"COMPARATIVE STUDY OF INTRAVENOUS DEXMEDETOMIDINE VERSUS INTRAVENOUS MIDAZOLAM IN PROLONGING SPINAL ANAESTHESIA WITH ROPIVACAINE"

By

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In partial fulfillment of the requirements for the degree of

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IN

ANAESTHESIOLOGY

Under the Guidance of

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ABBREVATIONS

Glossary	Abbreviations
GABA	Gamma aminobutyric acid
NMDA	N-methyl-D-aspartate
α-2	Alpha 2
CNS	Central Nervous System
SAB	Sub Arachanoid Block
mcg	Microgram
kg	Kilogram
hr	Hour
Min	Minute
CSF	Cerebrospinal fluid
L1	1st lumbar vertebrae
L3	3rd lumbar vertebrae
L4	4th lumbar vertebrae
L5	5th lumbar vertebrae
S2	2nd Sacral vertebrae
S3	3rd Sacral vertebrae
T4	4th Thoracic vertebrae
T10	10th thoracic vertebrae
$t_{1/2}$	Half life
µg	microgram
EA	Epidural anaesthesia
pH	Potential of hydrogen ion

mg	milligram
VAS	visual analogue scale
Group M	Group Midazolam
Group D	Group Dexmedetomidine
n	Number
DEX	Dexmedetomidine
RSS	Ramsay sedation score
IV	intravenous
T12	12^{th} thoracic vertebrae
L1	1^{st} lumbar vertebrae
BIS	Bi spectral index
PACU	Post anaesthesia care unit
CI	Confidence interval
RD	Ropivacaine + dexmedetomidine
RF	Ropivacine + Fentanyl
ASA	American society of anaesthesiologists
OT	Operation theatre
L	Litre
MBS	Modified bromage Score
SPO_2	Saturation of peripheral oxygen
Q-Q plot	Quantile - Quantile plot
IBM SPSS	International business machines statistical package for the social sciences
SD	Standard Deviation
P valve	Probability value
IQR	Interquartile range
bpm	Beats per minute
mm/hg	Millimeters of mercury
PR	Pulse rate

SBP	Systolic blood pressure
DBP	Diastolic blood pressure
MAP	Mean arterial pressure
kgs	kilogram
HR	Heart rate
BP	Blood pressure
RR	Respiratory rate

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ABSTRACT

"COMPARATIVE STUDY OF INTRAVENOUS DEXMEDETOMIDINE VERSUS INTRAVENOUS MIDAZOLAM IN PROLONGING SPINAL ANAESTHESIA WITH ROPIVACAINE"

ABSTRACT

BACKGROUND:

Spinal anaesthesia is the preferred choice of anaesthesia for the surgery below the umbilicus mainly due to easy of administration, rapid onset, efficient sensory and motor blockage, minimal cost and safety

AIMS:

The study's aim is to examine the effects of intravenous dexmedetomidine against midazolam on motor and sensory block duration, as well as analgesia, in patients having lower abdomen and lower extremities procedures using intrathecal ropivacaine anaesthesia.

MATERIALS & METHODS:

Cross section analytical study conducted for a time period of 1 year 5 months from January 2020 to May 2021.

RESULTS:

A total of 70 participants were listed in the study. The mean age (years)in the dexmedetomidine and midazolam group were identified as 45.17 ± 15.23 and 45.86 ± 15.9 respectively. The average onset of sensory block was identified as 3 (2 to 4) and 4 (3 to 4) in the dexmedetomidine and midazolam group. Whereas, the average onset of motor block was identified as 9 (8 to 9) and 8 (8 to 9) in the dexmedetomidine and midazolam group. Duration of analgesia (mins) was high in the dexmedetomidine group with 173.89 ± 14.81 as compared to the midazolam group with 142.83 ± 17.31.

CONCLUSION: Our findings showed that intravenously administered dexmedetomidine and midazolam may both prolong the duration of sensory and motor blockade, but dexmedetomidine has a longer duration of analgesia than midazolam. As a result, we recommended it for use under spinal anaesthesia, albeit heart rate should be closely monitored.

INTRODUCTION:

Spinal anaesthesia emerged as most favored anaesthesia for surgeries below the umbilicus area due to its sensory and motor blockage with a quick onset. with spared spontaneous respiration, considerable ease of administration, low cost, reduced blood loss, safety in patients with full stomach and the intestines and abdominal wall are completely relaxed, making surgery easier., eliminating the need for Intubation, and earlier return of intestinal motility.[1]Haemodynamic disturbances, failed spinal block, and failure to last for the duration of extended surgery are all problems of spinal anaesthesia that make it inappropriate for psychologically disturbed individuals. Total high spinal or spinal anaesthesia, headache, postdural puncture waist and back pain, and urine retention are few of the consequences.[2]

Different adjuvants like opioids, GABA agonist, calcium channel antagonist, adrenergics, NMDA receptor antagonist, cholinesterase inhibitors have been utilized to increase duration of spinal anaesthesia, with the decreased postoperative analgesic requirements .[34]Additionally, these agents help to ease the anxiety and fear of the patient with their calming effects.

The α-2 adrenergic agonists are being widely utilized as adjuvants as they deliver sedation, hypnosis, analgesia and sympatholysis without leading to respiratory depression. Previous studies has reported significant increase in the extent of the sensory and motor blockade with intrathecal addition of α-2 adrenergic agonists on local anaesthetics and hence, synergistic interaction between the two.[5],[6].Although, there exists dearth of literature regarding effects of intravenous α-2 agonists on the time period of spinal anaesthesia with ropivacaine.

Midazolam is an ideal supplemental sedative due of its quick onset and quick recovery. It delivers consistent depth of amnesia, effective anxiolysis, no signs of cumulation, and a speedy and clear-headed recovery, all with minimum side effects.[7]

Dexmedetomidine is a strong alpha 2 agonist with a high specificity for alpha 2 receptors. Analgesia, sedation, sympatholysis, and anxiolysis are all regulated by receptors in the locus coeruleus.. They can be found in various places throughout the body, including the spinal cord, peripheral tissues, and the central nervous system (CNS). The activation of alpha 2 receptors in the dorsal horn's substantia gelatinosa suppresses substance P release in the spinal cord.. Despite evidence for both supraspinal and peripheral sites of action, the spinal mechanism is the most important for dexmedetomidine's analgesic effects.[8]

NEED FOR THE STUDY

Dexmedetomidine has been demonstrated to extend the time period of sensory and motor blockade achieved by SAB while keeping the patient awake. When used as an adjuvant to prilocaine, hyperbaric ropivacaine, isobaric, and hyperbaric bupivacaine, several studies found that the sensory and motor blocks of spinal anaesthesia were prolonged with good sedation and a few adverse effects when administered intravenously at 1 mcg/kg loading dose over 10-20 mins and maintenance dose of 0.4-0.5 mcg/kg/hr.[910].It did not impair or disinhibit cognitive function in any way. The goal of this study was to examine the effects of intravenous midazolam with dexmedetomidine on sensory and motor block duration, as well as analgesia, in patients having lower extremities and lower abdomen procedures with intrathecal ropivacaine anaesthesia.

AIMS AND OBJECTIVES:

The study's aim is to examine the effects of intravenous dexmedetomidine against midazolam on sensory and motor block duration, as well as analgesia, in patients having lower limb and lower abdomen procedures using intrathecal ropivacaine anaesthesia.

REVIEW OF LITERATURE:

Spinal anesthesia

- Define

Spinal anaesthesia is a type of neuraxialanaesthesia in which the local anaesthetic is injected into cerebrospinal fluid in the lumbar spine in order to anesthetize nerves that exit the spinal cord. [11]Rapid onset of action, economical, easy to administer, lower side effects rate and shorter post-anaesthesia care unit stay are the pros of spinal anaesthesia. [1213]

Disadvantages includes the following [14]

a) Difficult needle placement
b) Inability to obtain CSF
c) Hypotension
d) Urinary retention
e) Infection
f) Possible conversion to general anaesthesia

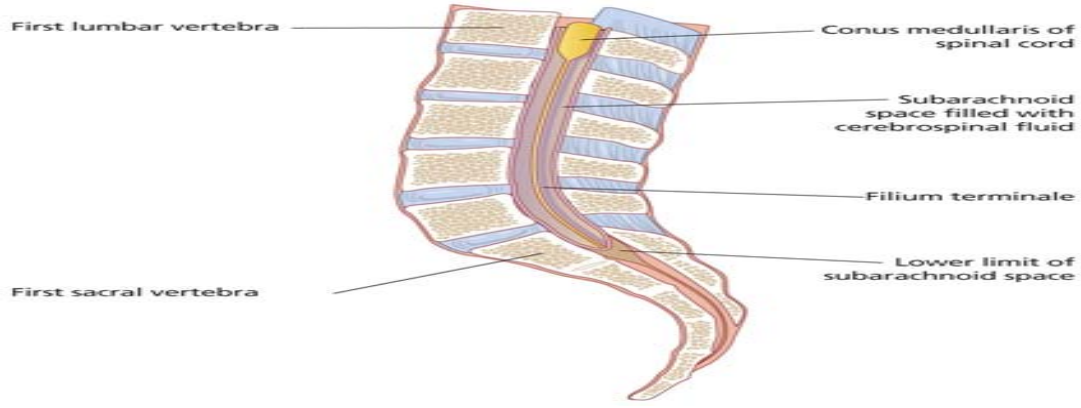
- Anatomy and physiology of spinal cord,

Appropriate positioning and knowledge of neuraxial anatomy are required for the administration of spinal anaesthesia. The delivery of adequate dose of anesthetic into the intrathecal (subarachnoid) space is the main the purpose of spinal anaesthesia. The spine is composed of seven cervical, twelve thoracics, five lumbar and five fused sacral vertebral bones. There is articulation of joints and ligaments where vertebrae are stacked end to end. It has a hollow space running through them referred as the spinal canal. The spinal cord is built in this canal. The lateral gaps between the pedicles of adjacent vertebrae are where the spinal nerves exit the spinal canal.

The lumbar area is where spinal anaesthesia is administered, primarily in the mid to lower lumbar levels, in order to protect the spinal cord and prevent any activity in the upper thoracic and cervical regions produced by intrathecally injected medications.The Conus medullaris is the caudal end of the spinal cord. It can be found on either the first or second lumbar vertebral body's lower border. It is a little less inferior in the paediatric population, usually ending around L3.In the adult population, the average conus position is in the lower part of L1. Conus position variation follows a normal distribution pattern. The majority of the dural sac extends to S2/3. As a result, the spinal needle is usually inserted in the L3/4 or L4/5 interspace for spinal anaesthesia. Spinal cord trauma is more prevalent when individuals choose higher interspaces, and it is more common in obese people.[15]

The needle crosses a lot of structures as it enters and starts at the skin. The method determines which structures are traversed. Understanding the level of blocking of target structures requires knowledge of dermatomal anatomy. Incisions for lower abdominal caesarean sections, for example, are frequently done below the T10 dermatome. To reduce the discomfort or suffering caused by peritoneal pulling, T4 dermatome covering is required.[16]

Figure 1: Anatomy of spinal cord. [17]



- Indications,

Neuraxial anaesthesia can be used as combination with general anaesthesia or single anaesthetic or for the procedures performed below the neck. For surgeries involving the lower abdomen, pelvis, perineum, and lower extremities, spinal anaesthesia is routinely used. it is also useful for procedures below the umbilicus. It is considered as the best for short procedures. [16]

- Contraindications,

Absolute contraindication of spinal anaesthesia includes the following [1819]

- Lack of consent from the patient
- Raised pressure mainly due to the infection at the procedure's area and intracranial mass

Relative contraindications includes the following

- Pre-existing neurological condition.
- Severe dehydration due to the risk of hypotension - Hypovolemia, age more than 40 to 50 years, emergency surgery, obesity, alcoholism that is chronic and chronic hypertension are the risk factors identified for hypotension.
- Thrombocytopenia or coagulopathy
- Severe valvular diseases.
- Left ventricular outflow obstruction

- Procedure,

History and physical examination are taken before the induction of neuraxial anaesthesia. Previous exposure to anaesthetic medication, review of allergies and family history of any anaesthetic problems can be gathered from the history of the patient. The physical examination is the focus of the spinal anaesthetic placement. The pre-procedural neurological assessment for strength and for systemic

or local skin infections, spinal abnormalities. Confirm the patient's name, proposed procedure, allergy, check for consent, and vocal statement of coagulation status during a procedural time-out.

After the patient has been properly selected, the best position for the procedure should be determined. The patient is usually in a sitting or lateral decubitus position during the surgery. The purpose of placement is to provide a straight passage for the needle to pass through between the vertebrae of the spine. In the lateral decubitus position, the spinal anatomy is not as symmetrical as it is in the sitting position. As a result, the sitting position is the most common.

The patient should be encouraged to maintain a flexed spine position in the sitting position, with one leg hanging over the edge of the bed, since this helps to open up the interspace. For spinal anaesthesia with a hyperbaric solution, the sitting position is ideal.

Palpation is done to choose the access site once the patient is in the right position. Because of the amount of subcutaneous fat between the skin and the spinous process, it is considered exceedingly difficult in obese people. The site of entrance is the gap between the two perceptible spinous processes. To maintain asepsis, the patient should cover his or her hair.

Strict aseptic procedure is always necessary, which can be done by using alcohol-based chlorhexidine antiseptics, hand-washing, and wearing a mask and cap. Cleaning usually begins by going in circles around the chosen approach site and then moving away from it. Allow time for the cleaning solution to dry. The drape is placed on the patient's back in the spinal kit to isolate the area of access. Skin infiltration is performed with a local anaesthetic, and a wheal is established at the access point, which is either midline or paramedian.

The midline approach to the intrathecal space is taken from the spine, with a straight line shot. The spinal needle is inserted into the skin, oriented slightly cephalad, after infiltration with lidocaine. The needle passes through the skin and into the subcutaneous fat. The supraspinous and interspinous ligaments will be engaged when the needle penetrates further. This will be interpreted by the practitioner as an increase in tissue resistance. The ligamentum flavum, which is identified as a "pop," will come next. The epidural space is approached after popping through this ligament. It is where epidurally delivered drugs and catheters are placed. It also shows the point at which the injection of saline or air causes a reduction of resistance. For spinal anaesthesia, the practitioner continues needle insertion until the dura-subarachnoid membranes are penetrated, as shown by free-flowing CSF. It was at that point that spinal medication is given.

The skin wheal from the local anaesthetic is implanted about 2 cm from the midline in the paramedian technique, and the spinal needle progresses at an angle toward the midline. This method avoids using the supraspinous and interspinous ligaments.. [16]

- Complications

Complications associated with the spinal anaesthesia consists of the following [20212223]

a) Backache
b) Postdural puncture headache
c) Nausea
d) Vomiting
e) Hypotension
f) Low-frequency hearing loss
g) Total spinal anesthesia
h) Neurological injury

i) Spinal hematoma

j) Arachnoiditis

k) Transient neurological syndrome

Adjuvants for prolonging spinal anaesthesia

- Adjuvants,

Adjuvants are medications that work synergistically with local anaesthetics in order enhance the and quality and duration of analgesia in regional techniques. [24]Opioids (morphine, fentanyl and sufentanil), α_2 adrenergic agonists (dexmedetomidine& clonidine), magnesium sulfate, neostigmine, ketamine, and midazolam are the adjuvants used to increase the quality of spinal anaesthesia for intrathecal local anaesthetics. [25]

- Classification of adjuvants and how adjuvants are used in prolonging spinal anaesthesia

The speed of onset and duration of analgesia can be improved by the addition of adjuvants. It can also counteract disadvantageous effects of local anaesthetics. The dose of local anaesthetics such as bupivacaine can be reduced by the addition of adjuvants. Hence, reduces its side effects such as myocardial depression, hypotension, bradycardia, heart block, and ventricular arrhythmias.

Adjuvants used for both peripheral and neuraxial nerve blocks are divided into non-opioids and opioids. Epinephrine, α_2-adrenoceptor agonists (clonidine and dexmedetomidine), acetylcholine esterase inhibitors (neostigmine), adenosine, ketorolac, midazolam, magnesium, sodium bicarbonate and hyaluronidase are included in non opioids while, lipophilic (fentanyl and sufentanyl) and hydrophilic (morphine) are included in opioids.[26]

Alpha$_2$-adrenergic agonists such as clonidine have enhanced the horizons of regional anaesthesia. Co-administration of clonidine together with local anaestheticsepidurally are practiced in abdominal surgeries, total knee replacement surgeries, labor analgesia, chronic pain and cancer pain treatment. [2728]

Role of intravenous dexmedeomidine in prolonging spinal anaesthesia

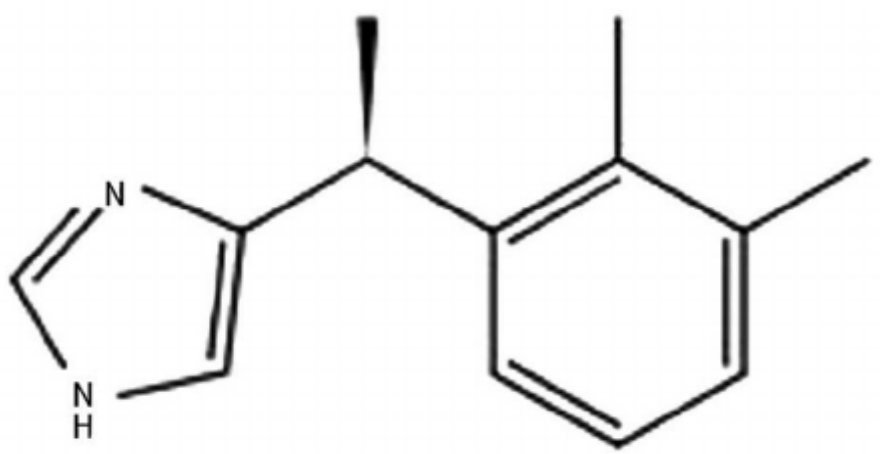


Figure 2: Chemical structure of dexmedeomidine[29]

Intranasal, intramuscular, buccal, sublingual, intragastric, neuraxial, regional, intraarticular are the several routes of administration of dexmedetomidine.[303132]. Pharmacokinetics of the active dexmedetomidine does not change with age, sex or in renal failure patients .[33]It undergoes more than 95% of biotransformation in liver into all inactive metabolites. [3435] It is main to reduce the typical dose of dexmedetomidine in hepatic failure patients, since there is significant $t_{1/2}$ in hepatic failure (7.5 hours). The elimination half-life is approximately 2 hours in healthy patients. [3637]

Minimal respiratory depression with cardioprotection, neuroprotection and renal protection are the advantages of dexmedetomidine.

Hypotension, bradycardia and hypertension are the most frequentadverse effects of dexmedetomidine. Stimulation of alpha subtypes of receptors in the vascular smooth muscles can cause hypertension. It can be prevented either by slow administration or omission of loading dose. Stimulation of presynaptic alpha receptors can lead to hypotension and bradycardia. [38]

As adjuvant to regional anaesthesia: α_2 adrenergic agonists have the analgesic and sedative properties when administered as an adjuvant in regional anaesthesia.

As an adjuvant to neuraxialanaesthesia: Intrathecal α_2 receptor agonists are identified to have antinociceptive action for the somatic and visceral pain. New experimental studies suggests that dexmedetomidine produces a dose-dependent increase in the period of the motor and sensory blocks induced by local anaesthetics regardless of the neuraxial route of administration (epidural, caudal or spinal).

Researchers have concluded that the 3 μgdexmedetomidine and 30 μg clonidine are equipotent when administered intrathecally. The addition of 5 μg of intrathecal dexmedetomidine can prolong the post-operative analgesic effect of ropivacaine by 8 hours.

Tekin et al study concluded that intravenous dexmedetomidine can remarkably increases the duration of motor block and sensory of spinal anaesthesia and can also provides a significantly high plane of sedation as compared to placebo in young surgical patients. The dose of clonidine is 1.5 to 2 times more than dexmedetomidine when administered in epidural route. Recommended dose of dexmedetomidine as an adjunct for EA is 1.5-2 μg /kg.[39]

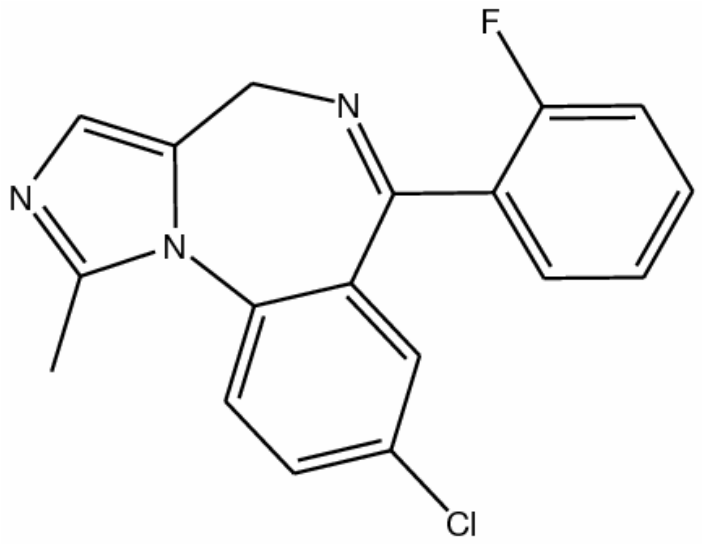
Figure 3 : Pharmacological actions and Indications of dexmedeomidine[39]

Pharmacological Actions	Clinical Use
Anxiolysis, antisialogouge, sedation	Premedication
Attenuation of pressor response to intubation, stable HD	Perioperative use in high risk patients
Analgesia, sedation, reduction in dose of general anaethetics & opioids	Adjuvant in general anaethesia
Reduction in dose & prolongation of action of LAs, antishivering	Adjuvant in locoregional anaethesia
Sympatholysis, renal protection	Controlled hypotension
Bioavailability by various noninvasive routes, minimal respiratory effect, smooth induction & emergence	Use in paediatrics, For monitored anaesthesia care
Minimal respiratory effect, stable HD	Use in upper airway surgery, morbidly obese patients

Role of intravenous midazolam in prolonging spinal anaesthesia

Midazolam is a benzodiazepine with a short elimination half-life. It also has a short duration of action and is un-ionized and lipophilic at physiological pH. As a result the onset of action after intravenous administration is rapid. The short elimination half-life and the negligible hypnotic effect of its metabolites makes its administration by intravenous infusion useful. [40]

Figure 4 : Chemical structure of midazolam [41]



Hiccoughs, cough, nausea, and vomiting, thrombophlebitis, thrombosis and pain on injection site are the common adverse effects. It also causes anterograde amnesia, drowsiness, ataxia, falls, and confusion in the elderly. Hypotension and tachycardia are identified with rapid intravenous administration. While, midazolam infusion syndrome and respiratory depression are identified with higher doses of midazolam. Respiratory depression can occur with a dose of 0.15 mg/kg. Acute angle-closure glaucoma, shock and hypotension are contraindications identified for midazolam. [42] Caution is necessary in patients with kidney and liver diseases, alcohol, drug-dependent individuals, pregnant individuals, children and individuals with comorbid psychiatric conditions. Intravenous midazolam is used for the induction of anesthesia and in the management of acute seizures. It is also used for the anxiolysis and hypnosis. [42]

Comparison of efficacy of intravenous midazolam with dexmedetomidinein prolonging spinal anaesthesiaregarding sensory and motor block duration analgesia in patients undergoing lower abdomen and lower limb procedures with intrathecal ropivacaine anaesthetic, and their efficacy in sedation

BalwinderKaurRekhi, et al., [43]concluded in his study, that intravenous dexmedetomidine, and not midazolam, can prolong spinal anaesthesia. It also produced sedation as well as additional analgesia. As a result, it was determined that dexmedetomidine is safe to use during spinal anaesthesia, though the heart rate must be monitored closely.

In Swetha N Sivachalam, et al., [44] study it was stated that the conscious sedation with intravenous dexmedetomidine at a loading dose of 0.5 μg/kg followed by a maintenance dose of 0.5 μg/kg/hr can enhance the duration of spinal anesthesia as compared with the midazolam at a loading dose of 0.03 mg/kg followed by a maintenance dose of 0.03 mg/kg/hr in patients undergoing infraumbilical surgeries. Also, dexmedetomidine is associated with more incidence of hemodynamic instability.

L, Chen et.al., (2021) had conducteda comparative study of dexmedetomidine versus and midazolam of patients who undergoing flexible bronchoscopy during general anesthesia. The patients were randomized into a two groups, dexmedetomidine group (Group D, n=40, 0.5μg/kg) and a midazolam group (Group M, n=40, 0.05 mg/kg) intravenously 10 min prior to induction. A likert scale survey conducted on ramsay sedation scale score (Ramsay score) and visual analogue scale (VAS) score were assessed and recorded. Patients in-group D had both Ramsay scores and VAS scores higher (2.9±0.6 and 79.4±4.0, respectively) than group M (2.4±0.7 and 75.0±6.0, respectively), with a statistically significant difference ($P<0.05$) between groups.

These the conclusions of the study produce a more efficacious sedation effect during the recovery period and improve the comfort level and satisfaction of patients.[45]

The prospective, randomized, comparative, and double-blinded study was conducted by **Kumar, Sanjay et. al., (2020)** to determine the effect of spinal block period by the one intravenous bolus dose of midazolam with dexmedetomidineand sedation in patients undergoing infra-umbilical surgeries. The 100 patients of (18-69 years) were included and divided into 2 groups (Group D and Group M). Dexmedetomidine group of (Group D, 0.5 μg.kg) and midazolam group (Group M, 0.05 mg.kg) as premedication 5 min before spinal anesthesia over 10 min. Vital parameters, Ramsay sedation score, duration of analgesia and few more scale were recorded and analyzed. The result and conclusion of the study dexmedetomidine prolonged increased the highest upper level of only sensory component of spinal anesthesia (6.42 ± 3.21 vs. 4.8 ± 1.21 thoracic segments higher than with midazolam sedation) and preventing undesirable prolongation of motor block and facilitating early ambulation in shorter of infra-umbilical surgeries. [46]

A prospective, double-blind, randomized control comprising study was conducted by **Abhishek, MS and Nagraj, TR et. al., (2020)** had finding the effectiveness of dexmedetomidine and clonidine in improving the analgesia quality and duration of the subarachnoid block. The includes 70 patients and were divided into two groups (Group C, n=35, isobaric ropivacaine with clonidine 1.0 μg./kg and (Group D, n=35, isobaric ropivacaine with dexmedetomidine 0.5 μg/kg intravenously. Preoperatively, heart rate, systolic blood pressure, diastolic blood pressure, and duration of sensory blockade were recorded. Time of onset of sensory block in Dexmedetomidine and Clonidine group was 2.70 ± 1.25 minutes and 3.50 ± 1.23 minutes respectively (P = 0.021). Similarly for time of onset of motor block, Time for 2 segment regressions of

sensory block were measured respectively. Hence, dexmedetomidine post operatively prolongs the duration of sensory and motor block significantly when compared to clonidine.[47]

M, Javahertalabet. al., (2020) had conducted a comparative study on the effectiveness of intravenous dexmedetomidine and clonidine for hemodynamic changes and block after spinal anesthesia with ropivacaine. The total 120 patients are included and divided into 3 groups using balanced block randomization: DEX group (n = 40; intravenous DEX 0.2 μg/kg), clonidine group (n = 40; intravenous clonidine 0.4 μg/kg), and placebo group (n = 40; intravenous normal saline 10 mL) in which pain scores were assessed using visual analogue scales and time to achieve and onset of sensory and motor block. Statistically significant differences were found in mean baseline (P = 0.001), Simultaneous administration of intravenous DEX with ropivacaine for spinal anesthesia prolongs the duration of sensory and motor block and relieves postoperative pain, and however, can decrease blood pressure. Although intravenous DEX as an adjuvant can be helpful during spinal anesthesia with ropivacaine.[48]

The prospective randomized control study was conducted by **Sivachalam, SwethaNet. al., (2019)** the comparative effects of midazolam with dexmedetomidine on duration of spinal anesthesia. The 43 patients were randomized into two groups. Group A received a loading dose of 0.5 μg/kg followed by 0.5 μg/kg/h of i.v.dexmedetomidine. Group B received a loading dose of 0.03 mg/kg followed by 0.03 mg/kg/h of i.v. midazolam. The mean time for two dermatomal regressions was significantly extended in Group A (2.3 ± 0.4 hr) than Group B (1.6 ± 0.5 hr, P = 0.001). Mean time for sensory was also prolonged in Group A (5.2 ± 0.83 hr) than in Group B (4.4 ± 0.87 hr, P = 0.01). Glycopyrrolate was administered in 45% of

patients in Group A and 21% in Group B, which was statistically significant (P = 0.039). However, dexmedetomidine is associated with higher incidence of hemodynamic instability.[49]

A prospective randomized double blind study was conducted by **Savant, KBet. al., (2017)** had a comparative and effect of intravenous dexmedetomidine infusion with intravenous midazolam infusion during spinal anaesthesia. The 60 patients were included and divided into 2 groups. In Group D, n=30, dexmedetomidine 1 μg/kg and In Group M, n=30, midazolam 0.04 mg/kg basal infusion for 10 min then S/A was given with hyperbaric bupivacaine (0.5%). Dexmedetomidine 0.5μg/kg/hr in group D and Inj. Midazolam 0.04mg/kg/hr by infusion started. The mean time required to achieved sedation score (RSS) of 3 were statistically significant shorter in group D as compared to in group M ($P < 0.05$). At the end of surgery, after stoppage of infusion of study drug, patients of group D achieved RSS score of 2 and that of group M which was comparable ($p > 0.05$). Thus, we conclude that, Dexmedetomidine provide rapid onset arousable sedation without causing respiratory and cardiovascular depression. [50]

The placebo-controlled single-blind study was conducted by **BK, Rekhiet. al., (2017)**compare intravenous midazolam to dexmedetomidine and placebo in terms of analgesia and sedation in patients undergoing lower abdominal and lower limbsurgeries with intrathecal ropivacaine anaesthesia. A total of 60 study participants were included and divided into three groups (n=20 each group). All patients received ropivacaine (15 mg) for spinal anaesthesia. Group D received a loading dose of 1 g/kg minutes, followed by a continuous infusion (0.5 g/kg/hr) over 10 minutes, whereas Group M received a loading dose of 0.05 mg/kg, followed by a continuous infusion (0.02 mg/kg/hr), and Group C received normal saline. When comparing Group D patients' sensory block duration (20819.358 minutes) to Group M and C patients'

sensory block duration (177±15.252 minutes) and other parameter duration (177±17.800 minutes), it was discovered that Group D patients' sensory block duration was significantly longer (208±19.358 minutes).. Hence, dexmedetomidine can be used safely during spinal anaesthesia, although heart rate needs to be monitored cautiously.[51]

Agrawal, Akansha et. al., (2016) had conducted a study to find the different routes of administration of alpha2 adrenergic receptor agonists have been found to longer the duration of spinal block. A 120 (18-60 years) patients with physical status I or II posted for elective fixation of fractures of lower limb under spinal anesthesia were selected. Spinal anesthesia was administered with 2.5 ml of 0.5% bupivacaine mixed with 10 μg fentanyl. The randomly divided into two groups intravenous (IV) dexmedetomidine 1 μg/kg/h for 15 min followed by infusion of 0.3 μg/kg/h (Group I), and IV Clonidine 2 μg/kg/h for 15 min followed by infusion of 0.5 μg kg/h (Group II). Sensory and Motor blockade were evaluated and time of regression of sensory block to T12/L1 dermatome was 230.75 ± 21.25 min (Group I), 196.25 ± 20.27 min (Group II) and 163.88 ± and regression of motor blocks to Bromage respectively, Bradycardia was seen in one patient in Group I and two patients in Group II. Hence, the dexmedetomidine produces a better clinical profile compared to clonidine.[52]

YY, Jo et. al., (2016) had conducted a comparative study for patients who underwent spinal anesthesia with midazolam or dexmedetomidine on hemodynamics and recovery profiles and the effects of bispectral index (BIS). A 160 adult patients were included, divided into two groups, Group D dexmedetomidine (dexmedetomidine group; n=58), and Group M midazolam (midazolam group; n=58) during spinal anesthesia. Bradycardia occurred more frequently in the dexmedetomidine group ($P<0.001$). Mean Ramsay sedation score was significantly lower in the

dexmedetomidine group after arrival in the PACU (P=0.025) Hypotension occurred more frequently in the midazolam group (P<0.001). Hence, BIS-guided dexmedetomidine sedation can attenuate intraoperative hypotension, but induces more bradycardia, and delays recovery from sedation in patients during and after spinal anesthesia as compared with midazolam sedation.[53]

Kiran Kumar S and KishanRao B (2015)had conducted a comparative study on clonidine, dexmedetomidine are used to local anaesthetics in order to increasethe duration of spinal anaesthesia. The duration of motor and sensory block, sedation scores, intra-operative haemodynamic stability of the patients, intraoperative and post-operative analgesia and side effects between the groups. The time of onset of sensory block (2.58±1.18min) and motor block (3.54+0.45min), time for attaining peak level of sensory block (11.6±1.9 min) were significantly reduced in dexmedetomidine group compared to clonidine and control groups. The Duration for 2 dermatomal Regression of sensory blockade (137.4±10.9 mins), duration of sensory blockade (269.8±20.7min) and duration for motor block regression to Modified Bromage scale 0 (220.7±16.5 mins) prolonged significantly than clonidine and control groups. The heart rate, systolic, diastolic and mean arterial pressures were stable indicating the hemodynamic stability. Hence, that intravenous dexmedetomidine and clonidine prolong the spinal anaesthesia and dexmedetomidine was an effective adjuvant than clonidine for bupivacaine spinal anesthesia.[54]

Rani, H.L. and Upendranath, I. (2015) had conducted a study on to evaluated whether bupivacaine alone could provide a non inferior duration of block compared with bupivacaine and fentanyl when intravenous dexmedetomidine was given intraoperatively. A 56 patients were included and undergone to the knee arthroplasty under spinal anesthesia. They were divided into two groups bupivacaine 13 mg with

intrathecal fentanyl 20 µg (Group BF) or bupivacaine 13 mg (Group B). Both groups underwent intravenous dexmedetomidine sedation throughout the surgery (1 µg /kg for 10 min, followed by 0.5 µg kg /hr). The primary result was the time to two-segment regression of the sensory block. Secondary outcomes included consumptions, and the incidences of pruritus, nausea, and vomiting. There was no significant difference in the two-segment regress time of sensory block, The mean difference in the two-segment regress time among the 2 groups was 4.8 min (95 % CI -8.9 to 18.6), demonstrating the non-inferiority of bupivacaine alone. Hence, result concluded that intrathecal fentanyl may not be required when intravenous dexmedetomidine is administered.[55]

The prospective, randomized, double blind, placebo controlled study was conducted by **Samantaray, Alokaet. al., (2015)**the effects of adding dexmedetomidine or midazolam to intrathecal bupivacaine on the duration of effective analgesia and the clinical safety profile are being investigated. A total of 60 patients were randomly assigned to one of three groups, each of which received 3 mL of 0.5 percent hyperbaric bupivacaine in combination with 5 mcg dexmedetomidine (dexmedetomidine group), 1 mg midazolam (midazolam group), or 0.5 mL of 0.9 percent saline (0.9 percent saline group) (control group). The groups were compared in terms of sensory block regression time, effective analgesia duration, and side effects. TWhen compared to the midazolam group (236.9 ±64.9 minutes) and the control group (212.7± 70.2 minutes), the duration of effective analgesia (time to first analgesic request) was substantially longer in the dexmedetomidine group (286± 64 minutes, P <0.01). Midazolam had no effect on the time it took for the two-segment sensory regression or the time it took to request analgesia for the first time. In compared to 1 mg midazolam or placebo (0.9 percent normal saline), the addition of

dexmedetomidine (5 mcg) to 3 mL of intrathecal hyperbaric bupivacaine (0.5 percent) significantly prolongs the duration of effective analgesia with comparable occurrences of adverse effects..[56]

The researchers conducted a prospective, randomised, double-blind, placebo-controlled experiment By **Lee, MiHyeonet. al.,(2014)** had evaluate to detect appropriate amounts of single-dose dexmedetomidine to lengthen the duration of spinal anesthesia. 60 patients were included and divided into three different groups receiving normal saline (control group, n = 20) or 0.5 or 1.0 ug/kg dexmedetomidine (D-0.5 group, n = 20; D-1, n = 20) intravenously prior to spinal anesthesia with 12 mg of bupivacaine. The two-dermatome pinprick sensory regression time (57.6 ± 23.2 vs 86.5 ± 24.3 vs 92.5 ± 30.7, P = 0.0002) and duration of the motor block (98.8 ± 34.1 vs 132.9 ± 43.4 vs 130.4 ± 50.4, P = 0.0261) were significantly increased in the D-0.5 and D-1 groups than in the control group. The RSS were significantly higher in the D-0.5 and D-1 groups than in the control group. Hence, the both 0.5 and 1.0 ug/kg of dexmedetomidine administered as isolated boluses in the absence of infusions prolonged the duration of spinal anesthesia.[57]

The prospective, randomized double-blind study was conducted by **Kaur, Sarabjitet. al., (2014)** the when supplemented with ropivacaine, the hemodynamic, sedative, and analgesic potentiating effects of epidurally delivered dexmedetomidine were compared. A 100 (20-65 Years) patients were divided into 2 groups undergoing lower limb surgeries were included after taking informed consent. Epidural anesthesia was given with 150 mg of 0.75% ropivacaine in Group A (n = 50) and 150 mg of 0.75% ropivacaine with dexmedetomidine (1 μg/kg) in Group B (n = 50). Significant difference was observed in relation to the duration of sensory block (375.20 ± 15.97 min in Group A and 535.18 ± 19.85 min in Group B [P - 0.000]), duration of motor

block (259.80 ± 15.48 min in Group A and 385.92 ± 17.71 min in Group B [P - 0.000]), duration of post-operative analgesia (312.64 ± 16.21 min in Group A and 496.56 ± 16.08 min in Group B [P < 0.001]) and consequently low doses of rescue analgesia in Group B (1.44 ± 0.501) as compared to Group A (2.56 ± 0.67). Hence, Sedation score was significantly more in Group B in the post-operative period. [58]

The researchers conducted a prospective, randomised, double-blind, placebo-controlled experiment.by**Bhat, Sonal N. et. al., (2013)**to assess the efficacy and safety of ropivacaine with bupivacaine intrathecally in patients undergoing lower abdomen and lower leg surgery. A total of 70 patients, ranging in age from 18 to 65, were randomly assigned to one of two groups, each with 35 individuals. With standardised spinal anaesthesia, Group A received 3 ml of (0.5%) isobaric bupivacaine (15 mg) and Group B received 3 ml of (0.75%) isobaric ropivacaine (22.5 mg). Onset of motor blockade was rapid in both the groups but duration of motor blockade was significantly shortened in ropivacaine group. As a result, ropivacaine was found to be as safe and effective as bupivacaine for lower abdomen and lower limb procedures..[59]

Bajwa, SukhminderJit Singh wt. al., (2011)has done a comparison and effects of epidurally administered fentanyl and dexmedetomidine when paired with ropivacaine on hemodynamic, sedative, and analgesic potentiating. A total of 100 patients (aged 21 to 56) were enrolled in the study and were randomly assigned to one of two groups: Ropivacaine + Dexmedetomidine (RD, n=50) or Ropivacaine + Fentanyl (RF, n=50). In both groups, 15 ml of 0.75 percent ropivacaine was delivered epidurally, with 1 g/kg of dexmedetomidine in the RD group and 1 g/kg of fentanyl in the RF group. Various block properties were extensively evaluated in addition to cardio-respiratory parameters and sedation scores. The RD group had considerably earlier

onset of sensory analgesia (7.122.44 vs 9.142.94) and establishment of complete motor blockage (18.164.52 vs 22.984.78).The RD group had considerably longer postoperative analgesia (366.6224.42), resulting in lower dosage consumption of local anaesthetic LA (76.8214.28 vs 104.3518.96) during epidural top-ups. The RD group had considerably better sedation scores, which were extremely significant (P<0.001). Hence, dexmedetomidine seems to be a better alternative to fentanyl as an epidural adjuvant as it provides comparable stable hemodynamics, early onset, and establishment of sensory anesthesia.[60]

The double-blind randomized placebo-controlled trial study was conducted by **Kaya, FatmaNuret. al., (2010)**In patients undergoing transurethral resection of the prostate, researchers compared the effects of intravenous midazolam, dexmedetomidine, and placebo on spinal block duration, analgesia, and sedation.. Dexmedetomidine 0.5 g/kg, midazolam 0.05 mg/kg, or saline intravenously before spinal anaesthesia with bupivacaine 0.5 % 15 mg (n = 25 per group) were given to 50 patients who were randomly divided into two groups. The time of sensory and motor regression, as well as the upper level of sensory block, were documented. Dexmedetomidine (T 6.4 ± 0.9; P < 0.001) produced more sensory block than midazolam () or saline (T 6.4 ± 0.8; P < 0.001). The dexmedetomidine group took 145 ±26 minutes for sensory regression of two dermatomes, which was significantly longer (P <0.001) than the midazolam (106± 39 minutes) or saline (97 ±27 minutes) groups. The dexmedetomidine and midazolam groups had higher maximum Ramsay sedation scores than the saline group (P < 0.001). As a result, dexmedetomidine, not midazolam, was used to prolong spinal bupivacaine sensory blockade.[61]

LACUNAE OF LITERATURE

There are few studies have been undertaken to evaluate the impact of intravenous alpha -2 agonists on the time period of ropivacaine spinal anaesthesia.. Also, there are limited studies comparing the effects of the two commonly used α2 adrenergic agonists given intravenously as premedication in subarachnoid block.

MATERIALS & METHODS

Study site: The research was conducted out at Sri Devaraj Urs Academy of Higher Education And Research, Tamaka, Kolar-563101, at the Department of Anaesthesiology.

Study population: All the eligible patients admitted for elective surgery done under Spinal anaesthesia in the Department of Anaesthesiology at Sri DevarajUrsAcademy Of Higher Education And Research were considered as study population.

Study design: The current study was a cross section analytical study.

Sample size: Two groups of 35 subjects each.

Sampling method: All the eligible subjects were recruited into the study consecutively by convenient sampling till the sample size is reached.

Study duration: The data collection for the study was done between January 2020 to May 2021 for a period of 1 year 5 months.

Inclusion Criteria:

1. Age 18 to 60 years
2. ASA physical status 1 or 2
3. Lower limb surgeries and below umbilicus surgery

Exclusion criteria:

1. Patients Who are critically ill or haemodynamically unstable or emergency surgeries.
2. Any pathology of spine or spinal related disease.
3. Patients at increased risk of Bleeding disorder, impaired coagulation and anti coagulation therapy
4. Patients on MAO inhibitors, Anti Depressants and beta blockers
5. Musculocutaneous abnormalities affecting the vertebrae.

Statistical Analysis:

Sample size was estimated based on the VAC score as reported in the study comparsion of intravenous dexmedetomidine with midazolam in prolonging spinal anaesthesia with ropivacaine.,with S.D of group1= 21.93 and S.D of group 25 with 90% power with α error of 1% the required sample size per group will be 34.Sample size was estimated

Formula:

$$n = \frac{2s_p^2[z_{1-\dot{\alpha}/2}+z_{1-ß}]^2}{\mu_d^2}$$

$$s_p^2 = \frac{s_1^2 + s_2^2}{2}$$

Where , s_1^2= Standard deviation in the first group

s_2^2= Standard deviation in the second group

μ_d^2= Mean difference between the samples

$\dot{\alpha}$ = Significance level

1-ß = Power

Ethical considerations: The study was approved by the human ethics committee of the university. All study participants gave their informed written consent, and only those who were willing to sign the informed consent were included in the study. The risks and benefits involved in the study and voluntary nature of participation were explained to the participants before obtaining consent. Confidentiality of the study participants was maintained.

Data collection tools: All the relevant parameters were documented in a structured study proforma.

Methodology:

Prospective randomized study was planned in patients aged between 18 to 60 years of both sexes belonging to ASA physical status 1 & 2, undergoing elective surgery under spinal anesthesia expected to last less than 2 hours were included in the study after ethical clearance from the college ethical committee.

Each patient was visited pre-operatively and procedure was explained, written and informed consent was obtained. All the routine investigations required for pre-operative evaluation was done for the proposed surgery.

Tab Alprazolam 0.5 mg on previous night and Tab Ranitidine 150mg on the morning of surgery will be given. Patients were allowed for period of fasting for atleast 8 hours. They were allocated into 2 groups

On arrival in the operating room I.V line was secured and the patient was shifted to the OT room ,under aspectic precaution patient was painted and draped, spinal was given in L3-L4 space. After checking the CSF back flow Drug administered. For all patients were administered Ropivacaine 0.5% (3ml) for spinal anesthesia and patient received oxygen 4 l/min through out the procedure.

- Group A – IV dexmedetomidine(A loading dose of 0.5 mcg/kg over 10 minute followed by maintenance dose of 0.5 mcg/kg/hr in form of infusion).
- Group B – Intravenous midazolam(A loading dose of 0.02 mg/kg, followed by infusion rate of 0.02 mg/kg/hr).

PARAMETERS OBSERVED:

1. Onset , Duration and action of drugs.

2. Number of insertion attempts and Time taken for each attempt i.e. procedure time.
3. Any technical difficulty and complications.
4. Sensory blockade and recovery time for sensory blockade.
5. Motor block was assessed by Modified Bromage Scale(MBS).Its action and duration was noted.
6. The patient's post-operative pain was assessed using a visual analogue scale (VAS).
7. $SPO_{2,,}$HR, BP and RR were recorded. Intraoperatively , the vitals were measured every 5 minutes for 30 minutes after injection , thereafter every 10 minutes through out surgery.
8. Any complication was detected in the preoperative and postoperative periods.

STATISTICAL METHODS:

VAS Score and duration of analgesia were considered as primary outcome variable.

Study Group (Group A v/s Group B) was considered as primary explanatory variable.

Normality distribution was cross verified by using statistical test like Shapiro-Wilk/ Kolmogorov's test and visual representation like Q-Q plot and histograms for all quantitative parameters.

For normally distributed Quantitative parameters the mean values were compared between study groups using independent sample t-test (2 groups) and non-normally distributed parameters were compared between study groups using Mann Whitney U test.

Data was also represented using clustered bar chart, error bar chart and box plot.

Categorical outcomes were compared between study groups using Chi square test /Fisher's Exact test (If the overall sample size was < 20 or if the expected number in any one of the cells is < 5, Fisher's exact test was used. P value<0.05 was considered as statistically significant. IBM SPSS was used for statistical analysis

OBSERVATIONS AND RESULTS

total of 70 participants were included in the final analysis with 35 participants in group A and 35 participants in group B.

Table 1: Comparison of baseline parameters between study group (N=70)

Parameter	Group (Mean± SD)		P value
	A (N=35)	B (N=35)	
Age (in years)	45.17 ± 15.23	45.86 ± 15.9	0.854$
Weight (in kg)	60.8 ± 5.47	61 ± 6.08	0.885$

In group A, the mean age among the study population was 45.17 ± 15.23 years and in group B, it was 45.86 ± 15.9 years. The mean weight among the study population in group A and group B was found to be60.8 ± 5.47 kg and 61 ± 6.08 kg respectively. There was statistically insignificant difference between mean age and mean weight between study group (P Value>0.05). (Table 1)

Table 2: Comparison of gender between study group (N=70)

Gender	Study Group		Chi square	P value
	A (N=35)	B (N=35)		
Female	12 (34.29%)	15 (42.86%)	0.543	0.461
Male	23 (65.71%)	20 (57.14%)		

Among the study population, there were 12 (34.29%) females and 23 (65.71%) males in group A and there were 15 (42.86%) females and 20 (57.14%) males in group B. There was not any difference that is statistically significant in gender between study group (P Value>0.05). (Table 2)

Figure 5: Clustered bar chart for comparison of gender between study group

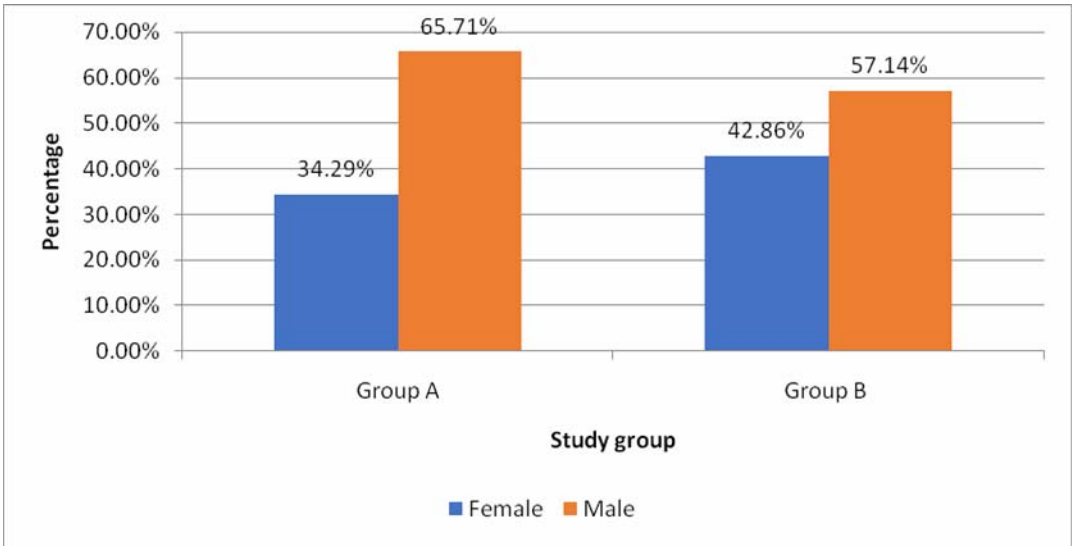


Table 3: Comparison of onset sensory and onset motor parameters between study group (N=70)

Parameters	Study Group [Median (IQR)]		P Value
	A (N=35)	B (N=35)	
Onset Sensory	3 (2 to 4)	4 (3 to 4)	0.001
Onset Motor	9 (8 to 9)	8 (8 to 9)	0.009

Among the study population, the median onset sensory was 3 (2 to 4) in group A and 4 (3 to 4) in group B. The median onset motor was 9 (8 to 9) in group A and 8 (8 to 9) in group B. There was a statistically significant difference in onset sensory and motor between study group (P Value<0.05). (Table 3)

Figure 6: Box plot for comparison of onset of sensory between study group

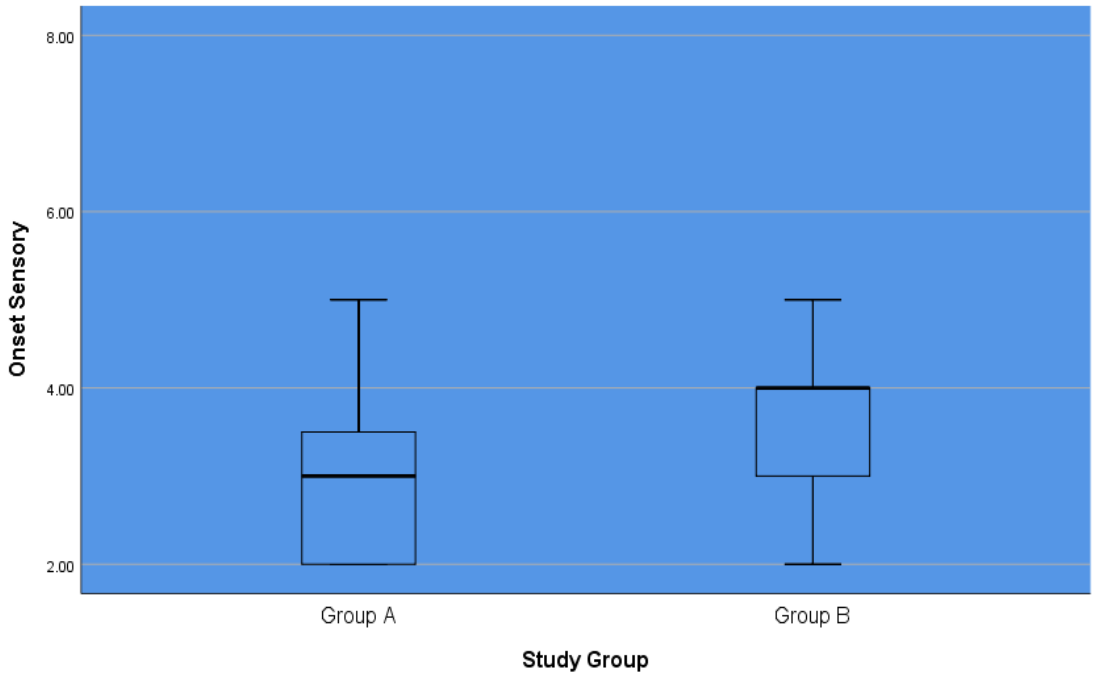


Figure 7: Box plot for comparison of onset of motor between study group

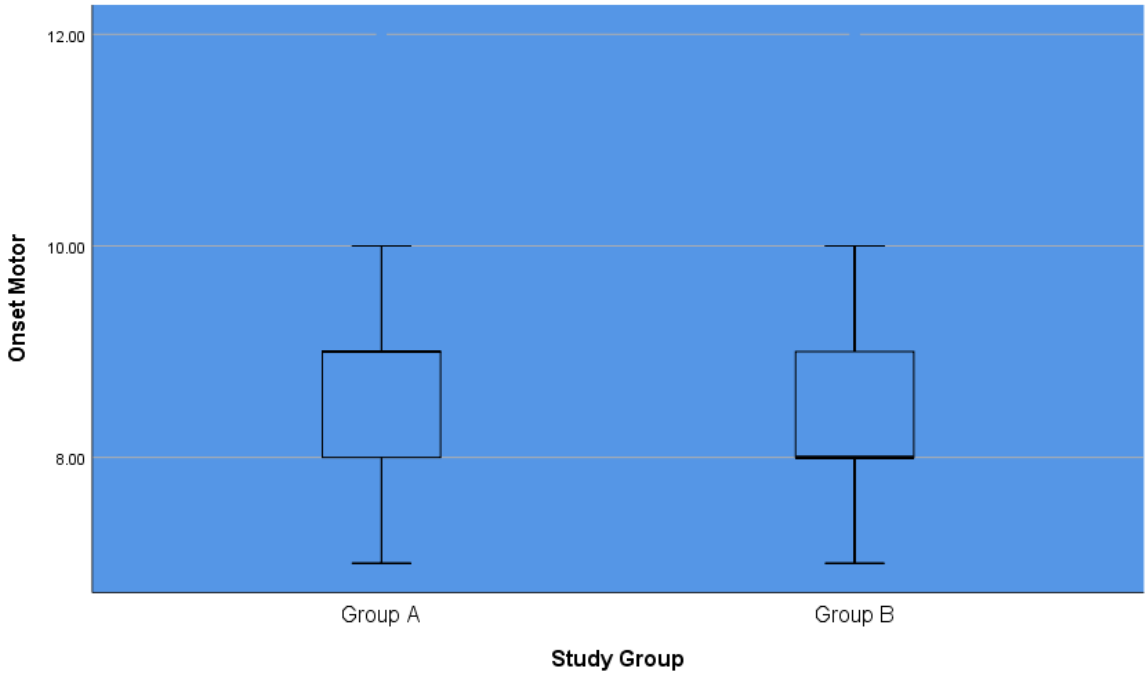


Table 4: Comparison of time span of sensory and motor block between study group (N=70)

Parameters	Study Group [Median (IQR)]		P Value
	A (N=35)	B (N=35)	
Time span of sensory block (in minutes)	180 (175 to 186)	150 (140 to 170)	<0.001
Time span of motor block (in minutes)	150 (145 to 155)	130 (110 to 148)	<0.001

Among the study population, the median (IQR)time span of sensory block was 180 (175 to 186) minutes in group A whereas it was150 (140 to 170) minutes in group B. The median (IQR)time span of motor block was 150 (145 to 155) minutes in group A and 130 (110 to 148) minutes in group B. There was a statistically significant difference in time span of sensory and motor block between the two study group (P Value<0.05). (Table 4)

Figure 8: Box plot for comparison of time span of sensory block between study group

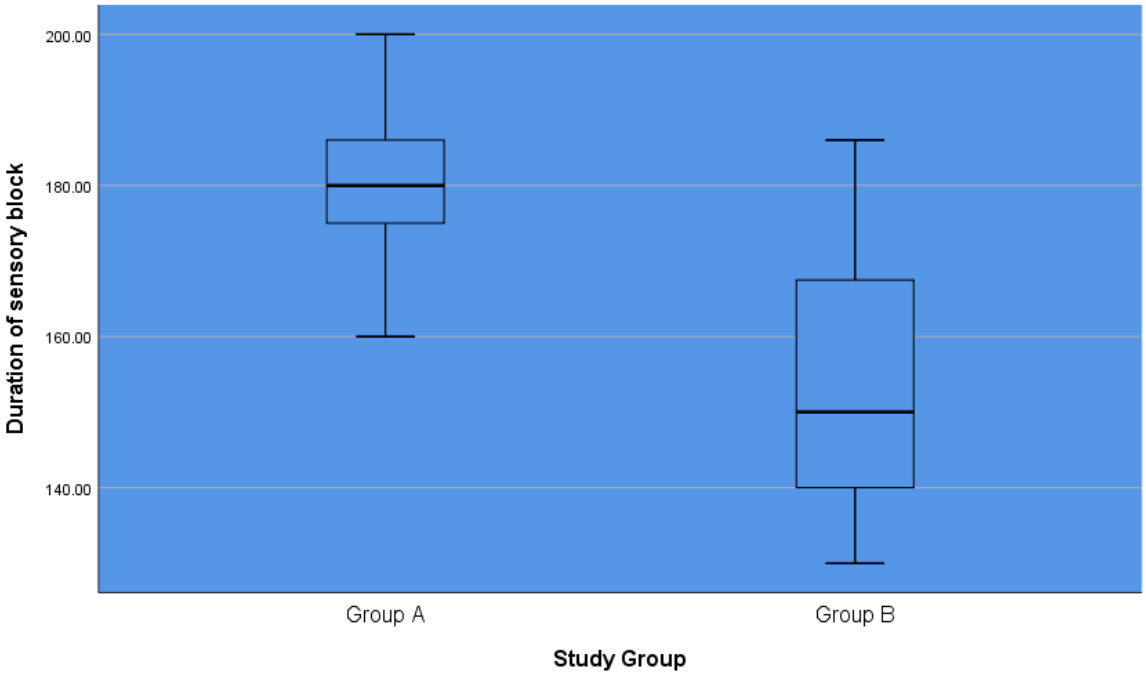


Figure 9 Box plot for comparison of time span of motor block between study group

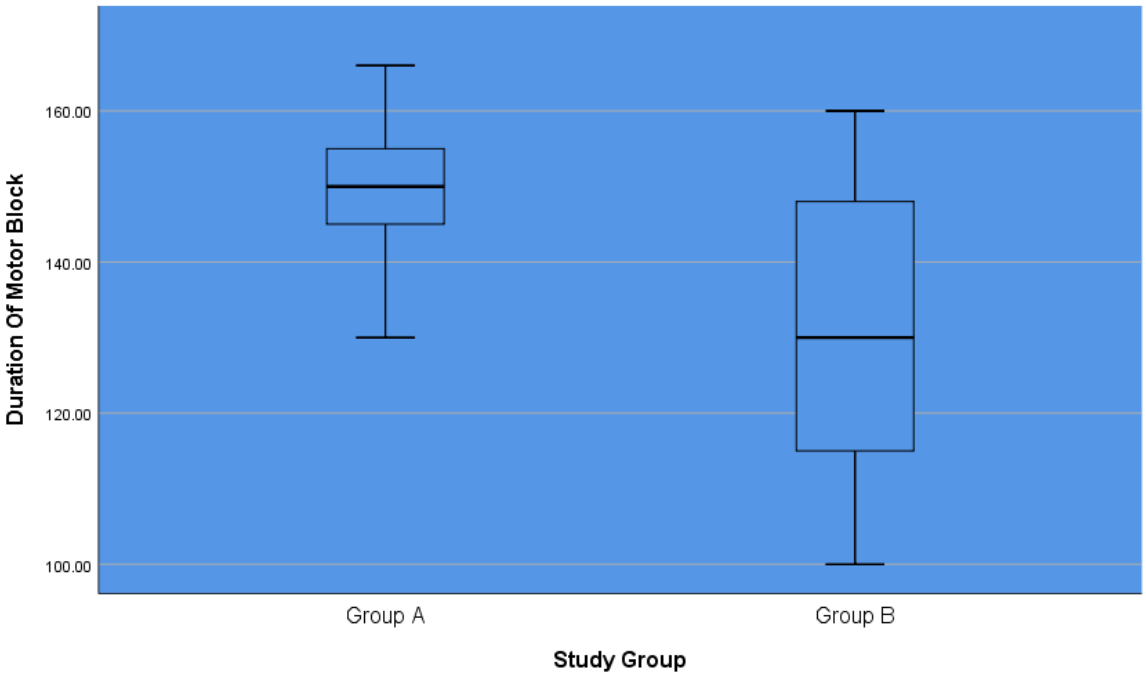


Table 5: Comparison of vital parameters at pre-operative between study group (N=70)

Parameter	Study Group		P value
	A (N=35)	B (N=35)	
Pulse Rate (bpm)	90 (83 to 98)	90 (82 to 98)	0.769#
Systolic Blood Pressure (mm/hg)	127 (118 to 134)	127 (121 to 134)	0.746#
Diastolic Blood pressure (mm/hg)	80 (76 to 89)	82 (76 to 89)	0.136#
Mean arterial pressure (mm/hg)	96.46 ± 8.49	97.97 ± 8.19	0.450$

#: Mann Whitney U test; $:IST

Among the study population at pre-operative stage, the median (IQR) pulse rate was 90 (83 to 98)bpm in group A and 90 (82 to 98)bpm in group B. The median (IQR)SBP was 127 (118 to 134) mm/hg in group A and 127 (121 to 134) mm/hg in group B. The median (IQR)DBP was 80 (76 to 89) mm/hg in group A and 82 (76 to 89) mm/hg in group B. The mean arterial pressure was 96.46 ± 8.49mm/hg in group A and 97.97 ± 8.19 mm/hg in group B. There was not a statistically significant difference in vital parameters (PR, SBP, DBP, MAP) at pre-operative stage between study group (P Value>0.05). (Table 5)

Table 6: Comparison of vital parameters at different time periods between study group (N=70)

Parameter	Study Group [Median (IQR)]		P value
	A (N=35)	B (N=35)	
At 1 minutes			
Pulse Rate (bpm)	81 (74 to 94)	86 (76 to 93)	0.588#
Systolic Blood Pressure (mm/hg)	120 (114 to 124)	121 (114 to 126)	0.681#
Diastolic Blood pressure (mm/hg)	78 (71 to 85)	79 (74 to 84)	0.689#
Mean arterial pressure (mm/hg) (Mean±SD)	90.23 ± 8.13	92.37 ± 8.89	0.296$
At 5 minutes			
Pulse Rate (bpm)	75 (70 to 80)	78 (75 to 86)	*0.020#*
Systolic Blood Pressure (mm/hg)	116 (109 to 118)	112 (108 to 120)	0.495#
Diastolic Blood pressure (mm/hg)	75 (71 to 78)	77 (70 to 79)	0.495#
Mean arterial pressure (mm/hg) (Mean±SD)	87.71 ± 5.5	87.29 ± 8.62	0.805$
At 10 minutes			
Pulse Rate (bpm)	72 (68 to 75)	78 (70 to 85)	*0.004#*
Systolic Blood Pressure (mm/hg)	108 (104 to 115)	107 (103 to 113)	0.962#
Diastolic Blood pressure (mm/hg)	72 (64 to 76)	71 (66 to 77)	0.733#
Mean arterial pressure (mm/hg) (Mean±SD)	81.6 ± 8.14	82.43 ± 7.03	0.650$
At 15 minutes			
Pulse Rate (bpm)	70 (68 to 75)	74 (68 to 80)	*0.033#*
Systolic Blood Pressure (mm/hg)	107 (104 to 113)	106 (103 to 110)	0.778#

Diastolic Blood pressure (mm/hg)	69 (63 to 72)	72 (65 to 74)	0.136#
Mean arterial pressure (mm/hg) (Mean±SD)	79.83 ± 9.6	82.31 ± 5.85	0.195$
At 30 minutes			
Pulse Rate (bpm)	70 (68 to 75)	76 (70 to 78)	*0.003*#
Systolic Blood Pressure (mm/hg)	110 (105 to 115)	108 (105 to 110)	0.140#
Diastolic Blood pressure (mm/hg)	73 (64 to 75)	69 (64 to 72)	0.122#
Mean arterial pressure (mm/hg) (Mean±SD)	83.6 ± 9.51	81.37 ± 4.17	0.208$
At 60 minutes			
Pulse Rate (bpm)	72 (66 to 77)	78 (74 to 80)	*0.001*#
Systolic Blood Pressure (mm/hg)	116 (113 to 119)	116 (111 to 118)	0.524#
Diastolic Blood pressure (mm/hg)	71 (67 to 76)	75 (69 to 81)	0.125#
Mean arterial pressure (mm/hg) (Mean±SD)	84.91 ± 8.39	88.09 ± 5.54	0.066$
At 120 minutes			
Pulse Rate (bpm)	74 (68 to 78)	80 (74 to 85)	*0.002*#
Systolic Blood Pressure (mm/hg)	122 (120 to 123)	123 (120 to 126)	0.304#
Diastolic Blood pressure (mm/hg)	80 (77 to 80)	80 (74 to 82)	0.793#
Mean arterial pressure (mm/hg) (Mean±SD)	93.49 ± 3.44	93.4 ± 5.63	0.939$

#:Mann Whitney U test; $:IST

Among the study population at 1 minute, the median pulse rate was 81 (74 to 94)bpm in group A and 86 (76 to 93)bpm in group B. The median (IQR) SBP was 120 (114 to 124) mm/hg in group A and 121 (114 to 126) mm/hg in group B. The median (IQR) DBP was 78 (71 to 85) mm/hg in group A and 79 (84 to 74) mm/hg in group B. The mean arterial pressure was 90.23 ± 8.13mm/hg in group A and 92.37 ± 8.89 mm/hg in group B.

At 5 minutes, the median pulse rate was 75 (70 to 80)bpm in group A and 78 (75 to 86)bpm in group B. The median (IQR) SBP was 116 (109 to 118) mm/hg in group A and 112 (108 to 120) mm/hg in group B. The median (IQR) DBP was 75 (71 to 78) mm/hg in group A and 77 (70 to 79) mm/hg in group B.The mean arterial pressure was 87.71 ± 5.5mm/hg in group A and 87.29 ± 8.62mm/hg in group B.

At 10 minutes, the median pulse rate was 72 (68 to 75)bpm in group A and 78 (70 to 85)bpm in group B. The median (IQR) SBP was 108 (104 to 115) mm/hg in group A and 107 (103 to 113) mm/hg in group B. The median (IQR) DBP was 72 (64 to 76) mm/hg in group A and 71 (66 to 77) mm/hg in group B.The mean arterial pressure was 81.6 ± 8.14mm/hg in group A and 82.43 ± 7.03 mm/hg in group B.

At 15 minutes, the median pulse rate was 70 (68 to 75)bpm in group A and 74 (68 to 80)bpm in group B. The median (IQR) SBP was 107 (104 to 113) mm/hg in group A and 106 (103 to 110) mm/hg in group B. The median (IQR) DBP was 69 (63 to 72)mm/hg in group A and 72 (65 to 74) mm/hg in group B. The mean arterial pressure was 79.83 ± 9.6mm/hg in group A and 82.31 ± 5.85 mm/hg in group B.

At 30 minutes, the median pulse rate was 70 (68 to 75)bpm in group A and 76 (70 to 78)bpm in group B. The median (IQR) SBP was 110 (105 to 115)mm/hg in group A and 108 (105 to 110) mm/hg in group B. The median (IQR) DBP was 73 (64 to

75)mm/hg in group A and 69 (64 to 72) mm/hg in group B. The mean arterial pressure was 83.6 ± 9.51mm/hg in group A and 81.37 ± 4.17 mm/hg in group B.

At 60 minutes, the median pulse rate was 72 (66 to 77)bpm in group A and 78 (74 to 80)bpm in group B. The median (IQR) SBP was 116 (113 to 119)mm/hg in group A and 116 (111 to 118)mm/hg in group B. The median (IQR) DBP was 71 (67 to 76)mm/hg in group A and 75 (69 to 81) mm/hg in group B. The mean arterial pressure was 84.91 ± 8.39mm/hg in group A and 88.09 ± 5.54 mm/hg in group B.

At 120 minutes, the median pulse rate was 74 (68 to 78)bpm in group A and 80 (74 to 85)bpm in group B. The median (IQR) SBP was 122 (120 to 123)mm/hg in group A and 123 (120 to 126) mm/hg in group B. The median (IQR) DBP was 80 (77 to 80)mm/hg in group A and 80 (74 to 82) mm/hg in group B. The mean arterial pressure was 93.49 ± 3.44mm/hg in group A and 93.40 ± 5.63 mm/hg in group B.

There was not a statistically significant difference in vital parameters (PR, SBP, DBP, MAP) at at all the time periods (1 min, 5 min, 10 min, 15 min, 30 min, 60 min and 120 min) between study group (P Value>0.05) except for the pulse rate at 5 min, 10 min, 15 min, 30 min, 60 min and 120 min between the study group (P Value<0.05). (Table 6)

Figure 10: Trend line for comparison of median pulse rate at different time periods between study group

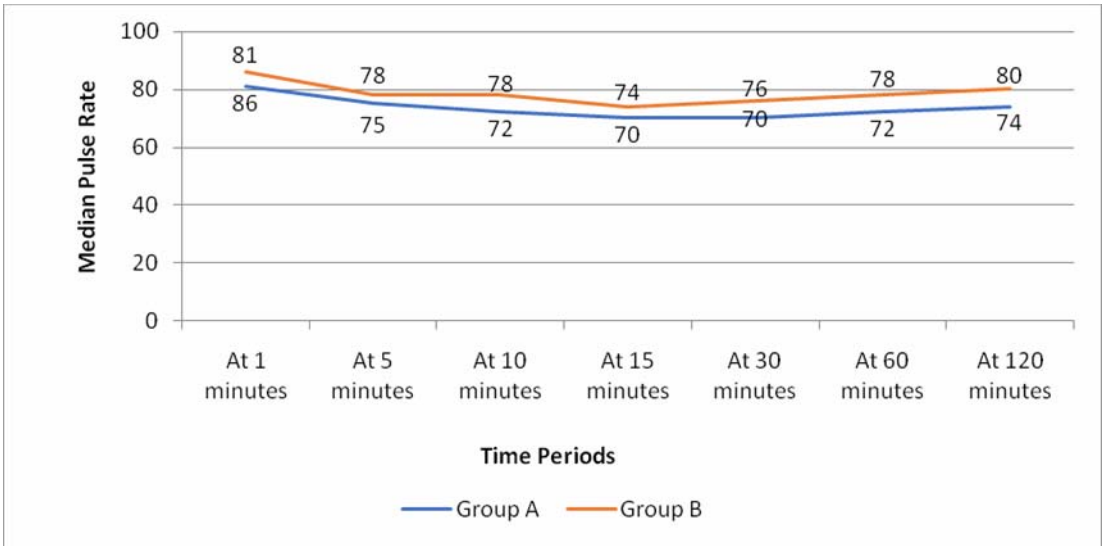


Figure 11: Trend line for comparison of mean arterial pressure at different time periods between study group

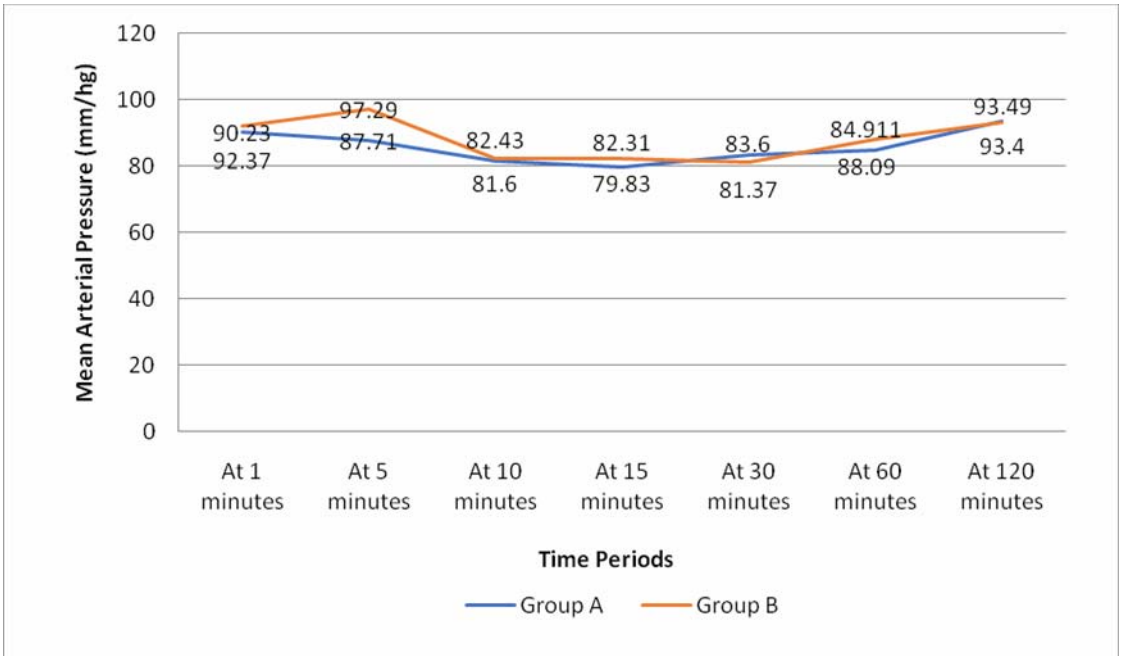


Figure 12: Box plot for comparison of pulse rate at 5 minutes between study group

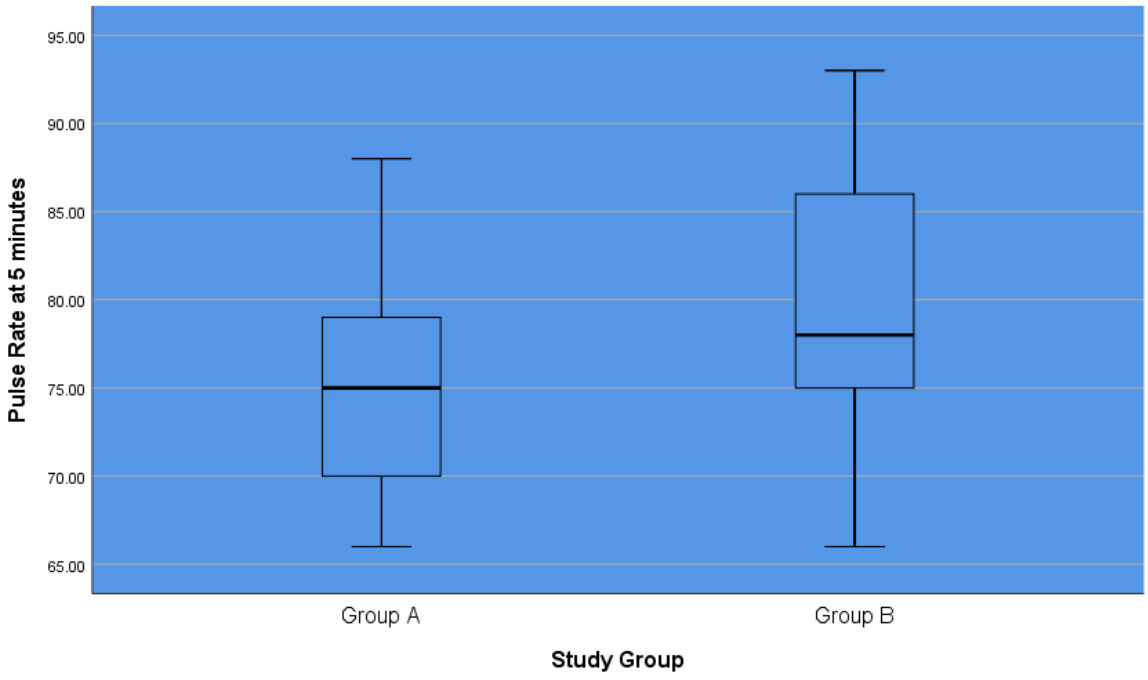


Figure 13:Box plot for comparison of pulse rate at 15 minutes between study group

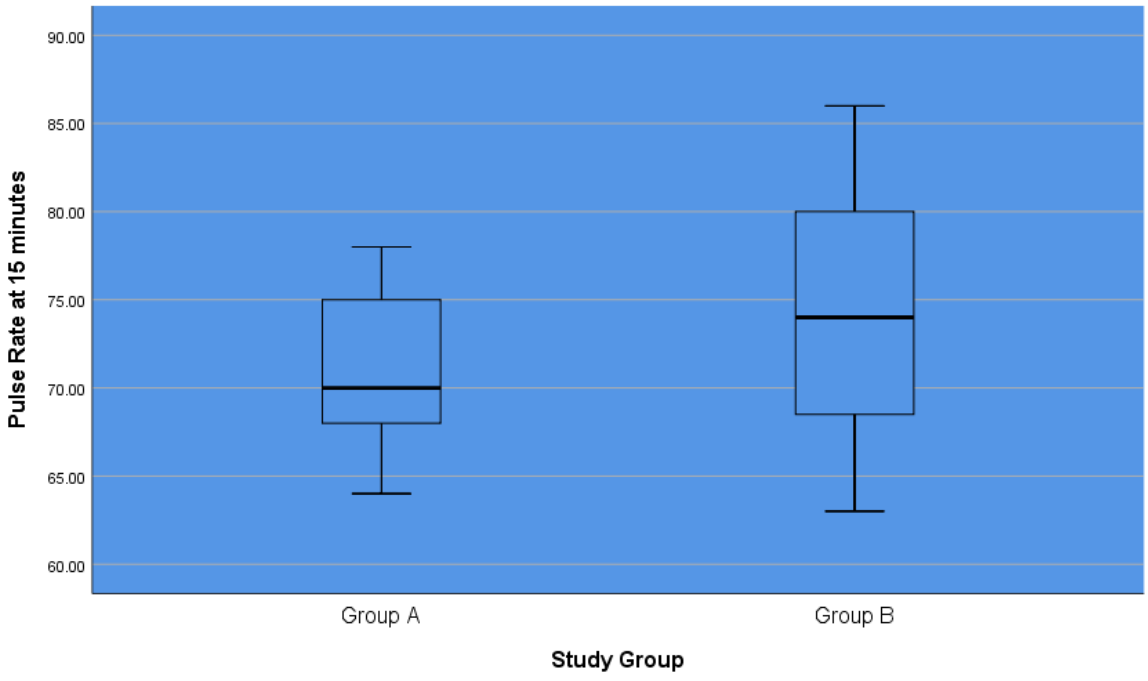


Figure 14 : Box plot for comparison of pulse rate at 120 minutes between study group

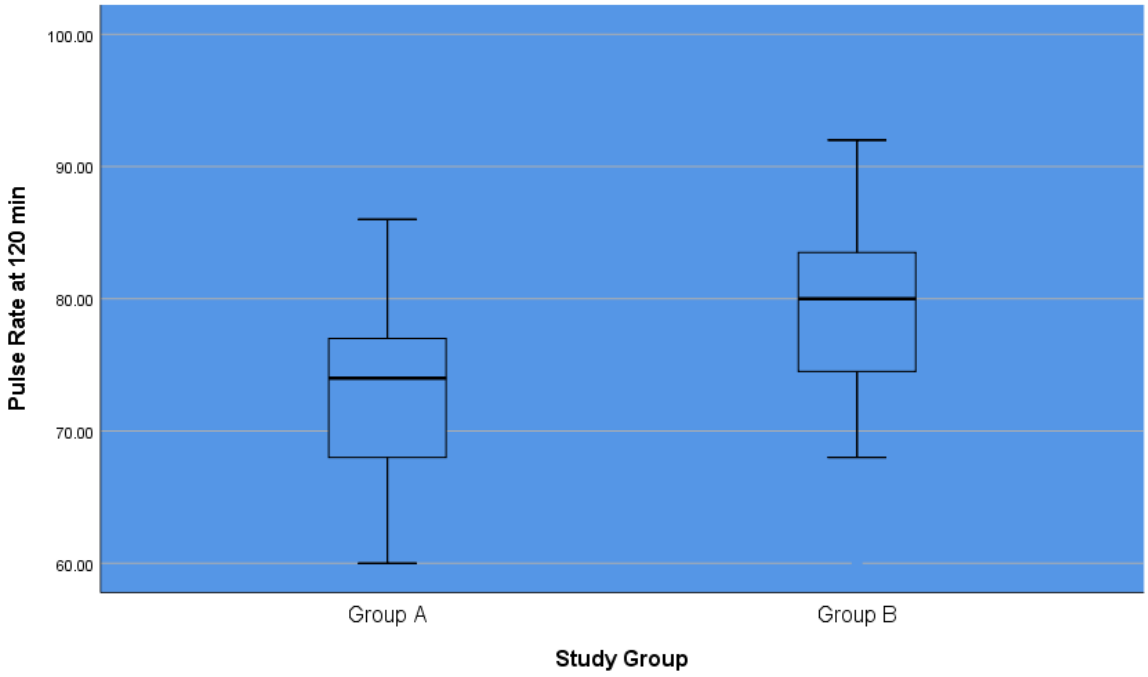


Table 7: Comparison of time span of surgery between study group (N=70)

Parameter	Group (Mean± SD)		P value
	A (N=35)	B (N=35)	
Duration of surgery (in minutes)	63.57 ± 15.37	63.29 ± 15.24	0.938

In group A, the mean time span of surgery among the study population was 63.57 ± 15.37 minutes whereas it was 63.29 ± 15.24 minutes in group B. There was not any statistically significant difference in mean time span of surgery between study group (P Value>0.05). (Table 7)

Figure 15: Error bar chart for comparison of time span of surgery between study group

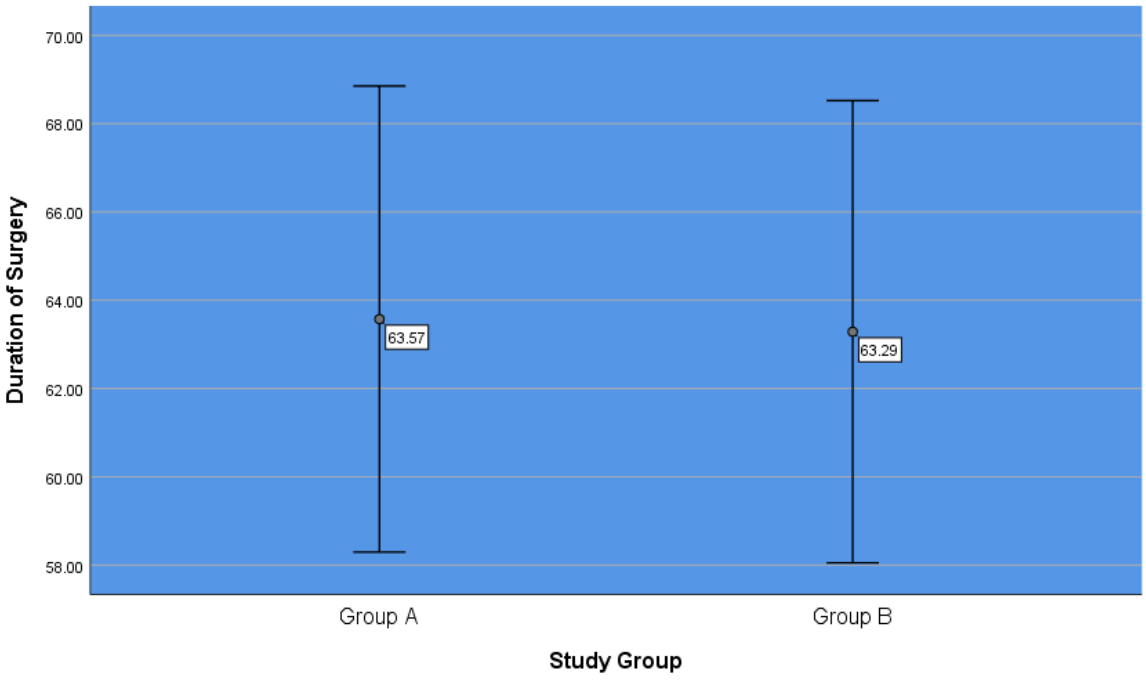


Table 8: Comparison of time span of analgesia between study group (N=70)

Parameter	Group (Mean± SD)		P value
	A (N=35)	B (N=35)	
Duration of analgesia (in minutes)	173.89 ± 14.81	142.83 ± 17.31	<0.001

In group A, the mean time span of analgesia among the study population was 173.89 ± 14.81 minutes and it was 142.83 ± 17.31 minutes in group B. There was a statistically significant difference in mean time span of analgesia between study group (P Value<0.05). (Table 8)

Figure 16: Error bar chart for comparison of time span of analgesia between study group

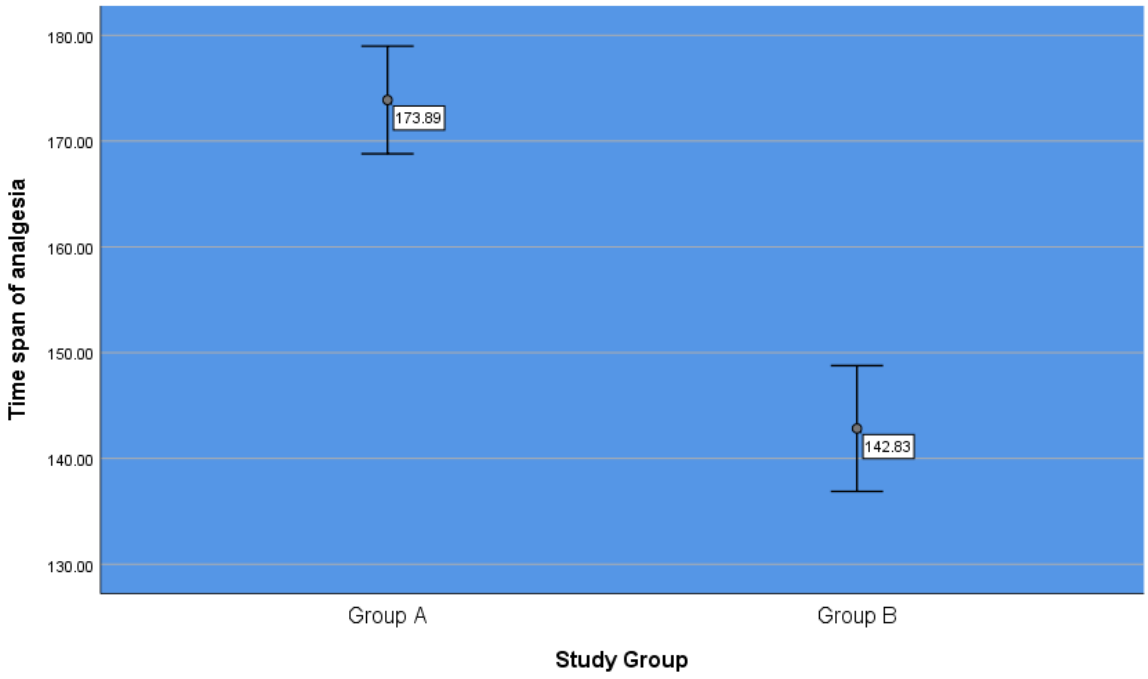
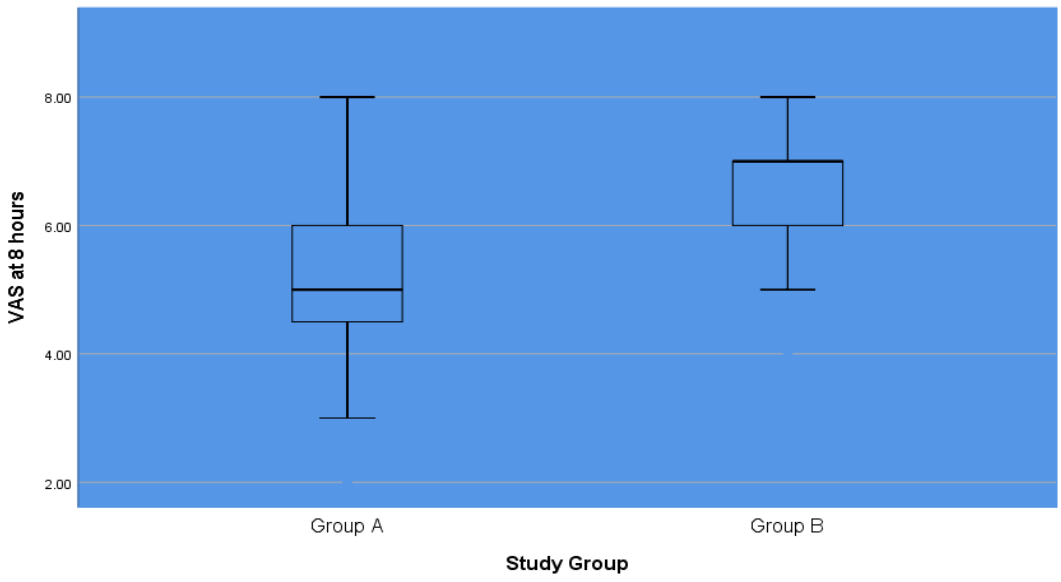


Table 9: Comparison of VAS Score at different time periods between study group (N=70)

VAS Score	Study Group [Median (IQR)]		P value
	A (N=35)	B (N=35)	
At 2 hours	2 (2 to 2)	3 (3 to 4)	<0.001
At 4 hours	2 (2 to 3)	5 (4 to 5)	<0.001
At 8 hours	5 (4 to 6)	7 (6 to 7)	<0.001

Among the study population, the median VAS score at 2 hours was 2 (2 to 2) in group A and 3 (3 to 4) in group B, the median VAS score at 4 hours was 2 (2 to 3) in group A and 5 (4 to 5) in group B and the median VAS score at 8 hours was 5 (4 to 6) in group A and 3 (3 to 4) in group B. There was a statistically significant difference in median VAS Scores (at 2 hours, at 4 hours and at 8 hours) between study group (P Value<0.05). (Table 9)

Figure 17: Error bar chart for comparison of VAS at 8 hours between study group



DISCUSSION:

Various intravenous adjuvants are used along with the spinal anesthesia in order to delay the onset of postoperative pain and also to reduce the analgesic requirement. Midazolam is one of the most often used sedatives for conscious sedation during a subarachnoid block.. Dexmedetomidine is considered as a highly selective alpha agonist with a sedative, analgesic and anxiolytic properties. It is not related with respiratory depression which makes it as a safer drug for the purpose of conscious sedation. Intravenous dexmedetomidine and midazolam are identified to lengthen the sensory and motor blockade of the subarachnoid block. The goal of this study was to examine the effects of intravenous midazolam with dexmedetomidine on sensory and motor block duration, as well as analgesia, in patients undergoing lower limb and lower abdomen procedures under intrathecal ropivacaine anaesthesia.

A total of 70 participants were enrolled in the study with 35 participants in dexmedetomidine group and 35 participants in midazolam group.

In the current study, 45.17 ± 15.23 and 45.86 ± 15.9 were identified as the mean age (years)in the dexmedetomidine and midazolam group. Similarly, 60.8 ± 5.47 and 61 ± 6.08 were identified as the mean weight (kgs) in the dexmedetomidine and midazolam group respectively.

BalwinderKaurRekhi , et al.,[43] conducted a single blind placebo controlled trial on 60 patients in which the mean of age (years) was higher in the midazolam Group with 36.35±12.97 years as compared to dexmedetomidine group with 33.40±9.98. While, the mean of weight (kgs) was higher in the dexmedetomidine group with 68.80±8.33 as compared to the midazolam Group with 65.60±9.57.

In our study and Sanjay Kumar, et al., [62] study, the mean age and weight does not show any statistically significant difference

Table 10 : Comparison of mean age between various studies

Study	population	Mean of age
Present study	**70**	**Dexmedetomidine (45.17 ± 15.23)** **Midazolam (45.86 ± 15.9)**
Sanjay Kumar, et al., [62]	100	**Dexmedetomidine** (39.86±13.51) **Midazolam (**39.8±13.75)
FatmaNur Kaya, et al., [63]	75	**Dexmedetomidine (**56.6 ± 8.5) **Midazolam (**54.8 ± 6.4)

Table11: Comparison of mean weight between various studies

Study	population	Mean of weight
Present study	**70**	**Dexmedetomidine (60.8 ± 5.47)** **Midazolam (61 ± 6.08)**
Sanjay Kumar, et al., [62]	100	**Dexmedetomidine (**52.22±6.02) **Midazolam (**52.18±6.08)
FatmaNur Kaya, et al., [63]	75	**Dexmedetomidine (**81.1 ± 12.4) **Midazolam (**78.5 ± 8.9)

In the current study, majority of the participants were identified as males in the dexmedetomidine and midazolam group with 65.71% and 57.14% respectively. Şenses., et al., [64] conducted a study on 80 participants in which majority of the participants were females with 61% followed by males with 39% which was contradictory to our study results.

In the current study, the median onset of sensory block was identified as 3 (2 to 4) and 4 (3 to 4) in the dexmedetomidine and midazolam group. Whereas, the median onset of motor block was identified as 9 (8 to 9) and 8 (8 to 9) in the dexmedetomidine and midazolam group.

In Sanjay Kumar, et al., [62]study the mean time of onset of sensory block (min) was identified as 2.52±0.32 in the dexmedetomidine group and 2.97±0.64 in the midazolam Group. Similarly, the mean time of onset of motor block (min) was 3.21±0.79 in the dexmedetomidine group and 3.64±0.84 in the midazolam Group.

In the current study, the median duration of sensory block was identified as 180 (175 to 186) and 150 (140 to 170) in the dexmedetomidine and midazolam group.. While, the median duration of motor block was identified as 150 (145 to 155) and 130 (110 to 148) in the dexmedetomidine and midazolam group respectively.

In BalwinderKaurRekhi , et al., [43] study the mean duration of sensory block was higher in the dexmedetomidine group with 208±19.36 min as compared to the midazolam Group with 177±15.25 min. Similarly, the mean duration of motor block was more in the dexmedetomidine group with 190.25±13.81min as compared to the midazolam Group with 136.50±17.54 min.

In our study, BalwinderKaurRekhi , et al., [43] and Nirmala B. et al., [65] study the duration of sensory and motor block were identified as higher in the dexmedetomidine group.

Table 12: Comparison of mean duration of sensory and motor block between various studies

Study	Population	Duration of sensory and motor block
Present study	**70**	**Sensory block** **Dexmedetomidine (180 (175 to 186))** **Midazolam Group 150 (140 to 170)** **Motor block** **Dexmedetomidine150 (145 to 155)** **Midazolam Group 130 (110 to 148)**
Nirmala B. et al., [65]	120	Sensory block Dexmedetomidine (265.32 ± 15) Midazolam (185.2 ± 15) Motor block Dexmedetomidine (198.8 ± 15) Midazolam (135.60)

In the present study, the pre-operative median of pulse rate (bpm), systolic blood pressure (mm/hg) and diastolic blood pressure (mm/hg)were identified as 90 (83 to 98), 127 (118 to 134) and 80 (76 to 89) in the dexmedetomidine group. While, it was 90 (82 to 98), 127 (121 to 134) and 82 (76 to 89) in the midazolam Group. Similarly, 96.46 ± 8.49 and 97.97 ± 8.19 were identified as the mean atrial pressure in the dexmedetomidine and midazolam group.

In BalwinderKaurRekhi , et al., [43]study the mean of pulse rate (bpm), systolic blood pressure (mm Hg), diastolic blood pressure (mm Hg) and arterial pressure (mm Hg) were identified as 83.15±6.77, 126.40±6.54, 79.40±6.68 and 95.05±6.45 in dexmedetomidine group. While, it was identified as 83.85±5.99, 124.3±6.46, 80.30±8.11 and 94.95±7.13 in the midazolam Group**.**

In our study and BalwinderKaurRekhi , et al., [43]study the vital parameters (PR, SBP, DBP, MAP) at pre-operative stage does not show any statistically significant difference between the two groups.

In the current study, the median of pulse rate (bpm), systolic blood pressure (mm/hg) and diastolic blood pressure (mm/hg) at 1 minute were identified as 81 (74 to 94), 120 (114 to 124) and 78 (71 to 85) in the dexmedetomidine group. While, it was 86 (76 to 93), 121 (114 to 126) and 79 (74 to 84) in the midazolam Group. Similarly, 90.23 ± 8.13 and 92.37 ± 8.89 were identified as the mean atrial pressure in the dexmedetomidine and midazolam group.

In the current study, the median of pulse rate (bpm), systolic blood pressure (mm/hg) and diastolic blood pressure (mm/hg) at 5 minutes were identified as 75 (70 to 80), 116 (109 to 118) and 75 (71 to 78) in the dexmedetomidine group. While, it was 78 (75 to 86), 112 (108 to 120) and 77 (70 to 79) in the midazolam Group. Similarly, 87.71 ± 5.5 and 87.29 ± 8.62 were identified as the mean atrial pressure in the dexmedetomidine and midazolam group.

In the current study, the median of pulse rate (bpm), systolic blood pressure (mm/hg) and diastolic blood pressure (mm/hg) at 10 minutes were identified as 72 (68 to 75), 108 (104 to 115) and 72 (64 to 76)in the dexmedetomidine group. While, it was 78 (70 to 85), 107 (103 to 113) and 71 (66 to 77) in the midazolam Group. Similarly, 81.6 ± 8.14 and 82.43 ± 7.03 were identified as the mean atrial pressure in the dexmedetomidine and midazolam group.

In the current study, the median of pulse rate (bpm), systolic blood pressure (mm/hg) and diastolic blood pressure (mm/hg) at 15 minutes were identified as 70 (68 to 75), 107 (104 to 113) and 69 (63 to 72) in the dexmedetomidine group. While, it was 74 (68 to 80), 106 (103 to 110) and 72 (65 to 74) in the midazolam Group. Similarly,

79.83 ± 9.6 and 82.31 ± 5.85 were identified as the mean atrial pressure in the dexmedetomidine and midazolam group.

In the current study, the median of pulse rate (bpm), systolic blood pressure (mm/hg) and diastolic blood pressure (mm/hg) at 30 minutes were identified as 70 (68 to 75), 110 (105 to 115) and 73 (64 to 75) in the dexmedetomidine group. While, it was 76 (70 to 78), 108 (105 to 110) and 69 (64 to 72) in the midazolam Group. Similarly, 83.6 ± 9.51 and 81.37 ± 4.17 were identified as the mean atrial pressure in the dexmedetomidine and midazolam group.

In the current study, the median of pulse rate (bpm), systolic blood pressure (mm/hg) and diastolic blood pressure (mm/hg) at 60 minutes were identified as 72 (66 to 77), 116 (113 to 119) and 71 (67 to 76) in the dexmedetomidine group. While, it was 78 (74 to 80), 116 (111 to 118) and 75 (69 to 81)in the midazolam Group. Similarly, 84.91 ± 8.39 and 88.09 ± 5.54 were identified as the mean atrial pressure in the dexmedetomidine and midazolam group.

In the current study, the median of pulse rate (bpm), systolic blood pressure (mm/hg) and diastolic blood pressure (mm/hg) at 120 minutes were 74 (68 to 78), 122 (120 to 123) and 80 (77 to 80)identified as in the dexmedetomidine group. While, it was 80 (74 to 85), 123 (120 to 126) and 80 (74 to 82) in themidazolam Group. Similarly, 93.49 ± 3.44 and 93.4 ± 5.63 were identified as the mean atrial pressure in the dexmedetomidine and midazolam group.

In our study the reduction of pulse rate was higher in the dexmedetomidine group as compared to the midazolam group for the first 30 minutes. Similar pattern of reduction was showed by BalwinderKaurRekhi , et al.,[43] study also.

In the present study, 63.57 ± 15.37 and 63.29 ± 15.24 were identified as the mean duration of surgery (mins) in the dexmedetomidine group and in the midazolam

Group. In BalwinderKaurRekhi , et al., [43] study the duration of surgery (Minutes) was higher in the dexmedetomidine group with 82.5±13.72 as compared to the with midazolam Group 72.5±19.70.

Sanjay Kumar, et al., [62] conducted a prospective, randomized, comparative, and double-blinded study in which 51.23±2.02 and 55.35±3.74 were identified as the duration of surgery (mins) in the dexmedetomidine and midazolam group respectively.

Table 13 : Comparison of duration of surgery between various studies

Study	**Population**	**Duration of surgery**
Present study	**70**	**Dexmedetomidine (63.57 ± 15.37)** **Midazolam (63.29 ± 15.24)**
FatmaNur Kaya, et al., [63]	**75**	**Dexmedetomidine (**38.7 ± 5.6) **Midazolam (**39.2 ± 6.1)
Nirmala B. et al., [65]	**120**	**Dexmedetomidine (**112.07 ± 21.51) **Midazolam(**115.8 ± 22.56)
Yongxin Liang, et al., [66]	**120**	**Dexmedetomidine (**102 ± 41) **Midazolam(**101 ± 30**)**

In the current study, duration of analgesia (mins) was high in the dexmedetomidine group with 173.89 ± 14.81 as compared to the midazolam group with 142.83 ± 17.31.

Mariko Watanabe, et al., [67] conducted a study in which mean duration of anaesthesia was higher in the dexmedetomidine group with79.3 ± 22.8 as compared to the midazolam group with 76.3 ± 30.5.

In our study and Mariko Watanabe, et al., [67] study the duration of analgesia was higher in the dexmedetomidine group.

In the present study, the median VAS score at 2, 4 and 8 hours were higher in the midazolam group with 3 (3 to 4), 5 (4 to 5) and 7 (6 to 7) as compared to the dexmedetomidinegroup with 2 (2 to 2), 2 (2 to 3) and 5 (4 to 6) respectively.

In Sanjay Kumar, et al., [62] study the mean VAS score at 4 h, 8 h, 12 h and 24 h were identified as 2.23, 4.5, 5.8 and 4.3 in the dexmedetomidine group while, it was 4.9, 5.1, 5.2, and 5.12 in the midazolam group.

In our study andSanjay Kumar, et al., [62] study the VAS scores were identified as higher in the midazolam group.

CONCLUSIONS:

Our findings showed that intravenously administered dexmedetomidine and midazolam may both prolong the duration of sensory and motor blockade, but dexmedetomidine has a longer duration of analgesia than midazolam. As a result, we recommended it for use under spinal anaesthesia, although heart rate should be closely monitored.

SUMMARY

Various intravenous adjuvants are used along with the spinal anesthesia in order to delay the onset of postoperative pain and also to reduce the analgesic requirement. Midazolam is one of the most often used sedatives for conscious sedation during a subarachnoid block.. Dexmedetomidineis considered as a highly selective alpha agonist with a sedative, analgesic and anxiolytic properties. It is not related with respiratory depression which makes it as a safer drug for the purpose of conscious sedation. Intravenous dexmedetomidine and midazolam are identified to prolong the sensory and motor blockade of the subarachnoid block. The goal of this study was to examine the effects of intravenous midazolam with dexmedetomidine on sensory and motor block duration, as well as analgesia, in patients undergoing lower limb and lower abdomen procedures under intrathecal ropivacaine anaesthesia.

A total of 70 participants were enrolled in the study.

The mean age (years)in the dexmedetomidine and midazolam group were identified as 45.17 ± 15.23 and 45.86 ± 15.9 respectively. Whereas, 60.8 ± 5.47 and 61 ± 6.08 were identified as the mean weight (kgs) in the dexmedetomidine and midazolam group respectively.The median onset of sensory block was identified as 3 (2 to 4) and 4 (3 to 4) in the dexmedetomidine and midazolam group. Whereas, the median onset of motor block was identified as 9 (8 to 9) and 8 (8 to 9) in the dexmedetomidine and midazolam group.

The median duration of sensory block was identified as 180 (175 to 186) and 150 (140 to 170) in the dexmedetomidine and midazolam group.. While, the median duration of motor block was identified as 150 (145 to 155) and 130 (110 to 148) in the dexmedetomidine and midazolam group respectively. The pre-operative median of pulse rate (bpm), systolic blood pressure (mm/hg) and diastolic blood pressure

(mm/hg)were identified as 90 (83 to 98), 127 (118 to 134) and 80 (76 to 89) in the dexmedetomidine group. While, it was 90 (82 to 98), 127 (121 to 134) and 82 (76 to 89) in the midazolam Group.

The mean duration of surgery (mins) in the dexmedetomidine group and in the midazolam Group were observed as 63.57 ± 15.37 and 63.29 ± 15.24 respectively. Duration of analgesia (mins) was more in the dexmedetomidine group with 173.89 ± 14.81 as compared to the midazolam group with 142.83 ± 17.31. The median VAS score at 2, 4 and 8 hours were more in the midazolam group with 3 (3 to 4), 5 (4 to 5) and 7 (6 to 7) as compared to the dexmedetomidinegroup with 2 (2 to 2), 2 (2 to 3) and 5 (4 to 6) respectively.

Our study concluded that the intravenously administered dexmedetomidine and midazolam can similarly prolong the duration of sensorial and motor blockade, while the duration of analgesia of dexmedetomidine is higher as compared to the midazolam We therefore, suggested it as appropriate during the spinal anaesthesia, although heart rate required to be monitored cautiously.

LIMITATION:

The sample size of the study was small. It could have been better with larger population size. Participants above the age of 60 years have been excluded from the study so effect of drug on older age group and associated cardiovascular status were not identified. A physiological saline group was not enrolled in the present study. The addition of a saline group as a placebo can be helpful for identifying the effects of dexmedetomidine itself on duration of the spinal anesthesia.

RECOMMENDATION

Further studies can be conducted in a larger population size. A control group along with older population can also be considered in the study.

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ANNEXURES

PROFORMA

"COMPARATIVE STUDY OF INTRAVENOUS DEXMEDETOMIDINE VERSUS INTRAVENOUS MIDAZOLAM in PROLONGING SPINAL ANAESTHESIA WITH ROPIVACAINE"

1. **Name of the patient:**
2. **Age/Sex:**
3. **IP no:**
4. **Ward:**
5. **ASA grade:**

- **General physical examination:**

Height: Weight: Pulse rate: BP:

Pallor/icterus/cyanosis/clubbing/lymphadenopathy/edema

- **Systemic examination:**

RS - **CVS -**

CNS - **P/A -**

- **Investigations :**

Blood group: Hb: WBC: Platelets:

RBS: Blood urea: Sr. Creatinine: Sodium: Potassium:

ECG:

- **Diagnosis :** **Surgery:**

- **GROUP A : IV DEXMEDETOMIDINE** loading dose of 0.5 mcg per kg over 10 minutes followed by maintenance dose of 0.5 mcg per kg / hr in form of infusion

- **GROUP B :IV MIDAZOLAM** loading dose of 0.02 mg per kg followed by infusion rate of 0.02 mg per kg/hr in form of infusion
- **Regional anesthesia procedure:**
- **Baseline vitals:**

HR: BP : MAP: SPO2:

1.Onset of sensory Blockade and duration of sensory blockade:

2. Onset of Motor Blockade and duration of motor blockade:

3.Duration of analgesia.

4..Assesment of post operative pain assessment VAS score at

At 2 hr

At 4 hr

At 8 hr

5.Vitals

TIME	HR	SBP	DBP	MAP	SPO2	DRUGS USED	SIDE EFFECTS
0 MIN							
2 MIN							
4 MIN							
6 MIN							
8 MIN							
10 MIN							
20 MIN							
30 MIN							
40 MIN							
60 MIN							
80 MIN							
90 MIN							

6.complications:

PATIENT INFORMATION SHEET

Study: "COMPARATIVE STUDY OF INTRAVENOUS DEXMEDETOMIDINE VERSUS INTRAVENOUS MIDAZOLAM IN PROLONGING SPINAL ANAESTHESIA WITH ROPIVACAINE"

Investigators: Dr Balaji J / Dr Ravi M

Study location: R L Jalappa Hospital and Research Centre attached to Sri Devaraj Urs Medical College, Tamaka, Kolar.

Details - All Patients posted for lower abdominal and lower limb surgeries under spinal anaesthesia will be included in this study. Patients with co morbid conditions will be excluded from the study.

This study aims to increase the action and duration of intravenous drug after spinal anaesthesia. Patients will have to undergo routine investigations. Patient and the attenders will be completely explained about the procedure being done i.e Intravenous Dexmedetomidine with midazolam in prolonging spinal anaesthesia and patients will be randomnly selected by computerized table . later put into in 2 groups - group A and group B.

Dexmedetomidine will be avoided in patients with comorbid conditions. Most common side effects associated with high dose like Hypotension which treated by Inj mephentermine 5mg, nausea, headache, dizziness, anxiety ,loss of appetite ,restlessness, sweating, palpitations, Bradycardia which treated by Inj Atrophine 0.6mg. Midazolam sedation effects were assessed by Ramsay 6 point sedation scale.

Please read the information and discuss with your family members. You can ask any question regarding the study. If you agree to participate in the study we will collect information . Relevant history will be taken. This information collected will be used only for dissertation and publication.

All information collected from you will be kept confidential and will not be disclosed to any outsider. Your identity will not be revealed. There is no compulsion to agree to this study. The care you will get will not change if you don't wish to participate. You are required to sign/ provide thumb impression only if you voluntarily agree to participate in this study.

For further information contact

Dr.Balaji J

Post graduate

Dept of Anaesthesia, SDUMC Kolar

Mobile no: 8971300799

INFORMED CONSENT FORM

COMPARATIVE STUDY OF INTRAVENOUS DEXMEDETOMIDINE VERSUS INTRAVENOUS MIDAZOLAM IN PROLONGING SPINAL ANAESTHESIA WITH ROPIVACAINE

Date

I, _____ aged _____

,after being explained in my own vernacular language about the purpose of the study and the risks and complications of the procedure, hereby give my valid written informed consent without any force or prejudice for taking intravenous dexmedetomidine and midazolam. The nature and risks involved have been explained to me to my satisfaction. I have been explained in detail about the studybeing conducted. *I have read the patient information sheet and I have had the opportunity to ask any question. Any question that I have asked, have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.* I hereby give consent to provide my history, undergo physical examination, undergo the procedure, undergo investigations and provide its results and documents etc to the doctor / institute etc. For academic and scientific purpose the operation / procedure, etc may be video graphed or photographed. All the data may be published or used for any academic purpose. I will not hold the doctors / institute etc responsible for any untoward consequences during the procedure / study.

A copy of this Informed Consent Form and Patient Information Sheet has been provided to the participant.

_____ _____

(Signature & Name of Pt. Attendant) (Signature/Thumb impression & Name of Patient/Guardian)

(Relation with patient)

Witness 1:

Witness 2:

(Signature & Name of Research person /doctor)

KEY TO MASTER CHART

PR	Pulse Rate
SBP	Systolic Blood Pressure
DBP	Diastolic Blood Pressure
MAP	Mean Arterial Pressure
mmHg	Millimetre Of Mercury
VAS	Visual Analog score
Hr	hour

MASTER CHART : GROUP A : IV DEXMEDETOMIDINE

S.No.	Group	Age	Sex	Wt.	R.No.	Diag.	Surg.	Pre-operative				Onset of Surgery		Duration of Surgery			1min.				5min.				10min.				15min.				30min				60min.				120min.				Duration of analgesia	VAS score		
								PR	SBP	DBP	MAP	Sensory	Motor		Block	Block	PR	SBP	DBP	MAP	PR	SBP	DBP	MAP	PR	SBP	DBP	MAP	PR	SBP	DBP	MAP	PR	SBP	DBP	MAP	PR	SBP	DBP	MAP	PR	SBP	DBP	MAP		2hrs	4hrs	8hrs
1	A	48	Male	57	858986	necortising fascitis of thigh	Fasciotomy and WD	96	137	89	105	4	10	45	180	150	74	125	90	97	74	115	74	88	75	109	72	84	78	106	67	80	75	124	80	95	72	117	74	88	83	121	78	92	210	2	4	6
2	A	22	male	60	859082	Appendicitis	open appendicectomy	86	127	70	88	4	9	60	187	145	68	122	68	81	70	121	60	84	66	104	70	77	77	115	98	105	75	115	98	105	77	117	51	66	78	123	85	100	194	2	3	5
3	A	27	Male	65	804512	Appendicitis	open appendicectomy	83	134	93	107	3	9	50	200	166	78	124	85	98	76	114	76	89	72	115	76	89	69	118	76	90	70	110	75	87	66	115	75	97	72	123	74	90	188	2	2	6
4	A	35	male	63	849756	Right inguinal hernia	herinoplasty	96	136	95	109	3	7	65	188	147	60	124	88	100	68	108	75	86	68	98	63	75	69	108	75	86	68	110	78	90	75	118	70	86	75	123	74	90	178	2	2	4
5	A	40	female	58	859557	Pilonidal sinus	Excision	74	116	78	91	4	9	60	170	150	72	113	79	90	66	109	76	87	69	108	75	86	68	106	72	83	78	116	78	69	80	118	71	87	82	122	78	93	184	2	2	3
6	A	48	Male	55	860010	Post op BKA	Flap closure	94	134	92	112	5	9	45	184	155	90	118	71	87	78	116	78	91	72	116	77	90	70	121	71	90	71	126	75	92	77	118	71	74	82	122	80	94	174	2	3	6
7	A	45	Male	64	852311	Non healing ulcer of L foot	Wound debridement	82	120	70	84	3	8	65	178	148	80	111	71	85	75	113	68	81	68	104	72	78	69	108	78	86	70	111	59	74	66	117	68	83	68	125	65	85	178	2	3	6
8	A	57	Male	58	866637	Wet gangrene of Right lower limb	Above knee amputation	80	129	73	89	4	9	70	180	155	77	120	69	84	70	116	71	85	68	98	61	73	68	109	59	66	74	113	55	70	70	116	61	83	74	120	80	93	160	4	5	5
9	A	51	male	60	963453	Right inguinal hernia	herinoplasty	100	136	91	107	4	8	55	186	160	98	126	95	103	88	123	88	97	83	124	83	97	76	118	73	82	70	105	69	75	76	107	64	78	80	130	80	97	158	2	3	5
10	A	37	Male	66	870261	umblical herina	meshplasty	85	130	55	80	3	9	65	182	152	81	120	66	81	78	121	65	83	74	108	61	73	86	80	60	66	78	104	50	67	74	107	44	63	75	118	80	93	175	1	2	5
11	A	48	male	78	860324	umblical herina	meshplasty	83	117	63	86	3	9	50	185	149	80	114	70	86	76	107	71	85	72	102	64	76	75	105	61	77	75	110	73	86	70	111	71	87	74	123	80	94	170	2	2	5
12	A	55	female	59	870560	Incisional hernia	Mesh repair	71	120	77	89	2	8	45	188	160	70	115	74	84	66	118	69	86	65	120	70	84	71	121	71	90	75	124	75	89	75	120	80	93	75	126	73	90	190	2	2	2
13	A	30	male	60	843798	Closed right tibia fracture	CRIF + IML nailing	88	115	79	96	4	8	90	188	164	84	109	77	88	74	106	80	89	75	104	80	88	68	113	71	81	68	107	74	85	66	125	70	88	74	131	71	91	170	2	2	4
14	A	35	Male	65	849676	Closed Diaplaced Fracture of L femur	CRIF + IML nailing	104	140	80	100	2	8	90	170	155	85	131	92	105	78	117	80	92	74	90	50	63	72	92	52	65	70	100	63	75	70	115	82	93	80	119	87	98	175	1	2	5
15	A	30	male	65	849229	3yr old PFN nail	Implant removal	90	116	81	97	2	9	80	186	165	86	107	61	72	75	103	68	80	72	102	56	70	70	107	61	72	68	116	81	97	74	120	80	93	76	125	77	93	165	2	2	5
16	A	36	Male	62	850375	Closed diaplaced fracture of right tibia	ORIF + plating	98	134	86	102	3	8	60	168	145	90	130	80	96	78	120	80	93	72	120	80	93	71	109	69	82	68	107	71	83	70	118	70	87	69	120	90	100	180	2	2	4
17	A	20	male	56	768116	9 month old nail	Implant removal	105	127	90	99	2	8	45	180	155	100	125	90	97	80	118	91	96	74	109	72	84	75	101	63	78	72	110	73	85	78	113	76	88	68	120	80	93	170	2	2	4
18	A	35	Male	60	850792	Closed displaced fracture of L tibia	ORIF + Plate fixing	98	130	91	106	3	9	60	180	135	95	127	86	99	80	117	78	92	78	108	73	83	74	97	63	73	70	110	80	90	78	112	79	94	75	123	85	100	165	3	3	5
19	A	25	Male	55	850373	Fracture of Femur	ORIF + TENS nailing	100	113	76	92	2	9	70	180	135	95	110	72	84	80	108	84	94	76	105	74	81	74	100	58	73	66	99	65	76	82	108	72	82	86	120	84	94	165	2	2	5
20	A	30	male	64	851725	Closed fracture of both bone right	ORIF +IML nailing of R tit	102	108	77	87	3	8	55	170	150	98	105	65	78	84	101	68	79	80	100	66	77	65	98	67	77	67	98	69	79	64	100	66	77	60	121	80	94	170	3	3	6
21	A	56	female	58	856184	left serous adenoma	TAH+BSO	75	130	90	102	3	9	60	186	160	74	124	81	95	66	122	80	94	62	123	79	94	64	104	64	77	64	106	64	78	68	111	78	89	62	122	78	93	145	2	2	3
22	A	50	Female	57	857223	Fibroid	TAH +Bso	99	118	78	96	2	9	90	185	140	95	116	71	87	80	118	70	82	77	107	63	75	75	105	66	77	71	105	64	71	90	113	84	90	71	116	78	91	180	2	2	4
23	A	38	Female	50	862913	Leiomyoma	TAH+BSO	100	127	86	99	3	10	60	168	135	95	113	84	90	72	109	74	77	85	105	63	73	67	108	74	84	67	108	74	84	62	116	81	93	66	123	80	94	170	2	2	5
24	A	52	Female	60	863448	Grade II UV prolapse	VH	90	120	80	93	2	9	90	165	145	86	116	78	91	75	117	75	89	65	113	72	66	78	107	72	64	80	116	61	93	69	120	61	81	67	119	82	94	170	2	2	5
25	A	55	female	63	850754	AUB	TAH+BSO	92	126	81	102	2	11	75	170	130	90	124	81	101	80	118	75	96	82	104	71	84	66	103	64	73	75	105	55	75	66	112	63	78	66	120	80	93	150	3	5	8
26	A	49	female	64	866255	Right ovarian cyst	TAH+BSO	95	134	86	102	2	10	80	175	150	94	122	81	95	76	110	73	85	67	110	71	84	65	108	69	82	64	110	73	85	72	118	71	87	71	122	80	94	160	2	3	5
27	A	56	Female	54	866234	Grade I UV prolpase	VH	70	117	63	86	2	10	80	185	150	68	114	70	86	70	107	71	85	68	102	64	76	65	105	61	77	65	110	73	86	60	111	71	87	65	116	78	91	180	2	5	9
28	A	50	female	50	847414	AUB	TAH +Bso	100	123	72	83	3	9	80	185	150	96	118	72	82	93	116	76	87	78	105	64	78	70	105	69	79	72	105	64	78	69	109	70	83	64	126	73	90	160	2	2	8
29	A	59	male	60	844861	Renal calculi	URSl + DJS	75	132	78	96	2	9	30	160	140	73	123	72	83	68	118	72	82	60	116	76	87	68	113	71	65	69	107	74	85	66	125	70	88	60	129	80	96	155	2	2	6
30	A	55	female	68	845064	L upper utretric calculi	L URSL + DJS	84	110	79	89	3	12	60	190	155	80	108	83	91	69	109	75	90	66	112	82	92	68	106	62	77	67	100	63	75	70	115	82	93	75	119	87	98	175	2	2	4
31	A	55	male	70	847969	BPA	TURP	70	122	81	100	2	9	80	175	150	72	120	75	84	70	109	72	84	71	107	71	83	68	103	69	80	70	100	66	77	74	129	68	88	76	123	74	90	170	2	2	5
32	A	50	female	62	851156	R uretheral calculi	R URSL + DJS	98	134	86	102	3	8	60	180	130	88	134	86	102	80	137	83	101	75	120	80	93	70	109	69	82	77	107	71	83	84	102	67	77	75	123	77	92	160	4	5	7
33	A	34	Male	57	848454	Desmoid tumor	Exploration	96	137	89	105	4	10	45	180	150	74	125	90	97	74	115	74	88	75	109	72	84	78	106	67	80	75	124	80	95	72	117	74	88	83	121	78	92	210	2	4	6
34	A	22	male	60	857257	Phimosis	circumcison	86	127	70	88	4	9	60	187	145	68	122	68	81	70	121	60	84	66	104	70	77	77	115	98	105	75	115	98	105	77	117	51	66	78	123	85	100	194	2	3	5
35	A	59	Male	65	865430	L epidymorthitis	Wound debridement	83	134	93	107	3	9	50	200	166	78	124	85	98	76	114	76	89	72	115	76	89	69	118	76	90	70	110	75	87	66	115	75	97	72	123	74	90	188	2	2	6

MASTER CHART : GROUP B :IV MIDAZOLAM

S.No.	Group	Age	Sex	Wt.	R.No.	Diag.	Surg.	Pre-operative				Onset of Surgery		Duration of Surgery			1min.				5min.				10min.				15min.				30min				60min.				120min.				Duration of analgesia	VAS score		
								PR	SBP	DBP	MAP	Sensory	Motor		Block	Block	PR	SBP	DBP	MAP	PR	SBP	DBP	MAP	PR	SBP	DBP	MAP	PR	SBP	DBP	MAP	PR	SBP	DBP	MAP	PR	SBP	DBP	MAP	PR	SBP	DBP	MAP		2hrs	4hrs	8hrs
1	B	55	Male	65	859307	Necortising fascitis of left leg	Fasciotomy and WD	86	122	80	94	3	9	65	150	155	68	114	77	89	66	109	77	88	70	107	74	85	68	109	77	88	70	102	72	78	78	120	69	86	80	125	65	85	160	4	5	7
2	B	55	female	55	859352	Necortizing fascitis of left leg	Fasciotomy and WD	100	136	100	115	3	7	55	154	148	95	126	95	103	88	123	88	97	86	124	83	79	84	118	73	82	76	105	66	78	82	118	73	82	86	120	84	94	168	3	5	7
3	B	53	Male	58	860364	Perianal abscess	I & D	99	128	89	99	5	10	35	175	158	94	118	80	90	78	108	94	99	65	103	58	66	64	98	73	81	70	104	72	78	80	115	75	88	90	121	80	94	160	4	6	6
4	B	28	Male	60	862064	Appendicitis	open appendicectomy	98	135	82	100	4	8	70	186	148	92	132	78	99	88	113	70	84	84	103	70	81	80	104	72	78	76	107	69	82	78	108	68	80	80	116	78	91	160	4	4	6
5	B	58	female	54	862570	Diabetic foot	Fasciotomy and WD	84	140	96	111	2	8	70	172	140	80	133	89	104	76	118	86	97	80	116	84	95	70	110	81	91	75	108	64	81	78	113	76	88	85	120	80	93	144	4	5	8
6	B	59	male	57	861296	Post in flammatory raw wound	SSG	75	127	79	95	4	7	60	186	160	74	121	70	87	72	118	70	82	70	107	63	75	68	105	66	77	76	105	64	81	80	113	84	90	82	116	78	91	150	3	3	6
7	B	23	Male	76	859209	Torsion testis	Exploration	78	120	80	94	4	8	60	185	150	76	102	64	77	70	89	60	70	75	101	69	80	76	100	65	77	70	101	69	80	84	116	81	93	86	123	80	94	154	3	5	7
8	B	34	Male	65	863592	Necortizing fascitis of Right leg	Fasciotomy and WD	84	136	93	108	5	8	60	179	148	80	134	90	105	86	124	88	100	84	108	75	86	78	104	72	78	82	106	72	83	78	116	78	91	80	134	90	105	144	3	5	7
9	B	58	Male	65	863968	Right inguinal hernia	herinoplasty	78	130	80	94	5	7	50	170	150	75	124	81	101	74	110	76	84	70	106	64	76	72	109	76	87	70	113	79	90	76	116	78	91	76	134	70	91	138	4	5	6
10	B	45	male	60	869850	Necortizing fascitis of left leg	Fasciotomy and WD	95	134	86	102	4	8	45	155	140	90	122	81	95	86	110	73	85	87	110	71	84	85	108	69	82	84	110	73	85	86	118	71	87	81	125	65	85	120	4	5	7
11	B	55	female	68	870436	umblical herina	meshplasty	83	122	82	95	5	7	65	155	130	80	119	76	90	78	112	75	87	80	103	73	83	78	100	71	81	76	110	74	86	78	117	76	89	80	129	80	96	150	4	5	6
12	B	18	Male	63	869598	Dry gangrene of Left toe	Wound debridement	98	129	84	114	4	9	55	160	140	97	121	77	99	90	120	78	88	89	111	74	91	86	102	70	84	78	110	70	83	73	120	61	80	78	131	71	91	145	2	4	6
13	B	52	female	55	846740	L closed bimallolar fracture	ORIF + mallolar screw	90	121	81	92	4	9	55	150	135	86	105	75	90	80	108	68	79	78	105	70	82	72	115	78	90	71	114	74	87	75	119	81	94	78	126	86	99	150	3	5	5
14	B	50	Male	63	834579	5yr old PFN nail	Implant removal	88	126	89	98	3	9	75	145	130	78	123	83	103	76	122	79	92	80	109	83	81	78	106	61	77	76	105	65	78	74	116	81	93	72	119	82	94	140	3	6	8
15	B	38	male	64	850536	Closed both bone fracture of R leg	ORIF + plating	94	116	73	87	4	8	55	145	125	88	107	63	74	85	103	65	78	74	102	69	80	63	103	61	75	70	108	63	78	75	117	72	87	70	135	95	108	150	3	5	7
16	B	54	male	68	850345	open type II fracture of metatrasals	Wound debridement	82	130	82	98	5	10	40	150	120	80	116	74	88	76	88	52	64	70	101	61	74	68	107	72	84	66	104	66	79	68	102	67	79	60	112	76	88	145	3	3	7
17	B	37	Male	58	851464	6 yr old Femur IMIL nail	Implant removal	120	130	90	105	3	9	65	130	100	88	133	80	98	75	91	63	72	68	99	70	80	70	126	86	99	78	112	66	81	78	134	82	99	68	130	80	97	154	4	4	6
18	B	20	female	58	851540	Closed R shaft of femur fracture	ORIF + IML nailing	90	120	80	93	4	12	50	135	100	88	118	84	94	84	108	73	83	80	104	66	80	76	105	74	81	78	103	71	83	84	115	75	97	90	115	75	87	154	3	3	7
19	B	34	Male	65	851757	open type III fracture of metatrasals	Wound debridement	74	117	78	89	4	9	60	130	100	72	114	77	79	76	114	77	91	71	103	71	83	73	99	72	85	72	90	69	76	65	108	68	80	74	114	77	91	130	4	4	7
20	B	59	female	63	838664	Closed fracture of both bone right	ORIF + IML nailing	78	118	80	78	2	8	65	176	135	75	113	73	90	72	109	75	90	73	113	80	97	69	108	80	92	70	110	78	95	69	111	81	96	75	123	74	90	130	3	5	7
21	B	38	Female	64	856108	DUB	TAH+BSO	98	110	85	94	3	8	70	140	120	94	107	63	74	85	108	62	85	86	105	66	77	80	104	60	76	84	108	64	81	78	113	76	88	82	120	80	93	140	3	5	8
22	B	26	Female	55	859018	DUB	TAH+BSO	94	121	70	88	4	8	75	145	130	90	118	71	87	89	116	78	91	85	116	77	90	84	110	54	73	88	108	64	81	90	108	63	95	92	119	87	98	120	5	7	9
23	B	59	female	60	855685	Adenomy	TAH+BSO	78	119	81	96	12	9	95	140	110	76	117	74	88	75	114	77	79	72	112	65	81	74	107	65	79	70	109	61	77	64	120	69	86	70	125	65	85	110	4	6	8
24	B	43	Female	65	862946	AUB	TAH+BSO	98	131	88	102	2	8	90	135	110	93	129	88	102	90	122	81	95	87	121	79	93	85	117	74	88	82	113	70	84	78	110	73	85	80	122	81	95	130	4	6	9
25	B	45	female	62	865281	AUB	TAH+BSO	100	135	88	100	3	8	90	140	125	98	129	82	94	93	123	77	92	90	111	73	86	82	104	64	77	80	107	64	78	85	107	64	78	80	123	77	92	180	2	3	4
26	B	45	female	59	866161	Grade III Uv prolapse`	VH	100	127	83	98	3	8	90	130	110	97	121	82	95	90	114	70	86	90	107	64	78	86	104	66	77	84	112	63	78	82	116	81	93	85	123	80	94	150	3	3	5
27	B	28	Female	58	867389	P1L2 LCB posted for tuboplasty	Tubal recannulization	83	122	82	95	3	8	60	140	100	74	119	76	90	76	112	75	87	80	103	73	83	78	100	71	81	76	110	74	86	78	117	76	89	80	125	77	93	125	3	6	8
28	B	59	female	63	835424	Fib.Ut.	TAH+BSO	78	122	80	93	4	8	90	140	100	74	122	79	93	72	123	79	93	70	120	77	91	72	113	72	85	71	110	70	83	73	120	61	80	78	131	71	91	130	3	5	7
29	B	26	male	64	845503	Stricture urthera	B/L DJS	90	136	90	105	4	8	55	165	120	88	126	87	100	75	118	83	95	78	116	79	91	72	115	78	90	71	114	74	87	75	119	81	94	78	126	86	99	120	4	5	7
30	B	44	male	63	843900	Stricture urthera	VIU	80	131	84	101	4	9	75	150	120	78	128	84	98	76	106	65	83	80	105	64	78	78	106	61	77	76	105	65	78	74	116	81	93	72	120	80	93	120	3	3	6
31	B	55	male	64	847812	Stricture urthera	urtheroplasty	94	116	73	87	3	9	50	145	100	88	107	63	74	85	103	65	78	74	102	69	80	63	103	61	75	70	108	63	78	75	117	72	87	70	135	95	108	130	3	5	6
32	B	26	female	60	851926	L VUT calculi	L URSI + DJS	82	140	82	101	3	7	65	130	120	82	134	84	101	71	134	79	97	70	123	73	89	68	119	64	83	67	105	68	81	68	132	68	89	60	126	73	91	110	3	3	8
33	B	56	male	65	856329	Stricture urthera	EJU	86	122	80	94	3	9	65	150	155	68	114	77	89	66	109	77	88	70	107	74	85	68	109	77	88	70	102	72	78	78	120	69	86	80	125	65	85	160	4	5	7
34	B	59	MALE	55	866911	Penile odema	Wound debridement	100	136	100	115	3	7	55	154	148	95	126	95	103	88	123	88	97	86	124	83	79	84	118	73	82	76	105	66	78	82	118	73	82	86	120	84	94	168	3	5	7
35	B	38	male	38	860346	B/l hydrocele	B/L Jaoulay	99	128	89	99	5	10	35	175	158	94	118	80	90	78	108	94	99	65	103	58	66	64	98	73	81	70	104	72	78	80	115	75	88	90	121	80	94	160	4	6	6