
**“A COMPARATIVE EVALUATION BETWEEN ISOBARIC
BUPIVACAINE AND ISOBARIC 1% 2- CHLOROPROCAINE FOR
SPINAL ANAESTHESIA IN PERIANAL SURGERIES - A ONE
YEAR HOSPITAL BASED RANDOMISED CONTROLLED
TRIAL”**

By
REG NO.BA0117004

Dissertation

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BELAGAVI, KARNATAKA**

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BELAGAVI, KARNATAKA**

Endorsement

This is to certify that the dissertation entitled “**A COMPARATIVE EVALUATION BETWEEN ISOBARIC BUPIVACAINE AND ISOBARIC 1% 2- CHLOROPROCAINE FOR SPINAL ANAESTHESIA IN PERIANAL SURGERIES - A ONE YEAR HOSPITAL BASED RANDOMISED CONTROLLED TRIAL**” is a bonafide research work done by **REG NO.BA0117004**

Dr. Rajesh Mane MD

Professor and Head,
Department of Anaesthesiology,
J. N. Medical College,
Nehru Nagar, Belagavi – 10

Date:

Place: Belagavi

Dr. (Mrs) N.S Mahantshetti MD(Paed)

Principal,
J. N. Medical College,
Nehru Nagar, Belagavi – 10

Date:

Place: Belagavi

PLAGIARISM CERTIFICATE



JAWAHARLAL NEHRU MEDICAL COLLEGE

(A constituent unit of KLE Academy of Higher Education & Research Deemed-to-be University)
Accredited 'A' Grade by NAAC (2nd Cycle) Placed in Category "A" by MHRD (GoI)
Nehru Nagar, Belagavi-590 010, Karnataka-India



Website : <http://www.jnmc.edu>
E-Mail : Principal@jnmc.edu

Office : +91-(0)831 2471350
FAX : +91 (0)831-2470759

Ref. No. : MOC/PG/2287

Date : 17/09/2019

To,

REG NO.BA0117004

Postgraduate Student
Department of Anaesthesiology.,
2017-18 Batch
J. N. Medical College,
Belagavi.

Sub: Acceptance Letter

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Yours sincerely,

Coordinator
Dept. of Anaesthesiology.,

Dr. S. N. SURESH
MD (Anaes)
Administrator OT Affairs
KMC No. 15788
KLES Dr. Prabhakar Kore Hospital &
MRC, Belagavi

Chairman,
Anti-plagiarism Committee.

Dr. Chaitanya A. Kulkarni
Consultant Anaesthesiologist
KMC Reg.No.-55536



LIST OF ABBREVIATIONS USED

ASA	-	American Society of Anaesthesiologists
mcg	-	Microgram
cc	-	Cubic centimeter
CNS	-	Central nervous system
CSF	-	Cerebrospinal fluid
CVS	-	Cardiovascular system
DBP	-	Diastolic blood pressure
ED	-	Effective dose
GA	-	General anaesthesia
HR	-	Heart rate
bpm	-	Beats per minute
IV	-	Intravenous
kg	-	Kilogram
L	-	Lumbar
m	-	Meters
MAP	-	Mean arterial pressure
mg	-	Milligram
v/s	-	Versus
Mins	-	Minutes
ml	-	Millilitre
NIBP	-	Non invasive blood pressure
O ₂	-	Oxygen
S	-	Sacral
SAB	-	Subarachnoid block

SBP	-	Systolic blood pressure
SD	-	Standard deviation
Sec	-	Second
SpO ₂	-	Peripheral saturation of oxygen
TNS	-	Transient neurological symptoms
	-	Alpha
	-	Beta
	-	Delta
μ	-	Micro
cm	-	centimeter
G	-	Gauge
mEq	-	milliequivalents
dl	-	decilitre

ABSTRACT

Background and Aims: The number of surgical procedures being performed on an outpatient basis under spinal anaesthesia has gradually increased since few years. The choice of local anaesthetic which provides rapid onset and offset of its action has played a crucial role in spinal anaesthesia. Chloroprocaine was used in the 1980s but was withdrawn due to reported cases of neurotoxicity. This was accounted to the presence of a preservative sodium bisulphite and a low pH. The drug has been reintroduced with a preservative-free formula for the use of ambulatory surgery making it an ideal local anaesthetic for short duration procedures. This study aims at comparing isobaric 0.5% bupivacaine and isobaric 1% 2-chloroprocaine - in terms of onset and duration of sensory and motor blockade and secondarily, in terms of hemodynamic changes and associated complications.

Methods: Seventy-eight patients belonging to American society of Anaesthesiologists I and II undergoing perianal surgeries under spinal anaesthesia were randomized into two groups. Group A received 3ml of 0.5% isobaric bupivacaine while Group B received 4ml of isobaric 1% 2-chloroprocaine. Student's unpaired t-test and the χ^2 test were used to analyze the results, using the SPSS version 18 software.

Results: The mean onset of sensory block was significantly faster in Group B (3.59 ± 0.9 mins) than in group A (5.41 ± 1.16 mins). The mean duration of sensory blockade was shorter in group B (78.00 ± 4.81 mins) than in group A (171.31 ± 4.48 mins). The mean onset of motor block was faster in group B (4.82 ± 0.79 mins) than group A (7.72 ± 0.89 mins). The mean duration of motor block was shorter in group B (66.28 ± 4.78 mins) than group A (128.54 ± 3.75 mins). Isobaric bupivacaine and isobaric bupivacaine had comparable hemodynamic stability.

Conclusion: Intrathecal isobaric 1% 2- chloroprocaine is associated with lesser duration of both sensory and motor blockade, thereby enabling quicker recovery from anaesthesia and has comparable hemodynamic stability with isobaric bupivacaine for perianal surgeries.

Keywords: Chloroprocaine, bupivacaine, isobaric, spinal anaesthesia,

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INTRODUCTION

Spinal anaesthesia is a simple technique with reliable outcomes being performed most frequently for all infraumbilical surgeries^{1,2,3}. The broad safety margin of this regional anaesthesia method has popularized its use in ambulatory surgeries. The number of procedures being conducted on an outpatient basis has gradually increased since few years^{1,2}.

This form of anaesthesia has made ambulatory surgery a convenient option to many patients. Due to a few drawbacks such as prolonged motor block, delayed ambulation and urinary retention, the correct choice of local anaesthetic is essential^{1,4,5}. It should exhibit rapid onset and short duration of its action for early patient discharge without any side effects hence making it an ideal local anaesthetic.

Chloroprocaine was developed to address the issue for a short acting spinal local anaesthetic that is reliable and has a positive well-being profile to help the developing requirement for day care medical procedures. It is an ester type of local anaesthetic with the shortest duration of action amongst all of the local anaesthetics^{6,7,8}. The drug was used in the 1980s^{9,7}. Few cases of neurotoxicity had been reported due to the combination of low pH and presence of sodium bisulphite^{1,7}. The alteration of pH and the presence of no preservative has led to the reintroduction of the drug.

Many local anaesthetics have been tried for this type of surgeries including hyperbaric bupivacaine, a longer acting local anaesthetic by using smaller doses of the drug. It led to insufficient anaesthesia and urinary retention making it unsuitable for ambulatory surgeries. With this rising trend of ambulatory surgeries, a need was felt

to have a drug available for spinal use. Hence, in this study we assessed the onset and duration of motor and sensory blockade caused by isobaric 1% 2-chloroprocaine and isobaric bupivacaine.

AIMS AND OBJECTIVES

Primary objective - To compare the onset and duration of sensory and motor blockade of isobaric 1% 2- chloroprocaine with isobaric 0.5% bupivacaine for spinal anesthesia in perianal surgeries.

Secondary objective- To study and evaluate the hemodynamic changes brought about by isobaric 1% 2-chlorprocaine and isobaric 0.5% bupivacaine.

REVIEW OF LITERATURE

Spinal anaesthesia is a form of regional anaesthesia which causes blockade of nerve roots by injecting a local anaesthetic into the subarachnoid space.

In 1885, Corning accidentally administered cocaine intrathecally in order to insert a catheter into urethra followed by Bier of Grifswald in Germany produced spinal anaesthesia in animals and man in the year 1898. In 1904, Eithon discovered procaine and synthesised the agent. Later on, Pitkin introduced agents intrathecally¹⁰.

Earlier lignocaine 5% was commonly used for spinal anaesthesia, but its use has declined^{4,11}. Since a few decades' lignocaine has been almost replaced with bupivacaine and ropivacaine. At present, many short duration surgeries are being done as an outpatient procedure under spinal anaesthesia^{12,13}. Hyperbaric bupivacaine, a long acting drug has been attempted to be used in lesser doses for ambulatory surgeries but resulted in insufficient blockade and caused a longer duration stay in the hospital¹⁴.

Foldes, in 1952, introduced a synthetic compound, which was an analogue of procaine, as one of the newer agents named chlorprocaine which was then marketed as nescaine.

After nearly thirty years of use of this drug, reports appeared of persistent neurological complications following epidural administration. The neurotoxicity was found to be due to 0.2% sodium bisulphite which was added as a preservative and not due to the drug itself^{15,16,17,18}.

In a study done by Yoos JR et al^{19,20} in February 2009, eight healthy volunteers were involved in the study. One group received 40mg of chlorprocaine while the other group received 7.5mg of bupivacaine. The peak block height, regression to L1

and tourniquet tolerance was assessed and did not differ between two drugs. The time to simulated discharge including complete block regression, ambulation and spontaneous voiding was found to be higher with bupivacaine and was statistically significant.

In another study done by An Temkens et al²¹ in 2016, ninety-nine patients undergoing knee arthroscopy in an outpatient setting were included in this double blind randomised controlled trial. Each group received 40mg 2- chloroprocaine, 40mg lidocaine or 5mg bupivacaine. The duration of sensory and motor blockade was the primary objective. Chloroprocaine as compared to lidocaine and bupivacaine was found to have a shorter duration of action.

Casati A et al conducted a double blind randomised controlled trial in 2007, comparing lignocaine and preservative free chloroprocaine²². Thirty ASA I-II patients undergoing knee arthroscopy was randomly divided to receive 50mg of either 1% plain lignocaine or 1% preservative free plain chloroprocaine. The median time for recovery of sensory, motor and unassisted ambulation and voiding were assessed. Patients who received chloroprocaine had a shorter sensory and motor duration of action. Earlier ambulation and voiding were observed in patients who received chloroprocaine.

In another study done by Ghisi D et al⁶ in 2015, a review was done on using chloroprocaine for ambulatory surgery. Three doses of chloroprocaine being 30mg, 40mg and 50mg was compared in forty five patients for short duration lower limb procedures. Patients receiving 30mg of chloroprocaine required intraoperative analgesic supplementation as compared to the other two groups. It was found that dose ranging between 30-60 mg chloroprocaine was adequate for short duration surgeries.

In another study conducted by Casati et al¹⁵ in 2006 forty-five patients of ASA I-II posted for outpatient elective lower limb surgery under spinal anaesthesia. 30mg, 40mg and 50mg of 1% preservative free chloroprocaine was compared. The time of onset was similar in all the three groups. It was found that the spinal block resolution and recovery of ambulation were faster in 30mg chloroprocaine than in groups receiving 40mg and 50mg. Outpatient perianal surgeries are being conducted under a low dose spinal anaesthesia technique as it being a simple and safe technique. Because of its short duration of action, preservative free plain chloroprocaine seems to be the right choice of drug to perform low dose spinal anaesthesia.

In a study done in 2014, by Gebhard V et al²³, the aim of this study was to determine the optimal dose of chloroprocaine for patients undergoing perianal surgeries. One hundred and twenty patients were included in this study. They were randomly divided to receive 10mg, 20mg or 30mg chloroprocaine intrathecally. It was found that 10mg of chloroprocaine can be successfully used for low dose spinal anaesthesia for perianal surgery. The occurrence of a profound clinically relevant motor block was higher with 30mg of the drug.

In another study H. Vaghadin et al²⁴ in April 2007 compared intrathecal use of lignocaine and chloroprocaine in combination with fentanyl to provide selective spinal anaesthesia for patients undergoing outpatient Transurethral resection of prostate (TURP). A double-blind randomised study including forty patients with ASA I-III outpatient undergoing TURP were enrolled. Group – I received 40 mg of chloroprocaine mixed with 12.5 micrograms fentanyl and group II received 35mg lignocaine with 12.5 micrograms fentanyl. The median time for onset and maximal level were measured and was found to be comparable. The duration of block was measured and was found to be shorter in the chloroprocaine group.

A study was conducted by Camponovo et al²⁵ in May 2014, comparing 50mg of preservative free 1% chloroprocaine with 10mg of plain 0.5% bupivacaine in outpatients undergoing lower abdominal and lower limb procedures. The time of onset, recovery of anaesthesia and ambulation were assessed. The authors found that the onset time was almost the same with 50mg of plain 1% chloroprocaine and 10mg of plain 0.5% bupivacaine. The time to recovery was found to be shorter in the group receiving chloropropane spinal anaesthesia having an earlier ambulation.

Using regional anaesthesia over general anaesthesia prevents the undue side effects of general anaesthesia such as postoperative sedation, postoperative nausea and vomiting, throat irritation and in few cases hypoxia^{12,26,27}. Total intravenous anaesthesia is no safer than general anaesthesia and demands the same manpower, monitoring and side effects of general anaesthesia.

A retrospective study was conducted using 1% chloroprocaine and general anaesthesia for ultra-short outpatient procedures undergoing knee arthroscopy by Camponovo et al²⁶. There was a clinically significant reduction in terms of discharge time and the cost of material and employers involved in patients care when 1% chloroprocaine was used.

Research has been going on about an ideal local anaesthetic for outpatient spinal anaesthesia. An amino ester local anaesthetic, 2- chloroprocaine, a newer drug is introduced¹. Few cases of neurotoxicity had been reported due to the combination of low pH and presence of sodium bisulfite²⁰. The pH of solution has been altered and a preservative free formula has been reintroduced. Hence, this study is to compare the efficacy of bupivacaine with 2- chloroprocaine for short duration surgeries.

METHODOLOGY

The present study titled “**A COMPARATIVE EVALUATION BETWEEN BUPIVACAINE AND 2-CHLOROPROCAINE FOR SPINAL ANAESTHESIA IN PERIANAL SURGERIES**”- A ONE YEAR HOSPITAL BASED RANDOMISED CONTROL STUDY was conducted in the Department of Anaesthesiology, KLE’s Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehru Nagar, Belagavi during the period of January 2018 to December 2018.

Source of data

Patients between the age group of 18-70 years, belonging to “ASA Grade I and II scheduled for elective perianal surgeries” at K.L.E`S Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehru Nagar, Belagavi between January 2018 to December 2018 were included.

Study Design:

A one year randomised controlled trial.

Study Period:

One year from January 2018 to December 2018.

Selection Criteria:

Inclusion Criteria:

- ASA physical status I and II
- Age between 18-70years.
- Patients undergoing elective perianal surgery of short duration (<60mins)
- The surgeries included: urologic surgeries, general surgeries and gynaecological surgeries (cystoscopy, circumcision, hydrocelectomy, haemorrhoidectomy, hysteroscopy, dilatation and curettage)
- Informed and written consent.
- Duration of surgery less than 1 hour.

Exclusion Criteria:

- Patients allergic to local anaesthetics.
- Patients with coagulation abnormalities.
- Patients with spinal abnormalities and neurological deficits.
- Patients with infection at the site of subarachnoid block.
- Hypovolemic patients.

Sample size:

Total sample size of 78 adult patients divided into two groups:

GROUP A (39 patients): patients receiving isobaric 0.5% bupivacaine

GROUP B (39 patients): patients receiving isobaric 1% 2- chloroprocaine

Sample size calculation:

Level of significance was taken as 5%

Power of the test used was taken as 80%

type I error rate = 0.05 and

type II error rate = 0.2

Taking the level of significance at 5% (=0.05), power of the test as 80% (=0.2), and

using one sided test we get $Z_{\alpha} = 1.96$ and $Z_{\beta} = 0.84$

S_1 was S.D of 0.5% isobaric bupivacaine is 93.

S_2 was S.D of 1% isobaric 2- chloroprocaine is 25.

\bar{X}_1 is the mean of the first group is 119

\bar{X}_2 is the mean of the second group is 76

Hence, $Z_{\alpha} = 1.96$

$$Z_{\beta} = 0.84$$

$$S_1 = 93$$

$$S_2 = 25$$

$$X_1 = 119$$

$$X_2 = 76$$

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

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

With these values the sample size obtained is 39.

Methodology:

- After obtaining the approval of ethical committee and written informed consent, a total of 78 patients undergoing elective perianal surgeries of minimum duration of 60minutes under spinal anaesthesia will be included in this study.

Patients will be randomly divided into two groups by using computed generated table.

The patients will be randomised to one of the two groups.

- Group A
- Group B

A thorough Pre- Anaesthetic Evaluation will be done. Detailed medical and personal history will be obtained. A detailed physical examination will be done. Patients will be advised overnight fasting. Routine investigations such as complete blood count, Random blood sugar, Serum creatinine, blood grouping and typing, Chest X-ray, Electrocardiography will be carried out.

In the preoperative holding area, a wide bore i.v. access will be secured and patients will be preloaded with ringer lactate 10ml/kg half an hour before induction of anaesthesia. Anaesthetic techniques will be standardised for all patients.

Inside the operation theatre, the patient will be shifted onto the operating table. Standard non-invasive monitors will be attached and baseline heart rate, BP, SpO₂ will be recorded.

Under strict aseptic precautions the following procedure will be carried out.

Monitors such as pulse oximeter, ECG, non-invasive BP are connected. Patient will be then made to sit holding a pillow, under strict aseptic precautions, L3- L4 space will be identified. 2ml of 2% lignocaine will be injected in L3- L4 space.

GROUP A: Using 23G Quincke spinal needle 3ml of 0.5% isobaric bupivacaine will be injected in L3- L4 subarachnoid space after confirming free flow of CSF.

GROUP B: Using 23G Quincke's spinal needle, 4ml of 1% 2-chloroprocaine will be injected in L3- L4 subarachnoid space after confirming free flow of CSF

Patient will then be immediately placed in supine position. Intraoperative and postoperative assessments will be performed.

The following parameters will be monitored/ measured:

A) Sensory blockade will be assessed by pin prick in mid axillary line every minute till T10 block occurs, following which it will be assessed at 10-minute intervals for next one hour.

Time taken for sensory blockade till T10 dermatome, highest sensory dermatome blocked and time for regression to S2 would be recorded.

Surgery would be allowed to start once T10 dermatome has been blocked but GA will be induced if this does not happen in 30minutes. Such cases will be labelled as block failure and excluded from final analysis.

B) Motor blockade will be assessed immediately after sensory block assessment using a Modified Bromage scale

Degrees	Evidence
0	Full leg movement, full flexion of knees and ankles
1	Inability to raise extended legs, just able to flex knees, full ankle flexion
2	Inability to flex knees, some flexion of ankles possible
3	No movement possible (unable to move legs or feet)

Motor block onset will be taken as the time to reach modified Bromage score 3 and total duration of motor block will be taken as the time for return to modified Bromage score 0.

In case patient doesn't attain Bromage score of 3, the highest score attained would be documented.

C) Post-operative analgesia: following surgery patient will not be put on regular analgesics.

Time for first rescue will be noted and will be treated with Inj. Diclofenac 75mg added to normal saline.

D) HR, BP and SpO₂ will be monitored throughout the surgery.

Hypotension will be defined as decrease in systolic BP by 20% from baseline values or a systolic less than 90mm of Hg and will be treated with incremental intravenous boluses of mephentermin 5 to 10mg and a bolus administration of 250ml of Ringer Lactate solution over 10mins.

Bradycardia will be defined as decrease in heart rate less than 50 beats per minute and will be treated with intravenous Atropine 0.6mg.

Supplementary oxygen will be given through facemask.

RESULT

This one year randomised clinical trial was conducted in the Department of Anaesthesiology, during the period of January 2018 to December 2018 at KLE'S Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehru Nagar, Belagavi.

A total of 78 patients undergoing perianal surgeries under spinal anaesthesia were randomly allocated into one of the two groups based on a computer-generated randomisation chart.

GROUP A: Using 23G Quincke spinal needle 3ml of 0.5% isobaric bupivacaine was injected in L3- L4 subarachnoid space after confirming free flow of CSF.

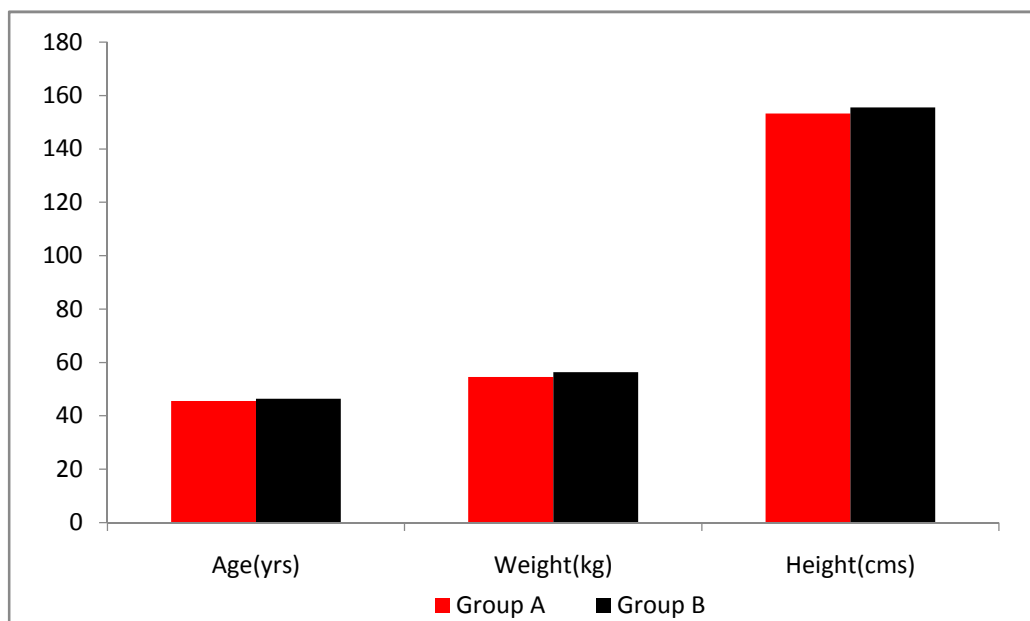
GROUP B: Using 23G Quincke's spinal needle, 4ml of 1% 2-chloroprocaine was injected in L3- L4 subarachnoid space after confirming free flow of CSF.

Data obtained was coded and analysed as below.

	Group A		Group B		P value
	Mean	Standard Deviation	Mean	Standard Deviation	
Age (years)	45.15	13.63	47.15	11.27	0.482
Weight(kgs)	55.08	4.86	57.54	5.76	0.045
Height (cms)	152.54	4.44	155.90	4.42	0.001

TABLE 1: MEAN AGE, WEIGHT, HEIGHT

GRAPH 1: MEAN AGE, WEIGHT, HEIGHT



In the present study we found no statistically significant difference between group A and group B with regards to mean age (45.15 ± 13.63 and 47.15 ± 11.27 years respectively; p = 0.482), mean weight (55.08 ± 4.86 and 57.54 ± 5.76 kgs respectively; p = 0.045) and mean height (152.54 ± 4.44 and 155.59 ± 4.42 cms respectively; p =0.001)

TABLE 2: SEX DISTRIBUTION

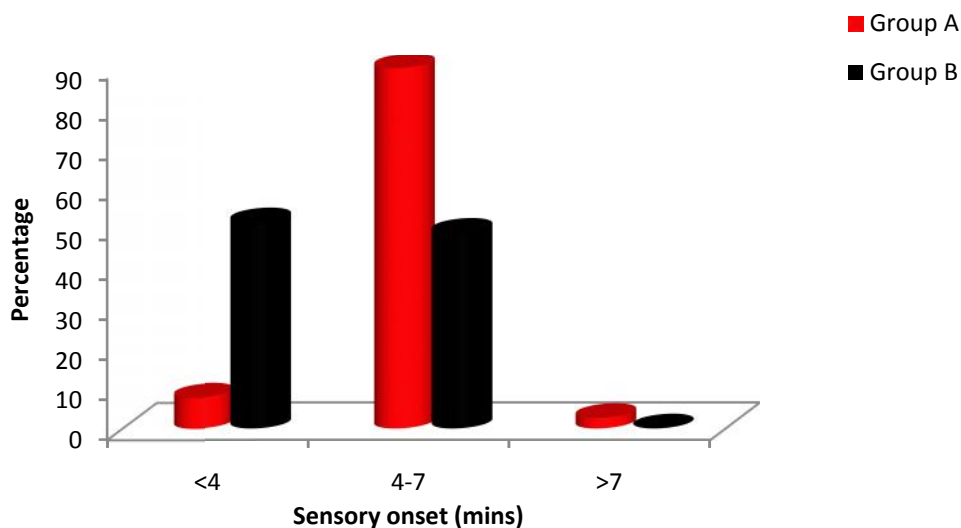
	Group A	%	Group B	%	Total
Female	10	25.6	5	12.8	15
Male	29	74.4	34	87.2	63
Total	39	100	39	100	78

In this study 74.4% were males and 25.6% were females in Group A and 87.2 % were males and 12.8% were females in Group B, suggesting both the groups had comparable demographic characteristics.

TABLE 3: ONSET OF SENSORY BLOCKADE:

Sensory Onset (mins)	Group A	Group B	Total
<4	3(7.7%)	20(51.3%)	23(29.5%)
4-7	35(89.7%)	19(48.7%)	54(69.2%)
>7	1(2.6%)	0(0%)	1(1.3%)
Total	39(100%)	39(100%)	78(100%)

GRAPH 2: ONSET OF SENSORY BLOCKADE

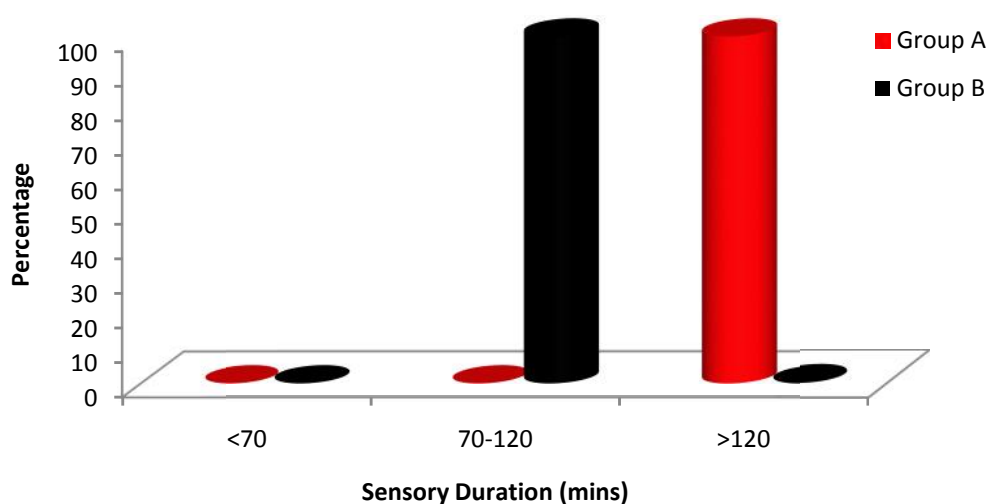


In our study, mean onset of sensory blockade was faster in Group B (3.59 ± 0.94 mins) than in group A (5.41 ± 1.16 mins) and was statistically significant ($p < 0.001$).

TABLE 4: DURATION OF SENSORY BLOCKADE

Sensory Duration (mins)	Group A	Group B	Total
<70	0(0%)	0(0%)	0(0%)
70-120	0(0%)	39(100%)	39(50%)
>120	39(100%)	0(0%)	39(50%)

GRAPH 3: DURATION OF SENSORY BLOCKADE

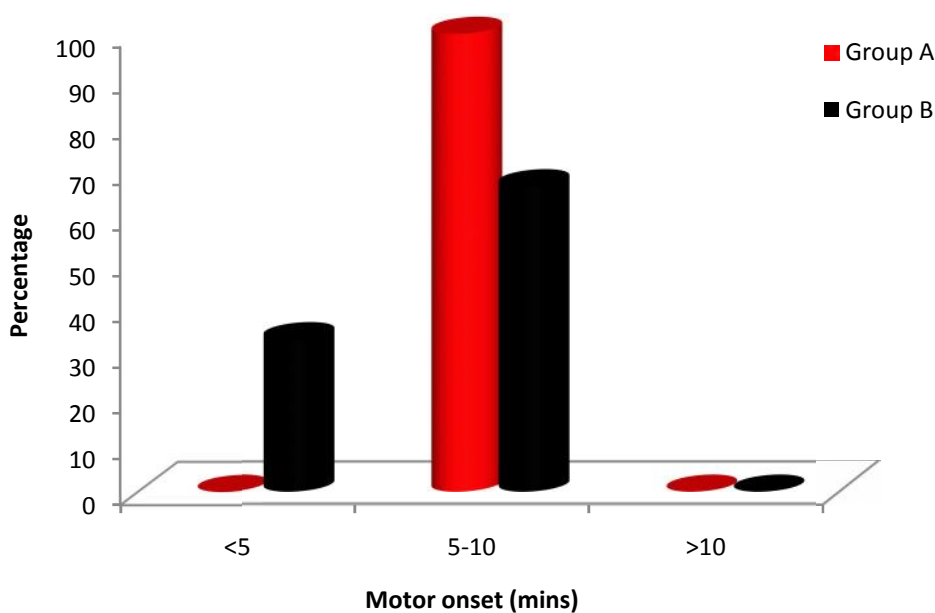


The mean duration of sensory blockade was shorter in group B (78.00±4.81mins) than in group A (171.31±4.48mins) and was statistically highly significant (p < 0.001)

TABLE 5: ONSET OF MOTOR BLOCKADE

Motor onset (mins)	Group A	Group B	Total
<5	0(0%)	13(33.3%)	13(16.7%)
5-10	39(100%)	26(66.7%)	65(83.3%)
>10	0(0%)	0(0%)	0(0%)
Total	39(100%)	39(100%)	78(100%)

GRAPH 4: ONSET OF MOTOR BLOCKADE

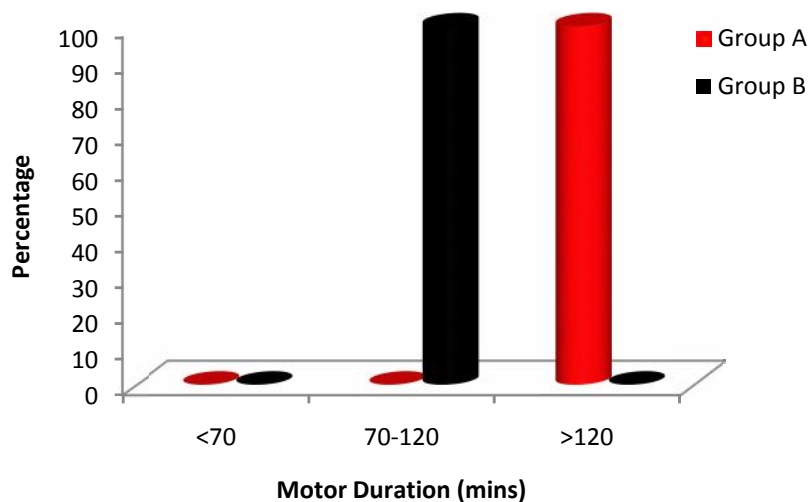


In the present study, mean onset of motor block was faster in group B (4.82 ± 0.79 mins) than group A (7.72 ± 0.89 mins) and was statistically highly significant ($p < 0.001$)

TABLE 6: DURATION OF MOTOR BLOCKADE

Motor Duration (mins)	Group A	Group B	Total
<70	0(0%)	31(79.5%)	31(39.7%)
70-120	2(5.1%)	8(20.5%)	10(12.8%)
>120	37(94.9%)	0(0%)	37(47.4%)
Total	39(100%)	39(100%)	78(100%)

GRAPH 5: DURATION OF MOTOR BLOCKADE

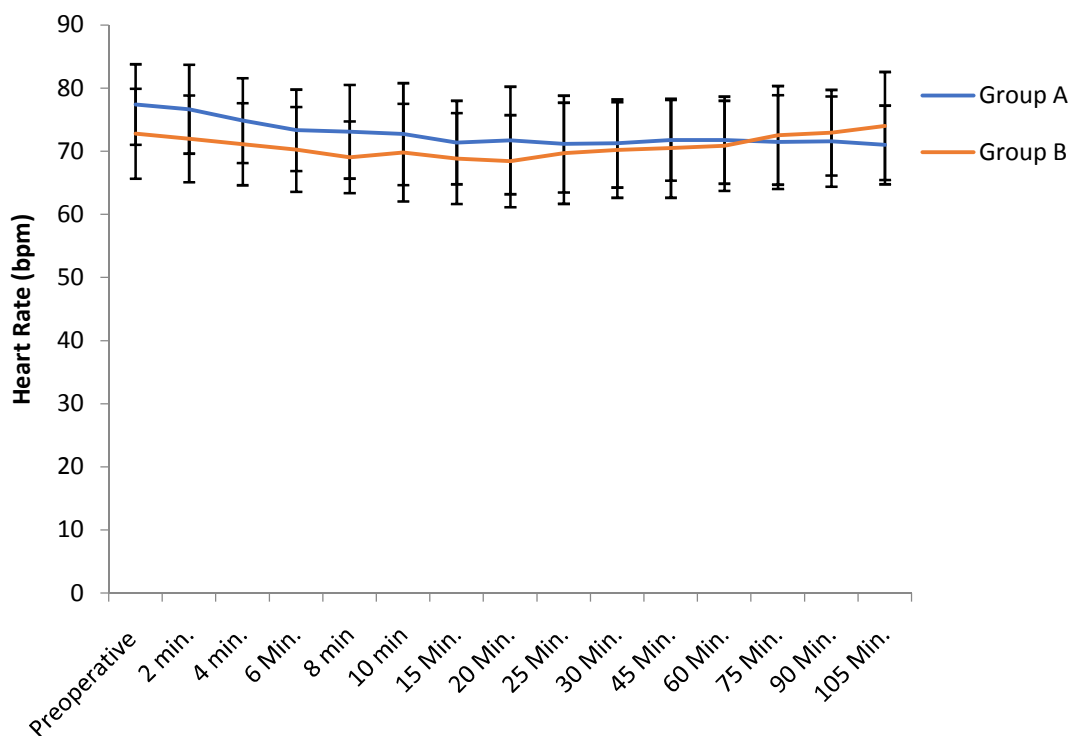


The mean duration of motor block was shorter in group B (66.28 ± 4.78 mins) than group A (128.54 ± 3.75 mins) and was statistically highly significant ($p < 0.001$)

TABLE 7: COMPARISON OF MEAN HEART RATE AT DIFFERENT TIME INTERVALS

Heart Rate (bpm)	Group A	Group B	Total	P value
Preoperative	77.41±6.38	72.77±7.13	75.09±7.12	0.003**
2 min.	76.67±7.04	71.97±6.87	74.32±7.30	0.004**
4 min.	74.87±6.72	71.13±6.51	73.00±6.84	0.015*
6 Min.	73.33±6.45	70.28±6.72	71.81±6.72	0.044*
8 min	73.10±7.42	69.05±5.68	71.08±6.87	0.008**
10 min	72.72±8.07	69.79±7.73	71.26±7.99	0.107
15 Min.	71.38±6.62	68.85±7.19	70.12±6.99	0.109
20 Min.	71.72±8.52	68.44±7.29	70.08±8.05	0.071+
25 Min.	71.15±7.67	69.69±8.01	70.42±7.82	0.413
30 Min.	71.23±6.97	70.21±7.57	70.72±7.25	0.535
45 Min.	71.74±6.38	70.49±7.85	71.12±7.13	0.440
60 Min.	71.77±6.90	70.87±7.14	71.32±6.99	0.574
75 Min.	71.46±7.43	72.53±7.81	71.99±7.59	0.542
90 Min.	71.54±7.14	72.94±6.79	72.18±6.97	0.399
105 Min.	71.00±6.24	74.00±8.56	72.21±7.34	0.150

GRAPH 6: COMPARISON OF HEART RATE AT DIFFERENT INTERVALS(bpm)



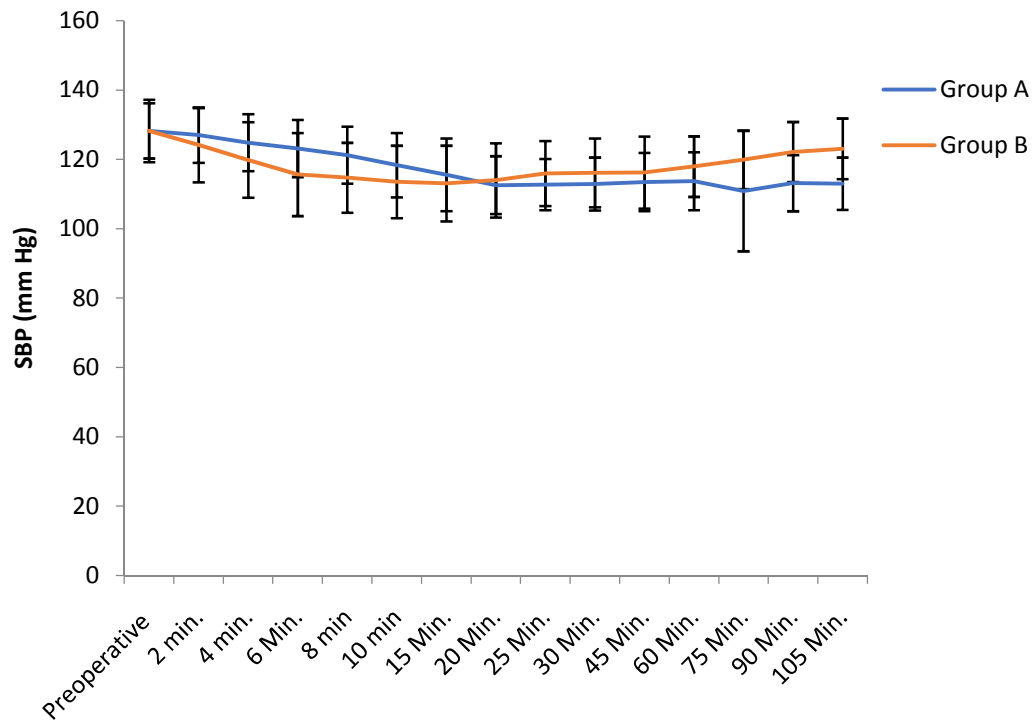
In this study the mean heart rate in the pre-operative phase was 77.41 ± 6.38 bpm in group and 72.77 ± 7.13 bpm in group B and was comparable ($p = 0.003$).

The heart rate fell to 71.77 ± 6.90 bpm at 60 minutes in group A while it fell to 70.87 ± 7.14 bpm at 60 minutes in group B.

TABLE 8: COMPARISON OF SYSTOLIC BLOOD PRESSURE AT DIFFERENT LEVELS (mm of Hg)

SBP (mm Hg)	Group A	Group B	Total	P value
Preoperative	128.21±7.97	128.21±9.01	128.21±8.45	1.000
2 min.	126.97±7.96	124.10±10.74	125.54±9.50	0.184
4 min.	124.82±8.23	119.82±10.89	122.32±9.91	0.025*
6 Min.	123.13±8.24	115.62±11.97	119.37±10.89	0.002**
8 min	121.21±8.23	114.69±10.09	117.95±9.71	0.003**
10 min	118.31±9.29	113.49±10.45	115.90±10.11	0.034*
15 Min.	115.54±10.47	113.03±10.91	114.28±10.69	0.302
20 Min.	112.56±8.34	113.95±10.70	113.26±9.55	0.526
25 Min.	112.74±7.40	115.90±9.38	114.32±8.54	0.103
30 Min.	112.90±7.63	116.10±9.91	114.50±8.93	0.114
45 Min.	113.49±8.37	116.18±10.39	114.83±9.47	0.211
60 Min.	113.69±8.37	117.90±8.72	115.79±8.75	0.033*
75 Min.	110.87±17.39	119.84±8.46	115.24±14.42	0.006**
90 Min.	113.13±8.11	122.12±8.66	117.25±9.46	<0.001**
105 Min.	112.97±7.55	123.05±8.75	117.04±9.41	<0.001**

GRAPH 7: COMPARISON OF SYSTOLIC BLOOD PRESSURE AT DIFFERENT LEVELS (mm of Hg)



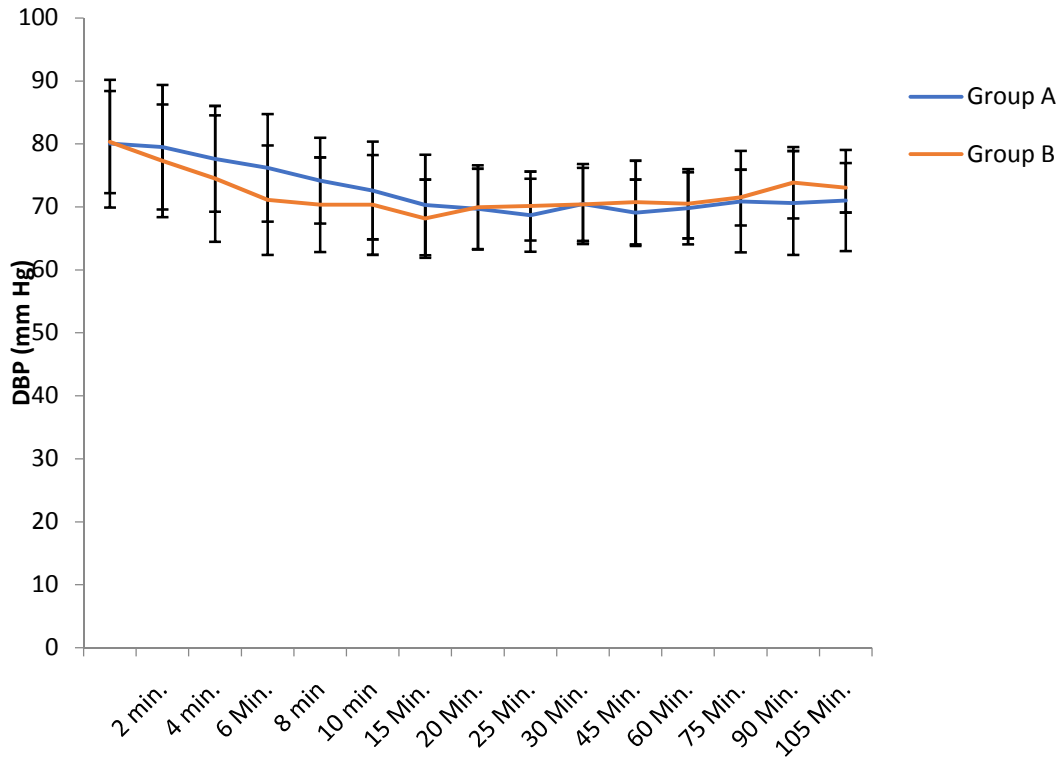
In this study the mean systolic BP in the pre-operative phase was 128.21 ± 7.97 mm of Hg in group A and 128.21 ± 9.01 in group B and was comparable ($p = 1.000$).

The systolic BP fell to 113.69 ± 8.37 mm of Hg at 60 minutes and 110.87 ± 17.39 mm of Hg at 75 minutes in group A while it fell to 117.90 ± 8.72 mm of Hg at 60 minutes and 119.84 ± 8.46 mm of Hg at 75 minutes in group B.

TABLE 9: COMPARISON OF DIASTOLIC BLOOD PRESSURE AT DIFFERENT LEVELS (mm of Hg)

DBP (mm Hg)	Group A	Group B	Total	P value
Preoperative	80.05±10.15	80.31±8.11	80.18±9.13	0.902
2 min.	79.49±9.88	77.33±8.95	78.41±9.43	0.316
4 min.	77.64±8.40	74.51±10.04	76.08±9.33	0.140
6 Min.	76.21±8.54	71.08±8.68	73.64±8.94	0.010**
8 min	74.18±6.82	70.36±7.51	72.27±7.38	0.021*
10 min	72.62±7.76	70.33±7.92	71.47±7.88	0.203
15 Min.	70.31±7.98	68.15±6.21	69.23±7.19	0.188
20 Min.	69.69±6.40	69.95±6.67	69.82±6.50	0.863
25 Min.	68.69±5.79	70.15±5.48	69.42±5.65	0.256
30 Min.	70.49±6.34	70.41±5.81	70.45±6.04	0.956
45 Min.	69.08±5.27	70.72±6.64	69.90±6.01	0.230
60 Min.	69.79±5.73	70.51±5.50	70.15±5.59	0.574
75 Min.	70.85±8.07	71.51±4.43	71.17±6.52	0.659
90 Min.	70.64±8.25	73.85±5.67	72.11±7.32	0.063+
105 Min.	71.03±8.03	73.05±3.93	71.85±6.71	0.292

GRAPH 8: COMPARISON OF DIASTOLIC BLOOD PRESSURE AT DIFFERENT LEVELS (mm of Hg)



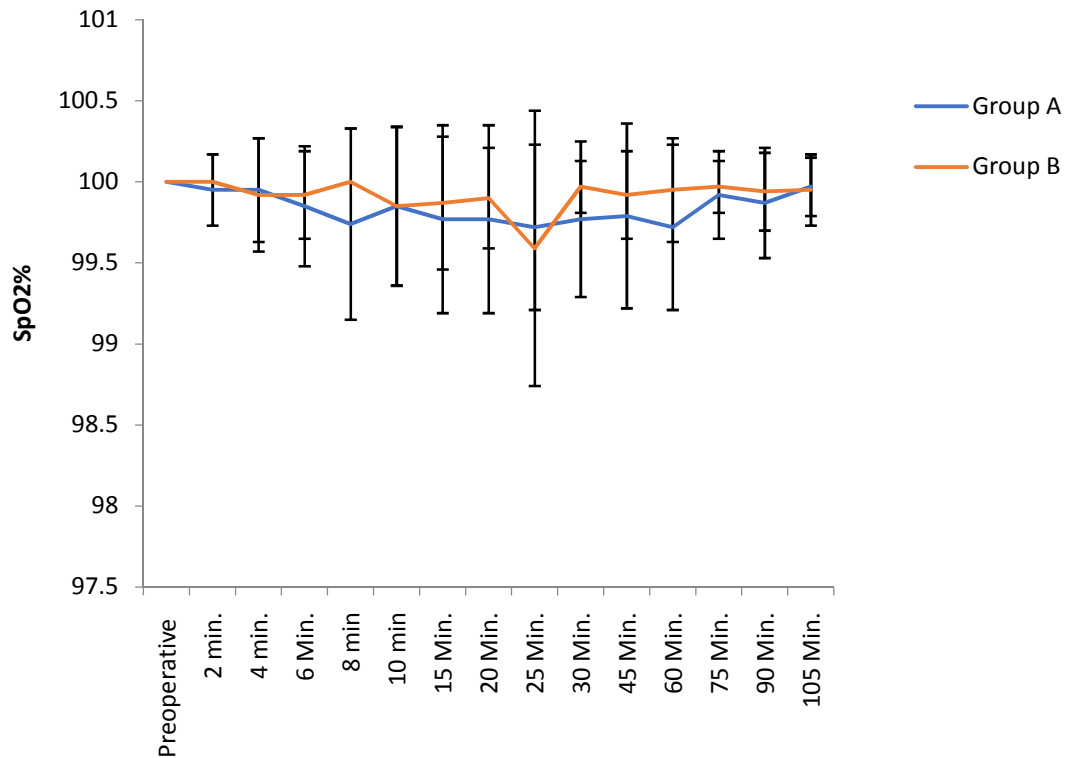
In this study the mean diastolic BP in the pre-operative phase was 80.05 ± 10.15 mm of Hg in group A and 80.31 ± 8.11 mm of Hg in group B and was comparable ($p = 0.902$).

The diastolic BP fell to 69.79 ± 5.73 mm of Hg at 60 minutes and 70.85 ± 8.07 mm of Hg at 75 minutes in group A while it fell to 70.51 ± 5.50 mm of Hg at 60 minutes and 73.05 ± 3.93 mm of Hg at 105 minutes in group B.

TABLE 10: COMPARISON OF SpO₂ AT DIFFERENT TIME INTERVALS (%)

SpO₂%	Group A	Group B	Total	P value
Preoperative	100.00±0.00	100.00±0.00	100.00±0.00	-
2 min.	99.95±0.22	100.00±0.00	99.97±0.16	0.156
4 min.	99.95±0.32	99.92±0.35	99.94±0.34	0.738
6 Min.	99.85±0.37	99.92±0.27	99.88±0.32	0.294
8 min	99.74±0.59	100.00±0.00	99.87±0.44	0.009**
10 min	99.85±0.49	99.85±0.49	99.85±0.49	1.000
15 Min.	99.77±0.58	99.87±0.41	99.82±0.50	0.371
20 Min.	99.77±0.58	99.9±0.31	99.83±0.47	0.228
25 Min.	99.72±0.51	99.59±0.85	99.65±0.70	0.422
30 Min.	99.77±0.48	99.97±0.16	99.87±0.37	0.014*
45 Min.	99.79±0.57	99.92±0.27	99.86±0.45	0.208
60 Min.	99.72±0.51	99.95±0.32	99.83±0.44	0.019*
75 Min.	99.92±0.27	99.97±0.16	99.95±0.22	0.337
90 Min.	99.87±0.34	99.94±0.24	99.90±0.30	0.342
105 Min.	99.97±0.18	99.95±0.22	99.96±0.19	0.783

GRAPH 9: COMPARISON OF SpO₂ AT DIFFERENT TIME INTERVALS (%)



In this study the SpO₂ in the pre-operative phase was 100 ± 0 % in both group A and group B and was thus identical.

The SpO₂ was comparable in both groups throughout the study period.

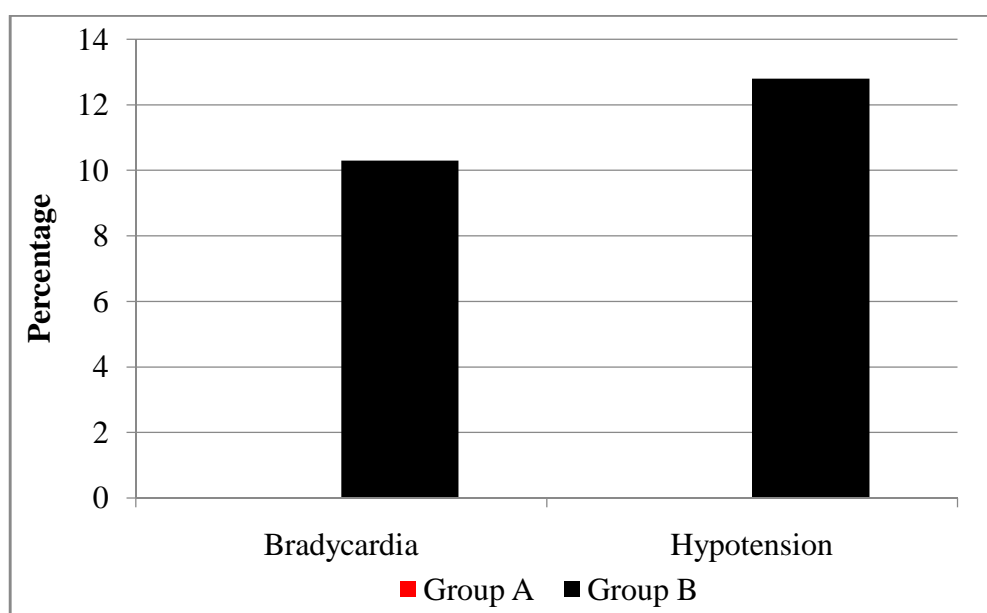
TABLE 11: COMPARISON OF COMPLICATIONS AND SIDE EFFECTS

OBSERVED

	Group A	Percentage	Group B	Percentage
Hypotension	-	-	5	12.8
Nausea and vomiting	-	-	-	-
Bradycardia	-	-	4	10.3

GRAPH 10: COMPARISON OF COMPLICATIONS AND SIDE EFFECTS

OBSERVED



In the present study, 10.3% of patients developed bradycardia and 12.8% patients developed hypotension in group B.

None of the patients in either group developed Nausea and vomiting or respiratory depression.

DISCUSSION

Regional anaesthesia is the choice of anaesthesia for most infraumbilical surgeries performed today worldwide, out of which perianal surgeries account for most of the infraumbilical surgeries being performed. These surgeries are mostly short duration surgeries and are being performed on an outpatient basis these days.^{23,28}

Spinal anaesthesia in outpatient surgeries increases patient choice and also provides post-operative analgesia. Hence, there is an urgent need of a short acting local anaesthetic for ambulatory spinal anaesthesia⁴. It has numerous potentially beneficial factors both clinically and economically. The main drawback is the prolonged motor block causing delayed ambulation and discharge.

In a study conducted by Camponovo et al²⁶ in December 2014, compared general anaesthesia and spinal anaesthesia in patients undergoing ultra-short outpatient procedures such as knee arthroscopy, they concluded that there was a clinically significant reduction in terms of discharge time, the cost of materials and manpower involved in patients care when spinal anaesthesia was used, proper selection of local anaesthetic makes spinal anaesthesia a suitable anaesthetic technique for surgeries requiring short duration.

Many local anaesthetics have been used for short duration surgeries performed under spinal anaesthesia. Lidocaine was being used for ambulatory surgeries initially⁹. Its usage has been stopped due to the high incidence of transient neurological symptoms^{17,9}. Bupivacaine is a common local anaesthetic being used in spinal anaesthesia, but due to its longer duration of action its role as the drug for day care

surgeries have been limited^{14,29}. Hence, we are in search of an ideal local anaesthetic for shorter duration of surgeries.

A study conducted by Camponovo et al²⁵ in May 2014 comparing 50mg of preservative free 1% chloroprocaine with 10mg of plain 0.5% bupivacaine in outpatients undergoing lower abdominal and lower limb procedures. The authors found that the onset time was almost the same between both the groups. The offset was found to be shorter in the group receiving chloroprocaine spinal anaesthesia.

In our study, it was found that time of sensory blockade was faster in group B than in group A. The mean duration of sensory blockade was shorter in group B than in group A and was found to be statistically significant.

The mean onset of motor block was faster in group B than in group A and the mean duration of motor block was shorter in group B than in group A. It was found to be statistically significant.

With the increasing popularity of ambulatory spinal anaesthesia chloroprocaine appears to be an ideal local anaesthetic.

In a study done by Yoos JR et al¹⁹ in February 2005, eight healthy volunteers were involved in this study. One group received 40mg of chloroprocaine while the other group received 7.5mg of bupivacaine. The peak block height, regression to L1 and tourniquet tolerance were assessed and did not differ between the two drugs. The time to simulated discharge including complete block regression, ambulation and spontaneous voiding was found to be higher with bupivacaine and statistically significant.

In another study done by An Temkens et al²¹ in 2016, ninety nine patients undergoing knee arthroscopy in an outpatient setting were included in this double blind randomised controlled trial. Patients were divided into three groups. Each group received 40mg 2- chloroprocaine, 40mg lidocaine or 5mg bupivacaine. The complete recovery of sensory block was the primary objective and the chloroprocaine group had a significantly shorter in the chloroprocaine group.

Casati et al²² conducted a double blind randomised controlled trial in 2007, comparing lignocaine and preservative free chloroprocaine. Thirty ASA I-II patients undergoing knee arthroscopy was randomly divided to receive 50mg of either 1% plain lignocaine or 1% preservative free plain chloroprocaine. The median time for recovery of sensory, motor and unassisted ambulation and voiding were assessed. Patients who received chloroprocaine had a shorter sensory and motor duration of action. Earlier ambulation and voiding were observed in patients who received chloroprocaine. Looking at the above evidence and to evaluate whether chloroprocaine can be used in day care surgeries we compared it to bupivacaine in our study.

The major factors of spread of intrathecal administered solutions are their dose, volume, concentrations and baricity.

The dose, volume and concentrations of an anaesthetic agent are inter related as dose is a product of volume and the concentration³⁰.

In our study, we used two solutions of different dosage with the same baricity for outpatient perianal surgeries and compared their effect in an attempt to

recommend an ideal solution for short duration surgery, allowing the patient to be discharged on the same day.

Many doses of chlorprocaine have been used for ambulatory surgery in previous studies. In a study done by Ghisi D et al² in 2015, a review was done on using chlorprocaine for ambulatory surgery. Three doses of chlorprocaine being 30mg, 40mg and 50mg was compared in forty-five patients posted for elective lower limb procedures. 33% of patients in the 30mg group required intraoperative analgesic supplementation as a result of inadequate analgesia. It was found that dose ranging between 30-60 mg of chlorprocaine was adequate for short duration surgeries.

In the present study 40mg of chlorprocaine was compared with 30mg of bupivacaine for short duration surgeries. The mean sensory onset in patient receiving chlorprocaine was 3.59 \pm 0.94 minutes and was found to be statistically significant. The mean sensory block duration in the same group was 66.28 \pm 4.78 minutes and was significant.

The motor blockade onset was lesser than five minutes in 33.3% patients having a mean of 4.82 \pm 0.79 minutes. All patients who received 40mg of chlorprocaine had a motor blockade lasting from 70-120 minutes with a mean of 78 \pm 4.81 minutes.

We found the mean peak block height was T7 and it did not ascend upwards.

These findings were similar to a previous study done by Gebhard V et al²³ in 2014. The aim of this study was to determine the optimal dose of chlorprocaine for patients undergoing perianal surgeries. One hundred and twenty patients were included in this study. They were randomly divided to receive 10mg, 20mg and 30mg

chloroprocaineintrathecally. It was found that 10mg of chloroprocaine can be successfully used for low dose spinal anaesthesia in perianal surgeries. The occurrence of a profound clinically relevant motor block was higher with 30mg of the drug.

The hemodynamic parameters including heart rate, systolic blood pressure and diastolic blood pressure was comparable and was not statistically significant.

Four patients receiving 1% 2 chloroprocaine were given injection atropine to counteract the bradycardia and no patients had severe bradycardia in patients receiving 0.5% bupivacaine. Five patients were administered injection mephentermineintraoperatively who received 1% 2-chloroprocaine.

A retrospective study was conducted using 1% 2- chloroprocaine and general anaesthesia for ultra short outpatient procedures undergoing knee arthroscopy by Camponovo et al²⁶. There was a significant reduction in terms of discharge time and cost of materials and employers involved in patient care when 1% 2-chloroprocaine was used. Proper local anaesthetic selection makes spinal anaesthesia an appropriate anaesthetic technique for short ambulatory procedures¹².

In a study done by H.Vaghadin et al²⁴ in April 2007 compared intrathecal use of lignocaine and chloroprocaine in combination with fentanyl to provide selective spinal anaesthesia for patients undergoing Transurethral resection of prostate(TURP). A double blinded randomised study including forty patients with ASA I-III outpatient undergoing TURP were enrolled. Group I- received 40mg of chloroprocaine mixed with 12.5micrograms fentanyl and group- II received 35mg lignocaine with 12.5 micrograms fentanyl. The median time for onset and maximal level was measured and

was found to be comparable. The duration of block was measured and was found to be shorter in the chloroprocaine group.

There has been an increasing trend in ambulatory surgeries worldwide. Regional anaesthesia has provided benefits of quick onset, good relaxation with sensory as well as motor blockade. Hence, we are in search of an ideal local anaesthetic that would provide early ambulation with no side effects.

CONCLUSION

Our study showed that isobaric 1% 2- chloroprocaine is an ideal drug for ambulatory surgery than 0.5% isobaric bupivacaine in terms of onset and duration of sensory and motor blockade in patients undergoing perianal surgeries under spinal anaesthesia.

The hemodynamic parameters including heart rate, systolic blood pressure and diastolic blood pressure was comparable in both groups.

Intrathecal isobaric 1% 2- chloroprocaine is associated with shorter duration of both sensory and motor blockade thereby enabling quicker recovery from anaesthesia and allowing early ambulation and discharge.

SUMMARY

This one year randomised controlled trial was conducted in the department of anaesthesiology, KLEs Dr Prabhakar Kore hospital and medical research centre, Belagavi during the period of January 2018 to December 2018. A total of 78 patients undergoing perianal surgeries under spinal anaesthesia were allocated into two groups namely, Group A (n=38, patients received 3.0 ml of 0.5% isobaric bupivacaine) and Group B(n =38, patients received 4ml of 1% isobaric 2- chloroprocaine). Sensory and motor block characteristics like onset and duration were studied. Hemodynamic parameters like heart rate, blood pressure and oxygen saturation were monitored continuously.

Demographic parameters were comparable in both the groups. In this study, onset of sensory block was significantly faster in group B (3.59+/-0.94 minutes) than in group A (5.41+/-1.16 minutes). Duration of sensory block was significantly shorter in group B (78.00+/-4.81minutes) than in group A (171.31+/-4.48 minutes). Onset of motor block was significantly faster in group B (4.82+/-0.79 minutes) than in group A (7.72+/-0.89 minutes). Duration of motor block was significantly shorter in group B (66.28+/-4.78 minutes) than in group A (128.54+/-3.75 minutes).

The hemodynamic parameters being heart rate, systolic blood pressure, diastolic blood pressure and oxygen saturation were found to be comparable in both the groups.

Overall, based on the findings of this study, it may be concluded that intrathecal isobaric chloroprocaine is associated with shorter duration of both sensory and motor blockade, thereby enabling quicker recovery from anaesthesia, early

ambulation and early discharge making it an ideal local anaesthetic for ambulatory surgeries.

It is recommended that still there is further scope for analysis with better statistical evaluation owing to the small sample size to evaluate a local anaesthetic for ambulatory regional anaesthesia.

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ANNEXURE I: CONSENT FORM

CONSENT FOR PARTICIPATION IN RESEARCH STUDY

Mr/Mrs/Miss. _____ we are requesting you to enrol in study titled “**A COMPARATIVE EVALUATION BETWEEN ISOBARIC BUPIVACAINE AND ISOBARIC 1% 2-CHLOROPROCAINE FOR SPINAL ANAESTHESIA IN PERIANAL SURGERIES**”- **A ONE YEAR HOSPITAL BASED RANDOMISED CONTROLLED TRIAL** conducted by Dr. Post Graduate in M.D. Anaesthesiology under the guidance of Dr. _____, Professor, Department of Anaesthesiology, J.N. Medical College, Belagavi under KAHER, Belagavi.

Respected Sir/Madam, we request you to kindly enroll in this study. During the study you will be asked some questions regarding your present complaint and you are supposed to answer to the best of your knowledge.

Your participation in this research is voluntary. Your decision whether or not to participate in the study will not affect your relationship with J.N. Medical College. If you decide not to participate you are free to withdraw at any time.

Purpose of the study:

The purpose of this study is to compare onset and duration of sensory and motor blockade between intrathecal 0.5% isobaric bupivacaine and 1% 2-chloroprocaine for perianal surgeries.

Procedure Involved:

If you agree to enroll in my study, I will ask you your present and past medical history. You will be clinically examined in detail and routine investigations like Hb, Platelet Count, will be done accordingly. You will be allotted into one of the two

groups randomly using a computer-generated software. One group will receive isobaric 1% 2-chloroprocaine and another group will receive isobaric 0.5% bupivacaine.

Benefits and risks:

The benefits of taking part in this research are that we can avoid GA with good quality of analgesia and early ambulation. The risks are minimal which include hypotension, bradycardia, headache, backache. There are no observable risks associated with the study.

Voluntary Participation/Withdrawal:

Taking part in the study is voluntary. You may choose not to enrol in this study. Your decision will not change present or future health care services offered to you at K.L.E. hospital.

Alternatives:

Even if you decline the participation in the study, you will get the routine line of management.

Privacy and Confidentiality:

The only people to know that you are a research subject are members of the research team. No information about you or information provided by you during the research will be disclosed to other without your written permission except:

1. In emergency to protect your rights and welfare.
2. If required by law.

Authorization to Publish Results:

When the results of the research are published or discussed, in a conference, no information will be displayed that would disclose your identity. Any information

that is obtained in connection with this study and that can be identified with your identity remaining confidential.

Financial Incentives for participation:

No financial incentives are being offered to enrolled patients. It is purely being done with the idea of research and all the cost of the study will be borne by the investigator.

Compensation:

In the event of injury related to the study, treatment will be made available through KLES' Hospital & MRC, Belagavi. There is no compensation or payment for such medical treatment by law.

Questions:

In case you have any questions related to the study, in future or in case of study related injury or illness, you can contact Dr. _____ HK, Department of Anaesthesiology, KLES Hospital and MRC, Belagavi, phone number: Or Dr.

_____, Professor, Dept. Of Anaesthesiology, KLES Hospital and MRC, Belagavi.

If you have any queries about your rights as a study subject, you may call Dr. RoopaBellad, Professor, Department of Pediatrics, J.N. Medical College Institutional Ethical Committee for Human Subjects Research, Phone number- or extension 4052 at J.N. Medical College, Belagavi.

Consent for participation in research trial. "A COMPARATIVE EVALUATION BETWEEN ISOBARIC BUPIVACAINE AND ISOBARIC 1% 2-

CHLOROPROCAINE FOR SPINAL ANAESTHESIA IN PERIANAL SURGERIES"-A ONE YEAR HOSPITAL BASED RANDOMISED CONTROLLED TRIAL.

I, Mr/Ms/Mrs _____ voluntarily agree for the participation of myself as a subject of study. By signing this consent form, I am not giving up any of my legal rights, I may withdraw from the study anytime. I am signing the consent form after having read or been read for me in vernacular language, including the risks and the benefits and having all my questions answered.

Subject Name : _____

Legally authorised relative: _____

Signature or the Left Thumb Print of parent/ legally authorised relative:

Date:

Witness Name : _____

Signature: _____

Date:

Investigators Name: _____

Signature: _____

Date : _____

Place: _____

ETHICAL CLEARANCE CERTIFICATE



K.L.E.UNIVERSITY'S
JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)
(Accredited 'A' Grade by NAAC)

Website: <http://www.jnmc.edu>
E-Mail : dome@jnmc.edu

Phone: (+ 91-(0)831 Office : 2471350
Principal: 2471701
Fax No. +91 (0)831 – 2470759

Ref: MDC/DOME/19

Date: 22/11/2017

To,

PG student in Anaesthesiology,
J.N.Medical College,
BELAGAVI.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled “**A COMPARATIVE EVALUATION BETWEEN BUPIVACAINE AND 2 – CHLOROPROCAINE FOR SPINAL ANAESTHESIA IN PERIANAL SURGERIES – A ONE YEAR HOSPITAL BASED RANDOMISED CONTROL STUDY**”, is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

(Dr. Arathi Darshan)
Member Secretary

JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

(Dr. Roopa M Bellad)
Chairman,

JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

ANNEXURE III – PROFORMA

“A COMPARATIVE EVALUATION BETWEEN ISOBARIC BUPIVACAINE AND ISOBARIC 1% 2-CHLOROPROCAINE FOR SPINAL ANAESTHESIA IN PERIANAL SURGERIES”- A ONE YEAR HOSPITAL BASED RANDOMISED CONTROLLED TRIAL.

Name & Address of the patient:

Age of the Patient: _____ IP. No. _____

Weight of Patient: _____ Height of patient: _____

Sex: _____ occupation: _____

Anaesthesiologist: _____ Surgeon: _____

PREANAESTHETIC EVALUATION:

Chief Complaints:

Past History:

- History of Diabetes Mellitus/Hypertension/Asthma/Tuberculosis
- Drug Therapy:
- Previous Anaesthetic procedure/Previous surgeries:
- History of renal disease, hepatic disease and neurological diseases.

Family History

General Physical Examination:

Weight: Temperature: Height: pallor: icterus:

Cyanosis: Pedal Oedema: Clubbing:

Pulse : B.P: RR:

Airway Assessment:

Mouth Opening: Teeth:

Jaw Movements: MP Grading:

SYSTEMIC EXAMINATION:

Cardiovascular System:

Respiratory System:

Per Abdomen:

Central Nervous system:

Spine assessment:

INVESTIGATIONS:

Methodology:

- After obtaining the approval of ethical committee and written informed consent, a total of patients undergoing elective perianal surgeries of minimum duration of 60minutes under spinal anaesthesia will be included in this study.

Patients will be randomly divided into two groups by using computed generated table.

- Group A
- Group B

A thorough Pre- Anaesthetic Evaluation will be done. Detailed medical and personal history will be obtained. A detailed physical examination will be done. Patients will be advised overnight fasting. Routine investigations such as complete blood count, Random blood sugar, Serum creatinine, blood grouping and typing, Chest X-ray, Electrocardiography will be carried out.

In the preoperative holding area, a wide bore i.v. access will be secured and patients will be preloaded with ringer lactate 10ml/kg half an hour before induction of anaesthesia. Anaesthetic techniques will be standardised for all patients.

Inside the operation theatre, the patient will be shifted onto the operating table. Standard non-invasive monitors will be attached and baseline heart rate, BP, SpO₂ will be recorded.

Under strict aseptic precautions the following procedure will be carried out.

Monitors such as pulse oximeter, ECG, non-invasive BP are connected. Patient will be then made to sit holding a pillow, under strict aseptic precautions, L3-L4 space will be identified. 2ml of 2% lignocaine will be injected in L3- L4 space.

GROUP A: Using 23G Quincke spinal needle, 3ml of 0.5% isobaric bupivacaine will be injected in L3- L4 subarachnoid space after confirming free flow of CSF.

GROUP B: Using 23G Quincke spinal needle 4ml of 1% isobaric 2- chloroprocaine will be injected in L3- L4 subarachnoid space after confirming free flow of CSF.

Patient will then be immediately placed in supine position. Intraoperative and postoperative assessments will be performed.

The following parameters will be monitored/ measured:

- A) **Sensory blockade** will be assessed by pin prick in mid axillary line every minute till T10 block occurs, following which it will be assessed at 10-minute intervals for next one hour.

Time taken for sensory blockade till T10 dermatome, highest sensory dermatome blocked, time for regression to 2 dermatomes from highest dermatome reached and time for regression to S2 would be recorded.

Surgery would be allowed to start once T10 dermatome has been blocked but GA will be induced if this does not happen in 30minutes. Such cases will be labelled as block failure and excluded from final analysis.

- B) **Motor blockade** will be assessed immediately after sensory block assessment using a Modified Bromage scale.

Bromage 0: free movement of legs and with ability to raise extended leg.

Bromage 1: inability to raise extended leg and knee flexion is decreased, but full flexion of ankle and feet is present.

Bromage 2: inability to raise leg or flex knees, flexion of ankle and feet present.

Bromage 3: inability to raise leg, flex knee or ankle or move toes.

Motor block onset will be taken as the time to reach modified Bromage score 3 and total duration of motor block will be taken as the time for return to modified Bromage score 0.

In case patient doesn't attain Bromage score of 3, the highest score attained would be documented.

- C) **Post-operative analgesia:** following surgery patient will not be put on regular analgesics.

Time for first rescue will be noted and will be treated with Inj. Diclofenac 75mg added to normal saline.

D) HR, BP and SpO₂ will be monitored throughout the surgery.

Hypotension will be defined as decrease in systolic BP by 20% from baseline values or a systolic less than 90mm of Hg and will be treated with incremental intravenous boluses of mephentermin 5 to 10mg and a bolus administration of 250ml of Ringer Lactate solution over 10mins.

Bradycardia will be defined as decrease in heart rate less than 50 beats per minute and will be treated with intravenous Atropine 0.6mg.

Supplementary oxygen will be given through face mask.

Observations:

Readings will be recorded in the following manner:

SENSORY BLOCK:

a) Onset at T ₁₀ (mins)	
b) Duration (mins)	
c) Level of sensory block	

MOTOR BLOCK:

a) Onset (mins)	
b) Total duration of motor block	

HEMODYNAMIC PARAMETERS

<u>TIME</u>	<u>HR</u>	<u>BLOOD PRESSURE</u>			<u>SP02</u>
		<u>SBP</u>	<u>DBP</u>	<u>MAP</u>	

SIDE EFFECTS:

ANNEXURE IV: PHOTOGRAPHS

Photograph 1: 0.5% Isobaric bupivacaine ampoule



Photograph 2: Isobaric 1% 2-chloroprocaine ampoule



Photograph 4: Spinal tray



Photograph 5: Procedure of spinal anaesthesia



Photograph6 : Monitoring during surgery



ANNEXURE-V

KEY TO MASTER CHART

ASA	-	American Society of Anaesthesiologists
F	-	Female
HR	-	Heart Rate (bpm)
SBP	-	Systolic Blood Pressure (mm Hg)
DBP	-	Diastolic Blood Pressure (mm Hg)
SpO ₂	-	Saturation of peripheral oxygen (%)
T	-	Thoracic sensory dermatomal level
mg.	-	Milligrams
min.	-	Minutes
kgs.	-	Kilograms
cms.	-	Centimeters

