Involved:

If you agree to enrolled in my study, I will ask you present, past and family history. Then you will be clinically examined in detail. You will be allotted into one of the two groups randomly using computer generated software. Group A will include patients in whom the block will be performed using Ropivacaine with Fentanyl. Group B will include patients in whom the block will be performed using Ropivacaine with Dexmedetomidine.Prior to being shifted in the main operating room, you will be examined thoroughly. After being shifted into the OT and induced for GA, the block will be given with the drug combination as per your assigned group.

Voluntary Participation/Withdrawal:

Taking part in the study is voluntary. You may choose not to enroll yourself in this study. Your decision will not change any health care services offered to you or your ward at K.L.E. S Hospital & MRC.

Benefits:

By inflating the cuff with the drugs mentioned can significantly reduce the incidence and severity of postoperative sore throat, hoarseness, and cough and improves patient comfort during recovery from general anesthesia with endotracheal intubation. Thereby potentially shortening hospital stays and reducing healthcare costs. This research provides evidence supporting the use of intracuff lignocaine over dexamethasone and normal saline, guiding anesthesiologists in choosing more effective agents for postoperative care.

Privacy and Confidentiality:

The only people to know that you are as research subject are you and members of the research team. No information provided by you during the research will be disclosed to other without your written permission except:

1. In emergency to protect your rights and welfare.
2. If required by law.

Authorization to Publish Results:

When the results of the research are published or discussed, in a conference, no information will be displayed that would disclose your identity. Any information that is obtained in connection with this study and that can be identified with your identity remaining confidential.

Financial Incentives for participation:

No financial incentives are being offered to enrolled patients. It is purely being done with the idea of research and all the cost of the study will be borne by the investigator. The patient shall bear no cost for the purposes of the study.

Compensation:

In the event of injury related to the study, treatment will be made available through KLES Hospital and MRC, Belagavi. There is no compensation or payment for such medical treatment by law.

Questions:

If you have any queries about your rights as a study subject, you may call Dr. Harsha Hegde, Chairperson, JNMC IEC, Scientist 'D' Indian

Council for Medical Research, National Institute of Traditional Medicine Belagavi, Mobile: +91-94804225001.

INFORMED CONSENT STATEMENT

I Mr./Ms./Mrs. _____ am making a voluntary decision to participate in the study "**THE EFFECT OF ULTRASOUND GUIDED ERECTOR SPINAE BLOCK USING ROPIVACAINE WITH FENTANYL, ROPIVACAINE WITH DEXMEDETOMIDINE ON POSTOPERATIVE PAIN AND OPIOID CONSUMPTION IN PATIENTS UNDERGOING LUMBAR SPINAL SURGERIES-A ONE YEAR RANDOMISED CLINICAL TRAIL**". voluntarily agree for the participation of as a subject of study. By signing this consent form, I am not giving up any of my legal rights, I may withdraw from the study anytime. I am signing the consent form after having read or been read for me in vernacular language, including the risks and the benefits and having all my questions answered.

Name of the participant:

Signature or left thumb impression of the participant:

Name of the witness:

Signature or left thumb impression of the witness:

Name of the investigator:

Signature of the investigator:

ANNEXURE 2 - PROFORMA

"THE EFFECT OF ULTRASOUND GUIDED ERECTOR SPINAE BLOCK USING ROPIVACAINE WITH FENTANYL, ROPIVACAINE WITH DEXMEDETOMIDINE ON POSTOPERATIVE PAIN AND OPIOID CONSUMPTION IN PATIENTS UNDERGOING LUMBAR SPINAL SURGERIES- A ONE YEAR RANDOMISED CLINICAL TRAIL" AT DR. PRABHAKAR KORE CHARITABLE HOSPITAL, BELAGAVI"

Group allotted :

Name	:	Age	:
Gender	:	Weight	:
Height	:	Date of Examination	:
Address	:	Occupation	:

Pre examination evaluation

Past History

- HTN ☐ DM ☐ IHD ☐ Arrhythmia ☐
  Valvular heart diseases ☐

- H/o previous surgery/(s) where airway difficulty will be encountered.
  Yes ☐ No ☐

General physical examination

Weight (Kg)	:	Temperature (^{0}F)	:	Pallor	:
Cyanosis	:	Pedal edema	:	Clubbing	:
PR	:	BP	:	RR	:

Musculoskeltal system

Teeth:	Jaw movements:
Airway assessment :	Spine:

Investigations

Hb%: Platelet Count :

TLC: INR:

FBS:

Systemic examination

CNS: RS:

CVS: GIT:

Preoperative physical status - American society of anesthesiologist **:** I ☐

II ☐

Diagnosis:

Proposed surgery:

Monitors attached:

Pulse oximetry:

NIBP:

ECG:

INTRAOPERATIVE PARAMETERS:

PARAMETERS	BEFORE BLOCK	AFTER BLOCK			
		5 MINS	10 MINS	15 MINS	20 MINS
Heart Rate					
Systolic blood pressure					
Diastolic blood pressure					
Mean arterial blood pressure					
Spo2					

POST OPERATIVE PARAMETERS:

Group A/B	**Time**	**Blood pressure**	**Heart rate**	**VAS score**	**Opioid usage**
	Post extubation				
	Immediate post op				
	2 hours				
	4 hours				
	6 hours				
	12 hours				
	24 hours				

ANNEXURE 3 – PHOTOGRAPHS

PHOTO 1 – ULTRASOUND MACHINE

PHOTO 2 - USG PROBE AND LOCAL ANAESTHETIC ROPIVACAINE

PHOTO 3 - ADDITIVES OF GROUP A –FENTANYL AND GROUP B - DEXMEDETOMIDINE

PHOTO 4 - EQUIPMENT USED TO PERFORM THE BLOCK

PHOTO 5a - POINT OF INSERTION OF NEEDLE

PHOTO 5b- SEPEARTION PF PLANE WITH DRUG INJECTION OF DRUG

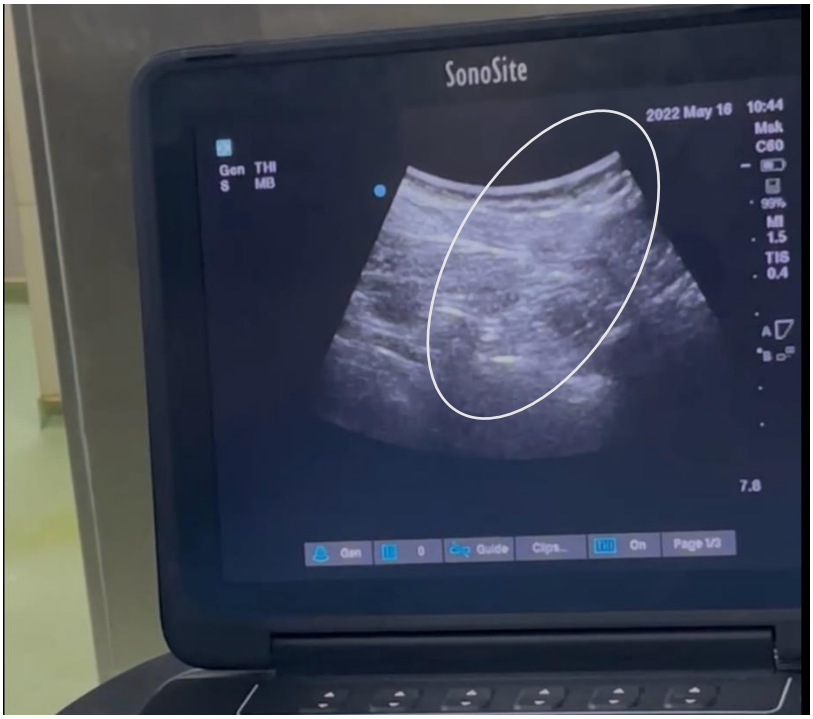


PHOTO 6a- TRAJECTORY OF NEEDLE

PHOTO 6b - SEPARATION OF PLANE WITH INJECTION OF DRUG

ANNEXURE 4 – MASTER CHART (GROUP-A)

| GROUP B - ROPIVACAINE WITH DEXMEDETOMIDINE | | |

ANNEXURE 4 – MASTER CHART (GROUP-B)

GROUP A - ROPIVACAINE WITH FENTANYL

Sno	Patient Name	Age	Sex	IP no	Heart Rate							Blood Pressure							Visual Analog Score						Opioid Analgesics Used					duration of block	
					post extubation	0mins	2hours	4hours	6hours	12hours	24hours	post extubation	0mins	2hours	4hours	6hours	12hours	24hours	post extubation	0mins	2hours	4hours	6hours	12hours	24hours	0mins	2hours	4hours	6hours	12hours	24hours	duration of block	depen total opioid usage in 24hours
1	Mahabub ali	32	M	11230279	66	64	72	74	68	66	68	110/70	130/80	140/90	130/70	150/90	165/80	140/90	NIL	NIL	NIL	NIL	100mg Tramadol	100mg Tramadol	100mg Tramadol	2 hours post op	300mg						
2	Jyotappa mariakapure	63	M	11236807	90	88	97	88	92	87	82	150/80	140/70	130/90	140/80	140/80	130/90	140/80	NIL	NIL	NIL	NIL	100mg Tramadol	100mg Tramadol	100mg Tramadol	6hours post op	300mg						
3	Basappa Karenpanavar	37	M	1152311	84	83	82	84	86	82	80	140/80	130/70	140/70	150/90	140/70	130/90	130/70	NIL	NIL	100mg tramadol	NIL	NIL	NIL	NIL	4 hours post op	100mg						
4	Ratan singh	51	M	11234453	82	84	80	86	86	83	84	140/70	130/80	130/90	130/80	130/80	130/90	130/70	0	0	0	2	2	2	NIL	Nil	100mg tramadol	Nil	NIL	6 hours post op	100mg		
5	Meena	50	F	1141831	78	82	86	84	86	86	86	130/90	130/90	140/90	130/70	120/90	120/70	130/80	0	2	3	3	3	5	NIL	NIL	100mg tramadol	100mg tramadol	100mg tramadol	6hours post op	300mg		
6	kempanna kurbet	60	M	11443693	76	82	80	84	84	82	82	110/80	130/70	120/90	120/80	130/80	130/80	130/70	2	2	3	5	5	4	NIL	NIL	100mg tramadol	100mg tramadol	100mg tramadol	4hours post op	300mg		
7	Gayatri Badiger	65	F	11446661	66	64	66	65	66	69	72	130/90	140/80	130/80	140/80	140/80	130/70	120/90	0	0	0	3	4	4	NIL	NIL	100mg tramadol	NIL	NIL	4hours post op	100mg		
8	Basaveraj rotagi	50	M	11219849	66	64	78	82	83	85	88	130/70	130/80	130/70	120/70	120/70	130/60	140/90	0	0	5	5	4	4	NIL	100mg tramadol	NIL	100mg tramadol	100mg tramadol	2hours post op	400mg		
9	Uday kamble	57	M	11539493	74	76	82	82	86	80	84	140/80	130/90	140/80	140/70	130/70	130/90	120/90	0	3	3	4	3	4	NIL	100mg tramadol	100mg tramadol	NIL	100mg tramadol	4hours post op	200mg		
10	Savitri toragal	42	F	11362230	90	84	86	86	85	84	86	130/90	120/90	130/70	140/70	130/70	130/90	130/70	0	0	3	4	3	4	NIL	100mg tramadol	Nil	NIL	100mg tramadol	4hours post op	200mg		
11	Indubai naik	39	F	11516227	78	86	84	80	82	84	84	110/60	110/70	110/80	110/80	110/80	120/90	120/80	0	0	2	4	3	3	NIL	Nil	100mg tramadol	Nil	NIL	4hours post op	100mg		
12	Jimmu shelaka	45	M	1143018	76	78	84	82	84	82	84	120/70	130/80	130/90	130/70	120/90	130/80	130/80	0	0	3	5	5	4	NIL	NIL	100mg tramadol	100mg tramadol	NIL	4hours post op	300mg		
13	Rajendra Ramachnadr	62	M	1140021	82	84	86	82	88	84	82	140/90	140/90	150/80	140/80	140/80	140/90	140/90	0	0	5	4	5	4	nil	100mg tramadol	NIL	100mg tramadol	100mg tramadol	2hours post op	400mg		
14	Sunanda basappa kam	54	F	1136807	68	72	76	78	82	76	78	130/80	130/70	120/80	110/80	120/90	130/70	120/90	0	2	5	4	3	3	NIL	100mg tramadol	NIL	NIL	NIL	2hours post op	100mg		
15	Vijay narayan chougale	31	M	1141922	62	69	70	72	78	73	74	110/80	100/70	100/80	110/70	110/90	122/70	120/80	0	0	3	3	3	4	NIL	NIL	100mg tramadol	NIL	NIL	12hours post op	100mg		
16	Sujatha mallappa chinn	40	F	11409589	88	92	92	90	92	89	92	110/70	120/80	150/70	140/70	120/90	140/80	140/80	0	0	6	6	6	5	NIL	100mg tramadol	NIL	100mg tramadol	100mg tramadol	2hours post op	400mg		
17	Mallikarjuna	19	M	11322355	86	88	86	88	89	90	96	130/99	120/80	150/80	140/70	130/90	150/80	140/80	0	0	5	5	4	4	NIL	100mg tramadol	NIL	100mg tramadol	100mg tramadol	2hours post op	400mg		
18	Ratanavva .D	50	F	11672977	69	74	77	82	86	86	90	110/70	100/60	130/80	130/80	130/80	130/80	120/90	0	0	2	3	4	4	NIL	NIL	100mg tramadol	NIL	100mg tramadol	6hours post op	300mg		
19	Anil kumar sannakkki	40	M	11388865	88	89	94	88	86	82	83	150/80	140/80	150/70	160/80	130/70	140/80	140/80	0	0	4	3	5	5	NIL	100mg tramadol	100mg tramadol	100mg tramadol	100mg tramadol	2hours post op	400mg		
20	Vittal shivappa pijer	51	M	11396356	86	86	83	89	90	89	88	120/90	130/80	120/90	130/70	130/70	120/70	110/90	0	2	4	5	4	4	NIL	100mg tramadol	NIL	100mg tramadol	rvil	2hours post op	300mg		
21	Nandini Mali	39	F	11557105	66	72	80	82	88	78	74	130/90	130/80	120/90	130/90	140/90	140/80	140/70	0	0	3	5	4	4	NIL	Nil	100mg tramadol	NIL	100mg tramadol	4hours post op	200mg		
22	Lagamappa	58	M	1141535	78	80	82	86	88	86	86	130/90	140/80	150/70	140/80	150/70	140/80	140/90	0	0	3	4	5	4	NIL	NIL	100mg tramadol	NIL	100mg tramadol	4hours post op	200mg		
23	Sadashiv	43	M	11410388	80	82	84	84	80	80	82	120/80	140/90	130/80	130/80	140/80	130/80	120/90	0	2	2	3	4	5	NIL	NIL	100mg tramadol	NIL	100mg tramadol	6hours post op	300mg		
24	Yashoda badiger	50	F	11341457	78	84	80	78	76	74	74	100/60	110/70	100/60	100/70	110/70	110/70	110/80	0	0	2	2	2	3	NIL	NIL	NIL	NIL	NIL	NIL	NIL		
25	Sanju ashok nikam	28	M	11339985	74	76	86	88	94	96	90	110/70	120/80	120/90	110/80	120/90	130/80	130/80	0	2	2	3	3	4	NIL	NIL	100mg tramadol	100mg tramadol	100mg tramadol	12hours post op	200mg		
26	Nagappa madiwalar	62	M	11240071	86	80	88	89	89	90	88	140/90	150/70	140/80	150/90	150/80	140/80	150/80	3	4	5	5	4	4	NIL	100mg tramadol	NIL	100mg tramadol	100mg tramadol	immediate post op	400mg		
27	Vijaykumar maneppagi	42	M	11234637	88	86	84	88	90	90	93	130/70	140/80	150/80	170/90	150/80	150/80	160/90	3	3	5	5	4	4	NIL	100mg tramadol	NIL	100mg tramadol	100mg tramadol	2hours post op	400mg		
28	Laxmi atrogal	60	F	11322779	74	80	92	78	72	70	70	100/60	120/70	120/80	110/80	110/70	110/60	100/60	0	0	2	2	3	4	NIL	NIL	100mg Tramadol	NIL	100mg Tramadol	12hours post op	100mg		
29	Manjula	40	F	11339342	68	64	64	66	68	68	70	100/80	110/80	110/70	110/70	130/70	123/80	120/70	0	2	3	3	4	4	NIL	100mg tramadol	100mg tramadol	NIL	100mg tramadol	6hours post op	200mg		
30	Bagirathi shirshail	60	F	11233331	82	80	80	82	80	86	84	110/70	110/70	110/80	120/80	110/80	130/80	120/70	0	0	2	2	3	3	NIL	Nil	100mg Tramadol	NIL	100mg Tramadol	12hours post op	100mg		
					###	####	2451	###	###	###	###	0	0	0	0	0	0	8	24	98	114	116	119	112	0	0	0	0	0	0		

ANNEXURE 5 - KEY TO MASTER CHART

M - Male

F – Female

Heart rate per minute

Blood pressure – millimeters of mercury

mg – milligrams

NIL – no drug is given