A COMPARATIVE STUDY OF THE ANALGESIC EFFICACY OF DEXAMETHASONE AND DEXMEDETOMIDINE AS ADJUVANTS TO LEVOBUPIVACAINE FOR INTERSCALENE BRACHIAL PLEXUS BLOCK IN PATIENTS UNDERGOING ORTHOPEDIC SHOULDER SURGERIES – A RANDOMIZED CLINICAL TRIAL

Dissertation submitted to

B.L.D.E (DEEMED TO BE UNIVERSITY)

SHRI B.M. PATIL MEDICAL COLLEGE HOSPITAL AND RESEARCH CENTRE

VIJAYAPUR 586103 KARNATAKA

BY

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P.G. IN ANAESTHESIOLOGY

In partial satisfaction of the criteria for attainment of the degree of.

DOCTOR OF MEDICINE IN ANAESTHESIOLOGY

Under the Guidance of

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ABBREVIATIONS

ELAM-1 – Endothelial Leukocyte Adhesion Molecule 1

GM-CSF – Granulocyte Monocyte Colony Stimulating Factor

ICAM – Intercellular Leukocyte Adhesion Molecule 1

ICU - Intensive care unit

ISBPB - Interscalene Brachial Plexus Block

IL – Interleukin

LA – Local Anesthetics

LTs – Leukotrienes

mg – Milligram

ml - Milliliter

NF-κβ – Nuclear Factor kappa beta

PAF – Platelet Activating Factor

PGs – Prostaglandins

q.s. – Quantum sufficit

QTc – corrected QT interval

TNF – Tumor Necrosis Factor

US – Ultrasound

VAS - Visual Analogue Score

ABSTRACT

BACKGROUND:

Shoulder surgery can cause significant postoperative pain. Therefore, control of postoperative pain is important by decreasing the pain to a tolerable level so that patients can return to their day-to-day activities.

Regional anesthesia in the form of an interscalene brachial plexus block (ISBPB) is used, either as an adjunct to general anesthesia or as the primary anesthetic to improve analgesia and facilitate early mobilization in patients.

Ultrasound-guided ISBPB is a less invasive, easy technique to perform, and has fewer complications than the other procedures. Levobupivacaine, the S-enantiomer of bupivacaine, has cardiotoxicity than bupivacaine. Therefore, it is an ideal neural blocking agent.

Dexamethasone is a systemic glucocorticoid with potent anti-inflammatory and analgesic effects. It is routinely used to reduce postoperative nausea, vomiting, and pain.

Dexmedetomidine is an alpha 2 adrenoceptor agonist. It is used as an adjuvant to local anesthetics in regional anesthesia.

AIMS AND OBJECTIVES:

To evaluate the onset time of sensory and motor block, duration of sensory and motor block, time taken for the first rescue analgesia, total dose of rescue analgesia, postoperative visual analogue score (VAS), and additive effects of dexmedetomidine and dexamethasone to levobupivacaine for interscalene brachial plexus block in patients undergoing orthopedic shoulder surgeries.

METHODOLOGY:

- Written informed consent was obtained. Nil by mouth status was confirmed. IV access was secured using an 18-gauge cannula in patients
- Patients underwent pre-anesthetic evaluation with detailed history, airway examination, and systemic examination. The patients have been explained the procedure of block and the visual analogue score. Routine blood investigations were done.

- The block was given with an in-plane technique using a 22 G needle, and Group A received 25 ml 0.5% levobupivacaine with 8 mg dexamethasone as an adjuvant. In contrast, Group B received 25 ml 0.5% levobupivacaine with 50 mcg dexmedetomidine and 1.5 ml sterile water as an adjuvant.
- Patients were evaluated for the onset time of sensory and motor block and the duration of sensory and motor block.
- Patients were also evaluated for the time taken for the first dose of rescue analgesia and the requirement of the total dose of rescue analgesia
- Patients were assessed for postoperative visual analogue scores for both groups at 2, 6, 8, 10, 12, and 24 hours post-surgery.

RESULTS:

- Age and gender were comparable and statistically insignificant.
- The onset time of sensory and motor blockade was significantly faster in Group A than in Group B.
- The duration of action was significantly longer in Group B than in Group A.
- The time taken for the first rescue analgesic is significantly longer in Group B than in Group A.
- The total dose of analgesic given was significantly lower in Group B than in Group A.
- VAS scores were significantly better in Group B than in Group A.

CONCLUSION:

In conclusion, with all the above findings, which are statistically significant, dexmedetomidine has better action as analgesia than dexamethasone when used as an adjuvant to levobupivacaine for ISBPB in patients undergoing shoulder surgeries.

KEYWORDS: Interscalene brachial plexus block, Dexmedetomidine, Dexamethasone, Levobupivacaine, VAS, Rescue analgesia.

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INTRODUCTION

The shoulder joint is supplied by the subscapular nerve (C5-C6), a branch of the posterior cord of the brachial plexus. The suprascapular, axillary, and lateral pectoral nerves supply the joint capsule. The suprascapular nerve supplies the superior and posterior aspects of the capsule. The axillary nerve supplies the anteroinferior part of the capsule. The lateral pectoral nerve supplies the rotator and anterosuperior part of the joint capsule.[1]

Shoulder surgeries like total shoulder replacement, proximal humerus fractures, arthroscopy, rotator cuff repair, etc., can cause postoperative pain. Managing pain after shoulder surgery is a challenge for anesthesiologists.

To improve analgesia and facilitate early mobilization in patients, regional anesthesia is used as an aide to general anesthesia or solely as the primary anesthetic in the form of an interscalenele approach to the brachial plexus. Regional anesthesia reduces the surgery time and postoperative complications like pain, nausea, and vomiting, and decreases the duration of hospital stay.[2]

The help of ultrasound (US) guidance in anesthesia has allowed for better visualization of anatomical structures (vessels, muscles, nerves, bones, and tendons) and the spread of local anesthetics during the injection. US guidance is advantageous as it avoids inadvertent intraneural or intravascular injection. US-guided blocks require less local anesthetic dose, faster onset of action, longer block duration, and better block quality. Ultrasonography is a crucial tool for anaesthesiologists in peripheral blocks, as recommended by international guidelines.

Using an Interscalene Brachial Plexus Block (ISBPB) as the anesthetic technique provides adequate anesthesia for shoulder surgeries, decreases blood loss, reduces adverse effects, decreases immediate postoperative pain, and shortens post-anesthesia care unit stay. Ultrasound-guided ISBPB is preferred because it is minimally invasive and has fewer difficulties compared to other approaches.[3]

Dexmedetomidine is an alpha-2 agonist drug. It is proven to have a better safety profile and is efficacious in prolonging the action of the peripheral blocks when used as an adjuvant.[4]

Dexamethasone, when used as an adjuvant, is proven to potentiate the action of local anesthetics by modifying the action of potassium channels. Also, by causing local vasoconstriction, it prolongs the duration of nerve blocks.[5]

Our study aims to evaluate the analgesic effects of dexmedetomidine and dexamethasone to levobupivacaine used for interscalene block in patients undergoing orthopedic shoulder surgeries.

AIMS AND OBJECTIVES

Primary objectives:

1. Assessment of onset time of sensory and motor block.

2. Assessment of duration of sensory and motor block.

3. To evaluate the additive effects of dexamethasone and dexmedetomidine on levobupivacaine.

Secondary objectives:

1. To monitor intraoperative hemodynamic stability.

2. To study the time taken for the first rescue analgesia and the requirement of the total dose of rescue analgesia.

3. To study ISBPB-related postoperative complications.

4. Assessment of postoperative visual analogue scores (VAS) for both groups at 2, 6, 8, 10, 12, and 24 hours post-surgery.

REVIEW OF LITERATURE

PHYSIOLOGY OF PAIN

Pain is an unpleasant sensory and emotional experience associated with tissue damage.[6] It varies in different individuals and is thus difficult to measure. Primary afferent nociceptors for pain are A-delta (small myelinated) and (unmyelinated) fibers.[7,8]

Patterns of pain

Based on duration and frequency, there are three patterns of pain[9]

1. **Acute pain** - starts suddenly and ends when the pathology is treated. It warns the body when there is any injury, disease, or stress. Common causes of acute pain are muscle strain, fractures, dental procedures, infections, and burns.
2. **Episodic pain** - occurs at irregular intervals. It may be associated with a condition like sickle cell disease.
3. **Chronic pain** - lasts for longer than three months.

Pain can also be categorized based on its source[9]

1. **Nociceptive pain**: caused by tissue damage and/or inflammation. It is sharp, aching, or pricking. Examples are pain from an infection or osteoarthritis.
2. **Neuropathic pain**: caused by nerve damage. It is burning, tingling, or shooting. Examples are diabetic neuropathy and sciatica.
3. **Nociplastic pain**: caused by changes in the nervous system. Examples include fibromyalgia and chronic low back pain.

Effects of pain on the organ system:

- Increased release of catecholamines via sympathetic stimulation leads to decreased peripheral perfusion, tachycardia, and hypertension, thus causing a compensatory increase in blood flow to vital organs like the heart and brain.
- Increased peripheral vascular resistance leads to increased myocardial contractility and can precipitate myocardial ischemia and infarction in high-risk patients.
- Decreased regional blood flow and increased cortisol levels delay wound healing.
- In chronic untreated pain, increased catabolism and decreased anabolism occur due to variations in the neuroendocrine functions, leading to lipolysis and proteolysis. This results in decreased immunoglobulin synthesis and impaired phagocytosis, leading to reduced immunocompetence.

The consequences of poorly controlled pain are as follows:

1. Reduced functional capacity
2. Sleep disturbance
3. Delayed wound healing
4. Decreased quality of life
5. Increased duration of hospital stay and increased cost burden of care.

Therefore, anaesthesiologists play a significant role in pain management along with managing anesthesia. Understanding the details of pain physiology is vital in the management of pain.

PAIN ASSESSMENT

Assessment of pain is a necessary component to achieve adequate pain control in the postoperative period. Few of the pain evaluation scales are used in an attempt to assess pain. Most of these scales can be used by the patients themselves to evaluate pain when the patient can express and communicate what pain feels like.

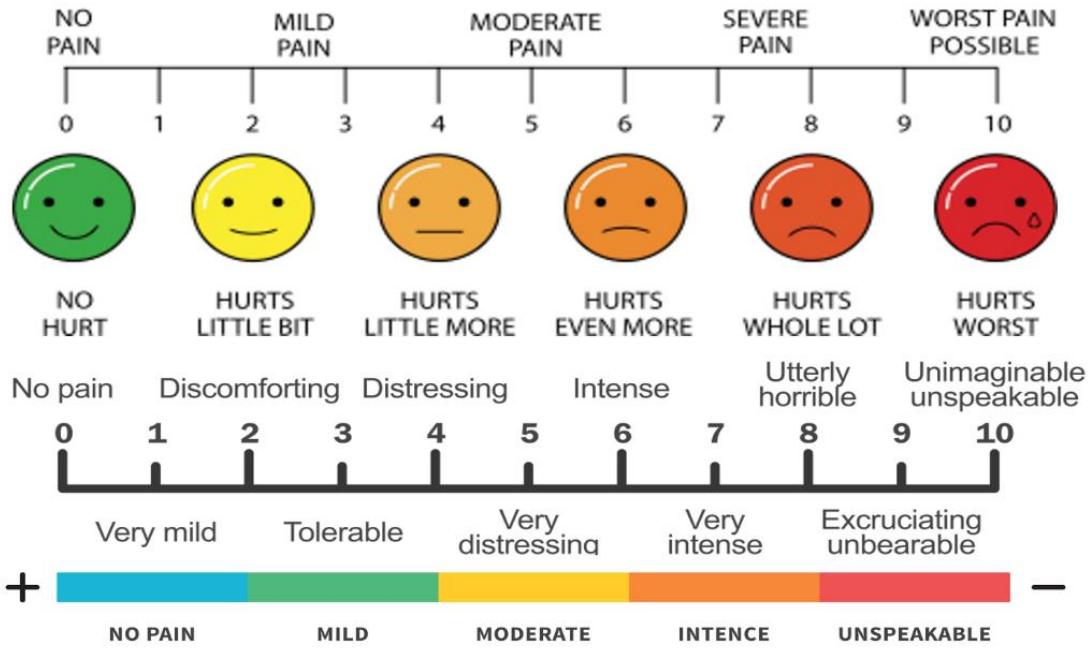
VISUAL ANALOGUE SCALE (VAS) [10,11,12]

Visual analogue scale in measurement was introduced in 1966 before which it was used in psychology to measure mood disorder. Since then, it has become a standard and a popular tool for pain assessment.

It consists of a line, typically 100 mm long, with anchor descriptions like "no pain" and "worst pain imaginable". The distance in millimeters between the patient's mark and the left endpoint is measured after the patient creates a mark that represents their perception. Recall period varies, but respondents are asked to report “current” or pain intensity “in the last 24 hours”.

The WONG-BAKER pain rating scale and Visual Analogue Scale facial expressions: It is a pictorial self-assessment tool that includes six faces. Each face conveys different emotions which range from a face with a cheerful smile to a face with a crying one. It is popular among the population such as younger and elderly patients, disoriented patients, and those who cannot comprehend local language or have any sort of difficulty in communication.

Fig 1: Visual analogue scores



Merits and demerits of VAS.

Merits[13]

- VAS is more sensitive to small changes.
- These scales are important when looking at change within individuals.
- Time taken for completion is less than one minute.
- One should be capable of measuring the distance by using a ruler to determine a VAS score.

Demerits[13]

- Assessment of score is subjective.
- It is less valuable when relating to a group of individuals.
- It is not managed orally or by phone because pen and paper are used to score the VAS.
- Caution is needed when a print of the scale is taken as there can be changes in the length of the 10-cm line.

CLINICAL ANATOMY OF BRACHIAL PLEXUS

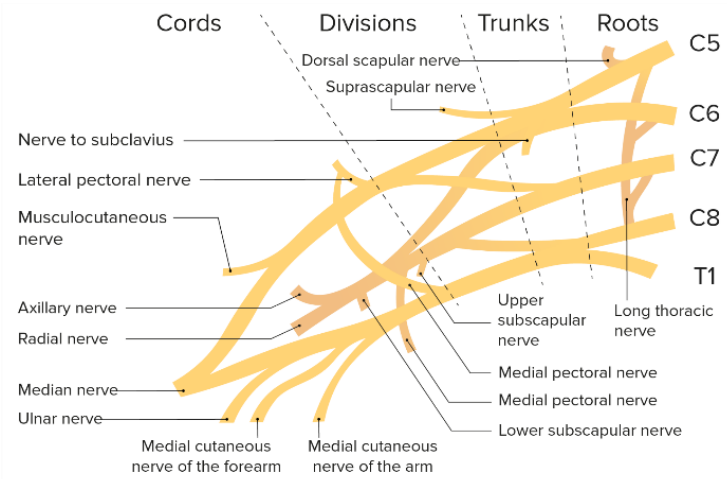
The brachial plexus is formed from the ventral rami of the fifth cervical nerve root to the first thoracic nerve root (C5, C6, C7, C8, and T1). It later descends into the root of the neck then under the clavicle through the axilla to the arm.[14]

From these separate nerve roots, the brachial plexus undergoes a complex series of convergences and divergences. As the nerve roots traverse the space between the muscles of anterior and middle scalene, they converge into three vertically arranged trunks (upper, middle, and lower), which shortly thereafter diverge into two divisions of anterior and posterior as they cross over the lateral border of the first rib.[14]

The posterior division innervates the posterior arm, mainly the radial and axillary nerves. As the divisions continue distally, they cover the second part of the axillary artery and form three clear-cut cords. The posterior cord is a continuation of the posterior division and lies posterior to the artery. The anterior division splits into the medial and lateral cords, which are defined by their relationship with the axillary artery. Both these cords contain portions that will become the median nerve. The musculocutaneous nerve is a derivative of the lateral cord and the ulnar nerve is a derivative of the medial cord.[14]

After reaching the axilla, the four terminal nerves remain separate for the remainder of their distal course. The musculocutaneous nerve courses within the fascia of the coracobrachialis muscle.

Fig 2: Brachial plexus



BRACHIAL PLEXUS BLOCK

History

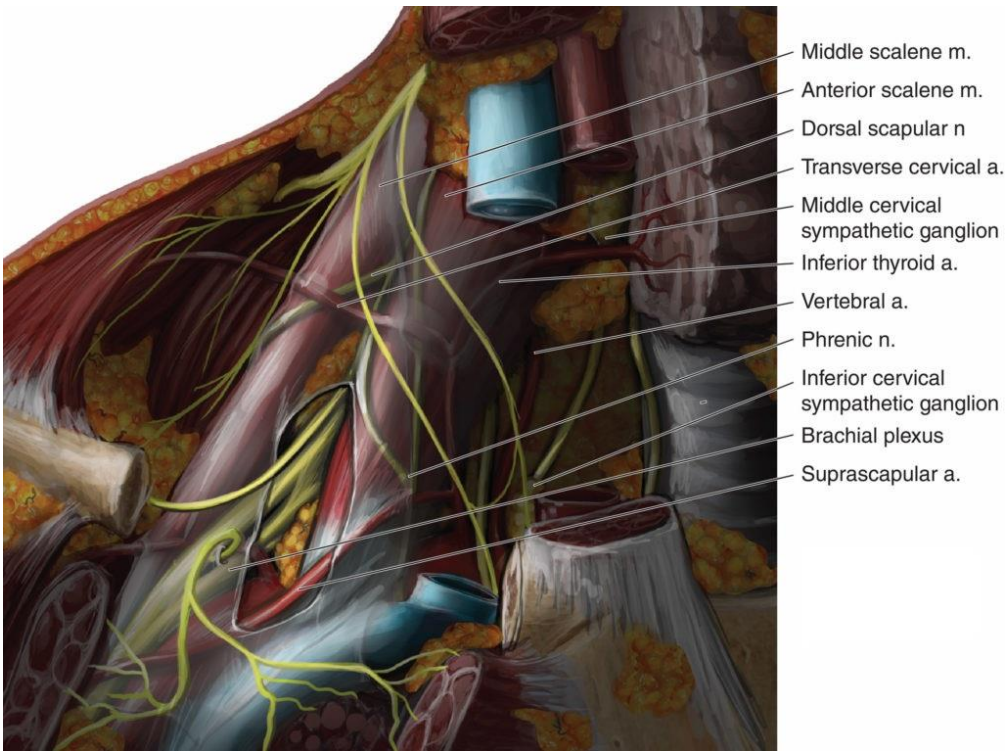
The first brachial plexus block was demonstrated by William Halsted in 1884.[15]

The brachial plexus block provides anesthesia to the upper limb. It offers better postoperative management than general anesthesia. It can be performed at different levels depending on the desired anesthetic outcome. The four most common approaches are the inter-scalene block, the supraclavicular block, the infra-clavicular block, and the axillary block.[16]

The brachial plexus block is the first among blocks to be done under ultrasound guidance. The pioneers used the Doppler technique to identify the subclavian artery position as a landmark for supraclavicular brachial plexus block.[16]

Active cellulitis or an abscess at the injection site, significant coagulation abnormalities, allergies to local anesthetics, and an inability to cooperate during block placement are some of the important contraindications of the brachial plexus block.[16]

Fig 3: Anatomy of brachial plexus at the low interscalene space



ANATOMY OF INTERSCALENE BRACHIAL PLEXUS BLOCK (ISBPB)

The inter-scalene block is given between the anteromedially located anterior scalene muscle and the postero-laterally located middle scalene muscle at the trunks of the brachial plexus. It is helpful for distal clavicle, shoulder, and proximal humerus procedures. This block is used in patients undergoing shoulder, upper arm, or elbow surgery.

The block is performed with the patient mildly sedated. A single injection or a continuous nerve block is given using a catheter. It is performed using techniques like landmark, nerve stimulation, ultrasound-guided, or a combination of ultrasonography and nerve stimulation methods.[17,18]

Landmark technique for ISBPB

The patient is placed in a supine or beach chair position. The head is turned away from the side of the block. The sternocleidomastoid muscle is made prominent by elevating the patient's head. The index and middle fingers of the nondominant hand are placed posterior to the lateral border of the sternocleidomastoid muscle, and a groove is felt between the muscles of the anterior and middle scalene. A 22G needle is inserted at the level of C6 in the groove in a slight caudal direction perpendicular to the skin. Paraesthesia is observed over the shoulder and upper arm. Local anesthetics are injected after confirming negative aspiration.[19]

Nerve stimulation technique for ISBPB

The patient is placed in a supine position or beach chair position. The head is turned away from the side of the block. The landmarks used are the clavicle, the clavicular head of the sternocleidomastoid muscle, and the external jugular vein. The anterior and middle scalene muscles are palpated with the nondominant index and middle fingers. A needle is connected to a nerve stimulator and is passed between these two fingers. The nerve stimulator is established to deliver 1mA (2Hz,100 micro sec) initially and then advanced till motor response of the brachial plexus is achieved. Local anesthetics are injected after intermittent negative aspiration to rule out the tip of the needle in a vessel.[19]

USG guided ISBPB

The patient is placed in a supine position, and the head is turned away from the side of the block. A linear USG probe (7-13 MHz) is positioned over the cricoid cartilage transversally. USG probe is moved laterally to identify the carotid artery, internal jugular vein, and anterior and middle scalene muscles. The roots of the brachial plexus

are identified as three hypoechoic dots seen between the scalene muscles in the groove. The local anesthetic is infiltrated around these structures after confirming a negative aspiration of blood. Another approach is the traceback technique, where the transducer is placed over the subclavian artery, the brachial plexus is identified and traced back to the interscalene groove, and a local anesthetic is injected around three hypoechoic structures.[19]

Anatomical variation of Brachial plexus

Anatomy of brachial plexus variation for the anterior scalene muscle is common where cephalad components (C5, C6) pass over or within the anterior scalene muscle. This problem is generally overcome by using ultrasound guidance over the nerve stimulation technique and landmark technique. Although cervical ribs are uncommon (occurring in 0.5% of the population), transducer manipulation will be difficult because of acoustic shadowing by bone over the brachial plexus.[17]

Fig 4: Ultrasonographic schematic representation of ISBPB

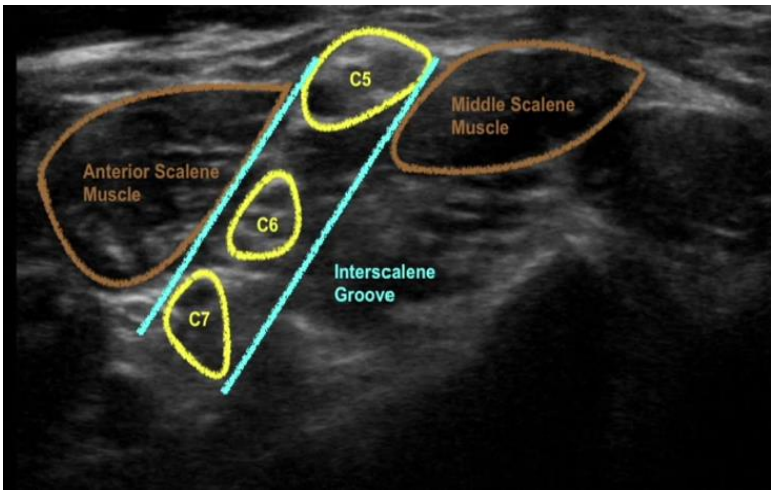
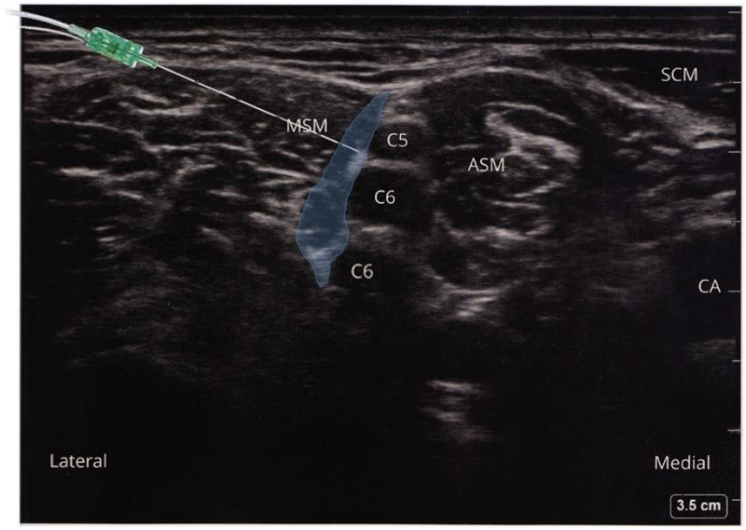


Fig 5: Sonoanatomy of ISBPB



Complications[20]

1. Infection
2. Bleeding/hematoma
3. The wrong placement of a needle can cause pneumothorax, nerve damage, and spinal cord trauma.
4. Horner's syndrome (ptosis, miosis, anhidrosis)
5. Hemi diaphragmatic paresis (blockade of the ipsilateral recurrent laryngeal nerve, stellate ganglion, and phrenic nerve due to the spread of injected anesthesia into adjacent tissue).
6. Inadvertent intravascular injection of local anesthetics.
7. Local anesthetics toxicity

Contraindications[20]

1. Infection at the site of injection.
2. Bleeding disorders.
3. Patients with existing vocal cord palsy.
4. Hypersensitivity/allergy to local anesthetics.

The efficacy of ISBPB is evaluated by confirming the loss of sensation over the cape of the shoulder and motor weakness in the deltoid and biceps muscles (C5/6).[2]

LOCAL ANAESTHETICS

Local Anesthetics (LAs) cause a revocable loss of sensory perception (pain) in a limited part of the body. When applied to mixed nerves, both sensory and motor impulses are interrupted. They provide anesthesia and analgesia for various procedures.[22]

CLASSIFICATION OF LOCAL ANESTHETICS

Local anesthetics contain a lipophilic and a hydrophilic structure linked by a hydrocarbon chain of an ester or amide chain.[22]

a. Ester-linked: Pprocaine, chloroprocaine, benzocaine, tetracaine, cocaine.

b. Amide-linked: Lidocaine, bupivacaine, ropivacaine, dibucaine, prilocaine.

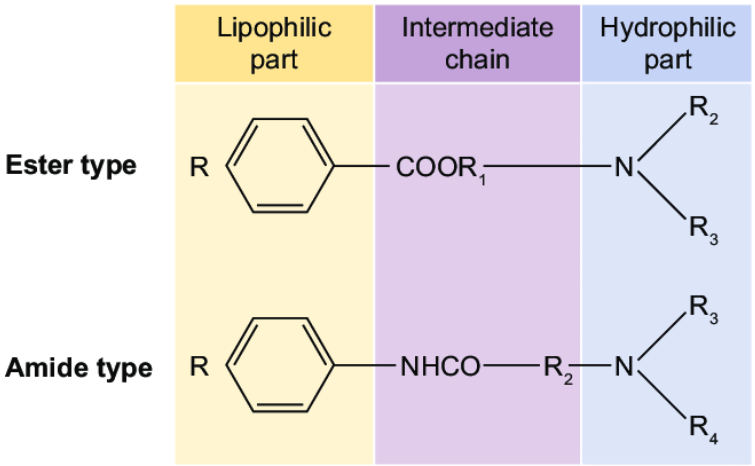


Fig 6: Chemical structure of local anesthetics

Depending on the duration of action, local anesthetics are classified into three groups:

a. Short-acting: Procaine, Chloroprocaine

b. Intermediate-acting: Lidocaine, Prilocaine

c. Long-acting: Bupivacaine, Ropivacaine, Tetracaine, Dibucaine

PHARMACOLOGY OF LEVOBUPIVACAINE

Levobupivacaine is a long-acting local anesthetic. It is highly potent and amide-linked. Being an S (−) enantiomer of bupivacaine, it has a lesser cardiotoxicity and neural toxicity compared to racemic bupivacaine. Hence levobupivacaine is safely preferred over bupivacaine in regional anesthesia. [23]

Chemical structure

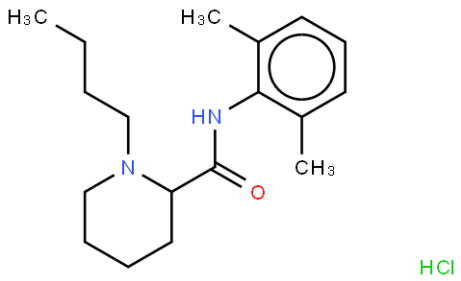


Fig 7: Chemical structure of Levobupivacaine

Formulation [24]

1. 0.25% solution for injection.
    - Each ml contains: Levobupivacaine Hydrochloride equivalent to Levobupivacaine 2.5 mg, Sodium Chloride 8.5 mg
2. 0.5% solution for injection.
    - Each ml contains: Levobupivacaine Hydrochloride equivalent to Levobupivacaine 5 mg, Sodium Chloride 8 mg

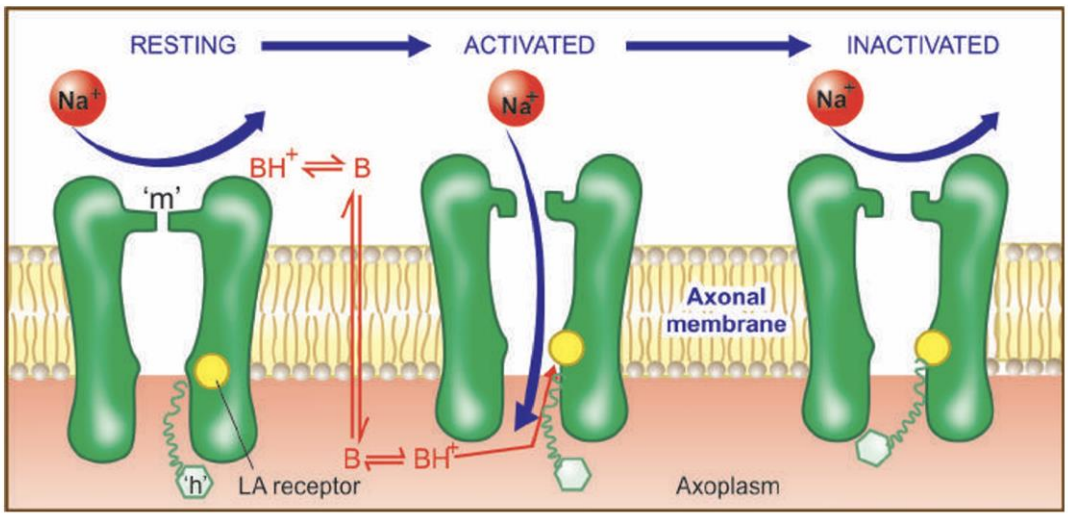
Mechanism of action

The local anesthetics block the conduction of the nerve by decreasing the entry of Na+ ions during an action potential (AP). Depolarization fails to reach the threshold potential, which results in a conduction block. Impulse conduction halts when the Na+ channels over a critical length of 2–3 nodes of Ranvier in the myelinated fiber are blocked.[22]

The progression of anesthesia depends on factors like myelination, diameter, and conduction velocity of the affected nerve fibers.[22]

When the diameter is the same, myelinated nerves are blocked before nonmyelinated. Autonomic fibers are more sensitive than somatic fibers. Among the somatic afferents, the sequence of blockade is: pain, temperature, touch, and lastly, deep pressure sense. When applied to the tongue, bitter taste is lost first, then sweet and sour, and salt.[22]

Fig 8: Mechanism of action of local anesthetics



Dosage [23]

1. Peripheral nerve blockade: 1-40 ml (maximum 150 mg)
2. Local infiltration in adults: 1-60 ml (maximum 150 mg)
3. Postoperative pain: 12.5-18.75 mg/hour

Pharmacokinetics

- The concentration of plasma depends on the site of administration.
- It is basic and therefore binds to α1 acid glycoprotein. It temporarily binds to tissues and nerves at the site of injection.

- Metabolized in the liver by CYP3A4 and CYP1A2 to 3-hydroxy and desbutyl-levobupivacaine.
- 3 hydroxy levobupivacaine is excreted in urine as conjugates of glucuronic acid and sulfate ester.[24,25]

Clinical uses [26]

Surgical anesthesia: in epidural, intrathecal, peripheral nerve block, and for local infiltration.

Pain management: single injection or continuous infusion of epidural administration for post-operative pain and labor analgesia.

DEXMEDETOMIDINE

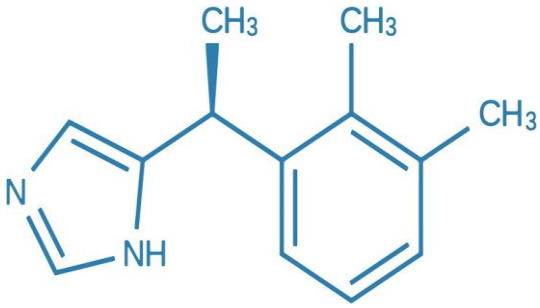


Fig 9: Chemical structure of Dexmedetomidine

Mechanism of action of Dexmedetomidine

Dexmedetomidine is a centrally acting, highly selective α2A agonist. It has a selectivity for the alpha 2 compared to the alpha 1 receptor (1600:1). It is an S-enantiomer of medetomidine.[22]

It acts as a sedative, anxiolytic, analgesic, and sympatholytic drug. By blocking the alpha receptors in the brainstem, it inhibits central sympathetic outflow and the release of catecholamines.[27]

Pharmacokinetics

- Metabolised by liver
- t ½ - 2 to 3 hours
- Excreted in urine and bile

Dose

1 mcg/kg – when used as an adjunct to LA in peripheral nerve block.[27]

Clinical uses [22,28]

- For sedation of intubated patients.
- For sedation during endoscopy, spinal, epidural, and regional anesthesia.
- Treatment of delirium, insomnia, and alcohol withdrawal.
- In schizophrenia and bipolar disorder cases, to control agitation.
- To prolong the duration of analgesia in peripheral nerve blocks.

Adverse effects

The common adverse effects are hypotension and bradycardia.

Hypotension and bradycardia are because by the stimulation of presynaptic alpha receptors, which decrease the release of norepinephrine.[29]

Dexmedetomidine shortens the time of onset and prolongs the duration of block. It also reduces the postoperative pain when added to local anesthetics in brachial plexus block .[30-32] Clonidine, verapamil, and magnesium sulfate are also used as adjuvants.[33-35]

Mechanisms include vasoconstriction, central analgesia, and anti-inflammatory effects.[36,37] It produces analgesia and sedation by inhibiting substance P release and by activating α_2 adrenoceptors in the brain.[38,39]

DEXAMETHASONE

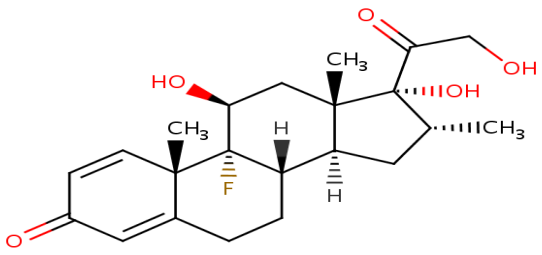


Fig 10: Chemical structure of Dexamethasone

Anti-inflammatory and immunosuppressant actions of glucocorticoids

- Induce annexins in macrophages, fibroblasts, and endothelium – inhibit phospholipase A2 – decrease PGs, LTs, and PAF
- Decrease production of interleukins, TNF-α, GM-CSF, γ interferon.
- Interfering with complement function by decreasing the production of acute-phase reactants
- Reduce transcription factor NF-κβ and histone acetylation
- Decrease production of collagenase and prevent tissue destruction
- Decrease ELAM-1 and ICAM-1 and interfere with the adhesion and localization of leucocytes.[22]

Pharmacokinetics

- Peak concentration (T max) is 1 hour.
- Terminal half-life is 4 hours
- Metabolized by CYP3A4 in the liver, and renal excretion is less than 10% of total body clearance.[40,41]

Dose

8 mg as an adjuvant to local anesthetic in peripheral nerve block.[40]

Clinical uses

- Treat allergies, inflammation, shock, and cerebral edema.
- Management of asthma, atopic, and contact dermatitis.
- Treatment of chemotherapy-induced nausea and vomiting.
- Prevention and treatment of acute mountain sickness.
- Used in terminally ill COVID-19 patients who require oxygen supplementation or ventilatory support.[42-44]

Adverse effects

- Cushing's habitus – when used for a prolonged duration of time.
- Hyperglycaemia, glycosuria
- Muscular weakness – proximal muscles, myopathy
- Susceptibility to infections
- Delayed wound healing
- Peptic ulcer
- Osteoporosis – vertebrae and flat spongy bones
- Posterior subcapsular cataract – after several years of use
- Glaucoma – topical use
- Psychiatric disturbances – mild euphoria, nervousness, sleep disturbances, mood changes.[22, 45]

The analgesic duration of dexamethasone is due to the action on nociceptive C-fibres and the up-regulation of potassium channels.[46-48] Dexamethasone prolongs the analgesic effect of ropivacaine and bupivacaine used for interscalene block.[49]

REVIEW OF LITERATURE OF PREVIOUS STUDIES

Bupivacaine and levobupivacaine have similar onset times of sensory and motor block for shoulder surgery.[50]

Some studies have shown that dexmedetomidine decreases the postoperative usage of opioids.[51,52]

A study by Rashmi HD et al. concluded that when dexmedetomidine was added to ropivacaine in ISBPP, the onset time of block was reduced, and the duration of sensory and motor block was prolonged.[53]

A study by Prapura BV et al. found that both dexmedetomidine and dexamethasone increase the duration of blockade with ropivacaine, but the effect is better with dexmedetomidine.[54]

A meta-analysis by Abdallah and Brull and research by Biswas et al., Agarwal et al., and Kaur et al. showed that dexmedetomidine, when used as an adjuvant to a local anesthetic agent in the brachial plexus block, reduces the onset and duration of sensory and motor block.[55-58]

Morita S, et al. reported that dexamethasone prolongs the duration of analgesia and decreases the total dose of analgesics for arthroscopic surgeries in ISBPP[59]

Research by Hamada et al. and Yadav et al. reported that the time required for the first dose of analgesia was longer with dexmedetomidine as compared to dexamethasone.[60,61]

MATERIALS AND METHODS

Source of data:

This study was conducted in the Department of Anaesthesiology, BLDE (DU) Shri B. M. Patil Medical College, Hospital and Research Centre, Vijayapura.

Method of collection of data:

Study Design: Prospective, randomized, double-blind Study.

Study Period: One and a half years

Sample Size: Eighty-four of both gender were randomly divided into two groups of 42 each.

Using G*Power ver 3.1.9.4 software for sample size calculation, The duration of analgesia (h) in dexmedetomidine group (Mean=19.30, SD=3.80) and dexamethasone group (Mean=2 2.40, SD=2.16) this study required total sample size of 84 (for each group 42, assuming equal group sizes), so to achieve a power of 97% for detecting a difference in Means: Inequality, two independent means (two groups)(t-test) with 5% level of significance.

Statistical analysis:

- The data collected was entered into a Microsoft Excel sheet for statistical analyses using SPSS software (Version 20).
- Results were presented in the form of Mean, SD, and percentages.
- An independent sample t-test was used for normally distributed variables, and the Mann-Whitney U test was used for not normally distributed variables.
- A chi-square test/Fisher's exact test was used to compare the categorical variables between the two groups.
- If $p < 0.05$, it was considered statistically significant.

INCLUSION CRITERIA

- Patients aged between 18-60 years.
- Patients of either sex.
- Patients admitted for shoulder surgeries under ISBPB with ASA Grade I and ASA Grade II

EXCLUSION CRITERIA

- Infection at the site of injection.
- Known allergy/hypersensitivity to local anesthetics.
- Presence of coagulopathies
- A history of cardiac, respiratory, hepatic, or renal failure.

Consent and Ethical Issues

- Written informed consent was obtained from all the subjects.
- Institutional ethical clearance was taken. Ref. No. BLDE(DU)/IEC/951/2023-24
- The study was registered on CTRI. Ref. No. CTRI/2024/05/067288

METHODOLOGY

Pre-anesthetic evaluation: Patients were included in the study by a thorough pre-operative evaluation

- History of underlying medical illness, previous history of surgery, previous anesthetic exposure, and hospitalization will be taken.
- The general condition of the patient, vital signs (heart rate, blood pressure, respiratory rate), height and weight, examination of the cardiovascular system, respiratory system central nervous system, airway assessment, and Mallampati grading was done.
- Routine investigations for the surgery such as Complete blood count, PT INR, blood sugars, blood urea and serum creatinine, serology, ECG, and chest radiography were performed

Procedure:

- This study was conducted on 84 patients who were undergoing shoulder surgeries under ultrasound-guided ISBPB in our institution.
- The patients were randomly divided into two equal groups of 42 each. Group A patients received ultrasound-guided ISBPB with 25 ml of 0.5% levobupivacaine with 8mg dexamethasone as an adjuvant. Group B patients received ultrasound-guided ISBPB with 25 ml of 0.5% levobupivacaine, 1.5 ml of sterile normal saline, and 50 mcg dexmedetomidine as an adjuvant.
- Patients were given Tab. Alprazolam 0.5 mg HS before surgery as pre-medication. They were educated about the visual analogue score during the pre-anesthetic evaluation.
- An IV cannula of 18G was secured pre-operatively and was started with IV fluid Ringer's lactate at the rate of 10ml/kg/hr.
- Patients were shifted to the operating theatre. Supplementation of oxygen was given by mask to all the patients who were undergoing surgery. They were monitored for pulse rate, ECG, SpO2, and NIBP by connecting to a multi-monitor. IV fluids RL/DNS/NS were started at a rate of 2ml/kg/hr.
- ISBB was performed in a supine position with the head turned to the opposite side (at 30 degrees). With all aseptic precautions, the area was painted and draped. Local infiltration of Inj. Lignocaine 2% was given before the block.
- A USG probe (A linear 7-13 MHz ultrasound-guided probe Sonosite M-Turbo, U.S.A.) was placed on cricoid cartilage transversally. The carotid artery and jugular vein were identified by moving the probe laterally. Further, moving the probe laterally, the anterior and medial scalene muscles were recognized. The roots of the Brachial plexus were identified as 3 hypoechoic dots lying near each other and surrounded by a hyperechoic area between the anterior and medial scalene muscles.
- The block was performed with an in-plane technique using a 20 G needle, and Group A received 25 ml 0.5% levobupivacaine with 8mg dexamethasone as an adjuvant, whereas Group B received 25 ml 0.5% levobupivacaine and 1.5 ml of sterile normal saline with 50mcg dexmedetomidine as an adjuvant. A local anesthetic was deposited around the roots of the brachial plexus.
- After injecting drugs, patients were evaluated for sensory and motor block for 10 min at every 2 min interval.

- Assessment of sensory block was done by the loss of sensation to the pinprick over the deltoid muscle area. Using a 3-point scale to pinprick (0 = normal sensation, 1 = sharp to pinprick, 2 = pinprick felt but not sharp, 3 = no sensation). Time to achieve adequate block was noted (0,1 = inadequate 2,3 = adequate)
- Assessment of motor block was done by asking a patient to abduct the shoulder (0 = normal abduction, 1 = decreased movements, 2 = unable to move). The time to achieve motor block was noted.
- The postoperative visual analogue score was assessed for both groups at 2, 6, 8, 10, and 12 hours post-surgery. If the VAS remained more than 3, intramuscular injection of diclofenac was given. If the control of pain remained unsatisfactory, an injection of Tramadol 1mg/kg infusion was given.
- The total number of rescue analgesics given to a patient in the first 24 hours after surgery was noted.

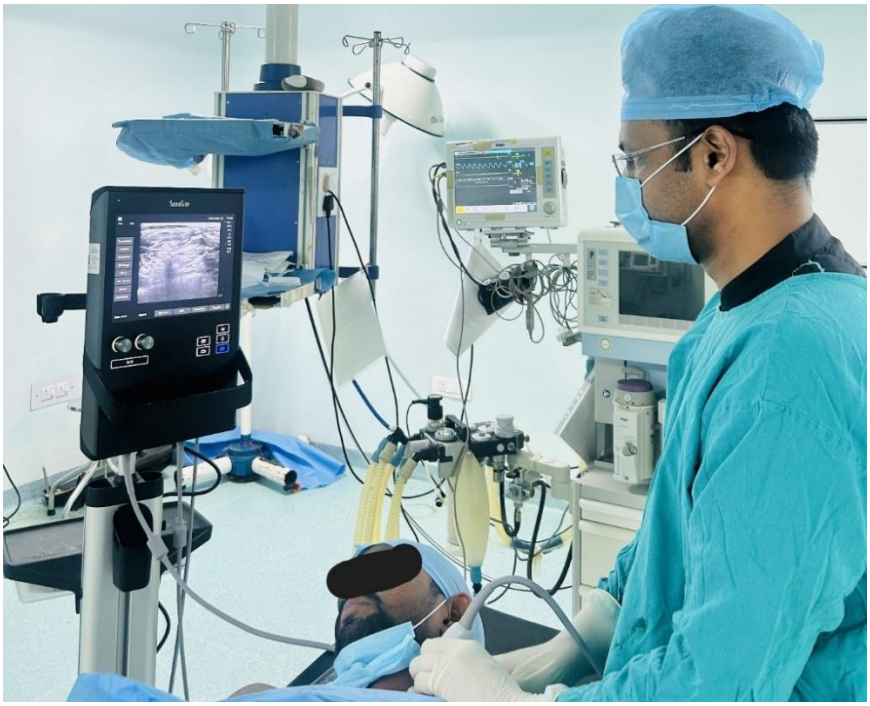


Fig 11: Approach of interscalene brachial plexus

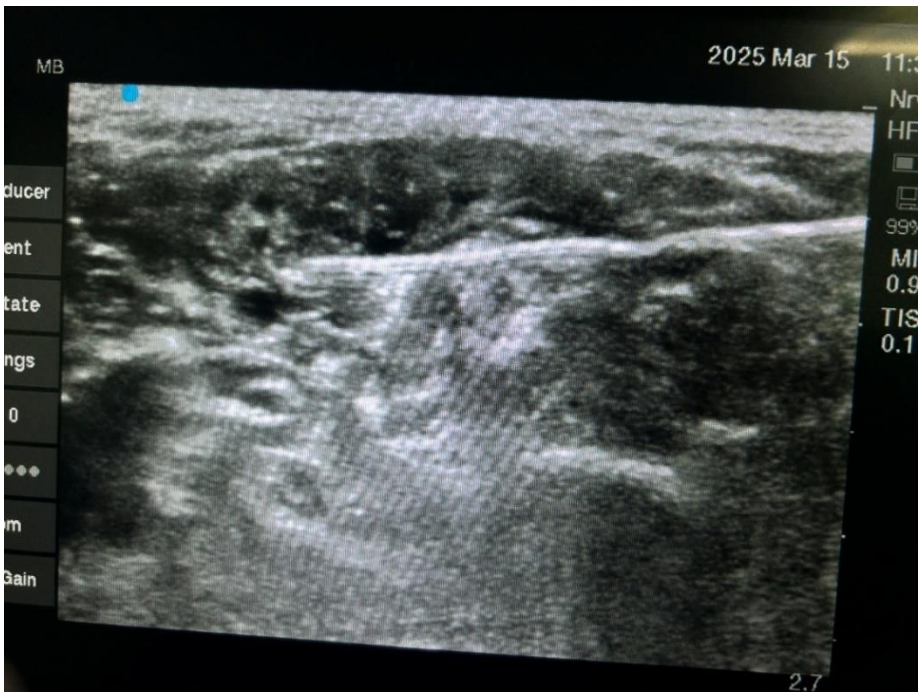


Fig 12: Needle depositing LA around the interscalene brachial plexus

VAS Score Intensity of pain

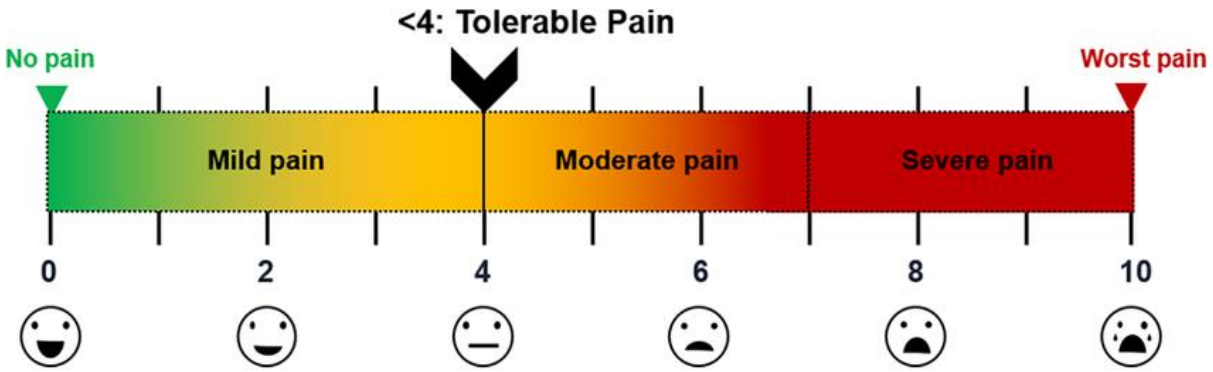
• 0 – 2- No pain to slight pain

• 1 – 3 - Mild pain.

• 4 – 6 - Moderate pain.

• 7 – 9 - Severe pain.

• 10 - Worst possible pain.



RESULTS

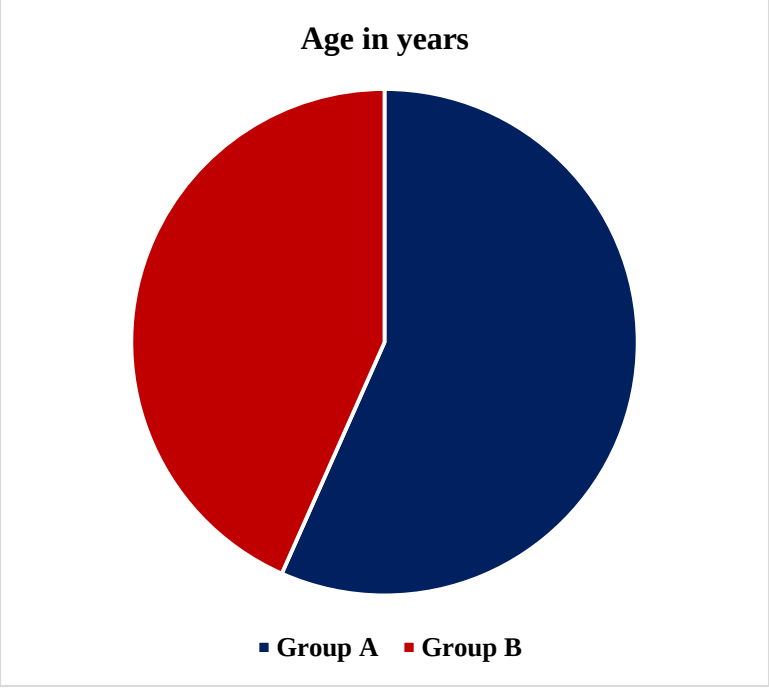
1. **Demographic data: comparison of age:**

- The values are represented as mean and standard deviation. The units are in years. 95% CI was used. "n" indicates the number of patients in each group.

Table 1: Comparison of age between the groups

Demographic data	Group A (n=42)		Group B (n=42)		P value
	Mean	SD	Mean	SD	
Age	46.33	11.682	35.45	10.194	0.000

Graph 1: Comparison of age between the groups



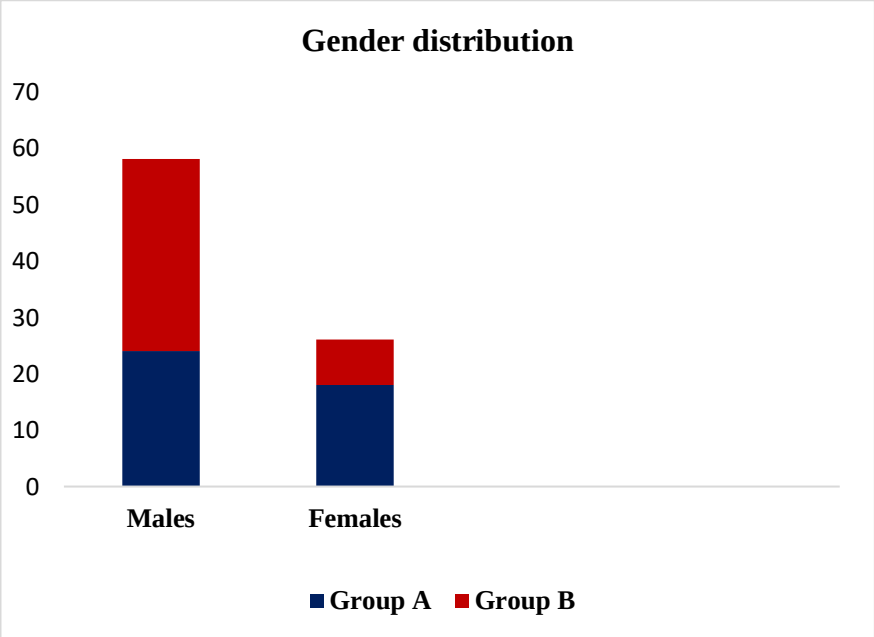
2. **Demographic data: comparison of gender distribution:**

- The values are represented as percentages.

Table 2: Comparison of sex distribution between the groups

Demographic data	Group A (n=42)		Group B (n=42)		P value
	No.	%	No.	%	
Male	24	41.4%	34	58.6%	
Female	18	69.2%	8	30.8%	0.018

Graph 2: Comparison of gender distribution between the groups



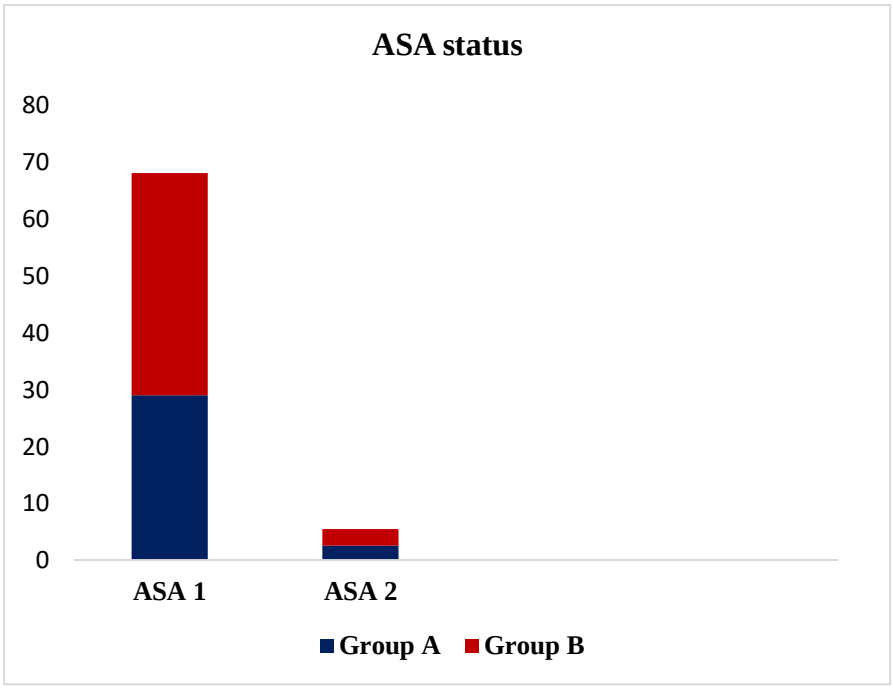
3. **Demographic data: comparison of ASA status:**

- The values are represented as percentages.

Table 3: Comparison of ASA status between the groups

Demographic data	Group A (n=42)		Group B (n=42)		P value
	No.	%	No.	%	
ASA 1	29	42.6%	39	57.4%	
ASA 2	13	81.3%	3	18.8%	0.005

Graph 3: Comparison of ASA status between the groups



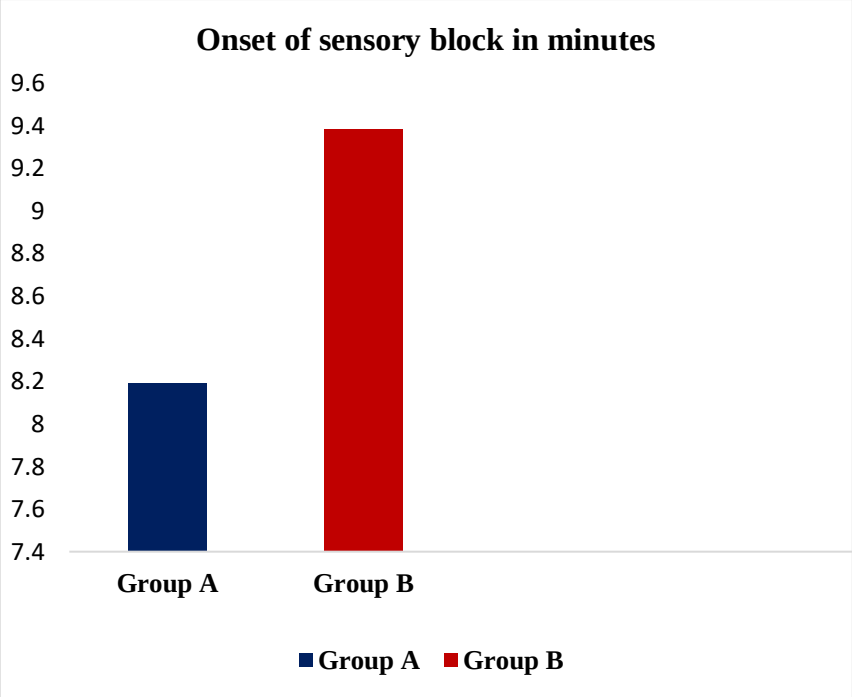
4. Onset of sensory block:

- The values are represented as mean and standard deviation. The units are in minutes.

Table 4: Comparison of onset of sensory block between the groups

Onset of sensory block (min)	Group A (n=42)		Group B (n=42)		P value
	Mean	SD	Mean	SD	
	8.19	1.756	9.38	1.431	0.001

Graph 4: Comparison of onset of the sensory block between the groups



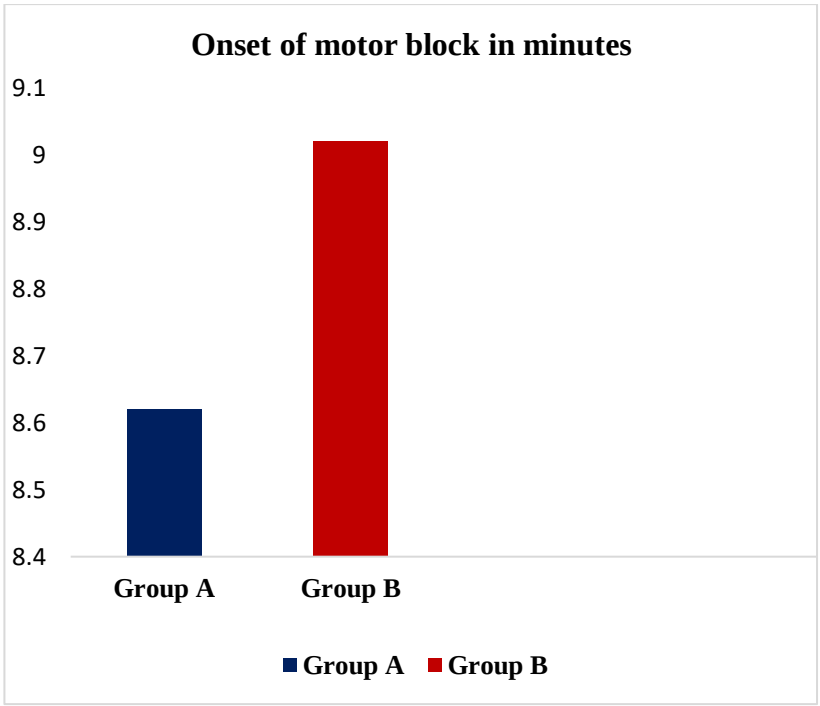
5. Onset of motor block:

- The values are represented as mean and standard deviation. The units are in minutes.

Table 5: Comparison of onset of motor block between the groups

Onset of motor block	Group A (n=42)		Group B (n=42)		P value
	Mean	SD	Mean	SD	
	8.62	2.036	9.02	1.854	0.344

Graph 5: Comparison of onset of the motor block between the groups



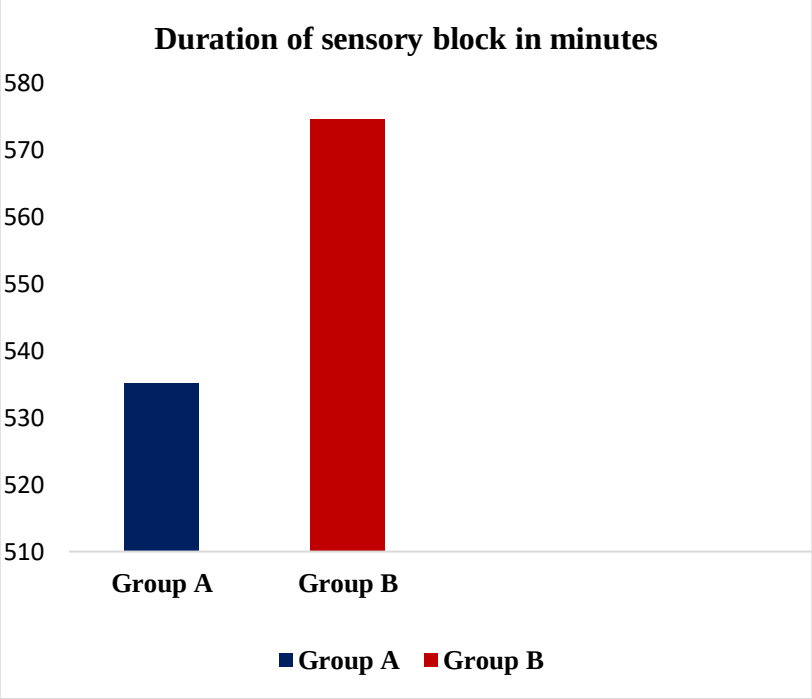
6. Duration of sensory block:

The values are represented as mean and standard deviation. The units are in minutes.

Table 6: Comparison of duration of sensory block between the groups

Duration of sensory block	Group A (n=42)		Group B (n=42)		P value
	Mean	SD	Mean	SD	
	535.12	73.679	574.52	74.619	0.017

Graph 6: Comparison of duration of the sensory block between the groups



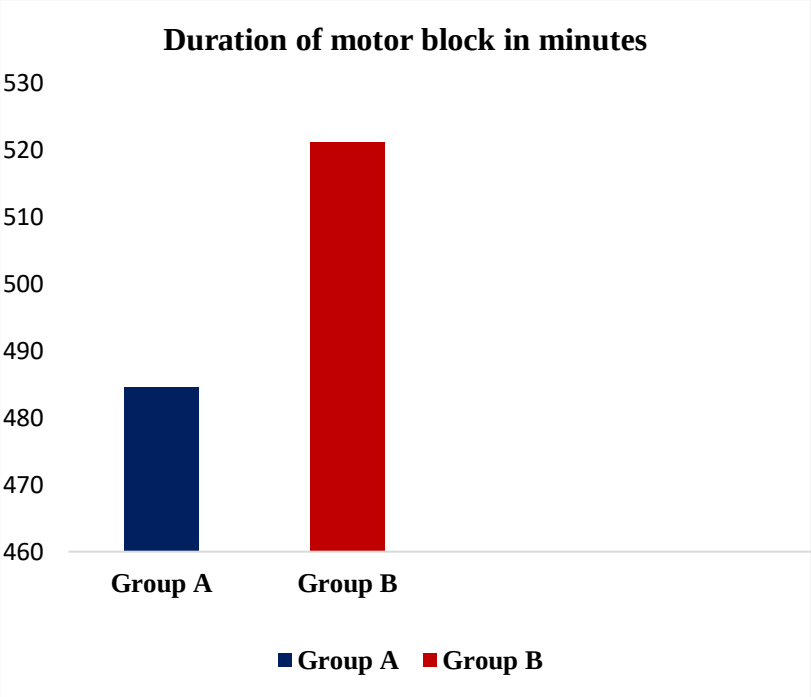
7. Duration of motor block:

- The values are represented as mean and standard deviation. The units are in minutes.

Table 7: Comparison of duration of motor block between the groups

Duration of motor block	Group A (n=42)		Group B (n=42)		P value
	Mean	SD	Mean	SD	
	484.52	75.594	521.07	72.394	0.026

Graph 7: Comparison of duration of the motor block between the groups



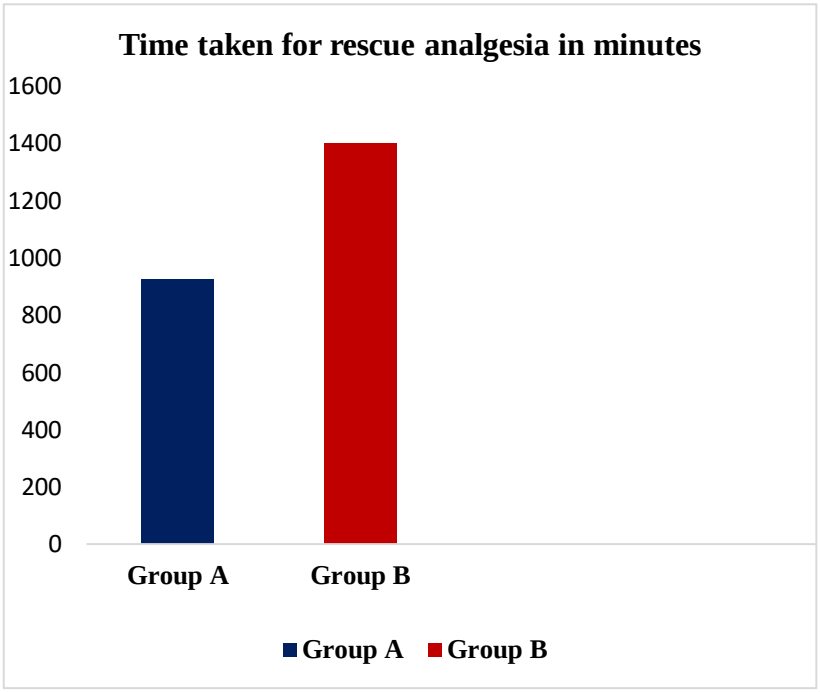
8. Time taken for first rescue analgesia:

- The values are represented as mean and standard deviation. The units are in minutes.

Table 8: Comparison of time taken for first rescue analgesia between the groups

Time taken for first rescue analgesia	Group A (n=42)		Group B (n=42)		P value
	Mean	SD	Mean	SD	
	925.83	248.964	1398.81	235.762	0.000

Graph 8: Comparison of time taken for first rescue analgesia between the group



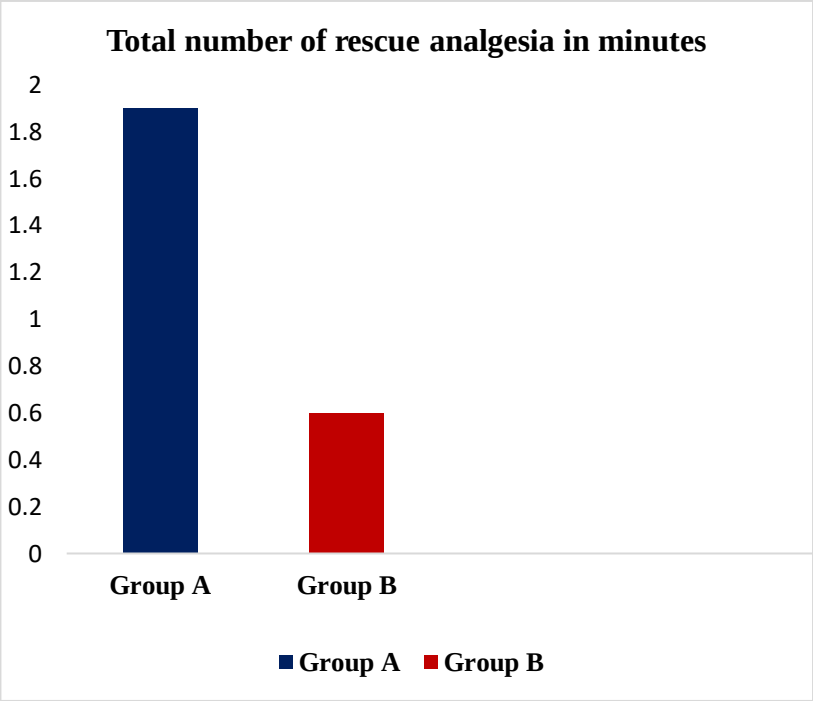
9. Total number of rescue analgesia:

- The values are represented as mean and standard deviation.

Table 9: Comparison of total number of rescue analgesia between the groups

Total number of rescue analgesia	Group A (n=42)		Group B (n=42)		P value
	Mean	SD	Mean	SD	
	1.90	0.532	0.60	0.701	0.000

Graph 9: Comparison of total number of rescue analgesia between the groups



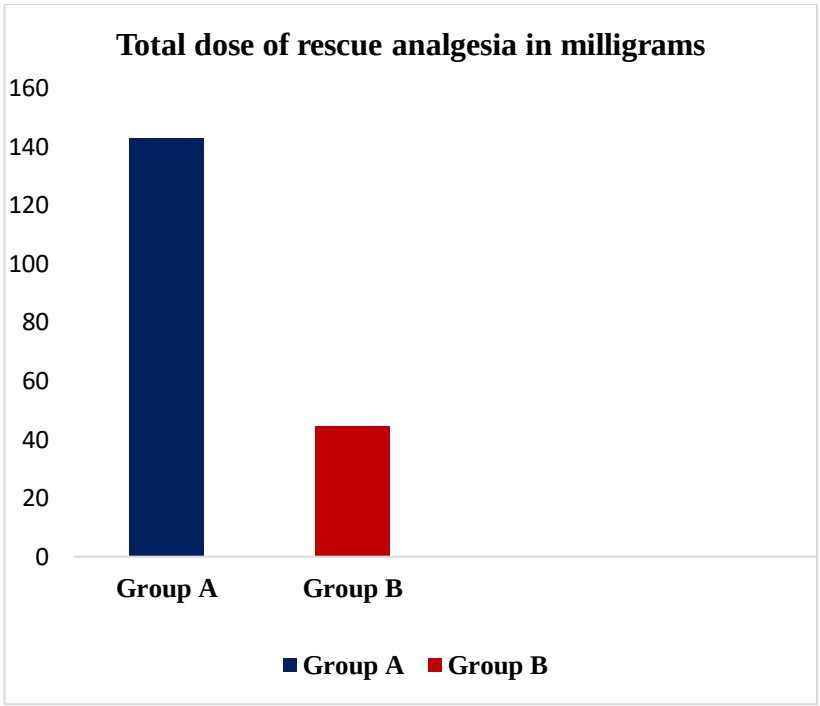
10. Total dose of rescue analgesia:

- The values are represented as mean and standard deviation. The units are in milligrams (mg).

Table 10: Comparison of total dose of rescue analgesia between the groups

Total dose of rescue analgesia	Group A (n=42)		Group B (n=42)		P value
	Mean	SD	Mean	SD	
	142.86	39.926	44.64	52.538	0.000

Graph 10: Comparison of the total dose of rescue analgesia between the groups



11. VAS at 2 hours:

- The values are represented as mean and standard deviation.

Table 11: Comparison of VAS at 2 hours between the groups

VAS at 2 hours	Group A (n=42)		Group B (n=42)		P value
	Mean	SD	Mean	SD	
	0.00	0.000	0.00	0.000	---

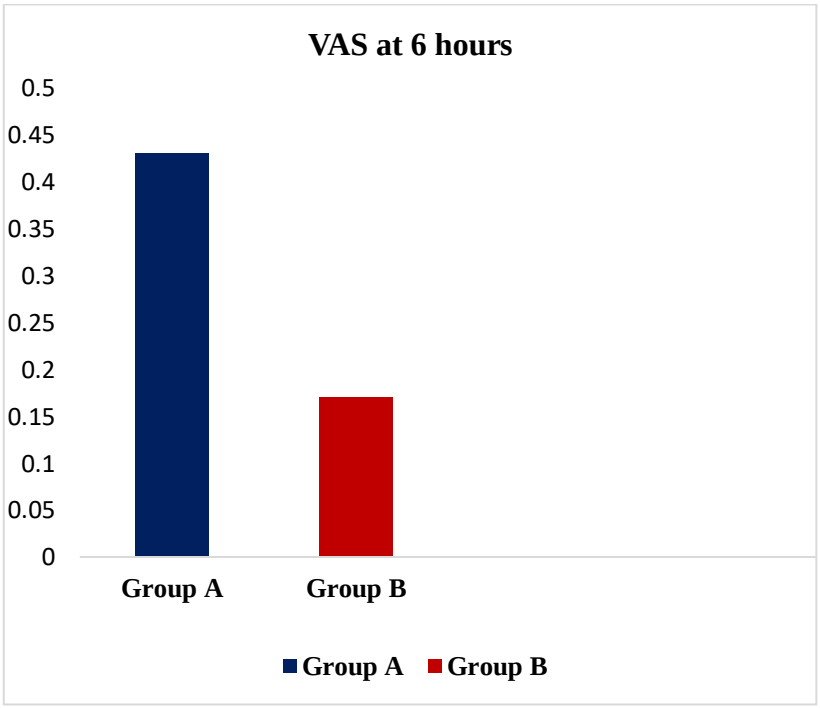
12. VAS at 6 hours:

- The values are represented as mean and standard deviation.

Table 12: Comparison of VAS at 6 hours between the groups

VAS at 6 hours	Group A (n=42)		Group B (n=42)		P value
	Mean	SD	Mean	SD	
	0.43	0.501	0.17	0.437	0.013

Graph 11: Comparison of VAS at 6 hours between the groups



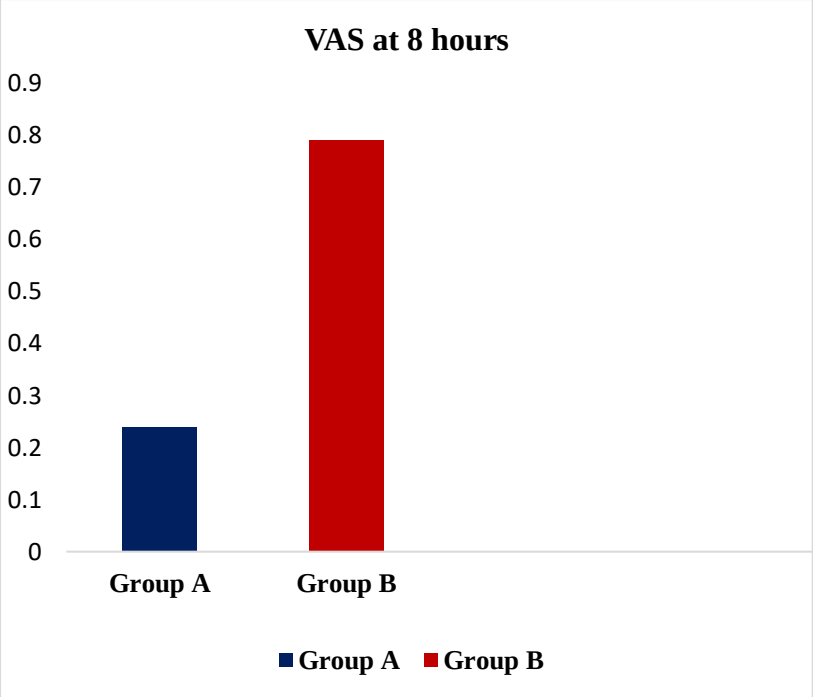
13. VAS at 8 hours:

- The values are represented as mean and standard deviation.

Table 13: Comparison of VAS at 8 hours between the groups

VAS at 8 hours	Group A (n=42)		Group B (n=42)		P value
	Mean	SD	Mean	SD	
	1.24	0.656	0.79	0.645	0.002

Graph 12: Comparison of VAS at 8 hours between the groups



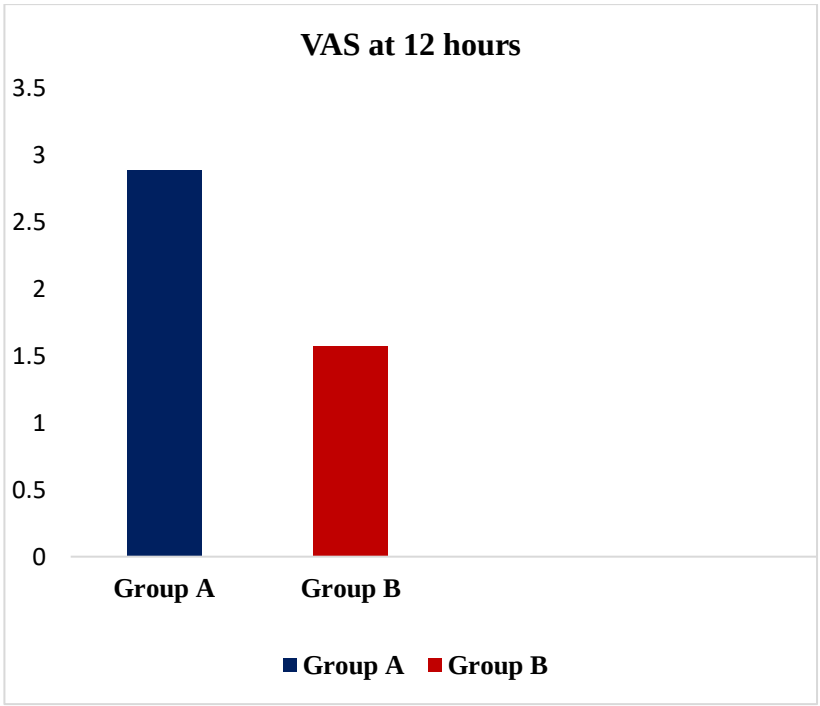
14. VAS at 12 hours:

- The values are represented as mean and standard deviation.

Table 14: Comparison of VAS at 12 hours between the groups

VAS at 12 hours	Group A (n=42)		Group B (n=42)		P value
	Mean	SD	Mean	SD	
	2.88	0.803	1.57	0.737	0.000

Graph 13: Comparison of VAS at 12 hours between the groups



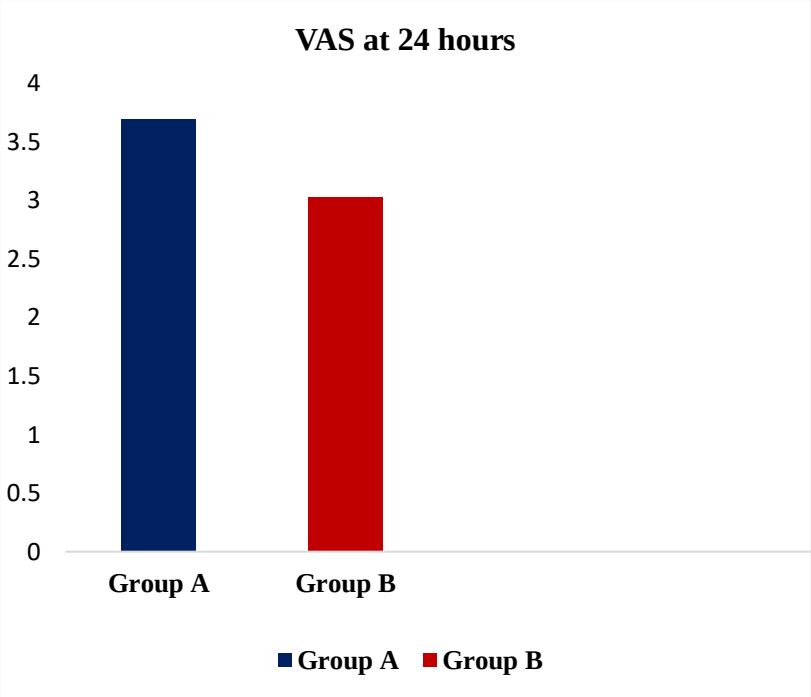
15. VAS at 24 hours:

- The values are represented as mean and standard deviation.

Table 15: Comparison of VAS at 24 hours between the groups

VAS at 24 hours	Group A (n=42)		Group B (n=42)		P value
	Mean	SD	Mean	SD	
	3.69	0.680	3.02	0.715	0.000

Graph 14: Comparison of VAS at 24 hours between the groups



DISCUSSION

1. Onset of sensory and motor block

Our study shows that the mean onset of sensory block was 8.19 min in the dexamethasone group and 9.38 min in the dexmedetomidine group. (p = 0.001, statistically significant)

The mean onset of motor block was 8.62 min in the dexamethasone group and 9.02 min in the dexmedetomidine group. (p = 0.344, statistically not significant)

Kaygusuz et al. reported that the onset of sensory block time was 7.75 and the onset of motor block was 14.25 when dexmedetomidine and 0.5% levobupivacaine were used in axillary brachial plexus block.[62]

A study by Yadav et al. showed that the onset of sensory block was 12.57 min, and the onset of motor block was 22.47 min when dexamethasone and clonidine were used as adjuvants to levobupivacaine in the supraclavicular brachial plexus block.[63]

Kaur et al. reported that the onset of sensory block was 6.9 min and the onset of motor block was 8.1 min in supraclavicular brachial plexus block when dexmedetomidine was used as an adjuvant to levobupivacaine.[58]

A study by Kaur et al. concluded that the onset of sensory block was 5.62 min with dexmedetomidine and 6.2 min with dexamethasone. The onset of motor block was 11.8 min with dexmedetomidine and 19.2 min with dexamethasone when these two drugs were compared in a supraclavicular block.[64]

2. Duration of sensory and motor block

In this study, the mean duration of sensory block was 535.12 min in the dexamethasone group and 574.52 min in the dexmedetomidine group. (p = 0.017, statistically significant)

The mean duration of motor block was 484.52 min in the dexamethasone group and 521.07 min in the dexmedetomidine group. (p = 0.026, statistically significant)

A study by Shamjit et al. reported that the duration of sensory block was 531 min, and the duration of motor block was 553 min when the efficacy of dexmedetomidine to levobupivacaine was compared in brachial plexus block.[65]

Vasconcelos MM et al. reported that the duration of sensory block was 1440 min when perineural dexamethasone was given with levobupivacaine in ISBPB.[66]

Research by Kaur et al. showed that the duration of a sensory and motor block with dexmedetomidine was 902.8 min and 858.2 min, respectively, and with dexamethasone, it was 736 min and 684.6 min, respectively, in a supraclavicular block.[64]

3. Time taken for first rescue analgesia

The mean time taken for first rescue analgesia in our study was 925.83 min in the dexamethasone group and 1398.81 min in the dexmedetomidine group. (p = 0.000, statistically significant)

A study by Kaur et al. concluded that a rescue analgesic dose was given after 874.6 min in the dexmedetomidine group and 772.6 min in the dexamethasone group when these two drugs were compared in a supraclavicular block.[64]

4. Total number of rescue analgesia

The mean total number of rescue analgesia in this study was 1.90 in the dexamethasone group and 0.6 in the dexmedetomidine group. (p = 0.000, statistically significant)

Research by Das A[67] et al. showed that the mean number of rescue analgesia in the ropivacaine with dexmedetomidine group was 1.15 compared to ropivacaine alone.

5. Total dose of rescue analgesia

Our study showed that the mean total dose of rescue analgesia (Inj. Diclofenac 75 mg in 100 ml NS iv) was 142.86 mg in the dexamethasone group and 44.64 mg in the dexmedetomidine group. (p = 0.000, statistically significant)

Kathuria S et al. reported that the mean total dose of rescue analgesia used was 56.2 mg when dexmedetomidine was given as an adjuvant to ropivacaine in a supraclavicular brachial plexus block .[68]

6. Comparison of VAS at 2, 6, 8, 12, & 24 hours

In our study at 2 hours, there was no change in VAS in both the groups.

At 6 hours, the mean VAS was 0.43 in the dexamethasone group and 0.17 in the dexmedetomidine group. (p = 0.013, statistically significant)

At 8 hours, the mean VAS was 1.24 in the dexamethasone group and 0.79 in the dexmedetomidine group. (p = 0.002, statistically significant)

At 12 hours, the mean VAS was 2.88 in the dexamethasone group and 1.57 in the dexmedetomidine group. (p = 0.000, statistically significant)

At 24 hours, the mean VAS was 3.69 in the dexamethasone group and 3.02 in the dexmedetomidine group. (p = 0.000, statistically significant)

In our study, no side effects were seen with dexamethasone or dexmedetomidine. Dexmedetomidine may cause side effects such as hypotension, bradycardia, and sedation at higher doses.[69] Studies have shown that corticosteroid-mediated neurotoxicity is due to the preservative benzyl alcohol used in steroids and sometimes because of the presence of vehicle polyethylene glycol.[70,71]

Margulis R, et al. reported that the use of opioids during surgery was reduced with dexmedetomidine compared to dexamethasone and ropivacaine. Dexmedetomidine can be used as a safe alternative for peripheral nerve blockade when dexamethasone is contraindicated, as it has a better safety profile.[72]

The efficacy of dexmedetomidine seems to be comparable to buprenorphine and dexamethasone for peripheral nerve block and exceeds that of clonidine, magnesium, and midazolam as an adjuvant.[73-83]

The reason for the inconsistency about the onset and duration of the block may be due to the patient's anatomical variations and differences in the spread of local anesthetic, category of LA drug used, type of nerve block, dose of the drug, and technique used to perform the block.[84]

CONCLUSION

Interscalene brachial plexus blockade provides postoperative pain management in the proximal humerus, clavicle fractures, and glenohumeral dislocations. It reduces the use of opioids in patients recovering from shoulder surgery.

Mixing local anesthetic with adjuvant drugs has prolonged analgesia for nerve blocks. Dexamethasone is a long-acting steroid that provides an effective analgesic effect. It is used to reduce postoperative nausea, vomiting, and pain. Dexmedetomidine is a centrally acting alpha 2 adrenoceptor agonist. In peripheral nerve blocks, these two drugs are used as adjuvants to local anesthetics.

Our study concludes that:

- The onset of sensory and motor blockade was faster with the dexamethasone group than the dexmedetomidine group.
- The duration of action was longer with the dexmedetomidine group than the dexamethasone group.
- The time taken for the first dose of rescue analgesia was prolonged with the dexmedetomidine group than the dexamethasone group. The total dose of rescue analgesics given was less with the dexmedetomidine group than the dexamethasone group.
- The postoperative VAS score was less with the dexmedetomidine group than the dexamethasone group.

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ETHICAL CLEARANCE

Azadi Ka Amrit Mahotsav

BLDE
(DEEMED TO BE UNIVERSITY)
Declared as Deemed to be University u/s 3 of UGC Act, 1956
Accredited with 'A' Grade by NAAC (Cycle-2)
The Constituent College
SHRI B. M. PATIL MEDICAL COLLEGE, HOSPITAL & RESEARCH CENTRE, VIJAYAPURA

BLDE (DU)/IEC/ 951/2023-24 10/4/2023

INSTITUTIONAL ETHICAL CLEARANCE CERTIFICATE

The Ethical Committee of this University met on **Saturday, 18th March, 2023 at 11.30 a.m. in the CAL Laboratory, Dept. of Pharmacology,** scrutinized the Synopsis/ Research Projects of Post Graduate Student / Under Graduate Student /Faculty members of this University /Ph.D. Student College from ethical clearance point of view. After scrutiny, the following original/ corrected and revised version synopsis of the thesis/ research projects has been accorded ethical clearance.

TITLE: "A COMPARATIVE STUDY TO KNOW THE ANALGESIC EFFICACY OF DEXAMETHASONE AND DEXMEDETOMIDINE AS ADJUVANT TO LEVOBUPIVACAINE FOR INTERSEALENE BRACHIAL PLEXUS BLOCK IN PATIENTS UNDERGOING ORTHOPAEDIC SHOULDER SURGERIES -A RANDOMISED CLINICAL TRIAL".

NAME OF THE STUDENT/PRINCIPAL INVESTIGATOR: DR.PRABHU S. ANGADI

NAME OF THE GUIDE: DR.VIJAY V. KATTI, ASSOCIATE PROFESSOR, DEPT. OF ANAESTHESIOLOGY.

Dr. Santoshkumar Jeevangi
Chairperson
IEC, BLDE (DU),
VIJAYAPURA
Chairman,
Institutional Ethical Committee,
BLDE (Deemed to be University)
Vijayapura

Dr.Akram A. Naikwadi
Member Secretary
IEC, BLDE (DU),
VIJAYAPURA
MEMBER SECRETARY
Institutional Ethics Committee
BLDE (Deemed to be University)
Vijayapura-586103. Karnataka

Following documents were placed before Ethical Committee for Scrutinization.

- Copy of Synopsis/Research Projects
- Copy of inform consent form
- Any other relevant document

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SAMPLE OF INFORMED CONSENT

A COMPARATIVE STUDY OF THE ANALGESIC EFFICACY OF DEXAMETHASONE AND DEXMEDETOMIDINE AS ADJUVANTS TO LEVOBUPIVACAINE FOR INTERSCALENE BRACHIAL PLEXUS BLOCK IN PATIENTS UNDERGOING ORTHOPEDIC SHOULDER SURGERIES – A RANDOMIZED CLINICAL TRIAL

I have briefly explained the reason for doing this study and selected myself/my ward as a subject for this study. I have also been given various choices for either being included or not in the study. I understand that I will be participating in the study. I understand that my ward's participation in this study will help in finding out the **onset and duration of sensory and motor block and the analgesic efficacy of dexmedetomidine and dexamethasone as an adjuvant to levobupivacaine for ISBPB in patients undergoing shoulder surgeries**. I understand that medical records produced by this study will become a part of the Hospital records and will be subjected to the confidentiality and privacy regulations of this hospital. The data are used for publication in the medical literature or for teaching purposes. No names will be used, and other identifiers such as pictures and audio or videotapes. I understand that I may see the photographs and videos and hear audiotapes before giving this permission. I understand that I may ask more questions about the study at any time, and Dr. Prabhu S Angadi is available to answer my questions or concerns. If during this study, or later, I wish to discuss my participation in or concerns regarding this study with a person not directly involved, I am aware that the social worker of the hospital is available to talk with me and that a copy of this consent form will be given to me for careful reading. I understand that my participation is voluntary, and I may refuse to participate or may withdraw consent and discontinue

participation in the study at any time without prejudice to my present or future care at this hospital.

I also understand that Dr. Prabhu S Angadi will terminate my participation in this study at any time after he/she has explained the reasons for doing so and has helped arrange for my continued care by my own physician or therapist if this is appropriate.

I understand that in the unlikely event of injury to me/my ward resulting directly due to my participation in this study, such injury will be reported promptly, and then medical treatment will be available to me, but no further compensation will be provided. I understand that by my agreement to participate in this study, I am not waiving any of my legal rights.

I have explained the purpose of this research, the procedures required, and the possible risks and benefits to the best of my ability in the patient's language.

Date: Dr. Vijay. V. Katti (Guide) Dr. Prabhu S Angadi (Investigator)

Place:

I confirm that Dr. Prabhu S Angadi has explained to me the purpose of this research, the study method that I will undergo, and the possible discomforts and benefits that I may experience in my language. I have explained all the above things briefly in my language, and I understand the same. Therefore, I agree to give consent to be a subject in the research project.

Date: **Dr. Prabhu S Angadi**

(Investigator)

Patient's signature

Witness to the above signature

B.L.D.E (DEEMED TO BE UNIVERSITY) &ರ್ರೀ ಬಿ.ಎಂ.ಪ ಟ್ಟೀಲ್ ಮೆಡಿಕಲ್ ಕಾಲೇಜು, ಆಸ್ಪತ್ರೆರ ಮತ್ತುತಸಂಶೆಂೀ ೞನಾ ಕೇಂದ್ರ, ವಿಜಯಪುರ-586103

ಪ್ರಬಂೞ/ಸಂಶೆಂೀ ೞನೆಯಲ್ಲಿಲ ಪಾಲೊ ಳ್ಳಲು ಮಾಹಿತಿ ಪಡೆದ ಸಮ್ಮತಿ

ನಾನು, ಕೆಳಗಿನವರು ಸಹಿಯಿಟ್ಟವರು, ಮಗ/ಮಗಳು/ಪತಿನಯ ವಯಸ್ಸು ವಷxಗಳು, ಸಾಮಾನ್ಯವಾಗಿ ನಿವಾಸಿಸುವ ಸ್ಥಳದ ಹೆಸರು , ಇಲ್ಲಿಲ ಹೇಳಿದೆದೀನೆ/ ೂಂೀಷಿಸುತಿತೀನೆ ಡಾಕ್ಟರ್ ಹೆಸರು ಅವರು ಆಸ್ಪತೆರ ಹೆಸರು ಅವರು ನನ್ನನುನ ಪೂಣxವಾಗಿ ಪರೀಕ್ಷಿಸಿದರು ದಿನಾಂಕದಲ್ಲಿಲ ಸ್ಥಳ ಹೆಸರು ಮತ್ತುತನನಗೆ ನನ್ನ ಭಾಷೆಯಲ್ಲಿಲವಿವರಿಸಲಾಗಿದೆ ನಾನು ಒಂದು ರೋೀ ಗ (ಸಿೞತಿ) ಅನುಭವಿಸುತಿತದೆದೀನೆ. ಮುಂದುವರಿದು ಡಾಕ್ಟರ್ ನನಗೆ ತಿಳಿಸಿದ್ದರೆ ಅವರು ಒಂದು ಪದ್ಧತಿ/ಸಂಶೆಂೀ ೞನೆ ನಡೆಸುತಿತದ್ದರೆ &ೀಷಿxಕೆಯುಳ್ಳ ಡಾಕ್ಟರ್ ಮಾಗxದಶxನದಲ್ಲಿಲನನ್ನ ಪಾಲೊ ಳ್ಳುವಿಕೆಯನುನ ಕೇಳಿದ್ದರೆ ಅಂೞಯನದಲ್ಲಿಲ.

ಡಾಕ್ಟರ್ ನನಗೆ ಇದನುನ ಕೂಡಾ ತಿಳಿಸಿದ್ದರೆ ಈ ಕ್ರಮದ ನಡೆವಲ್ಲಿಲ ಪ್ರತಿಕೂಲ ಫಲಿತಾಂಶಗಳನುನ ಎದುರಿಸಬಹುದು. ಮೇಲೆ ಹೇಳಿದ ಪ್ರಕಟಣೆಗಳಲ್ಲಿಲ, ಅಧಿಕಾಂಶವು ಚಿಕಿತಿ,ಸಬಹುದಾದರೂ ಅದನುನ ನಿರೀಕ್ಷಿಸಲಾಗುತಿತಲ್ಲ,ಆದ್ದರಿಂದ ನನ್ನ ಸಿೞತಿಯ ಹಿರಿದಾಗುವ ಅವಕಾಶವಿದೆ ಮತ್ತುತಅಪರೂಪದ ಸಂದಭxಗಳಲ್ಲಿಲಅದು ಮರಣಕಾರಕವಾಗಿ ಪರಿಣಮಿಸಬಹುದು ಹೊ ಂದಿದ ರೋೀ ಗನಿಧಾxರ ಮತ್ತುತ ಯಥಾಶಕ್ತಿತ ಚಿಕಿತೆ, ಮಾಡಲು ಹೊ ಂದಿದರೂ. ಮುಂದುವರಿದು ಡಾಕ್ಟರ್ ನನಗೆ ತಿಳಿಸಿದ್ದರೆ ನನ್ನ ಪಾಲೊ ಳ್ಳುವಿಕೆ ಈ ಅಂೞಯನದ ಫಲಿತಾಂಶಗಳ ಮೌಲ್ಯಮಾಪನದಲ್ಲಿಲಸಹಾಯಕವಾಗುತತ್ತದೆ ಇತರ ಸಮಾನ ಪ್ರಕರಣಗಳ ಚಿಕಿತೆ,ಗೆ ಉಪಯುಕ್ತಉಲ್ಲೀಖವಾಗಿದೆ, ಮತ್ತುತ ನಾನು ಅನುಭವಿಸುವ ರೋೀ ಗದಿಂದ ವಿಮುಕ್ತಿತ ಅಥವಾ ಗುಣಮುಖೊ ಳ್ಳುವಲ್ಲಿಲ ನನಗೆ ಪ್ರ£ೀಜನವಾಗಬಹುದು.

ಡಾಕ್ಟರ್ ನನಗೆ ಇದನುನ ಕೂಡಾ ತಿಳಿಸಿದ್ದರೆ ನನಿನಂದ ನೀಡಿದ ಮಾಹಿತಿ, ಮಾಡಿದ ಪರಿ&ೀಲನೆಗಳು / ೀಟೋೀಗ್ರಫ್ಗಳು / ವೀಡಿ£ೀ ಗ್ರಫ್ಗಳು ನನ್ನ ಮೇಲೆ ತೆಗೆದುಕೊಳ್ಳಲಾಗುವ ಅನೆವೀಷಕರು ರಹಸ್ಯವಾಗಿ ಇಡುವರು ಮತ್ತುತನಾನು ಅಥವಾ ನನಗೆ ಕಾನೂನು ದೃಷ್ಟಿಟಯಲ್ಲಿಲಸಂಬಂಧಿತrannu ಹೊ ರತುಪಡಿಸಿ ಇತರ ವ್ಯಕ್ತಿತಯಿಂದ ಮೌಲ್ಯಮಾಪನ ಮಾಡಲಾಗುವುದಿಲ್ಲ. ಡಾಕ್ಟರ್ ನನಗೆ ತಿಳಿಸಿದ್ದರೆ ನನ್ನ ಪಾಲೊ ಳ್ಳುವಿಕೆ ಶುದ್ಧವಾಗಿ ಸೆವೀಚಾಯಿತ, ನನಿನಂದ ನೀಡಿದ ಮಾಹಿತಿಯ ಆಧಾರದ ಮೇಲೆ, ಚಿಕಿತೆ, / ಅಂೞಯನದ ಸಂಬಂೞದಲ್ಲಿಲ ರೋೀ ಗನಿಧಾxರ, ಚಿಕಿತೆ,ಯ ವಿಧಾನ, ಚಿಕಿತೆ,ಯ ಫಲಿತಾಂಶ ಅಥವ ಆ ಭವಿಷ್ಯದ ಪ್ರವೃತಿತಗಳು ಬಗೆ ಯಾವುದೇ ಸ್ಪಷ್ಟತೆ ಕೇಳಬಹುದು. ಅದೇ ಸಮಯದಲ್ಲಿಲ ನನಗೆ ತಿಳಿಸಲಾಗಿದೆ ನಾನು ಯಾವುದೇ ಸಮಯದಲ್ಲಿಲ ಈ ಅಂೞಯನದಲ್ಲಿಲ ನನ್ನ ಪಾಲೊ ಳ್ಳುವಿಕೆಯನುನ ನಿಲ್ಲಿಲಸಬಹುದು ನಾನು ಬಯಸಿದರೆ ಅಥವಾ ಅನೆವೀಷಕರು ಅಂೞಯನದಿಂದ ಯಾವುದೇ ಸಮಯದಲ್ಲಿಲನನ್ನನುನ ನಿಲ್ಲಿಲಸಬಹುದು.

ಪ್ರಬಂೞ ಅಥವಾ ಸಂಶೆಂೀ ೞನೆಯ ಸ್ವಭಾವ, ಮಾಡಿದ ರೋೀ ಗನಿಧಾxರ ಮತ್ತುತ ಚಿಕಿತೆ,ಯ ವಿಧಾನವನುನ ಅಥxಮಾಡಿಕೊಂಡು, ನಾನು ಕೆಳಗಿನ &ರ್ರೀ / &ರ್ರೀಮತಿ ನನ್ನ ಪೂಣxವಾದ ಪ್ರcೆಯ ಸಿೞತಿಯಲ್ಲಿಲಹೇಳಿದ ಸಂಶೆಂೀ ೞನೆ / ಪ್ರಬಂೞದಲ್ಲಿಲಪಾಲೊ ಳ್ಳಲು ಒಪ್ಪುತಿತೀನೆ.

ರೋೀ ಗಿಯ ಸಹಿ ಡಾಕ್ಟರನ ಸಹಿ ಸಾಕ್ಷಿಗಳು

1)

2)

SCHEME OF CASE TAKING

A COMPARATIVE STUDY OF THE ANALGESIC EFFICACY OF DEXAMETHASONE AND DEXMEDETOMIDINE AS ADJUVANTS TO LEVOBUPIVACAINE FOR INTERSCALENE BRACHIAL PLEXUS BLOCK IN PATIENTS UNDERGOING ORTHOPEDIC SHOULDER SURGERIES – A RANDOMIZED CLINICAL TRIAL

Name: Age/ Sex:

I.P No: DATE

Group allotted by randomization: Group A / Group B

Type of surgery:

Significant History:

General Physical Examination:

Pallor Y/N IcterusY/N CyanosisY/N ClubbingY/N

Koilonychia Y/N Lymphadenopathy Y/N EdemaY/N TeethY/N

DenturesY/N

Vital Parameters

Pulse (beats per minute): Blood Pressure:

Respiratory Rate: Temperature:

Systemic Examination

1. CVS:
2. RS:
3. CNS:
4. Per Abdomen:

Airway Assessment:

Mallampati grade: Cervical spine:

Mouth opening: Neck movement:

ASA grade:

Investigations:

Hemoglobin: TLC:

S. Urea: S. Creatinine

RBS: Platelet count:

Urine Routine:

Chest X-ray: ECG:

Block start time: Block end time:

Surgery start time: Surgery end time:

Time	Sensory block	Motor block
0 min		
2 min		
4 min		
6 min		
8 min		
10 min		

Post op VAS scale:

	VAS SCORE
30 minutes	
1 hours	
2 hours	
6 hours	
8 hours	
12 hours	
24 hours	

PARAMETERS

Sl no	TIME FROM BLOCK	PR	BP	MAP	REMARKS

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MASTER CHART

Sl No	IP No	Name	Age (yr)	Gender	ASA grade	Group	Onset of sens	Onset of moto	Duration of sensory	Duration of motor	Time taken for 1st rescue	Dose of analgesi	No of rescue	VAS at 2 h	VAS at 6	VAS at 8	VAS at 12	VAS at 24 h
1	148880	Savitha	36	F	1	A	10	10	365	330	850	150	2	0	1	1	4	4
2	158242	Yasubai	49	F	1	A	8	8	345	305	945	150	2	0	1	1	3	2
3	244995	Parashuram	36	M	1	A	6	6	480	435	1050	75	1	0	1	2	3	3
4	230387	Ravindra	46	M	1	A	8	8	500	445	965	150	2	0	1	2	3	4
5	243099	Supriya	19	F	1	A	8	8	525	480	880	150	2	0	1	1	2	4
6	165770	Sapnil	24	M	1	A	10	15	460	410	660	150	2	0	1	2	3	4
7	304164	Mananda	40	F	1	A	6	8	545	510	1320	75	1	0	0	1	2	4
8	340582	Renuka	55	F	1	A	8	8	705	665	1415	75	1	0	0	0	1	3
9	333952	Arvind	60	M	1	A	8	10	610	555	1535	75	1	0	0	0	1	2
10	317915	Ashok	45	M	1	A	14	10	610	535	1495	75	1	0	0	1	2	3
11	348906	Shankraya	43	M	1	A	12	10	585	530	910	150	2	0	0	1	3	2
12	300262	Anand	61	M	2	A	10	10	565	505	655	225	3	0	0	2	3	3
13	416770	Laxmi	51	F	1	A	8	8	610	610	850	150	2	0	0	1	3	4
14	520200	Aiyappa	60	M	1	A	8	8	540	500	830	150	2	0	0	0	2	3
15	119785	Mallappa	36	M	1	A	6	6	520	480	615	225	3	0	0	1	3	4
16	184556	Seetabai	52	F	2	A	8	10	490	430	1040	150	2	0	1	1	3	4
17	160004	Jevibai	60	F	1	A	8	8	610	555	1380	75	1	0	0	1	2	4
18	190946	Siddawwa	52	F	2	A	8	8	610	565	1065	75	1	0	0	1	2	4
19	160270	Shantava	50	F	1	A	8	8	600	545	865	150	2	0	0	1	3	4
20	148231	Basangouda	44	M	1	A	8	8	530	490	810	150	2	0	1	1	4	4
21	183618	Ghaleppa	43	M	2	A	8	8	450	370	860	150	2	0	1	2	4	4
22	177832	Viresh	32	M	1	A	8	8	530	490	840	150	2	0	1	1	3	4
23	196479	Gurulingappa	53	M	2	A	8	8	550	490	820	150	2	0	0	2	3	4
24	151597	Revanasiddha	29	M	1	A	8	8	440	395	510	225	3	0	1	3	3	4
25	231480	Kasturi	46	F	2	A	6	8	620	585	785	150	2	0	0	1	3	4
26	235734	Muragesh	52	M	2	A	6	8	460	400	760	150	2	0	1	1	3	4
27	238333	Rajendra	60	M	2	A	6	8	440	375	850	150	2	0	1	2	3	4
28	488033	Pundalik	60	M	1	A	6	6	580	530	790	150	2	0	0	1	3	4
29	180560	Bwanasab	60	M	1	A	8	6	540	485	855	150	2	0	0	1	4	4
30	333630	Hunagodappa	43	M	1	A	6	8	610	560	910	150	2	0	0	1	3	4
31	175243	Channamma	60	F	2	A	8	10	520	450	880	150	2	0	1	2	3	4
32	374502	Mahadevi	60	F	2	A	10	10	500	450	860	150	2	0	1	1	4	5
33	220919	Bandagisab	41	M	1	A	8	6	500	430	850	150	2	0	1	2	3	4
34	374061	Shantava	58	F	1	A	8	10	650	590	880	150	2	0	0	1	4	3
35	326020	Maibubsab	45	M	1	A	10	10	490	440	795	150	2	0	1	2	4	4
36	6204	Mahadevi	52	F	2	A	10	15	460	410	660	150	2	0	1	2	3	4
37	617126	Mallamma	60	F	2	A	8	10	610	555	1535	75	1	0	0	0	1	2
38	277247	Shrishail	27	M	1	A	6	6	520	480	615	225	3	0	0	1	3	4
39	8055	Jayashree	35	F	1	A	8	8	600	545	865	150	2	0	0	1	3	4
40	86552	Sanjog	40	M	1	A	8	8	550	490	820	150	2	0	0	2	3	4
41	97241	Shahzad	23	M	1	A	8	6	540	485	855	150	2	0	0	1	4	4
42	28430	Munera	48	F	2	A	12	12	510	465	1155	150	2	0	0	1	2	4

Sl No	IP No	Name	Age (yr)	Gender	ASA grade	Group	Onset of	Onset of m	Duration o	Duration o	Time taker	Dose of res	No of rescu	VAS at 2 h	VAS at 6 h	VAS at 8 h	VAS at 12 h	VAS at 24 h
1	165778	Dharesh	23	M	1	B	8	10	500	440	1440	75	1	0	0	1	1	3
2	159442	Irfan	35	M	1	B	6	4	360	325	1215	75	1	0	1	2	2	4
3	239001	Naseer	27	M	1	B	10	6	620	570	990	150	2	0	0	1	4	3
4	148753	Parashuran	47	M	1	B	10	10	390	330	710	150	2	0	2	3	2	4
5	228116	Vitthal	40	M	1	B	8	14	610	560	1580	75	1	0	0	1	1	2
6	347404	Shivaraj	25	M	1	B	12	15	620	555	1175	75	1	0	0	0	1	3
7	350406	Ramchandr	40	M	1	B	8	8	520	475	775	150	2	0	1	2	3	3
8	347325	Dayanand	29	M	1	B	10	8	520	485	905	150	2	0	0	1	3	4
9	291184	Agham	18	M	1	B	8	8	545	505	925	150	2	0	0	1	3	4
10	503030	Ramesh	35	M	1	B	8	8	510	440	1055	75	1	0	1	1	2	4
11	126544	Vijay	32	M	1	B	10	10	500	460	1310	75	1	0	1	1	2	3
12	305625	Ansuya	42	F	1	B	8	8	590	545	1615	75	1	0	0	1	1	2
13	198326	Suvarna	47	F	1	B	10	8	530	450	1470	75	1	0	1	1	2	3
14	130577	Mitibai	45	F	2	B	10	10	660	590	1450	75	1	0	0	0	1	2
15	159024	Rajesh	29	M	1	B	10	10	550	480	1390	75	1	0	0	1	1	3
16	165510	Arshad Ali	30	M	1	B	12	10	540	490	1430	75	1	0	0	1	2	4
17	211676	Sangamesh	22	M	1	B	10	12	600	550	1580	0	0	0	0	0	1	2
18	728331	Madanna	23	M	1	B	10	10	510	460	1360	75	1	0	0	1	2	4
19	192081	Alladin	43	M	1	B	12	10	580	530	1620	0	0	0	0	1	2	4
20	214324	Gowravva	58	F	2	B	12	10	560	515	1320	75	1	0	0	1	2	3
21	218819	Siddaram	35	M	1	B	10	8	535	475	1540	0	0	0	0	1	1	3
22	198837	Asif	30	M	1	B	10	8	600	550	1640	0	0	0	0	0	1	2
23	112747	Marappa	27	M	1	B	10	8	580	530	1510	0	0	0	0	1	1	3
24	227169	Shivanand	24	M	1	B	10	8	520	470	1510	0	0	0	0	1	1	3
25	249528	Sadashiv	18	M	1	B	8	10	580	530	1380	75	1	0	0	1	2	4
26	253195	Chidanand	40	M	1	B	8	8	600	540	1480	0	0	0	0	1	2	3
27	255810	Anil	42	M	1	B	8	10	630	575	1525	0	0	0	0	0	1	2
28	260765	Shashikala	43	F	1	B	8	8	500	465	1555	0	0	0	0	1	1	3
29	222266	Bhimappa	55	M	1	B	8	10	700	660	1500	0	0	0	0	0	1	3
30	183618	Nanagouda	52	M	1	B	8	8	630	575	1535	0	0	0	0	0	1	3
31	184556	Sunil	21	M	1	B	8	8	660	605	1575	0	0	0	0	0	1	3
32	174310	Gurubai	41	F	1	B	10	8	690	635	1505	0	0	0	0	0	1	3
33	255810	Anil	42	M	1	B	10	8	530	470	1470	0	0	0	0	1	1	2
34	246728	Raju	35	M	1	B	8	10	700	650	1520	0	0	0	0	0	1	2
35	262126	Indubai	41	F	1	B	10	10	600	545	1505	0	0	0	0	1	2	4
36	258374	Nagesh	34	M	1	B	10	8	590	540	1530	0	0	0	0	1	2	4
37	215501	Mallu	35	M	1	B	10	8	530	485	1565	0	0	0	0	1	1	3
38	285980	Savita	33	F	1	B	10	8	520	475	1490	0	0	0	0	1	2	3
39	217653	Jumanna	55	M	1	B	8	8	660	600	1560	0	0	0	0	0	1	2
40	13455	Naseer	29	M	1	B	12	10	670	590	1600	0	0	0	0	1	1	2
41	52029	Aravind	27	M	1	B	10	10	660	590	1405	75	1	0	0	0	2	3
42	6493	Mallappa	40	M	2	B	8	8	630	575	1535	0	0	0	0	0	1	3

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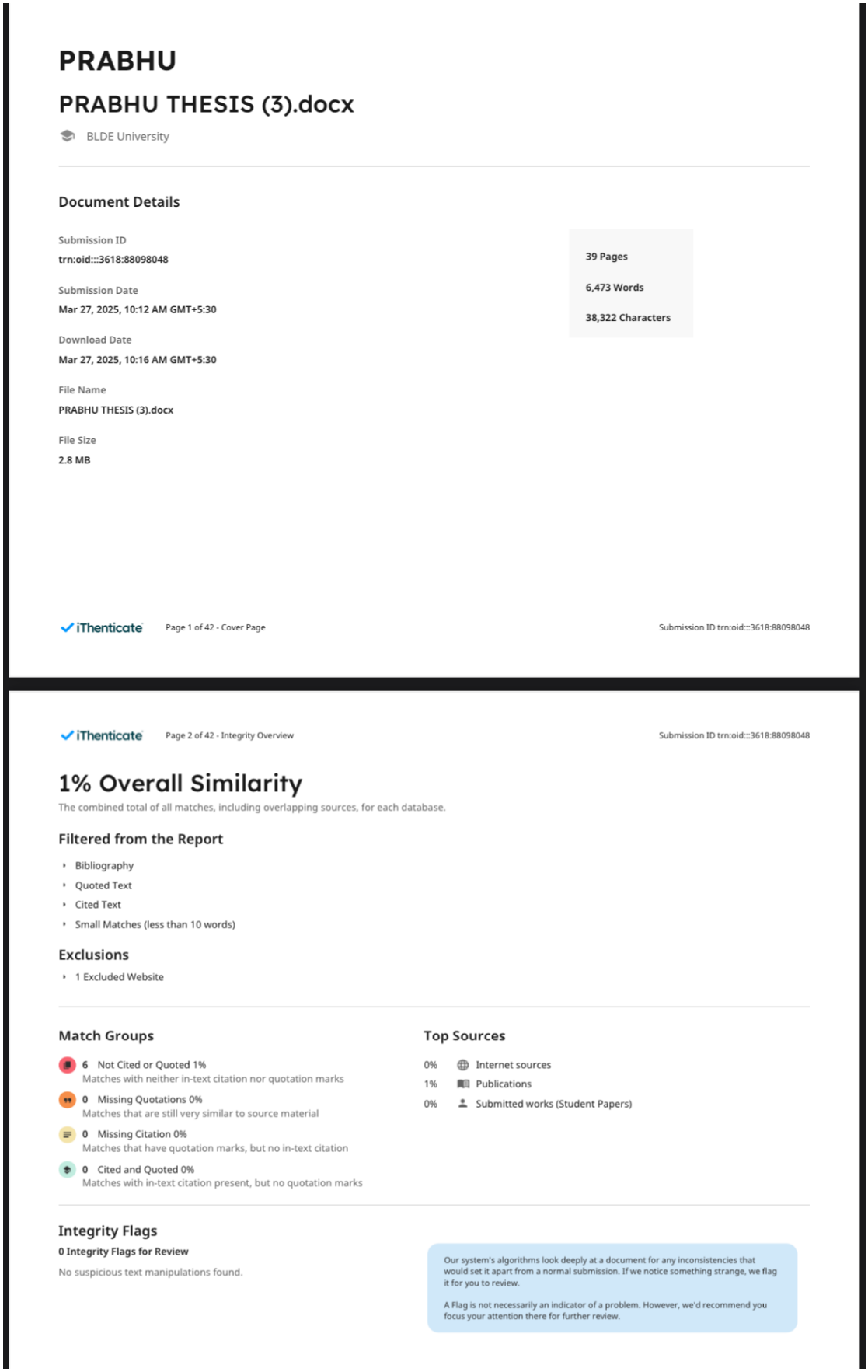

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