"THE STUDY OF CLINICAL EFFECTS OF SEQUENTIAL COMBINED SPINAL EPIDURAL ANAESTHESIA AND SPINAL ANAESTHESIA IN PATIENTS UNDERGOING ORTHOPEDIC SURGERIES"

By

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

In partial fulfillment of the requirements for the degree of

DOCTOR OF MEDICINE

IN

ANAESTHESIOLOGY

Under the Guidance of

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ACKNOWLEDGEMENT

*First and foremost I thank my **"Almighty God"** for giving me his blessings and giving me the strength during my post graduation and providing me everything that I required in completing my dissertation.*

I would like to acknowledge all those who have supported me, not only to complete my dissertation, but helped me throughout my post graduation course.

*I wish to express my sincere thanks and owe a deep sense of gratitude to my mentor and guide **Dr RAVI M,** Professor & Head, Department of Anaesthesiology, for being very helpful throughout the study, whose valuable guidance has helped me patch this dissertation and make it a complete dissertation book. His suggestions and his instructions have served as the major contribution towards the completion of this study. His dedication, keen interest, professional knowledge and overwhelming attitude to help students had been solely and mainly responsible for completing my work.*

*I am extremely thankful and indebted to my co guide **Dr DINESH K**, Professor and Head, Department of Emergency Medicine, for encouraging me to complete this study. His moral support encouragement at every stage of my study and his timely suggestions and enthusiasm have enabled me to complete my study.*

*It gives me immense pleasure to extend my sincere thanks to Professors **Dr.SURESH KUMAR N, Dr. KIRAN N** and Associate Professors **Dr. SUJATHA M P, Dr. LAVANYA K, Dr. THREJA C K& Dr. VISHNUVARDHAN V** for their guidance, motivation and moral support during my entire post-graduate course which enabled me to complete my work.*

I am extremely thankful to Assistant Professors, ***Dr. SUMANTH T, Dr.SHIVAKUMAR K M, Dr. AHMEDI FATHIMA, Dr. NAGASESHU KUMARI VASANTHA, &Dr. SINDHU*** *for their constant help and guidance throughout the course. They were source of encouragement, support and for patient perusal to which I am deeply obliged.*

I express my gratefulness to my seniors and my well wishers ***Dr. MANJULA S, Dr. SRAVANTHI G N S & Dr. SANDEEP*** *providing me the inspiration, vital encouragement and advice to finish this dissertation and hope during my post graduation*

My heartfelt thanks to senior residents ***Dr. LAKSHMI K SWAMY, Dr.ABHINAYA,DR. GAJANAN BABU, Dr. HUCHAPPA,****and my super seniors,* ***Dr. NAGARAJ S K, Dr. SREENIDI R, Dr. ARPITHA MARY****for their practical tips, advice and constant encouragement.*

I express my sincere thanks to my colleagues and dearest friends ***Dr.SINCHANA B, Dr. ISHITA RAJ, Dr. PREETHI R, Dr. SHRI EASWARI, Dr.CHANDRAMOHAN K,& Dr. BALAJI J****for their co-operation and help in carrying out this study. I thank my* ***JUNIORS*** *for providing useful tips and clues in completing this vast work.*

I extend my sincere thanks to all the ***SURGEONS*** *who played an important role during the study.*

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

*Thanks to my beloved **PARENTS** my mother **Smt. RATHNA B P,** my father **Sri. NISARGA NARAYANA SWAMY L N &**my aunty **NAGARATHNA B P** The countless times they have helped and supported me throughout this journey Their encouragement when the times got rough are much appreciated and duly noted. Also, my gratitude goes to my brothers **RAMANANDA SAGAR L N,** my sister **HEMAVATHI L N and SHREYA L N** for always being there to help me in all possible ways and lending their hand in editing this dissertation work.*

*I also thank my friends **KUSUMA S, SHANTHI, SURESH & NAVEEN,** for their love and support during the stressful time. I am also thankful to **Dr. SURESH,** statistician for helping me with the statistical analysis.*

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

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ABBREVATIONS

HR	Heart rate
Bpm	Beats per minute
PR	Pulse rate
SBP	Systolic blood pressure
DSP	Diastolic blood pressure
MAP	Mean arterial blood pressure
NIBP	Non invasive blood pressure
ECG	Electrocardiogram
SPO2	Peripheral capillary oxygen saturation
CVS	Cardiovascular system
RS	Respiratory system
CNS	Central nervous system
VAS	Visual analogue scale
IV	Intravenous
NS	Normal saline
RL	Ringer lactate
ICU	Intensive care unit
SCSE	Sequential Combined Spinal Epidural technique
SA	Spinal Anaesthesia

SAB	Subarachnoid block
EP	Epidural space
PDPH	Post-dural-puncture headache
CSF	Cerebra spinal fluid
ICP	Increased intracranial pressure
ASRA	American Society of Regional Anaesthesia
PACU	Post anaesthesia care unit
PE	Pulmonary embolism
DVT	Deep vein thrombosis
EA	Epidural anaesthesia
HTN	Hypertension
CSEA	Combined Spinal Epidural anesthesia
PNS	Peripheral nervous system
C AMP	cyclic adenosine monophosphate
CO	Cardiac output
GA	General anaesthesia
COPD	Chronic obstructive pulmonary disease
EVE	Epidural volume extension
ASA	American Society of Anaesthesiologist
LA	Local anaesthesia
CBC	Complete blood count
HB	Haemoglobin
BT	Bleeding time
CT	Clotting time
WBC	White blood count

RFT	Renal function test
mcg	microgram
Hrs	Hours
mins	Minutes
ETCO2	End tidal carbon dioxide
mmhg	Millimetre of mercury
Kg	Kilogram
cm	Centimetre
SD	Standard deviation
ml	Millilitre
g	Gram
i.e	That is
gp	group

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ABSTRACT

"THE STUDY OF CLINICAL EFFECTS OF SEQUENTIAL COMBINED SPINAL EPIDURAL ANAESTHESIA AND SPINAL ANAESTHESIA IN PATIENTS UNDERGOING ORTHOPEDIC SURGERIES""

INTRODUCTION:

In Orthopaedics surgeries, the usage of neuraxial blockade has been increasing to provide excellent surgical conditions and prolonged post-operative analgesia.

The introduction of Sequential Combined Spinal Epidural technique (SCSE) provides benefits of all Spinal Anaesthesia(SA) and Epidural Anaesthesia.

The focus of this thesis was to analyze the clinical benefit of SCSE and SA in patients undergoing Orthopedics surgeries.

OBJECTIVES OF THE STUDY:

- To find the time needed in both groups to attain a desired level of sensory block.
- To compare the period of sensory block between the 2 groups.
- To study the intraoperative hemodynamics.

MATERIALS AND METHODS:

Study Design: Prospective Cohort study

Sample Size: Two groups of 68 subjects each

Duration of study: From January 2020 to May 2021

Sampling Method: Patients posted for lower limb surgeries 2-3 hrs under subarachnoid block(SAB).

RESULT:

We discovered that the time taken for desired level of sensory block less in the group with SA and the duration of sensory block was better in the group with spinal anaesthesia when compared to SCSE. But ,the intraoperative hemodynamics and analgesic effects was better with SCSE technique.

CONCLUSION:

we conclude that spinal anesthesia provided faster sensory blockade when compared to SCSE technique but in terms of intraoperative hemodynamic stability and requirement of postoperative analgesia, SCSE was better.

KEY WORDS: Epidural space(EP), orthopedic surgeries**,** sequential combined spinal epidural anaesthesia, spinal anaesthesia.

INTRODUCTION

Anaesthesia seems to be common procedure applied during orthopaedic surgery that might alter temperature regulation, infection, haemorrhage, oxygen consumption, and other issues, can impair the surgical outcome.[1] Hence, it is critical to develop new methods of anaesthetic to enhance the results and prognosis of orthopaedic surgery. The ease of postoperative recovery, including control of postoperative pain, nausea and vomiting, and urine retention, are important factors for selecting the kind of anaesthetic. These side effects could cause a delay in hospital release or an unanticipated readmission.[2]Neuraxial anesthesia subsumes spinal and epidural anesthesia, the two majority regional methods. Because of their simplicity and portability, epidural and SA are safe and straightforward procedures for lower limb surgery.[3]

A spinal block is a main procedure that uses a minimal amount of local anaesthetic to quickly generate an intense and reliable block.[4]The efficacy of spinal anaesthetic in orthopaedic surgery is contrast tot hat of general anaesthesia.[5] SA is fair and effective procedure that has a success rate-90%.[2]Furthermore, for some procedures such as lumbar spine surgery, spinal anaesthetic is thought to be less cost-effective.[2]Epidural anaesthesia allows for continuous but intermittent delivery of analgesic and anaesthetic agents intraoperatively and postoperatively, allowing for optimal treatment of intra and postoperative pain in orthopaedic surgery.[6]Furthermore, epidural anaesthesia is particularly useful in orthopaedic surgery since multiple doses of the anaesthetic agent can be administered intraoperatively while keeping the patient's pain threshold in mind.[7]

However, both techniques have drawbacks. Because of the intrusive nature of spinal anaesthesia, a variety of problems can develop with varying frequency. Hypotension is a

common side effect of spinal anaesthesia.[8]A decrease in body temperature is commonly encountered after neuraxial anaesthesia.[9]Post-dural-puncture headache (PDPH) is a bothersome complication of spinal anaesthesia that frequently manifests as nuchal rigidity in the fronto-occipital area and begins after transitioning from a supine to a sitting or standing position. CSF seeping through the dural opening might cause PDPH.Some individuals may have vertigo, nausea, and vomiting .[10]Another concern associated with CSF loss during spinal anaesthesia is hearing loss.[11]Following spinal anaesthesia, radicular symptoms such as discomfort, a burning sensation in the buttocks, dysaesthesia, and paraesthesia may be seen. These symptoms usually go away after two days. However, these clinical traits are concerning for catastrophic repercussions.[12]

So, to negate the disadvantages of spinal and epidural, CSEA being used for most orthopaedic surgeries. Soresi's introduction Of SCSE in 1937, which used a single needle-single interspace technique, demonstrated that by combining the two methods,several disadvantages of both are eliminated, and their benefits are increased to an almost unbelievable degree.[13]

CSEA has a substantial advantage - it enable for the administration of low-dose intrathecal local anaesthetics while knowing that the epidural catheter utilised to extend the block as needed.[14]Due to fast sympathetic blocking, spinal anaesthesia cause a quick onset of hypotension. Patients with a low cardiac reserve or low intravascular volume, this can be dangerous. The first low anaesthetic dose injected intrathecally can induce a speedy onset of block with a CSEA approach, but the epidural catheter inserted afterwards used to ensure an acceptable level of sensory blockade and to prolong the block for surgical anaesthesia or post-operative analgesia.Enhanced cephalad spread of

the spinal anaesthetic in the intrathecal region can result from epidural bolus injection and thecal sac compression during CSEA.[15]

Incomplete sensory blocking and low sacral spread may be linked with epidural anaesthesia.[16]It does, however, allow for progressive dosage and intermittent measurement of sensory blockage completeness and blood pressure changes. When compared to epidural anaesthesia alone, a CSEA with a low-dose spinal anaesthetic can produce comparable stable hemodynamics while reliably delivering dense, non-patchy sensory blocking with enhanced sacral distribution.[17]The phenomena of local anaesthetic flowbeyond the dural puncture site has been offered as one explanation for the better block after CSEA. If dura perforated with a 26-gauge spinal needle prior to an epidural bolus, Suzuki et al.[18] detected that the local anaesthetic spread more caudally than when the epidural was given alone. When compared to traditional spinal anaesthesia, both unilateral single shot SA and SCSEA give prolonged blocking with a lower occurrenceof hypotension. Sequential CSEA, has been proven to produce much more stable hemodynamics, and benefit of longer blocking and postoperative analgesia.[19]

AIMS & OBJECTIVES

- To find the time needed in both groups to attain a desired level of sensory block.
- To compare the period of sensory block in the 2 groups.
- To study the intraoperative hemodynamics.

PHARMACOLOGY

SPINAL ANESTHESIA

Spinal anaesthesia was the first regional anaesthetic treatment used, and August Bier performed first spinal anaesthesia procedure in 1898 in Germany.Appropriate placement and knowledge of neuraxial anatomy are needed for the delivery of spinal anaesthesia. The goal is to get anaesthesia into the intrathecal (subarachnoid) region at the right dose. [20]To avoid harm to the spinal cord and to prevent intrathecally-injected drugs from having any activity in the higher thoracic and cervical regions, spinal anaesthesia is exclusively used in the lumbar area, specifically the mid to low lumbar levels. The conus medullaris is located near lower border of the first or second lumbar vertebral body.[21] As the dural sac extends to S2/3, spinal needle is frequently inserted in the L3/4 or L4/5 interspace for spinal anaesthesia. When adopting higher interspaces, spinal cord injuries is more likely, especially in obese patients.[22]

ANATOMY AND PHYSIOLOGY

Because spinal medicines must be given inside its bounds, the arachnoid membrane is an important structure. Tight connections linksheets that connect epithelial cells to form the arachnoid membrane. Because of this anatomic structure, arachnoid membrane, rather than the dura, serves as the primary meningeal barrier (90 percent resistance) to materials entering and exiting the cerebrospinal fluid (CSF).The arachnoid membrane not only acts as a passive container for CSF, but it actively transports substances that try to pass through the meninges.[23] Active transport of compounds through the arachnoid membrane occurs in the form of neural root cuffs, where unidirectional flow of materials from the

CSF into the epidural space occurs, and contribute to the clearance of spinal anaesthetic medications. After spinal anaesthetic delivery, dilution with the CSF happens before to affecting effector regions in the CNS.[23]

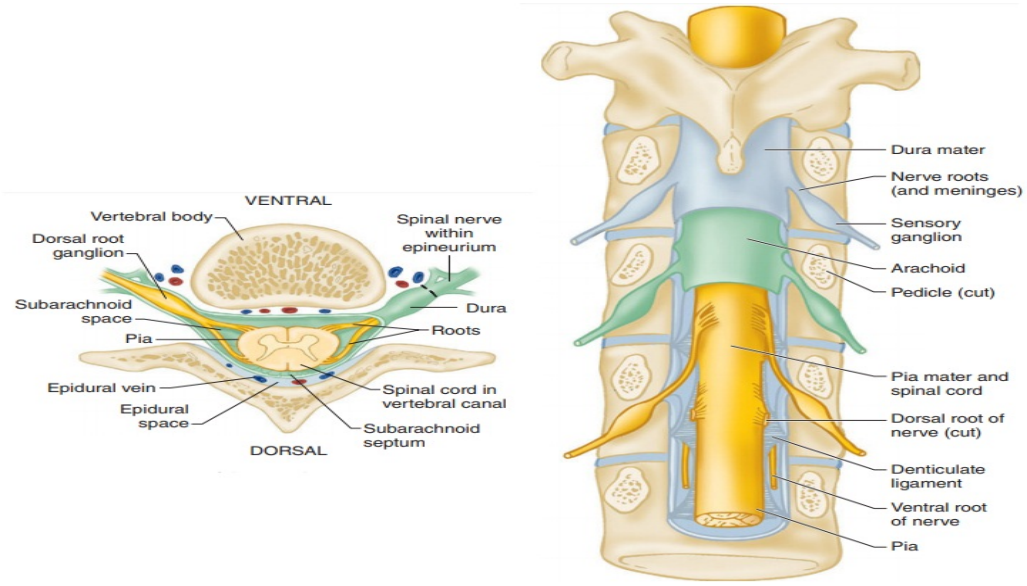


FIG 1: MENINGEAL LAYERS OF SPINAL CORD

Hypotension and bradycardia are the common significant adverse effects of spinal anaesthesia, and closed claims surveys of 40,000–550,000 spinal anaesthetics show a heart arrest rate of 0.04–10 per 10,000. [2425]Block height >= T5, age >= 40 years, baseline SBP 120 mmHg, and spinal puncture above L3 >= 4 are risk factors for hypotension in non-obstetrical populations. Baseline HR 60 beats/min, ASA I, beta blocker use, prolonged PR interval on ECG, and block height >= T5 are risk factors for the development of bradycardia in non-obstetrical populations. The provision of sedation to generate a sleep-like condition without spontaneous verbalization and the lack of early delivery of epinephrine were prevalent patterns of therapy in cases of cardiac arrest, according to an analysis of closed claims for cardiac arrest under spinal anaesthesia.[25]

INDICATIONS

For surgical procedures comprising the lower abdomen, pelvis, perineum, and lower extremities, spinal anaesthetic is commonly used; it is especially effective for treatments below the umbilicus.

Patients must be counselled about the surgery, and signed informed permission is required. Because the surgery is frequently performed on awake or minimally sedated patients, conversations about need of spinal anaesthesia and what to expect during neuraxial implantation, as well as risks, advantages, and alternative procedures, might help reduce anxiety. It is critical to explain patients that they will have little or no mobility in their lower extremities until the bloc is resolved.[26]For short procedures, spinal anaesthesia is the best option. General anaesthesia is frequently preferred for longer treatments or procedures that put the patient's breathing in jeopardy.

CONTRA INDICATIONS

Number of documented risks associated with neuraxial anaesthesia (spinal and epidural). Lack of patient consent, increased intracranial pressure (ICP), primarily owing to intracranial mass, and infection at the surgery site are all absolute contraindications (risk of meningitis).

The following are relative contraindications:[2728]

- Existing neurological conditions (particularly those that wax and wane, e.g., multiple sclerosis)

- Hypovolemia (severe dehydration) due to the danger of hypotension - hypovolemia, age greater than 40 to 50 years, emergency surgery, obesity, chronic alcohol intake, and chronic hypertension are risk factors for hypotension.
- Coagulopathy or thrombocytopenia
- Severe mitral and aortic stenosis, as well as left ventricular outflow restriction seen in hypertrophic obstructive cardiomyopathy.

Placement of a neuraxial block must be re-evaluated in the presence of coagulopathy. The American Society of Regional Anesthesia (ASRA) has released new neuraxial anaesthesia guidelines for patients who are using oral anticoagulants, antiplatelets, thrombolytic treatment, unfractionated, or low molecular weight heparin. Before beginning the treatment, make sure you have the most up-to-date guidelines.

Overall, because these are elective treatments, a risk/benefit appraisal is required before proceeding.

EFFICACY

SA, which is commonly employed in general orthopaedic and vascular surgery, provides a number of advantages that have been shown in the literature, including a faster start, decreased intraoperative blood loss, thrombotic events, pulmonary problems, and postoperative cognitive dysfunction. It also allows the patient to breathe spontaneously and move themselves during the process to avoid compression injuries. Epidural anaesthesia via catheter infusion and spinal anaesthesia via injection are two options for spinal anaesthesia.[29] Several trials comparing GA with SA for lumbar surgery have found

shorter operating times, less postoperative discomfort, less time in the postanesthesia care unit (PACU), less urine retention, less postoperative nausea, and better cost-effectiveness.[30]

COMPLICATIONS

To avoid common problems related with neuraxial anaesthesia, proper patient selection should be established. Many of the consequences are quite rare, it's still important to be aware of them. Although severe problems are thought to be rare, their occurrence is likely underestimated.Some common ones are[3132]

- Backache
- Postdural puncture headache. A non-cutting needle utilized for patients with high risk for PDPH, and smallest gauge needle recommendation for all patients.[33]
- Nausea, vomiting
- Hypotension
- Low-frequency hearing loss
- Total spinal anesthesia
- Neurological injury
- Spinal hematoma
- Arachnoiditis[34]
- Transient neurological syndrome (with lidocaine)

TYPES OF SPINAL NEEDLE

Commonly used needle quincke and size are 23,25,26G

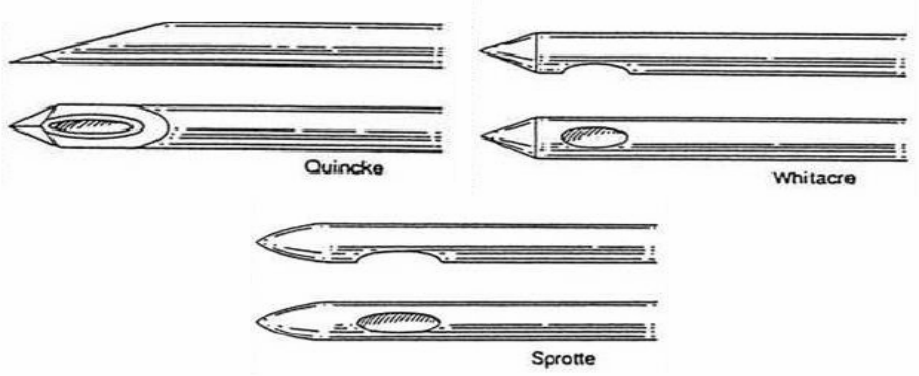


FIG 2: TYPES OF SPINAL NEEDLE

EPIDURAL ANESTHESIA

- Epidural anaesthesia is a perioperative pain control treatment that has a variety of uses in anesthesiology. It can used as a main anaesthetic, although it's most usually utilised as a pain reliever adjuvant. For long-term pain treatment, it might be a single shot or a continuous infusion. Aside from the potential for great analgesia, its use minimises the need for other anaesthetics and analgesics, lowering the risk of side effects. It has also been found to lower cortisol levels, speed up the healingof bowel function, decrease in risk of PE and DVT in the postoperative phase, and cut in-hospital stays in half.[353637]
- Although Dogliotti is credited with popularising segmental EA for surgery, the first caudal epidural anaesthesia was performed in 1901 by Cathelin of France. Pages elaborated on the lumbar approach to the epidural space in 1921. In 1945, the Tuohy subarachnoid needle was adapted, which sparked interest in neural blockade techniques and helped to improve epidural blockade for surgical anaesthetic.[38]

ANATOMY AND PHYSIOLOGY

- In adults, the spinal cord is typically 45 cm shorter than the spinal canal. In 50 percent of adults, it finishes at L1 and in roughly 40 percent, it ends at L2. It decreases to L2-L3 in newborns. The lumbar and sacral nerves converge to form the cauda equine. The arachnoid membrane surrounds the spinal cord, which is suspended in Cerebrospinal Fluid. In adults, the arachnoid (and subarachnoid space) extends to S2, S3 in children, and S4 in newborns. The dura mater is near to the arachnoid. The outer endosteal component of the dura is linked to the spine.It envelops the brain intracranially, the spine, and the epineural connective tissues of the spinal nerves through the foramina intervertebralia. Fatty and connective tissues, as well as arteries and lymph channels, make up the spinal epidural space. These capillaries may widen in pregnancy or ascites, increasing the risk of bleeding puncture. Distance between the EP and the skin varies based on factors such as age and weight. It can range from 4 centimetres in healthy persons to 8 centimetres or more in obese patients. The ligamentum flavum limits the epidural space on the dorsal side.The ligamentum interspinale (between the spinous processes), ligamentum supraspinale (on the surface of the spinous processes), subcutaneous tissue, and skin are the remaining layers on the surface.[39]
- If put in the midline, the epidural needle pierces - skin, subcutaneous tissue, supraspinous ligament, interspinous ligament, and ligamentum flavum and reach the space.[40]

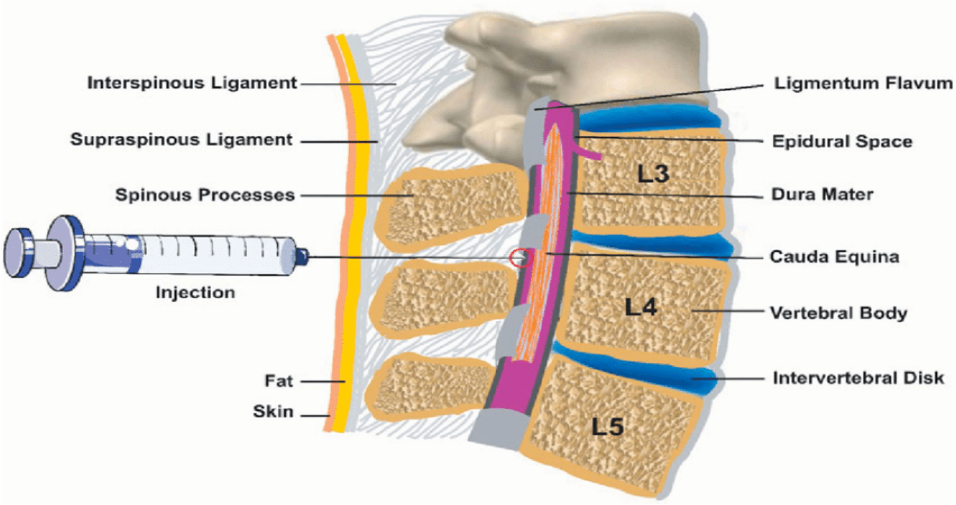


FIG 3: LAYERS FROM SKIN TO EPIDURAL SPACE[78]

INDICATIONS

- If muscle relaxation is not required, epidurals are suitable for surgical anaesthetic in thoracic surgery, large intra-abdominal surgery, or spine surgery. This approach can used to alleviate pain during or after surgery. Potential to reduce surgical risk and morbidity in particular patient populations, for examplethose with ischemic heart disease. It has also been found to reduce post-operative pulmonary problems and improve the restoration of function of the intestine after abdominal surgery.[3937]

CONTRAINDICATIONS

- The absolute contraindications include refusal of the patient, bacteremia, local infection at the site of puncture, hemorrhagic diathesis or therapeutic anticoagulation and increased intracranial pressure.
- The relative contraindications are significant aortic stenosis, right to left shunt and pulmonary HTN and anatomical deformities of the spine.[39]

COMPLICATIONS

- During epidural anaesthetic procedures, complications can occur due to needle placement or medication delivery.
- Infection, hematoma, drug injections intravascularly or subdurally, direct nerve injuries, air embolism, penetration into a disc space, urine retention, radiation exposure, and hypersensitivity reactions are all possible dangers.
- Lumbar epidural injection complications are extremely uncommon. Most, if not all, of them can be avoided by using precise needle placement, hygienic measures, and a detailed understanding of the pertinent anatomy and fluoroscopic imaging contrast patterns.[41]

EPIDURAL NEEDLES

- Variety of epidural needles are utilised. The most popular needles are Tuohy needles, which are 16 to 18 g in size and have a 15- to 30-degree curved, blunt "Huber" tip to lessen the chance of an accidental dural puncture. The needle shaft is marked at 1-cm intervals to indicate the depth of entry. The catheter is made of radiopaque plastic that is flexible, calibrated, and durable. It has a single end hole or many side orifices near the tip.[78]

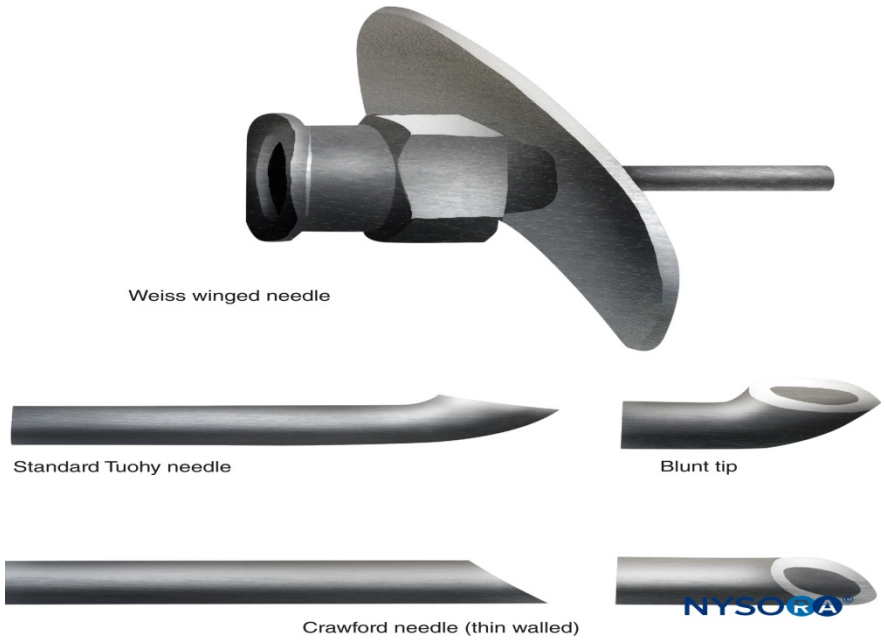


FIG 4: TYPES OF EPIDURAL NEEDLE

COMBINED SPINAL EPIDURAL ANESTHESIA

- CSEA approach combines the advantages of spinal block with the versatility of an indwelling epidural catheter for sustain analgesia further to postoperative period by injecting a low dose of subarachnoid local anaesthetic and then extending the block by injecting drug through the epidural catheter. Soresi used the single needle – single interspace technique to introduce it in 1937.[13] Later on, other adaptations and approaches were developed, each with its own set of advantages. Curelaru, performed the first combination spinal anaesthetic and catheter-based epidural anaesthesia in 1979.Major procedures below the umbilical level necessitate excellent operating circumstances as well as long-term, efficient analgesia. CSEA

has been advocated as a substitute for normal spinal anaesthesia.[42]In 1979, Dr. I. Curelaru published study using CSE anaesthesia, which involved 150 patients and was performed in two separate interspaces: The epidural catheter inserted first, followed by a subarachnoid injection of Dixidextracaine two levels below the epidural catheter insertion level. Dr. Curelaru found that CSE anaesthesia has various benefits, including high-quality conduction anaesthesia that may be extended as needed, sustained postoperative analgesia, analgesia that covers a sufficient number of dermatomes, low local anaesthetic toxicity, and no pulmonary problems.[43]

SCSE TECHNIQUE

- The notion of anti nociceptive interaction guides the selection of drugs in CSEA: Fentanyl or sufentanil are subarachnoid lipid soluble opioids that give fast relief (within 5-10 min) the onset of analgesia, improve surgical blockade quality, and enhance the effect of small subarachnoid local anaesthesia.[44] The block can sustained as needed with low-dose epidural medicines, subarachnoid injection yields quick action with minimal doses of local anaesthetics with opioids. Furthermore, the sequential CSE approach can be utilised to prolong the block's dermatomal dissemination with small amount of drug.[42] The addition of an epidural catheter improves the safety of CSE anaesthesia by allowing the lowest effective local anaesthetic dose to be used, preventing overshooting in terms of spinal anaesthesia duration.

RELEVANT ANATOMY AND PHYSIOLOGY

- Epidural space is a gap between the ligamentum flavum and the dura mater that includes fatty tissue and thin-walled blood vessels and covers the dural sac.Epidural space is tight in the thoracic area due to spinal cord protuberances in the upper thoracic region and protrusions in the lower thoracic region, but it is wider underneath the level where the spinal cord ends.[45]Because epidural fat, rather than connective tissue, controls the course of the epidural catheter within the epidural space, distribution of epidural fat is also important. According to periduroscopic studies, the epidural needle end makes touch with the dura when it enters the epidural space.[46] Puncture the elastic dura with the needle-through-needle CSE method, parameter further progress of the spinal needle further than epidural needle tip is necessary. Length between the edge of the epidural needle and the posterior wall of the dural sac are more than 10 mm in the midline; even so, the spinal needle used for CSE must be longer than standard spinal needles because the test injection included to recognise the epidural space may move the dura quite far back. [4748]As a result, CSE sets feature extra-long spinal needles, and it's critical to execute CSE caudad to the spinal cord's termination at L2.[45]

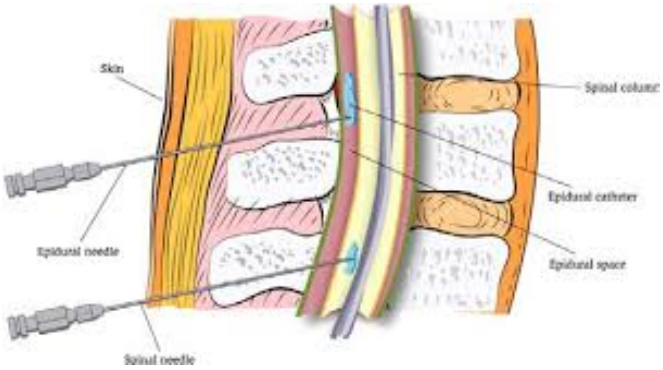


FIG 5: ANATOMY CSEA[79]

- When compared to dosages required with epidural anaesthetic alone, CSE anaesthesia generally causes extensive block than predicted, and epidural dosage needed to prolong the block is frequently lower. There are two plausible reasons for this observation. First, by reducing sub-atmospheric pressure prior injecting the local anaesthetic, Tuohy needle lower the amount of subarachnoid space in dural sac and prolong the degree of spinal anaesthesia.[49] Second,Transport of local anaesthetic molecules out from epidural to subarachnoid area through the dural hole is possible owing to dural sac distortion after injection of local anaesthetic in pidural region.[50]

TECHNIQUES

- Coates described the first "spinal needle through epidural needle" approach.[47] Needle is used as an introducer after identifying the EP and spinal needle is pushed via the epidural needle, puncturing dura. Epidural catheter is implanted after medications are administered into the subarachnoid area.After a dura perforation, the "hanging drop" method is indicated for locating the spinal space.[51]
- The two components of CSE (spinal and epidural injection) are administered using separate needles in the same or different intervertebral spaces in the separate needle technique. The epidural needle is put first in this approach to function as an introducer for spinal needle, which is positioned at the same interspace. Following the advancement of the epidural catheter, the spinal needle is advanced to penetrate the dura and allow the subarachnoid injection.[52]

INDICATIONS AND CONTRAINDICATIONS

- Although CSE anaesthesia was first explained for urologic surgery, its applications have grown in recent years. In obstetrics (for labour analgesia and caesarean sections), orthopaedic surgery, trauma, abdominal, vascular, and gynecologic surgery, CSE is currently routinely employed. [43]Due to the synergistic interaction between subarachnoid and epidural medicines, CSE anaesthesia allows for the use of relatively low subarachnoid medication dosages. The CSE anaesthesia is ideal for outpatient surgery since the anaesthetic wears off quickly, allowing patients to ambulate and be discharged home sooner.[48]CSE approach has grown in popularity over the last two decades, it is a more sophisticated procedure that necessitates a thorough understanding of epidural and spinal physiology and pharmacology. Contraindications to CSEA are the same as for any neuraxial block.

EFFICACY

- CSEA is a treatment that combines two approaches to improve efficacy and cost effectiveness. The advantage of this approach is its ability to combine speed, density, and dependability of a SAB with flexibility of continuous epidural block to titrate desired sensory level, vary block severity, manage anaesthetic duration, and give postoperative analgesia.Selective blockade has been achievable thanks to lower drug dosages in CSE anaesthesia, andLow-dose CSE plus local anaesthetic as well as opioid, or low-dose epidural block alone, provide good analgesia with little motor and proprioceptive block. Several patients have been able to walk and bear weight regularly during childbirth and recovery thanks to this specific

blockage. CSE anaesthesia useful for ambulatory surgical operations of undetermined duration. [48]

- A RCT comparing CSE vs. spinal vs. epidural anaesthesia in 75 patients for major orthopaedic surgery found that both spinal and CSE gave effective and reliable block with muscle relaxation and favourable operative conditions quickly, and both methods were superior to epidural anaesthesia. [53]In institutions where expensive delivery devices, such as infusion pumps for continuous epidural analgesia, are not accessible, postoperative discomfort after abdominal surgery (particularly surgery involving more than one organ) is a challenge. [54]

COMPLICATIONS

- Failure of the spinal and/or epidural components, spinal migration of epidural catheter, the risk of subdural block, and the possibility of subarachnoid delivery of drugs intended for epidural use are all potential issues associated with the clinical use of CSE.
- Failure of the test dose, post-dural puncture headache, and very uncommon catastrophic sequelae, such as CNS damage or infection, are all possible issues.[44]
- The probability that the epidural catheter could migrate into subarachnoid space through hole made by spinal needle on the dura is debatable. According to published statistics, rotating epidural needle is unnecessary since dural puncture with 26-gauge spinal needle poses no risk of epidural dislodgement into the subarachnoid space.[55]

- Paresthesias occur in 2.6 percent to 10% of CSE instances when spinal needle is advanced, prevalence has been reported high i.e 29% when lengthy spinal needles are utilised. To limit the danger of meningitis, meticulous aseptic technique is required during CSE, and great care must be taken to maintain sterility during preparation of drug solutions.[42] Some of the uncommon consequences of CSEA include epidural abscess, paraplegia owing to adhesive arachnoiditis with severe syringomyelia , and subdural hematoma.[44]

COMPARISON OF SCSEA AND SA IN PATIENTS UNDERGOING ORTHOPEDIC SURGERIES

- Good surgical analgesia in the spinal group was 92 percent, relative to 88 percent in the CSEA unit.[58]Onset of sensory block was rapid in CSEA and spinal anesthesia groups but duration was prolonged in CSEA group by the epidural drug. The highest level of sensory block was T10 in CSEA group, whereas the highest level of sensory block in spinal group was T6.[14]2.5 ml (12.5 mg) of 0.5 percent hyperbaric bupivacaine with 25 g fentanyl induced analgesia for an average of 180 minutes in the spinal anaesthesia group. To extend the duration of surgical analgesia, all patients in the CSEA group got a first top up dosage 11/2–2 hours after the start of surgery, depending on the number of dermatomal regressions.[14]
- No patients in the CSEA group developed hypotension in the beginning, but after supplementation of epidural drug, 13.4% developed hypotension requiring a single dose of vasopressor, whereas 56.6 % of patients in the spinal group developed hypotension and required a single dose of vasopressor in study to compare effects

of CSEA versus spinal anesthesia in patients posted for major orthopedic surgery. In the CSEA group, 13.4% of patients had bradycardia; none of the patients had developed hypotension at the outset, but 13.4% of patients developed hypotension after supplementing the epidural drug, whereas none of the patients in the spinal group had bradycardia.[59]

- Only 6.67 % of patients in the CSEA group suffered hypotension and required a single dose of vasopressor (ephedrine 6 mg) to maintain systolic arterial blood pressure of 100 mmHg, whereas 66.67 % of patients in the spinal group suffered hypotension and required a single dose of vasopressor (ephedrine 6 mg) to maintain systolic arterial blood pressure of 100 mmHg in a study comparing the clinical effects of CSEA versus spinal anesthesia in high-risk geriatric patients undergoing surgeries around the hip joint.[14]

PHARMACOLOGY OF FENTANYL

It is a synthetic, lipophilic phenylpiperidine opioid agonist N-(1-(2-phenethyl)-4-piperidinyl-N-phenyl-propanamide

Molecular formula: $C_{22}H_{28}N_2O$;

Molecular weight: 336.471 g/mol

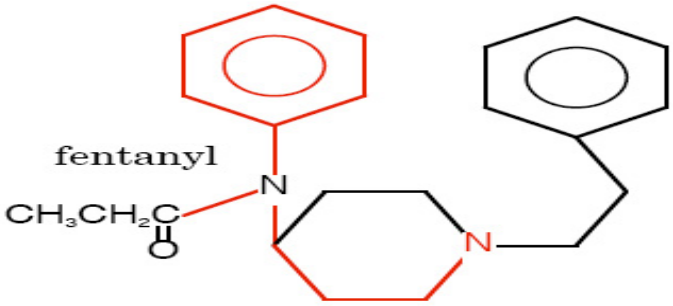


FIGURE 6: CHEMICAL STRUCTURE OF FENTANYL

MECHANISM OF ACTION

Fentanyl's pharmacological effects are mediated via the mu opioid receptor, which has a lower affinity for delta and kappa receptors. Mu receptors are classified into two types: mu1 and mu2. Pain relief is caused by the Mu1 receptor. Mu2 receptors are involved in bradycardia, respiratory depression, and physical dependency. These receptors are present in CNS and PNS.

G protein coupled receptors are involved in the action of opioids. When opioid agonists activate this receptor, voltage-dependent calcium channels are blocked, lowering cAMP levels. This causes painkiller by blocking the release of neurotransmitters such as glutamate and substance P from nociceptive fibres.[73]

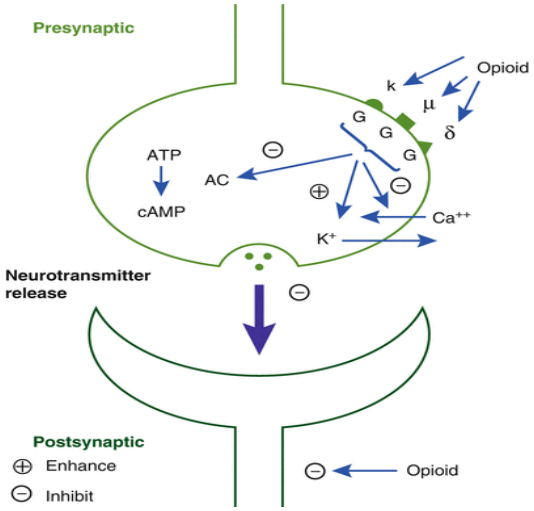


FIGURE 7: MECHANISM OF ACTION OF OPIOD AGONISTS[73]

PHARMACOKINETICS - FENTANYL

Fentanyl is rapidly transported from plasma into highly vascularised compartments after an intravenous bolus. It is transferred into muscle and fat tissues from the systemic circulation. [64]

- Elimination half-life 219 - 853 minutes.
- Distribution volume of 3.5-8 litres per kilogramme.
- High clearance (30-72L/hr).[64]

DISTRIBUTION

Fentanyl interacts to plasma proteins because it is very lipophilic. The dose adjusted serum fentanyl concentrations were considerably lower in patients with serum albumin less than 3.5g/dl.[64] At a pH of 7.4, the drug's unionised fraction is 8.5 percent.

METABOLISM

Dealkylation of fentanyl by CYP3A4 in the liver results in inactive metabolites such as norfentanyl. When compared to mild liver failure, severe liver failure resulted in a seven-fold reduction in fentanyl clearance.[64] Of the metabolites discharged unchanged in urine, 10% are found in faeces, and 9% are found in urine.[74]

SYSTEMIC EFFECTS OF FENTANYL

ANALGESIA

The mu1 receptors, which are essential for analgesia, are primarily affected by fentanyl. A plasma fentanyl content of 1.3 ng/ml causes pain to be reduced by 50%.[65]

CARDIOVASCULAR SYSTEM

Myocardial oxygen demand will be reduced due to peripheral vasodilatation and thereby causing a drop in preload and afterload. CO,MAP and HR are also decreased slightly. Change in hemodynamics is minimal[66].

RESPIRATORY SYSTEM

Upper airway reflexes are abolished in a dose dependent manner. Only with subsequent doses laryngospasm and apnoea occurs.[67]

Fentanyl give rise to respiratory depression. It is shown by elevated $ETCO_2$ levels, dose response curve for carbon dioxide will be declined. Once the end tidal carbon dioxide reaches 50 mmHg, then minute ventilation will be increased.[75] When fentanyl is accompanied with other sedatives like midazolam, respiratory depression will be more enhanced. Therefore, such patients are monitored and also supplemented with oxygen.[68]

ENDOCRINE SYSTEM

When fentanyl is administered at dose of 10mcg/kg, there will be fall in plasma levels of epinephrine, growth hormone, cortisol, glucose and free fatty acids. On contrary, when it was given in a dose less than 5 mcg/kg, there is no effect on hormones.[69]

INDICATIONS FOR FENTANYL

- Analgesic: dose- 1-2 mcg/kg IV.
- Adjuvant to GA: dose-2-10 mcg/kg
- Individual anaesthetic agent: at 50-150 mcg/kg.
- As an adjuvant in spinal anaesthesia. A dose of 25 mcg of fentanyl is added to bupivacaine.
- As a adjuvant in labour analgesia in epidural anaesthesia in a dose of 2 mcg/ml.[5]

SIDE EFFECTS

- Respiratory depression
- Myoclonic movements
- Apnoea
- Myoclonic movements
- Muscle rigidity
- Nausea and vomiting
- Bradycardia

CONTRAINDICATIONS FOR FENTANYL:

- Patient with history of bronchial asthma and COPD or allergic history, Patients on MAO inhibitors and head injury[72]

PHARMACOLOGY OF BUPIVACAINE

BUPIVACAINE :[75,76,77]

Bupivacaine is an amide local anaesthetic first used in 1963.[76]

CHEMICAL STRUCTURE :

Bupivacaine HCL (1-butyl-2', 6' pipecoloxylidide hydrochloride) is along actingamide local anaesthetic

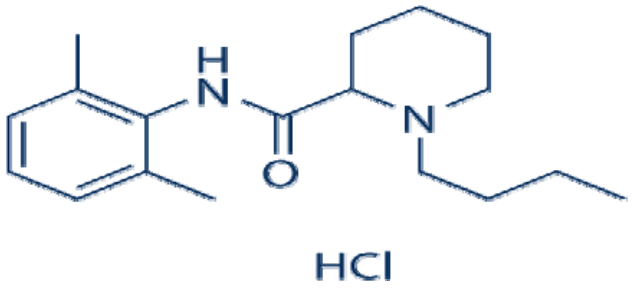


FIGURE 8: CHEMICAL STRUCTURE OF BUPIVACAINE

MECHANISM OF ACTION:

Binding to an intracellular portion of sodium channels that blocks sodium influx into nerve cells which prevents depolarization. It inhibits NMDA receptor transmission in the dorsal horn of the spinal cord.

Dose of Bupivacaine: 2-3mg/kg

Onset of action: 5 to 7 minutes

Duration of action: 4 to 6 hours

Pharmacokinetics:

- Molecular weight (base) – 288 daltons.
- Pka - 8.1.
- Bound in plasma - 95%.
- Volume of distribution - 0.9 - 0.4 litres/kg.
- Clearance - 7.1-2.8 ml/min/kg.
- Lipid solubility - 2.4-1.2 hours.
- Peak time - 0.17-0.5 hour.
- Toxic plasma concentration - >1.5microgram /ml.
- Plasma protein binding site - alpha1 acid glycoprotein.
- Enzymatic degradation – liver
- Excretion - kidney

CLINICAL USES:

- Central neuraxial blockade (intrathecal, epidural, caudal)
- For peripheral nerve blocks and infiltration analgesia.

TOXICITY:

Toxicity because of accidental intravascular injection or systemic absorption depend on the dose administered, presence of adrenaline (adrenaline in solution decreases the systemic absorption by one third), property of the drug and vascularity of the tissue.[76]

VARIOUS TOXIC FEATURES ARE:

 Mild systemic symptoms - circumoral numbness, auditory changes like tinnitus, agitation.

 Central nervous system toxic effects - CNS depression, seizures, coma and respiratory arrest.

 Cardiovascular system toxic features - tachycardia, bradycardia, hypotension or hypertension, ventricular arrhythmias and cardiac arrest.

Treatment for toxic doses of Bupivacaine:

- Airway management.
- Seizure suppression – Thiopentone/ Benzodiazepines /neuromuscular blockingAgents.
- Cardiac arrest – ACLS
- Use small initial doses of epinephrine (10–100 mg boluses), Vasopressin is not recommended.
- Avoid calcium channel blockers, beta adrenergic blockers, and Local anaesthetics (lidocaine, procaine).
- Ventricular arrhythmias – Amiodarone.
- Lipid emulsion therapy - at first signs of LAST, 1.5 ml/ kg bolus of 20% lipid emulsion. Infusion at 0.25 ml/kg/min for 10 min after return of circulatory stability, second bolus increasing infusion to 0.50 ml/ kg if circulatory stability is not attained. Upper limit of lipid emulsion for the first 30min is 10 ml /kg. Cardiopulmonary bypass .

REVIEW OF LITERATURE

Begum et al., (2020)[60] conducted a prospective comparative study to compare peri-operative pulmonary status of CSEA and spinal anaesthesia (SA) in geriatric patients underwent lower extremity surgeries. Mean duration of anaesthesia, mean time to achieve target level of sensory block and mean time to achieve complete motor block were significantly higher in CSEA group ($p< 0.001$). Mean RR, SpO2, EtCO2,and PEFR of both groups were not significantly different ($p > 0.05$). Peri-operative side effects of anaesthesia and post-operative VAS were significantly less in CSEA group patients ($p < 0.05$). The study concluded that CSEA is effective; produces stable peri-operative pulmonary status with prolonging analgesia and fewer side effects as compared to spinal anaesthesia in geriatric patients.

Karim et al., (2020)[61] designed a randomized, double-blind study to compare between SCSEA versus epidural volume extension in lower limb surgery as regards hemodynamics, sensory, and motor blocks.Hemodynamic changes were insignificant. Anesthesia readiness time was significantly faster in EVE group. Motor block and sensory block were better in SCSE. Postoperative bupivacaine consumption was statistically insignificant between the two groups.All SCSE and EVE are utilised in high-risk elderly patients following orthopaedic surgery to retain hemodynamics with low-dose subarachnoid block.

Mutahar et al. (2019)[56]evaluatedIn a prospective, randomised, double-blind research, changes in hemodynamic parameters while utilising SCSE block and SA for lower limb procedures. Sixty people with an ASA grade I or II physical condition being split into two groups: spinal and SCSE. There was a notable increase in pulse rate in the spinal

group from 2 to 20 minutes, which was accompanied with a reduction in BP (p value 0.05). Both groups were equivalent after 60 minutes. In comparison to spinal anaesthesia, CSEA preserves hemodynamic balance with few consequences, according to the study.

Magar et al., (2017)[19] studied the safety and efficacy of unilateral spinal anaesthesia vs sequential mixed spinal epidural anaesthesia in orthopaedic surgery. The time to reach anaesthesia ready was shorter in unilateral SA ($p < 0.001$). In sequential CSEA, incidence of hypotension (p-value 0.0059) and the mean ephedrine dose were significantly lower.Sequential CSEA gives much more consistent haemodynamics with the ability to prolong block, according to the study. In high-risk patients, sequential CSEA favoured to unilateral SA, especially for major lower-limb orthopaedic procedures.

Patel et al., (2017)[59] in a study to compare clinical effects of combined spinal epidural anaesthesia versus spinal anaesthesia in 60 patients undergoing major orthopaedic surgery used 1ml(0.5%) of hyperbaric Bupivacaine plus 25 µgm fentanyl for spinal block and 2ml of 0.5% plain Bupivacaine for every unblocked segment through epidural catheter(CSEA). The mean onset of sensory block in spinal group was 7.76 ± 2.2 minutes and 6.9±1.7 minutes in the CSEA group. 13.4% of patients in spinal group had bradycardia while none of patients in CSEA group had bradycardia and it was stastically significant ($p<0.05$). The study concluded that sequential CSEA results in high success rate, obviates a separate needle placement and minimizes the patient's discomfort.

Sundar et al., (2017)[62] conducted a study to compare CSE & Epidural block in lower limb and abdominal surgeries and found that the mean onset time and duration of analgesia in CSEA group is very significantly shorter than in epidural group. Majority of patients received CSE had good quality of analgesia when compared to epidural route

alone. This relationship is very significant in the CSEA group with p value. There were no hemodynamic differences in both group.

Tummala et al., (2015)[14]Research to evaluate clinical benefit of CSEA vs SA by randomly assigning 60 patients >65 years old with ASA II and IV to two equal groups, one receiving CSEA and other SA. Compared to the spinal anaesthetic group B, both groups had rapid onset, great analgesia, and great quality motor block, but the CSEA group had a lower rate of hypotension (P 0.01) and provided extending analgesia. For high-risk senior patients undergoing hip joint operations, the study indicated that CSEA is safe.

Talikota et al., (2015)[58] Randomised, single-blind controlled trial, researchers examined effectiveness and risk of SCSEA and spinal block for lower abdominal operations. In comparison to SA, the CSEA provides hemodynamic stability. When relative to SA, the benefit of prolonging and extension of the block. The administration of analgesia postsurgical. Both groups had nearly identical analgesic quality and start of effect. Muscle relaxation, on the other hand, is much less with the CSE approach.

Yun et al., (2014)[57] investigated the anesthetic effect of reduced doses of spinal bupivacaine with epidural top ups in comparison with those of spinal and to determine the adequate doses of drugs used during lower extremity surgeries.The levels of peak sensory block were similar with different doses of spinal bupivacaine (P > 0.05). They noted that during combined spinal-epidural anesthesia, 7.5 mg of spinal bupivacaine and epidural 1.5% lidocaine 10 ml produced faster motor recovery than did 10 mg of spinal bupivacaine.

MATERIALS AND METHODS

Source of data:

This study was conducted on patients admitted for elective lower limb Orthopedic surgeries done in R. L. Jalappa Hospital and Research centre, Tamaka, Kolar. Study Design: Prospective Cohort study Sample Size: Two groups of 68 subjects each Duration of study: Jan-2020 to May-2021

Method of collection of data:

Inclusion criteria:

- Age: 18-65 years
- Gender: Female and Male
- American Society of Anaesthesiologist(ASA) grade 1 and 2
- Patients posted for lower limb orthopedic surgeries 2-3 hrs under subarachnoid block .

Exclusion criteria:

- ASA grade 3 and 4
- Bleeding disorder or patient on anticoagulant therapy.
- Local infection at the site of block
- Neurological deficits

SAMPLING PROCEDURE: After receiving ethical authorization from the institutional ethical council, a prospective randomised research with 134 patients was planned.

Pre-operatively, each patient was seen and the process discussed, and written, informed consent acquired. For the intended surgery, all of the normal investigations required for pre-operative evaluation were completed.

Patients premedicated - alprazolam 0.5 mg at 10 PMprior the day of the procedure and at 6 AM on the day. The patients were divided into 2 groups Group A and Group B based on randomization table.

Group A –Patients received SCSEA. Epidural catheter(20G) was secured at L2-L3 space using a 18G Tuohy needle and the catheter fixed after giving a test dose of 3ml of 2% lignocaine with adrenaline. Following this SAB was performed at L3-L4 space using 25G quinke babcocks needle and 1.5 ml (7.5 mg) of 0.5% hyperbaric bupivacaine with 25mcg fentanyl will be given. The final level of sensory level achieved was noted and if the level achieved is below T8 epidural top up will be given with 2ml per segment of 0.5% bupivacaine to achieve a sensory level of T8.

Group B- Patients received SAB. In this group SAB was given in sitting position at L3-L4 space using 25G quinke Babcock needle and 3ml of 0.5% hyperbaric bupivacaine with 25 mcg of fentanyl was given. Patient then positioned supine and level of sensory block was monitored once the level reaches T8 table was tilted to prevent further ascent to main a sensory level of T8.

Patient shifted in OT and was monitored with ECG, RR, NIBP, Pulse oximetry and basal vitals were noted. Intravenous line was secured with 18G IV cannula and preloaded 500 ml of RL. The anaesthetic procedure was performed according to the group to which to patient belongs to based on the randomization table.

Following the procedure patients was put into supine position and was monitored. The following data were recorded

1. Time taken to achieve a sensory level of T8 .

2. Total dose of epidural bupivacaine required to establish desired level of block .

3. Time for 2 segment regression of sensory block

4. Intraoperative haemodynamic parameters –Heart Rate and MAP.

5. Supplementation with general anaesthesia.

6. Complications

Haemodynamic variables such as blood pressure(Systolic, diastolic and mean blood pressure) and heart rate were recorded before administering anaesthesia and throughout the intraoperative period every 5 mins for the initial half an hour and every 10 mins later on till the end of surgery Ifsystolic blood pressure is less than 90 mm Hg , 3-6 mg of mephenteramine was administered intravenously. Bradycardia, which was defined as heart rate < 60 beats / min will be treated with 0.6 mg atropine intravenously.

After the surgery, all the patients were transferred to PACU. In the post operative period, patients in Group A received inj bupivacaine 0.125% 10ml with 20mcg fentanyl through epidural catheter and group B received IV tramadol 50 mg on demand for pain relief. The patient was monitored for pain using VAS score in the post operative period .Total requirement of analgesics postoperative period for 24 hrs noted .

STATISTICAL ANALYSIS

Study design: Randomised Control Study

Statistical analysis:

Data was entered in Ms Excel, MS word and analyzed using SPSS 22 version software. Qualitative data was presented in the form of proportions and bar charts was used to represent graphically. Quantitative data was presented as mean, standard deviation. The one-way analysis of variance (ANOVA) was employed to determine whether there were any statistically significant differences between the means of three or more independent (unrelated) groups. P value<0.05 was been considered as statistically significant.

Sample size:

Sample size has been selected based on the differences in major outcome variables like heart rate, systolic blood pressure, diastolic blood pressure to assess hemodynamic response in patients.

$$n = \frac{2Sp^2[Z_{1-\alpha/2} + Z_{1-\beta}]^2}{\mu^2 d}$$

$$S^2_p = \frac{S_1^2 + S_2^2}{2}$$

- S_1^2 = standard deviation in first group
- S_2^2 = standard deviation in second group

μ^2 = mean difference between sample

- α = significance level
- $1-\beta$ = power

Sample size : 67 each group[59]

RESULTS

TABLE 1: GENDER- FREQUENCY DISTRIBUTION OF PATIENTS IN TWO GROUPS STUDIED

Gender	Group A	Group B	Total
Female	13(19.4%)	18(26.9%)	31(23.1%)
Male	54(80.6%)	49(73.1%)	103(76.9%)
Total	**67(100%)**	**67(100%)**	**134(100%)**

P=0.306, Not Significant, Chi-Square Test

In this study 23% female and 80% male and No significant difference in gender between two group, chi square test used.

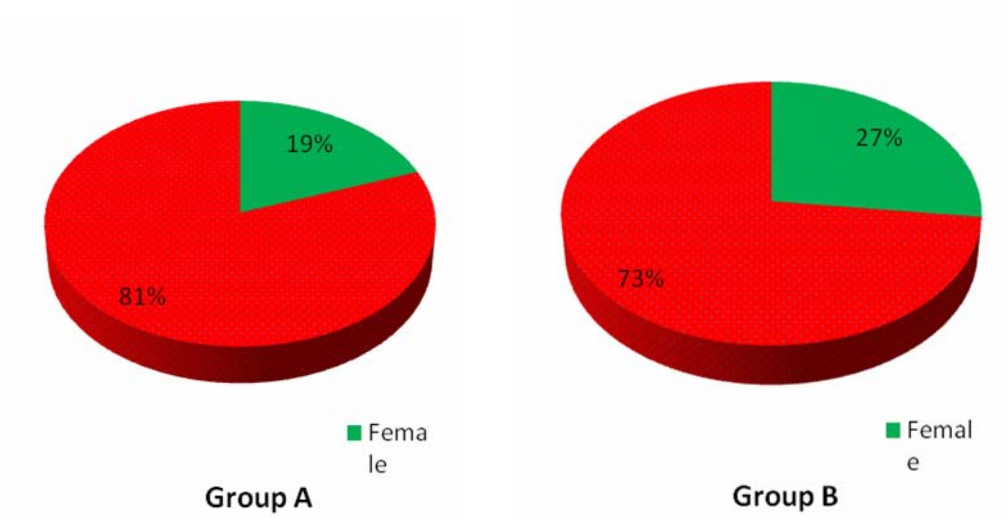


FIGURE NO 9: PIE CHART SHOWING GENDER DISTRIBUTION BETWEEN TWO GROUPS

TABLE 2: AGE IN YEARS - FREQUENCY DISTRIBUTION OF PATIENTS IN TWO GROUPS STUDIED

Age in Years	Group A	Group B	Total
<30	22(32.8%)	22(32.8%)	44(32.8%)
30-40	18(26.9%)	22(32.8%)	40(29.9%)
41-50	12(17.9%)	8(11.9%)	20(14.9%)
51-60	9(13.4%)	9(13.4%)	18(13.4%)
>60	6(9%)	6(9%)	12(9%)
Total	**67(100%)**	**67(100%)**	**134(100%)**
Mean ± SD	**39.11±13.91**	**38.13±14.86**	**38.62±14.35**

P=0.693, Not significant, Student t test

No significant difference in mean age groups with P value 0.693

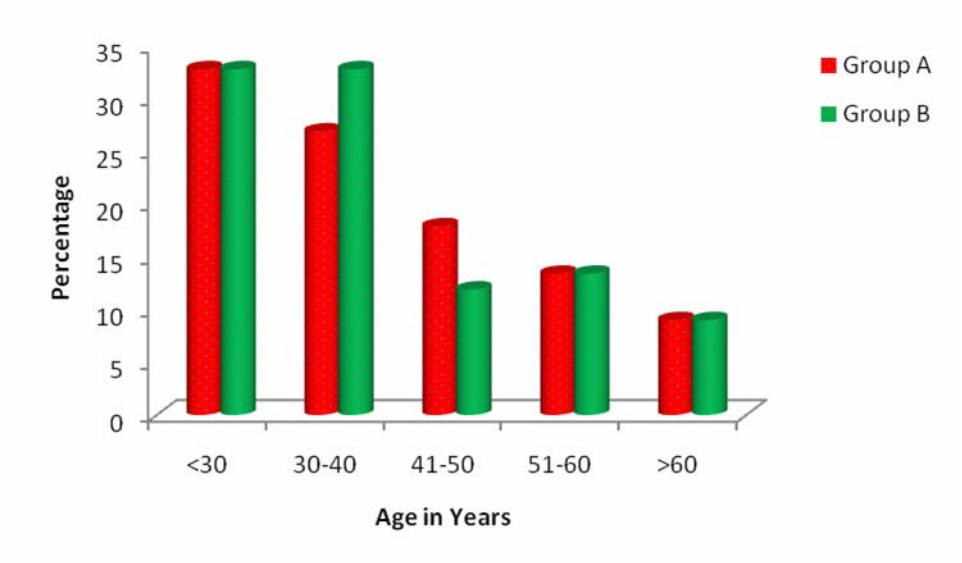


FIGURE NO 10: BAR DIAGRAM SHOWING AGE DISTRIBUTION BETWEEN TWO GROUP

TABLE 3 : ASA GRADE- FREQUENCY DISTRIBUTION OF PATIENTS IN TWO GROUPS STUDIED

ASA Grade	Group A	Group B	Total
I	55(82.1%)	52(77.6%)	107(79.9%)
II	12(17.9%)	15(22.4%)	27(20.1%)
Total	**67(100%)**	**67(100%)**	**134(100%)**

P=0.518, Not Significant, Chi-Square Test

In this study 79% belongs to ASA I and 27% belongs to ASA II.

No significant difference in ASA grading with P value of 0.518

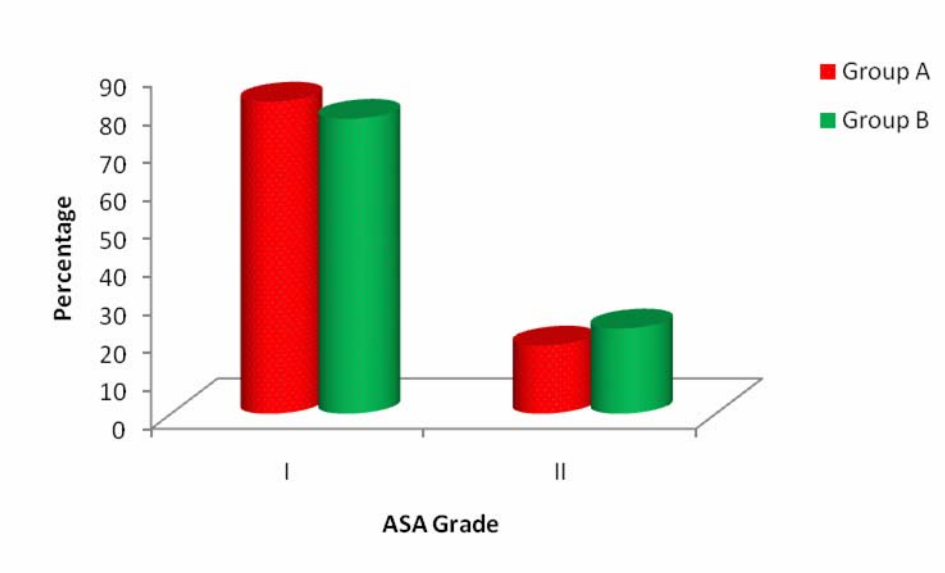


FIGURE NO 11: BAR DIAGRAM SHOWING ASA GRADE DISTRIBUTION IN TWO GROUPS:

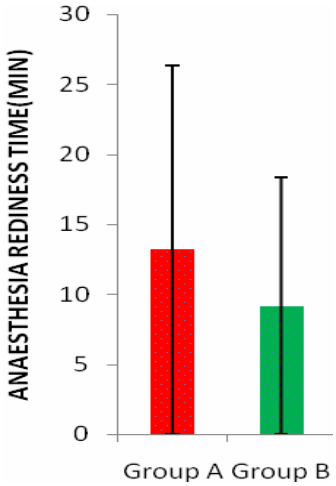
TABLE 4: COMPARISON OF STUDY VARIABLES IN TWO GROUPS OF PATIENTS STUDIED

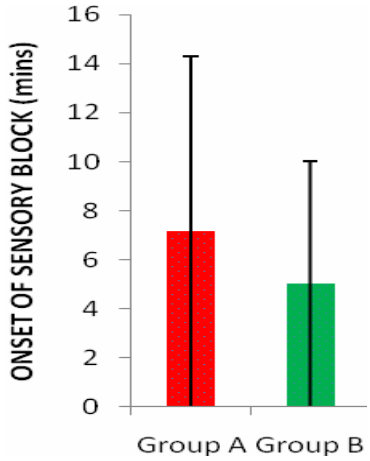
Variables	Group A	Group B	Total	P Value
ANAESTHESIA REDINESS TIME(MIN)	13.19±1.68	9.17±0.96	11.18±2.43	<0.001**
ONSET OF SENSORY BLOCK (mins)	7.15±0.75	5.01±0.88	6.08±1.35	<0.001**
ONSET OF MOTOR BLOCK (mins)	9.64±1	7.13±0.8	8.39±1.55	<0.001**
TIME TO ACHIEVE T8 LEVEL (mins)	12.92±1.83	9.22±1.24	11.07±2.42	<0.001**
DURATION OF SURGERY (mins)	105.82±32.71	101.04±34.21	103.43±33.43	0.410
TIME FOR TWO SEGMENT REGRESSION (mins)	108.34±29.5	135.24±12.88	121.79±26.39	<0.001**
DURATION OF MOTOR BLOCK (mins)	167.39±9.31	194.33±14.35	180.86±18.11	<0.001**
TIME FOR FIRST ANALGESIC REQUEST (hours)	7.01±0.99	4.33±0.87	5.67±1.64	<0.001**
TOTAL BUPIVACAINE CONSUMPTION(mg)	**40.3±5.29**	**15±0**	**27.65±13.23**	**<0.001****

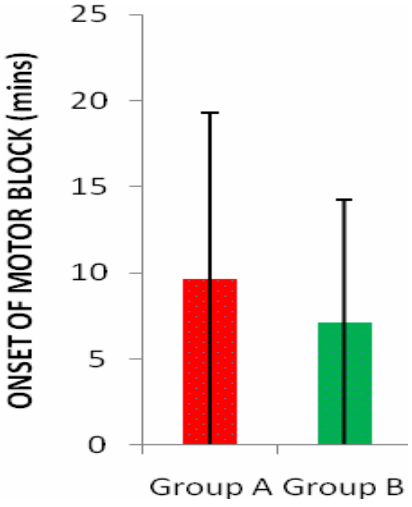
Onset of sensory blockade: Time taken for sensory blockade in group A 7.15±0.75 and 5.01±0.88 in group B . Compare to Group A , Group B has faster onset

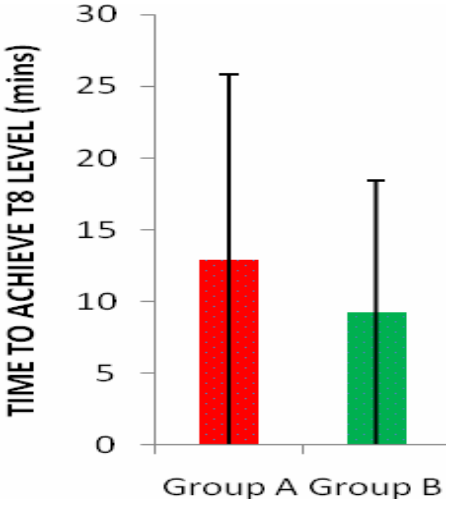
Onset of motor blockade: Time taken to achieve motor block in group A was 9.64±1 and in group B 7.13±0.8. Group B has better motor blocked

Time for two segment regression: Time for two segment regression in group A was 86.77±3.60, in group B it was 106.4±8.01 Shows that group B has better onset of sensory blocked.









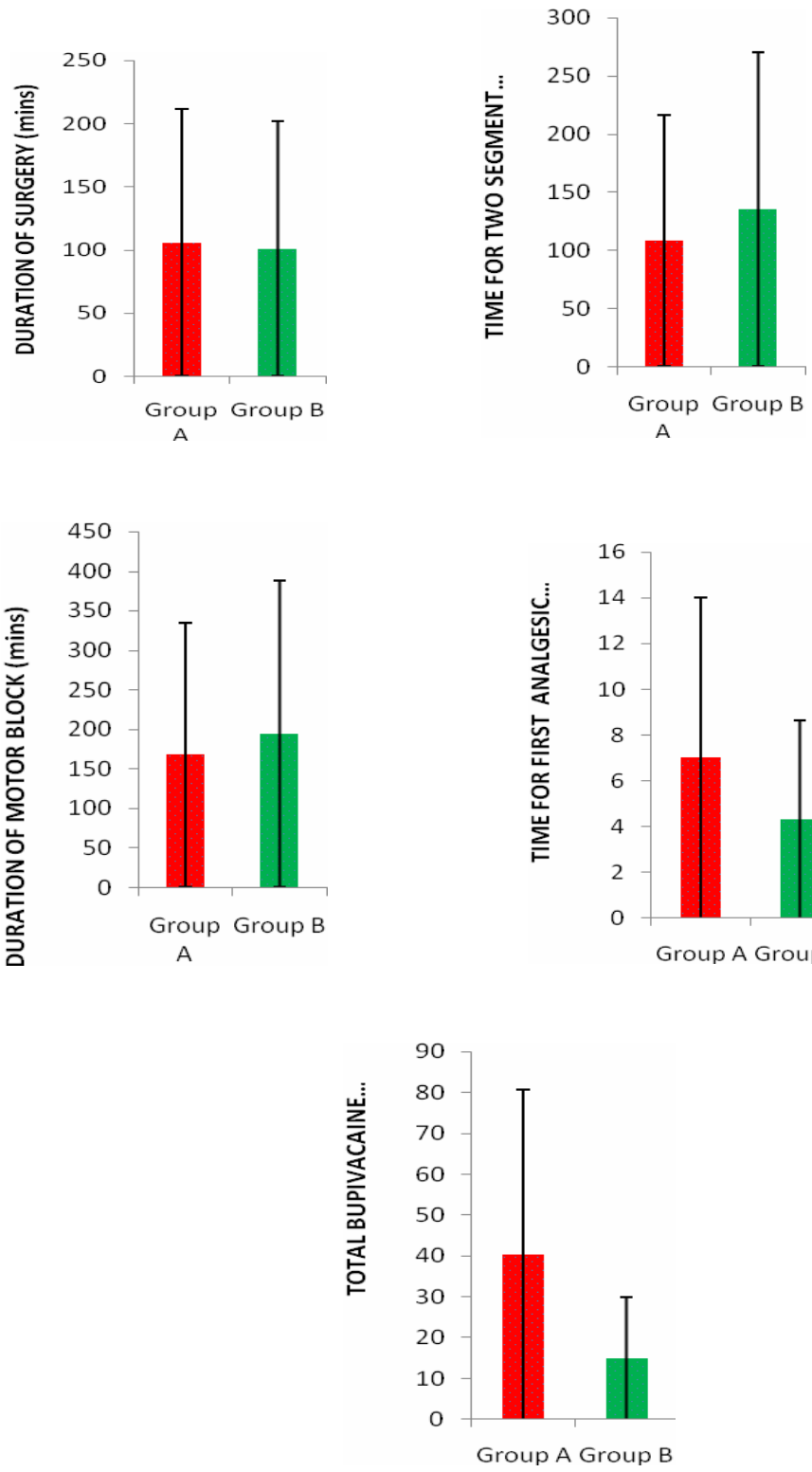


FIGURE NO 12: BAR DIAGRAM SHOWING DISTRIBUTIONOF VARIABLES IN BOTH GROUPS:

TABLE 5: PR(BPM)- COMPARISON IN TWO GROUPS OF PATIENTS STUDIED

PR(bpm)	Group A	Group B	Total	P Value
BASLINE	84.28±10.38	84.48±9.78	84.38±10.05	0.911
0 min	83.13±9.94	83.82±9.88	83.48±9.88	0.689
5 min	80.1±9.36	74.61±10.22	77.36±10.14	<0.001**
10 min	78.01±9.85	70.42±13.48	73.22±12.09	0.006**
15 min	74.54±11.18	68.21±10.22	70.87±10.69	0.374
20 min	74.9±11.19	70.43±11.6	71.66±11.38	0.336
30 min	75.51±10.82	72.61±11.74	74.56±11.3	0.183
40 min	74.82±10.99	78.81±13	76.81±12.16	0.058+
50 min	74.7±12.09	79.64±12.96	77.17±12.73	0.024+
60 min	74.7±12.33	80.61±12.41	77.66±12.68	0.007**
70 min	78.27±16.12	82.64±16.09	80.54±16.19	0.126
70 min	99.17±0.76	99.13±0.74	99.15±0.74	0.803

Baseline PR (bpm) were comparable in two groups, which were 84.28±10.38 and 84.48±9.78 in group A, group B. After 10 minutes PR decrease more in gp B (p-<0.05)

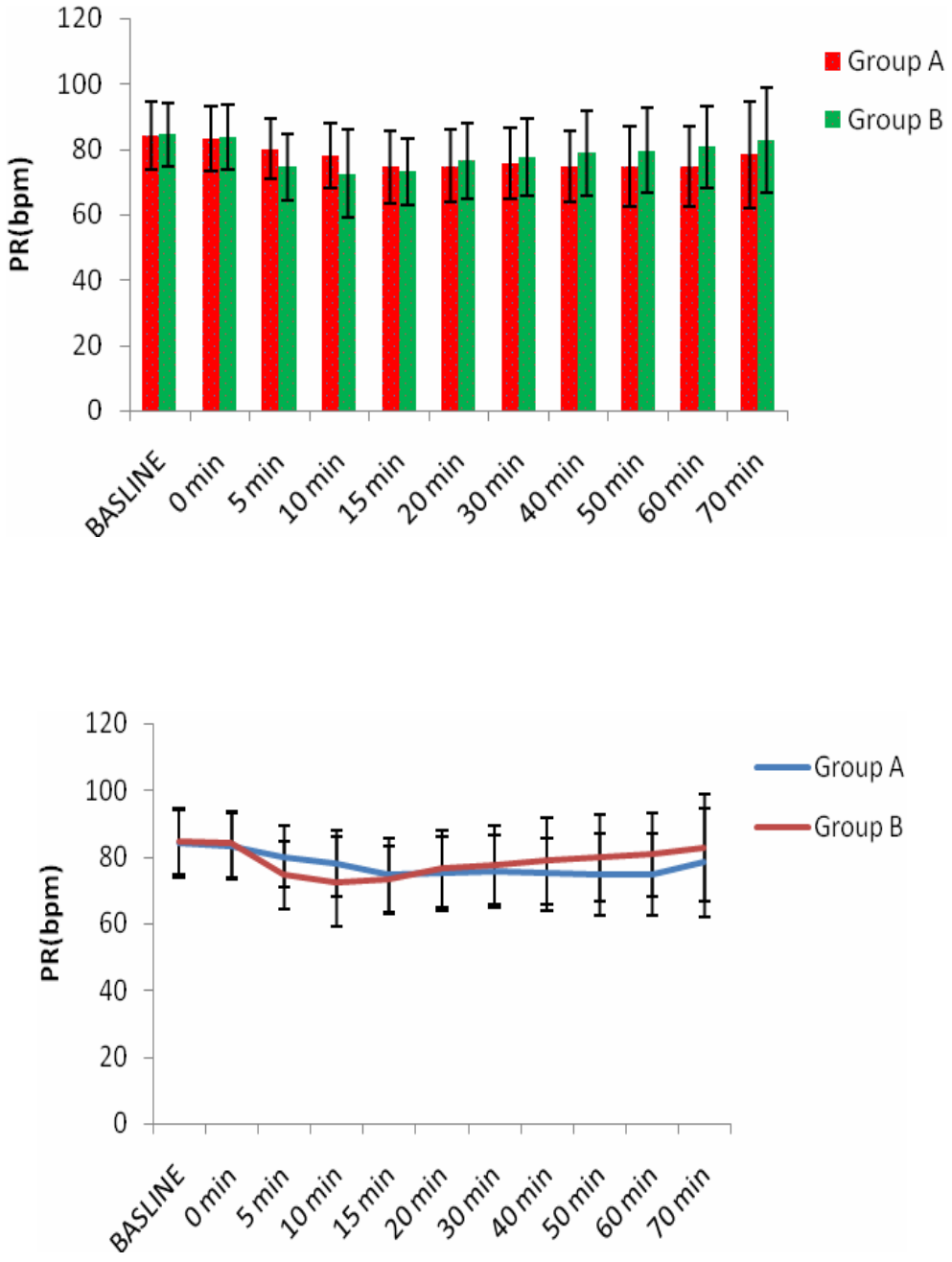


FIGURE NO13 : BAR DIAGRAM SHOWING COMPARISON OF PULSE RATE IN TWO GROUPS

TABLE 6: SYSTOLIC BLOOD PRESSURE(MMHG)- COMPARISON IN TWO GROUPS OF PATIENTS STUDIED

SYSTOLIC BLOOD PRESSURE(mmHg)	Group A	Group B	Total	P Value
BASLINE	124.9±13.02	116.61±10.98	120.75±12.7	<0.001**
0 min	130.42±14.57	126±10.64	128.21±12.9	0.047*
5 min	125.12±12.42	111.88±10.27	118.5±13.15	<0.001**
10 min	120.36±13.71	104.91±10.48	112.63±14.42	<0.001**
15 min	118.64±15.36	102.94±10.58	110.79±15.32	<0.001**
20 min	118.81±15.66	106.16±10.12	112.49±14.58	<0.001**
30 min	118.18±13.95	111.24±12.88	114.71±13.82	0.003**
40 min	119.39±15.17	113.39±14.76	116.39±15.21	0.022*
50 min	121.16±16.41	115.78±15.36	118.47±16.06	0.052+
60 min	121.72±16.16	117.85±15.48	119.78±15.88	0.160
70 min	123.53±16.54	119.99±15.41	121.72±16.01	0.206

Baseline SBP in all the two groups were124.9±13.02and116.61±10.98

in gp A, gp B respectively. SBP after 20 minutes less fall that is 118.81±15.66 in Group A Where as Group B 106.16±10.12.that shows Group a has better hemodynamic.

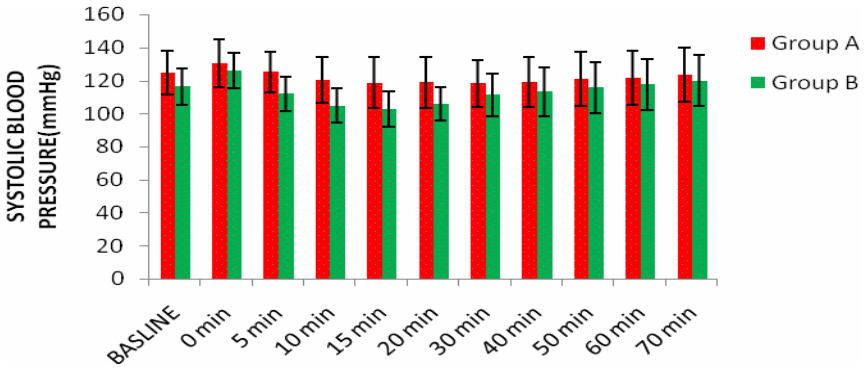


FIGURE NO 14: BAR DIAGRAM SHOWING COMPARISON OF SBP IN TWO GROUPS

TABLE 7: DIASTOLIC BLOOD PRESSURE(MMHG) - COMPARISON IN TWO GROUPS OF PATIENTS STUDIED

DIASTOLIC BLOOD PRESSURE(mmHg)	Group A	Group B	Total	P Value
BASLINE	82.27±11.69	81.97±9.83	82.12±10.75	0.872
0 min	83.63±10.64	81.76±10.13	82.69±10.39	0.301
5 min	78.28±13.58	65.51±9.37	71.9±13.27	<0.001**
10 min	75.88±11.41	60.99±8.55	68.43±12.52	<0.001**
15 min	71.73±16.41	63.63±9.64	67.68±14.01	<0.001**
20 min	71.64±16.25	64.21±9.17	67.93±13.66	<0.001**
30 min	74.4±12.91	67.55±11.73	70.98±12.76	0.002**
40 min	74.51±12.66	68.01±12.35	71.26±12.88	0.003**
50 min	75.85±13.46	69.64±13.55	72.75±13.81	0.009**
60 min	75.73±12.85	70.28±13.37	73.01±13.35	0.018*
70 min	77.37±13.66	70.95±14.45	74.18±14.37	0.012*

Baseline DBP in all two groups were 82.27±11.69and 81.97±9.83 in group A and group B respectively. In Group B after 5 minuts there is a significant fall in DBP i.e 65.51±9.37.

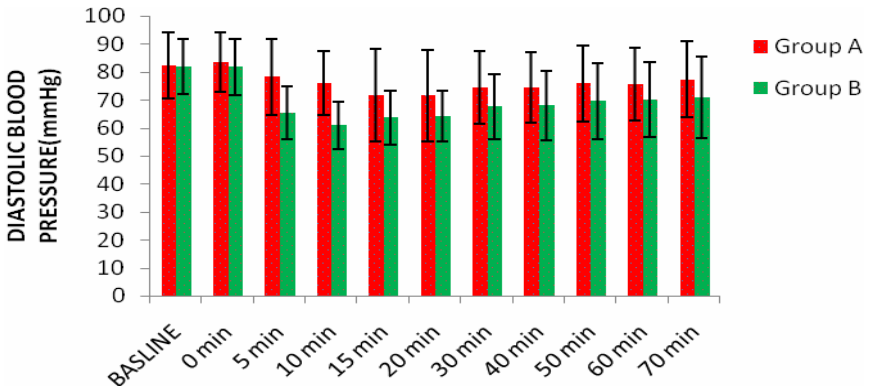


FIGURE NO 15: BAR DIAGRAM SHOWING COMPARISON OF DBP IN ALL TWO GROUPS

TABLE 08: MEAN ARTERIAL BLOOD PRESSURE (MM HG)- COMPARISON IN TWO GROUPS OF PATIENTS STUDIED

MEAN ARTERIAL BLOOD PRESSURE (mm Hg)	Group A	Group B	Total	P Value
BASLINE	95.95±13.33	93.52±8.96	94.73±11.38	0.218
0 min	105.87±12.54	102.84±11.96	104.35±12.3	0.155
5 min	102.75±21.91	90.36±12.99	96.55±18.99	<0.001**
10 min	80.67±10.49	75.93±9.39	78.3±10.2	0.007**
15 min	76.91±14.64	70.36±9.05	73.63±12.56	0.002**
20 min	92.66±11.94	77.42±8.97	85.04±13	<0.001**
30 min	92.1±12.45	81.81±8.06	86.96±11.66	<0.001**
40 min	88.79±13.24	79.94±8.38	84.37±11.9	<0.001**
50 min	89.04±12.65	80.75±9.49	84.9±11.89	<0.001**
60 min	88.7±13.04	80.67±9.32	84.69±11.99	<0.001**
70 min	89.79±13.05	84.69±11.33	87.16±12.41	0.018*

Baseline MAB in all two groups were 95.95±13.33and 93.52±8.96 in group A and group B respectively. 5min later p value <0.05

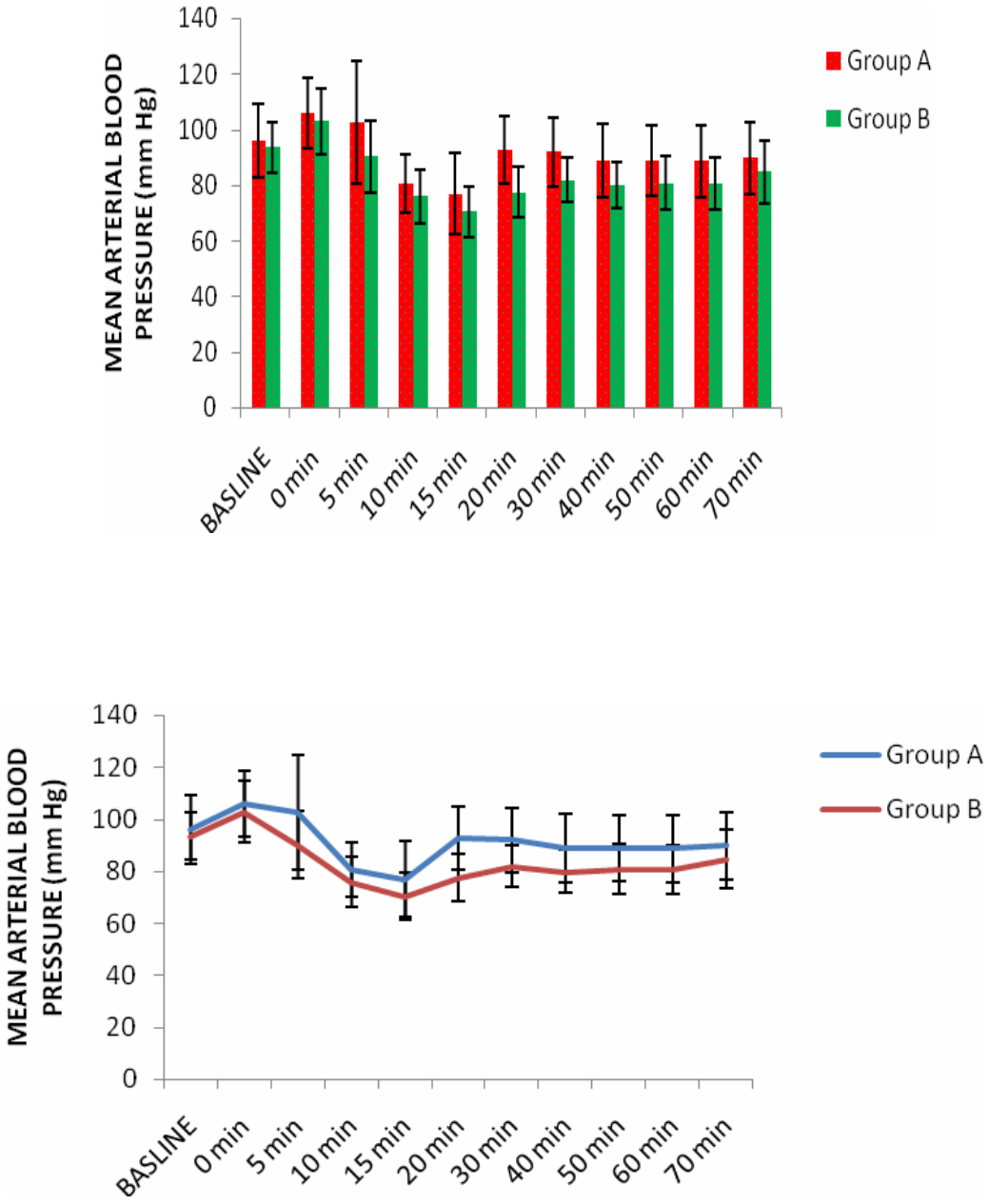


FIGURE NO 16: BAR DIAGRAM SHOWING COMPARISON OF MAP IN BOTH GROUPS

TABLE 09: SPO2%- COMPARISON IN TWO GROUPS OF PATIENTS STUDIED

SPO2%	Group A	Group B	Total	P Value
BASLINE	98.88±0.98	98.9±0.96	98.89±0.96	0.929
0 min	99.4±0.74	99.39±0.74	99.4±0.74	0.907
5 min	99.1±0.84	99±0.89	99.05±0.86	0.485
10 min	98.96±1.04	98.78±0.93	98.87±0.99	0.295
15 min	99.12±0.93	98.7±1.63	98.91±1.34	0.071
20 min	-	-	-	-
30 min	-	-	-	-
40 min	97.61±11.65	99.03±0.94	98.32±8.26	0.322
50 min	97.7±11.65	98.96±0.89	98.33±8.25	0.381
60 min	99.15±0.77	99.06±0.74	99.11±0.75	0.483

There is no significant change in spo2 in both group i.e group A 98.88±0.98, group B 98.9±0.96

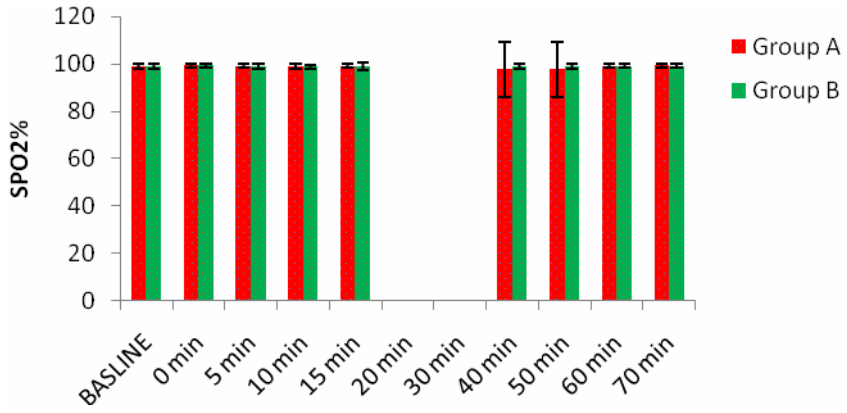


FIGURE NO 17: BAR DIAGRAM SHOWING COMPARISON OF SPO2 IN TWO GROUPS.

TABLE 10: COMPLICATIONS

Complications	Group A	Group B	Total
0	1(1.5%)	0(0%)	1(0.7%)
No	66(98.5%)	67(100%)	133(99.3%)
Total	67(100%)	67(100%)	134(100%)

P=1.000, Not Significant, Fisher Exact Test

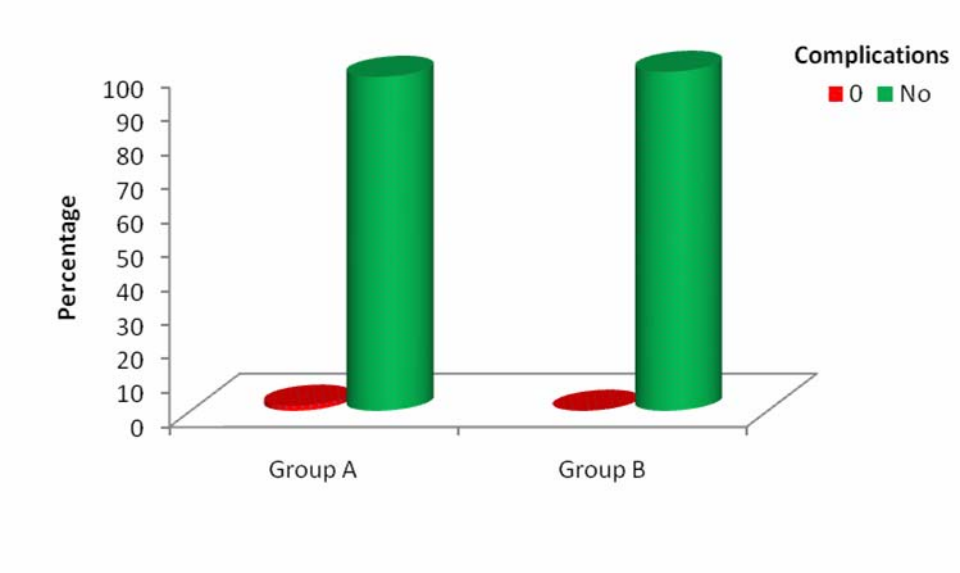
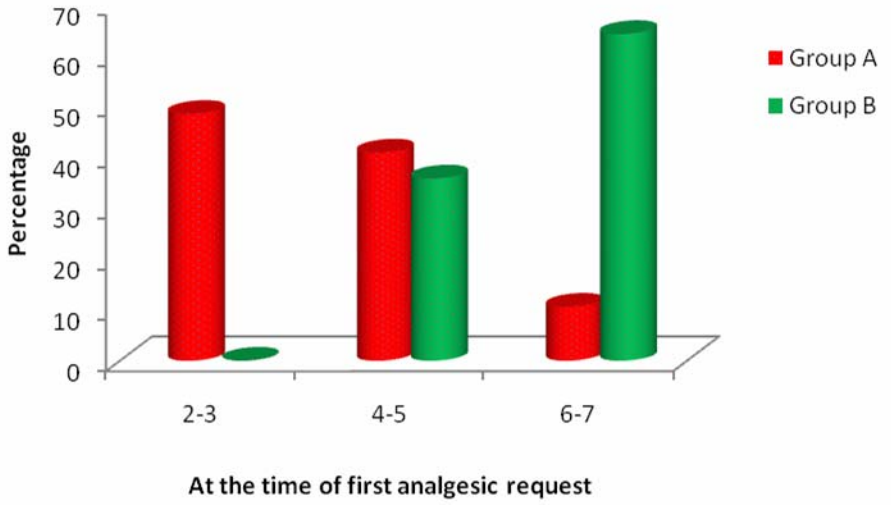


FIGURE NO 18: BAR DIAGRAM SHOWING COMPLICATION IN ALL GROUPS

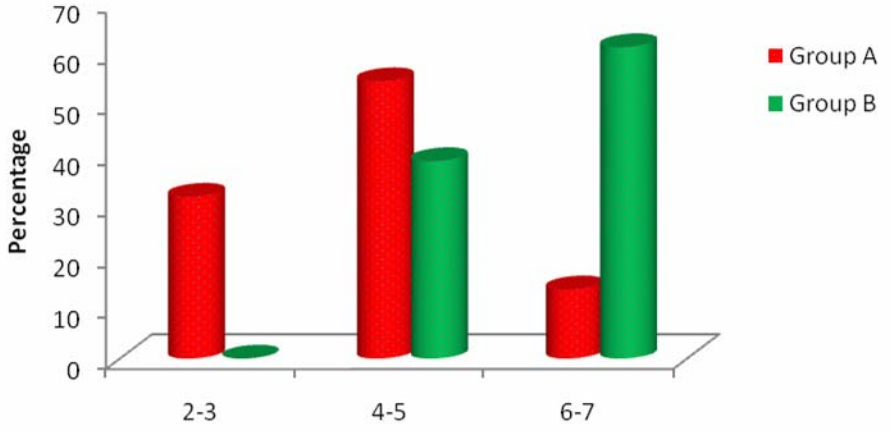
TABLE 11: VAS SCORE (1-10)

VAS SCORE (1-10)	Group A	Group B	Total	P Value
At the time of first analgesic request				
• 2-3	32(48.5%)	0(0%)	32(24.1%)	<0.001**
• 4-5	27(40.9%)	24(35.8%)	51(38.3%)	
• 6-7	7(10.6%)	43(64.2%)	50(37.6%)	
6 hours after surgery				
• 2-3	21(31.8%)	0(0%)	21(15.8%)	<0.001**
• 4-5	36(54.5%)	26(38.8%)	62(46.6%)	
• 6-7	9(13.6%)	41(61.2%)	50(37.6%)	
12hours after surgery				
• 2-3	13(19.7%)	0(0%)	13(9.8%)	<0.001**
• 4-5	53(80.3%)	31(46.3%)	84(63.2%)	
• 6-7	0(0%)	36(53.7%)	36(27.1%)	
24hours after surgery				
• 2-3	15(22.7%)	0(0%)	15(11.3%)	<0.001**
• 4-5	47(71.2%)	35(52.2%)	82(61.7%)	
• 6-7	4(6.1%)	32(47.8%)	36(27.1%)	
Total	66(100%)	67(100%)	133(100%)	

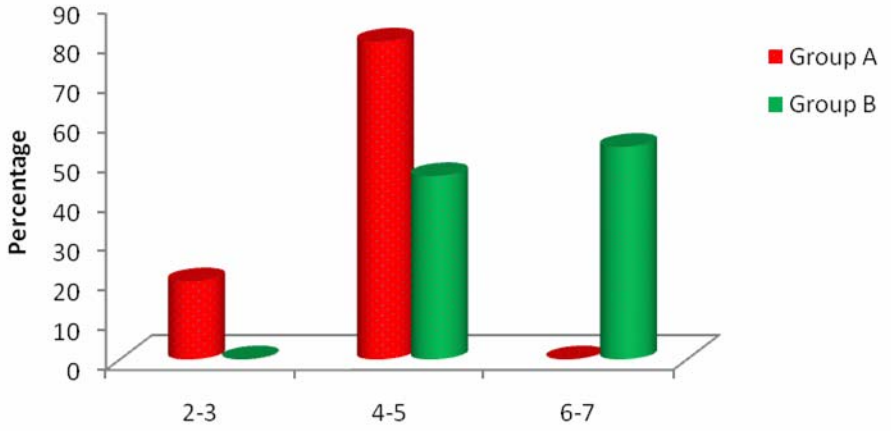
Chi-Square Test/Fisher Exact Test (P<0.05)



At the time of first analgesic request



6 hours after surgery



12 hours after surgery

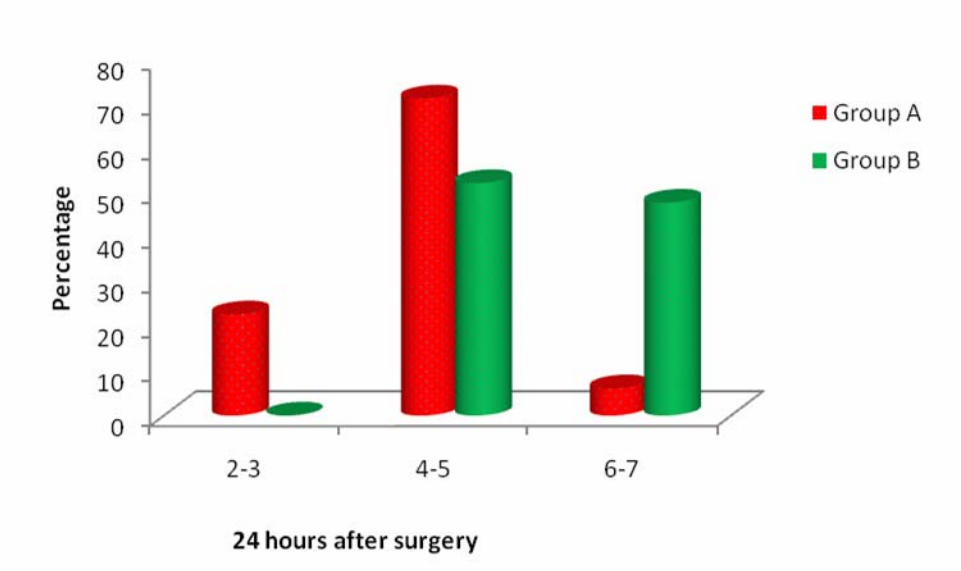


FIGURE NO 19: BAR DIAGRAM SHOWING COMPARISON OF VAS SCORE AT DIFFERENT TIME INTERVAL

TABLE 12: VAS SCORE (1-10)- COMPARISON IN TWO GROUPS OF PATIENTS STUDIED

VAS SCORE (1-10)	Group A	Group B	Total	P Value
At the time of first analgesic request	3.74±1.14	5.81±0.74	4.78±1.41	<0.001**
6 hours after surgery	4.08±1.11	5.78±0.76	4.93±1.27	<0.001**
12hours after surgery	4.15±0.73	5.66±0.73	4.91±1.05	<0.001**
24hours after surgery	4.18±0.89	5.51±0.79	4.85±1.07	<0.001**

Vas score at the time of first analgesic request in Group A 3.74±1.14, Group B 5.81±0.74

Hence good analgesia with group A (P <0.05)

DISCUSSION

In Orthopaedic surgeries, the usage of neuraxial blockade has been increasing to provide excellent surgical conditions and prolonged post operative analgesia. Among the regional techniques, Spinal and Epidural anaesthesia are the two most common procedures done.Though it is a simple procedure with a quick onset of action, spinal anaesthesia (SA) has drawbacks such as hypotension, bradycardia, Post Dural Puncture Headache, and a short sustained release. Epidural anaesthesia necessitates a large volume of local anaesthesia (LA) with a greater concentration and a later onset. Hypotension and bradycardia are less common and occur at a slower rate, providing us more time to address hemodynamic alterations.. CSE technique offers rapid onset, longer duration of action, efficacy and minimal toxicity. This technique has various benefits mainly stable haemodynamic status , easier to control the duration of anaesthesia and deliver postoperative analgesia.[58,59]

The study was conducted on patients admitted for elective lower limb surgeries done in R. L. Jalappa Hospital and Research centre and sample size was 134 in that 67 for each group.

Group A : SCSEA with Epidural- lignocaine with adrenaline(2%)3ml

Spinal - bupivacaine(0.5%)1.5ml-7.5mg + inj. Fentanyl.25mic

Group B: SAB with Spinal - bupivacaine(0.5%)3ml-15mg + inj. Fentanyl.25mic

Data recorded were Time taken to achieve a sensory level of T8 , Total dose drug requirement, 2 segment regression time , Intraoperativehaemodynamic

Onset of sensory blockade: Time taken for sensory blockade in group A 7.15±0.75and5.01±0.88 in group B . Compare to Group A , Group B has faster onset of senory block.

Onset of motor blockade: Time taken to achieve motor block in group A was 9.64±1 and in group B 7.13±0.8. Group B has better motor blocked

Time for two segment regression: Time for two segment regression in group A was 86.77±3.60, in group B it was 106.4±8.01 Shows that group B has better onset of sensory blocked.

Hemodynamic stability: Baseline PR (bpm comparable in two groups, which were 84.28±10.38 and 84.48±9.78 in group A, group B. Compare to Group A, Group B shows drop in PR to 68.21±10.22 after 10 minutes of procedure.

Baseline SBP in all the two groups were124.9±13.02and116.61±10.98 in group A group B respectively.

In group A there were fall in SBP only after 20minutes of epidural which was 118.81±15.66and was gradually increasing as the time proceeded, it was 123.53±16.54 after 70 minutes of epidural.

In group B -Significant fall in SBP after 05 minutes of spinal which was 104.91±10.48and it remained on the lower side for long time.

Baseline DBP in all two groups were 82.27±11.69and 81.97±9.83 in group A and group B respectively.

In group A there was no much in fall in DBP after 20minutes of epidural it was 71.64±16.25and it remained the same all throughout the procedure.

In group B - Significant reduction in DBP after 05minutes of spinal it was 60.99±8.55 and it was on the lower side thereafter.

Baseline DBP in all two groups were 82.27±11.69and 81.97±9.83 in group A and group B respectively.

In group A there was no much in fall in DBP after 20minutes of epidural it was 71.64±16.25and it remained the same all throughout the procedure.

In group B there was a significant reduction in DBP after 05minutes of spinal it was 60.99±8.55 and it was on the lower side thereafter.

It shows that Group A has better hemodynamics when compare to Group B

Analgesia: Vas score at the time of first analgesic request in Group A 3.74±1.14, Group B 5.81±0.74, good analgesia and better patient comfort.

In my study – duration of motor block in CSEA better i.e 167.39±9.31 and Time taken for sensory blockade in group A 7.15±0.75 and group B5.01±0.88. compare to group A, group B has faster onset of sensory block. **Begum SA, Akhtaruzzaman AKM et al.[60]** observed that. Mean (±SD) duration of anaesthesia was significantly higher in CSEA group than spinal group (256.57 ± 33.56 minutes versus 214.71 ± 18.03 minutes, $p < 0.001$). Mean (±SD) time to achieve target level of sensory block was significantly higher in CSEA group than spinal group (11.21 ± 2.2 minutes versus 3.5 ± 1.5 minutes, $p < 0.001$). Mean (±SD) time to achieve complete motor block was also significantly higher in CSEA group than spinal group (12.29 ± 2.53 minutes versus 7.02 ± 2.11 minutes, $p < 0.001$).[60]

In present study CSEA group shows fall in SBP only after 20 mins of epidural which was 118.81±15.66 from 124.9±13.02 and in SA group 106.16±10.12 from 116.61±10.98 I.e

no much chances in SBP. It has proven in study **Holmström B, Laugaland K et al**[53]A controlled study to compare the surgical analgesia and motor block amongspinal, epidural and CSEA for total hip and knee arthroplasty noted that the median level in patients receiving epidural block was T8 (range T3-T12), in patients receiving spinal blocks T8 (range T4-T10) and in patients receiving CSE blocks T 6 (range T3-T10) ($P < 0.05$). No differences were noted among the groups regarding the incidence of hypotension or the number of patients requiring ephedrine.[53]

In this study foud that fall in BP after 20 mintues in CSEA less when compare to SA i.e <0.05 and was proved in**Mutahar S, Madhavi S et al**[56]A prospective, randomised, double blind study to compare changes in vital parameters using sequential CSEA and subarachnoid block for lower limb surgeries reported the decrease in BP less in sequential CSEA in comparison with spinal block. From 2 min to 60 min there was fall in mean blood pressure in spinal group in comparison to sequential CSEA group ($p<0.05$).[56]

Here we found that two segment regression faster in CSEA compare to SA and proved by **Yun MJ, Kwon MYet al**[57] Among patients posted for lower limb surgeries, those who received only spinal (10 mg of spinal bupivacaine), and CSEA at different doses (7.5 mg of spinal bupivacaine + epidural 1.5% lidocaine 10 ml) or (5 mg of spinal bupivacaine + epidural 1.5% lidocaine 10 ml), the change of sensory block levels including the peak sensory block level and the time to reach it were similar ($P > 0.05$), but the regression to the L1 dermatome was faster in the CSEA group with 5 mg spinal bupivacaine than in the other two groups ($P = 0.004$).[57]A spinal block with long-acting bupivacaine and an epidural top-up with a high concentration of intermediate-acting lidocaine, rather than a

spinal block alone or CSEA with saline as an epidural top-up, can give appropriate surgical anaesthetic and speedier motor recovery.[57]

Study proved that onset of motor block faster in SA(7.13±0.8) than in CSEA(9.64±1) and analgesia longer in CSEA group**.** proven in study**talikota n, muntha bet al** [58].In randomised, single-blind controlled study contrasting the efficacy and safety of sequential CSEA technique and SA for lower abdominal surgeries, the time taken for onset of anaesthesia in the SA group was 5.48 minutes, compared to 7.40 minutes in the CSEA group . Analgesia lasted 115.6 minutes in spinal and 124.5 minutes in CSEA.

CONCLUSION

In our study it was observed that sequential combined spinal epidural anesthesis has greater haemodynamical stability and extended analgesic effect. where as spinal anaesthesia shows sudden change in hemodynamics but reveals greater motor and sensory blocked.

SUMMARY

Double blinded randomized control prospective study done at R.L.Jalappa Hospital and Research, Tamaka, Kolar, from Jan 2019 to June 2020.

One thirty four patients of age group 18 – 65 years with ASA grade I, II

GROUP A : Epidural- lignocaine with adrenaline(2%)3ml

Spinal - bupivacaine(0.5%)1.5ml-7.5mg + inj. Fentanyl.25mic _

GROUP B : Spinal - bupivacaine(0.5%)3ml-15mg + inj. Fentanyl.25mic

HR, NIBP, ECG, and SPO2 were measured at baseline. The following aspects of blockage and hemodynamic parameters were recorded.

The essential information will be kept on file:

1. The time it took to reach a T8 sensory level.

2. The total amount of epidural bupivacaine needed to achieve the desired level of blockage.

3. Time for two-segment sensory block regression

4. Intraoperative haemodynamic measures, including heart rate and mean arterial pressure

5. The use of general anaesthesia as a supplement.

6. Complications

There were no statistical differences between the two groups in terms of age, sex, and ASA physical status grade in the study.

Between the two groups, there was a substantial difference in mean heart rate.

The mean systolic and diastolic blood pressures were significantly different.

There was a substantial difference in the beginning of motor and sensory blockage, as well as the severity of the blockade. among two groups, as well as postoperative analgesics

We found that consecutive combination spinal epidural anaesthetics provide improved haemodynamic stability and a longer duration of analgesia. Spinal anaesthesia, is a type of anaesthesia that reveal hemodynamical changes.

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ANNEXURES

PROFORMA

Sl.No. Date of admission:

Name: Hospital No.

ASA status:

Age: Height:

Sex: Weight:

Diagnosis and type of surgery:

Informed consent: BMI:

HISTORY

General examination:

Systemic examination:

Investigations:

Haemoglobin: ECG:

Coagulation profile: Chest X ray:

Blood sugar: Blood group:

Blood urea: Serum creatinine:

Serum Electrolytes:

PRE OPERATIVE

Pulse: BP: RR:

Spo2:

INTRAOPERATIVE RECORD

1.Haemodynamic variables:

MIN	10	20	30	40	50	60	70	80
HR								
SBP								
DBP								
MAP								
SPO2								

2.Respiratory parameters:

MIN	10	20	30	40	50	60	70	80
RR								

3.Study parameters:

variables	**Group CSEA**	**Group SA**
Anaesthesia rediness time in min		
Peak sensory level		
Degree of motor block		
Time to regression of sensory block to T10 in min		
Duration of analgesia in min		
Supplementation with general anaesthesia		
Total bupivacaine consumption(mg)		
complications		

INFORMED CONSENT FORM

Date :

Place :

I,Mr/Mrs……..son/

daughter/wife of Mr/Mrs……..,aged……..years have been explained in a language understood by me about the study entitled

THE STUDY OF CLINICAL EFFECTS OF SEQUENTIAL COMBINED SPINAL EPIDURAL ANAESTHESIA AND SPINAL ANAESTHESIA IN PATIENTS UNDERGOING ORTHOPEDIC SURGERIES at the Department of Anaesthesiology, SDUMC, Kolar

I have been explained about the procedures and investigations that will be done during this study.

I have no objections for sharing the medical information and details in the case records with the investigators of this study. I am aware that the data generated in the study may be used for publication/dissertation purpose and personal identity will not be revealed.

I confirm that I have not been offered any financial incentives for participating in this study or I shall not derive any financial benefits from the study.

I understand that my son/daughter/wife ‘s participation in this study is entirely voluntary and wilfully give consent regarding participation in the study for specified duration

PARTICIPANT’S NAME: SIGNATURE OF INVESTIGATOR :

SIGNATURE/THUMB IMPRESSION OF PATIENT:

PATIENT ATTENANDANT/WITNESS’S NAME: SIGNATURE

PATIENT INFORMATION SHEET

THE STUDY OF CLINICAL EFFECTS OF SEQUENTIAL COMBINED SPINAL EPIDURAL ANAESTHESIA AND SPINAL ANAESTHESIA IN PATIENTS UNDERGOING ORTHOPEDIC SURGERIES at the Department of Anaesthesiology, SDUMC, Kolar

NAME OF THE INVESTIGATOR: DR.MAHIMA L.N

NAME OF THE GUIDE: Dr. RAVI M

IF YOU AGREE TO PARTICIPATE IN THE STUDY, THE FOLLOWING WILL BE DONE

Under strict aseptic precautions LP done at level L3. L4 After confirmation of CSF back flow and negative aspiration blood ,ing.bupivacaine 3ml will be given intra thecally. Successful procedure causes loss of sensation to pain and motor blockade. Continuous monitoring is done intraoperatively. If there is incomplete or failed procedure, general anesthesia will be given. Preventive and resuscitative measures will be kept ready in case, complications arise.

BENEFITS & RISKS: The approach are useful in all lower limb surgeries. The risks of the techniques include PDPH,hypotension, nerve damage and vascular damage.

CONFIDENTIALITY OF RECORDS: This study will become a part of hospital records and will be subject to the confidentiality. If the data are used for publication, no name will be used. And photographs will be used with special written permission

INJURY STATEMENT: In the unlikely event of injury resulting directly from participation in this study, the injury will be reported promptly and the appropriate treatment will be given

MASTER CHART

SL NO	UHID number	AGE	SEX	GROUP	KNEE AFFECTED		GRADE OF OA	DATE OF FIRST INJECTION	PLATELET COUNT		DATE OF SECOND INJECTION	PLATELET COUNT		CO-MORIDITIES		VAS				WOMAC				BMI	RANGE OF MOTION								COMPLICATIONS
																									PRE-INJECTIOI		1 MONTH		3 MONTH		6 MONTH		
									BLOOD PLATELET COUNT	PLATELET COUNT IN PRP		BLOOD PLATELET COUNT	PLATELET COUNT IN PRP	DIABETES	HYPERTENSION	INJECTION	6 WEEKS	3 MONTH	6 MONTH	INJECTION	6 WEEKS	3 MONTH	6 MONTH		RIGHT	LEFT	RIGHT	LEFT	RIGHT	LEFT	RIGHT	LEFT	
1	930247	56	F	S-PRP	**RIGHT**	LEFT	GRADE 1	12/18/2019	100,000	813,000	NA	NA	NA	NO	NO	7	4	2	2	56	48	38	40	27	0-120	0-120	0-125	0-125	0-130	0-130	0-135	0-135	PAIN
2	930286	60	F	S-PRP	RIGHT		GRADE 2	12/20/2019	190,000	743,000	NA	NA	NA	NO	NO	6	3	3	3	54	48	34	44	30	0-120	0-135	0-120	0-135	0-125	0-135	0-130	0-135	
3	931146	55	F	S-PRP	**RIGHT**	LEFT	GRADE 2	12/22/2019	275,000	710,000	NA	NA	NA	NO	NO	7	6	4	2	56	42	36	24	30	0-120	0-125	0-125	0-130	0-130	0-130	0-130	0-130	
4	925470	58	F	S-PRP	**RIGHT**	LEFT	GRADE 2	1/2/2020	152,000	645,000	NA	NA	NA	NO	NO	6	4	3	2	56	50	38	20	28	0-120	0-125	0-125	0-130	0-125	0-130	0-130	0-130	PAIN
5	919935	50	F	S-PRP	**RIGHT**		GRADE 1	12/18/2019	125,000	630,000	NA	NA	NA	YES	NO	8	7	7	6	56	42	30	20	29	0-120	0-135	0-125	0-135	0-130	0-135	0-130	0-135	
6	931885	60	F	S-PRP	RIGHT	**LEFT**	GRADE 2	1/12/2020	150,000	625,000	NA	NA	NA	NO	NO	7	6	4	1	58	44	32	24	26	0-120	0-110	0-130	0-120	0-135	0-125	0-130	0-130	
7	931403	60	F	S-PRP	**RIGHT**	LEFT	GRADE 2	1/22/2020	110,000	900,000	NA	NA	NA	YES	YES	6	2	3	1	52	46	34	22	28	0-110	0-120	0-125	0-120	0-135	0-135	0-135	0-135	
8	932134	57	M	S-PRP	RIGHT	**LEFT**	GRADE 2	1/24/2020	290,000	655,000	NA	NA	NA	YES	NO	6	5	4	2	56	50	38	36	26	0-120	0-110	0-125	0-125	0-130	0-130	0-135	0-130	
9	920887	60	F	S-PRP	RIGHT	LEFT	GRADE 2	1/25/2020	160,000	540,000	NA	NA	NA	NO	NO	7	6	5	4	54	46	38	18	27	0-110	0-120	0-120	0-120	0-125	0-135	0-125	0-135	
10	931479	50	M	S-PRP	RIGHT		GRADE2	2/1/2020	218,000	540,000	NA	NA	NA	NO	NO	6	6	4	3	58	48	34	20	28	0-120	0-130	0-125	0-130	0-125	0-130	0-130	0-135	
11	934783	62	F	S-PRP	**RIGHT**	LEFT	GRADE 1	2/18/2020	190,000	680,000	NA	NA	NA	YES	NO	7	5	4	1	52	40	32	24	28	0-110	0-120	0-120	0-130	0-130	0-130	0-130	0-130	
12	935147	56	F	S-PRP	**RIGHT**	LEFT	GRADE 2	2/23/2020	138,000	590,000	NA	NA	NA	NO	NO	7	5	3	5	56	44	36	66	28	0-120	0-110	0-130	0-125	0-135	0-130	0-135	0-135	
13	933120	58	M	S-PRP	RIGHT	**LEFT**	GRADE 2	2/3/2020	275,000	730,000	NA	NA	NA	YES	NO	6	4	3	1	52	42	34	18	27	0-120	0-110	0-130	0-120	0-130	0-120	0-130	0-130	
14	936585	60	F	S-PRP	**RIGHT**	**LEFT**	GRADE 2	2/20/2020	273,000	640,000	NA	NA	NA	NO	NO	7	5	4	6	60	48	34	34	27	0-110	0-120	0-120	0-130	0-130	0-130	0-130	0-135	
15	939139	55	F	S-PRP	RIGHT	**LEFT**	GRADE 2	2/20/2020	188,000	740,000	NA	NA	NA	NO	YES	8	6	5	4	52	46	32	20	28	0-120	0-110	0-130	0-130	0-135	0-135	0-135	0-135	
16	934174	60	F	S-PRP	**RIGHT**	LEFT	GRADE 2	3/10/2020	280,000	680,000	NA	NA	NA	YES	YES	7	6	4	3	56	48	31	26	27	0-110	0-130	0-120	0-135	0-135	0-140	0-135	0-140	SWELLING
17	935197	46	M	S-PRP	**RIGHT**	LEFT	GRADE 2	3/12/2020	127,000	620,000	NA	NA	NA	NO	NO	6	5	3	4	56	46	36	22	28	0-120	0-130	0-125	0-130	0-130	0-135	0-135	0-135	
18	935268	55	F	S-PRP	RIGHT	**LEFT**	GRADE 1	3/20/2020	316,000	800,000	NA	NA	NA	NO	NO	7	6	4	3	58	48	36	24	26	0-130	0-120	0-130	0-125	0-130	0-125	0-135	0-130	
19	907621	56	F	S-PRP	RIGHT	**LEFT**	GRADE 2	3/16/2020	214,000	813,000	NA	NA	NA	NO	NO	6	5	3	5	56	46	38	28	27	0-110	0-120	0-120	0-130	0-130	0-130	0-130	0-130	
20	897216	52	F	S-PRP	RIGHT		GRADE 2	4/19/2020	140,000	630,000	NA	NA	NA	YES	NO	7	6	5	5	56	43	36	24	26	0-110	0-135	0-120	0-135	0-125	0-135	0-135	0-135	
21	896389	55	F	S-PRP	**RIGHT**		GRADE 2	4/20/2020	219,000	745,000	NA	NA	NA	NO	YES	6	6	4	3	54	44	34	28	27	0-110	0-120	0-120	0-135	0-130	0-140	0-135	0-140	
22	896388	59	F	S-PRP	**RIGHT**	**LEFT**	GRADE 2	4/28/2020	190,000	590,000	NA	NA	NA	NO	NO	8	6	4	2	52	48	32	26	29	0-110	0-110	0-120	0-130	0-130	0-135	0-135	0-140	
23	893914	54	F	S-PRP	**RIGHT**	LEFT	GRADE 2	5/4/2020	288,000	620,000	NA	NA	NA	NO	YES	7	6	4	5	56	48	34	24	27	0-110	0-120	0-120	0-135	0-130	0-135	0-135	0-135	
24	854382	57	F	S-PRP	**RIGHT**	LEFT	GRADE 2	5/13/2020	223,000	590,000	NA	NA	NA	NO	NO	7	5	4	1	54	46	38	28	30	0-110	0-110	0-120	0-120	0-125	0-130	0-130	0-135	
25	899526	60	F	S-PRP		LEFT	GRADE 2	5/20/2020	190,000	710,000	NA	NA	NA	NO	NO	6	5	4	3	52	42	32	24	32	0-130	0-110	0-135	0-120	0-130	0-130	0-135	0-140	
26	847174	52	F	S-PRP	**RIGHT**	LEFT	GRADE 2	5/21/2020	290,000	820,000	NA	NA	NA	NO	NO	7	5	4	1	56	42	34	26	27	0-110	0-125	0-120	0-130	0-130	0-135	0-135	0-135	
27	866677	58	F	S-PRP	RIGHT	**LEFT**	GRADE 2	5/28/2020	167,000	780,000	NA	NA	NA	NO	NO	7	6	4	2	58	40	36	24	28	0-120	0-110	0-130	0-120	0-130	0-125	0-135	0-135	
28	832922	56	M	S-PRP	**RIGHT**		GRADE 1	5/28/2020	219,000	685,000	NA	NA	NA	NO	YES	6	5	3	1	56	48	38	28	29	0-120	0-135	0-125	0-135	0-135	0-130	0-140	0-135	
29	850148	59	F	S-PRP	**RIGHT**	LEFT	GRADE 1	5/31/2020	183,000	625,000	NA	NA	NA	NO	NO	6	5	4	2	60	46	36	26	34	0-120	0-130	0-125	0-130	0-135	0-135	0-135	0-135	
30	849536	56	F	S-PRP	**RIGHT**	**LEFT**	GRADE 1	5/31/2020	236,000	610,000	NA	NA	NA	NO	NO	7	6	4	2	56	44	34	24	28	0-120	0-125	0-125	0-125	0-130	0-130	0-135	0-135	PAIN, SWELLING
31	-849142	54	F	S-PRP	**RIGHT**		GRADE 1	5/31/2020	230,000	840,000	NA	NA	NA	NO	NO	7	6	4	1	58	48	38	24	26	0-130	0-120	0-130	0-125	0-135	0-135	0-135	0-135	
32	848193	43	F	S-PRP	**RIGHT**	LEFT	GRADE 2	6/8/2020	217,000	900,000	NA	NA	NA	NO	NO	6	5	4	2	58	44	34	26	28	0-110	0-130	0-120	0-130	0-130	0-135	0-135	0-135	
33	836389	45	M	S-PRP	RIGHT	LEFT	GRADE 2	11/25/2019	290,000	780,000	NA	NA	NA	YES	YES	7	6	3	2	54	40	38	24	28	0-120	0-125	0-140	0-130	0-140	0-130	0-140	0-135	
34	897216	45	M	S-PRP	**RIGHT**	LEFT	GRADE 1	11/28/2019	156,000	826,000	NA	NA	NA	NO	NO	6	6	4	1	54	44	40	26	26	0-125	0-130	0-130	0-130	0-130	0-135	0-135	0-140	PAIN
35	896389	60	F	M-PRP	RIGHT	**LEFT**	GRADE 2	12/16/2019	167,000	945,000	14.03.2020	######	849,000	NO	NO	8	7	3	4	52	46	32	28	28	0-125	0-110	0-130	0-120	0-130	0-125	0-135	0-130	
36	884541	50	F	M-PRP	RIGHT	LEFT	GRADE 1	12/26/2020	237,000	925,000	2.02.2020	######	872,000	NO	NO	7	6	5	3	52	42	34	28	28	0-120	0-135	0-125	0-135	0-130	0-135	0-140	0-140	
37	892338	46	F	M-PRP	**RIGHT**	LEFT	GRADE 1	1/27/2020	240,000	930,000	26.03.2020	######	782,000	NO	YES	8	6	4	2	56	46	36	24	26	0-120	0-135	0-130	0-135	0-130	0-135	0-135	0-140	
38	893002	58	M	M-PRP	**RIGHT**	LEFT	GRADE 1	1/30/2020	265,000	670,000	4.04.2020	######	620,000	NO	NO	8	6	4	5	58	44	38	26	26	0-120	0-130	0-130	0-135	0-140	0-140	0-140	0-140	PAIN
39	874768	40	M	M-PRP	**RIGHT**	LEFT	GRADE 2	1/31/2020	256,000	930,000	23.03.2020	######	820,000	NO	NO	8	6	4	3	56	48	36	24	26	0-120	0-120	0-135	0-125	0-135	0-130	0-140	0-130	
40	892410	40	M	M-PRP	RIGHT	LEFT	GRADE 1	3/11/2020	288,000	848,000	12.05.2020	######	783,000	YES	NO	7	6	4	1	58	46	34	28	27	0-125	0-140	0-130	0-140	0-135	0-140	0-140	0-140	
41	876383	59	M	M-PRP	**RIGHT**	LEFT	GRADE 1	3/13/2020	295,000	1,032,000	1.06.2020	######	640,000	NO	YES	8	6	5	1	52	42	38	20	27	0-120	0-130	0-130	0-140	0-135	0-140	0-140	0-140	
42	890870	59	M	M-PRP	**RIGHT**	LEFT	GRADE 2	3/13/2020	102,000	860,000	2.05.2020	######	810,000	NO	NO	8	6	5	2	54	44	34	24	25	0-120	0-120	0-140	0-130	0-140	0-135	0-140	0-140	SWELLING
43	882246	41	F	M-PRP	**RIGHT**	LEFT	GRADE 2	3/15/2020	195,000	1,160,000	6.05.2020	######	790,000	YES	NO	8	6	5	1	54	46	36	28	29	0-120	0-135	0-135	0-135	0-135	0-135	0-135	0-140	
44	889605	60	F	M-PRP	**RIGHT**	**LEFT**	GRADE 2	3/15/2020	266,000	820,000	5.05.2020	######	823,000	YES	YES	8	6	5	1	58	44	38	24	26	0-115	0-130	0-125	0-135	0-130	0-135	0-135	0-135	
45	888198	57	F	M-PRP	**RIGHT**	LEFT	GRADE 2	4/4/2020	169,000	880,000	06.07.2020	######	670,000	YES	NO	8	6	5	2	52	48	32	26	26	0-120	0-130	0-125	0-130	0-130	0-135	0-135	0-135	

MASTER CHART

46	886796	53	F	M-PRP	**RIGHT**	LEFT	GRADE 1	4/8/2020	210,000	900,000	09.06.2020	######	740,000	NO	NO	8	6	5	2	58	46	38	24	28	0-120	0-120	0-130	0-130	0-135	0-140	0-140	0-140	PAIN, SWELLING
47	887454	50	M	M-PRP	RIGHT	**LEFT**	GRADE 1	4/11/2020	110,000	885,000	15.06.2020	######	670,000	NO	NO	7	6	4	2	56	48	32	28	27	0-120	0-120	0-125	0-130	0-125	0-130	0-130	0-130	SWELLING
48	888147	49	M	M-PRP	**RIGHT**		GRADE 1	4/15/2020	286,000	890,000	18.06.2020	######	990,000	YES	YES	8	6	4	5	54	48	33	24	29	0-120	0-120	0-125	0-130	0-125	0-130	0-130	0-135	
49	888183	49	F	M-PRP	**RIGHT**	**LEFT**	GRADE 1	4/18/2020	128,000	830,000	19.07.2020	######	820,000	NO	NO	8	6	5	1	58	40	36	26	26	0-120	0-110	0-125	0-120	0-130	0-125	0-130	0-130	
50	880977	54	F	M-PRP	**RIGHT**	LEFT	GRADE 2	4/21/2020	234,000	910,000	23.06.2020	######	780,000	YES	NO	8	6	5	1	52	48	38	26	26	0-110	0-120	0-120	0-130	0-125	0-130	0-125	0-130	
51	882684	56	M	M-PRP	**RIGHT**	LEFT	GRADE 1	4/26/2020	260,000	1,010,000	21.07.2020	######	670,000	NO	NO	8	6	5	1	52	46	34	24	27	0-120	0-130	0-125	0-130	0-130	0-130	0-135	0-135	
52	881428	57	M	M-PRP	RIGHT	**LEFT**	GRADE 1	4/28/2020	291,000	695,000	13.07.2020	######	562,000	YES	NO	8	6	5	2	58	48	38	28	28	0-120	0-110	0-125	0-120	0-130	0-130	0-135	0-135	
53	877027	60	M	M-PRP	**RIGHT**	LEFT	GRADE 2	4/30/2020	237,500	840,000	11.06.2020	######	670,000	NO	NO	8	6	4	1	56	44	36	24	27	0-110	0-130	0-120	0-130	0-125	0-130	0-130	0-130	
54	829822	64	M	M-PRP	**RIGHT**	**LEFT**	GRADE 2	5/4/2020	242,500	695,000	13.07.2020	######	762,000	YES	NO	9	6	6	4	54	42	38	26	29	0-120	0-135	0-125	0-135	0-130	0-135	0-135	0-135	
55	875390	42	M	M-PRP		LEFT	GRADE 1	5/6/2020	213,000	730,000	12.07.2020	######	820,000	NO	YES	8	6	5	2	52	44	34	24	25	0-135	0-120	0-135	0-120	0-135	0-125	0-135	0-130	
56	875311	44	M	M-PRP	**RIGHT**		GRADE 2	5/9/2020	232,600	815,000	13.08.2020	######	780,000	NO	NO	8	6	5	1	56	42	36	22	28	0-110	0-135	0-120	0-135	0-135	0-130	0-135	0-135	PAIN
57	874395	45	F	M-PRP	RIGHT		GRADE 2	5/13/2020	245,000	660,000	24.08.2020	######	450,000	NO	NO	8	6	5	2	52	46	38	16	26	0-120	0-135	0-130	0-135	0-130	0-135	0-135	0-140	PAIN
58	832922	45	F	M-PRP	**RIGHT**		GRADE 2	5/21/2020	260,000	845,000	17.08.2020	######	640,000	NO	NO	8	6	5	4	56	44	40	20	27	0-120	0-130	0-125	0-130	0-125	0-130	0-130	0-135	
59	873031	42	F	M-PRP	RIGHT		GRADE 2	5/25/2020	285,000	920,000	3.07.2020	######	789,000	NO	NO	8	6	5	1	58	50	36	24	29	0-110	0-135	0-120	0-135	0-135	0-135	0-125	0-135	
60	869920	56	F	M-PRP	**RIGHT**	LEFT	GRADE 2	5/26/2020	127,000	424,000	4.07.2020	######	568,000	NO	YES	7	6	4	2	54	46	38	24	31	0-110	0-120	0-120	0-130	0-130	0-130	0-135	0-135	
61	847174	48	F	M-PRP	**RIGHT**	LEFT	GRADE 2	5/30/2020	197,000	911,000	6.08.2020	######	793,000	YES	NO	7	6	5	2	52	48	36	26	27	0-110	0-120	0-130	0-130	0-130	0-130	0-135	0-135	
62	826154	40	M	M-PRP	**RIGHT**	**LEFT**	GRADE 2	5/30/2020	103,000	945,000	5.07.2020	######	548,000	NO	NO	8	6	5	2	50	42	36	24	31	0-120	0-110	0-130	0-120	0-130	0-125	0-135	0-135	
63	875903	50	M	M-PRP	**RIGHT**	LEFT	GRADE 2	5/30/2020	220,000	880,000	4.07.2020	######	624,000	NO	NO	7	6	5	1	60	44	38	24	27	0-110	0-120	0-120	0-130	0-130	0-130	0-135	0-135	PAIN, SWELLING
64	856342	60	F	M-PRP	**RIGHT**	LEFT	GRADE 2	5/31/2020	276,000	873,000	5.08.2020	######	873,000	YES	NO	8	6	5	1	56	48	40	26	29	0-120	0-110	0-130	0-120	0-130	0-125	0-135	0-130	