DISSERTATION ON

A PROSPECTIVE RANDOMIZED CONTROLLED STUDY COMPARING ANAESTHETIC EFFICACY OF INTRATHECAL NALBUPHINE HYDROCHLORIDE WITH BUPIVACAINE AND BUPIVACAINE ALONE FOR INFRAUMBILICAL SURGERIES

Dissertation submitted in partial fulfillment of the regulations for the award of the degree of

M.D ANESTHESIOLOGY

BRANCH-X

Of

TAMIL NADU Dr. M.G.R. MEDICAL UNIVERSITY

CHENNAI, TAMILNADU

ESIC- MEDICAL COLLEGE & POSTGRADUATE INSTITUTE OF MEDICAL SCIENCE AND RESEARCH, KK NAGAR, CHENNAI-78.

APRIL 2017

ENDORSEMENT BY THE DEAN/
THE HEAD OF THE INSTITUTION

This is to certify that this dissertation titled **"A PROSPECTIVE RANDOMIZED CONTROLLED STUDY COMPARING ANAESTHETIC EFFICACY OF INTRATHECAL NALBUPHINE HYDROCHLORIDE WITH BUPIVACAINE AND BUPIVACAINE ALONE FOR INFRAUMBILICAL SURGERIES"** submitted by **Dr.Karthick.K,** appearing for M.D Degree Branch–X ANAESTHESIOLOGY examination in April 2017 is a bonafide record of work done by him under my direct guidance and supervision in partial fulfillment of the regulations of Tamil Nadu Dr. M.G.R Medical University, Chennai. I forward this to the Tamil Nadu Dr. M.G.R Medical University, Chennai Tamil Nadu, India.

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This is to certify that the dissertation entitled **"A PROSPECTIVE RANDOMIZED CONTROLLED STUDY COMPARING ANAESTHETIC EFFICACY OF INTRATHECAL NALBUPHINE HYDROCHLORIDE WITH BUPIVACAINE AND BUPIVACAINE ALONE FOR INFRAUMBILICAL SURGERIES"** is a bonafide research work done by Dr.Karthick.K**,** in partial fulfillment of the requirement for the degree of M.D. in Anesthesiology.

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This is to certify that the dissertation named **"A PROSPECTIVE RANDOMIZED CONTROLLED STUDY COMPARING ANAESTHETIC EFFICACY OF INTRATHECAL NALBUPHINE HYDROCHLORIDE WITH BUPIVACAINE AND BUPIVACAINE ALONE FOR INFRAUMBILICAL SURGERIES"** is a bonafide work performed by **Dr.KARTHICK.K,** postgraduate student, Department of Anesthesiology, ESIC Medical college & PGIMSR, Chennai – 78, under my guidance and supervision in fulfillment of regulations of The Tamil Nadu Dr. M.G.R Medical University for the award of M.D. Degree during the academic year 2014 – 2017.

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DECLARATION

I solemnly declare that this dissertation entitled **"A PROSPECTIVE RANDOMIZED CONTROLLED STUDY COMPARING ANAESTHETIC EFFICACY OF INTRATHECAL NALBUPHINE HYDROCHLORIDE WITH BUPIVACAINE AND BUPIVACAINE ALONE FOR INFRAUMBILICAL SURGERIES"** has been conducted by me at ESIC Medical College & PGIMSR, Chennai, under the guidance and supervision of **Dr.K.RADHIKA, M.D. and Dr. ILANGO GANESAN, M.D.,** Department of Anesthesiology, ESIC Medical College & PGIMSR, Chennai. This dissertation is submitted to **The Tamil Nadu Dr. M.G.R. Medical University, Chennai** in partial fulfillment of the University regulations for the award of the degree of **M.D. Branch X (Anesthesiology).**

Date:

Place: Chennai **(Dr.KARTHICK. K)**

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I am thankful to my parents, my wife and family members for their unconditional love and support.

Dr. KARTHICK. K

CERTIFICATE OF APPROVAL

To

Dr. Karthick K,
PG in Department of Anaesthesiology,
ESIC Medical College & PGIMSR,
KK Nagar, Chennai-78.

Dear Dr. Karthick K,

The Institutional Ethical Committee of ESIC Medical College & PGIMSR reviewed and discussed your application for approval of the proposal entitled **"A prospective randomized controlled study comparing anaesthetic efficacy of intrathecal nalbuphine hydrochloride with bupivacaine and bupivacaine alone for infraumbilical surgeries"** at ESIC Medical College & PGIMSR, K K Nagar, Chennai 60Q 078", No. **04-03/07/2015**

The following members of the Ethical Committee were present in the meeting held on 03.07.2015 conducted at ESIC Medical College & PGIMSR, KK Nagar, Chennai-78.

S.No.	ETHICAL COMMITTEE MEMBERS
1.	Prof. A.V. Srinivasan, Chairperson, EC Member
2.	Prof. V, Rajalakshmi, Member Secretary, Registrar, ESIC Medical College & PGIMSR, EC Member
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12.	Dr. Napinai, Clinical Psychologist, EC Member
13.	Dr. C.V. Aravindan, Scientist, EC Member
14.	Shri. K M Venugopal, Advocate, EC Member

The proposal is approved to be conducted in its presented form.

The Institutional Ethical Committee expects to be informed about the progress of the study and significant adverse effects occurring in the course of the study, any changes in the protocol and patients information / informed consent and asks to be provided a copy of the final report.

[DR. A.V. SRINIVASAN]
CHAIRPERSON
ETHICAL COMMITTEE

Date: 03.07.2015
Place : Chennai 78

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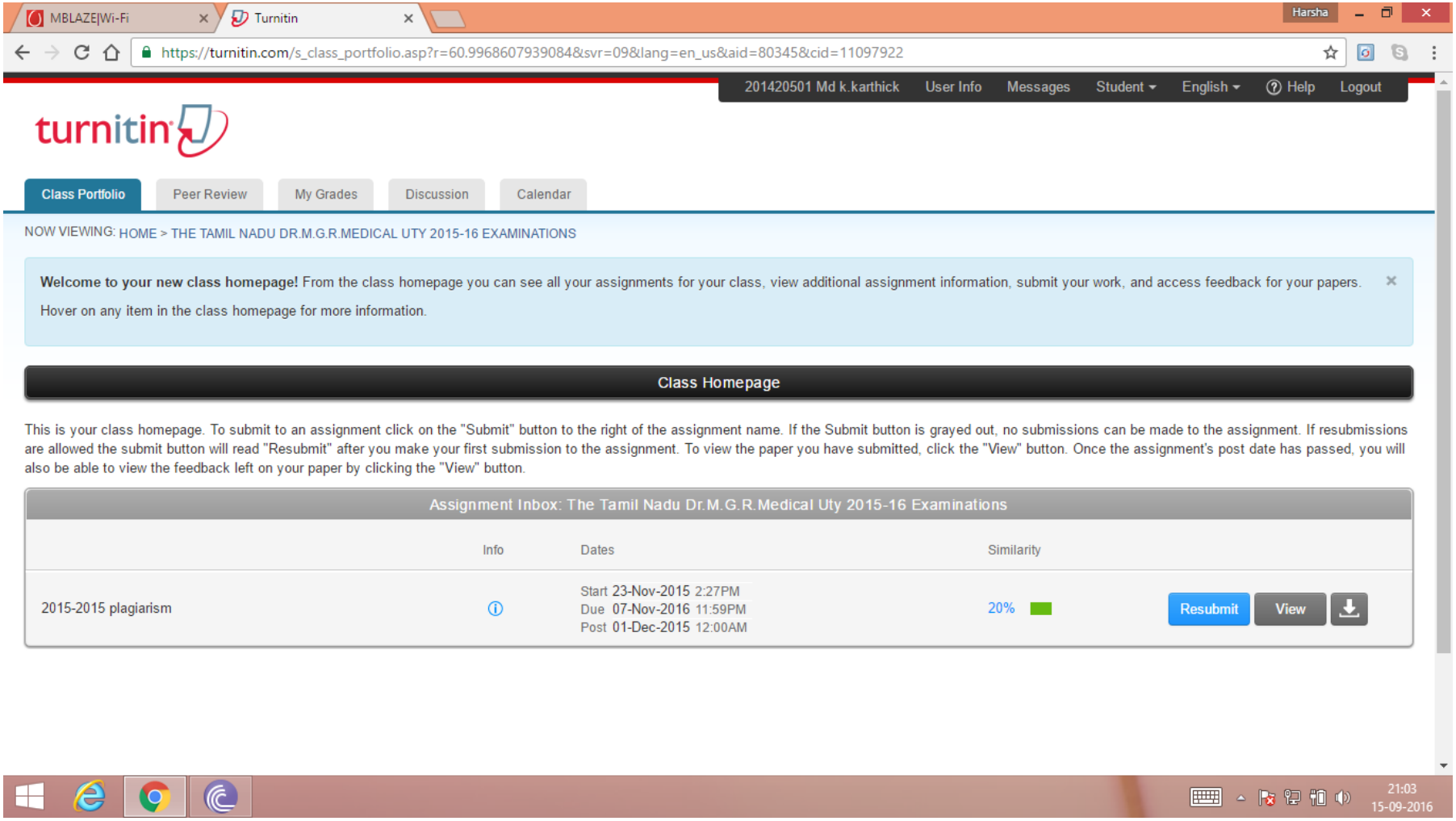

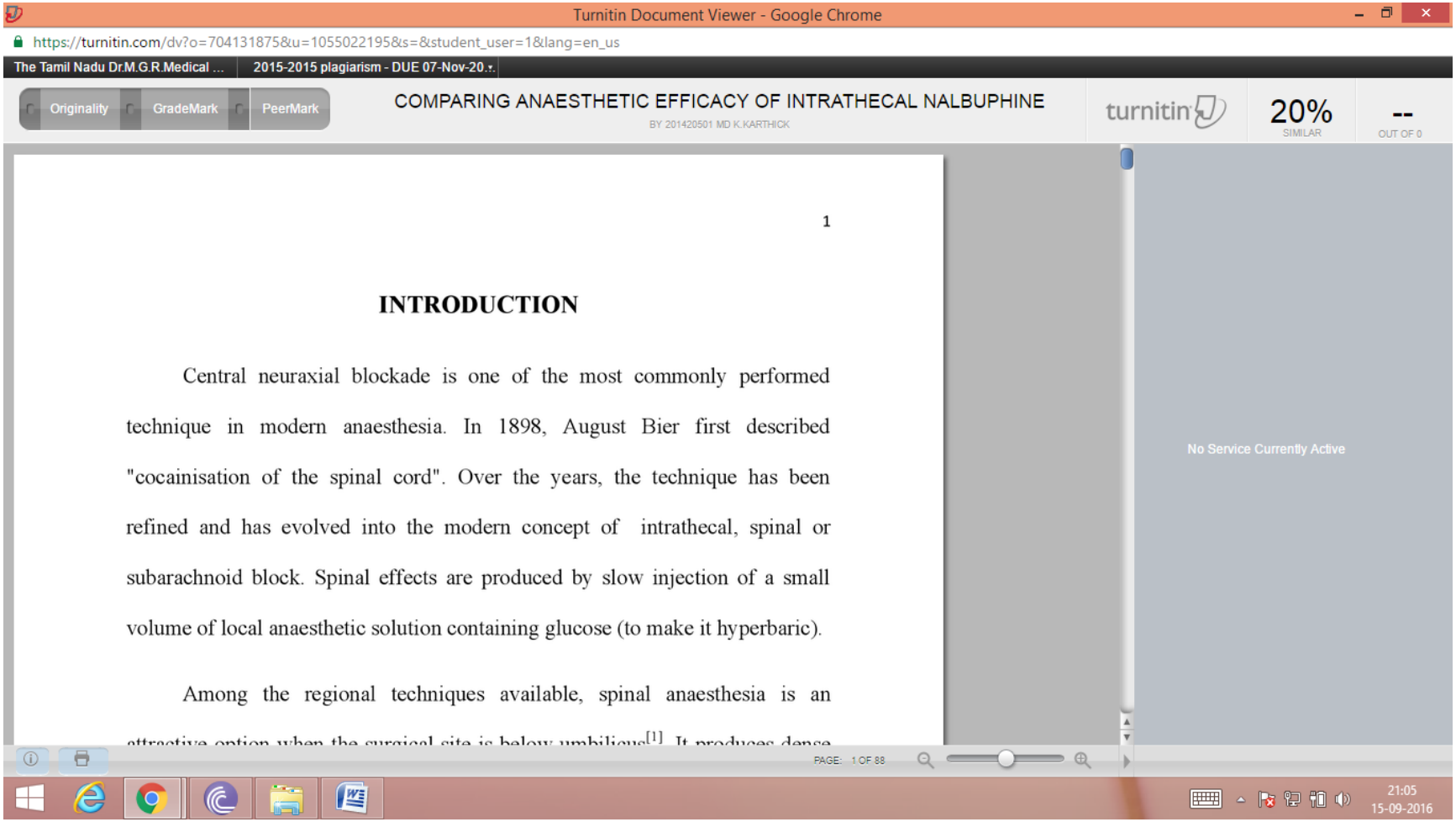
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INTRODUCTION
Central neuraxial blockade is one of the most commonly performed technique in modern anaesthesia. In 1898, August Bier first described "cocainisation of the spinal cord". Over the years, the technique has been refined and has evolved into the modern concept of intrathecal, spinal or subarachnoid block. Spinal effects are produced by slow injection of a small volume of local anaesthetic solution containing glucose (to make it hyperbaric).
Among the regional techniques available, spinal anaesthesia is an
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Introduction

INTRODUCTION

Central neuraxial blockade is one of the most commonly performed technique in modern anaesthesia. In 1898, August Bier first described "cocainisation of the spinal cord". Over the years, the technique has been refined and has evolved into the modern concept of intrathecal, spinal or subarachnoid block. Spinal effects are produced by slow injection of a small volume of local anaesthetic solution containing dextrose (to make it hyperbaric).

Among the regional techniques available, spinal anaesthesia is an attractive option when the surgical site is below umbilicus[1]. It produces dense sensory, motor and sympathetic blockade. It has the advantages of low cost, better postoperative pain relief, decreased PONV, low incidence of thromboembolism when compared to general anaesthesia. Subarachnoid block is associated with reduced stage I recovery time and patients can resume their normal oral intake quickly. Because of these benefits, spinal anaesthesia is one of the emerging technique in day care surgeries in recent times.

Spinal anaesthesia is beneficial in terms of decreasing intraoperative blood loss, blunting the stress response to surgery and

reducing mortality and morbidity in high risk surgical patients. Subarachnoid block is a preferred technique in patients who are prone to aspiration like obesity, full stomach, GERD and in patients with reduced respiratory drive.

In spite of the above benefits, the major limitation of subarachnoid block is short lived duration of anaesthesia. Normally, spinal anaesthesia with bupivacaine heavy (H) lasts for 2 to 2.5 hours[2]. Addition of adjuvants like opioids, neostigmine and epinephrine to the local anaesthetics intrathecally, results in prolongation of duration of anaesthesia.

In 1979, Wang and his colleagues[3] first used intrathecal opioids for acute pain treatment. Intrathecal opioid is widely used in treating intraoperative, postoperative, obstetric, traumatic and chronic cancer pain. The technique of intrathecal opioid administration along with local anaesthetics is to improve the quality of analgesia and decrease the requirement of postoperative analgesics[4].

The basis for the combination of local anesthetics and opioids is that these two groups of drugs provide analgesia by their action at two different sites. Local anesthetics have their action at the spinal nerve axon

and opioids act at the receptor site in the spinal cord[5]. Various opioids have been used intrathecally like morphine, fentanyl, buprenorphine and nalbuphine to fasten the onset and prolong the duration of sensory and motor blockade.

Nalbuphine is an opioid, synthetically prepared with mixed μ antagonist and κ agonist properties[6]. Nalbuphine when administered intrathecally binds to kappa receptors in the spinal cord and brain producing analgesia and sedation without μ adverse effects. It has minimal respiratory depressant effect and low abuse potential compared to other centrally acting opioid analgesics. Side effects like shivering, nausea, vomiting and urinary retention are infrequent with nalbuphine hydrochloride. Increased drug dosage is not required, Since nalbuphine reaches ceiling effect at lower intrathecal dosage. This also explains the safety margin of the drug.

In this study, we investigated the addition of nalbuphine hydrochloride as an adjuvant to hyperbaric bupivacaine in subarachnoid block, in comparison with hyperbaric bupivacaine alone in order to evaluate the beneficial effects of nalbuphine.

Aim of the study

AIM OF THE STUDY

The aim of the study was to compare the anaesthetic efficacy of mixture of intrathecal bupivacaine 0.5% heavy and nalbuphine hydrochloride with intrathecal bupivacaine 0.5% heavy alone for infraumbilical surgeries.

Objectives

OBJECTIVES

The objective of the study was to compare the

1. Onset of sensory and motor blockade

2. Duration of sensory, motor blockade and postoperative analgesia between the two groups of patients who had undergone infraumblical surgeries under spinal anaesthesia using bupivacaine heavy with or without nalbuphine.

Review Of Literature

REVIEW OF LITERATURE

Khosrou Naghibi, Hamid Saryazdi, Farnaz Rohani[7] et al conducted a study in 2013 titled "The comparison of spinal anesthesia with general anesthesia on the postoperative pain scores and analgesic requirements after elective lower abdominal surgery". It was a prospective randomized controlled double blinded study. After obtaining informed written consent, sixty eight patients under American Society of Anaesthesiologist physical status I and II in the age group of 20-65 planned for elective lower abdominal surgery under general anaesthesia or spinal anaesthesia were included in the study. Patients were randomly divided into GA or SA by using sealed envelopes with thirty four patients in each group. VAS score was explained to all the patients prior to surgery. On arrival to the operating room, basic monitors [Electrocardiography, Noninvasive blood pressure, Pulse oximetry] were connected and IV line started with 18G cannula.

- Group SA - received 3ml of 0.5% hyperbaric bupivacaine (15mg) intrathecally, at L3-L4 interspace and 2μ/kg fentanyl intravenously for intraoperative analgesia.

- Group GA - received Na thiopental 6mg/kg, fentanyl 2 μ/kg, morphine 0.15mg/kg, atracurium 0.6mg/kg for induction followed by tracheal intubation. Maintenance with O2/N20/isoflurane. Reversal with 0.02mg/kg atropine and 0.04 mg/kg neostigmine.

The pain scores and the analgesic requirements were noted in the recovery room for 24 hours after surgery. The authors concluded that the patients in SA group had comparatively lower VAS scores than the patients in GA group for the first 6 hours (3.4±1.6 and 4.1±1.2 vs 5.2±1.5 and 5.8±0.9 at 2nd and 4th hour postoperatively). Postoperative analgesic requirements was also significantly ($p<0.05$) reduced in SA group. However there was no significant difference between the two groups after 6 hours.

Mukherjee A, Pal A, Agrawal J[8] et al did a study in 2011 titled "Intrathecal nalbuphine as an adjuvant to subarachnoid block: What is the most effective dose?". It was a randomized, prospective double blind controlled study. Hundred patients of ASA physical status I and II posted for elective lower limb orthopedic surgery under subarachnoid block were included in the study .They were allotted into four groups A, B,C and D by computer generated randomisation.

- Group A - received 0.5ml Normal Saline with 12.5mg bupivacaine 0.5% (H)
- Group B - received 0.2mg Nalbuphine with 12.5mg bupivacaine 0.5% (H)
- Group C - received 0.4mg Nalbuphine with 12.5mg bupivacaine 0.5% (H)
- Group D - received 0.8mg Nalbuphine with 12.5mg bupivacaine 0.5% (H).

Haemodynamic parameters like heart rate, mean arterial pressure(MAP) & peripheral oxygen saturation were noted throughout the procedure. They compared the onset of sensory and motor blockade and duration of sensory and motor blockade between the groups. They used Bromage scale for motor block and visual analogue scale for assessing pain. The onset time of sensory and motor blockade was significantly ($p<0.05$) reduced and the duration of block was increased in nalbuphine groups. They observed that the analgesic effect of bupivacaine was significantly prolonged when nalbuphine was added as an adjuvant. The authors concluded that 0.4mg Nalbuphine is the most effective intrathecal dose that prolongs post operative analgesia with no side-effects.

Jyothi B, Shruthi Gowda, Safiya Shaikh[9] conducted a study in 2014 titled "A comparison of analgesic effect of different doses of intrathecal nalbuphine hydrochloride with bupivacaine and bupivacaine alone for lower abdominal and orthopedic surgeries". Hundred patients of both sexes under American Society of Anaesthesiologists I and II were enrolled in the study. They were randomly allocated into four groups I,II,III,IV. It was a double blind randomized controlled study. Prior to SAB, monitors like ECG, pulse oximetry, non invasive blood pressure (NIBP) were connected and base line values were recorded. Patients were preloaded with 500ml of RL solution. Subarachnoid block was performed using 25G Quincke needle in L3-L4 interspace with 15mg bupivacaine + 0.5ml NS(Group I) or 15mg of bupivacaine with either of nalbuphine 0.8mg, 1.6 and 2.5mg (Group II,III and IV). The time to two segment regression of sensory blockade and the duration of analgesia was significantly prolonged in nalbuphine groups. The postoperative pain scores were drastically reduced in group II to IV than group I (3.4±0.4 vs 4.08±0.5). The authors concluded addition of 0.8mg nalbuphine to bupivacaine 0.5% intrathecally provides excellent analgesia without any side effects. Nalbuphine exhibits analgesic ceiling effect at 0.8mg dosage, further increase in dose did not rise the analgesic efficacy.

Shehla shakooh, Pooja Bhosle[10] performed a study titled "Intrathecal nalbuphine: An effective adjuvant for post operative analgesia". It was a prospective randomised double blind study. After approval by the ethics committee, 60 patients under ASA PS I and II posted for elective lower abdominal and lower limb surgery were included in the study. Patients were divided into two groups by slips in the box technique. Group N received 0.5% heavy bupivacaine (3cc) with 0.8mg nalbuphine. Group B received 0.5% heavy bupivacaine (3cc). Intraoperatively basic monitors were connected and subarachnoid block was performed by 25G Quincke needle in right lateral position. Hemodynamic parameters were observed throughout the procedure. Sensory and motor block were assessed by pinprick and Bromage scale respectively. The authors concluded that the onset of sensory and motor blockade were faster in group N with a significant p value (0.001). The duration of sensory & motor block and the postoperative analgesia duration were superior in group N as compared to group B. No significant side effects were reported between the two groups.

Mostafa Galal, Mohamad F[11] et al performed a study in 2011 regarding "Which has greater analgesic effect: Intrathecal Nalbuphine or Intrathecal Tramadol?". Sixty patients posted for Transurethral resection

of the bladder tumor (TURBT) under the ASA physical status I and II were enrolled in the study. They were randomly divided into two groups

- Group T - received 15mg of 0.5% hyperbaric bupivacaine plus 50mg of tramadol hydrochloride preservative free (Total volume = 4ml).

- Group N - received 15mg of 0.5% hyperbaric bupivacaine plus 2mg of nalbuphine hydrochloride preservative free (Total volume = 4ml).

Spinal block was performed with 25G Quincke's needle in L3-L4 space with the patient in right lateral decubitus position. They studied postoperative analgesic requirements, sedation scores, Visual Analog Scale for pain intensity and side effects. The authors concluded that intrathecal tramadol and nalbuphine when used with bupivacaine 0.5% produce similar postoperative analgesia, however sedation scores were higher in tramadol group.

Lin M L[12] conducted a study in 1992 regarding "The analgesic effect of subarachnoid administration of tetracaine combined with low dose of morphine or nalbuphine for spinal anaesthesia". Sixty adult patients under the American Society of Anaesthesiologists (ASA) I and II

posted for lower limb surgeries were included in the study. Patients were randomized into two groups using computer generated random numbers. One group received 0.4mg morphine with tetracaine and another group received 0.4mg nalbuphine with tetracaine. Prior to spinal anaesthesia monitors like ECG, pulse oximetry for SPO2 and non invasive blood pressure were connected. Patients were preloaded with 500ml of Ringer Lactate solution. Spinal block was done with 26gauge Quincke's needle at L3-L4 interspace in sitting posture. Sensory level, motor block, VAS score were recorded serially. They found that addition of nalbuphine or morphine to hyperbaric tetracaine for SAB significantly decreases the onset time of sensory block, prolongs the duration of sensory and motor blockade and the time for first postoperative analgesic requirement. Side effects were less in nalbuphine group than in morphine group.

Ravikiran J Thote, Prashant Lomate, Shilpa Gaikwad[13] et al performed a study in 2015 titled " Comparison among intrathecal fentanyl and nalbuphine in combination with bupivacaine and plain bupivacaine for lower limb surgeries". The study design was a prospective randomised controlled double blind study. Sixty patients of both sexes posted for lower limb surgeries under ASA PS I and II were enrolled in the study.

They were segregated into three groups of 20 patients each using computer generated random numbers.

- Group I - received 2.5ml of 0.5% bupivacaine plus 0.5ml of 25mcg of fentanyl.

- Group II - received 2.5ml of 0.5% bupivacaine plus 0.5ml of 500mcg nalbuphine.

- Group III - received 2.5ml of 0.5% bupivacaine plus 0.5ml of normal saline.

Basic monitors of blood pressure, heart rate and oxygen saturation (SPO2) were connected. Intravenous lines started with an 18G cannula and RL infusion was started. SAB was performed with 25G gauge pencil point needle at L3-L4 interspace. The onset of sensory and motor blockade were significantly shorter in fentanyl and nalbuphine group. However the duration of sensory block was increased with nalbuphine-bupivacaine combination than fentanyl bupivacaine combination. Arousable sedation without any respiratory depression was noted with nalbuphine.

Xavier Culebras, Giovanni Gaggero[14] et al performed a study in 2000 titled "Advantages of Intrathecal Nalbuphine, Compared with Intrathecal Morphine, After Cesarean Delivery:An Evaluation of Postoperative Analgesia and Adverse Effects". After the approval from ethical committee and getting informed consent, ninety healthy parturients at term for elective cesarean delivery under spinal anaesthesia were included in the study. It was a randomized, prospective double blinded study. Patients received 10mg of 0.5% heavy bupivacaine with either morphine 0.2mg (category A), nalbuphine 0.2mg (category B), nalbuphine 0.8mg (category c), nalbuphine 1.6mg (category D). They found that postoperative analgesia was significantly longer in the morphine category than nalbuphine ($P < 0.0001$). Among the nalbuphine categories, postoperative analgesia was longer with 0.8mg. Adverse effects like pruritus, nausea and vomiting were frequently encountered with morphine when compared to nalbuphine. APGAR scores were similar in all groups. There was no newborn or maternal respiratory depression. The authors had concluded that 0.8mg intrathecal nalbuphine provides good intraoperative analgesia and improves postoperative analgesia without adverse effects.

Fournier R, Van Gessel E, Macksay M, Gamulin Z[15] performed a study in 1998 regarding "The onset and offset of intrathecal morphine versus nalbuphine for postoperative pain relief after total hip replacement". The objective of the study was to compare the postoperative analgesia caused by intrathecal morphine and nalbuphine. After the approval from ethical committee, twenty four geriatric patients posted for elective total hip replacement (THR) under continuous spinal anesthesia were randomized into two double blinded groups. Spinal block was performed by 25G quincke needle in L3-L4 space with 3.5ml of 0.5% bupivacaine heavy. In the recovery room, when they experienced pain (VAS > 3), either 160μgram morphine or 400μgram nalbuphine (diluted in 4ml NS) were given intrathecally. Patients were followed up for the next 24 hours after surgery. The authors found that intrathecal nalbuphine produces faster onset of pain relief but shorter duration of analgesia than morphine.

Moustafa AA, Baaror AS, Abdelazim IA[16] et al performed a study titled "Comparative study between nalbuphine and ondansetron in prevention of intrathecal morphine -induced pruritus in women undergoing cesarean section". After approval from the Institute Ethical committee and after informed written consent, ninety pregnant women of

ASA physical status II scheduled for cesarean delivery under spinal anaesthesia were recruited for this study. They were divided into three groups. SAB performed in left lateral position at L3-4 interspace using 25G Quincke spinal needle with 2.2ml of 0.5% (H) bupivacaine and 0.2 mg morphine. Immediately after delivery of baby they received one of the following

- Placebo group (P) - received 4ml of normal saline(NS) IV injection.
- Nalbuphine group (N) - received 4ml of 4mg nalbuphine IV.
- Ondansetron group (O) - received 4ml of 4mg ondansetron IV.

Patients were observed for pruritus scores, blood pressure, heart rate and SPO2 in the post anaesthesia care unit (PACU) for four hours. Both nalbuphine and ondansetron were effective for prevention of intrathecal morphine induced pruritus in parturients undergoing cesarean delivery. However nalbuphine was preferred because it is not excreted in breast milk.

Chatrath V, Attri[17] et al conducted a study regarding "The effect of epidural nalbuphine for postoperative analgesia in orthopedic surgery". A double blind prospective randomised study was performed

with eighty adult patients of American Society of Anaesthesiologists (ASA) I and II category posted for elective lower limb orthopedic surgeries under combined spinal epidural anaesthesia. Patients were divided into two categories using computer randomisation method.

- Group A - received epidurally 10ml of 0.25% bupivacaine along with 10mg nalbuphine.

- Group B - received epidurally 10ml of 0.25% bupivacaine along with 100mg tramadol.

Baseline hemodynamic parameters like heart rate, mean arterial blood pressure and oxygen saturation were noted. Subarachnoid block was given with 0.5% of 2.5ml bupivacaine in both the groups. Epidural top up was given at sensory regression to T10. Mean duration of analgesia and mean sedation score were compared between the groups. They concluded that the quality of analgesia and patient satisfaction score were better with nalbuphine epidurally than with tramadol.

Ananda Bangera, Krishna Prasad[18] et al conducted a study titled "Nalbuphine as an alternate analgesic to morphine in total abdominal hysterectomy". After approval from Institutional ethics committee (IEC) and obtaining informed consent, fifty patients under the ASA PS I and II

scheduled for total abdominal hysterectomy (TAH) were included in the study. Visual Analog Scale for pain assessment was explained to the patients prior to surgery. Patients were allocated randomly into two groups by closed envelope method. Injection diazepam 0.1mg/kg was given 30 minutes prior to induction of anaesthesia. General anaesthesia was standardised in both the groups. After preoxygenation

- Group N received 0.2mg/kg nalbuphine IV
- Group M received 0.1mg/kg morphine IV

Both groups were induced with propofol 2mg/kg and paralysed with vecuronium bromide 0.1mg/kg, followed by tracheal intubation. Anaesthesia was maintained with O2/N2O/isoflurane. At the end of surgical procedure, patients were reversed with neostigmine 50mcg/kg and glycopyrrolate 10mcg/kg and extubated. Intraoperative hemodynamics and duration of post operative analgesia were noted. Duration of analgesia was significantly more in nalbuphine patients than morphine patients (437±63.87 min vs 255±43.75min). The time to first analgesic requirement was significantly longer with intravenous nalbuphine in addition to better intraoperative hemodynamic stability.

Mohamed Abdelhaq, Mohamed Adly[19] conducted a study regarding the "Effect of nalbuphine as adjuvant to bupivacaine for ultrasound-guided supraclavicular brachial plexus block". It was a randomised double blind control study. VAS score was explained to all candidates where 0 corresponds to no pain and 10 is indicative of worst unbearable pain. After obtaining ethical committee approval, 56 patients posted for forearm and hand surgeries in the age group of 18-60 years under the ASA physical status I and II were enrolled in the study. Patients were randomly allocated into two equal study groups.

- Group C - received 25 ml of 0.5% bupivacaine and 1 ml normal saline

- Group N - received 25 ml of 0.5% bupivacaine and 1 ml nalbuphine (20mg).

On arrival to the operating room, IV line started with an 20G intravenous cannula and Ringer lactate infusion was started. Baseline values of blood pressure, heart rate and haemoglobin oxygen saturation were recorded. The supraclavicular block was performed with the ultra sound system. The authors concluded that addition of nalbuphine to bupivacaine in supraclavicular block is associated with increase in

duration of both sensory and motor block and duration of postoperative analgesia (835.18±42.45 min vs 708.14±54.57).

Maha M.I. Youssef, Nashwa S. EiZayyat[20] performed a study in 2014 titled "Lidocaine-nalbuphine Versus lidocaine-tramadol for intravenous regional anesthesia". After approval from local ethics committee and taking informed consent, sixty patients in the age group of 20 - 60 years under the American Society of Anaesthesiologists physical status I and II scheduled for minor hand surgeries were included in the study. The pain score was assessed by 10 point verbal rating scale. By random allocation patients were divided into three equal groups using computer based lists. Group L received 3mg/kg lidocaine 0.5% diluted in 40 ml isotonic saline. Group LT received 3mg/kg lidocaine 0.5% and 100mg tramadol diluted in 40 ml isotonic saline. Group LN received 3mg/kg lidocaine 0.5% and 10mg nalbuphine diluted in 40 ml isotonic saline. In the operating room, patients were monitored by ECG, NIBP and SPO2. Intravenous regional anesthesia was performed by using double pneumatic tourniquet and Esmarch elastic bandage in all patients. The parameters like latency time, duration of sensory and motor block and duration of analgesia were noted. The use of nalbuphine and tramadol as adjuvants accelerate the onset and prolongs the duration of both sensory

and motor block. Nalbuphine seems to be superior to tramadol in prolonging the duration of postop analgesia.

Lefevre B, Freysz M[21] et al conducted a study in 1992 titled "Comparison of nalbuphine and fentanyl as intravenous analgesics for medically compromised patients undergoing oral surgery". Twenty four patients of both sexes scheduled for oral surgery under the ASA physical status III or IV were included in the study. They had been double blindly randomized into two groups. Upon arrival to the operating room IV line was started with 18G Quincke needle and RL infusion started. One group received IV analgesia with 0.2mg/kg nalbuphine and another group received IV analgesia with 2mcg/kg fentanyl. Three minutes later local anaesthesia was administered in both the groups. Respiratory rate, oxyhemoglobin saturation (SpO2), heart rate and arterial blood pressure were recorded before and during surgery. The parameters like quality of analgesia, sedation scores, respiratory depression were noted. The authors concluded that there was no significant differences regarding analgesia and sedation between the two drugs. They also empathised that nalbuphine produce less respiratory depression and it should be a suitable alternative to fentanyl in medically compromised patients undergoing oral surgery.

Hala Mostafa Gomaa, Nashwa nabil Mohamed[22] et al conducted a study in 2013 titled "A comparison between post-operative analgesia after intrathecal nalbuphine with bupivacaine and intrathecal fentanyl with bupivacaine after cesarean section". Sixty pregnant females posted for elective LSCS under the ASA physical status II were included in the study. The patients after obtaining informed consent were divided into two groups. Group F received 2ml of 0.5% hyperbaric bupivacaine plus 0.5ml fentanyl(25µg) intrathecally. Group N received 2ml of 0.5% hyperbaric bupivacaine plus 0.5ml nalbuphine hydrochloride(0.8mg) intrathecally. The time to reach the T10 sensory segment was not significantly different between the two groups. However, the duration of intraoperative analgesia and early postoperative analgesia was prolonged in group N compared to group F.

Pallavi Ahluwalia, Amit Ahluwalia[23] et al conducted a study in 2015 titled "A prospective randomized double-blind study to evaluate the effects of intrathecal nalbuphine in patients of lower abdominal surgeries under spinal anaesthesia". After obtaining informed consent, seventy adult patients of both sexes aged between 18-60 years under ASA PS I and II posted for lower abdominal surgeries were included in the study. They were randomly divided into two groups. Group N received 2.5ml of

0.5% bupivacaine + nalbuphine 0.8mg (made upto 0.5ml) intrathecally. Group C received 2.5ml of 0.5% bupivacaine + normal saline (0.5ml) intrathecally. Prior to spinal anaesthesia monitors like NIBP, pulse oximetry, ECG were connected and the patients were hydrated with RL at 10ml/kg. Intradural puncture was performed at L3-L4 space with 25G Quincke needle in lateral decubitus position. They concluded that the addition of nalbuphine as adjuvant to bupivacaine intrathecally fastens the onset of sensory blockade (1.29±0.43min vs 3.78±1.31min) and prolongs the duration of sensory and motor blockade. The time to first analgesic requirement was longer in group N as compared to group C (298.43±30.92min vs 201.31±34.31min).

Priti M Chawda, Mayuresh K Pareek[24] et al did a study titled "Effect of nalbuphine on haemodynamic response to orotracheal intubation". After obtaining ethics committee(IEC) approval, sixty patients of both sexes under ASA grade I and II scheduled for laproscopic surgery were included in the study. Patients were divided into two equal groups. All the patients were premedicated with glycopyrrolate 4μg/kg and midazolam 1 mg 10 mins prior to induction of anaesthesia. Patients were monitored for ECG, MAP, SPO2 and capnography. Group I received 5ml normal saline (NS)and Group II received 5ml of 0.2mg/kg

nalbuphine five minutes before induction. Preoxygenation followed by induction with thiopentone 5mg/kg, Scoline 1.5mg/kg and orotracheal intubation was performed within 30 secs. HR and MAP were measured just after intubation and every 1 minute upto 10 mins. Anaesthesia maintained with O2/N20/sevoflurane. Reversal with 0.02mg/kg atropine and 0.04 mg/kg neostigmine and the patients were extubated. Pressor response were compared between the two groups before and after intubation. They concluded that nalbuphine prevented a marked rise in heart rate(HR) and mean arterial pressure(MAP) associated with laryngoscopy and tracheal intubation.

Chandrakar N, Lalwani J, Sahare KK[25] et al conducted a study regarding "The use of patient controlled analgesia using I.V tramadol and I.V nalbuphine for postoperative pain management after major abdominal surgery". The study was a prospective randomised controlled double blind trial. Eighty patients of ASA I and II were selected after approval from ethics committee and obtaining informed consent. 40 patients were allocated in each group. During the preoperative assessment, use of Patient Controlled Analgesia (PCA) for postoperative pain relief and VAS scale was explained. Injection glycopyrrolate 0.004 mg/kg, midazolam 0.05 mg/kg were given as premedicants. General anesthesia

was standardised in both groups. Pentazocine 0.5 mg/kg, thiopental 5 mg/kg and atracurium 0.5mg/kg were given for tracheal intubation. Anaesthesia was maintained with O2/N2O/isoflurane. Reversal was done with neostigmine 50mcg/kg and glycopyrrolate 10mcg/kg. PCA was started in the immediate postoperative period.

- Group T - received IV tramadol (10 mg bolus dose in concentration of 5mg/ml, lockout interval 10 min)

- Group N - received IV nalbuphine (2 mg bolus dose, lock out interval 10 min)

VAS scale and sedation score were assessed for 24 hours. The authors concluded that Visual Analog Scale was significantly reduced in nalbuphine group compared to tramadol. They also found that nalbuphine provides better hemodynamic stability, good sedation and significantly lower incidence of nausea and vomiting.

RH Saleh, MF Yousef[26] et al conducted a study regarding "The effect of nalbuphine as an adjuvant on levobupivacaine induced caudal analgesia in children undergoing surgical procedures". 40 patients aged 1-9 years scheduled for pelvi-abdominal surgeries under ASA PS I and II were included in the study. They were randomly segregated into two

groups. Standard monitors like ECG, NIBP, pulse oximetry were connected. Anaesthesia was induced using sevoflurane 4% (inhalational route), then an IV cannula was inserted and atropine 0.01mg/kg administered. Anaesthesia was maintained with 100% oxygen/isoflurane 2-3% with spontaneous breathing. Then caudal block was performed according to their group.

- Group L - received levobupivacaine 0.25% with the dose of 1ml/kg.

- Group L+N - received levobupivacaine 0.25% with the dose of 1ml/kg and nalbuphine 0.1 mg/kg.

Hemodynamic variables, pain score and sedation score were recorded. The postoperative requirement of fentanyl and time to first analgesic requirement were noted. The authors concluded that caudal nalbuphine is safe in paediatric surgeries and effectively reduces postoperative pain. Nalbuphine may cause early postoperative sedation but without respiratory depression.

Opioids
and
Opioid Receptors

OPIOIDS

Opioid is derived from the Greek word *opos* means juice. An opioid is any substance regardless of its origin or structure, which acts on opioid receptors and produces morphine like effects that are blocked by antagonists such as nalaxone. It includes natural, semi synthetic and synthetic agents.

Opiates includes the natural alkaloids like morphine, thebaine and codeine which are derived from the juice of *Papaver somniferum*. Frederick sertuner first isolated crystalline substance from opium and he named as morphine in 1806.

Papaver somniferum

ENDOGENOUS OPIOIDS

Endogenous opioids are found within the brain, which acts through opioid receptor. They are of primarily three classes - enkephalins, endorphins and dynorphins.

CLASSIFICATION

NATURAL	SEMI SYNTHETIC	SYNTHETIC
Morphine	Heroin	Pethidine
Codeine	Dihydromorphone	Pentazocine
Thebaine	Oxymorphone	Fentanyl
		Buprenorphine
		Nalbuphine etc.,

USES OF OPIOIDS

- Analgesia (both intraoperative and postoperative)
- As a premedicant
- As an induction agent
- To blunt intubation response
- Sedation in ICU

- To prevent and control shivering
- As an adjuvant to local anesthetic in intrathecal or epidural space.

OPIOID RECEPTORS

Opioid receptors are the receptors which primarily mediate the analgesic and other effects of opioid drugs (like morphine) and endogenous opioid peptides. It belongs to the G protein-coupled receptor family. They all inhibit adenylate cyclase[27] and reduce cellular cyclic adenosine monophosphate content. Opioid receptors are present in brain, spinal cord and gastrointestinal tract.

In the brain, opioid receptors are expressed in amygdala, mesencephalic reticular formation, periaqueductal gray matter, lamina I & IV of thalamus, mid brain and rostral ventral medulla.

SUB TYPES OF OPIOID RECEPTORS

Opioid receptors[28] are subdivided into three subtypes. They are mu(μ), kappa(κ), delta(δ).

- **mu(μ) receptors** - gene on chromosome 6. They are again subdivided into μ_1, μ_2, μ_3.

μ_1	μ_2	μ_3
- analgesia	-respiratory depression	- Vasodilation
-Physical dependence	- miosis,	-Increase GH and prolactin
	-constipation	
	- euphoria	

- **kappa(κ) receptors -** gene on chromosome 8. They are again subdivided into κ_1, κ_2, κ_3. They mediates analgesia, dysphoria, miosis, sedation, diuresis.

- **delta(δ) receptors -** gene on chromosome 1 and 4. They mediates analgesia, respiratory depression, dependence.

Newer opioid receptors

- Nociceptin receptor
- Zetta receptor.

Based on receptor interaction opioids are classified into pure agonist(+), mixed agonist/antagonist(+/-) and pure antagonist(-).

Pure agonist(+)	Mixed agonist/ antagonist(+/-)	Pure antagonist(-)
morphine,	pentazocine,	naloxone,
fentanyl,	**nalbuphine,**	naltrexone,
alfentanil,	nalorphine,	nalmefene.
pethidine ,	buprenorphine,	
remifentanil,	butorphanol,	
sufentanil.	dezocine, etc.,	

MECHANISM OF ACTION OF OPIOIDS

Opioids produce analgesia through spinal, supraspinal and peripheral mechanisms.

Supraspinal

It activates pain control circuits (corticospinal tract), which descend from midbrain via rostral ventromedial medulla to the spinal cord, thereby blocking nociceptive stimuli.

Spinal

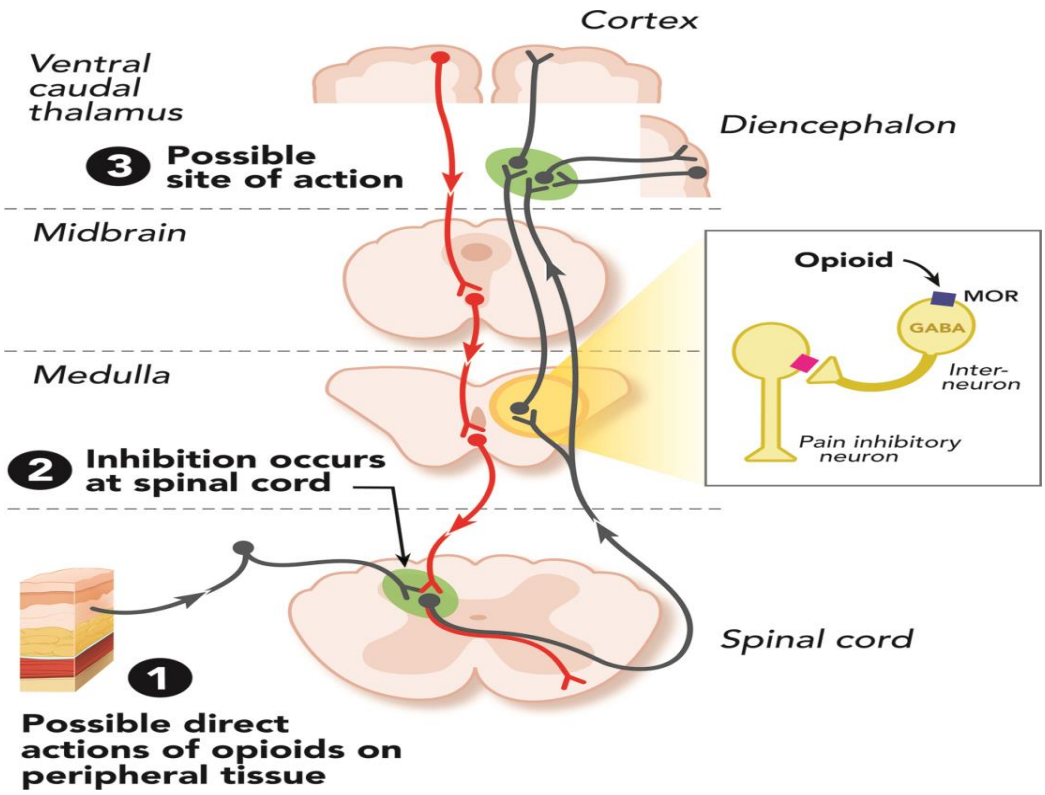
They act in substantia gelatinosa of dorsal horn cells, where they inhibit substance P release and directly inhibit the ascending transmission of nociceptive stimuli.

Peripheral mechanisms

Stimulates G protein synthesis and increase cAMP which causes

Increased K^+ - Hyperpolarization of membrane

Decreased Ca^{2+} - ↓Excitability



Site of action of opioids

Pharmacology Of Nalbuphine

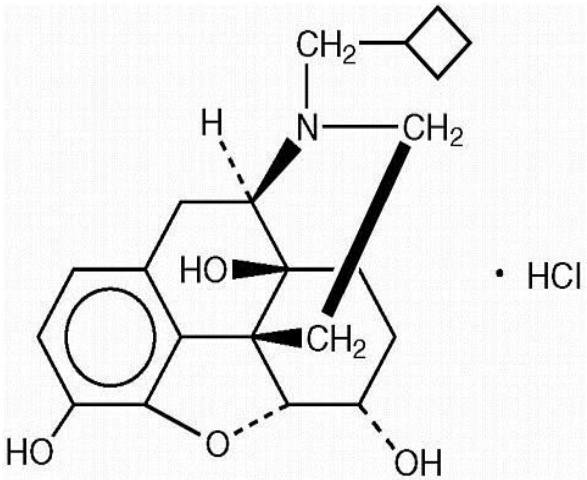
PHARMACOLOGY OF NALBUPHINE

Narcotic analgesics are associated with significant abuse potential. To overcome the abuse potential, various synthetic opioids were developed. Those substances are referred to as mixed agonist-antagonist analgesics. Nalbuphine is one among them.

CHEMISTRY

Nalbuphine hydrochloride, a synthetic narcotic agonist-antagonist analgesic of the phenanthrene series. Chemically, it is related to the opioid antagonist naloxone and opioid agonist oxymorphone. Nalbuphine is soluble in water at 25^{o}C, ethanol 0.8% and available only as an injectable solution.

CHEMICAL STRUCTURE



CHEMICAL NAME

17-(cyclobutylmethyl)-4,5-epoxy-,morphinan-3,6,14-triol, hydrochloride

RECEPTOR INTERACTION

Nalbuphine binds to mu(μ), kappa(κ), and delta(δ) receptors, but not to sigma receptors. Nalbuphine is primarily a κ agonist/μ antagonist analgesic. Nalbuphine has an analgesic potency[29] similar to that of morphine on a milligram for milligram basis. The narcotic antagonist activity of nalbuphine is one-fourth($1/4^{th}$) as potent as that of nalorphine and ten times that of pentazocine. When administered subsequent or concurrent with μ agonist opioid analgesics (e.g., morphine, fentanyl), nalbuphine may partially reverse or block opioid-induced respiratory depression from the μ agonist analgesic.

MECHANISM OF ACTION

By its agonist action, nalbuphine stimulates κ receptors thereby inhibiting the release of neurotransmitters like substance P that mediate pain. It acts as a post-synaptic inhibitor on the "inter neurons & output

neurons" of the Spino-thalamic tract which transport nociceptive information.

PHARMACEUTICAL INFORMATION

Molecular formula	-	C_{21} H_{27} NO_4 .HCl
Molecular Mass	-	393.91 g/mol
pKa	-	8.71

PHARMACOKINETICS

Nalbuphine is inactive orally and intravenous route is the conventional route of administration. It can also be administered by intramuscular, subcutaneous, neuraxial routes.

Bio-availability is around 80%.

Volume of distribution is 3.8litres/kg.

Onset of action
- intravenous administration is within 2-3 mins
- Subcutaneous, intramuscular < 15 mins

Plasma half life - 5 hrs

Duration of analgesia - 3 to 6 hours

Nalbuphine is primarily metabolised in the liver and the metabolites are excreted via kidney. Hence the dosage of nalbuphine must be decreased in patients with hepatic and renal failure.

USES OF NALBUPHINE

- As an adjuvant to general anesthesia
- As an adjuvant to neuraxial anesthesia
- Obstetric analgesia during labor and delivery
- As an adjuvant to peripheral nerve blocks.
- In the management of postoperative pain.

OFF LABEL USES

- Opioid induced pruritus.
- Opioid induced respiratory depression[30]
- Post anesthesia shivering
- Sickle cell anemia with crisis

PREPARATIONS AND STORAGE

- Available as 10mg, 20mg solutions in 1ml ampoule.
- Should be stored at room temperature (15°c to 30°c).
- Protect from excessive light.

Inj. Nalbuphine Ampoule

ADVERSE EFFECTS

The most common side effects of nalbuphine are sedation, sweating, nausea, vomiting, dizziness, vertigo, dry mouth, headache. Other effects are bradycardia, hypotension, urinary urgency. Because of the ceiling effect,[31] nalbuphine causes less respiratory depression compared to other opioids. It is classified as category 'B' (animal studies have failed to demonstrate fetal risk and there are no controlled studies in pregnant women) drug in pregnancy. It should be avoided in patients who are hypersensitive to the drug or its components.

Pharmacology Of Bupivacaine

PHARMACOLOGY OF BUPIVACAINE

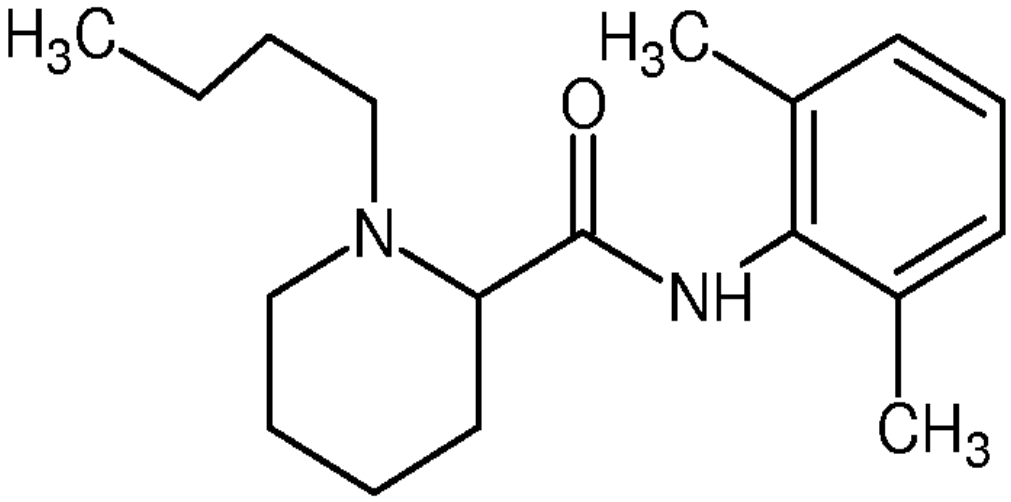
Bupivacaine belongs to amide group of local anaesthetics. This long acting local anaesthetic was first synthesized by A.F. Ekenstam in 1957.

Commercial bupivacaine is a racemic mixture of R(dextro) and S(levo) stereoisomers. It is 4 times more potent than Xylocaine. It is available as hydrochloride salt for anaesthesia.

CHEMICAL NAME

(2S)-1-Butyl-N-(2,6-dimethylphenyl)-piperidinecarboxamide

CHEMICAL STRUCTURE

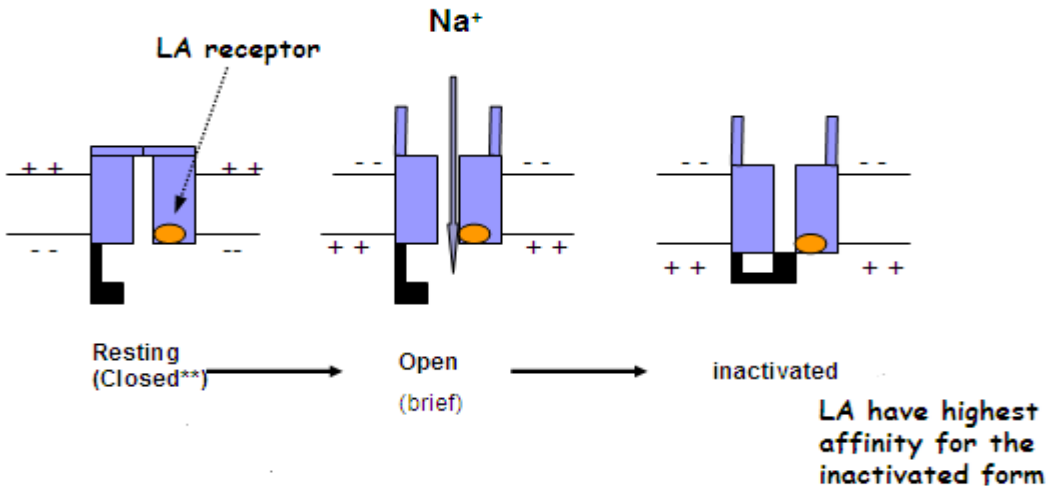


PHYSIO- CHEMICAL PROPERTIES

Molecular Formula	-	C18H28N2O
Molecular Weight	-	290 gm/mol
Plasma protein binding	-	95%
Lipid solubility	-	28 mg/L
Solubility in water	-	1 in 25
Solubility in alcohol	-	1 in 8

MECHANISM OF ACTION

All local anaesthetics causes blockade of voltage gated sodium channels, resulting in decreased entry of sodium ions into the cells thereby preventing depolarization. Hence the nerve signals and action potential cannot be propagated.



PHARMACOKINETICS

After administration it is rapidly absorbed from the injection site. The route of administration determines the rate of rise of plasma concentration as well as the peak plasma concentration. Steady state volume of distribution is about 70 litres and the clearance is approximately 0.48L/min.

UPTAKE OF BUPIVACAINE IN SPINAL CORD

First method - simple diffusion from the CSF into the piamater and subsequently into the spinal cord.

Second method - by extension into the Virchow-Robin spaces (layers of piamater).

METABOLISM

Bupivacaine is metabolised by one of the following pathways

- aromatic hydroxylation
- amide hydrolysis
- N-methyl dealkylation
- conjugation

Metabolites are primarily excreted in the liver, 5-10% of the drug is excreted unchanged in urine.

Onset of action (spinal) - 5 to 10 mins.

Duration of spinal block - 90 to 120 mins.

USES

- Central neural blockade (spinal & epidural anaesthesia)
- Peripheral nerve blocks
- Infiltration anaesthesia

COMMERCIAL PREPARATIONS

- It is available in 4ml ampoules for intrathecal injection - 5mg/ml of 0.5% bupivacaine and 80mg of dextrose.
- As 10 and 20ml vials with the concentration of 0.25%, 0.5% solutions.

CONTRAINDICATIONS

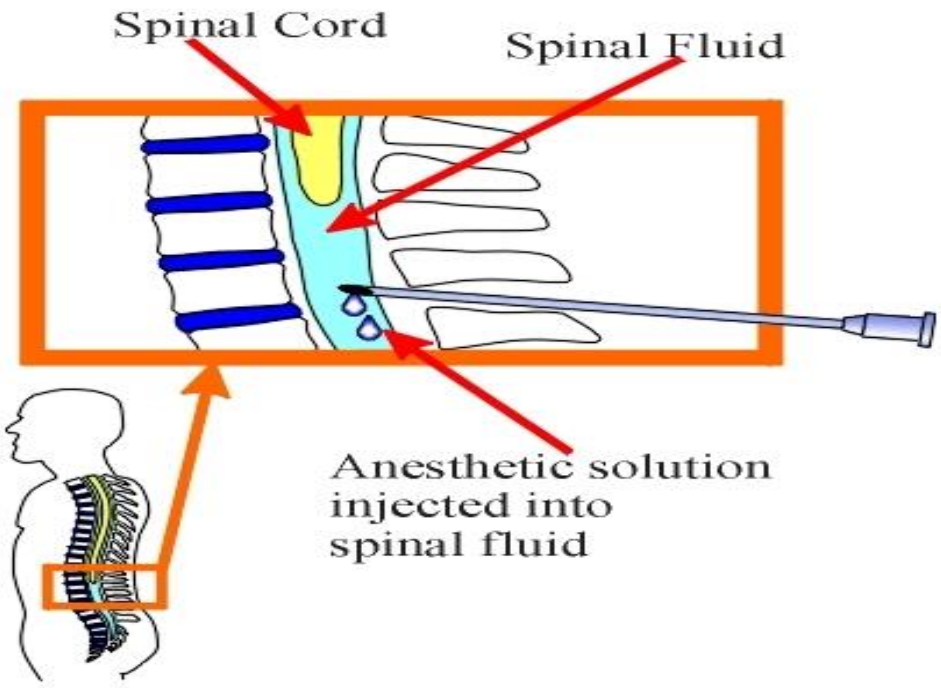
- Hypersensitivity to local anaesthetics
- Intravenous regional anaesthesia (Bier's block)
- Paracervical block

Subarachnoid Block

ANATOMY OF SUBARACHNOID BLOCK

Spinal anaesthesia was introduced by AUGUST BIER in 1898. It involves single injection of a local anesthetic solution into the subarachnoid space usually at the lumbar level (commonly at L3 – L4). Principal site of action for central neuraxial blockade is the nerve root. SAB produces

- Sympathetic blockade
- Sensory blockade
- Motor blockade

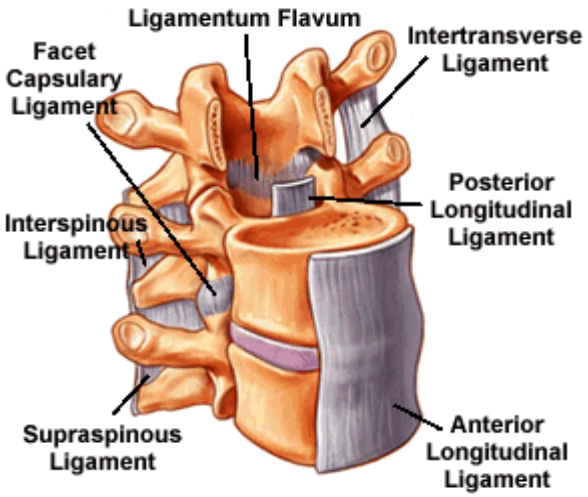


Site of Injection of Drug

The spinal cord extends from foramen magnum (base of the skull) to lower border of L1 in adults, hence spinal puncture below L1 is advised to prevent trauma to the cord. In children the cord extends upto L3 and adult level is achieved by 2 years**.**

VERTEBRAL LIGAMENTS

Supraspinous ligament	Connects the tip of each spinous process to the other.
Interspinous ligament	Connects the vertebral spines
Ligamentum flavum ("yellow ligament")	Connects the lamina above and below
Anterior Longitudinal Ligament	Connects the front (anterior) of the vertebral body to the front of the annulus fibrosus.
Posterior Longitudinal Ligament	Connects the back (posterior) of the vertebral body to the back of the annulus fibrosus.



Vertebral Ligaments

DERMATOLOGICAL SEGMENT LEVELS

Touffier's line - Line drawn between the highest points of both iliac crests. It usually corresponds to L4 spine or L4-L5 interspace

C7	Spinous process of 7th cervical vertebrae. It is prominent and easily palpable.
T4	Nipple
T6	Xiphisternum
T7	Inferior angle of scapula
T10	Umblicus
L1	Inguinal ligament
S1 to S4	Perineum

BLOCK REQUIREMENTS

Surgery	Level required
Cesarean section, Gynecologic, Intestinal surgery	T6
Transurethral resection of prostate(TURP), Transurethral resection of bladder tumor(TURBT)	T10
Knee surgery	L1
Foot and ankle surgery	L2
Perineal and anal surgery	S2-S4

STRUCTURES PIERCED BY SPINAL NEEDLE

Skin

⇩

Subcutaneous tissue

⇩

Supraspinous ligament

⇩

Interspinous ligament

⇩

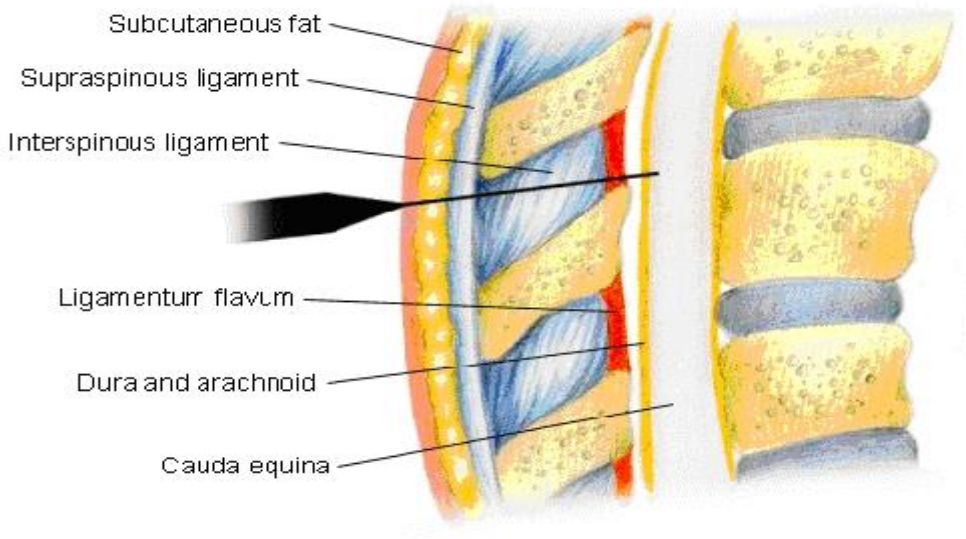
Ligamentum flavum

⇩

Dura and Arachnoid

⇩

Subarachnoid space



Structures encountered during spinal anaesthesia

ADVANTAGES OF SPINAL ANAESTHESIA

- Patient is alert during surgery
- Lower incidence of Nausea/Vomiting/sore throat
- Better Pain Control
- Economical
- Sympathectomy→ vasodilation→ ↑↑blood flow to legs → ↓ incidence of DVT

INDICATIONS

- General surgery - lower abdominal, urogenital, Inguinal & rectal surgery

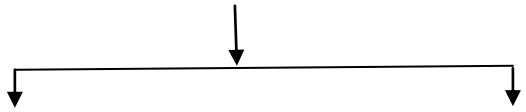
- Orthopaedic surgery- all lower limb surgeries, few pelvic surgeries
- Urologic surgery - Bladder, Prostrate and ureteric surgery
- Gynaecologic and obstetrics surgery - Lower segment cesarean section, Hysterectomy, Dilatation & Curettage.

CONTRAINDICATIONS

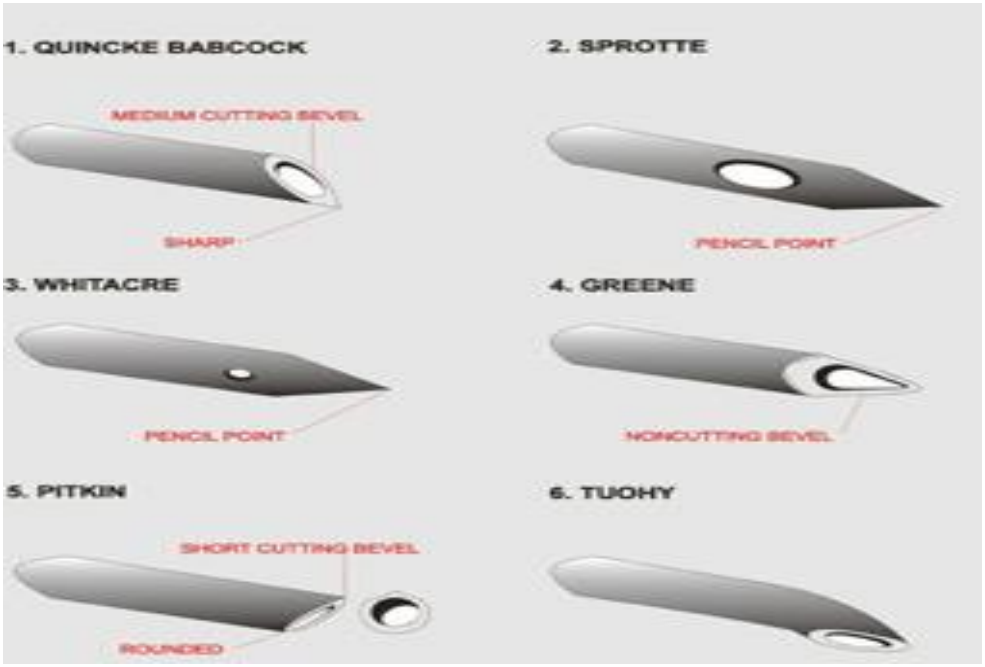
- Refusal by the patient
- Overt coagulopathy
- Increased intracranial tension
- Infection at injection site
- Shock, severe hypovolemia
- Fixed cardiac output lesions like mital stenosis, aortic stenosis, complete heart block.

TECHNIQUES

Spinal Needles



Dura cutting	Dura Separating
(PDPH incidence is high)	(PDPH incidence is less)
- Quincke-Babcock	- Whitacre
- Greene	- Sprotte
	- Pitkin



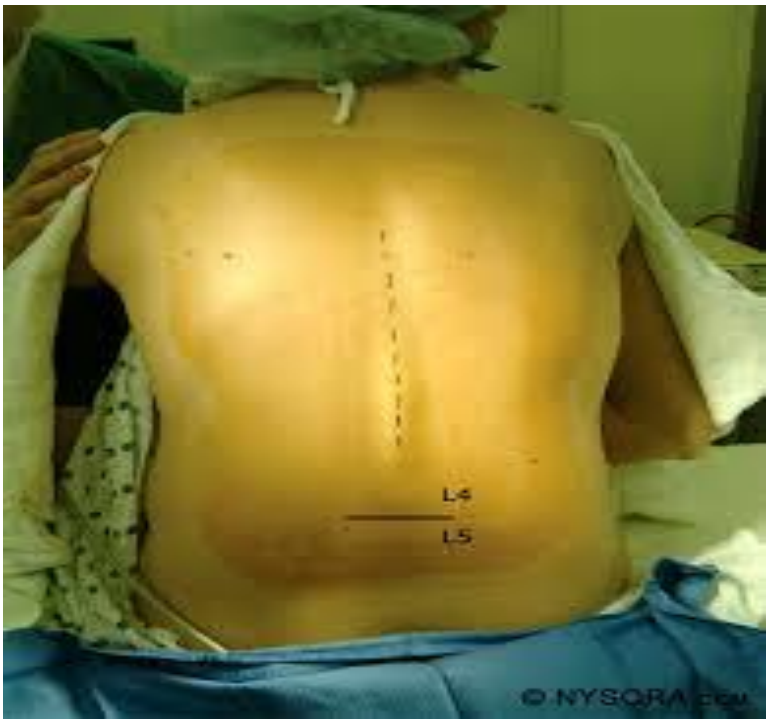
Spinal needles

Spinal needles are available in sizes ranging from 16 - 30 gauge.

POSITIONING

Proper positioning is important for technical ease and successful block. The various positions are

1. Lateral decubitus
2. Sitting
3. Prone (using hypobaric drug)



Sitting posture

APPROACH

The different approaches are

1. Midline approach

Needle is introduced in the midline and directed slightly cephalad. Two pop ups are felt, one is supraspinous ligament and the other is ligamentum flavum. The needle is advanced to penetrate the dura and then subarachnoid membrane as signalled by free flowing CSF. The best sign of correct lumbar puncture is free flowing CSF.

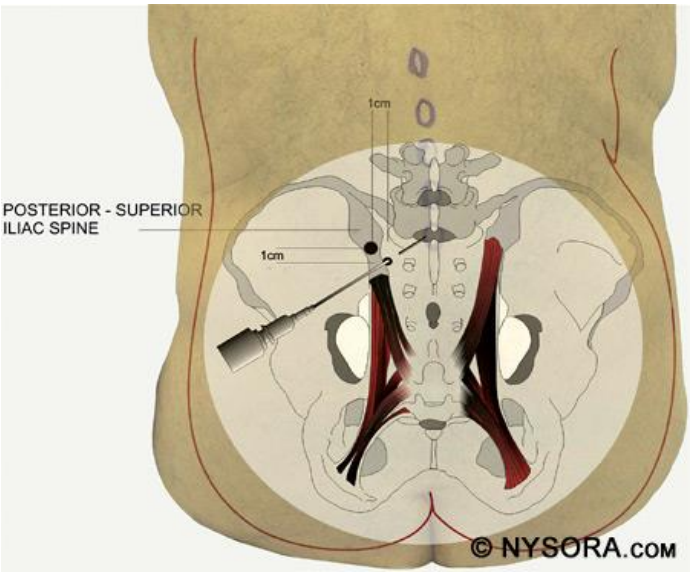
2. Lateral or Paramedian approach

Indicated in patients with positioning difficulty (Kyphoscoliosis, Sclerotic lesions). The needle is inserted 1cm lateral and 1cm caudal to the inferior aspect of spinal process. Here the first resistance felt is ligamentum flavum.

Lateral approach

3. Taylor's approach

It is a type of paramedian technique in which the needle is directed towards L5-S1 space. Point of insertion is 1cm medial and 1cm inferior to posterior superior iliac spine. Used in conditions of lumbar spine deformity.



Taylor's approach

DRUGS USED

Drug	Doses	Duration
Lignocaine 5%	1-2ml	1-1.5 hr
Bupivacaine 0.5%	2-4ml	2-4 hr
Ropivacaine 0.75%	2-4ml	2-4 hr
Levobupivacaine 0.5%	2-4ml	2-3 hr

BARICITY OF THE SOLUTION

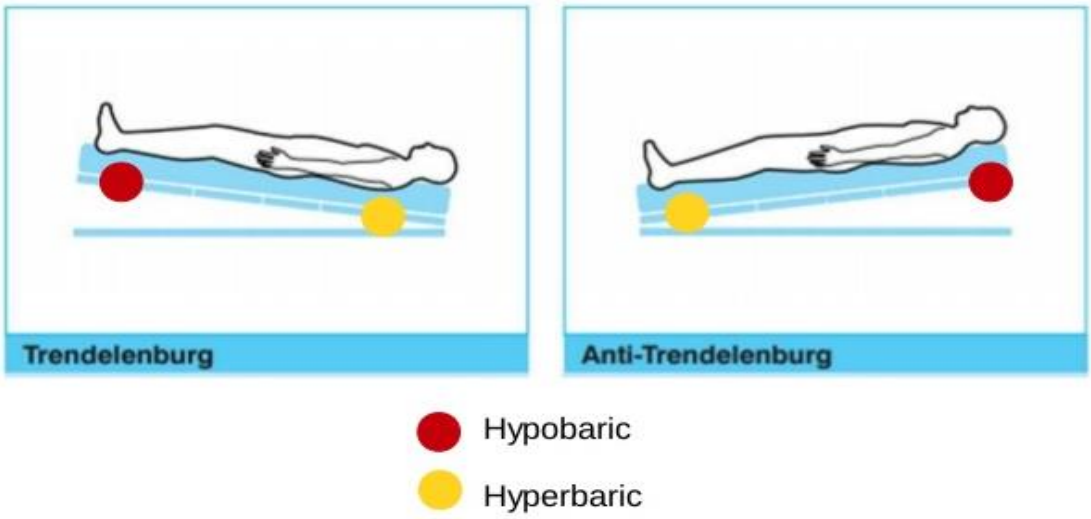
Baricity refers to the specific gravity of the local anesthetic solution in relation to CSF. It determine the spread of local anesthetic in the subarachnoid space. The specific gravity of CSF is 1.0069.

HYPERBARIC SOLUTIONS

Density of local anesthetic is greater than density of CSF. So the deposited drug flows to dependent sites. The position of the patient determines the height of block while using hyperbaric & hypobaric solution.

HYPOBARIC SOLUTIONS

Density of local anesthetic is less than density of CSF. So the deposited drug flows from dependent sites.



Body Position and Baricity Interaction

ISOBARIC SOLUTIONS

Density of local anesthetic is approximately equal to density of CSF. So the deposited drug stays there itself. The position of the patient has no effect.

FACTORS AFFECTING HEIGHT OF BLOCK

Modifiable factors

- Dose of the drug(volume & Concentration)
- Site of injection
- Posture of patient
- Baricity of LA

Non-modifiable factors

- Volume of Cerebro Spinal Fluid.
- Density of Cerebro Spinal Fluid.

FACTORS AFFECTING DURATION OF BLOCK

- Dose of the drug (volume & Concentration)
- Pharmacological profile of the drug like protein binding, lipid solubility.

- Type of the drug (Bupivacaine > lignocaine)
- Added opioids.

ORDER OF BLOCKING NERVE FIBER

1. Preganglionic sympathetic B fibers
2. Temperature (Cold > Warm)
3. Pinprick
4. Pain
5. Touch
6. Pressure
7. Proprioception
8. Somatic motor fibers.

Sequence of block is autonomic first, followed by sensory and then motor fibres.

COMPLICATIONS

- Cardiovascular disturbances like hypotension, bradycardia
- High spinal block

- Local anesthetic induced neurotoxicity & neurological damage
- Postdural puncture headache
- Backache
- Transient neurological symptoms (lignocaine)
- Others- Meningitis, Arachnoiditis, Cauda equina syndrome, Hematoma formation.

Materials and Methods

MATERIALS AND METHODS

"Prospective randomized controlled study evaluating anaesthetic efficacy of mixture of intrathecal bupivacaine 0.5% heavy and nalbuphine hydrochloride with intrathecal bupivacaine 0.5% heavy alone for infra umbilical surgeries".

The study was duly submitted before the Institutional Ethical Committee and approval was obtained before the commencement of the study.

STUDY DESIGN

It was a Prospective Randomized controlled study.

SAMPLE SIZE CALCULATION

The study population comprised of 60 adult patients classified under the ASA PS 1 or 2 posted for lower abdominal surgery and lower limb orthopaedic surgery.

INCLUSION CRITERIA

- 30 - 60 years of age
- ASA physical status 1 or 2

- Patients who gave valid informed written consent
- Patients undergoing lower abdominal surgery and lower limb orthopaedic surgery.

EXCLUSION CRITERIA

- Lack of valid informed written consent
- Infection at the subarachnoid block injection site
- Patients with neurological and musculoskeletal disease
- Patients with bleeding disorders
- Patients on anticoagulants
- Pregnancy
- History of allergy to local anaesthetic

STUDY CENTRE & STUDY PERIOD

ESIC MEDICAL COLLEGE & PGIMSR, KK NAGAR, CHENNAI from September 2015 to June 2016.

PRE-OPERATIVE ASSESSMENT

All the patients were duly examined on the day prior to surgery and pre-operative assessment sheet was checked. The height, weight, body

mass index of the patient were measured. The airway assessment, spine examination and the nutritional status of the patient were evaluated.

A detailed general and systemic examination was done. Pre-operative investigations like complete haemogram, renal function tests, random blood sugar, blood grouping and typing, electrocardiography and chest X ray were evaluated properly.

INFORMED WRITTEN CONSENT

All the patients were informed about the nature of the study and a valid informed written consent was obtained.

PREMEDICATION

All the patients were fasted overnight and they were pre-medicated with tablet ranitidine 150mg, tablet metoclopramide 10mg, tablet alprazolam 0.5mg on the night before surgery.

PREPARATION

Upon arrival to the operating room, standard monitors like non invasive blood pressure(NIBP), Electrocardiography(ECG) and pulse oximetry were connected and baseline values were recorded. An

intravenous line was secured with 18G cannula and patients were preloaded with10ml/kg of Ringer Lactate (RL) solution. Patients were randomly divided into either of the two groups- Group A or Group B by slips in the box technique.

MATERIALS:

DRUGS

- Nalbuphine Hcl - Inj
- 0.5% bupivacaine heavy - Inj
- Normal saline
- Emergency drugs

EQUIPMENTS

- 25 G Quincke needle
- Sponge holding forceps
- Sterile 5ml & 10ml syringe
- Sterile drape
- Sterile gauze pieces.

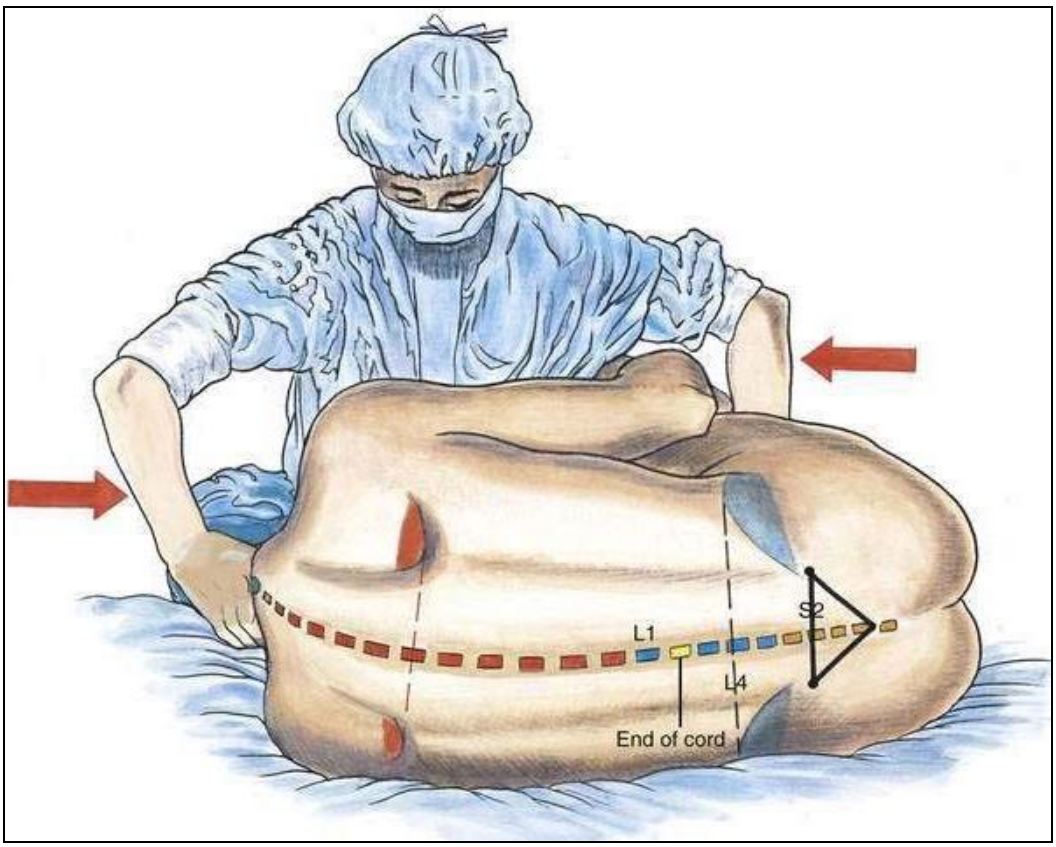
TECHNIQUE:

The patient was placed in the right lateral decubitus position. Under strict aseptic precautions, lumbar puncture was performed at L3-L4 intervertebral space with 25 G quincke needle using the median approach. After free flow of clear cerebrospinal fluid(CSF), drug was injected at 0.2ml/sec.

Group A received 15mg (3 ml) of 0.5% bupivacaine (H) and nalbuphine 0.5 mg (0.5ml) - Total volume 3.5 ml.

Group B received 15mg (3 ml) of 0.5% bupivacaine (H) and normal saline 0.5 ml (0.5ml)- Total volume 3.5ml.

Oxygen at 4l/min was administered through face mask. Hemodynamic parameters like peripheral oxygen saturation, non invasive blood pressure, pulse rate were recorded at regular intervals intraoperatively and postoperatively up to 24 hours.



Position for Subarachnoid Block

MONITORING

- Hypotension - Systolic blood pressure less than 90mm Hg or less than 20% from baseline. Treatment given- Inj. Mephentermine 6mg IV bolus.

- Bradycardia - Heart rate less than 50 beats/min. Treatment given - Inj. Atropine 0.6 mg.

BLOCK EVALUATION

SENSORY BLOCK

Sensory block was assessed by pinprick method in the mid-clavicular line using 27G needle, every minute until the block reached T6 dermatome. After that, level was checked every 2 mins until maximal sensory block was attained.

GRADES OF SENSORY BLOCKADE

GRADE 0	-	Sharp pain felt
GRADE 1	-	Analgesia, dull sensation felt
GRADE 2	-	Anesthesia, no sensation felt

Onset of sensory blockade was defined as the time interval between the end of anesthetic injection to loss of sensation to pinprick at T10 level.

MOTOR BLOCKADE

Quality of motor block was assessed by modified Bromage scale.

- GRADE 0 - no motor blockade, able to lift the leg at the hip.

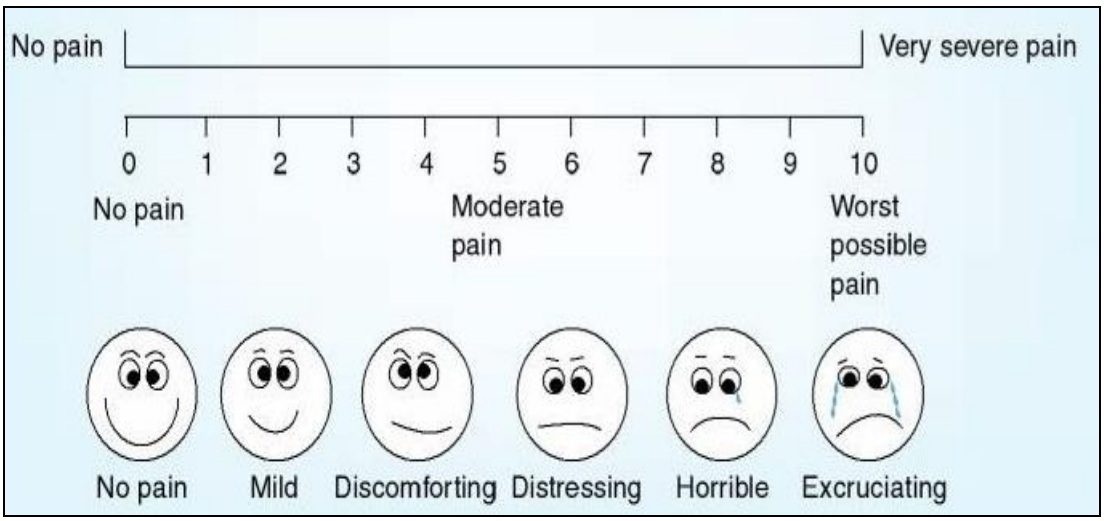
- GRADE 1 - Able to flex the knee and ankle but not able to lift the leg at the hip (hip blocked)
- GRADE 2 - Able to move the foot only (hip and knee blocked)
- GRADE 3 - Unable to move even the foot (hip, knee and ankle blocked).

Onset of complete motor blockade was defined as the time interval between the completion of study drug injection until Bromage 3 registered.

Surgery was started when complete anaesthesia was attained. After the completion of the surgery, both sensory and motor level were noted. Two segment regression time from the maximal level and regression to level L1 was also noted. Postoperatively, patients were regularly followed up in the recovery and postoperative ward for pain score using VAS scale.

VISUAL ANALOG SCALE

Preoperatively patients were explained in detail about Visual Analog Scale. The scores were evaluated in the postoperative ward and rescue analgesia was given at a VAS score of 4 or more.

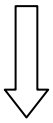


0-10 VAS Numeric Pain Distress Scale

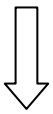
SCORE 0-2	NO PAIN
SCORE 2-4	MILD PAIN
SCORE 4-6	MODERATE PAIN
SCORE 6-8	SEVERE PAIN
SCORE 8-10	UNBEARABLE PAIN

PATIENT FLOW CHART

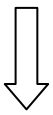
ASSESMENT CLINIC: ASA I and ASA II (30 - 60 years of either sex) posted for Infra umbilical surgeries



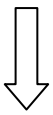
Informed written consent obtained



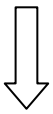
Patient shifted to operation theatre



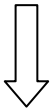
WHO checklist followed



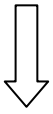
Groups allocated by slips in the Box technique



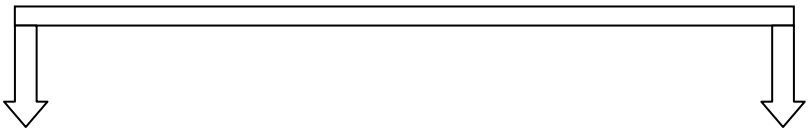
ECG, Pulse oximetry, NIBP monitors connected



IV access secured and preloaded with RL 10ml/kg



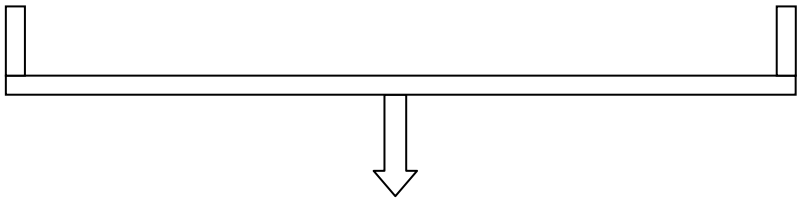
Subarachnoid block performed using 25G Quincke needle



Group A | Group B

15mg of Bupivacaine 0.5% (H) (3ml) + 0.5mg Nalbuphine (0.5ml)

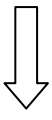
15mg of Bupivacaine 0.5% (H) (3ml) + Normal Saline 0.5ml



Block assessment

Sensory - Pin prick method

Motor - Modified Bromage scale



Post-operative follow up

Duration of analgesia- VAS scale

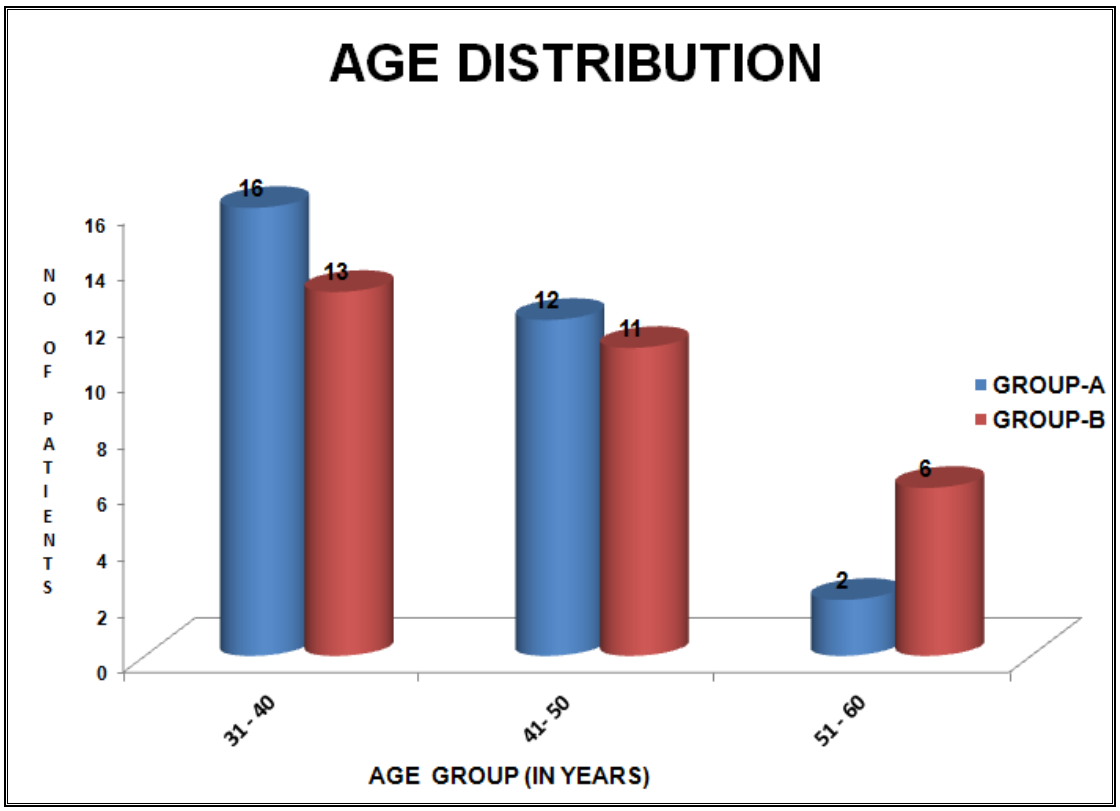
Statistics and Results

RESULTS AND STATISTICS

Sample size was calculated using n.master 2.0 software. Sample size based on clinical trials-parallel design-hypothesis equivalence/ bioequivalence. Equivalence margin is 1, observed / expected difference - 0.68, Standard deviation - 0.5, Effect size - 0.64, Power (1-β) - 80, α Error (%) - 5, Group A-30, Group B - 30. For Statistical analysis IBM SPSS (Version 21) software was used. The demographic data of the patients in both the groups were studied and the analysis revealed no significant difference between the two groups.

Table-1: AGE DISTRIBUTION

Age (Years)	**GROUP-A**		**GROUP-B**	
	No of Patients (N)	**Percentage (%)**	**No of Patients (N)**	**Percentage (%)**
31 - 40	16	53.33	13	43.33
41 - 50	12	40.00	11	36.67
51 - 60	2	6.67	6	20.00
TOTAL	30	100	30	100
Chi-square Value	2.35			
p-value	0.31			
Significant	**Not Significant**			



GROUP A - BUPIVACAINE + NALBUPHINE

GROUP B - BUPIVACAINE + NORMAL SALINE

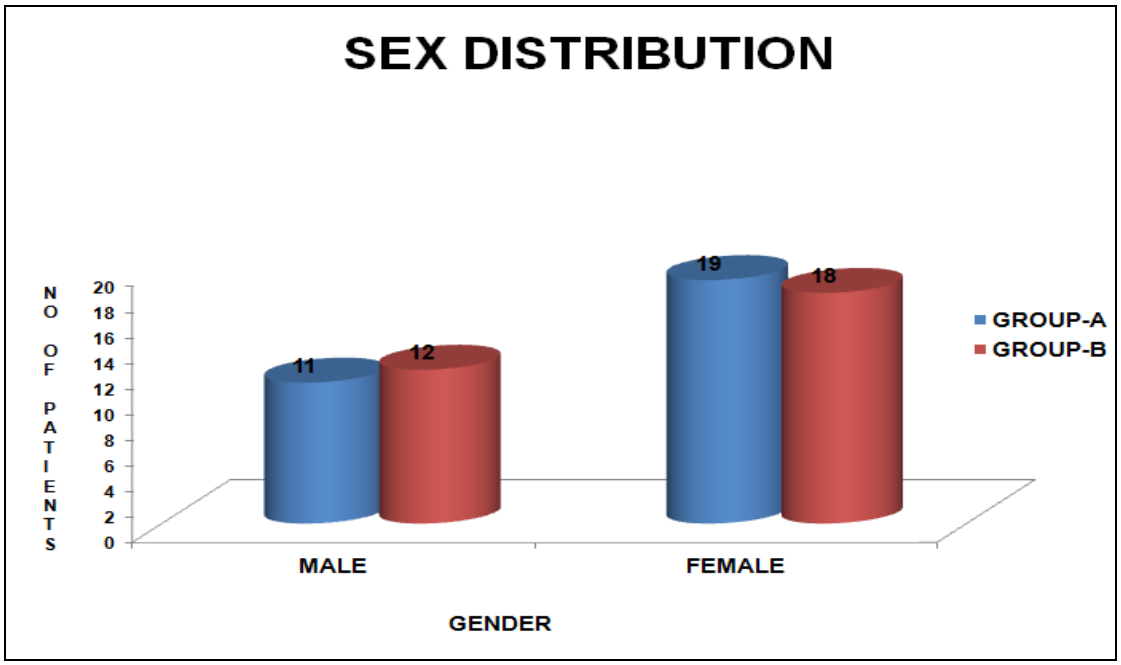
Both the groups are identical in distribution in terms of age.

Mean Age (in Years)

Group	Mean	Standard Deviation
GROUP-A	39.90	7.60
GROUP-B	42.57	8.40
t-value	1.29	
p-value	0.20	
Significant	**Not Significant**	

Table-2: SEX DISTRIBUTION

SEX	GROUP-A		GROUP-B		TOTAL	
	No of Patients (N)	%	No of Patients (N)	%	No of Patients (N)	%
MALE	11	36.67	12	40.00	23	38.33
FEMALE	19	63.33	18	60.00	37	61.67
TOTAL	30	100	30	100	60	100
Chi-square value	0.07					
p-value	0.79					
Significant	**Not Significant**					



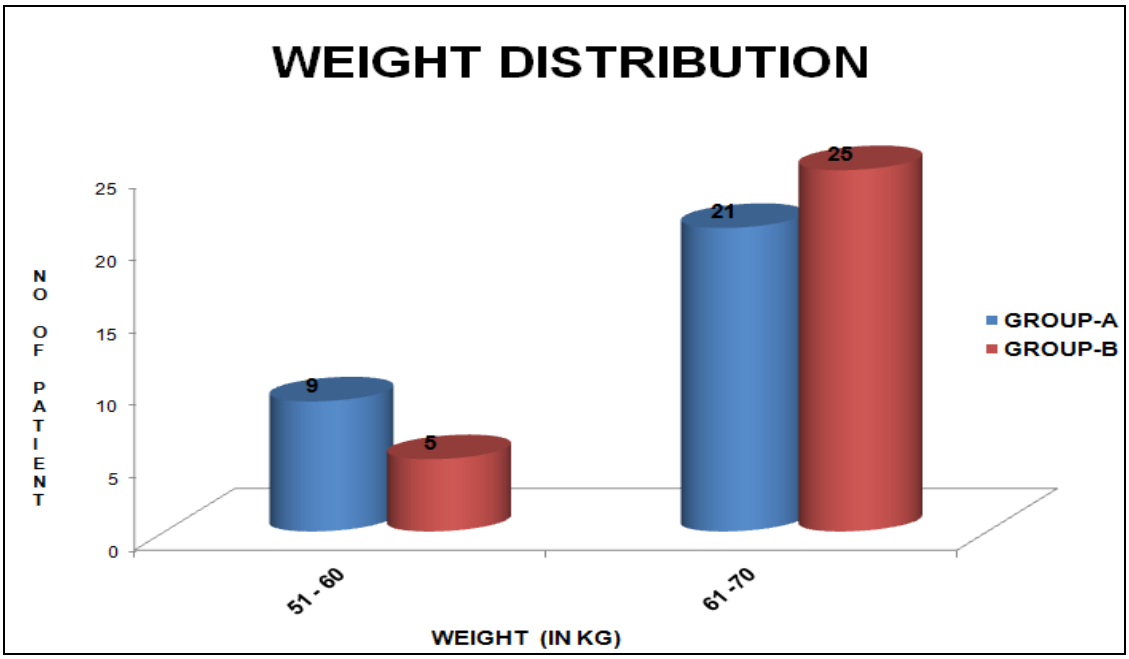
GROUP A - BUPIVACAINE + NALBUPHINE

GROUP B - BUPIVACAINE + NORMAL SALINE

No statistically significant difference in sex distribution between two groups.

Table-3:WEIGHT DISTRIBUTION

Weight in kgs	GROUP-A		GROUP-B	
	No of Patients (N)	%	No of Patients (N)	%
51 – 60	9	30.00	5	16.67
61 -70	21	70.00	25	83.33
TOTAL	30	100	30	100
Chi-square Value	1.49			
p-value	0.22			
Significant	**Not Significant**			



GROUP A - BUPIVACAINE + NALBUPHINE

GROUP B - BUPIVACAINE + NORMAL SALINE

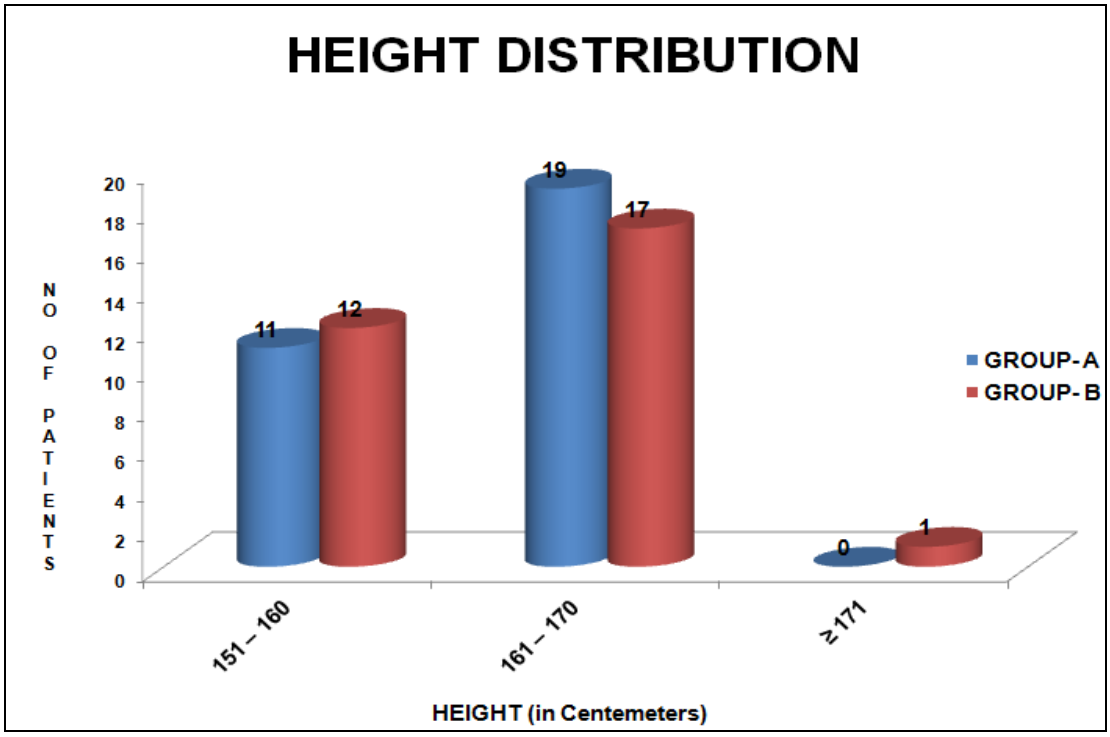
Mean Weight (Kg)

Group	Mean	Standard Deviation
GROUP-A	63.13	5.20
GROUP-B	64.67	4.27
t-value	1.25	
p-value	0.22	
Significant	**Not Significant**	

The mean weight distribution between the two groups are similar.

Table-4 : HEIGHT DISTRIBUTION

Height in cms	GROUP- A		GROUP- B	
	No of Patients (N)	%	No of Patients (N)	%
151 – 160	11	36.67	12	40.00
161 – 170	19	63.33	17	56.67
171 –180	0	0	1	3.33
TOTAL	30	100	30	100
Chi-square Value	1.16			
p-value	0.56			
Significant	**Not Significant**			



GROUP A - BUPIVACAINE + NALBUPHINE

GROUP B - BUPIVACAINE + NORMAL SALINE

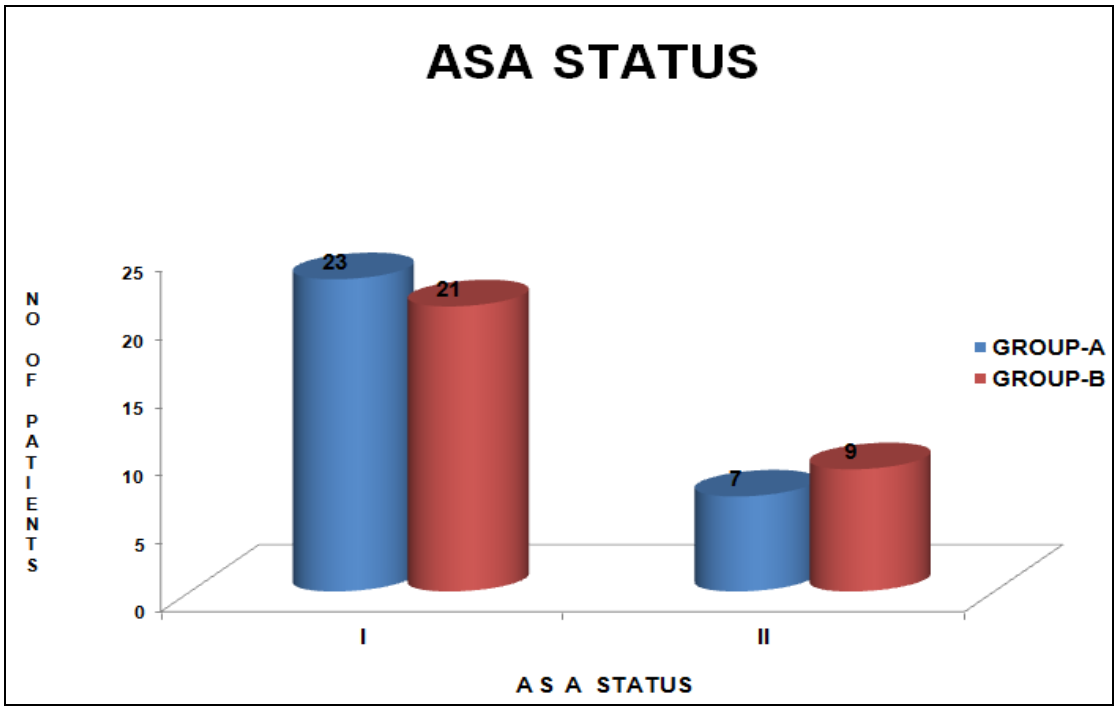
Mean Height (Centimeter)

Group	Mean	Standard Deviation
GROUP-A	162.60	4.52
GROUP-B	162.30	4.94
t-value	0.25	
p-value	0.81	
Significant	**Not Significant**	

The mean height distribution between the two groups are similar.

Table-5: ASA DISTRIBUTION

ASA	GROUP-A		GROUP-B	
	No of Patients (N)	%	No of Patients (N)	%
I	23	76.67	21	70.00
II	7	23.33	9	30.00
TOTAL	30	100	30	100
Chi-square Value	0.34			
p-value	0.56			
Significant	Not Significant			



GROUP A - BUPIVACAINE + NALBUPHINE

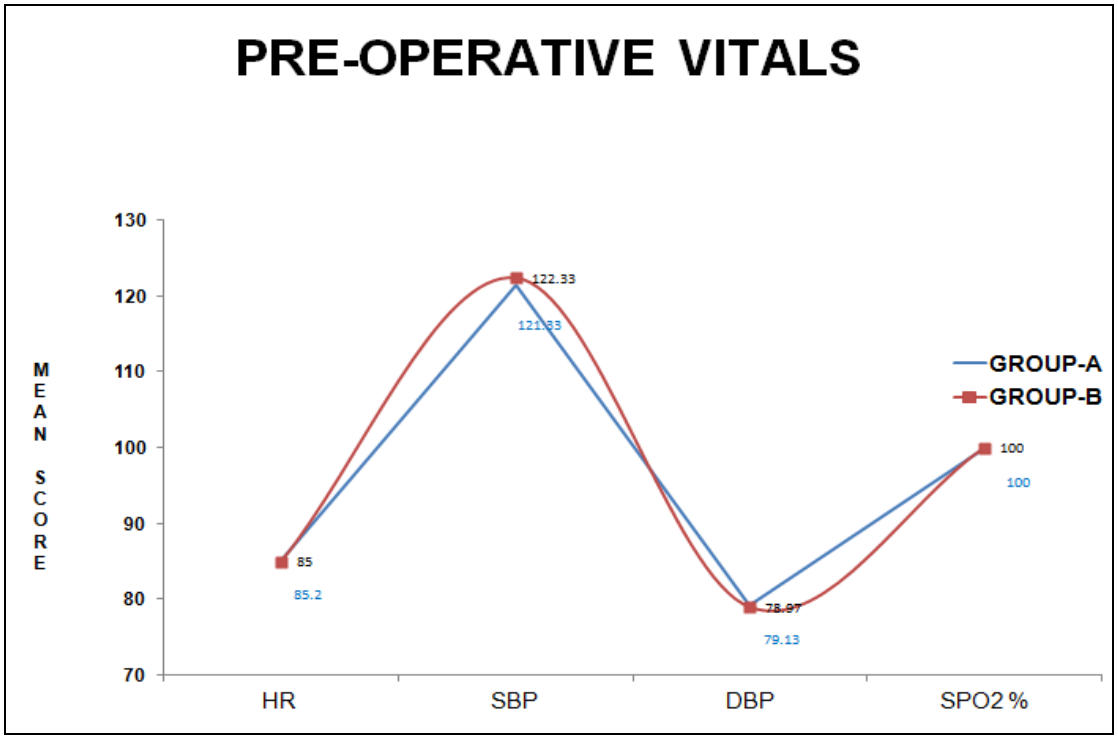
GROUP B - BUPIVACAINE + NORMAL SALINE

ASA - American Society of Anesthesiologist

Table-6:PRE-OPERATIVE VITALS

Variables	GROUP-A		GROUP-B		t-value	p-value	Significant
	MEAN	SD	MEAN	SD			
PR (Min)	85.20	4.39	85.00	4.09	0.18	0.86	NS
SBP (mmHg)	121.33	7.45	122.33	8.02	0.50	0.62	NS
DBP (mmHg)	79.13	4.33	78.97	3.38	0.17	0.87	NS
SPO2 %	100	0	100	0	-	-	-

NS-Not Significant



GROUP A - BUPIVACAINE + NALBUPHINE

GROUP B - BUPIVACAINE + NORMAL SALINE

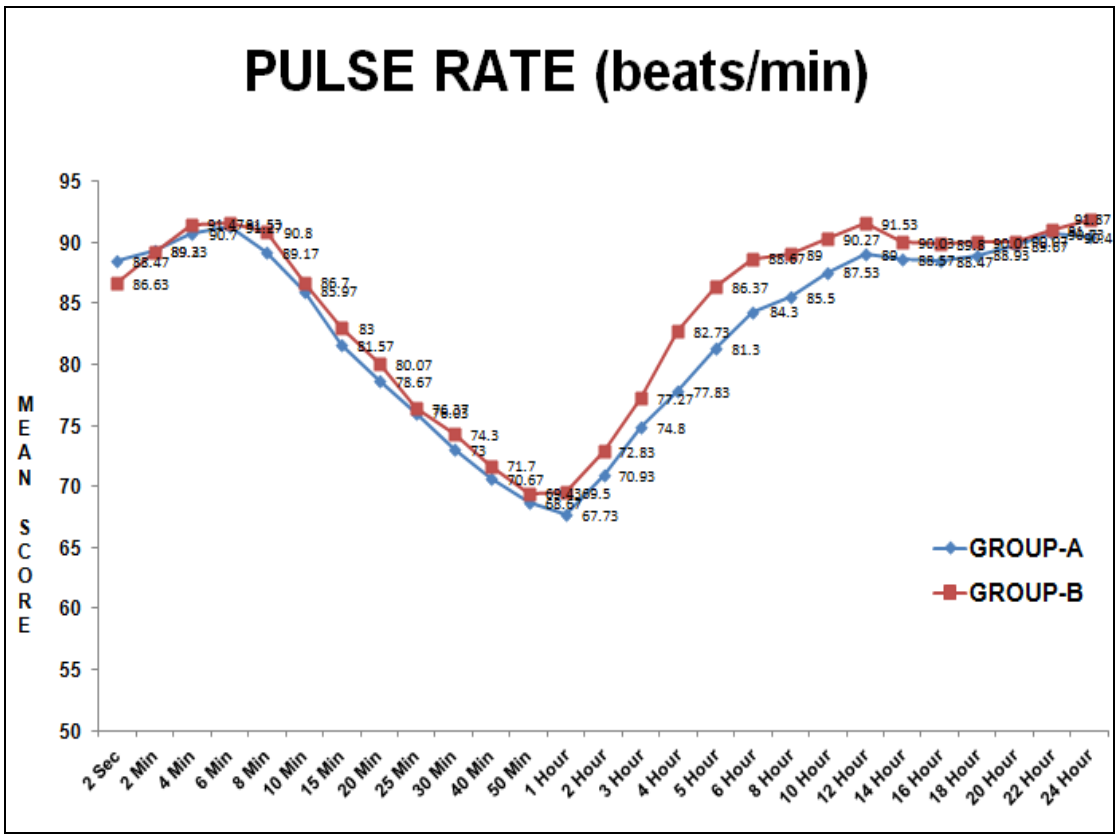
No statistically significant difference between the two groups in terms of preoperative vitals.

STUDY PERIOD

Table-7:PULSE RATE (beats/min)

TIME	GROUP-A		GROUP-B		t-value	p-value	Significant
	MEAN	SD	MEAN	SD			
2 Sec	88.47	4.00	86.63	4.23	0.16	0.88	NS
2 Min	89.30	3.64	89.23	3.14	0.08	0.94	NS
4 Min	90.70	4.04	91.47	3.49	0.79	0.44	NS
6 Min	91.27	4.74	91.53	3.96	0.24	0.81	NS
8 Min	89.17	5.36	90.80	5.32	1.19	0.24	NS
10 Min	85.97	5.70	86.70	5.33	0.52	0.61	NS
15 Min	81.57	6.29	83.00	5.02	0.98	0.33	NS
20 Min	78.67	5.88	80.07	5.30	0.97	0.34	NS
25 Min	76.03	6.57	76.37	5.01	0.22	0.83	NS
30 Min	73.00	7.05	74.30	5.25	0.81	0.42	NS
40 Min	70.67	7.47	71.70	6.25	0.58	0.56	NS
50 Min	68.67	7.01	69.43	4.57	0.50	0.62	NS
1 Hour	67.73	5.51	69.50	5.85	1.20	0.23	NS
2 Hour	70.93	5.08	72.83	6.49	1.26	0.21	NS
3 Hour	74.80	6.04	77.27	6.06	1.59	0.12	NS
4 Hour	77.83	6.11	82.73	5.60	3.24	0.002	Significant
5 Hour	81.30	5.77	86.37	4.45	3.81	0.001	Significant
6 Hour	84.30	5.47	88.67	4.71	3.31	0.002	Significant
8 Hour	85.50	5.33	89.00	3.92	2.90	0.005	Significant
10 Hour	87.53	4.62	90.27	4.39	2.34	0.002	Significant
12 Hour	89.00	4.47	91.53	3.93	2.33	0.002	Significant
14 Hour	88.57	3.36	90.03	5.73	1.21	0.23	NS
16 Hour	88.47	3.09	89.80	5.39	1.18	0.25	NS
18 Hour	88.93	3.81	90.01	4.05	1.13	0.04	NS
20 Hour	89.67	4.06	90.07	3.64	0.30	0.05	NS
22 Hour	90.73	3.37	91.00	3.17	0.36	0.75	NS
24 Hour	90.40	2.82	91.87	4.24	1.58	0.12	NS

NS- Not Significant



GROUP A - BUPIVACAINE + NALBUPHINE

GROUP B - BUPIVACAINE + NORMAL SALINE

From the above graph, it was clearly evident that the mean pulse rate for the first three hours after spinal anaesthesia was similar in both the groups, after that patients in the nalbuphine group had significantly lower pulse rate than the control group from 4 to 10 hours.

Table-8:SYSTOLIC BLOOD PRESSURE (mm Hg)

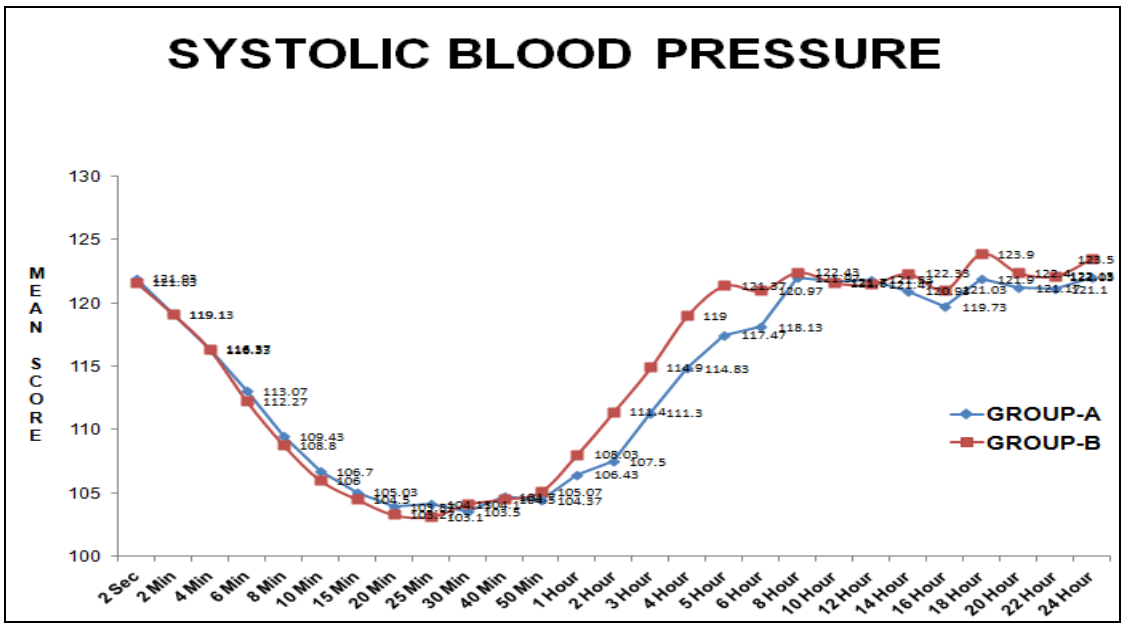
TIME	GROUP-I		GROUP-II		t-value	p-value	Significant
	MEAN	SD	MEAN	SD			
2 Sec	121.93	6.81	121.63	7.01	0.17	0.87	NS
2 Min	119.10	6.28	119.13	6.38	0.02	0.98	NS
4 Min	116.37	6.17	116.33	6.22	0.02	0.98	NS
6 Min	113.07	7.24	112.27	5.83	0.47	0.64	NS
8 Min	109.43	7.61	108.80	7.74	0.34	0.73	NS
10 Min	106.70	7.82	106.00	6.25	0.38	0.73	NS
15 Min	105.03	6.25	104.50	6.27	0.33	0.74	NS
20 Min	103.87	4.52	103.27	5.34	0.47	0.64	NS
25 Min	104.13	5.53	103.10	4.58	0.79	0.43	NS
30 Min	103.50	4.78	104.10	5.41	0.46	0.65	NS
40 Min	104.70	5.93	104.50	4.95	0.14	0.89	NS
50 Min	104.37	5.82	105.07	5.19	0.49	0.63	NS
1 Hour	106.43	5.38	108.03	5.47	1.14	0.26	NS
2 Hour	107.50	7.78	111.40	4.94	3.11	0.003	Significant
3 Hour	111.30	6.39	114.90	5.09	2.41	0.02	Significant
4 Hour	114.83	6.24	119.00	5.73	2.40	0.001	Significant
5 Hour	117.47	5.85	121.37	4.43	2.42	0.02	Significant
6 Hour	118.13	5.45	120.97	5.15	1.84	0.003	Significant
8 Hour	121.97	57.74	122.43	6.45	0.30	0.77	NS
10 Hour	121.70	6.06	121.60	6.55	0.06	0.95	NS
12 Hour	121.83	5.81	121.47	5.07	0.26	0.80	NS
14 Hour	120.93	5.33	122.33	6.13	0.94	0.35	NS
16 Hour	119.73	4.84	121.03	5.86	0.94	0.35	NS
18 Hour	121.90	4.41	123.90	5.13	1.62	0.11	NS
20 Hour	121.17	4.74	122.40	5.33	0.95	0.35	NS
22 Hour	121.10	4.88	122.13	5.51	0.77	0.45	NS
24 Hour	122.03	4.17	123.50	5.13	1.22	0.23	NS

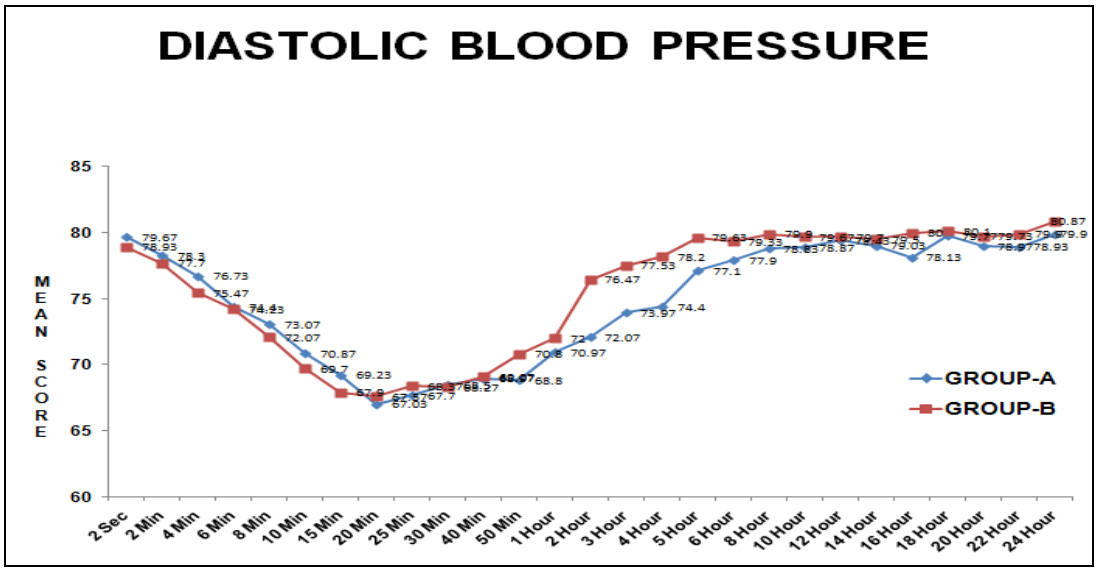
NS – Not Significant

Table-9:DIASTOLIC BLOOD PRESSURE (mm Hg)

TIME	GROUP-I		GROUP-II		t-value	p-value	Significant
	MEAN	SD	MEAN	SD			
2 Sec	79.67	3.98	78.93	3.36	0.77	0.73	NS
2 Min	78.30	2.91	77.70	2.58	0.85	0.40	NS
4 Min	76.73	3.25	75.47	4.49	1.25	0.22	NS
6 Min	74.40	5.26	74.23	4.58	0.13	0.90	NS
8 Min	73.07	5.22	72.07	5.56	0.72	0.48	NS
10 Min	70.87	6.68	69.70	4.45	0.80	0.43	NS
15 Min	69.23	6.72	67.90	5.42	0.85	0.40	NS
20 Min	67.03	5.49	67.57	5.73	0.37	0.71	NS
25 Min	67.70	4.85	68.37	5.03	0.52	0.60	NS
30 Min	68.50	5.91	68.27	5.94	0.15	0.88	NS
40 Min	68.97	6.82	69.07	4.31	0.07	0.95	NS
50 Min	68.80	6.20	70.80	4.59	1.42	0.16	NS
1 Hour	70.97	5.64	72.00	4.64	0.78	0.44	NS
2 Hour	72.07	5.55	76.47	4.79	2.79	0.003	Significant
3 Hour	73.97	4.71	77.53	5.06	2.24	0.001	Significant
4 Hour	74.40	5.61	78.20	4.01	3.02	0.004	Significant
5 Hour	77.10	5.33	79.63	3.21	2.23	0.03	Significant
6 Hour	77.90	3.99	79.33	3.08	1.56	0.12	NS
8 Hour	78.83	3.50	79.90	3.41	1.20	0.24	NS
10 Hour	78.87	3.69	79.67	3.34	0.88	0.38	NS
12 Hour	79.43	3.72	79.70	4.40	0.25	0.80	NS
14 Hour	79.03	4.61	79.50	3.29	0.45	0.65	NS
16 Hour	79.13	3.34	80.00	2.73	1.37	0.42	NS
18 Hour	79.77	2.89	80.10	2.51	0.48	0.64	NS
20 Hour	78.97	3.80	79.73	2.91	0.88	0.38	NS
22 Hour	78.93	3.51	79.90	3.45	1.07	0.29	NS
24 Hour	79.90	2.81	80.87	3.08	1.27	0.21	NS

NS-Not Significant





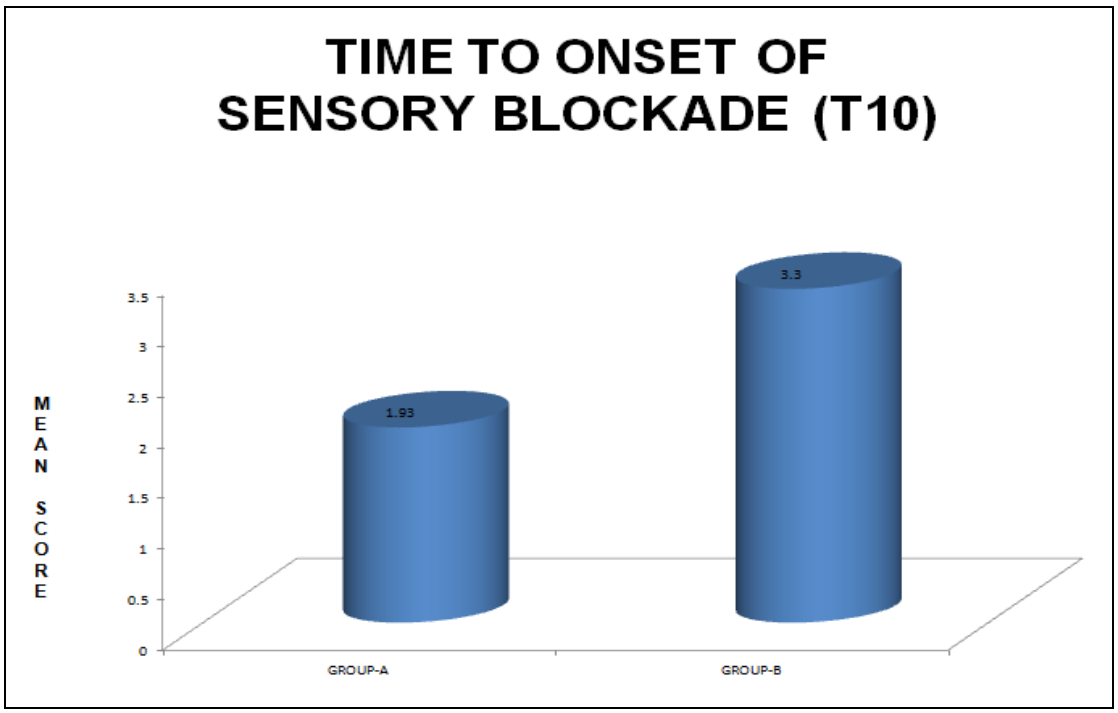
GROUP A - BUPIVACAINE + NALBUPHINE

GROUP B - BUPIVACAINE + NORMAL SALINE

These graphs shows that the mean systolic pressure (SBP) and diastolic blood pressure (DBP) were comparatively low in the nalbuphine group than the control group from 2 to 6 hrs.

Table-10:TIME TO ONSET OF SENSORY BLOCK AT T10(MINS)

Group	Mean	Standard Deviation
GROUP-A	1.93	0.45
GROUP-B	3.30	0.54
t-value	10.71	
p-value	0.000	
Significant	**Significant**	



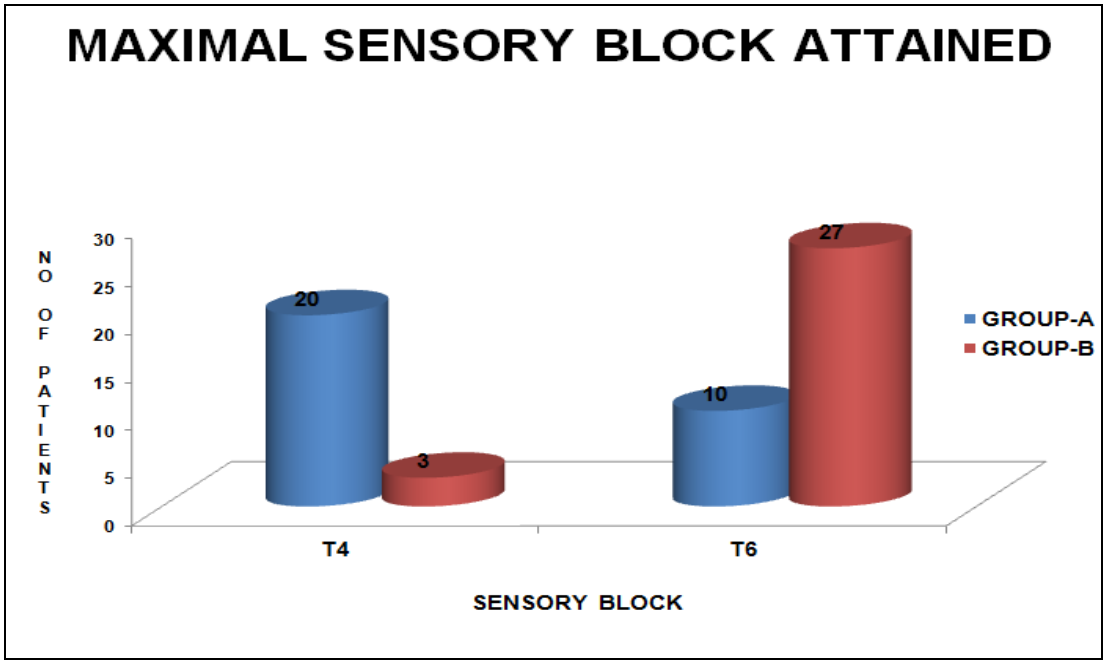
GROUP A - BUPIVACAINE + NALBUPHINE

GROUP B - BUPIVACAINE + NORMAL SALINE

Mean onset time of sensory block in group A (Nalbuphine) was 1.93± 0.45mins and found to be significantly earlier than group B.

Table-11: MAXIMAL SENSORY BLOCK ATTAINED

SENSORY BLOCK ATTAINED	GROUP-A		GROUP-B	
	No of Patients (N)	%	No of Patients (N)	%
T4	20	66.67	3	10.00
T6	10	33.33	27	90.00
TOTAL	30	100	30	100
Chi-square value	20.38			
p-value	0.000			
Significant	**Significant**			



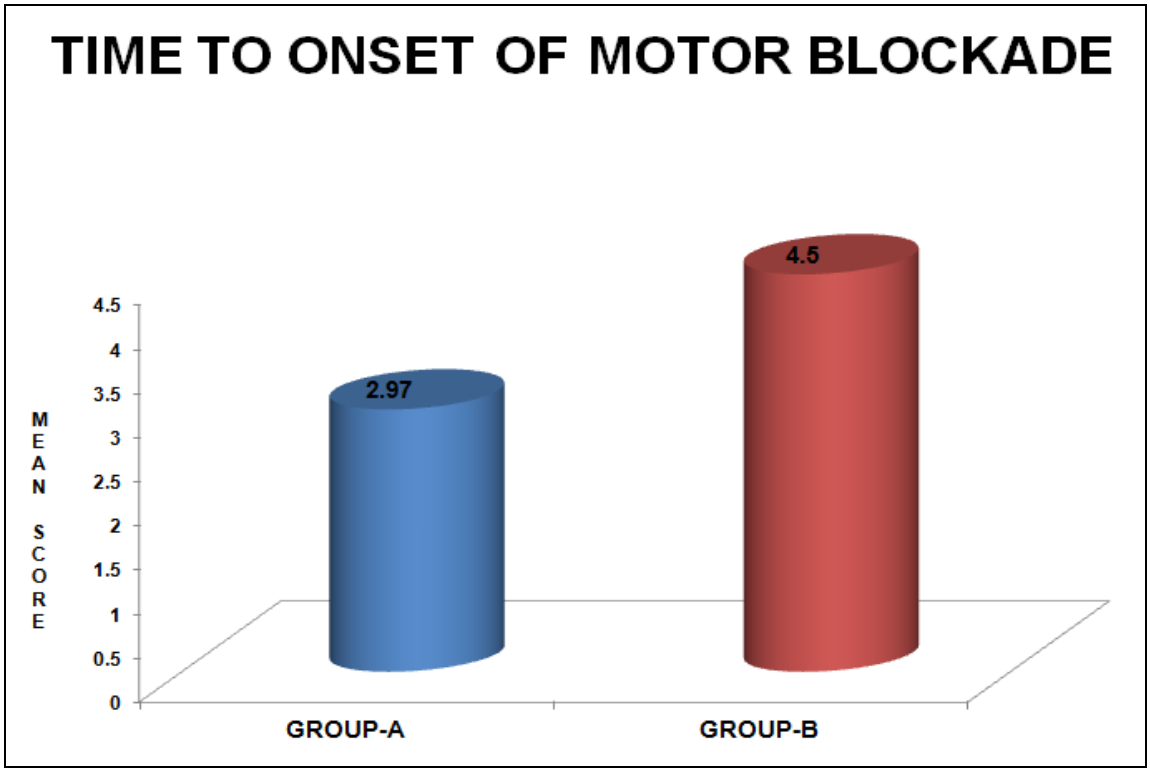
GROUP A - BUPIVACAINE + NALBUPHINE

GROUP B - BUPIVACAINE + NORMAL SALINE

More number of patients in group A attained maximal sensory block (T4) than group B and was found to be statistically significant.

Table-12:TIME TO ONSET OF MOTOR BLOCKADE (MINS)

Group	Mean	Standard Deviation
GROUP-A	2.97	0.56
GROUP-B	4.50	0.63
t-value	9.99	
p-value	0.000	
Significant	**Significant**	



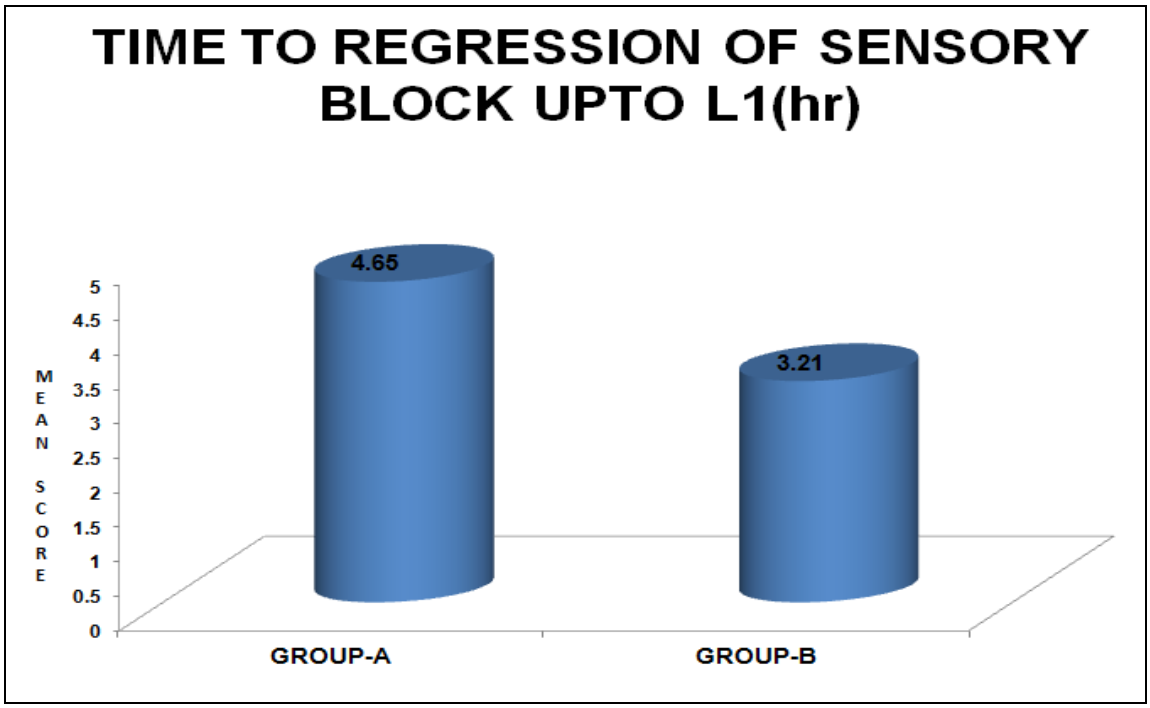
GROUP A - BUPIVACAINE + NALBUPHINE

GROUP B - BUPIVACAINE + NORMAL SALINE

Mean onset time of motor block in the nalbuphine group was 2.97± 0.56 minutes and was found to be significantly earlier than group B.

Table-13:TIME TO REGRESSION OF SENSORY BLOCK UPTO L1(hr)

Group	Mean	Standard Deviation
GROUP-A	4.65	1.03
GROUP-B	3.21	0.57
t-value	6.86	
p-value	0.000	
Significant	**Significant**	



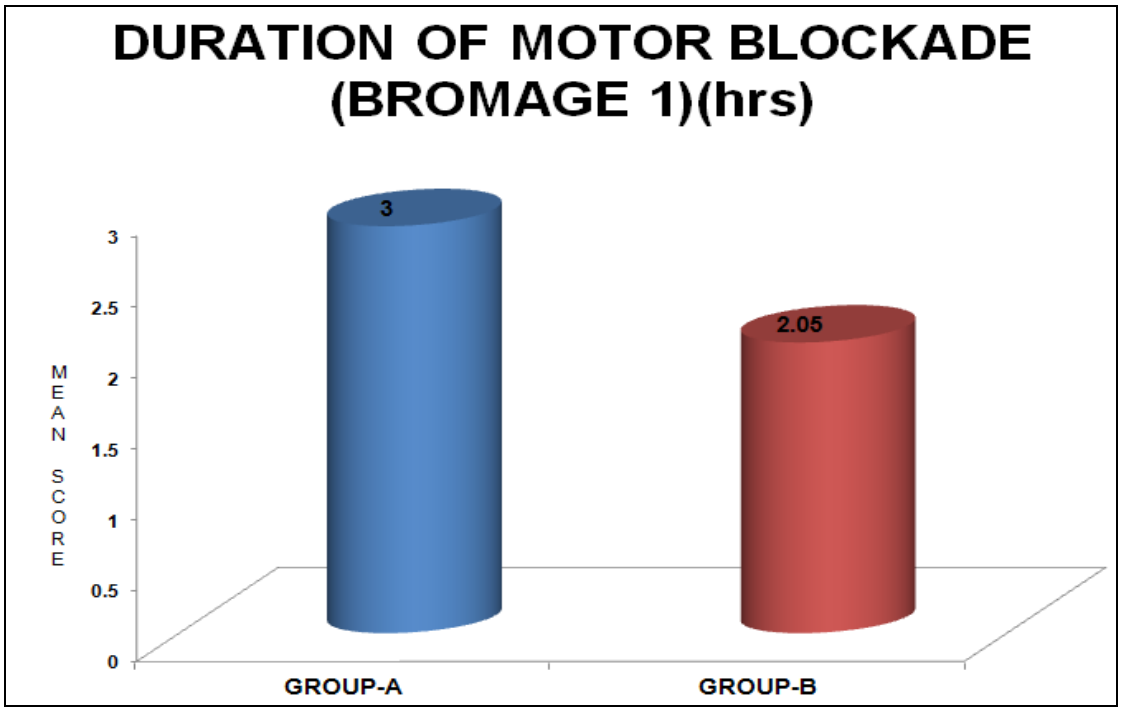
GROUP A - BUPIVACAINE + NALBUPHINE

GROUP B - BUPIVACAINE + NORMAL SALINE

Mean time to regression of sensory block upto L1 was 4.65±1.03hrs in nalbuphine group and found to be significantly longer than the control group which was 3.21±0.57hrs.

Table-14:DURATION OF MOTOR BLOCKADE (BROMAGE 1)(hrs)

Group	Mean	Standard Deviation
GROUP-A	2.87	0.39
GROUP-B	2.05	0.34
t-value	7.66	
p-value	0.000	
Significant	**Significant**	



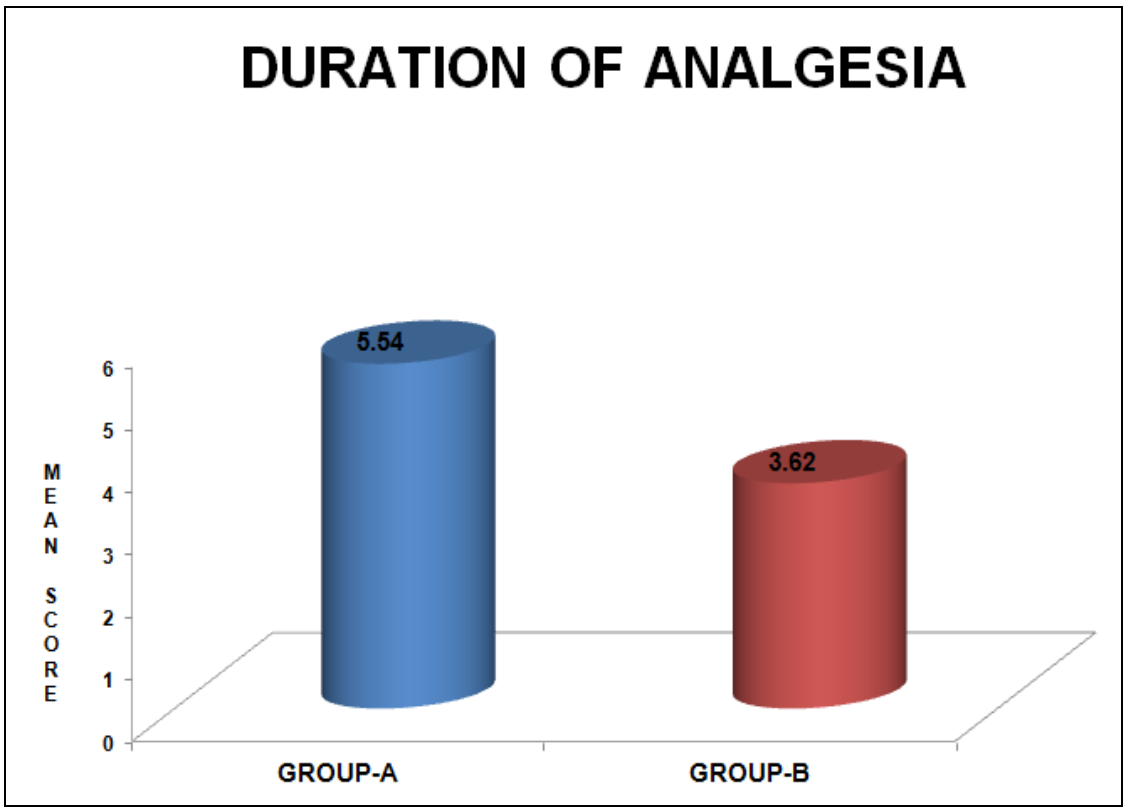
GROUP A - BUPIVACAINE + NALBUPHINE

GROUP B - BUPIVACAINE + NORMAL SALINE

Mean duration of motor blockade in group A (Nalbuphine) was 2.87±0.39hrs and in group B was 2.05±0.34hrs. This shows significant prolongation of motor block in nalbuphine group.

Table-15: DURATION OF ANALGESIA (Hrs)

Group	Mean	Standard Deviation
GROUP-A	5.54	1.05
GROUP-B	3.62	0.61
t-value	7.00	
p-value	0.000	
Significant	**Significant**	



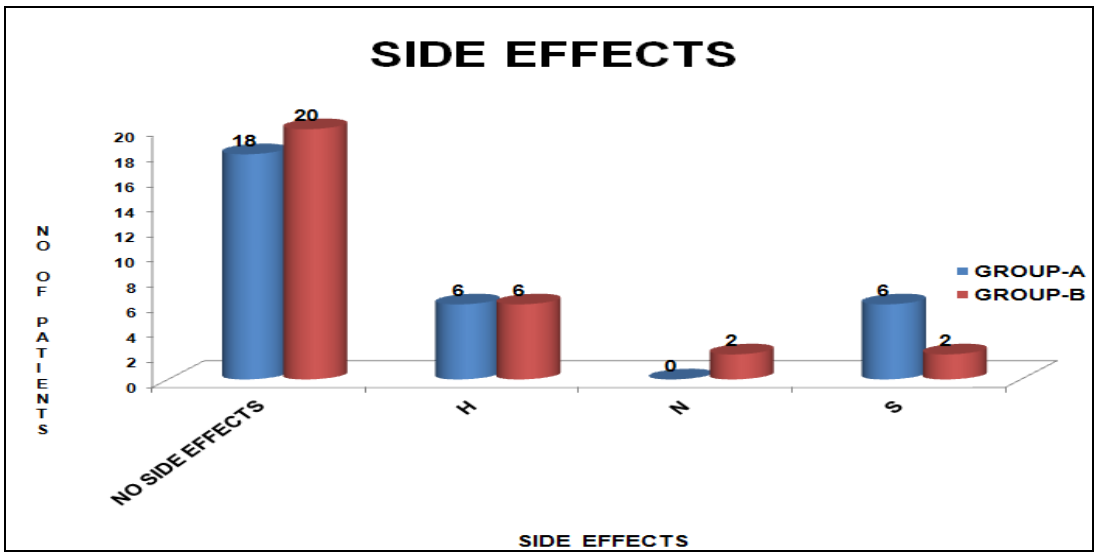
GROUP A - BUPIVACAINE + NALBUPHINE

GROUP B - BUPIVACAINE + NORMAL SALINE

The mean duration of analgesia in the nalbuphine group was 5.54±1.05 hrs and found to be significantly longer than control group (3.62±0.61hrs).

Table-16: SIDE EFFECTS

Side effects	GROUP-A		GROUP-B	
	No of Patients	%	No of Patients	%
Nil	18	60.00	20	66.66
Hypotension (H)	6	20.00	6	20.00
Nausea (N)	0	0	2	6.67
Shivering (S)	6	20.00	2	6.67
TOTAL	30	100	30	100
Chi-square value	4.11			
p-value	0.25			
Significant	**Not Significant**			



GROUP A - BUPIVACAINE + NALBUPHINE

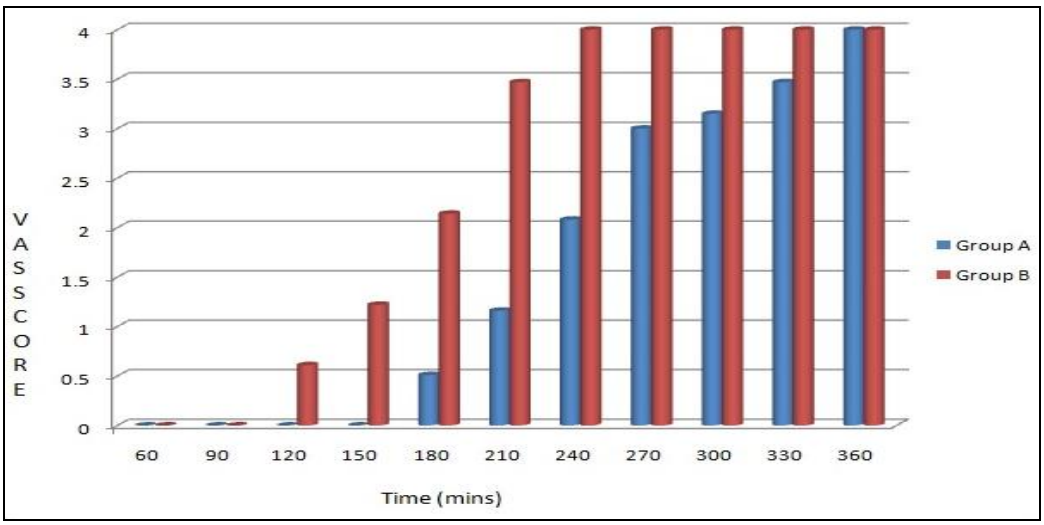
GROUP B - BUPIVACAINE + NORMAL SALINE

The side effects reported between the two groups was not statistically significant. Hence nalbuphine can be safely administered intrathecally.

Table-17: VAS SCORES

Time (mins)	Group A		Group B	
	Mean	SD	Mean	SD
60	0	0	0	0
90	0	0	0	0
120	0	0	0.61	0.56
150	0	0	1.22	0.27
180	0.51	0.55	2.14	0.22
210	1.16	0.23	3.47	0.15
240	2.08	0.2	R	
270	3	0.13		
300	3.15	0.23		
330	3.47	0.05		
360	R			

(R - Rescue Analgesic, VAS - Visual Analog Scale)



GROUP A - BUPIVACAINE + NALBUPHINE

GROUP B - BUPIVACAINE + NORMAL SALINE

Patients in the nalbuphine group had less mean VAS scores compared to control group.

Discussion

DISCUSSION

Over the years, extensive research have been done to improve the quality of spinal anaesthesia by varying drug regimens and technical methods. Normally adjuvants are added to hyperbaric bupivacaine 0.5% and administered intrathecally to prolong the anaesthetic effects. They produce antinociceptive effect by acting perineurally or at different receptor sites in the spinal cord.

Intrathecal opioids when used as adjuvants are capable of producing early onset of sensory, motor blockade and prolonged postoperative analgesia. They also allow early ambulation of patients due to their sympathetic and motor sparing activities.

Nalbuphine hydrochloride is a mixed μ antagonist and κ agonist opioid. It has been found to cause prolongation of the effects of local anaesthetics in intrathecal, epidural and peripheral nerve blocks with the advantages of minimal respiratory depression and better hemodynamic stability.

This prospective randomised controlled study performed in 60 patients who underwent infraumbilical surgeries under spinal anaesthesia demonstrated that nalbuphine in the dose of 0.5mg when added to

hyperbaric bupivacaine had earlier onset of sensory and motor blockade and prolonged duration of analgesia.

Both the study and control groups were comparable in demographic parameters like age, weight and height. The mean age of the patients in the nalbuphine group (A) was 39.90±7.60 years. The mean age of the patients in the control group (B) was 42.57±8.40 years. The mean weight of the patients in the nalbuphine group was 63.3±5.20 kgs. The mean weight of the patients in the control group was 64.67±4.27 kgs. The mean height of the patients in the nalbuphine group was 162±4.52 cm. The mean height of the patients in the control group was 162.30±4.97 cm. The variables were compared using independent sample test and Levene's test for equality of variances and p value was found to be not significant.

The mean pulse rate of the patients in the nalbuphine group was around 77 bpm whereas in the control group it was around 83 bpm at 4^{th}hour. The systolic and diastolic pressures of the patients in the nalbuphine group were 114±6.24 mmHg and 74.40±5.61 mmHg respectively, whereas in the control group it was around 119±5.73 mmHg and 78.20±4.01 mmHg at 4^{th} hour. Statistical analysis of the mean blood pressure and mean pulse rate was done and p value was found to be significant between 3 to 6 hrs.

The sensory and motor block were checked after performance of subarachnoid block using pinprick and modified Bromage scale respectively. The mean onset time of sensory block (T10) in the nalbuphine group was found to be 1.93±0.45 mins whereas in the control group it was found to be 3.30±0.54 mins. The mean onset time of motor block was found to be 2.97±0.56 mins in the nalbuphine group whereas in the control group it was found to be 4.50±0.63 mins. The statistical analysis by the independent sample test and the t test for equality of means has shown faster onset time for sensory and motor block significantly with a p value of 0.0001 in the nalbuphine group. More number of patients in the nalbuphine group (A) achieved higher sensory level (T4) than the patients in the control group (B).

The mean time to regression of sensory block upto L1 in the nalbuphine group was found to be 4.65±1.03 hrs, whereas in the control group it was found to be 3.21±0.57 hrs. Mean duration of motor blockade in the nalbuphine group was 2.87±0.39hrs and in the control group was 2.05±0.34hrs. Statistical analysis were done and p value (0.0002) was found to be significant.

The patients were followed in the postoperative period for the presence of pain by the Visual Analog Scale. The VAS score of 4 is

considered as the termination of analgesia. When the patients had a VAS score of 4 rescue analgesic (1g IV paracetamol) was given. The mean duration of analgesia in the nalbuphine group was found to be 5.54±1.05 hrs and in the control group it was found to be 3.62±0.61hrs. Statistical analysis revealed significant p value (0.0001) between the two groups.

Shakooh[10] et al in their study of 60 patients had demonstrated similar faster onset of sensory and motor block - 1.43±0.57 minutes and 3.47±1.01 minutes respectively on addition of 0.8mg of nalbuphine to 0.5% hyperbaric bupivacaine. They also demonstrated significant ($p<0.05$) prolongation of the duration of two segment sensory regression & motor blockade - 218.50±34.72 mins and 243.3±56.46 mins. The duration of postoperative analgesia in their study was 298±51.02 mins. Side effects like bradycardia and urinary retention were not reported. Hence in our study, we decided to add a low dose of nalbuphine intrathecally to hyperbaric bupivacaine to produce desired results without adverse effects. The results obtained in this study was comparable with them.

Pallavi Ahluwalia[23] et al in their study of 70 patients demonstrated that the onset time of sensory block was found to be earlier in nalbuphine group (1.29±0.43 mins) compared to the control group (3.78±1.31mins).

The duration of motor blockade and the duration of analgesia in the nalbuphine group were 256.41 mins and 298.43 mins. We obtained similar results in our study.

Mukherjee[8] et al formulated 'a study to determine whether nalbuphine prolongs analgesia by comparing with control group and also to determine the optimum dose of intrathecal nalbuphine'. It was observed that 0.4mg of nalbuphine with 0.5% hyperbaric bupivacaine produces prolongation of the duration of postoperative analgesia without any side effects. Hence we used 0.5mg of nalbuphine intrathecally.

Lin[12] et al demonstrated 'the analgesic effect of subarachnoid administration of tetracaine combined with 0.4 mg of nalbuphine or 0.4 mg of morphine'. They reported 0.4 mg of nalbuphine or morphine improves the effectiveness of intraoperative and postoperative analgesia but the side effects are less in nalbuphine group compared to morphine group. In our study we added nalbuphine to bupivacaine intrathecally and obtained similar quality of analgesia.

Intrathecal nalbuphine was in practise over 20 years with no neurotoxic side effects. Earlier studies have been conducted on parturient women did not reveal any untoward effects. There was an animal study

by Rawal[32] et al that examined the effects of intrathecal nalbuphine and reported no behavioral and systemic histo-pathologic abnormalities .

All the patients in our study both nalbuphine and control groups were monitored in the postoperative period and oxygen was supplemented at the rate of 2 litres/minute through ventimask.

Conclusion

CONCLUSION

Nalbuphine hydrochloride in the dose of 0.5mg when added as an adjuvant to hyperbaric bupivacaine 0.5% in subarachnoid block had a faster onset of sensory and motor blockade. The two segment dermatome regression time was significantly prolonged and the duration of postoperative analgesia was also increased in nalbuphine group. There was no increase in the risk of side effects like pruritus, hypotension, bradycardia and urinary retention.

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Annexures

PROFORMA

Name of the patient: **Age:**

Sex: **Group:**

Weight: **Height:**

Insurance No: **Diagnosis:**

Date: **Procedure:**

Anaesthetic plan: **Anaesthetist:**

Surgeon: **OT:**

PREOPERATIVE DETAILS
ASA grade
Remarks

PREOP: **PR:** **NIBP:** **Spo2:**

Temp. **RR:**

Hb	**RBS**	**RFT**	**ECG**	**X ray**	**Others**

INTRAOPERATIVE DETAILS	
Time of spinal drug injection	**Space**
Drug	**Needle**
Time to onset of sensory block at T10	
Maximal sensory block attained	
Time to onset of maximal sensory block	
Time to onset of motor block (Bromage 3)	
Maximal motor block attained	

POSTOPERATIVE DETAILS	
Time to regression of sensory block (upto L1)	
Duration of analgesia	
Rescue analgesic	**Time**
Duration of motor blockade (Bromage 1)	
Time to first spontaneous micturition	

SIGNATURE OF INVESTIGATOR **SIGNATURE OF THE PARTICIPANT**

WITNESS:

INTRAOP VITALS

vitals	**2 s**	**2 min**	**4 min**	**6 min**	**8 min**	**10 min**	**15 min**	**20 min**	**25 min**	**30 min**	**40 min**	**50 min**	**1 hr**	**2 hr**	**3 hr**	**4 hr**	**5 hr**	**6 hr**	**8 hr**	**10 hr**	**12 hr**	**14 hr**	**16 hr**	**18 hr**	**20 hr**	**22 hr**	**24 hr**
PR (min)																											
SBP (mm Hg)																											
DBP (mm Hg)																											

SIDE EFFECTS NOTED:

TREATMENT GIVEN:

PATIENT CONSENT FORM

STUDY TITLE

A prospective randomized controlled study comparing anaesthetic efficacy of mixture of intrathecal nalbuphine hydrochloride and bupivacaine 0.5% heavy with bupivacaine 0.5 %heavy alone for infraumbilical surgeries.

STUDY CENTRE

ESIC MEDICAL COLLEGE & PGIMSR, K.K.NAGAR, CHENNAI -78

PARTICIPANT NAME :

AGE: **SEX:**

I confirm that I have understood the purpose of procedure for the above study . I have the opportunity to ask the question and all my questions and doubts have been answered to my satisfaction.

I have been explained about the pitfalls in the procedure. I have been explained about the safety, advantage and disadvantage of the technique. I understand that my participation in the study is voluntary and that I am free to withdraw at anytime without giving any reason.

I understand that investigator, regulatory authorities and the ethics committee will not need my permission to look at my health records both in respect to current study and any further research that may be conducted in relation to it, even if I withdraw from the study . I understand that my identity will not be revealed in any information released to third parties or published , unless as required under the law. I agree not to restrict the use of any data or results that arise from the study.

I understood that I will receive drugs to prolong the duration of analgesia using nalbuphine in subarachnoid block. I have been explained that the anesthetic technique is a standard and approved technique. This may help in future research in the field of anesthesia. I consent to undergo this procedure.

INSURANCE NO:

DATE:

Signature / thumb impression of patient

ஒப்புதல் படிவம்

1. எனக்கு.....அறுவை சிகிச்சையை செய்யுமாறு மருத்துவர் மற்றும் குழுவினரை வேண்டிக்கொள்கிறேன்.

2. நோயின் தன்மை :

   சிகிச்சை முறை :

   இவை அனைத்தும் எனக்கு மருத்துவர் மூலம் தெளிவாக விளக்கப்பட்டன.

3. எனக்கு முதுகில் மரத்துப் போகிற ஊசி போட்டு மரத்துப் போகச்செய்து அறுவை சிகிச்சை செய்ய ஒப்புதல் தருகிறேன்.

4. இவற்றின் பின்விளைவுகளை மருத்துவர் மூலம் அறிந்து கொண்டேன்.

5. அனைத்து மருத்துவ சிகிச்சை முறைகளின் நிறைகளும் குறைகளும் எனக்கு விளக்கப்பட்டன

6. மேலே கொடுக்கப்பட்டுள்ள அனைத்தும் மருத்துவமனை நன்னெறி (Ethics) குழுவின் வரைமுறைக்கு உட்பட்டே நடக்கும் என மருத்துவர் விளக்கினார். மேலும் இந்த சிகிச்சை முறைகளுக்கு

உடன்பட மறுக்கவும் எனக்கு உரிமை உண்டு என்பதை நான் அறிவேன்.

7. என் சிகிச்சையின் போது கிடைக்கும் தகவல்களை மருத்துவ ஆராய்ச்சிக்கு பயன்படுத்தவும் சம்மதம் அளிக்கிறேன்

நான் இந்த ஒப்புதல் படிவத்தை படித்த பின்னரே / படித்துக் காண்பிக்கப்பட்ட பின்னரே இதன் சாராம்சத்தை முழுவதுமாக புரிந்து கொண்டு பின்பே முழுமனதுடன் சம்மதித்து கையெழுத்திடுகிறேன்.

சாட்சி : ஒப்புதல் அளிப்பவர் :.....

Master Chart

KEY TO MASTER CHART

GROUPS

GROUP A = Bupivacaine + Nalbuphine

GROUP B = Bupivacaine + Normal Saline

PARAMETERS

ON-SB = onset of sensory block

MAX-SB = maximum sensory block level

ON-MB = onset of motor block

REG-SB = regression of sensory block upto L1

DU-MB = duration of motor block

DU-ANAL = duration of analgesia

PR = pulse rate

SBP = systolic blood pressure

DPB = diastolic blood pressure

SI-EF = side effects

N = Nausea

H = Hypotension

S = Shivering

MASTER CHART

NAME	AGE	SEX	ht	wt	GROUP	ASA	TOS	MSL	TOMSL	TOM	MML	TOMML	TRS	DOA	DOM	PRE PR
SARAVANA PERUMAL	20	M	155	58	B	I	4	T6	11	2	3	14	2.47	2.97	3.47	90
SUDHAKAR	26	M	162	58	B	I	3	T4	12	1	3	13	3.37	3.17	2.75	98
RAVI	46	M	156	55	B	II	1	T6	2	3	3	5	3	4.08	4	104
IYYAPPAN	43	M	158	60	B	I	2	T6	3	2	3	15	3.93	4.43	5.93	92
AMUTHA	34	F	158	65	B	I	7	T4	11	5	3	10	5.62	6.12	5.17	88
DEVENDIRAN	51	M	156	60	B	II	4	T4	6	3	3	5	4.77	4.93	4.28	72
SELVARAJ	40	M	157	60	B	I	3	T6	5	2	3	4	5	6.17	5.52	74
STEPHEN	62	M	170	65	B	II	8	T6	10	4	3	10	6	6.5	6.4	68
SYED JAWAHAR	45	M	155	55	B	II	2	T4	5	2	3	3	4.45	5.2	6.7	78
SHANKAR	43	M	170	65	B	II	4	T8	5	3	2	5	4.93	5.43	5.95	92
DEEPAK MECH	28	M	163	55	B	I	4	T10	8	2	3	20	4.07	4.57	4.6	68
BINU PAUL	60	M	158	70	B	II	11	T10	18	3	3	11	4.92	5.42	5.55	96
KUMAR	36	M	150	50	B	I	8	T6	15	3	3	5	3.77	4.3	6.67	76
SARAVANAN	26	M	168	55	B	I	6	T6	10	3	3	5	6.77	7.27	6.82	72
PANEERSELVAM	26	M	165	55	B	I	11	T6	18	1	3	15	5.82	6.32	6.73	92
SUBRAMANIAM	60	M	160	60	B	II	0	T12	6	3	3	10	ND	ND	4.2	90
MUTHURAJ	35	M	158	50	B	I	3	T6	10	2	3	12	3.2	3.3	2.63	96
ELUMALAI	45	M	154	55	B	I	4	T8	7	1	3	5	4	4.58	5	78
KESAVAN	60	M	154	56	B	II	5	T6	10	2	2	12	3.3	3.2	2.9	98
DAKSHINAMOORTHY	50	M	150	53	B	I	3	T8	6	2	3	14	4	4.47	5.33	64
LAKSHMANAN	47	M	154	52	B	I	3	T6	10	4	3	8	5.5	6	5.13	88
MOHAN	31	M	154	65	B	I	3	T6	9	3	3	15	3.13	2.97	3.33	90
ARUN KUMAR	23	M	155	58	B	II	4	T6	10	2	3	5	3	3.3	2.67	86
THANGAM	46	F	156	55	B	II	1	T8	2	3	3	5	3	4.08	4	104
GANESAN	51	M	155	60	B	II	4	T6	6	3	3	4	4.67	5	5.83	90
CHANDRAN	64	M	160	65	B	II	5	T6	6	4	3	6	4.63	5	4.3	70
SUNDAR	27	M	160	50	B	I	4	T6	5	4	3	8	3.17	3.13	3.33	92
PONNAMMAL	38	F	158	55	B	II	2	T6	2	3	3	5	3.13	3.17	3.07	88
VENKATESAN	21	M	160	58	B	I	2	T6	5	2	3	12	3.33	4.17	5	68
ELUMALAI	41	M	160	58	B	I	3	T4	4	2	3	4	4.33	5	6	74
GANESH BABU	36	M	155	55	A	I	5	T4	12	2	3	6	4.47	4.27	4	108
BANUMATHY	48	F	156	60	A	I	7	T6	12	4	3	6	3.3	3.18	3.05	93
PALANI	37	M	166	55	A	I	4	T6	8	1	3	3	4.2	6.2	4.7	92
PITCHANDI	54	M	160	65	A	I	8	T8	12	5	3	25	4.95	5.11	4	86
MURUGESAN	54	M	150	50	A	I	7	T6	10	5	3	8	5	6	5	62
RAMANI	50	F	152	70	A	II	3	T6	4	2	1	5	5	5.2	5	114
SUDHAM JENA	28	M	158	50	A		4	T4	10	2	3	8	4.9	5.9	3.9	93
RAMESH	40	M	156	55	A	I	1	T6	2	1	3	3	4.41	4.17	4.33	92
THIRUMOORTHY	27	M	170	68	A	I	1	T4	8	1	3	2	2.98	3.23	2.23	83
LAKSHMANAN	22	M	168	55	A	I	7	T6	9	4	3	6	4.89	4.88	4.43	86
SRINIVASAN	51	M	162	60	A	I	7	T6	10	3	3	9	4	5.23	4	86
SUGUNA	34	F	156	65	A	I	1	T6	3	5	3	6	2.87	3.11	3.3	98
GOPAL	49	M	160	55	A	I	15	T4	20	5	3	6	3.4	3.5	4	77
KRISHNAVENI	51	F	158	50	A	I	7	T8	9	6	3	8	6.77	8.52	7.78	108
PANDIAN	41	M	168	65	A	II	20	T6	22	3	3	6	7.22	7.17	7.22	71
RAJAGOPAL	60	M	160	60	A	I	5	T4	8	3	3	6	4.72	5.22	6.75	63
PANJAYAN	60	M	160	50	A	I	2	T6	10	2	3	6	4.72	4.97	5.22	62
KARTHICK	28	M	158	60	A	I	6	T6	12	2	3	10	6.15	6.9	7.22	68
MURUGANAND	55	M	160	60	A	II	4	T6	5	2	3	7	4.18	4.93	5.22	82
SHANTHI	47	F	156	52	A	II	6	T6	3	3	3	5	3.15	3.4	3.95	77
VALLIAMMAL	40	F	150	56	A	II	8	T4	10	3	3	7	6.67	7.47	6.33	78
MOHANDAS	40	M	157	52	A	I	2	T6	8	2	3	5	4.08	4.47	5.33	70
CHITTI BABU	54	M	158	60	A	I	6	T6	10	3	3	8	6	6.67	6.87	68
SUBRAMANIAM	60	M	154	55	A	II	15	T6	20	3	3	3	6.67	6.13	7	71
VELU	64	M	156	57	A	I	6	T6	10	2	3	5	6	7.5	6.67	69
MAHABOOBI	33	F	160	62	A	II	18	T6	20	2	3	5	7.53	7.8	7	71
SIVAKUMAR	46	M	156	60	A	II	5	T6	10	5	3	16	5	5.17	4.67	85
RAMAN	54	M	158	60	A	I	7	T6	8	5	3	6	4.3	5.97	5.17	72
SRIKAR	24	M	154	59	A	I	10	T6	15	5	3	8	3.17	4.17	5	78
KARTHIKEYAN	19	M	156	50	A	I	7	T6	8	3	3	8	3	3.5	4	76

NAME	2s	2m	4m	6m	8m	10m	15min	20min	25min	30min	40min	50min	1hr	2hr	3hr	4hr	5hr	6hr	8hr	10hr	12hr	14hr	16hr	18hr	20hr	22hr	24hr
SARAVANA PERUMAL	90	92	90	87	84	91	92	90	88	82	67	91	90	92	88	86	84	82	80	84	86	88	90	92	94	90	86
SUDHAKAR	97	99	96	93	92	90	86	84	88	76	74	78	75	73	72	70	72	74	76	74	76	74	72	72	72	80	81
RAVI	104	103	104	102	101	100	102	85	88	86	88	90	92	96	98	94	86	88	84	82	86	84	82	86	84	80	80
IYYAPPAN	92	90	86	86	90	91	90	96	94	98	92	93	72	77	76	74	73	74	72	72	74	76	74	72	73	74	76
AMUTHA	88	66	68	76	77	79	81	80	68	70	73	65	66	64	62	66	68	70	72	71	70	72	71	70	74	76	72
DEVENDIRAN	76	68	63	60	59	53	52	54	52	53	54	52	53	54	68	66	64	60	64	68	66	68	70	72	70	74	72
SELVARAJ	74	68	64	66	64	62	66	62	66	64	66	57	58	59	60	62	63	66	64	68	70	72	74	73	76	74	70
STEPHEN	74	71	64	82	70	61	62	64	65	68	70	72	74	72	71	72	68	74	78	66	70	74	72	72	76	74	78
SYED JAWAHAR	78	70	68	64	66	66	64	66	68	66	64	66	67	68	66	64	70	72	74	72	74	76	72	78	74	78	80
SHANKAR	92	86	88	84	72	78	74	76	78	76	70	74	80	82	86	88	82	78	80	82	86	80	78	76	72	74	78
DEEPAK MECH	68	69	79	72	75	73	78	78	64	62	62	60	72	74	78	76	80	80	82	88	86	80	84	80	78	74	76
BINU PAUL	96	94	93	94	96	94	97	94	92	90	86	80	84	86	82	78	72	76	78	72	68	74	70	72	76	84	82
KUMAR	78	75	76	74	74	70	68	66	64	68	66	60	59	58	60	66	64	68	70	71	72	74	76	74	73	72	70
SARAVANAN	72	69	68	67	69	67	64	68	62	66	68	70	71	72	73	70	72	70	71	72	70	72	73	70	71	70	68
PANEERSELVAM	92	94	85	90	85	86	78	73	83	80	84	82	86	88	84	86	82	80	84	78	74	72	72	70	76	74	72
SUBRAMANIAM	92	79	76	77	77	74	78	75	72	70	62	68	66	68	70	74	76	74	72	75	76	74	75	76	78	74	72
MUTHURAJ	92	93	95	90	92	90	86	88	84	78	72	78	73	73	72	74	72	70	76	72	76	75	72	79	72	81	81
ELUMALAI	68	70	76	76	70	73	78	72	64	68	65	60	78	74	78	76	81	82	82	86	87	80	83	84	76	73	75
KESAVAN	96	99	98	93	90	90	84	85	88	74	75	78	75	72	72	71	72	72	76	74	78	74	70	72	74	80	82
DAKSHINAMOORTHY	65	70	75	71	75	72	78	77	64	60	62	61	72	72	78	74	80	81	82	87	86	82	84	81	78	72	76
LAKSHMANAN	86	66	67	76	76	79	82	80	69	70	71	65	65	64	62	66	65	70	70	71	71	72	70	70	76	76	78
MOHAN	91	92	92	87	82	91	88	91	88	92	71	91	92	92	86	86	82	82	81	84	88	88	91	92	95	91	86
ARUN KUMAR	88	90	82	84	88	76	78	75	78	80	82	78	75	72	72	74	74	78	76	74	74	78	70	70	80	78	80
THANGAM	104	103	104	102	101	100	102	85	88	86	88	90	92	96	98	94	86	88	84	82	86	84	82	86	84	80	80
GANESAN	88	84	86	84	72	78	76	76	74	78	70	72	82	82	84	88	80	80	82	80	84	82	78	76	70	72	74
CHANDRAN	74	68	66	64	64	60	62	58	60	62	68	67	64	66	68	66	68	64	68	66	68	70	72	74	72	72	70
SUNDAR	94	88	86	88	82	89	84	85	86	78	78	78	76	74	74	72	74	74	76	78	78	72	74	72	78	82	84
PONNAMMAL	86	82	85	78	70	74	80	82	80	78	70	78	72	72	72	74	70	72	74	72	78	74	70	78	74	80	82
VENKATESAN	68	70	72	70	74	70	78	78	70	78	68	68	70	72	78	74	82	82	84	88	86	82	88	82	78	76	74
ELUMALAI	76	72	68	66	66	66	68	68	66	66	64	68	67	68	66	70	72	74	72	70	72	76	72	74	72	76	78
GANESH BABU	98	92	96	90	88	86	88	85	79	72	81	82	75	72	70	76	74	72	76	74	78	70	68	66	69	72	74
BANUMATHY	92	94	91	92	90	82	84	86	82	72	76	78	74	76	74	72	70	68	72	70	68	82	84	86	88	78	74
PALANI	92	88	86	92	93	90	91	92	96	90	92	93	92	86	88	84	82	86	82	80	83	82	84	80	86	88	84
PITCHANDI	86	88	90	92	91	92	82	76	70	72	69	71	70	72	68	64	62	64	66	68	70	71	72	73	80	81	74
MURUGESAN	62	62	63	62	60	56	58	42	66	74	86	88	90	92	86	88	84	80	76	74	72	70	74	76	78	72	74
RAMANI	114	122	124	130	110	84	82	85	83	85	87	88	86	84	90	92	86	84	80	82	80	74	76	72	74	76	78
SUDHAM JENA	93	80	82	86	84	88	72	66	54	58	60	61	63	68	67	65	66	68	67	68	72	70	82	80	81	82	80
RAMESH	92	87	86	78	71	68	65	66	67	61	62	62	58	55	62	66	68	70	72	74	76	74	82	80	81	82	84
THIRUMOORTHY	81	80	76	66	65	64	61	59	57	63	62	61	57	67	66	68	67	70	72	74	80	82	86	80	84	86	80
LAKSHMANAN	86	87	88	84	80	86	84	84	86	78	68	66	60	64	68	72	76	80	82	90	83	84	86	80	88	88	86
SRINIVASAN	88	86	87	92	96	93	88	80	84	86	79	81	77	79	93	90	88	92	79	93	90	72	70	68	72	74	70
SUGUNA	97	98	92	100	91	97	96	88	84	78	77	90	78	88	84	86	88	82	84	80	86	82	80	84	78	74	76
GOPAL	77	72	66	62	68	69	72	70	68	66	68	68	70	71	72	71	70	72	76	74	78	74	76	78	72	70	88
KRISHNAVENI	108	100	96	94	98	94	96	94	92	92	86	88	84	82	86	84	88	80	78	76	74	72	74	76	78	76	74
PANDIAN	70	69	79	77	76	77	77	73	75	74	74	72	74	73	76	78	80	82	79	78	74	76	78	77	78	79	70
RAJAGOPAL	63	62	60	57	56	52	50	52	55	56	55	53	40	60	62	64	66	68	70	72	74	72	70	68	72	70	72
PANJAYAN	62	58	56	60	58	59	61	60	58	59	57	58	60	62	64	68	70	66	64	62	68	69	68	70	71	68	64
KARTHICK	68	56	55	58	54	52	49	53	50	57	56	55	54	58	60	68	70	68	72	70	72	68	70	74	72	70	68
MURUGANAND	81	66	70	70	67	64	62	60	62	61	66	56	58	60	64	68	72	74	70	80	82	84	86	84	82	80	80
SHANTHI	76	72	68	62	68	69	72	70	66	65	68	72	70	71	72	70	70	72	76	74	74	74	76	78	70	70	86
VALLIAMMAL	76	68	66	69	67	65	62	65	60	61	62	70	72	76	73	71	70	70	75	72	72	72	74	70	73	70	65
MOHANDAS	64	57	58	62	58	55	60	62	58	58	57	54	60	61	64	65	70	64	64	60	68	67	68	71	71	65	64
CHITTI BABU	67	57	55	59	64	52	50	52	55	56	56	54	54	57	62	68	71	66	73	70	70	68	70	75	72	71	68
SUBRAMANIAM	72	68	78	75	76	76	77	74	75	73	74	71	74	74	76	77	80	81	78	78	75	76	76	77	78	79	72
VELU	70	54	54	56	54	52	48	53	52	57	55	55	50	58	61	68	72	68	70	70	71	68	78	74	70	70	67
MAHABOOBI	71	68	76	68	69	78	76	72	74	72	74	70	72	71	75	77	81	80	78	77	76	75	77	78	79	80	81
SIVAKUMAR	86	86	88	89	90	92	88	76	71	72	68	71	71	72	67	64	70	74	71	70	70	72	72	75	80	82	74
RAMAN	70	68	65	66	60	62	64	59	60	72	82	88	85	90	88	86	87	82	78	76	74	72	76	78	77	78	76
SRIKAR	74	70	68	68	66	68	70	72	70	72	68	68	70	71	70	72	74	74	76	72	74	72	78	72	70	71	80
KARTHIKEYAN	74	70	68	68	70	70	72	72	68	68	70	72	72	70	72	74	72	70	76	74	78	74	76	76	72	72	80

NAME	PRE SBP	2s	2m	4m	6m	8m	10min	15min	20min	25min	30min	40min	50min	1hr	2hr	3hr	4hr	5hr	6hr	8hr	10hr	12hr	14hr	16hr	18hr	20hr	22hr	24hr
SARAVANA PERUMAL	128	132	142	140	131	124	117	115	112	98	100	86	113	112	110	115	112	110	110	112	116	120	120	122	120	118	110	116
SUDHAKAR	130	130	135	137	142	140	138	135	130	128	125	124	124	124	130	126	126	125	120	122	126	125	129	120	122	126	124	121
RAVI	150	140	145	144	140	140	138	130	138	135	130	135	130	128	124	120	128	128	120	120	120	120	126	126	126	126	120	120
IYYAPPAN	150	140	130	120	120	116	114	116	118	120	121	122	115	111	108	110	108	112	114	116	120	122	124	126	120	122	124	126
AMUTHA	132	122	124	119	108	108	106	106	106	108	107	104	102	100	102	106	104	120	121	122	126	124	120	121	120	120	122	121
DEVENDIRAN	144	144	136	132	130	126	121	121	120	122	121	120	120	125	125	126	124	122	128	124	126	122	120	124	122	121	120	122
SELVARAJ	120	120	110	116	118	98	96	98	95	100	101	104	96	100	110	112	116	120	122	120	120	120	126	124	130	128	126	124
STEPHEN	150	152	150	160	160	164	166	165	158	155	150	140	142	146	140	140	138	136	132	130	140	140	138	130	136	140	140	136
SYED JAWAHAR	132	132	110	85	90	84	92	94	92	98	100	101	98	96	98	100	100	104	110	116	130	132	130	130	126	122	120	120
SHANKAR	130	132	126	120	121	120	122	120	118	116	118	112	114	116	120	122	120	126	120	124	120	121	122	124	124	126	120	120
DEEPAK MECH	126	126	124	125	123	123	116	120	120	116	114	111	110	112	120	120	120	124	124	120	120	124	120	128	120	120	120	120
BINU PAUL	140	140	136	144	140	146	144	140	130	124	129	130	132	130	130	130	130	132	134	130	132	140	140	140	142	146	140	142
KUMAR	138	140	137	135	136	134	132	130	132	128	126	128	129	127	126	124	126	128	125	126	124	120	126	128	124	126	128	124
SARAVANAN	128	128	117	117	116	118	124	118	116	120	122	124	120	120	128	130	126	124	120	128	126	124	125	126	124	128	122	128
PANEERSELVAM	124	124	126	125	124	125	124	125	127	125	126	124	122	120	124	126	128	130	124	128	126	122	120	120	122	126	128	124
SUBRAMANIAM	150	154	150	152	150	149	148	146	145	144	146	147	145	146	138	134	136	134	136	132	130	128	130	128	126	130	132	130
MUTHURAJ	128	130	136	135	140	136	136	135	126	128	120	124	124	121	130	124	126	123	118	124	120	125	130	120	120	126	124	121
ELUMALAI	121	125	120	123	124	120	114	118	116	115	114	110	111	112	118	116	114	120	122	123	120	124	126	128	124	120	122	120
KESAVAN	130	132	134	128	130	132	131	133	128	127	124	124	126	124	127	126	128	125	121	122	126	124	129	120	120	126	124	118
DAKSHINAMOORTHY	119	121	118	120	123	122	114	120	115	116	112	111	111	110	120	121	120	112	124	122	120	123	120	128	118	120	120	116
LAKSHMANAN	132	120	124	119	107	106	106	104	106	106	107	103	102	101	102	105	104	121	121	120	126	122	120	120	120	118	122	120
MOHAN	125	128	135	138	130	128	118	116	110	99	101	88	115	116	115	118	112	112	118	120	121	120	122	119	122	123	128	130
ARUN KUMAR	128	126	124	120	128	126	124	120	120	118	124	120	120	114	118	120	116	124	120	120	126	124	126	118	120	124	122	120
THANGAM	150	140	145	144	140	140	138	130	138	135	130	135	130	128	124	120	128	128	120	120	120	120	126	126	126	126	120	120
GANESAN	128	128	126	122	122	124	126	128	120	118	120	110	116	118	120	122	121	124	122	124	122	121	120	124	122	124	122	118
CHANDRAN	124	124	126	122	120	116	121	120	120	122	124	120	122	126	125	126	124	120	118	114	116	122	120	124	120	118	118	122
SUNDAR	128	128	130	128	125	130	128	130	128	126	124	122	126	124	126	128	126	124	120	122	124	122	126	122	124	126	120	118
PONNAMMAL	124	128	126	130	136	132	134	132	128	126	122	124	122	120	128	124	126	122	120	118	116	120	128	122	122	126	124	120
VENKATESAN	120	122	118	120	122	120	118	118	116	116	114	110	121	118	120	122	120	118	122	124	122	122	120	124	120	122	124	118
ELUMALAI	128	122	112	110	112	110	98	100	102	104	100	106	110	112	114	108	108	110	112	116	126	122	128	126	124	126	122	124
GANESH BABU	140	140	130	122	120	122	112	115	98	93	92	85	99	99	100	102	104	105	108	110	112	120	120	122	120	120	120	120
BANUMATHY	124	122	118	115	112	110	110	108	107	105	110	98	86	98	110	116	112	110	108	106	104	112	120	122	120	124	120	120
PALANI	130	130	126	121	119	118	120	121	126	122	118	110	115	112	113	114	115	120	121	120	122	120	128	120	126	124	122	121
PITCHANDI	143	146	150	155	152	150	152	140	137	130	132	133	131	130	132	120	122	100	124	120	122	120	128	126	124	120	124	124
MURUGESAN	122	122	120	110	112	108	109	110	100	112	132	131	130	128	124	120	126	122	110	110	112	118	120	120	124	124	126	120
RAMANI	140	140	134	130	119	103	99	92	97	96	97	96	98	100	110	112	118	116	120	124	122	126	120	124	128	124	120	122
SUDHAM JENA	126	129	136	139	125	120	112	108	84	101	102	100	98	97	101	108	102	110	112	118	110	110	112	120	122	124	126	122
RAMESH	128	129	117	111	100	96	94	94	94	93	94	93	93	97	98	101	108	110	112	114	112	110	114	112	110	112	110	112
THIRUMOORTHY	123	123	120	94	101	100	101	101	100	98	92	97	98	96	95	100	104	106	108	112	114	110	120	122	123	124	126	120
LAKSHMANAN	122	122	120	121	114	110	112	110	112	108	110	101	97	100	101	112	114	116	122	120	120	122	120	126	124	120	120	122
SRINIVASAN	130	132	129	125	122	121	114	112	114	110	108	103	101	105	100	105	104	100	104	108	110	114	120	122	124	120	121	120
SUGUNA	130	129	121	118	116	116	117	116	114	112	114	116	109	103	106	108	104	106	108	110	112	116	114	120	122	121	123	118
GOPAL	148	148	136	132	130	130	127	121	120	122	121	118	113	112	110	112	114	116	118	120	122	120	121	122	123	125	126	128
KRISHNAVENI	150	150	140	142	140	138	136	134	138	135	138	140	140	142	144	140	138	136	132	130	128	126	124	126	128	126	130	130
PANDIAN	116	119	121	120	126	124	121	126	124	124	123	121	122	120	126	120	130	128	126	130	132	132	130	110	116	120	122	126
RAJAGOPAL	133	133	123	128	126	124	120	124	116	116	114	110	116	110	122	120	122	120	120	116	130	128	130	130	130	128	126	120
PANJAYAN	150	150	152	155	153	150	148	146	146	145	147	153	150	148	145	140	138	130	130	122	120	120	124	126	128	130	132	126
KARTHICK	138	138	136	130	128	130	128	129	125	123	117	115	114	112	120	120	124	122	126	130	132	130	128	125	126	128	127	126
MURUGANAND	142	141	108	106	106	104	103	100	101	102	104	102	103	100	116	112	114	120	124	126	128	130	128	126	124	122	126	124
SHANTHI	148	146	136	130	130	130	128	121	120	123	121	118	114	112	116	112	114	122	118	120	124	120	123	122	123	125	126	128
VALLIAMMAL	125	124	115	116	123	120	121	116	114	118	121	120	121	120	126	130	128	124	121	125	126	126	122	126	120	128	122	126
MOHANDAS	148	145	134	135	136	130	138	140	144	142	147	150	132	134	145	136	138	131	130	128	132	130	128	124	126	130	130	126
CHITTI BABU	134	138	130	130	128	130	125	129	120	123	118	115	111	112	114	120	120	122	124	130	128	130	126	125	126	127	127	128
SUBRAMANIAM	116	120	121	122	126	122	121	125	124	124	123	120	122	121	126	120	128	128	126	126	132	132	131	110	116	118	122	126
VELU	138	132	136	131	128	126	128	127	125	120	117	114	114	110	120	118	124	120	126	128	132	131	128	124	126	127	127	125
MAHABOOBI	115	118	120	118	126	122	121	126	124	125	123	121	123	120	126	122	130	126	126	128	130	131	128	114	114	119	120	126
SIVAKUMAR	138	130	135	136	130	140	130	132	135	131	128	133	129	131	130	120	123	101	122	123	122	125	127	128	120	118	120	124
RAMAN	128	125	126	130	126	125	120	121	118	119	120	114	116	118	120	122	126	122	126	120	118	118	120	120	124	124	124	120
SRIKAR	136	130	128	126	124	122	120	120	118	122	121	118	116	112	116	112	114	118	118	120	124	122	121	120	124	125	124	126
KARTHIKEYAN	128	126	126	120	120	120	118	120	118	120	122	118	116	120	118	116	116	120	118	122	124	122	124	120	122	124	124	126

NAME	PRE DBP	2s	2min	4min	6min	8min	10min	15min	20min	25min	30m	40m	50m	1hr	2hr	3hr	4hr	5hr	6hr	8hr	10hr	12hr	14hr	16hr	18hr	20hr	22hr	24hr	RRV	SE
SARAVANA PERUMAL	80	80	82	82	78	73	71	70	68	72	68	48	65	64	62	62	64	70	72	70	72	80	82	80	86	89	72	82	A	H
SUDHAKAR	80	81	80	87	80	81	72	70	76	86	80	72	74	76	82	80	82	80	81	82	83	80	82	86	80	81	82	80	A	0
RAVI	92	92	90	92	90	90	84	80	86	87	86	86	88	74	76	74	70	72	80	82	80	80	80	82	80	84	80	78	A	0
IYYAPPAN	90	90	80	83	80	69	70	72	74	76	74	72	78	71	74	70	72	74	70	72	76	78	74	76	71	72	74	70	A	0
AMUTHA	95	78	76	74	70	69	68	68	67	66	65	63	64	63	65	66	64	65	66	64	60	62	63	64	66	65	62	64	A	N
DEVENDIRAN	92	92	90	91	90	89	87	87	86	85	87	83	82	82	81	80	84	82	81	82	84	86	80	82	80	81`	82	84	A	0
SELVARAJ	95	95	90	92	90	92	86	88	68	70	72	74	70	70	70	72	70	80	86	80	80	80	82	80	80	82	78	80	A	0
STEPHEN	90	92	90	90	90	92	101	100	90	86	80	90	90	92	92	90	86	80	84	90	90	90	80	80	82	90	90	80	A	0
SYED JAWAHAR	86	86	74	50	50	56	60	66	68	60	70	74	68	61	68	66	70	72	78	74	80	82	80	80	84	82	80	80	A	H
SHANKAR	80	82	80	78	74	76	74	72	70	72	80	82	74	70	80	84	80	82	80	82	80	82	80	82	80	86	80	80	A	0
DEEPAK MECH	82	82	94	84	84	83	82	82	80	76	77	75	70	72	80	80	80	84	86	82	80	80	80	86	80	80	80	80	A	S
BINU PAUL	90	96	90	95	90	96	95	90	80	82	80	82	86	84	80	80	80	86	80	84	86	90	90	90	92	90	90	90	A	S
KUMAR	80	86	87	85	82	84	82	80	84	82	78	80	80	80	80	82	78	75	76	78	74	78	76	74	72	78	76	74	A	0
SARAVANAN	82	80	79	78	71	76	78	75	74	76	72	75	74	76	74	75	76	72	74	75	76	72	74	72	72	74	72	74	A	0
PANEERSELVAM	83	83	81	81	81	80	82	84	76	77	78	76	74	72	76	74	70	72	72	76	74	72	74	76	70	72	68	74	A	0
SUBRAMANIAM	90	92	90	92	96	94	92	90	80	82	81	83	84	86	80	82	81	78	74	78	76	78	76	80	82	81	84	82	A	0
MUTHURAJ	86	81	82	85	80	82	78	70	74	86	82	72	75	76	74	80	81	82	80	82	84	80	76	78	80	80	82	78	A	0
ELUMALAI	88	80	90	86	84	82	82	85	80	75	78	75	71	72	82	80	83	84	85	82	80	84	80	88	80	81	80	82	A	S
KESAVAN	80	81	82	87	83	81	87	70	76	84	80	71	74	74	82	80	76	81	81	83	83	84	82	85	80	80	82	81	A	0
DAKSHINAMOORTHY	82	80	94	90	84	82	82	86	80	78	77	74	70	70	80	81	80	82	86	80	80	81	80	85	80	81	80	82	A	0
LAKSHMANAN	95	76	76	78	70	68	68	67	67	68	65	65	64	66	65	68	64	72	71	70	68	70	73	74	76	75	69	70	A	0
MOHAN	82	80	88	86	78	74	71	72	66	70	69	48	65	68	66	64	66	71	72	72	74	81	83	80	85	88	71	80	A	H
ARUN KUMAR	82	80	82	86	82	80	78	72	74	84	82	78	74	76	80	82	84	82	80	80	84	82	84	88	82	80	80	78	A	0
THANGAM	92	92	90	92	90	90	84	80	86	87	86	86	88	74	76	74	70	72	80	82	80	80	80	82	80	84	80	78	A	0
GANESAN	82	84	82	76	72	78	72	74	72	70	82	78	74	76	78	78	82	80	82	80	82	80	82	80	82	84	82	78	A	0
CHANDRAN	86	88	82	90	84	88	87	86	88	84	86	80	82	84	80	82	84	86	80	82	84	88	82	80	82	82	86	84	A	0
SUNDAR	82	80	82	86	84	80	86	80	74	72	78	72	74	72	80	82	78	80	80	78	80	82	80	84	82	84	82	80	A	0
PONNAMMAL	84	85	84	84	86	82	78	72	74	82	80	70	74	76	72	82	80	84	82	80	74	82	84	78	78	82	84	78	A	0
VENKATESAN	80	82	80	88	84	86	82	84	82	78	78	76	72	74	82	82	84	80	84	82	82	80	78	80	82	80	82	84	A	0
ELUMALAI	80	84	78	68	68	70	72	70	68	72	70	72	68	68	72	74	76	70	74	72	80	82	82	80	82	80	82	80	A	0
GANESH BABU	90	90	86	82	72	70	64	66	65	59	58	51	56	61	68	64	66	68	64	70	72	76	70	80	82	82	80	84	A	NH
BANUMATHY	88	86	85	72	70	68	67	64	66	68	70	66	61	70	72	84	72	70	72	74	74	78	84	80	80	82	80	86	A	H
PALANI	80	80	82	80	82	80	86	90	86	82	76	74	76	74	76	72	70	76	78	80	82	81	86	80	79	72	73	80	A	0
PITCHANDI	92	91	100	102	101	100	102	92	96	90	91	93	91	90	92	80	86	60	82	84	82	80	82	80	82	80	80	86	A	0
MURUGESAN	86	86	82	72	70	68	67	72	68	67	82	86	80	84	82	80	84	80	70	72	70	74	80	80	84	84	82	80	A	B
RAMANI	92	92	92	90	64	60	57	53	58	56	58	56	54	62	72	70	74	74	80	82	80	84	82	82	86	80	80	82	A	H
SUDHAM JENA	89	86	83	75	73	70	68	60	50	69	68	67	68	65	68	67	68	67	70	72	76	74	80	82	86	84	86	83	A	H
RAMESH	82	82	76	73	70	56	57	56	54	58	57	57	61	64	62	72	70	72	78	76	70	70	70	68	69	78	75	74	A	0
THIRUMOORTHY	90	92	90	50	49	50	50	52	52	51	51	50	51	51	53	54	60	62	68	64	66	68	70	72	74	75	76	86	A	0
LAKSHMANAN	82	82	80	76	82	78	76	70	76	68	70	80	74	70	68	72	70	72	80	86	84	82	80	82	84	82	80	80	A	0
SRINIVASAN	90	92	94	92	92	90	80	76	74	68	70	71	70	72	72	77	70	68	67	72	78	72	80	86	84	82	86	80	A	S
SUGUNA	89	85	76	74	73	74	77	75	72	74	72	68	73	70	67	68	65	66	70	71	72	74	73	74	70	75	76	75	A	0
GOPAL	95	95	92	88	84	80	81	86	843	86	84	78	77	76	74	75	76	73	72	70	72	74	76	70	78	74	76	78	A	0
KRISHNAVENI	90	90	90	90	90	88	82	80	68	66	67	90	90	90	92	90	90	90	90	90	88	84	80	82	80	82	80	80	A	0
PANDIAN	79	81	82	86	84	82	79	79	80	82	82	81	80	80	82	80	80	80	80	82	80	86	80	72	78	80	82	82	A	0
RAJAGOPAL	91	91	90	83	77	76	82	76	78	74	72	70	72	70	86	80	82	80	80	80	80	80	90	80	90	82	84	80	A	B
PANJAYAN	90	90	90	90	89	88	87	87	90	90	91	92	90	86	82	80	82	80	80	82	80	80	82	80	80	80	82	80	A	0
KARTHICK	88	88	84	82	84	84	82	84	82	83	83	83	82	84	83	80	82	84	81	82	80	80	82	86	82	80	84	80	A	0
MURUGANAND	78	79	76	74	74	73	72	70	72	70	68	68	71	72	74	76	74	72	78	74	78	76	74	75	70	75	76	78	A	S
SHANTHI	94	95	90	88	82	87	81	87	84	85	84	76	77	75	74	72	76	74	75	68	72	75	76	70	71	74	77	75	A	0
VALLIAMMAL	80	80	78	78	72	76	78	76	74	76	72	76	74	76	74	78	76	72	74	74	76	72	74	72	72	74	72	74	A	0
MOHANDAS	92	91	92	90	88	87	86	87	91	89	90	92	91	88	80	81	82	82	80	84	80	86	82	84	81	80	83	80	A	0
CHITTI BABU	82	87	84	84	84	83	82	80	82	80	81	82	84	86	83	88	80	82	81	80	80	81	82	84	82	85	84	83	A	0
SUBRAMANIAM	78	81	81	86	84	80	79	78	80	81	82	80	80	86	82	82	80	80	81	82	84	86	81	72	76	80	80	82	A	S
VELU	88	87	82	82	86	84	85	84	80	83	82	83	80	84	82	80	89	84	80	82	81	80	83	86	86	80	87	80	A	0
MAHABOOBI	78	80	81	85	83	84	78	76	81	80	81	80	86	82	83	84	85	88	81	83	82	86	86	72	76	80	81	82	A	0
SIVAKUMAR	98	91	96	102	100	100	101	92	89	90	92	93	90	91	92	82	86	68	82	80	82	82	82	87	82	78	80	88	A	0
RAMAN	88	86	80	78	70	68	78	70	68	68	70	76	80	82	82	84	84	80	78	72	74	76	82	81	84	86	82	78	A	0
SRIKAR	88	90	88	86	84	82	80	84	86	88	90	78	76	76	74	70	76	72	72	74	70	72	76	72	78	76	78	78	A	0
KARTHIKEYAN	88	90	88	86	80	86	80	86	84	86	84	78	78	74	76	78	76	72	74	70	68	74	72	72	74	72	76	74	A	0