"COMPARISON BETWEEN EFFICACY OF INTRATHECAL TRAMADOL-BUPIVACAINE(H) AND FENTANYL-BUPIVACAINE(H) IN LOWER ABDOMINAL SURGERIES – A ONE YEAR HOSPITAL BASED RANDOMIZED CONTROL TRIAL CONDUCTED AT KLES DR. PRABHAKAR KORE CHARITABLE HOSPITAL AND RESEARCH CENTRE"

By

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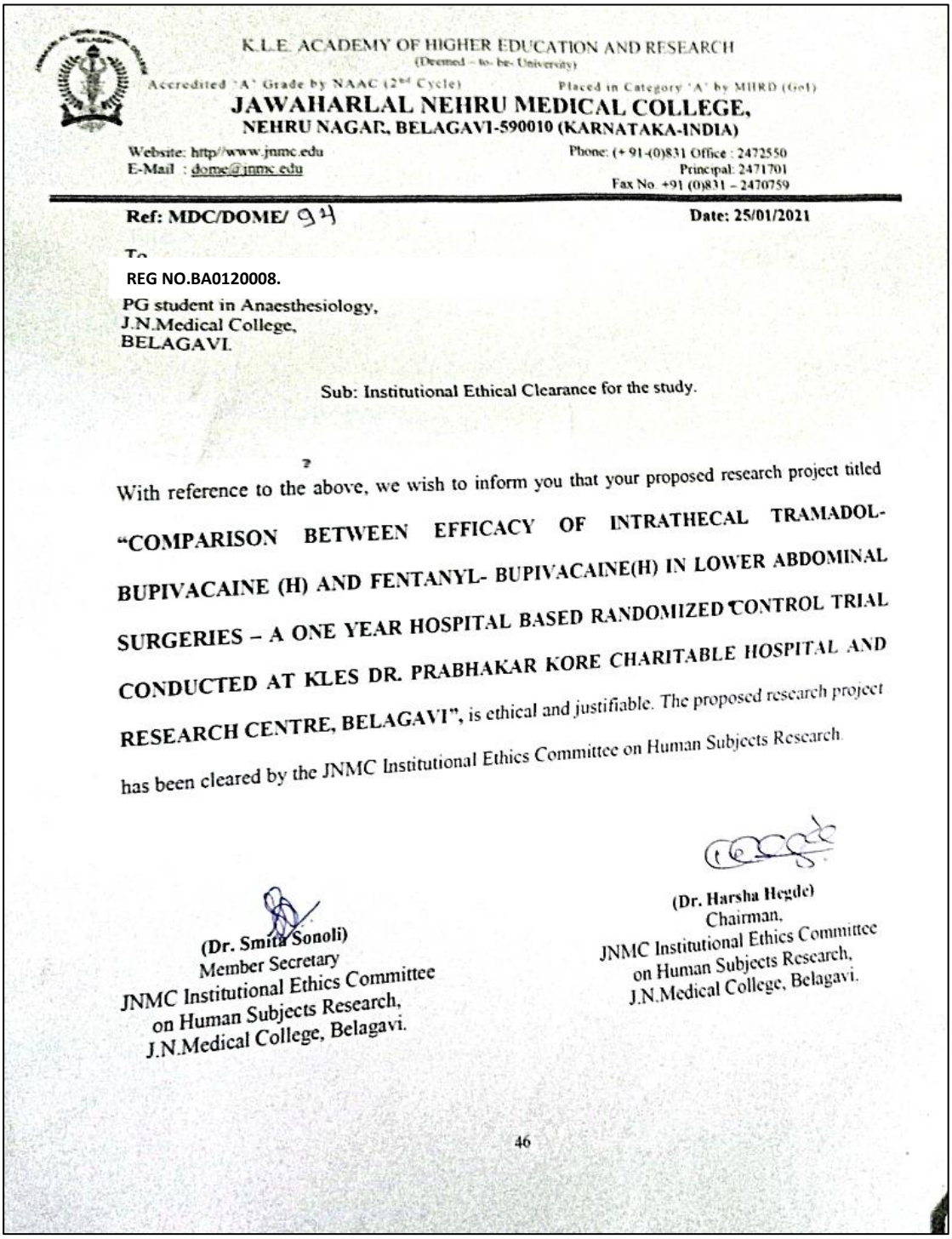

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Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"COMPARISON BETWEEN EFFICACY OF INTRATHECAL TRAMADOL-BUPIVACAINE (H) AND FENTANYL- BUPIVACAINE(H) IN LOWER ABDOMINAL SURGERIES – A ONE YEAR HOSPITAL BASED RANDOMIZED CONTROL TRIAL CONDUCTED AT KLES DR. PRABHAKAR KORE CHARITABLE HOSPITAL AND RESEARCH CENTRE, BELAGAVI"**, is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

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ABSTRACT

Background:

Neuraxial block is a preferred alternative to general anaesthesia for lower abdomen and lower limb procedures due to various benefits. Various additives are employed intrathecally in modern practice to achieve appropriate post-operative analgesia and ideal operating conditions. When combined with local anaesthetics, neuraxial opioids are known to hasten the start of action, prolong the duration of the motor and sensory block, and enhance the quality of postoperative analgesia. Additionally, there are negative consequences when these opioids are used with local anaesthetics. In the current prospective randomised trial, two opioids—Fentanyl and Tramadol—were compared in lower abdominal procedures when they were combined with hyperbaric bupivacaine 0.5%.

Methods:

After receiving approval from the ethical committee, 100 patients from ASA I and II who were between the ages of 18 and 50 were divided into two groups. Sub-arachnoid block was administered with 3.0 ml of 0.5% Bupivacaine(H) and 25 mcg of Fentanyl to the first group and 3.0 ml Bupivacaine(H) and 25 mg Tramadol to the second group. Monitoring was done for the onset, duration, sedation, hemodynamic parameters, and the timing of the rescue analgesia

Results:

When compared to the Tramadol group, the Fentanyl group's onset of sensory and motor blockage was quicker (164.43 and 192.61 seconds for sensory blockade and 202.04 and 223.27 seconds for motor blockade respectively). In addition, the Fentanyl group's duration of sensory and motor blockage lasted longer than the Tramadol group's (236.43 and 196.73 minutes for motor blockade duration and 261.55 and 217.24 minutes for sensory blockade duration respectively).

Other factors including bradycardia and sedation score were comparable between the two groups. The time of request of rescue analgesia was also longer in fentanyl group than in tramadol group (300.10±24.25 minutes and 242.45±37.49 minutes)

Conclusion:

This study suggests that, when added to bupivacaine, fentanyl has a quicker start and longer duration of block than tramadol in subarachnoid block. The Tramadol group requests initial rescue analgesia more quickly than the Fentanyl group does.

Keywords: Subarachnoid block, opioids, fentanyl, and tramadol.

LIST OF ABBREVIATIONS USED

SAB	Sub Arachnoid Block
ASA	American Society of Anaesthesiologists.
CNS	Central Nervous System
O_2	Oxygen
CVS	Cardio Vascular System
RS	Respirator System
SBP	Systolic Blood Pressure
DBP	Diastolic Blood Pressure
MAP	Mean Arterial Pressure
ECG	Electrocardiogram
GIT	GastroIntestinal System
Hb	Haemoglobin
HR	Heart Rate
PR	Pulse Rate
Inj.	Injection
IV	Intravenous
Kgs	Kilograms
L	Litre
Mg	Milligrams
Mins	Miuntes
Ml	Millileters
Mcg	Micrograms
MPG	Mallampatti Grade
RBS	Random Blood Sugar
RR	Respiratory Rate
SPO_2	Oxygen Saturation
Temp	Teamperature
TLC	Total Leukocyte Count
NSAIDs	Non Steroidal Anti-inflammatory Drugs
T	Thoracic Vertebral Level

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INTRODUCTION

The technique of spinal anaesthesia is typically used for surgery on the lower abdomen, lower limbs, urology, and perineum. It is technically simpler, acts quickly, and has a low failure rate. It is cost-effective and safe. The patient can describe and relate early signs of complications and is awake and conscious. Compared to general anaesthesia, it can reduce surgical pain for several hours.

By preventing the entrance of sodium ions through channels or ionophores in neuronal membranes, local anaesthetics prevent neural conduction. All local anaesthetics have a three-part molecular structure: a lipophilic aromatic ring, an intermediate ester or amide bond, and a tertiary amine. The solubility of a local anaesthetic in lipids determines its potency. The potency of the local anaesthetic is also increased by an increase in lipid solubility. Because of this, bupivacaine, a drug that is more lipid soluble than drugs like artecaine or lignocaine that are less lipid soluble, has a far higher potency.

Traditional local anaesthetics when used alone, without adjuvants, have a shorter duration of action, which causes early postoperative analgesic need. For some surgeries, it is becoming more crucial to extend the time of sensory and motor blockade. In order to reduce postoperative pain and discomfort, the sensory blockade's duration should be increased.

Numerous intrathecal adjuvants have been employed in the context of augmentation of neuraxial blockade[(1)]. These include Non-opioids like midazolam, ketamine, neostigmine, and clonidine and opioids like morphine, fentanyl, and buprenorphine. The most researched and widely used of them have been opioids.

One of the first opioids to be administered intrathecally was morphine[(2)]. As intrathecal adjuvants, tramadol, buprenorphine, fentanyl, and sufentanyl have also

been employed. The availability of a specific opioid receptor antagonist, Naloxone, is another significant benefit of opioids with intrathecal local anaesthetics.

Opioids can be categorised according to how well they dissolve in fat. Opioids that are lipophilic, have a shorter half-life than opioids that are hydrophilic. (Morphine is a hydrophilic opioid, while buprenorphine, fentanyl, sufentanyl, butorphanol, and pethidine are lipophilic opioids. The sensory blocking of local anaesthetics is amplified by intrathecal opioids, but sympathetic activity is unaffected. In spite of the fact that they extend post-operative analgesia, they raise the risk of nausea, vomiting, itching, and respiratory depression.

Eckenstam first introduced bupivacaine[(3)] in 1957, and Telivno first applied it in a therapeutic setting in 1963. Almost all surgical procedures now combine opioids and hyperbaric bupivacaine. The amide type of local anaesthetic bupivacaine has a long duration of action, a gradual onset (5-8 minutes), and great potency. Even while intrathecal bupivacaine by itself provides effective sensory blockage, a large percentage of patients still experience some pain and discomfort and could need analgesic supplements during surgery. Opioids are added, which not only enhances the quality of intraoperative anaesthesia but also lengthens the analgesic effect's duration in the postoperative period.

The goal is to compare the effectiveness of bupivacaine with tramadol and bupivacaine with fentanyl with respect to changes in heart rate, blood pressure, and sedation scales, as well as to evaluate the stability of the patient's hemodynamics throughout the surgery, the onset and duration of sensory and motor block, and the duration of post-operative analgesia[(26)].

Hypothesis: There is significant difference between the onset and duration of anaesthesia and analgesic effects and time of request of rescue analgesia between Fentanyl and Tramadol with 0.5% Hyperbaric Bupivacaine in subarachanoid block with Fentanyl having better outcome than Tramadol.

OBJECTIVES

Primary objective:

1. To compare the onset and duration of sensory and motor blockage between 0.5% Bupivacaine (H) with Fentanyl(25 mcg) vs Tramadol (25 mg) respectively.

Secondary objective:

1. To compare sedation between intrathecal Tramadol and Fentanyl (using modified Wilson score), nausea and bradycardia between two groups.
2. To compare time of request of rescue analgesia.

REVIEW OF LITERATURE

In 1853, Alexander Wood [(4)] inserted a hollow needle with a glass syringe In the Sub Arachnoid space. Carl Koller made a clinical demonstration of analgesia with cocaine in 1884. These two landmarks were the direct precursors to spinal analgesia.

J. Leonard Corning[(5)], a neurologist, administered the first spinal analgesia in 1885 while doing tests on dogs. Later, he purposefully gave individuals an intradural injection. However, his method wasn't entirely dependable. He overlooked the potential for surgery. Later, Quinke and Essex[(6)] described and popularised the ideal lumbar puncture technique. August Bier carried out the first human intentional spinal analgesia for surgery on August 16, 1898. His aide Hildebrandt actually performed the surgery for the first time on Bier.

Arthur Barker[(7)] at London University described the progression of spinal anesthesia procedures in 1907, comprising the usage of a hyperbaric local anesthetic, importance of the sterile techniques, and the comfort of using midline techniques over the paramedian approach for spinal anesthesia.

In 1992, Sergio D. Belzarena[(8)] investigated the effectiveness of intrathecal Fentanyl at various doses in patients undergoing caesarean sections. He came to the conclusion that combining bupivacaine with a low dose of fentanyl (25 mcg) produced great anaesthesia, prolonged postoperative analgesia, and few side effects in five out of ten patients.

Another investigation was conducted in 2006 by Fauzia Bano et al[(9)]. in J Coll Physician Surg. Pak. where they looked at the effects of mixing intrathecal Bupivacaine 0.5% with Fentanyl. 60 female patients belonging to ASA I & II undergoing elective LSCS under SAB was randomly selected and were divided into

2 groups getting Bupivacaine 0.5% with either 0.25ml of NS or 0.25ml of Fentanyl. It was observed how long and how well the SAB lasted as well as how it affected the patient. The study's findings showed that adding Fentanyl to intrathecal Bupivacaine causes analgesia to start more quickly and to be more effective during surgery without causing more side effects.

In a subsequent study, Naina P. Dalvi and Narendra Patil[10] examined intrathecal Fentanyl and Tramadol as adjuvants to Bupivacaine and found that intrathecal Fentanyl increased the duration of anaesthesia and provided greater post-operative analgesia than Tramadol.

Another study evaluating the duration of post-operative analgesia with Fentanyl and Tramadol as adjuvants to Bupivacaine for intrathecal administration was carried out by Surhan Ozer and Hacer Sebem Turk[11] in Turkey in 2018.

The study by Biswas et al[12]. on intrathecal fentanyl with hyperbaric bupivacaine improves analgesia during caesarean delivery and in the early postoperative period revealed that the dose of intrathecal fentanyl 12.5 microgram increased the duration of effective analgesia (time from injection to first parenteral analgesic). The study's findings suggested that using 12.5 micrograms of fentanyl in combination with hyperbaric bupivacaine 0.5% for spinal anaesthesia would significantly enhance intraoperative anaesthesia and decrease the need for postoperative analgesics while improving maternal satisfaction and foetal wellbeing .

Two segment regression and the length of analgesia were demonstrated in the Effect of Intrathecal Fentanyl on Subarachnoid Block with 0.5% Hyperbaric Bupivacaine study by Chavan et al[13]. They showed that adding fentanyl to bupivacaine considerably lengthened both two segment regression and the duration of anaesthesia.

In their study comparing Fentanyl and Tramadol as additions to Bupivacaine in labouring patients, Veena Chatrath and colleagues found that while tramadol delivers longer-lasting analgesia, fentanyl has a quicker start of analgesia. Due to tramadol's activity on 5-hydroxytryptamine receptors, nausea and vomiting were major side effects in the tramadol group[(14)]. Where as the fentanyl group exhibited more shivering, pruritus, and transient foetal bradycardia. The tramadol group also scored higher in terms of patient satisfaction.

J. M. Afolayan and his colleagues in Nigeria investigated the effects of fentanyl and tramadol on sub arachnoid block and found no discernible difference between the two drugs in respect to onset of block. Although both the groups were better than the placebo group, which received regular saline, in terms of block onset, duration, and adverse effect profile. They also came to the conclusion that adding additives like opioids lengthens the duration of the block. Additionally, the time of request of rescue analgesia is much longer in the Fentanyl group than the Tramadol group[(15)].

In their investigation, Supriya S. Kulkarni and colleagues discovered that there was no significant difference between intrathecal Fentanyl and Tramadol in terms of haemodynamic measures. At every point during the trial, the heart rate, systolic blood pressure, diastolic blood pressure, and mean blood pressure were comparable. However, there was a big difference in prevention of shivering between the two groups[(16)]. Shivering was least common in the Tramadol group both during surgery and thereafter.

In a research comparing intrathecal Fentanyl and Tramadol in patients undergoing LSCS by Chatterji R et al., came to the conclusion that tramadol, when combined with hyperbaric bupivacaine, produced pain relief that lasted longer than

intrathecal fentanyl and decreased post-operative analgesic demand in the first 24 hours without having any negative effects on hemodynamics[17].

In a study on patients undergoing LSCS, Bogra J. and colleagues found that the combination of bupivacaine and fentanyl abolished visceral pain, decreased the incidence of nausea, increased hemodynamic stability, and prolonged postoperative analgesia[18]; however, there was no effect on bradycardia, nausea, vomiting, shivering, maternal or neonatal respiration. Overall, the combined impact of fentanyl and bupivacaine is better than bupivacaine alone because, in addition to its positive effects, fentanyl also delays the negative ones while also lowering the doses of bupivacaine.

Another study by A. Subedi and colleagues comparing the effects of adding fentanyl and tramadol to bupivacaine for sub-arachnoid block in pregnant women found that tramadol 10 mg showed a longer duration of analgesia with a lower incidence of shivering when used as an adjunct to bupivacaine for sub-arachnoid block for caesarean section[19].

BASIC SCIENCES

Applied anatomy

It is essential to know the basic anatomy of the vertebral column by every anaesthesiologist for the purpose of safe administration of sub-arachnoid block. The vertebral column of human body with its 33 vertebrae forms the axial skeleton. The adult vertebral column has 33 vertebrae with 31 pairs of spinal nerves.

Region	Vertebrae	Pairs of Spinal Nerves
Cervical	7	8
Thoracic	12	12
Lumbar	5	5
Sacral	5	5
Coccygeal	4	1

A typical vertebra is composed of the following parts:

Body	Weight bearing and separated from adjoining vertebral bodies by the intervertebral disc.
Vertebral arch	Composed of pedicles and laminae which surround and protect the spinal cord and its coverings.
Transverse process	Give attachment to ligaments.
Spinous process	Gives attachments to ligaments and to muscles.

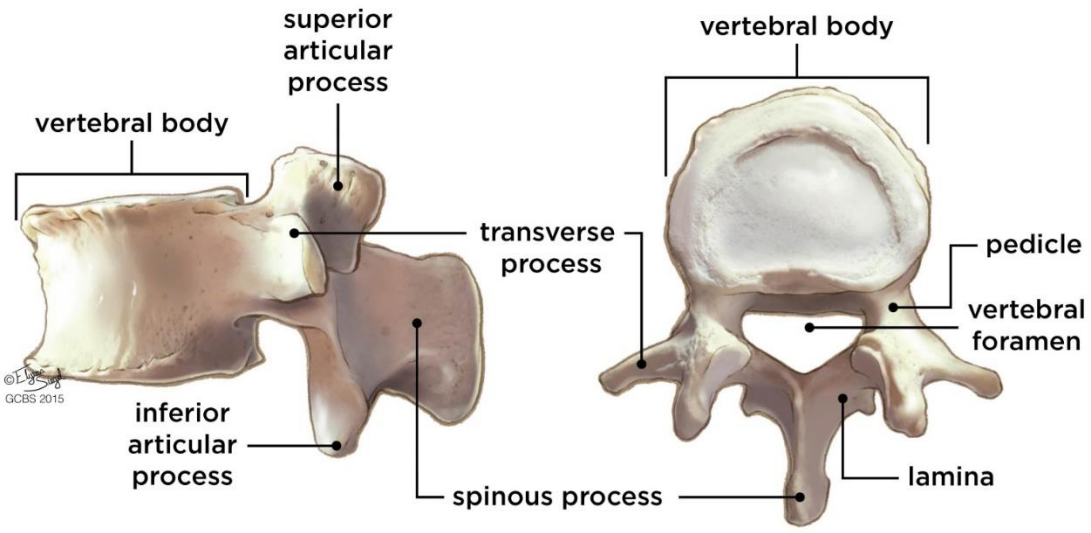


Fig. 1

Spinous process of the cervical, the first two thoracic and the last lumbar vertebrae are all practically horizontal and are therefore opposite the bodies of their respective vertebrae. The other Spinous processes are inclined downwards, their tips being opposite the bodies of the vertebrae next below.

Intervertebral disc:

These are principal connecting links between vertebral bodies, and account for nearly 25% of the length of the spine. In the cervical and lumbar regions they are somewhat wedge shaped and this contributes to the characteristic curves of the column. Each disc adheres above and below to the hyaline articular cartilage which covers facet of adjacent vertebral body and in front and behind each is attached to anterior and posterior longitudinal ligaments. This disc is made up of peripheral fibrous tissue and fibro cartilage, arranged in concentric rings termed “annular fibrosus” and a central core of soft pulpy elastic tissue “nucleus pulposus” which represents the remnant of embyronal notochord.

Curvatures of the vertebral column :

The vertebral column has curvatures in them. These curvatures also have an effect on the spread of local anaesthetic injected. The highest and lowest points in these curvatures with the subjects in supine position on horizontal surface are found to be at the level of L3 and T5 respectively.

- Cervical curve - anterior convexity
- Thoracic curve- anterior concavity
- Lumbar curve - anterior convexity

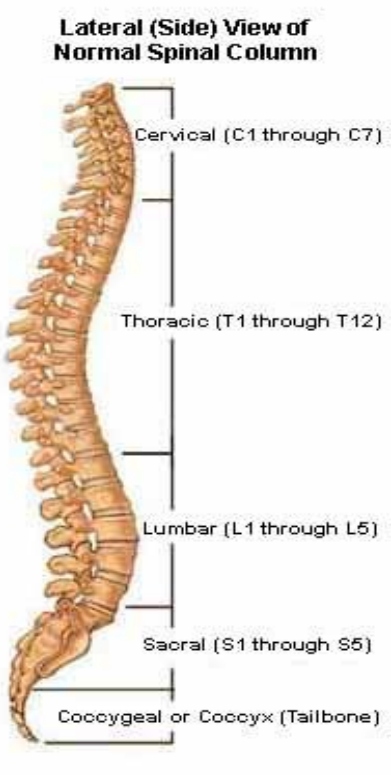


Fig.2

LIGAMENTS OF THE VERTEBRAL COLUMN:

- **Supraspinous Ligament**:

It is a continuation of the ligamentum nuchae, and joins together the tips of the spinous processes from the C7 vertebra to the sacrum. It increases in thickness from above downwards and is thickest and widest in the lumbar region[25].

- **Interspinous Ligaments**:

They connect adjacent spinous processes. The fibres are membranous and fuse with the supraspinous ligament posteriorly and with the ligamentum flavum anteriorly. In the lumbar region they are wide and dense.

- **Ligamentum Flavum**:

It is composed entirely of yellow elastic fibres. Laterally it blends with the capsule of the facet joint and medially with the interspinous ligament, or with its fellow on the opposite side. It is thinnest in cervical region and thickest in the lumbar region. It measures 3-5mm thick and 16-20mm wide.

- **Anterior Longitudinal Ligament**:

It runs along the front of the vertebral bodies from C2 to upper sacrum becoming progressively wider from above downwards.

- **Posterior Longitudinal Ligament**:

It transverses the posterior surface of vertebral bodies. It corresponds in its attachments to those of the anterior longitudinal ligament.

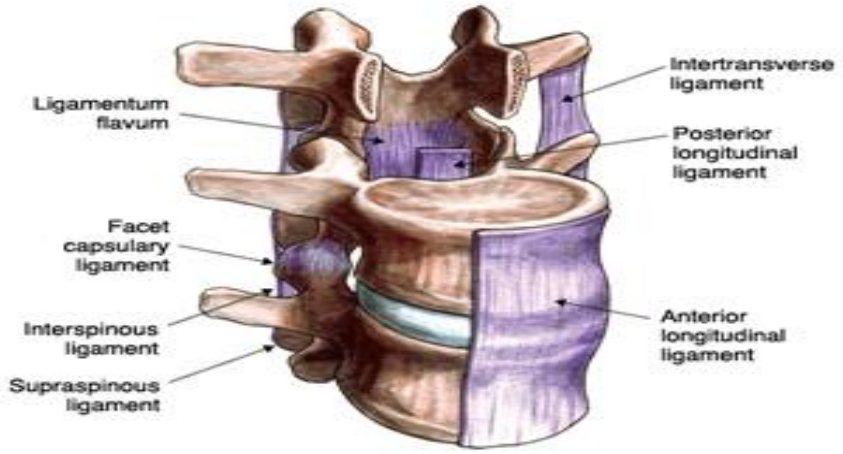


Fig.3

Spinal Nerves:

These are 31 pairs in number:

- 8 cervical
- 12 thoracic
- 5 lumbar
- 5 sacral
- 1 coccygeal

- Anterior root is efferent and motor sympathetic preganglionic axons arise from cells in the intermediolateral horn of spinal cord from T1 to L2.
- Posterior root is larger than anterior. All the afferent impulses from whole body, including viscera pass into the posterior roots. Each posterior root has a ganglion and conveys fibres of
    - 1) pain
    - 2) touch
    - 3) temperature
    - 4) deep or muscle sensation from bones, joints, tendons.
    - 5) Afferent from the viscera and
    - 6) vasodilator fibres.

- The anterior and posterior roots each with its covering of pia-arachnoid and dura cross the extra dural space and unite in the inter vertebral foramina to form the main spinal nerve trunks.

Blood Supply of spinal Cord:

The main arterial supply of the cord is derived from spinal arteries and a reinforcement with the help of radicular arteries exists.

Spinal Arteries include:

- Anterior Spinal Artery
- Posterior Spinal Artery

Anterior Spinal Artery: It is formed by two vertebral arteries at the level of foramen magnum. It lies in the anterior median fissure and supplies a major portion of the anterior 2/3rd of the cord.

Posterior Spinal Artery: They are 2 in number. One lies on front of the attachment of dorsal nerve root and the other, a larger artery behind the attachment. They arise behind the base of brain either directly from vertebral artery or posterior inferior cerebellar artery which is the largest branch of each vertebral artery. These supply posterior 1/3rd of cord, posterior grey columns and white columns on either side.

Reinforcement: The above arteries are reinforced by spinal branches of vertebral, ascending cervical, posterior intercostals, spinal lumbar, and several lateral arteries. These form anterior and posterior radicular arteries, reinforcing the main supply.

Often one of the anterior radicular arteries is of considerable size and termed arteria radicularis magna, usually arising in the lower thoracic or upper lumbar region (artery of Adamkiewicz).

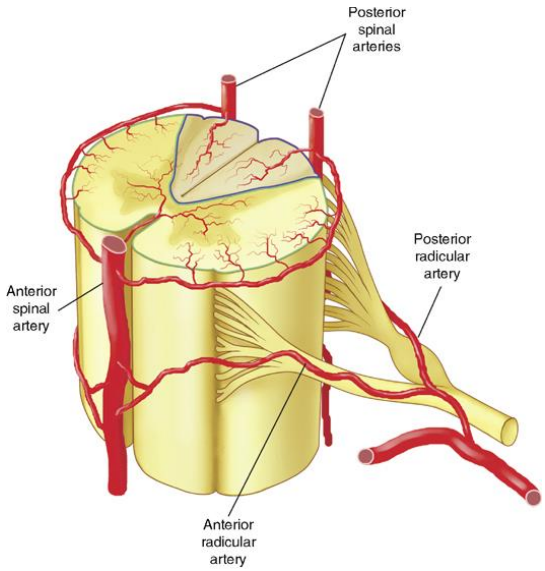


Fig.4

Spinal Cord:

The spinal cord, a direct continuation of the medulla oblongata. It begins at the upper border of the atlas and ends at the lower border of L1 in adults. It is 42– 45 cm in length. It has an elongated cylindrical shape but is flattened anteroposteriorly especially in lumbar region. It is not uniform in diameter but bears a cervical and lumbar enlargement which corresponds to the origins of brachial and lumbosacral plexuses. Below, it ends in conus medullaris from the apex of which filum terminale descends as far as the coccyx.

At birth, spinal cord ends at the level of lower border of L3 vertebra

In adults - 50% cases at lower border of L1

- 40% cases at upper border of L2

- 03% cases at upper border of L3

Meninges:

Duramater:

It is the outermost layer among the meninges. Lies just below the bones of skull and Vertebral column. It is thick, tough and inextensible. Dura has two layers of connective tissue sheets:

- Periosteal layer: lines the inner surface of the bones of the cranium
- Meningeal layer: deep to periosteal layer inside the cranial cavity.It is the onlylayer present in the vertebral column.

Between these 2 layers, dural venous sinuses are located. They are responsible for the venous vasculature of the cranium, draining into the internal jugular veins.

Arachnoid Mater:

It is a thin transparent sheath closely applied to the dura. It surrounds cranial and spinal nerves as far as their point of exit from skull and vertebral canal.

Piamater:

This closely invests the cord and is separated from arachnoid by subarachnoid space filled with CSF. It sends delicate septa into its substance. Piamater ends as a prolongation of the filum terminale, which pierces the distal end of the dural sac and is attached to periosteum of the coccyx.

Denticulate Ligament:

The denticulate ligaments are folds of the piamater that extend laterally along the lines of attachments of the anterior and posterior roots and fuse with the arachnoid and duramater. Structurally they act as struts to hold the spinal cord suspended within the subdural space.

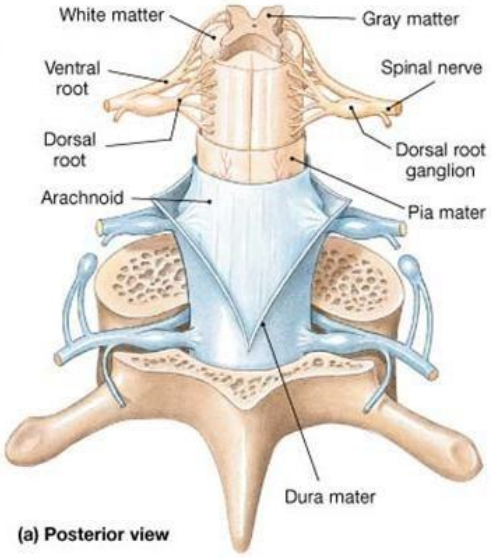


Fig.5

Cerebrospinal fluid (CSF):

It is clear, colourless liquid that fills and surrounds the brain and the spinal cord and provides a mechanical barrier against shock. Formed primarily in the ventricles of the brain, the cerebrospinal fluid supports the brain and provides lubrication between surrounding bones and the brain and spinal cord. When an individual suffers a head injury, the fluid acts as a cushion, dulling the force by distributing its impact. The fluid helps to maintain pressure within the cranium at a constant level. An increase in the volume of blood or brain tissue results in a corresponding decrease in the fluid. Conversely, if there is a decrease in the volume of matter within the cranium, as occurs in atrophy of the brain, the CSF compensates with an increase in volume. The fluid also transports metabolic waste products, antibodies, chemicals, and pathological products ofidisease away from the brain and spinal-cord tissue into the bloodstream. CSF is slightly alkaline and is about 99 percent water.

Composition :

Volume : 120 – 150ml (25-35ml in spinal space)

Specific gravity : 1.003 – 1.009 (at 37 degree Celsius)

CSF pressure: 60-80 mm Hg in lumbar space

pH : 7.27-7.37

PCO2: 48mmHg HCO3:23mEq/L

Sodium : 135-145 mEq/L

Magnesium : 2-2.5mEq/L

Chloride : 15-20 mEq/L

Calcium : 2-3mEq/L

Phosphorous : 1.6mg/dl

Proteins : 23-38mg/dl

Physiology of Subarachnoid Block

Spread, duration, density and dose are the most important factors that determine the spread and duration of subarachnoid anesthesia. Density is the ratio of the mass of a substance to its volume. Baricity is the ratio ofitwo densities; here, the density of CSF and that of the injected local anesthetic. Currently used local anesthetics are made hyperbaric by mixing with dextrose. Plain local anesthetic solutions are isobaric or slightly hypobaric.

Hyperbaric local anesthetics are denser than CSF and will flow with gravity to the dependent areas of the spine, usually the upper thoracic region in supine patients. Positioning patients upright orilateral can limit the initial spread of hyperbaric local anesthetic. But, when the patient returns to the supine position, even after 20 to 30 minutes, the sensory level reaches the usual mid-thoracic dermatomes. Bulk

displacement determines the initial spread of isobaric drug. Subsequently, movement of CSF by either transmission of cardiac pulsations or gross patient movements (i.e., turning from lateral to supine position) will determine the ultimate spread of block. In nonpregnant patients, hyperbaric local anesthetics produce more consistent levels of sensory block than isobaric drug. When used for subarachnoid anesthesia for cesarean section, there is little difference between equal doses of isobaric or hyperbaric bupivacaine. (1)

CENTRAL NERVOUS SYSTEM

The exact site of action of subarachnoid remains unknown. Local anesthetic can be detected throughout the spinal nerve rootlets and spinal cord after intrathecal injection. Intrathecal local anesthetics reduce, but do not routinely eliminate, somato-sensory evoked potentials (SSEPs). Cortical evoked potentials from direct spinal cord stimulation diminish but persist. These results suggest that some block of spinal cord conduction occurs but that subarachnoid anesthesia occurs mostly within the spinal nerve roots. (2) Differential Nerve Block- Neuraxial local anesthetics have different potencies on motor,sensory, and sympathetic nerves. This differential block is largely related to the size ofdifferent nerves. Large motor nerves (and larger lumbar and sacral nerve roots) are most resistant to local anesthetic block. Analgesia (loss of sensation of sharpness to pinprick)extends two or more segments more cephalad than anesthesia (loss of sensation to touch). Sympathetic block (as measured by increase skin temperature) may extend as many as six spinal segments higher than the upper limit of sensory block. (11)

CARDIOVASCULAR SYSTEM

Intrathecal injection of local anesthetics produces extensive sympathetic block. Cardiac output increases after induction of subarachnoid anesthesia and that a fall in systemic vascular resistance leads to lower blood pressures. The degree of hypotension varies widely among patients. Risk factors include pregnancy, hypovolemia, advanced age, obesity, concurrent general anesthesia, and sensory level above T6. Heart rate mayincrease, decrease, or remain unchanged. Thoracic levels of anesthesia can produce cardiac sympathetic block (T1–T4). The resultant vagal predominance can decrease heartrate.

GARTROINTESTINAL SYSTEM

Neuraxial anesthesia-induced sympathetic block leads to unopposed vagal stimulation of the gastrointestinal system. Secretions increase, sphincters relax and the bowel constricts.Many patients experience nausea and vomiting. Risk factors for nausea and vomiting include: female gender, opioid premedication and high level of block. [(1)]

SPLEEN

Enlarges 2-3 times in high blocks when its sympathetic efferent fibres are paralysed. Colonic blood supply and oxygen availability are increased in animals following spinal anaesthesia, an important factor in preventing anastomotic breakdown following gut resection.

LIVER

No effects of major significance

ENDOCRINE SYSTEM

SAB delays adrenal response to injury and trauma, so the is no change in 17-hydroxy corticosteroids

SAB depresses the hyperglycaemic response to surgery and stress and so is useful in diabetic patients. The response to insulin is augmented-hypoglycaemia.

GENITOURINARY SYSTEM

Sympathetic supply to kidney is from T11 to L1 via lower splanchnic nerve. Any changes in renal blood flow is due to hypotension

Postspinal retension of urine may be prolonged as S2 to S3 contain small autonomic fibres and their paralysis lasts longerithan that of larger sensory and motor fibres.

UTERUS

No effect on tone of uterus. Small dose of LA required because ofidecreased extradural space in prgnancy.

BODY TEMPERATURE-Vasodilatation favours heat loss.

COMPLICATIONS OF INTRATHECAL ANESTHESIA

1) **HYPOTENSION**: Approximately one-third of patients will suffer from hypotension following an intrathecal anesthetic. Hypotension is more likely in the older patient, in patients with higher blocks (T5 and above), and in cases in which a high lumbar puncture site is used. It is defined as a fall in 25-30% from the preoperative blood pressure. Treatment for normalizing BP should be started at this point. The fall in blood pressure is due to the thoracolumbar sympathectomy produced by the local anesthetic solution, which produces a decrease in systemic vascular resistance and an increase in venous pooling. Venous pooling may be corrected with intravenous fluids, elevation of the legs, or with beta-adrenergic agonists. A slight head-down tilt will

encourage venous return in patients undergoing intrathecal anesthesia. Caution may be required with head-down tilt as this may encourage further cranial spread of the local anesthetic block if this is undertaken in the early stages of intrathecal anesthesia . Consider administration of vasoactive drugs. Ephedrine is often the first choice of vasopressor. This drug has a predominantly beta-adrenergic agonist effect and produces an increase in heart rate, with some effect on the venous pooling but little direct effect on peripheral resistance. This is advantageous in pregnancy, when preservation of uterine blood flow in the presence of hypotension is important.

2) **BRADYCARDIA:** Bradycardia is more likely with a high block (T5 and above), in patients with a normal heart rate of less than 60 beats per minute and patients on beta-adrenergic antagonists. If the fluctuations in blood pressure is not significant, then careful monitoring is adequate. If significant hypotension or other cardiovascular events present then treatment is indicated. If the heart rate drops to 50 beats per minute or less then treatment will be necessary for the older patient and the patient with heart disease. Intravenous glycopyrrolate, 0.2mg or atropine 0.6 mg, should be administered. The circulation time will be much prolonged by the bradycardia and thus patience may be required to avoid administration of further, unnecessary doses of the drugs. If hypotension and bradycardia prove resistant to treatment, administration of intravenous epinephrine should be considered.

3) **NAUSEA AND VOMITING:** Nausea and vomiting are commonly associated with hypotension, bradycardia, and a high block. Treatment of the cardiovascular problem often relieves these symptoms, but not in every case. The use of conventional antiemetics can be beneficial.

4) **POST DURAL PUNCTURE HEADACHE**: Headache has always been recognized as a side-effect of dural puncture and therefore of intrathecal anesthesia. The

headache is believed to be the result of CSF leak, both at the time of the dural puncture and more importantly, continuing afterward.

Factors known to increase the likelihood of PDPH include the size of the needle used for the dural puncture (the larger the needle, the higher the incidence), the age of the patient (younger patients are more likely to have a headache than older patients) and early ambulation. Newer needle designs (Sprotte and Whitacre) are associated with a significantly lower incidence of PDPH especially in higher risk groups.

PDPH is characteristically throbbing in nature, is eased by lying down and returns on standing. It is unusual for the headache to present more than 48h after lumbar puncture. The conservative management of PDPH (bed rest, simple analgesia and good fluid intake) is not successful in all cases. Severe PDPH will render the patient bed bound and merits more aggressive treatment if conservative management is ineffective after 24h.

The most reliable and effective method of treatment is the autologous extradural blood patch: 20-30mL of blood is removed aseptically from the patient and injected into the extradural space. It is usual for two doctors to be involved in this procedure, one to remove the blood and one to perform the extradural injection. The headache usually disappears within minutes of the injection with a good long-term safety record. If the patient is pyrexial it is not advisable to use this technique.

5) **HIGH BLOCK (TOTAL SPINAL):** If the block extend above the T4 level, then severe cardiovascular problems may develop with bradycardia and hypotension. These should be managed with appropriate aggressive intravenous therapy and the administration of chronotropic and vasoconstrictor drugs. Very rarely with subarachnoid anesthesia the block may extend higher and the patient may develop

respiratory difficulties if the phrenic nerves (C3, C4, and C5) are affected. There may be warning of this developing if the patient complains of tingling or numbness in the hands.

If respiratory difficulties are reported then the anesthesiologist should be prepared to intubate and ventilate the patient. It is important to remember that, although the patient may be unable to breathe, he or she may still be conscious and a small dose of an intravenous induction agent is indicated to render the patient unconscious. Upper airway reflexes may also still be active and muscle relaxants may be needed to facilitate intubation. The patient may require some form of general anesthesia to maintain unconsciousness until the block wanes and spontaneous respiration returns.

If the block is high enough then unconsciousness will occur, but consciousness may return before the patient can breathe spontaneously. The accidental injection of a large dose/volume of local anesthetic into the subarachnoid space can be a complication of extradural blockade and may result in a total spinal anesthetic.

6) **URINARY RETENTION**: Although the neural block provided by subarachnoid anesthesia usually only lasts for a few hours, urinary retention can sometimes be a problem even after the block has regressed. Some anesthesiologists routinely catheterize the bladder in patients having intrathecal anesthesia, either before or after the block has been instituted. If intravenous fluids have been administered as part of the management of the block, then this fluid may cause problems as it is excreted by the kidneys. Retention is a particular problem in the older male patients, who may have pre-existing problems related to prostatatic enlargement.

7) NEUROLOGIC COMPLICATIONS:

Neurologic complications following central neural blockade fall into one of two categories: first, those that occur by coincidence with the central blockade and second, those that are directly related to the regional anesthetic procedure. Central neural blockade is a safe anesthetic technique with a very low incidence of permanent neurological damage related directly to the procedures. However, there is no doubt that there are some factors that appear to increase the risk of neurologic damage following central blockade and clearly, the anesthesiologist should be aware of these before considering the use of extradural or intrathecal anesthesia. Such factors include:

- Physical trauma: injury from needle and catheter placement;
- Chemical trauma: local anesthetic toxicity, wrong drug injected;
- Ischemia following severe, prolonged hypotension
- Spinal hematoma: pathological and pharmacologic clotting problerns.
- Systemic infection

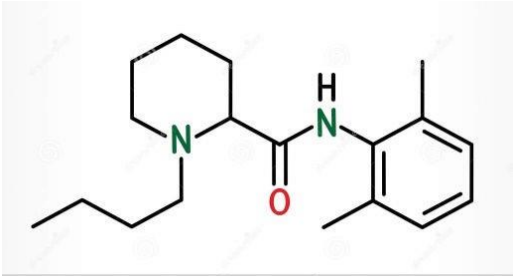
PHARMACOLOGY OF LOCAL ANAESTHETICS

Local anaesthetics are chemical compounds which are capable of reversibly inhibiting the propagation of impulses in nerve cells. Classification: Clinically useful agents can be classified into two groups depending on the link between the aromatic portion and the intermediate chain. The amino ester group have an ester link and include procaine, chloroprocaine and amethocaine. The amino amides have an amide link between the aromatic head and the intermediate chain and include lignocaine, bupivacaine, mepivacaine, prilocaine, etidocaine and ropivacaine.

BUPIVACAINE HYDROCHLORIDE:

C18 H28N2o, HCl(±) –1–Butyl–N–(2,6–dimethyl phenyl)–2– piperidine–decarboxamide.

It was synthesized in 1957 by Ekemstan and hydrochloride monohydrate was first clinically used in 1963 by L. J. Telivuo.



Bupivacaine

fig.6

PHYSICOCHEMICAL PROPERTIES:

Molecular weight (free base) 342.9 (288.4) pKa 8.115 Bupivacaine hydrochloride is a white, odourless, crystalline powder with a bitter, numbing taste. It is prepared by chemical synthesis. The hydrochloride salt is available in solution with and without epinephrine. A preparation marketed specifically for intrathecal use contains dextrose.

Presentation:

Vials of 20ml containing a clear colourless solution of 0.25% & 0.5% Bupivacaine hydrochloride. 20 ml vials of 0.25% - 0.5% Bupivacaine without preservative are also available. Ampoules containing 4ml of 0.5% (heavy) solution with dextrose for spinal anaesthesia.

Mechanism of action:

Bupivacaine, like other local anaesthetics prevents the generation and the conduction of the nerve impulse. Their primary site of action is the cell membrane. Local anaesthetics block conduction by decreasing or preventing the large transient increase in the permeability of excitable membranes to Na+ that normally is produced by a slight depolarization of the membrane. This action of local anaesthetics is due to their direct interaction with voltage-gated Na+ channels. As the anaesthetic action progressively develops in a nerve, the threshold for electrical excitability gradually increases, the rate of rise of the action potential declines, impulse conduction slows, and the safety factor for conduction decreases. These factors decrease the probability of propagation of the action potential, and nerve conduction eventually fails.

Toxicity of Bupivacaine:

It is relatively free of side effects if administered in an appropriate dosage. It is more cardiotoxic than lignocaine and this is made worse by hypoxia, hypercapnia and by pregnancy.

1. **Central nervous system toxicity[23]:**

The principal effect of Bupivacaine is reversible neural blockade which leads to a characteristically biphasic effect in the CNS. Initially, excitation (light headedness, dizziness, visual and auditory disturbances and fits) occurs, due to the blockade of inhibitory pathways in the cortex. With increasing doses, depression of both facilitatory and inhibitory pathways occur leading to CNS depression (drowsiness, disorientation and coma). Disorientation and occasional feeling of drowsiness may occur. Objective signs are usually excitatory in nature which includes shivering, muscular twitching and tremors; initially involving muscles of the face (perioral numbness) and part of extremities. At still higher doses cardiovascular or

respiratory arrest may occur. Acidosis increases the risk of CNS toxicity from bupivacaine, since an elevation of PaCO2 enhance cerebral blood flow, so that more anaesthetic is delivered rapidly to the brain. Bupivacaine is more lipid soluble and protein bound. This limits its passage across the placenta to foetus. Bupivacaine is undetectable in neonatal plasma 24 hours after cesarean section using Bupivacaine.

2. Cardiovascular system toxicity:

Bupivacaine depresses rapid phases of depolarization (Vmax) in purkinje fibres and ventricular musculature to a greater extent than lignocaine[(27)]. It also decreases the rate of recovery from a dependant block than that of lignocaine. This leads to incomplete restoration of Vmax between action potential at high rates, in contrast to complete recovery by lignocaine. This explains why lignocaine has antiarrythmic property while bupivacaine has arrythmogenic potential. High level of bupivacaine prolongs conduction time through various parts of heart and extremely high concentration will depress spontaneous pacemaker activity, resulting in bradycardia and arrest. Cardiac resuscitation is more difficult following bupivacaine induced cardiovascular collapse and hypoxia along with acidosis which markedly potentiates cardiac toxicity. Bretylium but not lignocaine could raise the ventricular tachycardiac threshold that was lowered by bupivacaine. Pregnancy enhances the cardiotoxicity of bupivacaine. 0.75% is no longer recommended for use in labour analgesia. CVS toxicity includes atrio-ventricular block, ventricular arrhythmias and cardiac arrest. CC / CNS dose ratio is 3.7 ± 0.516.Cardiovascular collapse is more difficult to resuscitate and pregnant women are more sensitive to the cardiovascular effects than non- pregnant women. Bupivacaine is used in obstetric analgesia due to its longer duration of action, limited placental transfer, high degree of sensory block than motor block, less cumulation and no tachyphylaxis

3. Respiratory system:

Respiratory depression may be caused if excessive plasma level is reached which in turn results in depression of medullary respiratory centre. Respiratory depression may also be caused by paralysis of respiratory muscles as may occur in high spinal or total spinal anaesthesia.

4.Autonomic nervous system:

Myelinated preganglionic beta fibres have a faster conduction time and are more sensitive to the action of local anaesthetic including bupivacaine. Involvement of preganglionic sympathetic fibres is the cause of widespread vasodilation and consequent hypotension that occurs in epidural and paravertebral block. When used for conduction blockade all local anaesthetic particularly bupivacaine produces higher incidence of sensory blockade than motor fibres.

Pharmacokinetics of Bupivacaine:

Bupivacaine is rapidly absorbed from the site of injection, the rate of rise in plasma concentration and the peak plasma concentration depending on the particular local anaesthetic technique being used. There is also some inter individual variation and peak systemic concentrations may occur between 5 and 30 min after administration.

1. Absorption:

The site of injection, dose and addition of a vasoconstrictor determine systemic absorption of bupivacaine. The maximum blood level of bupivacaine is related to the total dose of the drug administered from any particular site.

2. Distribution:

This can be described by a two compartment model. The rapid distribution phase is believed to be related to uptake by rapid equilibrating tissue (i.e., tissues that have

high vascular perfusion). The slow distribution phase is mainly a function of distribution to slowly equilibrating tissue, biotransformation and excretion of the compound. More highly perfused organs show higher concentrations of the drug. Bupivacaine is rapidly extracted by lung tissue. Though skeletal muscle does not show particular affinity for bupivacaine it is the largest reservoir of the drug.

3. Biotransformation and excretion:

Bupivacaine undergoes enzymatic degradation primarily in the liver. The excretion occurs via the kidney. Renal perfusion and factors affecting urinary pH affect urinary excretion. Less than 5 percent of unchanged drug is excreted via the kidney through urine. The major portion of injected agent appears in urine in the form of 2, 6, pipecolyloxylidine (PPx) which is a N-dealkylated metabolite of bupivacaine. Renal clearance of this drug is related inversely to its protein binding capacity and pH of urine[32] .

4. Dosage:

Maximal dose is 2mg/kg body weight (25-30 ml 0.5% solution) and the strength used is 0.125% - 0.75%.

PHARMACOLOGY OF TRAMADOL

Structural & Chemical Formula of Tramadol

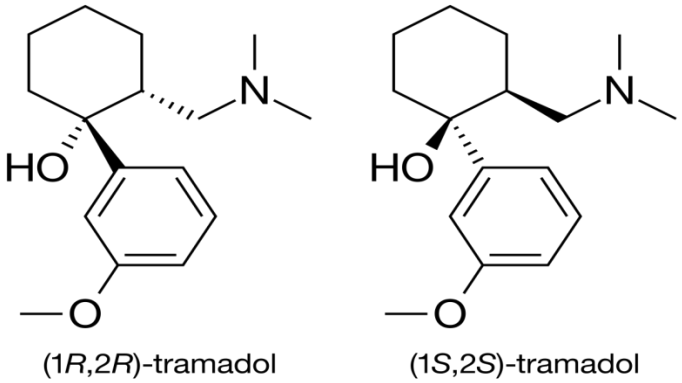


Fig.7

It is an opioid. It is a racemic mixture of two enantiomers, one of which is responsible for inhibition of norepinephrine uptake, whereas the other responsible for inhibition of 5 – hydroxytryptamine reuptake and facilitation of its release, plus the actions of this drug at mu receptors.

Pharmacokinetics:

- Bioavailability: 70-75 % orally, 77% rectal, 100% IM.
- Protein binding: 20%
- Metabolism: liver mediated demethylation and glucuronidation via CYP2D6 & CYP3A4.
- Onset of action: less than 1 hour by mouth.
- Elimination half-life: 6.3 +/- 1.4 hours.
- Duration of action: 6 hours.

Mechanism of action:

Tramadol is a centrally acting analgesic that has moderate affinity for mu receptors and weak kappa and delta opioid receptor affinity but is 5-10 times less potent than morphine as an analgesic. Tramadol enhances the function of the spinal descending inhibitory pathways by inhibition of neuronal reputake of norepinephrine and 5- hydroxytryptamine as well as presynaptic stimulation of 5 – hydroxytryptamine release.

Action on Respiratory system:

In therapeutic dose of tramadol no significant effect on Respiratory rate, tidal volume, minute ventilation. Overdose may cause respiratory depression.

Action on Cardiovascular system:

In therapeutic dose, tramadol has no significant effect on CVS, except for a transient reduction in pulmonary artery pressure, so it is suitable for pain relief in acute MI , diagnostic cardiac catheterisation.

Dosage: 1-2 mg/ kg. {Maximum dose is 400mg}

Side Effects:

- Nausea
- Dizziness
- Dry mouth
- Constipation
- Headache

PHARMACOLGY OF FENTANYL

It is an opioid.

Molecular Formula: C22H28N2O

Chemical Structure

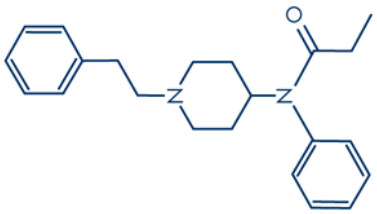


Fig.8

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 anaesthesia and analgesia. During anaesthesia it is often used along with propofol. It is also administered in combination with midazolam to produce sedation for endoscopy, cardiac cathetarization 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 in order to prevent large amount 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.

- **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 signalling 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.

MATERIAL AND METHODS

SOURCE OF DATA:

Patients scheduled for elective lower abdominal surgeries at KLE's Dr.Prabhakar Kore Hospital and Medical Research Centre and KLE's Dr.Prabhakar Kore Charitable hospital who are between the ages of 18 and 50 and belonging to ASA Grade I and II.

Type of study: Randomized control study

STUDY DURATION AND STUDY POPULATION:

According to inclusion and exclusion criteria, patients of both sexes between the ages of 18 and 50 who fall into ASA 1 and ASA 2 between January 2021 and December 2021 will be recruited for elective surgeries at KLE's Dr. Prabhakar Kore Charitable Hospital and Medical Research Center, Nehru Nagar, Belagavi, 590010.

INCLUSION CRITERIA:

Patients undergoing elective lower abdominal procedures are required to meet the inclusion criteria.

- Patients with ASA Grade I and II
- Age 18 to 50 years old.
- Patient providing consent,
- Weight between 50 and 70 kg
- Height between 150 and 175 cm.

EXCLUSION CRITERIA:

- Patients with spinal deformities,
- Hypovolemic patients,
- Uncooperative patients,
- Pregnant patients,

- Patients not providing consent,
- Hepatic/Renal disease, CVS, RS, CNS,
- Lower extremity neurological abnormalities that were present prior to the procedure.

100 participants were enrolled in the trial after receiving ethical committee clearance and written informed consent for their elective lower abdomen operations under SAB.

CALCULATION OF SAMPLE SIZE:

Formula for sample size:

The minimum sample size formula based on mean and standard deviation is

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

where z_α is linked with the level of significance and z_β is linked with the power of the test. For 5% level of the significance z_α =1.96 and z_β =0.84 for 80% power of the test. $\bar{X}_1$ is the mean of the first group (304) and $\bar{X}_2$ is the mean of the second group (238).s_1 is the standard deviation of the first group (67.9) and s_2 is the standard deviation of the second group (61.2).

There will be two groups each with size **50**.

So the total sample size would be "**100**"

Two steps of randomization

Group A received 0.5% Bupivacaine(H) and 25 mcg of FENTANYL.

Group B received 0.5% Bupivacaine(H) and 25 mg of TRAMADOL.

With the aid of a computer-generated randomization table, patients will be randomly assigned to one of the two groups after taking into account the inclusion and exclusion criteria and obtaining informed consent.

• Groups A and B

There will be a complete pre-anaesthetic assessment. We will gather comprehensive medical and personal history. There will be a thorough physical examination. Overnight fasting will be required of the patients. Standard investigations will be performed, including CBC, RBS, S. Creatinine, blood grouping and type, CXR, and ECG. Half an hour prior to the induction of anaesthesia, patients were preloaded by given RL 20ml/Kg in the preoperative holding room. The day before surgery, patients were given T.Alprazolam 0.25mg and T.Pantoprozole 40mg. Standard non-invasive monitors were attached inside the operating room, where the baseline values of HR, BP, and SpO2 were recorded. The L3-L4 space was identified in sitting position or in lateral position and under the strict asceptic precautions 2% Lignocaine was infiltrated in skin. Then using 23G or 25G Quincke's spinal needle, lumbar Sub Arachnoid space was identified.

- The L3-L4 SAS was injected with 3ml of 0.5% hyperbaric Bupivacaine and 0.5ml (25 mcg) of Fentanyl in Group A.
- In group B, 3.0 ml of 0.5% hyperbaric Bupivacaine and 0.5 ml(25 mg) of preservative free Tramadol was injected.

The subsequent variables were measured:

Sensory Blockade: Assessed by using a needle or spirit swab along the mid-axillary line every minute till the T10 level is reached. This will be noted as the time taken for the onset of action. The highest level reached would also be noted. Surgery would be

allowed to start after the T10 dermatome is blocked. The sensory blockade would be assessed once in every 15 min.

If the SAB does not act and GA or any other type of anaesthesia is given the case would be excluded from the study.

Motor Blockade

Assessed using Modified Bromage Scale[20]

- Bromage 3(complete)- Unable to move feet or knees
- Bromage 2(almost complete)- Able to move feet only.
- Bromage 1(partial)-just able to move knees and feet.
- Bromage 0 (none)-Full flexion of hip,knees and feet.

Motor blockage onset-Time taken to reach Bromage grade 3.

Total duration of motor blockade is the time taken to return back to Bromage grade 3 to 0. If the Bromage 3 is not attained then the highest grade reached would be noted.

The Modified Wilson Sedation Scale[21] is used to rate the patient's level of sedation Following onset during the time under anesthesia level of sedation in patient is graded using Modified Wilson Sedation Scale.

1 Oriented, eyes may be closed but can respond

2 Drowsy , eyes closed , arousable only to command

3 Arousable to mild physical stimulation (earlobe tug)

4 Unarousable to mild physical stimulation

Postoperative Pain Management:

After surgery the time when the first rescue analgesia is given would be noted. (Inj. Diclofenac 75mg in 100ml NS given)

Vitals :

Heart Rate, BP (systolic, diastolic, mean), Saturation will be noted throughout the surgery.

Hypotension would be defined as a decrease in the systolic BP by 20% from the baseline values / systolic BP less than 90 mmHg. It would be treated with bolus fluid administration, if still low, then mephentermine 6-12 mg would be used to treat.

Bradycardia –decrease in HR less than 50bpm & would be treated with IV atropine 0.6mg.

STATISTICAL ANALYSIS:

This study is focused on comparison between two groups. For the continuous quantitative variables mean and standard deviation were calculated. The inter group continuous variables were compared using suitable tools of statistics like unpaired student's t test. Two quantitative variables, within a group, were compared using student's paired t test.

Discrete variables were represented by median. Suitable graphs were used to depict the comparison. The categorical data was expressed in terms of rates, ratios and percentages. The association between the outcome, clinical and demographic characteristics were tested using Chi-square test or Fisher's exact test.

For all the tests the value of p less than 5% (0.05) was considered significant.

RESULTS

At Dr. Prabhakar Kore hospital and medical research centre, a one-year hospital-based randomised trial was carried out on patients undergoing lower abdomen surgical procedures under spinal anaesthesia.

100 patients in total were enlisted and randomly assigned using computer-based randomization. The recruited patients were in ASA classes I or II. Group A and Group B were created from these. Patients in Group A got an intrathecal injection of 3 ml of Bupivacaine (H) and 25 micrograms (0.5 ml) of fentanyl. The intrathecal injection of 25 milligrammes of preservative-free Tramadol (0.5 ml) was given to Group B along with 3 ml of bupivacaine (H). The total injection volume in each group was 3.5 ml.

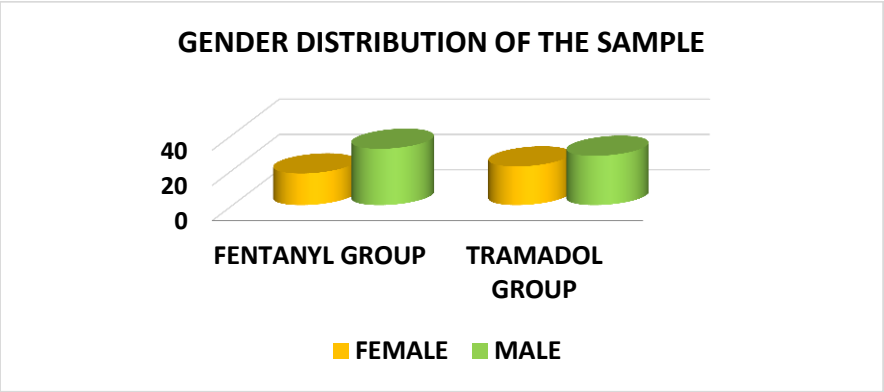
The findings from the tabulated and analysed results are discussed below.

Table 1: Gender distribution:

	GROUP (A)		GROUP (B)	
GENDER	**NUMBER**	**%**	**NUMBER**	**%**
FEMALE	18	36.00	22	44.00
MALE	32	64.00	28	56.00
TOTAL	50	100.00	50	100.00

36% of patients recruited in Group A were females and 44% of patients recruited in Group B were females as compared to 64% males in Group A and 56% males in Group B.

Graph 1: Gender distribution:

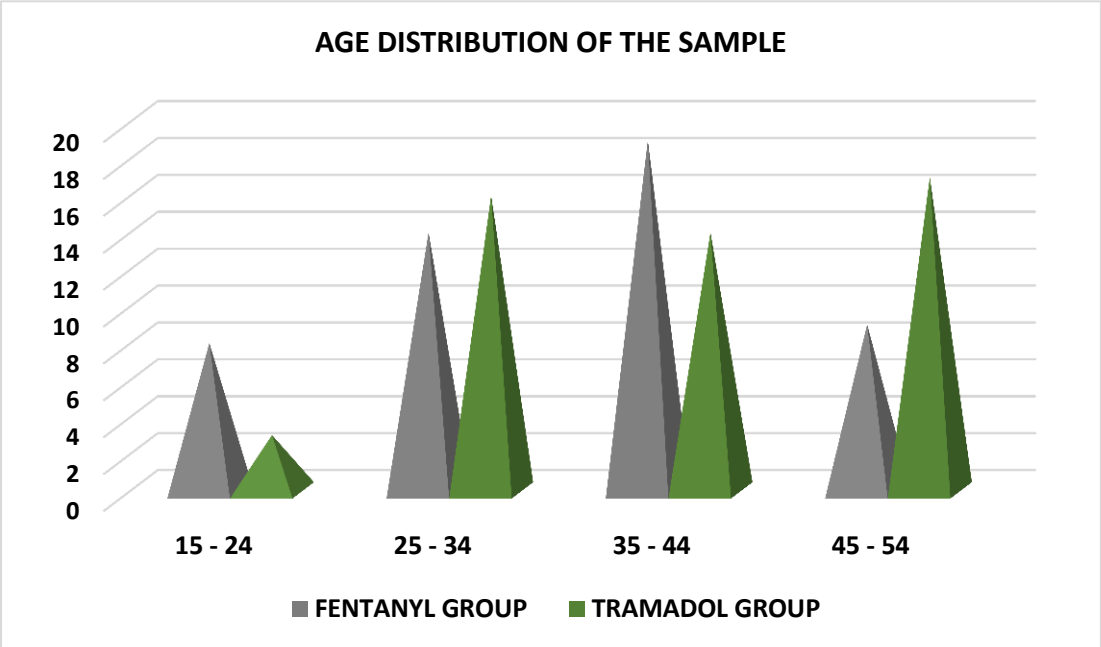


AGE AND ANTHRAPOMETRIC DATA

Table 2 Distribution of age:

	GROUP (A)		GROUP(B)	
AGE	**NUMBER**	**%**	**NUMBER**	**%**
15 - 24	8	16.00	3	6.00
25 - 34	14	28.00	16	32.00
35 - 44	19	38.00	14	28.00
45 - 50	9	18.00	17	34.00
TOTAL	50	100.00	50	100.00

Graph2: distribution of age



IN THE FOLLOWING TABLES p VALUES ARE CALCULATED USING STUDENT'S

"t" TEST TO COMPARE THE TWO GROUPS TO COMPARE THE MEANS OF EACH GROUP(INTRA GROUP COMPARISION) WIH RESPECT TO THE BASELINE VALUE.

Table 3 Distribution of age:

	GROUP (A)				GROUP(B)					
	MEAN	**S.D.**	**MIN**	**MAX**	**MEAN**	**S.D.**	**MIN**	**MAX**	**p VALUE**	**INFERENCE**
AGE	34.98	8.83	18	50	37.80	8.88	18	50	0.1145	NS

The p value of age in the two groups is 0.1145 which tells there is no significant difference in the two groups regarding age and are comparable.

Table4 Distribution of weight and height:

	GROUP A				GROUP B					
	MEAN	**S.D.**	**MIN**	**MAX**	**MEAN**	**S.D.**	**MIN**	**MAX**	**p VALUE**	**INFERENCE**
WEIGHT	65.72	3.96	56	70	66.90	4.37	56	70	0.1603	NS
HEIGHT	166.36	6.63	150	175	165.32	6.79	150	175	0.4403	NS

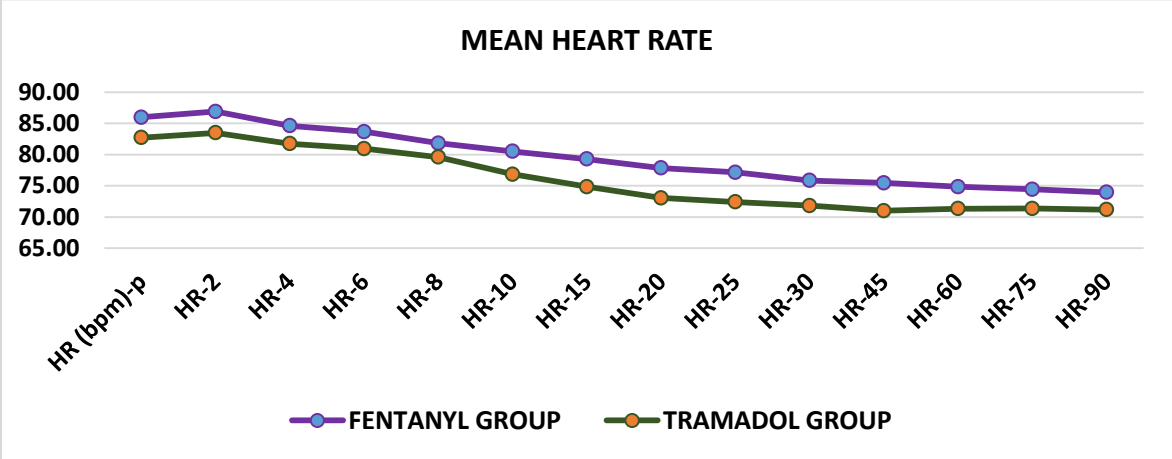
The mean weight in groups A and B are65.72±3.96 and 66.90±4.37 kilograms and the p value is 0.1603 which indicates the two groups are comparable and there is no significant difference. The mean height in groups A and B are 166.36±6.63 and 165±6.79 centimeters and the p value is 0.44 which indicates that there is no significant difference and the groups are comparable.

Table 6:

Comparision of mean heart rate between two groups:

	GROUP A				GROUP B					
	MEAN	**S.D.**	**MIN**	**MAX**	**MEAN**	**S.D.**	**MIN**	**MAX**	**p VALUE**	**INFERENCE**
HR (bpm)-p	85.98	5.55	76	100	82.71	6.55	68	98	0.0091	VS
HR-2	86.90	5.95	65	103	83.49	7.29	64	96	0.0128	S
HR-4	84.61	6.57	64	102	81.73	6.96	60	94	0.0379	S
HR-6	83.65	7.12	61	102	80.94	6.93	58	93	0.0589	NS
HR-8	81.82	7.34	60	100	79.59	7.77	57	98	0.1485	NS
HR-10	80.51	8.14	61	96	76.84	7.00	58	91	0.0185	S
HR-15	79.29	7.94	58	93	74.84	7.25	55	90	0.0047	VS
HR-20	77.84	8.07	53	91	73.06	7.00	55	88	0.0023	VS
HR-25	77.14	7.50	55	87	72.41	6.66	52	85	0.0013	VS
HR-30	75.86	6.79	54	86	71.82	6.80	54	84	0.0041	VS
HR-45	75.47	6.10	52	86	71.00	6.90	50	86	0.0010	VS
HR-60	74.84	5.68	53	85	71.35	6.80	53	89	0.0070	VS
HR-75	74.43	5.23	54	83	71.37	6.37	54	88	0.0108	S
HR-90	73.96	5.15	55	83	71.18	6.35	54	87	0.0195	S

Graph 3: Comparision of heart rate between two groups

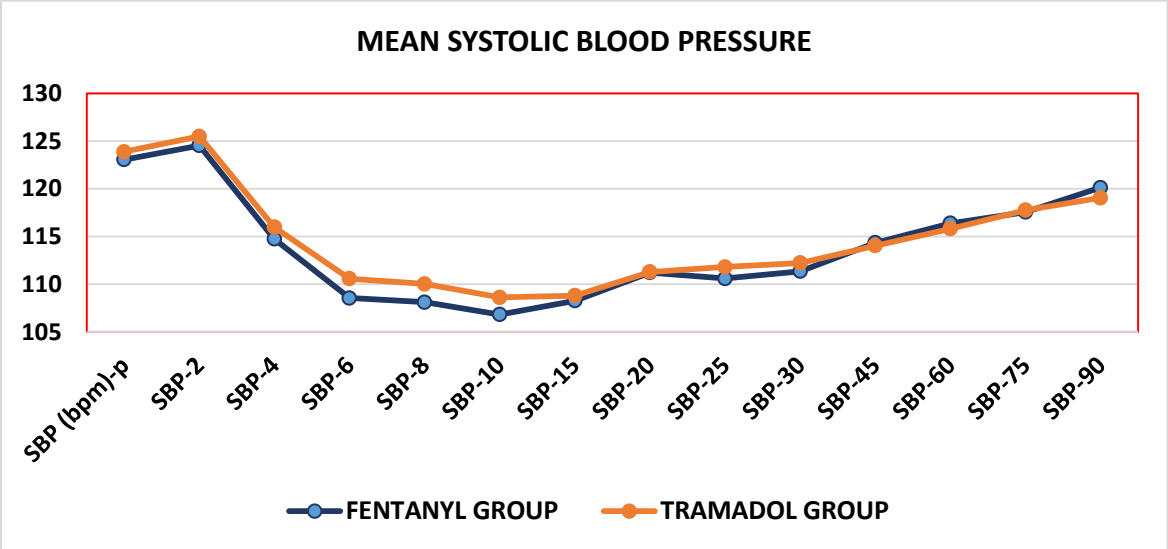


In this study the mean heart rate at preoperative period in Group A was noted as 85.98± 5.55 bpm and in Group B 82.71 ±6.55 bpm, which was statistically significant. At 10minutes the mean heart rate in Group A was 80.51± 8.14 bpm and in Group B was 76.84± 7.00 bpm with a significant difference (p=0.0185). At 90 minutes the mean heartrate in Group A was 73.96± 5.15 bpm and in Group B was 71.18± 6.35 bpm with a significant difference (p=0.0195).

TABLE 7: COMPARISON OF MEAN SYSTOLIC BLOOD PRESSURE (mm Hg) AT DIFFERENT INTERVALS (min) BETWEEN GROUP A AND GROUP B

	GROUP A				GROUP B					
	MEAN	S.D.	MIN	MAX	MEAN	S.D.	MIN	MAX	p VALUE	INFERENCE
SBP (bpm)p	123.06	8.95	110	140	123.88	7.59	110	140	0.6273	NS
SBP-2	124.53	9.60	108	143	125.49	8.50	108	148	0.6018	NS
SBP-4	114.73	19.21	11	138	115.98	9.63	100	145	0.6860	NS
SBP-6	108.55	9.79	95	132	110.57	10.28	96	145	0.3218	NS
SBP-8	108.12	10.50	90	128	110.02	9.75	90	142	0.3562	NS
SBP-10	106.82	8.49	93	128	108.61	8.54	89	126	0.2993	NS
SBP-15	108.27	7.83	90	128	108.80	7.28	93	123	0.7292	NS
SBP-20	111.22	8.76	93	124	111.29	7.67	97	128	0.9707	NS
SBP-25	110.59	7.32	99	127	111.80	6.79	99	126	0.4005	NS
SBP-30	111.35	8.18	96	131	112.22	8.03	92	131	0.5932	NS
SBP-45	114.33	7.50	96	129	114.04	7.77	91	135	0.8534	NS
SBP-60	116.39	6.85	104	126	115.82	6.79	101	131	0.6793	NS
SBP-75	117.55	5.90	105	128	117.76	6.31	104	134	0.8690	NS
SBP-90	120.12	6.15	106	134	119.04	5.24	104	128	0.3513	NS

Graph 4 Comparision of mean systolic blood pressure(spb)

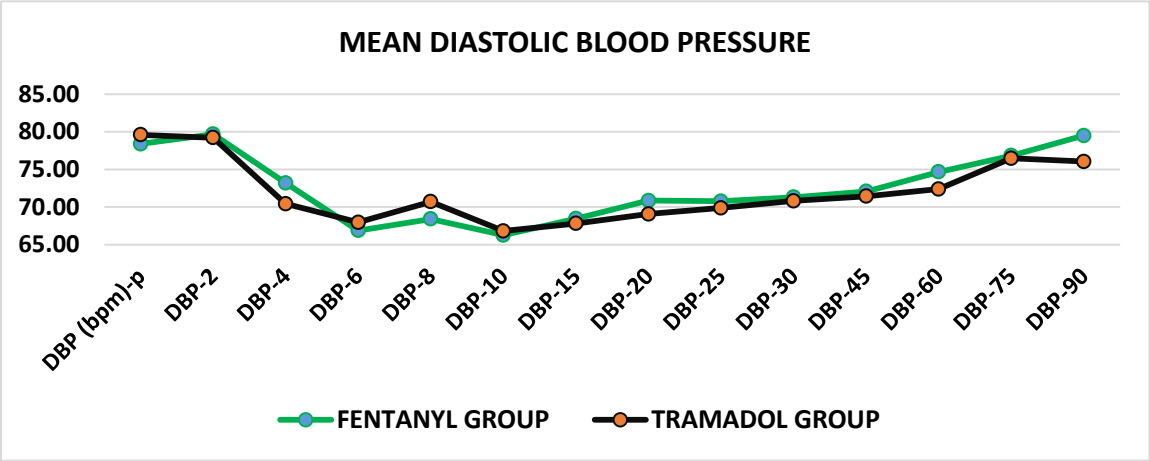


In this study, the mean systolic blood pressure in group A & B at frequent interval was noted. There was a slight fall in SBP as the duration of block progressed from 2 min to 6 min and further fall observed at about 15 min after which the change in SBP was almost the comparable between the two groups. At 20 min mean SBP in Group A was 111.22± 8.76 mmHg and that in Group B was 111.29±7.67 mmHg. At 30 min mean SBP in Group A was 111.35± 8.18 mmHg and that in Group B was 111.22±8.03 mmHg. At 90 min mean SBP in Group A was 120.12± 6.15 mmHg and that in Group B was 119.04±5.24 mmHg. However the mean SBP at all intervals in Group A & B were comparable (p>0.05).

TABLE 8: COMPARISON OF MEAN DIASTOLIC BLOOD PRESSURE (mm Hg) AT DIFFERENT INTERVALS(min) BETWEEN GROUP A AND GROUP B

	GROUP A				GROUP B					
	MEAN	S.D.	MIN	MAX	MEAN	S.D.	MIN	MAX	p VALUE	INFERENCE
DBP (bpm)-p	78.37	3.73	70	80	79.59	4.55	60	90	0.1484	NS
DBP-2	79.67	6.06	68	98	79.20	8.49	66	98	0.7535	NS
DBP-4	73.18	8.70	56	93	70.43	7.49	60	94	0.0962	NS
DBP-6	66.88	7.90	53	94	67.96	7.38	59	93	0.4855	NS
DBP-8	68.41	6.79	56	80	70.69	6.51	59	91	0.0923	NS
DBP-10	66.24	6.35	47	77	66.80	6.75	48	85	0.6784	NS
DBP-15	68.45	5.47	56	81	67.80	6.99	47	84	0.6076	NS
DBP-20	70.84	7.26	55	84	69.06	6.94	46	86	0.2188	NS
DBP-25	70.76	6.15	56	84	69.86	7.11	56	86	0.5052	NS
DBP-30	71.29	6.10	62	86	70.80	7.93	44	99	0.7327	NS
DBP-45	72.06	6.02	56	84	71.43	7.22	44	88	0.6386	NS
DBP-60	74.65	7.09	61	83	72.37	6.96	61	95	0.1105	NS
DBP-75	76.82	5.79	64	84	76.47	5.33	65	89	0.7583	NS
DBP-90	79.49	5.27	67	86	76.04	4.75	65	85	0.0010	VS

Graph 5: Comparision of mean diastolic blood pressure:

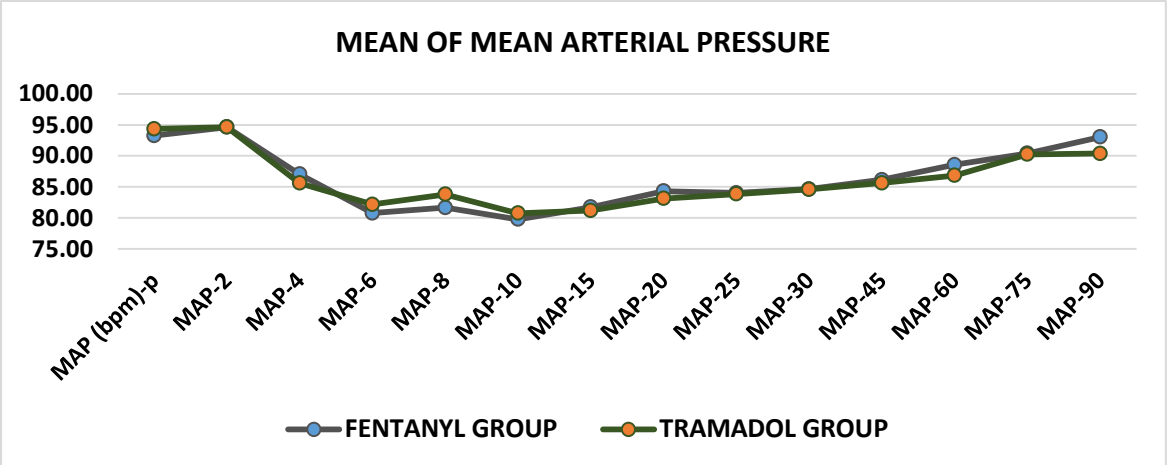


In this study, the mean diastolic blood pressure in group A & B at frequent interval was noted. There was a slight fall in DBP as the duration of block progressed from 2 min to 6 min and further fall observed at about 15 min after which the change in DBP was comparable between the two groups. At 20 min mean DBP in Group A was 70.84± 7.26 mmHg and that in Group B was 69.06±6.94 mmHg. At 30 min mean DBP in Group A was 71.29± 6.10 mmHg and that in Group B was 70.80±7.93 mmHg. At 90 min mean DBP in Group A was 79.49± 5.27 mmHg and that in Group B was 76.04±4.75 mmHg. However the mean DBP at all intervals in Group A & B were comparable (p>0.05).

TABLE 9: COMPARISON OF MEAN ARTERIAL PRESSURE(mmHg) AT DIFFERENT INTERVALS (min) BETWEEN GROUP A AND GROUP B.

	GROUP A				GROUP B					
	MEAN	S.D.	MIN	MAX	MEAN	S.D.	MIN	MAX	p VALUE	INFERENCE
MAP (bpm)-p	93.27	4.98	83.33	100.00	94.35	4.96	76.67	106.67	0.2810	NS
MAP-2	94.63	6.65	81.33	108.33	94.63	7.47	81.33	114.67	0.9962	NS
MAP-4	87.03	10.90	49.67	104.33	85.61	7.56	75.33	111.00	0.4551	NS
MAP-6	80.77	8.12	69.67	105.33	82.16	7.95	71.33	110.33	0.3925	NS
MAP-8	81.65	7.78	67.33	95.33	83.80	6.65	70.33	108.00	0.1438	NS
MAP-10	79.77	6.73	62.33	94.00	80.74	6.56	61.67	96.67	0.4706	NS
MAP-15	81.72	5.96	67.33	94.00	81.20	6.28	62.33	96.00	0.6768	NS
MAP-20	84.30	7.50	67.67	97.00	83.14	6.43	64.00	100.00	0.4116	NS
MAP-25	84.03	5.90	74.33	97.00	83.84	6.23	71.33	99.33	0.8725	NS
MAP-30	84.64	6.42	74.33	101.00	84.61	7.35	60.00	109.67	0.9806	NS
MAP-45	86.15	5.96	74.33	97.00	85.63	6.83	59.67	103.67	0.6907	NS
MAP-60	88.56	6.82	75.33	97.33	86.85	6.46	75.67	107.00	0.2045	NS
MAP-75	90.39	5.59	78.67	98.33	90.23	5.28	79.33	102.00	0.8822	NS
MAP-90	93.03	5.38	80.00	102.00	90.37	4.45	81.33	98.00	0.0090	VS

Graph 6 Comparision of mean arterial pressure between two groups



In this study, the mean arterial pressure in group A & B at frequent interval was noted. There was a slight fall in MAP as the duration of block progressed from 2 min to 6 min and further fall observed at about 15min after which the change in MAP was comparable between the two groups. At 20 min mean MAP in Group A was 84.30± 7.50 mmHg and that in Group B was 83.14±6.43 mmHg. At 30 min mean MAP in Group A was 84.64± 6.42 mmHg and that in Group B was 84.61±7.35 mmHg. At 90 min mean MAP in Group A was 93.03± 5.38 mmHg and that in Group B was 90.37±4.45 mmHg. However the mean MAP at all intervals in Group A & B were comparable ($p>0.05$).

TABLE 10: COMPARISON OF MEAN ONSET OF SENSORY BLOCK (SB)

SB-ONSET (SECONDS)									
GROUP (A)				GROUP (B)					
MEAN	S.D.	MIN	MAX	MEAN	S.D.	MIN	MAX	p VALUE	INFERENCE
164.43	28.10	120.00	230.00	192.61	32.98	120.00	245.00	< 0.0001	HS

The onset of sensory block in Group A is 164.43±28.10seconds and in Group B is 192.61±32.98 seconds. The p value is 0.0001 which denote that the difference in onset of sensory block is significant.

TABLE 11: COMPARISON OF MEAN ONSET OF MOTOR BLOCK

MB-ONSET (SECONDS)									
GROUP (A)				GROUP (B)					
MEAN	S.D.	MIN	MAX	MEAN	S.D.	MIN	MAX	p VALUE	INFERENCE
202.04	29.38	150.00	280.00	223.27	31.17	150.00	300.00	0.0008	HS

The onset of motor block in Group A is 202.04±29.38 seconds and in group B is 223.27±31.17 seconds. The p value is 0.0008 which denotes that the difference in onset of motor blockade between two groups is significant.

TABLE 12: COMPARISON OF DURATION OF MOTOR BLOCK

MB-DURATION (MINUTES)									
GROUP (A)				GROUP (B)					
MEAN	S.D.	MIN	MAX	MEAN	S.D.	MIN	MAX	p VALUE	INFERENCE
236.43	24.77	180.00	290.00	196.73	34.78	160.00	275.00	< 0.0001	HS

The mean duration of motor blockade in Group A is 236.43±24.77 minutes and in Group B is 196.73±34.78 minutes. The p value is less than 0.0001 which denotes that the difference in duration of motor blockade is significant.

TABLE 13: COMPARISON OF DURATION OF SENSORY BLOCK

SB-DURATION (MINUTES)									
GROUP (A)				GROUP (B)					
MEAN	S.D.	MIN	MAX	MEAN	S.D.	MIN	MAX	p VALUE	INFERENCE
261.55	44.43	26.00	315.00	217.24	37.00	185.00	295.00	< 0.0001	HS

The mean duration of sensory blockade in Group A is 261.55±44.43 minutes and in Group B is 217.24±37.00 minutes. The p value is less than 0.0001 which denotes that the difference in duration of sensory blockade is significant.

TABLE 14: COMPARISON OF TIME OF REQUEST OF RESCUE ANALGESIA

RESCUE ANALGESIA (MINUTES)									
GROUP (A)				GROUP (B)					
MEAN	S.D.	MIN	MAX	MEAN	S.D.	MIN	MAX	p VALUE	INFERENCE
300.10	24.25	240.00	345.00	242.45	37.49	200.00	320.00	< 0.0001	HS

The mean time of request of rescue analgesia in Group A is 300.10±24.25 minutes and in Group B is 242.45±37.49 minutes. The p value is less than 0.0001 which denotes that the difference in time for request of rescue analgesia is significant.

DISCUSSION

SAB is the most commonly used technique for lower abdominal surgeries. SAB has many advantages over general anaesthesia which includes

- lesser stress response,
- avoidance of tracheal intubation
- better post-operative compliance and analgesia.

Addition of opioids along with the local anaesthetics further increases the efficacy of the drug acting synergistically. The local anaesthetic and the opioids act on different receptors. The opioids act on the opioids receptors in the substantia gelatinosa[22] while the local anaesthetic blocks the impulse transmission at the root of the neurons. The combined effect results in the synergic action and prolonged post-operative pain relief. In our study design, we had two groups with two different doses of drugs used. The Group A received 3 ml of 0.5% Bupivacaine with 25 mcg of Inj Fentanyl while Group B received 3 ml of 0.5% bupivacaine with 25 mg of Inj Tramadol. The drug was injected subarachnoid space for Spinal anaesthesia for patients posted for lower abdominal surgeries. There have been numerous studies showing the efficacy of adding an opioid to the local anesthetic for regional anesthesia[24].

In this study there was no statistical difference observed between Group A and B with regards to distribution of sex, mean age, mean weight and mean height. These findings suggests that the demographic and pre anaesthetic characteristics between group A and B are comparable.

In this study, the baseline hemodynamic parameters i.e; mean systolic blood pressure, mean diastolic pressure and mean arterial pressure were comparable between the two groups throughout the period of SAB block. At 20 min mean SBP in Group A was 111.22± 8.76 mmHg and that in Group B was 111.29±7.67 mmHg. At

30 min mean SBP in Group A was 111.35± 8.18 mmHg and that in Group B was 111.22±8.03 mmHg. At 90 min mean SBP in Group A was 120.12± 6.15 mmHg and that in Group B was 119.04±5.24 mmHg.

At 20 min mean DBP in Group A was 70.84± 7.26 mmHg and that in Group B was 69.06±6.94 mmHg. At 30min mean DBP in Group A was 71.29± 6.10 mmHg and that in Group B was 70.80±7.93 mmHg. At 90 min mean DBP in Group A was 79.49± 5.27 mmHg and that in Group B was 76.04±4.75 mmHg.

At 20 min mean MAP in Group A was 84.30± 7.50 mmHg and that in Group B was 83.14±6.43 mmHg. At 30 min mean MAP in Group A was 84.64± 6.42 mmHg and that in Group B was 84.61±7.35 mmHg. At 90 min mean MAP in Group A was 93.03± 5.38 mmHg and that in Group B was 90.37±4.45 mmHg.

The p values of all the haemodynamic parameters throughout the study were >0.005 and hence not statistically significant denoting that they are comparable.

In a similar study done by Surhan Ozer and Hacer Sebnem Turk[11] comparing Fentanyl and Tramadol resulted in no significant difference in Systolic, Diastolic and Mean arterial BP throughout the duration of block.

In this study, there is significant difference in the time of onset of sensory and motor blockade between the two groups. The onset of sensory block in Group A is 164.43±28.10 seconds and in Group B is 192.61±32.98 seconds. The p value is <0.0001. The onset of motor block in Group A is 202.04±29.38 seconds and in group B is 223.27±31.17 seconds. The p value is 0.0008.

There was no significant statistical difference in time of onset of sensory and motor block in a similar study done by Ozer S[11] between Fentanyl and Tramadol group (4.80±1.47 and 6.11±2.46 minutes for sensory onset and 5.12±2.95 and 4.92±1.85 minutes for motor onset).

There is also significant difference in duration of sensory and motor blockade between two groups. The mean duration of sensory blockade in Group A is 261.55±44.43 minutes and in Group B is 217.24±37.00 minutes. The p value is less than 0.0001.

In a study conducted by Naina P Dalvi and Narendra Patil[10], there was significant difference in duration of sensory blockade between Intrathecal Fentanyl and Tramadol (314.66 and 261.66 minutes respectively.)

The mean duration of motor blockade in Group A is 236.43±24.77 minutes and in Group B is 196.73±34.78 minutes. The p value is less than 0.0001. In both these parameters, the p value being far less than 0.005 denotes that there is significant difference in time of onset and duration.

Similarly in the study conducted by Naina P Dalvi[10], there was significant in duration of motor blockade between Fentanyl and Tramadol (263.66 and 214.66 minutes respectively).

The time of request for rescue analgesia is also compared. The mean time of request of rescue analgesia in Group A is 300.10±24.25 minutes and in Group B is 242.45±37.49 minutes. The p value is less than 0.0001 which denotes that the difference in time for request of rescue analgesia is significant in between two groups.

Similarly in a study by Afolayan, et al[15], the time of request of rescue analgesia was more in Fentanyl group than in Tramadol group (304 ± 67.91 and 238.39 ± 61.28 minutes respectively) which was statistically significant with p value = 0.001(<0.005).

Also in a study by Naina P Dalvi and Narendra Patil[10], the patients remained pain free for 412±97.88 minutes and 301.33±38.75 minutes in Fentanyl and Tramadol group respectively with p value < 0.001 which is statistically very significant.

CONCLUSION

Based on this study, it may be concluded that

- The time of onset of sensory block and time of onset of motor block was significantly lower in Fentanyl group than in Tramadol group.
- The duration of sensory and motor block was significantly higher in Fentanyl group than in Tramadol group.
- The time of request of rescue analgesia was also significantly higher in Fentanyl group compared to Tramadol group.
- Other parameters like haemodynamics and sedation were comparable to each other.

So it can be concluded that addition of Fentanyl to Bupivacaine for spinal anaesthesia offers better operating conditions and prolonged duration of anaesthesia in comparision with addition of Tramadol to Bupivacaine.

The hypothesis is proven correct.

SUMMARY

SAB is the most prevalent mode of anaesthesia in lower abdominal surgeries. In our study titled "COMPARISON BETWEEN EFFICACY OF INTRATHECAL TRAMADOL-BUPIVACAINE(H) AND FENTANYL-BUPIVACAINE(H) IN LOWER ABDOMINAL SURGERIES – A ONE YEAR HOSPITAL BASED RANDOMIZED CONTROL TRIAL CONDUCTED AT KLES DR. PRABHAKAR KORE CHARITABLE HOSPITAL AND RESEARCH CENTRE", we conducted our study on patients of age group 18-50 years belonging to ASA I-II posted for lower abdominal surgeries. Written informed consent were taken from the patients and ethical committee clearance was acquired. Patients were randomly allocated into two groups with 50 patients each in two groups.

Group A - 3ml ofi0.5% Hyperbaric Bupivacaine with 0.50ml (25 mcg) of Fentanyl making a total volume of 3.50 ml of drug is injected in L2-L3 SAS.

Group B - 3ml of 0.5% hyperbaric Bupivacaine with 0.50ml (50mg) of Tramadol making a total volume of 3.50 ml of drug is injected in L2-L3 SAS.

In both the groups, the demographic variables and the gender distribution were comparable and were statistically insignificant.

The time of onset of sensory blockade was faster in group A compared to group B and the difference was found to be statistically significant (Group A is 164.43±28.10seconds and Group B is 192.61±32.98 seconds for sensory blockade and $p<0.0001$).

The time of onset of motor blockade was also faster in group A compared to group B and the difference was found to be statistically significant (Group A is 202.04±29.38 seconds and in group B is 223.27±31.17 seconds. The p value is 0.0008).

A declining trend in heart rate was observed in both the groups after induction but the decline was more in group B compared to group A and the difference was significant ($p<0.05$).

The SBP, DBP and MAP all are comparable between the two groups since the beginning ($p>0.05$).

The mean duration of sensory block in Group A (261.55±44.43 minutes), is longer when compared to Group B (217.24±37.00) minutes. This difference was found to be statistically significant. The p value is less than 0.0001.

The total duration of motor blockade similarly is longer in Group A (236.43±24.77 minutes), when compared to Group B (196.73±34.78 minutes), and this difference is statistically significant. The p value is less than 0.0001.

Time required for first post-operative rescue analgesia was more delayed in Group A (300.10±24.25 minutes), when compared to Group B (242.45±37.49 minutes), and this difference was again significant. The p value is less than 0.0001.

The sedation scores of the two groups are comparable between the two groups.

Overall, the combination of intrathecal Bupivcaine-Fentanyl had early onset of sensory and motor block and prolonged duration of sensory and motor block and the time required for rescue analgesia was longer when compared to the combination of intrathecal Bupivacaine – Tramadol without having much difference in haemoodynamic control.

SCOPE AND LIMITATIONS

Limitations of this study include smaller sample size, single centre study, and study being done only in ASA 1 and 2 patients. Pregnant women were not included in the study. Blinding was not observed.

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ANNEXURE I

INFORMED CONSENT

"Comparison between Efficacy of Intrathecal Tramadol-Bupivacaine(H) and Fentanyl-Bupivacaine(H) in lower abdominal surgeries – a one year hospital based randomized control trial conducted at KLEs Dr.PRABHAKAR KORE charitable hospital and research centre, Belagavi."

PRINCIPAL INVESTIGATOR: **REG NO: BA0120008**

Post Graduate student

Department of Anaesthesiology

CO- INVESTIGATOR : **DR. _____**

Professor

Department of Anaesthesiology

INTRODUCTION AND PURPOSE:

The present study is conducted among adult patients scheduled for various elective surgeries under subarachnoid block in the department of Anaesthesiology at KLE's Dr. Prabhakar Kore Charitable Hospital and Medical Research Centre, Belagavi. You are requested to participate in the study and your participation is completely voluntary.

The purpose of research is:

1. To compare the onset and duration of sensory and motor blockage between 0.5% Bupivacaine (H) with Fentanyl and Tramadol respectively Fentanyl-25mcg Tramdol 25mg.

2. To compare the level of sedation caused by intrathecal opoids- fentanyl and Tramadol (using "Modified Wilson Scale")

PROCEDURE:

If you agree to enroll in my study, I will ask your 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 F will be given Fentanyl as adjunct with SAB while Group T will be given Tramadol.

BENEFITS:

Prolonged anaesthesia and minimal heamodynamic change

Patient will not be eligible for any kind of monetary benefits or free services by virtue of your participation in the study.

RISKS:

Methods applied to do the study are safe.

COST OF PARTICIPATION:

The cost of the investigation will be borne by the study subject. The other indirect expenses will be borne by the investigator.

PRIVACY AND CONFIDENTIALITY:

The results of the study may be published in journals for scientific purposes. However, your identity will not be revealed. All information collected will be coded so that no one other than the investigator will know your identity.

WITHDRAWAL FROM THE STUDY:

You can withdraw from the study at any time if you wish to do so.

ALTERNATIVES:

In case you opt out of the study, it will not affect your relationship with KLE's Dr. Prabhakar Kore Hospital.

AUTHORIZATION TO PUBLISH RESULTS:

The researcher may use the information gathered from this study for presentation in scientific meetings. However, your identity will not be revealed.

INSTITUTIONAL/ SPONSORS POLICY:

In the event of any injury related to this study, no reimbursement or compensation will be given by law. However, treatment will be made available at KLE's Hospital & MRC, Belgaum. If you face any untoward event, you may contact **REG NO: BA0120008** at Department of Anaesthesiology, KLE's Hospital & MRC.

LEGAL RIGHTS: By signing this consent form, you are not waiving any of your legal rights

QUERIES AND CONTACT:

If you have any queries regarding to the study, you can contact **REG NO: BA0120008** Department of anesthesiology, J.N.Medical college or by Ph.No:_____ and the guide Dr._____ Dept of Anaesthesiology J.N Medical College, Belagavi.

If you have any queries about your rights as research participant, you can contact Dr. Roopa Bellad M.D, Professor, Dept of Paediatrics and chairman, J.N Medical College Institutional Ethical Committee for Human Subjects Research.

CONSENT SUMMARY:

I have been explained all the contents of this consent form in my local language and having understood and clarified all my queries about the study to the best of my knowledge, I hereby give my voluntary consent for participation in the study. I do sign the informed consent form in front of an eye witness whom I recognize.

Name and Signature/ left thumb impression of the participant:

Name and Signature of the investigator:

Name and Signature/ left thumb impression of the eye witness (Relative):

Signature of the Guide: **Date:**

Informed Consent for Participation In Research Trial

"Comparison between Efficacy of Intrathecal Tramadol-Bupivacaine(H) and Fentanyl-Bupivacaine(H) in lower abdominal surgeries – a one year hospital based

randomized control trial conducted at KLEs Dr.Prabhakar KORE charitable hospital and research centre, Belagavi."

I,Mr/Mrs _____voluntarily agree for the participation of my child as a subject for the study, by signing this consent form I am not giving up any of my legal rights, I may withdraw from the study any time. I am signing the consent form after having read or been read to me in the vernacular language ,including the risk and the benefits and having all my queries cleared.

Signature or the left thumb impression of parent/guardian:

Name of study patient:

Name and signature of witness: _____

_____

Name and signature of investigator: _____

_____

Date: Place:

PROFORMA

ANNEXURE II

Patients Name : I.P No. :

Age : Weight:

Height : Gender:

Date of operation: Occupation:

Address: Anaesthesiologist:

Preanaesthetic evaluation

Chief complaints Past History

- HTN / DM/ IHD / Arrhythmia / LVH / Valvular heart disease
- H/o uncontrolled hypertension/diabetes mellitus
- H/o previous surgery.
- Drug therapy

Family History

General physical examination

Weight (Kg) : Temperature (0F) : Pallor :

Icterus : Cyanosis : Pedal oedema:

Clubbing: PR : BP: RR:

Systemic examination:

RS: CNS:

CVS: GIT:

Musculoskeletal disorders:

Jaw movements : Teeth:

Airway assessment : Spine:

Investigations

Hb%:TLC: Platelet Count : INR:FBS:

Diagnosis

Pre-operative physical state: ASA I / II / III / IV / V

Proposed surgery

Pre-operative baseline values

HR : BP: SpO2:

Following monitoring was done throughout the procedure

Pulse oxymetry: NIBP:

Gro

up: A BSensory Block:

a)	Onset at T10(min)	
b)	Duration at T10(min)	
c)	Highest level of sensory block	

Motor Block:

a)	Onset (min) Grade 3 motor blockade	
b)	Total duration of Motor blockade (min)	

Sedation Score: 1 / 2 / 3 / 4

Vital Parameters:

Time	HR	SBP	DBP	MAP	SpO2
2min					
4min					
6min					
8min					
10min					
15min					
20min					
25min					
30min					
45min					
60min					
75min					
90min					
105min					
120min					

Post-operative Analgesia:

Time to request for first post-operative rescue analgesia either diclofenac/paracetamol(min):

- SIGNATURE OF THE ANAESTHESIOLOGIST:

- SIGNATURE OF THE WITTNESS -

SIGNATURE OF THE PRINCIPAL INVESTIGATOR -

ANNEXURE III PHOTOS

Photo 1: Bupivacaine(heavy)

Photo 2: Lignocaine 2%)

Photo 3: Tramadol

Photo 4:Fentanyl

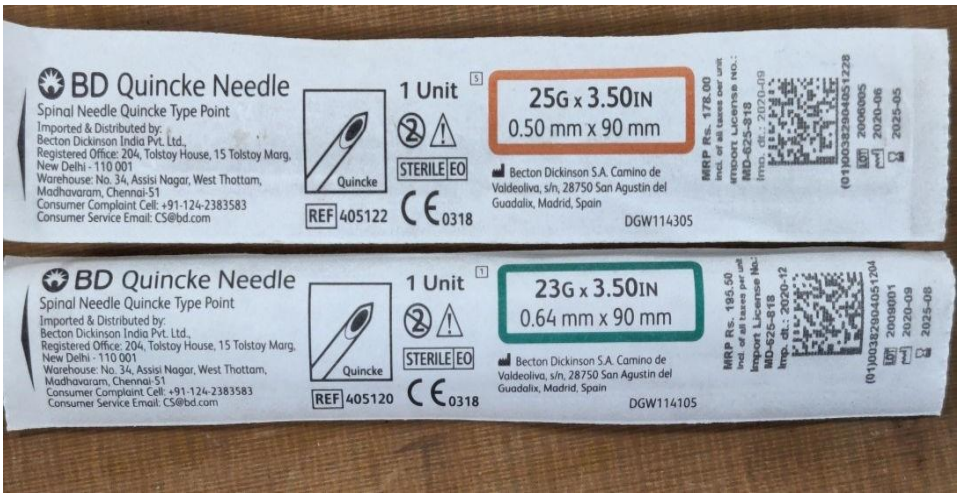

Photo 5: Spinal Needles

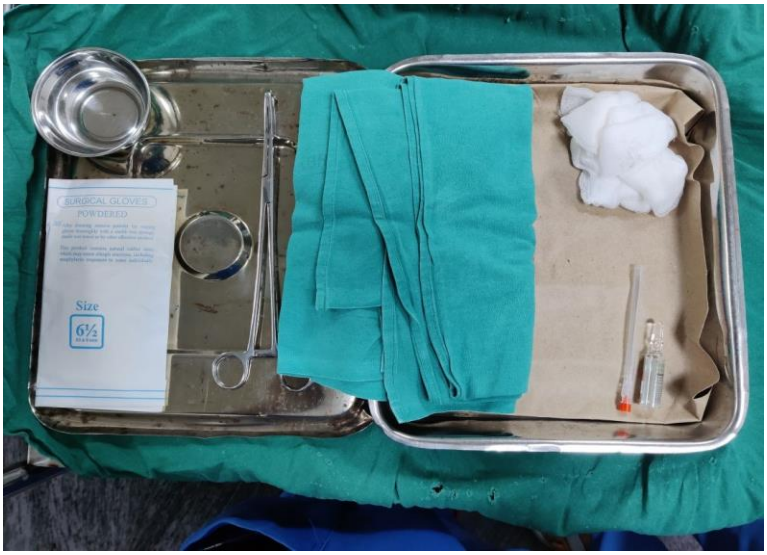

Photo 6: Spinal set

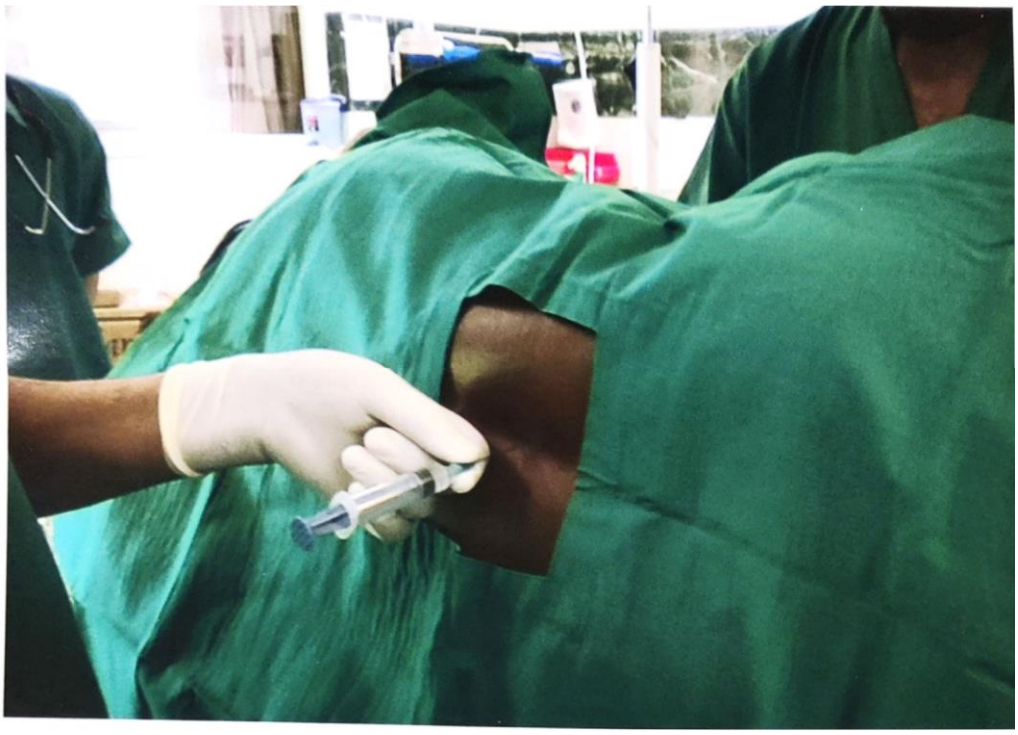

Photo 7: Administering SAB

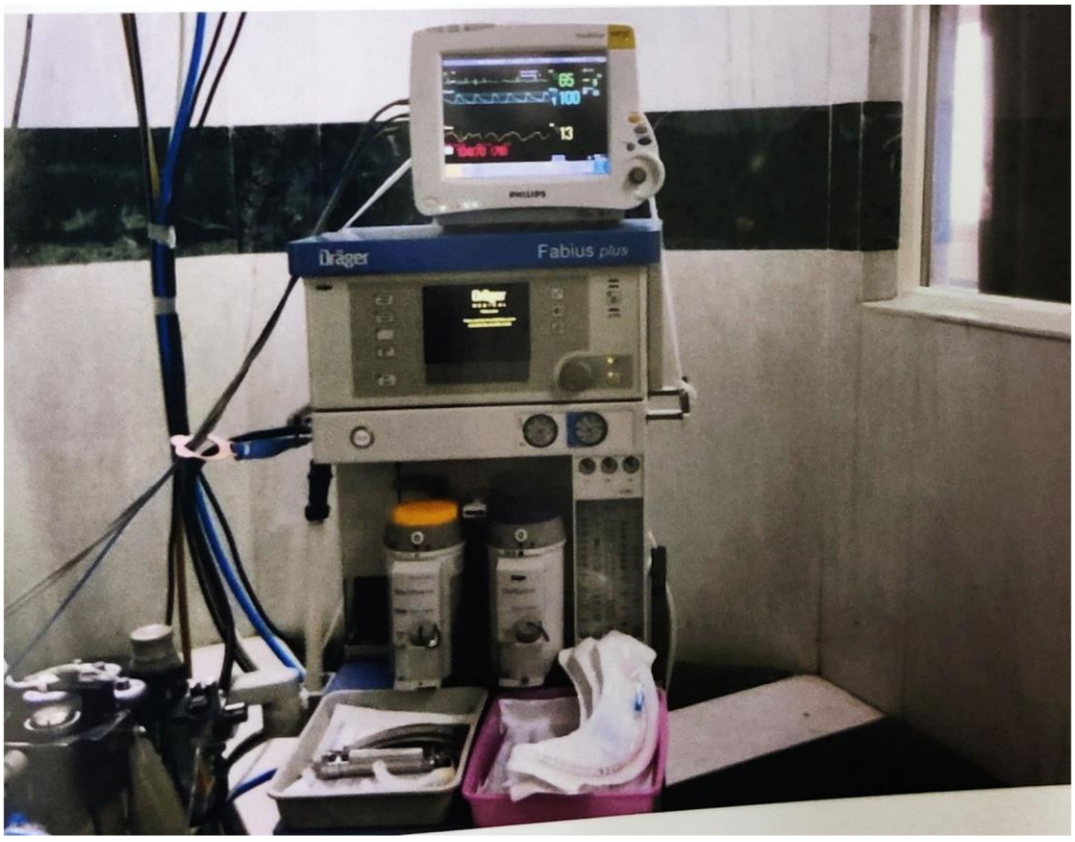

Photo 8: Anaesthesia Work Station and Monitor

KEY TO MASTER CHART

HR	-	Heart rate
SBP	-	Systolic Blood Pressure
DBP	-	Diastolic Blood Pressure
MAP	-	Mean Arterial Pressure
spO2	-	Saturation
SB	-	Sensory Block
MB	-	Motor Block
TAH	-	Total Abdominal Hysterectomy
DJS	-	Double J Stenting
I&D	-	Incision & Drainage
STSG	-	Split Thickness Skin Grafting
PCNL	-	Percutaneous Nephro Lithotomy
URS	-	Ureteroscopic Lithotripsy
ORIF	-	Open Reduction Internal Fixation

FENTANYL

Serial no.	I.P NO	Sex	Age (yrs)	weight (kgs)	Height(cms)	ASA	Proposed surgery	HR (bpm)-p	SBP-P	DBP-P	MAP-P	SPO2-P	HR-2	SBP-2	DBP-2	MAP-2	HR-4	SBP-4	DBP-4	MAP-4	HR-6	SBP-6	DBP-6	MAP-6	HR-8	SBP-8	DBP-8	MAP-8	HR-10	SBP-10	DBP-10	MAP-10
1	1040072	F	42	62	154	1	TAH	84	140	80	100	100	84	140	80	100	80	100	60	73	79	95	58	70	77	97	60	72	79	93	52	66
2	1040756	M	35	70	158	1	HERNIOPLASTY	100	110	70	83	100	103	110	70	83	102	103	65	78	102	101	62	75	100	93	59	70	96	96	61	73
3	1046482	M	24	62	170	1	HERNIOPLASTY	98	110	80	90	100	85	121	77	92	84	111	73	86	85	117	70	86	81	112	67	82	77	93	47	62
4	1054896	F	39	69	168	1	DJS	82	120	80	93	100	88	126	72	90	87	121	70	87	85	119	67	84	83	113	67	82	81	119	67	84
5	1054710	F	37	58	168	1	DJS	80	110	70	83	100	84	110	70	83	82	100	63	75	80	96	61	73	78	102	68	79	79	108	71	83
6	1062033	M	32	61	153	1	HAEMORRHOIDECT	81	110	70	83	100	84	125	98	107	72	126	72	90	74	123	75	91	70	118	78	91	70	126	74	91
7	1064434	M	39	70	173	1	CYSTOSCOPY	84	120	80	93	100	95	125	83	97	96	130	89	103	94	132	73	93	88	128	77	94	82	128	77	94
8	1069552	M	40	70	173	1	I&D	84	130	80	97	100	84	130	80	97	76	120	73	89	71	110	70	83	73	105	65	78	65	103	62	76
9	1068893	M	48	62	175	2	STSG	83	140	80	100	100	83	120	82	95	76	114	75	88	71	114	75	88	71	111	75	87	66	103	67	79
10	1069838	M	25	68	161	1	HAEMORRHOIDECT	76	120	80	93	100	74	128	74	92	71	127	74	92	71	119	73	88	72	116	72	87	71	111	71	84
11	1070847	F	40	70	169	1	ANAL FISTULA REPA	81	110	70	83	100	84	114	73	87	83	99	56	70	78	103	53	70	75	128	79	95	71	119	74	89
12	1071501	F	37	63	159	1	FISSURECTOMY	78	130	80	97	100	84	116	75	89	83	110	69	83	84	103	65	78	81	104	71	82	82	101	67	78
13	1078786	M	33	70	162	1	ANAL FISTULA REPA	91	120	80	93	100	91	120	80	93	89	108	71	83	88	96	59	71	86	110	68	82	85	103	63	76
14	1080119	M	50	62	174	2	DEBRIDEMENT	78	130	80	97	100	84	116	75	89	83	110	69	83	84	103	65	78	81	104	71	82	82	101	67	78
15	1082176	M	35	66	174	1	HERNIOPLASTY	91	120	80	93	100	91	120	80	93	89	108	71	83	88	96	59	71	88	103	63	76	87	110	68	82
16	1100969	M	35	70	172	1	URSL	78	130	80	97	100	84	116	75	89	83	110	69	83	84	103	65	78	81	104	71	82	82	101	67	78
17	1082198	M	50	62	173	2	HERNIOPLASTY	84	130	80	97	100	84	140	83	102	81	135	81	99	82	113	72	86	78	108	65	79	75	104	63	77
18	1082237	F	22	56	150	1	D&G	81	110	70	83	100	84	114	73	87	83	99	56	70	78	103	53	70	75	128	79	95	71	119	74	89
19	1082237	F	22	56	152	1	DEBRIDEMENT	89	120	80	93	100	93	128	84	99	91	126	81	96	92	102	66	78	90	94	59	71	91	111	71	84
20	1073746	F	30	62	159	1	D&G	84	140	80	100	100	84	143	83	103	81	135	81	99	82	113	72	86	78	108	65	79	75	104	63	77
21	1089022	F	45	58	162	1	DJS	89	130	80	97	100	88	126	85	99	86	121	79	93	84	117	72	87	83	103	68	80	82	101	66	78
22	1089188	F	49	68	153	1	UV FISTULA REPAIR	91	120	80	93	100	91	120	80	93	89	108	71	83	88	96	59	71	86	110	68	82	85	103	63	76
23	1080452	M	42	62	170	1	DJS REMOVAL	84	130	80	97	100	84	140	83	102	81	135	81	99	82	113	72	86	78	108	65	79	75	104	63	77
24	1089433	M	23	70	170	1	CYSTOSCOPY	89	120	80	93	100	93	128	84	99	91	126	81	96	92	102	66	78	90	94	59	71	91	111	71	84
25	1089482	F	45	64	162	1	DJS REMOVAL	94	130	80	97	100	91	120	80	93	89	108	71	83	88	96	59	71	86	96	59	71	86	110	68	82
26	1089321	M	22	66	164	1	HYPOSPADIAS REPA	91	120	80	93	100	94	133	83	100	92	125	79	94	90	123	75	91	93	117	76	90	92	103	67	79
27	1089502	M	28	70	171	1	DJS	81	110	70	83	100	84	114	73	87	83	99	56	70	78	103	53	70	75	128	79	95	71	119	74	89
28	1089509	M	40	62	171	1	DJS	91	130	80	97	100	91	131	79	96	90	115	68	84	90	113	69	84	88	110	63	79	89	103	56	72
29	1089532	F	28	64	163	1	DJS	82	120	80	93	100	65	114	73	87	64	99	56	70	61	103	53	70	60	128	79	95	61	119	74	89
30	1117057	M	32	70	174	1	PCNL	82	120	80	93	100	79	128	84	99	77	126	81	96	76	111	71	84	71	102	66	78	68	94	59	71
31	1116603	M	50	70	174	1	DJS	80	120	80	93	100	84	128	90	103	82	127	93	104	81	128	94	105	82	118	80	93	80	116	77	90
32	1120156	F	35	65	166	1	DJS	82	120	80	93	100	84	116	75	89	83	11	69	50	84	103	65	78	81	104	71	82	82	101	67	78
33	1119611	M	34	70	174	1	STRICTURE REPAIR	89	120	80	93	100	93	128	84	99	91	126	81	96	92	102	66	78	90	94	59	71	91	111	71	84
34	1120460	M	22	68	166	1	DJS	84	140	80	100	100	84	143	83	103	81	135	81	99	82	113	72	86	78	108	65	79	75	104	63	77
35	1120197	f	26	66	165	1	DJS	91	120	80	93	100	91	120	80	93	89	108	71	83	88	96	59	71	86	110	68	82	85	103	63	76
36	1120220	M	35	66	169	1	CYSTOLITHOTRIPSY	81	110	70	83	100	84	114	73	87	83	99	56	70	78	103	53	70	75	128	79	95	71	119	74	89
37	1121296	M	30	70	168	1	URS	89	120	80	93	100	89	143	91	108	81	138	83	101	78	123	76	92	78	117	69	85	77	110	62	78
38	1121831	F	29	65	165	1	DJS REMOVAL	89	130	80	97	100	88	126	85	99	86	121	79	93	84	117	72	87	83	103	68	80	82	101	66	78
39	1122104	M	20	68	168	1	CIRCUMCISION	86	120	80	93	100	84	108	68	81	84	104	69	81	83	102	68	79	82	102	72	82	81	93	55	68
40	1121907	M	37	66	174	1	DJS	86	120	80	93	100	88	126	85	99	86	121	79	93	84	117	72	87	83	103	68	80	83	101	66	78
41	1121933	M	31	66	173	1	DJS	94	130	80	97	100	94	133	83	100	92	125	79	94	90	123	75	91	93	117	76	90	92	108	71	83
42	1122235	M	38	65	172	1	DJS	89	120	80	93	100	93	128	84	99	91	126	81	96	92	102	66	78	90	94	59	71	91	111	71	84
43	1122517	F	39	68	165	1	URS	89	120	80	93	100	93	128	84	99	91	126	81	96	92	102	66	78	90	94	59	71	91	111	71	84
44	1122535	M	50	67	161	2	URS	78	130	80	97	100	84	116	75	89	83	110	69	83	84	103	65	78	81	104	71	82	82	101	67	78
45	1122419	M	40	69	172	1	DJS	84	130	80	97	100	84	140	83	102	81	135	81	99	82	113	72	86	78	108	65	79	75	104	63	77
46	1123081	M	46	68	169	1	DJS REMOVAL	92	140	80	100	100	84	128	79	95	83	119	74	89	84	113	72	86	81	109	71	84	80	114	62	79
47	1122563	F	18	62	160	1	DJS	84	110	70	83	100	85	108	68	81	84	104	69	81	82	102	68	79	83	90	56	67	82	93	55	68
48	1122563	M	41	70	168	1	DJS	94	130	80	97	100	91	120	80	93	89	108	71	83	88	96	59	71	86	96	59	71	86	110	68	82
49	1123220	M	32	68	167	1	DJS	91	120	80	93	100	94	133	83	100	92	125	79	94	90	123	75	91	93	117	76	90	92	103	67	79
50	1123370	F	27	66	165	1	DJS	91	120	80	93	100	91	120	80	93	89	108	71	83	88	96	59	71	88	103	63	76	87	110	68	82

Serial no.	HR-15	SBP-15	DBP-15	MAP-15	HR-20	SBP-20	DBP-20	MAP-20	HR-25	SBP-25	DBP-25	MAP-25	HR-30	SBP-30	DBP-30	MAP-30	HR-45	SBP-45	DBP-45	MAP-45	HR-60	SBP-60	DBP-60	MAP-60	HR-75	SBP-75	DBP-75	MAP-75	HR-90	SBP-90	DBP-90	MAP-90	SpO2	SB-Onset (SECONDS)	Highest level	MB-Onset(SECONDS)	MB-Duration(mins)	SB-Duration(mins)	rescue analgesia(MINUTES)
1	80	90	56	67	83	93	55	68	80	99	62	74	80	99	62	74	81	101	73	82	84	110	70	83	80	113	72	86	83	110	71	84	100	150	T6	180	250	270	320
2	91	99	65	76	84	108	73	85	81	113	78	90	75	106	73	84	71	123	84	97	71	125	82	96	80	127	84	98	79	125	80	95	100	155	T6	195	290	315	325
3	74	102	60	74	76	110	60	77	75	108	58	75	74	115	67	83	76	119	62	81	79	104	61	75	78	109	69	82	78	108	68	81	100	150	T6	190	275	305	325
4	83	123	75	91	77	119	70	86	74	113	69	84	72	111	65	80	72	117	73	88	76	117	70	86	75	116	78	91	75	118	76	90	100	150	T6	190	275	310	325
5	79	106	73	84	81	110	72	85	85	110	74	86	83	110	67	81	83	113	68	83	81	106	61	76	81	115	67	83	80	110	78	89	100	130	T6	160	285	310	330
6	72	121	70	87	69	119	67	84	74	123	71	88	71	113	70	84	72	121	69	86	73	115	65	82	72	118	69	85	72	116	76	89	100	170	T6	250	180	220	250
7	82	128	72	91	78	124	72	89	79	127	72	90	77	118	69	85	76	119	69	86	78	121	68	86	75	115	66	82	74	116	79	91	100	120	T6	150	190	220	260
8	69	103	60	74	73	108	63	78	68	106	68	81	74	110	73	85	76	112	75	87	75	114	78	90	75	115	79	91	74	120	81	94	100	135	T6	190	240	290	315
9	60	113	81	92	57	113	78	90	55	102	69	80	54	96	65	75	52	96	65	75	53	106	68	81	54	105	69	81	55	106	67	80	100	160	T6	220	250	280	310
10	68	96	68	77	65	104	69	81	66	107	72	84	67	108	68	81	70	104	67	79	69	111	68	82	68	115	76	89	69	117	67	84	100	150	T6	200	240	270	300
11	73	113	72	86	72	109	71	84	74	103	64	77	71	104	62	76	73	103	64	77	74	108	65	79	74	110	70	83	72	122	81	95	100	140	T6	180	230	260	300
12	79	111	72	85	76	123	78	93	77	110	70	83	74	108	69	82	75	117	74	88	74	125	83	97	74	121	82	95	72	126	86	99	100	160	T6	190	230	260	310
13	86	107	67	80	85	109	68	82	82	115	71	86	79	113	74	87	78	112	71	85	76	115	78	90	74	116	79	91	76	121	83	96	100	150	T6	190	230	270	300
14	79	111	72	85	76	123	78	93	77	110	70	83	74	108	69	82	75	117	74	88	74	125	83	97	74	121	82	95	72	126	86	99	100	140	T6	190	260	290	320
15	87	112	71	85	85	107	67	80	81	109	68	82	82	115	71	86	78	113	74	87	77	107	68	81	76	115	72	86	76	118	81	93	100	135	T6	170	240	260	300
16	79	111	72	85	76	123	78	93	77	110	70	83	74	108	69	82	75	117	74	88	74	125	83	97	74	121	82	95	72	126	86	99	100	200	T6	230	250	290	320
17	74	101	62	75	74	98	60	73	71	108	73	85	75	106	71	83	74	117	72	87	72	126	83	97	73	124	82	96	73	124	83	97	100	180	T6	220	250	280	320
18	73	113	72	86	72	109	71	84	74	103	64	77	71	104	62	76	73	103	64	77	74	108	65	79	74	110	70	83	72	122	81	95	100	150	T6	180	240	290	310
19	88	117	74	88	87	124	80	95	86	123	84	97	86	122	82	95	86	122	81	95	85	125	82	96	83	126	84	98	82	123	83	96	100	140	T6	180	230	26	290
20	74	101	62	75	74	98	60	73	73	101	64	76	75	102	66	78	73	111	71	84	72	114	73	87	72	115	78	90	73	114	74	87	100	170	T6	200	230	260	300
21	82	103	68	80	81	108	73	85	81	106	71	83	78	104	73	83	78	109	74	86	75	116	75	89	75	124	79	94	74	126	81	96	100	190	T6	220	250	300	320
22	86	107	67	80	85	109	68	82	82	115	71	86	79	113	74	87	78	112	71	85	76	115	78	90	74	116	79	91	76	121	83	96	100	184	T6	210	230	280	310
23	74	101	62	75	74	98	60	73	71	108	73	85	75	106	71	83	74	117	72	87	72	126	83	97	73	124	82	96	73	124	83	97	100	170	T6	210	240	280	300
24	88	117	74	88	86	123	84	97	87	124	80	95	82	131	86	101	78	125	82	96	76	123	81	95	76	126	83	97	72	134	86	102	100	210	T6	240	230	250	290
25	85	103	63	76	86	107	67	80	86	109	68	82	85	115	71	86	83	113	74	87	80	112	71	85	80	115	79	91	80	116	78	91	100	195	T6	210	230	270	300
26	93	108	71	83	91	111	72	85	86	108	78	88	84	119	76	90	82	125	78	94	81	122	81	95	78	124	84	97	78	125	86	99	100	210	T6	240	230	270	310
27	73	113	72	86	72	109	71	84	74	103	64	77	71	104	62	76	73	103	64	77	74	108	65	79	74	110	70	83	72	122	81	95	100	200	T6	230	260	290	320
28	86	106	65	79	82	113	72	86	79	111	71	84	79	111	71	84	78	109	69	82	77	109	70	83	76	113	68	83	76	114	78	90	100	220	T6	240	250	280	310
29	58	109	71	84	53	108	65	79	55	103	67	79	55	103	67	79	58	113	72	86	58	104	62	76	57	108	64	79	58	109	69	82	100	220	T6	245	240	280	310
30	62	113	72	86	59	123	84	97	61	117	74	88	61	125	74	91	63	129	79	96	64	124	81	95	65	128	81	97	64	124	80	95	100	130	T6	160	190	210	250
31	76	124	79	94	75	122	79	93	73	125	79	94	71	123	79	94	71	122	79	93	71	120	82	95	70	114	76	89	70	115	76	89	100	140	T6	170	230	270	310
32	79	111	72	85	76	123	78	93	77	108	69	82	75	111	72	85	77	110	70	83	75	116	79	91	76	114	78	90	75	121	79	93	100	200	T6	220	230	260	310
33	88	117	74	88	86	123	84	97	87	124	80	95	82	131	86	101	78	125	82	96	76	122	81	95	75	110	70	83	76	111	72	85	100	140	T6	170	220	240	300
34	74	101	62	75	74	98	60	73	73	101	64	76	75	102	66	78	73	111	71	84	72	114	73	87	72	115	78	90	73	114	74	87	100	148	T6	160	220	220	280
35	86	107	67	80	85	109	68	82	82	115	71	86	79	113	74	87	78	112	71	85	76	115	78	90	74	116	79	91	76	121	83	96	100	162	T6	210	220	235	280
36	73	113	72	86	72	109	71	84	74	103	64	77	71	104	62	76	73	103	64	77	74	108	65	79	74	110	70	83	72	122	81	95	100	160	T6	240	230	260	300
37	78	108	63	78	76	101	60	74	75	104	61	75	76	113	64	80	75	115	68	84	74	114	64	81	74	121	79	93	72	125	81	96	100	145	T6	170	235	250	310
38	82	103	68	80	81	108	73	85	81	106	71	83	78	104	73	83	78	109	74	86	75	116	75	89	75	124	79	94	74	126	81	96	100	161	T6	210	250	280	310
39	82	97	60	72	81	110	71	84	78	118	56	77	76	108	78	88	75	111	72	85	76	118	78	91	73	115	78	90	72	119	78	92	100	230	T6	280	285	315	345
40	83	101	68	79	82	103	68	80	78	108	73	85	75	106	71	83	76	101	61	74	75	108	74	85	74	114	69	84	74	115	72	86	100	161	T6	210	250	280	310
41	83	103	67	79	82	111	72	85	84	108	78	88	82	103	72	82	83	119	76	90	82	116	75	89	81	113	74	87	80	119	78	92	100	128	T6	190	225	260	290
42	88	117	74	88	87	124	80	95	86	123	84	97	86	122	82	95	86	122	81	95	85	125	82	96	83	126	84	98	82	123	83	96	100	145	T6	170	200	220	240
43	88	117	74	88	86	123	84	97	87	124	80	95	82	131	86	101	78	125	82	96	76	123	81	95	76	126	83	97	72	134	86	102	100	140	T6	170	200	220	240
44	79	111	72	85	76	123	78	93	77	110	70	83	74	108	69	82	75	117	74	88	74	125	83	97	74	121	82	95	72	126	86	99	100	200	T6	230	190	210	240
45	74	101	62	75	74	98	60	73	71	108	73	85	75	106	71	83	74	117	72	87	72	126	83	97	73	124	82	96	73	124	83	97	100	148	T6	160	220	240	280
46	77	108	65	79	77	105	68	80	77	103	69	80	76	117	70	86	75	115	67	83	74	116	76	89	75	125	82	96	75	124	83	97	100	155	T6	210	275	300	320
47	80	97	60	72	78	102	72	82	77	110	71	84	78	113	72	86	74	118	56	77	75	121	76	91	76	118	79	92	76	123	83	96	100	210	T6	250	250	280	310
48	85	103	63	76	86	107	67	80	86	109	68	82	85	115	71	86	83	113	74	87	80	112	71	85	80	115	79	91	80	116	78	91	100	160	T6	210	220	250	290
49	93	108	71	83	91	111	72	85	86	108	78	88	84	119	76	90	82	125	78	94	81	122	81	95	78	124	84	97	78	125	86	99	100	160	T6	210	220	240	290
50	87	112	71	85	85	107	67	80	81	109	68	82	82	115	71	86	78	113	74	87	77	107	68	81	76	115	72	86	76	118	81	93	100	180	T6	220	230	255	300

TRAMADOL

Serial no.	I.P NO	Sex	Age (yrs)	weight (kgs)	Height(cms)	ASA	Proposed surgery	HR (bpm)-p	SBP-P	DBP-P	MAP-P	SPO2-P	HR-2	SBP-2	DBP-2	MAP-2	HR-4	SBP-4	DBP-4	MAP-4	HR-6	SBP-6	DBP-6	MAP-6	HR-8	SBP-8	DBP-8	MAP-8	HR-10	SBP-10	DBP-10	MAP-10	HR-15	SBP-15	DBP-15	MAP-15	HR-20	SBP-20	DBP-20	MAP-20	HR-25	SBP-25	DBP-25	MAP-25	HR-30	SBP-30	DBP-30	MAP-30	HR-45	SBP-45	DBP-45	MAP-45	HR-60	SBP-60	DBP-60	MAP-60	HR-75	SBP-75	DBP-75	MAP-75	HR-90	SBP-90	DBP-90	MAP-90	SpO2	SB-Onset (mins)	Highest level	MB-Onset(Mins)	MB-Duration(mins)	SB-Duration(mins)	rescue analgesia
1	1030877	F	45	61	155	1	TAH	78	120	80	93	100	96	110	70	83	91	103	65	78	91	101	62	75	84	93	59	70	81	96	61	73	75	99	65	76	71	108	73	85	77	113	78	90	78	106	73	84	75	123	84	97	79	125	82	96	81	122	81	95	83	126	84	98	100	230	T6	270	260	280	300
2	1031261	M	42	62	158	1	HERNIOPLASTY	68	120	80	93	100	66	125	66	86	60	115	63	80	58	115	64	81	57	110	64	79	58	110	63	79	55	110	63	79	55	105	60	75	52	105	60	75	54	104	63	77	50	106	63	77	53	114	65	81	54	115	68	84	54	117	70	86	100	150	T6	200	185	200	205
3	1031809	M	24	59	151	1	DEBRIDEMENT	74	120	80	93	100	84	110	70	83	82	100	63	75	80	96	61	73	81	102	68	79	72	108	71	83	74	106	73	84	75	110	72	85	71	110	74	86	73	110	71	84	72	114	74	87	71	116	78	91	70	117	79	92	70	121	83	96	100	210	T6	245	260	290	300
4	1031845	M	26	60	155	1	HAEMORRHOIDECTOMY	69	120	80	93	100	84	120	80	93	82	108	63	78	81	106	61	76	78	113	68	83	77	117	70	86	82	115	67	83	74	117	68	84	78	123	81	95	73	117	68	84	73	117	68	84	75	121	80	94	73	126	82	97	72	128	83	98	100	130	T6	180	275	295	305
5	1035813	M	49	70	161	2	I&D	89	140	90	107	100	86	140	90	107	85	120	86	97	86	120	85	97	84	120	83	95	80	120	85	97	76	120	84	96	74	124	84	97	75	126	86	99	73	120	85	97	75	120	86	97	78	123	84	97	76	121	83	96	77	121	74	90	100	240	T6	260	260	285	320
6	1035650	F	26	64	158	1	APPENDICECTOMY	84	120	80	93	100	84	108	68	81	83	102	69	80	83	104	69	81	82	103	71	82	79	102	72	82	76	100	72	81	75	102	70	81	72	103	70	81	73	109	71	84	75	112	70	84	79	120	74	89	81	120	80	93	79	122	79	93	100	150	T6	190	240	270	305
7	1037591	F	45	65	158	1	TAH	79	130	80	97	100	79	124	76	92	77	111	68	82	76	96	61	73	71	117	76	90	68	107	72	84	68	107	72	84	64	111	76	88	62	108	74	85	59	118	81	93	57	101	70	80	68	123	75	91	74	127	78	94	76	125	74	91	100	125	T6	160	250	270	300
8	1040476	M	33	67	168	1	HERNIOPLASTY	68	110	60	77	100	78	108	78	88	80	106	72	83	80	108	76	87	72	110	70	83	68	110	70	83	66	108	74	85	68	108	68	81	70	104	70	81	66	106	72	83	65	104	74	84	65	108	76	87	68	106	72	83	66	104	70	81	100	240	T6	300	270	295	320
9	1040326	M	43	60	156	1	CRIF	84	130	80	97	100	82	130	80	97	81	116	73	87	82	108	71	83	79	102	71	81	76	109	62	78	74	97	58	71	72	108	67	81	71	126	78	94	73	124	74	91	68	134	82	99	67	128	79	95	68	134	82	99	67	128	81	97	100	130	T6	190	265	285	310
10	1043474	M	38	68	156	1	STSG	88	130	90	103	100	85	130	90	103	85	108	67	81	84	103	60	74	81	113	68	83	78	114	65	81	80	111	66	81	83	121	72	88	81	123	75	91	81	128	74	92	78	123	75	91	76	127	83	98	81	123	79	94	80	125	81	96	100	170	T6	200	250	290	320
11	1054347	F	42	69	150	2	HAEMORRHOIDECTOMY	82	140	80	100	100	94	124	76	92	91	111	68	82	87	96	61	73	81	107	72	84	83	111	76	88	76	118	81	93	74	101	70	80	78	108	74	85	83	113	68	83	82	123	78	93	83	128	75	93	82	127	78	94	81	125	82	96	100	165	T6	195	270	290	310
12	1054974	M	43	63	157	2	DEBRIDEMENT	92	140	80	100	100	84	135	84	101	83	127	77	94	81	116	73	87	76	98	68	78	73	104	74	84	74	107	72	84	68	112	77	89	63	121	77	92	62	121	79	93	65	123	81	95	62	121	83	96	64	126	83	97	62	125	79	94	100	135	T6	190	190	215	240
13	1079042	F	35	66	158	1	TAH	98	130	80	97	100	96	148	98	115	92	145	94	111	85	145	93	110	82	142	91	108	77	89	48	62	72	106	64	78	68	97	56	70	73	102	56	71	84	92	44	60	86	91	44	60	89	103	62	76	88	106	71	83	87	109	76	87	100	120	T6	150	230	250	290
14	1079042	F	35	69	162	1	TAH	82	120	80	93	100	88	120	80	93	86	708	71	283	89	96	59	71	86	110	68	82	80	98	66	77	73	107	67	80	74	109	68	82	73	115	71	86	68	113	74	87	64	112	71	85	63	118	73	88	64	123	84	97	65	121	78	92	100	180	T6	200	170	190	235
15	1080666	M	31	68	161	1	IMPLANT REMOVAL	78	130	80	97	100	84	131	69	90	82	127	62	84	83	115	71	86	81	121	63	82	80	119	62	81	81	118	56	77	78	120	64	83	74	121	64	83	72	120	67	85	73	124	69	87	72	121	73	89	71	121	78	92	70	126	82	97	100	190	T6	210	190	210	250
16	1081943	F	48	56	159	2	TAH	82	130	80	97	100	85	139	93	108	86	137	92	107	84	99	63	75	85	94	77	83	84	99	61	74	82	103	69	80	81	128	86	100	76	99	70	80	74	131	99	110	72	135	88	104	75	131	95	107	73	128	89	102	72	124	85	98	100	170	T6	180	180	200	230
17	1092661	M	50	69	161	1	HERNIOPLASTY	78	120	80	93	100	78	130	80	97	76	115	68	84	77	110	63	79	78	113	69	84	76	110	65	80	74	103	56	72	71	108	68	81	70	109	69	82	68	106	65	79	67	113	72	86	68	111	71	84	69	126	81	96	67	123	76	92	100	195	T6	230	170	185	210
18	1092092	F	45	70	165	1	I&D	82	110	70	83	100	84	110	76	87	82	112	72	85	81	108	71	83	80	90	62	71	81	100	68	79	82	112	69	83	84	116	71	86	81	112	72	85	80	108	69	82	80	113	74	87	79	115	76	89	78	116	79	91	78	116	72	87	100	195	T6	230	180	200	240
19	1093251	M	23	65	164	1	IMPLANT REMOVAL	84	120	80	93	100	84	116	75	89	82	110	69	83	81	103	65	78	80	104	71	82	76	101	67	78	74	111	72	85	72	123	78	93	73	110	70	83	71	108	69	82	70	113	76	88	70	115	67	83	71	116	78	91	68	117	77	90	100	215	T6	235	180	195	230
20	1100172	M	46	70	173	2	DJS	87	130	90	103	100	85	125	98	107	84	126	72	90	85	102	67	79	83	93	59	70	81	89	53	65	82	103	68	80	81	114	70	85	80	113	68	83	81	103	68	80	79	121	70	87	78	123	68	86	77	125	86	99	76	121	83	96	100	210	T6	240	175	195	230
21	1101038	M	33	70	173	1	PCNL	94	130	80	97	100	95	126	72	90	94	121	70	87	93	119	67	84	94	113	70	84	89	119	67	84	87	123	75	91	58	121	70	87	81	119	70	86	83	113	69	84	81	111	65	80	80	114	61	79	78	113	72	86	76	110	71	84	100	220	T6	240	185	200	225
22	1102473	F	45	64	168	1	PCNL	89	120	80	93	100	88	125	98	107	87	126	72	90	85	123	75	91	84	126	78	94	81	119	67	84	78	123	71	88	72	113	70	84	71	113	78	90	70	106	73	84	72	121	70	87	74	117	72	87	72	108	73	85	73	117	74	88	100	195	T6	220	175	200	220
23	1099919	M	47	70	167	1	DJS	89	130	80	97	100	64	130	90	103	66	110	70	83	64	108	70	83	60	112	66	81	58	110	70	83	60	118	70	86	58	112	70	84	55	110	80	90	58	116	77	90	56	110	74	86	56	115	73	87	57	117	76	90	56	117	65	82	100	210	T6	240	180	200	230
24	1100234	M	40	70	169	1	DJS	86	120	80	93	100	76	130	70	90	74	110	60	77	74	112	66	81	70	116	70	85	68	118	70	86	64	120	68	85	68	114	70	85	64	112	70	84	62	116	68	84	62	120	70	87	64	118	72	87	63	119	76	90	64	123	79	94	100	215	T6	245	180	195	210
25	1103902	M	49	70	172	1	HERNIOPLASTY	72	120	80	93	100	84	139	87	104	82	123	65	84	83	119	60	80	82	112	65	81	81	116	67	83	78	113	66	82	77	119	65	83	75	114	63	80	73	119	63	82	72	117	68	84	71	117	68	84	71	116	65	82	72	121	70	87	100	210	T6	240	180	195	220
26	1101253	F	50	63	161	1	CONTRACTURE RELEASE	76	120	80	93	100	74	128	74	92	71	127	74	92	71	119	73	88	72	116	72	87	71	111	71	84	68	96	68	77	65	104	69	81	66	107	72	84	67	108	68	81	70	104	67	79	69	111	68	82	68	115	76	89	69	117	67	84	100	215	T6	240	175	190	230
27	1100612	F	30	64	161	1	DEBRIDEMENT	76	110	70	83	100	76	126	72	90	74	121	70	87	71	113	70	84	72	111	65	80	71	114	61	79	72	113	69	84	73	123	75	91	72	104	67	79	72	107	72	84	71	104	69	81	71	113	67	82	70	115	67	83	72	118	72	87	100	200	T6	240	175	190	230
28	1101443	F	30	62	163	1	IMPLANT REMOVAL	81	120	80	93	100	76	130	70	90	74	110	60	77	74	112	66	81	70	116	70	85	68	118	70	86	64	120	68	85	68	114	70	85	64	112	70	84	62	116	68	84	62	116	68	84	62	120	70	87	64	118	72	87	63	121	82	95	100	220	T6	250	180	200	215
29	1102011	M	43	69	173	1	ORIF	84	120	80	93	100	88	125	98	107	86	126	72	90	85	123	75	91	87	121	70	87	84	126	78	94	81	119	67	84	80	123	71	88	74	113	70	84	72	106	73	84	71	109	71	84	71	104	62	76	70	113	72	86	70	119	74	89	100	230	T6	250	190	210	230
30	1101735	F	35	65	166	1	DJS	76	110	70	83	100	78	126	74	91	77	116	71	86	76	107	68	81	77	96	68	77	79	106	64	78	75	107	65	79	72	110	70	83	71	116	80	92	70	123	82	96	71	116	84	95	70	118	79	92	70	121	76	91	70	119	76	90	100	210	T6	240	210	230	245
31	1101729	M	33	70	172	1	URSL	88	120	80	93	100	84	126	72	90	81	121	70	87	81	119	67	84	82	113	70	84	78	111	65	80	79	114	61	79	76	119	67	84	75	119	67	84	72	121	70	87	70	116	78	91	71	122	79	93	71	125	81	96	69	123	83	96	100	195	T6	240	170	190	220
32	1117104	M	18	64	167	1	CIRCUMCISION	77	120	80	93	100	78	123	73	90	77	108	63	78	76	107	63	78	72	111	74	86	72	109	71	84	70	106	62	77	70	98	57	71	68	110	57	75	69	112	66	81	68	113	66	82	67	115	70	85	67	120	78	92	65	121	74	90	100	245	T6	270	175	190	210
33	1117089	M	30	69	172	1	CYSTOLITHOTRIPSY	92	120	80	93	100	92	133	83	100	91	125	79	94	92	123	75	91	91	117	76	90	91	108	71	83	90	103	67	79	88	111	72	85	85	108	78	88	82	103	72	82	81	119	76	90	76	123	82	96	74	121	79	93	74	124	81	95	100	215	T6	245	180	200	220
34	1117018	M	25	68	174	1	DJS	82	120	80	93	100	84	120	82	95	83	114	75	88	81	111	75	87	81	113	81	92	76	103	67	79	74	102	69	80	72	103	67	79	70	113	78	90	71	118	66	83	68	108	70	83	69	113	76	88	72	116	75	89	74	119	73	88	100	200	T6	220	180	195	210
35	1117482	M	50	69	172	1	URS	89	120	80	93	100	85	121	77	92	84	111	73	86	85	117	70	86	81	111	69	83	79	112	67	82	77	93	47	62	75	108	58	75	74	115	67	83	71	111	67	82	72	110	68	82	73	113	69	84	67	115	74	88	71	119	76	90	100	175	T6	190	170	190	210
36	1117439	M	50	66	169	1	TURP	77	120	80	93	100	78	123	73	90	77	108	63	78	78	107	63	78	71	111	74	86	70	123	76	92	66	109	71	84	67	106	62	77	64	110	57	75	65	98	57	71	66	112	66	81	64	113	66	82	68	116	75	89	69	123	74	90	100	245	T6	270	175	190	210
37	1118016	F	48	66	164	1	DJS	88	120	80	93	100	94	120	81	94	91	108	71	83	90	96	59	71	89	110	68	82	86	103	63	76	81	107	67	80	82	104	65	78	81	115	71	86	78	112	71	85	76	109	68	82	75	105	67	80	76	113	65	81	74	114	72	86	100	195	T6	230	165	195	230
38	1117992	M	27	72	174	1	DJS	88	120	80	93	100	94	120	81	94	91	108	71	83	90	96	59	71	90	106	59	75	86	104	59	74	85	113	77	89	82	122	77	92	81	112	63	79	79	115	79	91	76	115	69	84	78	112	63	79	77	116	78	91	75	121	74	90	100	195	T6	230	160	190	235
39	1118149	F	35	62	161	1	URS	84	120	80	93	100	85	121	77	92	84	111	73	86	85	117	70	86	81	111	69	83	79	112	67	82	76	102	60	74	77	108	58	75	74	115	67	83	76	110	68	82	74	111	67	82	73	114	72	86	76	116	79	91	75	114	75	88	100	175	T6	190	170	190	210
40	1118523	F	45	68	171	1	DJS REMOVAL	89	130	80	97	100	84	134	80	98	83	108	70	83	81	102	64	77	78	98	66	77	74	100	72	81	73	102	78	86	74	102	76	85	75	100	60	73	73	104	70	81	72	115	73	87	73	113	68	83	72	116	79	91	74	115	76	89	100	170	T6	190	170	190	215
41	1118519	F	33	70	173	1	DJS	85	130	80	97	100	84	124	80	95	83	110	60	77	81	100	60	73	80	108	70	83	81	116	68	84	78	102	78	86	79	104	70	81	78	102	64	77	77	108	70	83	79	111	67	82	76	115	72	86	75	121	79	93	73	118	76	90	100	195	T6	220	190	210	230
42	1118492	F	30	69	170	1	CYSTOSCOPY	79	120	80	93	100	84	124	74	91	83	115	69	84	84	112	63	79	81	106	89	95	79	100	48	65	77	104	59	74	73	113	77	89	72	122	77	92	73	115	79	91	74	112	63	79	72	114	75	88	71	116	78	91	72	118	78	91	100	160	T6	180	210	230	250
43	1118006	F	35	68	168	1	PCNL	85	130	80	97	100	74	124	84	97	74	110	60	77	70	100	60	73	98	108	70	83	70	116	68	84	65	118	66	83	68	122	70	87	70	120	70	87	68	120	70	87	70	115	79	91	71	112	63	79	71	114	75	88	73	115	69	84	100	195	T6	220	190	210	225
44	1117196	M	30	70	173	1	DJS	87	120	80	93	100	86	120	70	87	80	108	70	83	80	104	67	79	76	110	72	85	74	108	68	81	66	112	76	88	66	110	68	82	68	106	60	75	66	120	70	87	64	116	68	84	63	115	72	86	65	118	76	90	66	113	75	88	100	230	T6	255	170	185	200
45	1119203	M	50	70	172	1	DJS	86	140	80	100	100	94	135	84	101	88	130	81	97	86	127	77	94	87	104	74	84	85	98	68	78	82	107	72	84	81	104	74	84	80	112	77	89	79	121	79	93	77	108	73	85	81	102	69	80	79	108	74	85	79	113	77	89	100	200	T6	230	185	210	240
46	1119109	F	35	67	168	1	DJS REMOVAL	82	130	80	97	100	71	120	70	87	70	110	60	77	71	110	60	77	68	120	70	87	66	120	66	84	66	110	66	68	64	112	66	81	66	114	66	82	64	112	68	83	64	118	70	86	64	115	76	89	63	110	74	86	64	116	78	91	100	230	T6	250	170	190	210
47	1118978	M	35	70	171	1	DJS	84	120	80	93	100	94	125	79	94	92	122	69	87	87	126	81	96	89	128	78	95	86	95	55	68	88	104	54	71	83	100	46	64	78	104	57	73	76	95	56	69	72	110	61	77	69	112	65	81	68	115	79	91	65	119	72	88	100	143	T6	190	170	185	210
48	1118496	F	30	66	168	1	PCNL	78	130	80	97	100	83	140	85	103	81	132	82	99	81	123	78	93	80	116	75	89	78	110	69	83	77	103	65	78	78	108	69	82	75	102	62	75	73	106	73	84	72	104	71	82	73	101	67	78	71	104	67	79	73	107	72	84	100	195	T6	220	170	190	200
49	1118477	F	50	70	173	2	PCNL	84	130	80	97	100	78	128	74	92	77	127	74	92	77	119	73	88	76	96	68	77	77	104	69	81	74	107	72	84	72	104	67	79	71	108	68	81	72	111	71	84	70	116	72	87	70	108	64	79	68	110	66	81	68	115	72	86	100	205	T6	240	190	215	240
50	1119500	M	30	69	175	1	pyelolithotomy	62	110	70	83	100	74	128	84	99	73	126	81	96	74	111	71	84	71	102	66	78	70	94	59	71	69	113	72	86	70	129	88	102	68	117	74	88	67	125	74	91	66	129	79	96	68	122	79	93	66	123	79	94	66	123	84	97	100	195	T6	220	170	190	210