



COMPARATIVE STUDY OF INTRATHECAL TRAMADOL WITH BUPIVACAINE & INTRATHECAL BUPIVACAINE PLAIN ON PREVENTION OF PERI-OPERATIVE SHIVERING IN INFRA UMBILICAL SURGERIES

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ABSTRACT

Introduction: Peri-operative shivering cause patient discomfort because of severe muscle movement and it also induces elevated blood pressure and tachycardia. This eventually leads to increased oxygen consumption, increased carbon dioxide synthesis that results in an increased ventilator work and cardiac workload and an increase in the metabolic rate by up to 400%. It increases the metabolic rate and oxygen consumption up to 100-600%.

Aims and Objectives: The aim of the study was to Comparative study of intrathecal tramadol (10mg & 20mg) with bupivacaine & intrathecal bupivacaine plain on prevention of peri-operative shivering in infra umbilical surgeries.

Methods: This descriptive cross-sectional study was carried out at the Department of Anaesthesiology, Pacific Institute of Medical Sciences, Umarda, Udaipur. Prospective, comparative double blinded randomized design. The calculated sample size was 30 subjects for each of three groups at α error 0.5 and power 80%, assuming difference in mean to be detected 0.5 μ g.

Result: The mean BMI of patients in group A, B and C was 21.607 ± 3.91 , 23.204 ± 3.53 and 21.652 ± 3.21 Kg/m² respectively. Majority of patients (70%) of group C had ASA grade I. There were equal number of patients belonging to ASA grade I and II. The study observed that PR at 240 min was 76.73 ± 7.59 , 81.1 ± 6.3 , and 74.00 ± 4.02 respectively.

Conclusion: In conclusion, the study found that the longest onset of sensory block was in the group that received Hyperbaric 0.5% Bupivacaine 3.0ml and 0.5ml normal saline, while the shortest onset of motor block was in the group that received Hyperbaric 0.5% Bupivacaine 3.0 ml and tramadol 20 mg (0.4 ml). The shortest duration of motor block was found in the group that received Hyperbaric 0.5% Bupivacaine 3.0ml and 0.5ml normal saline.

Keywords: peri-operative, Shivering, Bupivacaine, Intrathecal bupivacaine plain, Hyperbaric

1. INTRODUCTION

Regional anaesthesia is a safe and popular anaesthetic technique for various surgeries. Ease of administration, relatively few contraindications and good relaxation makes it preferred method of anaesthesia for infra umbilical surgeries.

Around 40-60% of patients under regional anaesthesia develop shivering¹. Shivering is a common problem faced during intra-operative and post-operative period. In regional anaesthesia shivering is seen in both peri-operative and post-operative period whereas in general anaesthesia it is seen in post operative period.

Peri-operative shivering cause patient discomfort because of severe muscle movement and it also induces elevated blood pressure and tachycardia². This eventually leads to increased oxygen consumption, increased carbon dioxide synthesis that results in an increased ventilator work and cardiac workload and an increase in the metabolic rate by up to 400%². It increases the metabolic rate and oxygen consumption up to 100-600%. It can induce arterial hypoxemia and acidosis. It increases intraocular pressure and intracranial tension. It causes stretch on suture lines. It interferes with monitoring like ECG, pulse oximetry, non invasive blood pressure measurement & also distracts the operating surgeon. It can be detrimental to patients with low cardio respiratory reserve¹.

Many physical and pharmacological interventions are used to decrease the incidence and to reduce the severity of peri-operative shivering. Non pharmacological methods like warming² the intravenous fluids, warm waterbeds, warm covers which use specialised equipments are not practical in all clinical settings³ & not always available in small surgical centres.

Many pharmacological agents like Pethidine, Clonidine, Magnesium Sulphate, Amytryptiline, Urapidil, Dolasetron, Doxapram are used to control shivering. These drugs have side effects like respiratory depression, bradycardia, hypotension etc³.

Among the pharmacological interventions, Tramadol, which belong to Opioids was found effective in many studies. Tramadol has been used as an analgesic for labor pain without adversely affecting mother or the newborn. With pharmacodynamic advantage of causing less side effects, Tramadol has the potential for use in controlling shivering and hence is emerging as a new and safe drug to be used for prevention & treatment of post anaesthetic shivering⁴.

Post anaesthesia shivering is a common complication following subarachnoid block (SAB); reported incidence varying from 40% to 70%.⁵ It can be defined as spontaneous, involuntary and oscillatory fasciculations, or tremor - like hyperactivity of the skeletal muscles.⁶ Shivering induced severe muscle movements and an awake state during the SAB makes it distressing both for the patient and the surgeon. It increases metabolic rate, oxygen consumption, carbon dioxide production, heart rate (HR), and blood pressure.^{5,6} These by increasing cardiac workload may prove deleterious, particularly in patients with limited cardiac reserves. It may increase wound pain, delay wound healing, and hospital discharge. Shivering also interferes with the perioperative vital monitoring and increases intraocular and intracranial pressures.⁵ The abovementioned sequelae coupled with the high incidence of post anaesthesia shivering makes its prophylaxis imperative. Prophylaxis with intravenous (IV) tramadol has been demonstrated to produce a dose-dependent reduction in the incidence of post anaesthesia shivering.^{7,8} The routine administration of pharmacological shivering prophylaxis has however been questioned.⁸ Tramadol is a commonly employed intrathecal (IT) adjuvant owing to its low cost, easy availability and its ability to prolong the duration of sensory block, motor block, and postoperative analgesia.^{9,10} A few studies have also shown IT tramadol to have anti shivering efficacy.^{6,10} Administration of a single IT adjuvant like tramadol with multipronged benefits would obviate the need of administering additional systemic drugs either for prophylaxis or treatment of pain and shivering; hence avoiding the associated side-effects. The literature evaluating the anti shivering efficacy of different doses of IT tramadol is however lacking.

This study was designed to compare the efficacy of anti-shivering effect of intrathecal tramadol 10 mg and 20 mg with bupivacaine and intrathecal bupivacaine in peri-operative period in patients undergoing infra umbilical surgeries under spinal anaesthesia and thereby to determine its clinical efficacy and side effects if any.

2. AIMS AND OBJECTIVES

Aim

Comparative study of intrathecal tramadol (10mg & 20mg) with bupivacaine & intrathecal bupivacaine plain on prevention of peri-operative shivering in infra umbilical surgeries.

Objectives

1. To study the efficacy of anti-shivering effect of intrathecal Bupivacaine.
2. To study the efficacy of anti-shivering effect of intrathecal Bupivacaine with Tramadol 10mg.
3. To study the efficacy of anti-shivering effect of intrathecal Bupivacaine with Tramadol 20mg.
4. To compare the efficacy of intrathecal tramadol (10mg & 20mg) with bupivacaine & intrathecal bupivacaine plain on prevention of peri-operative shivering in infra umbilical surgeries.

3. LITERATURE REVIEW

Gupta et al., (2018) conducted Dexamethasone has been used widely in clinical specialties including anaesthesia. It is regarded as one of the ideal perioperative agent being readily available, cheap, anti-inflammatory agent, prevents and treats post-operative nausea and vomiting (PONV), promotes appetite, suppress inflammation, a good analgesic agent both as intravenously or as an adjuvant to peripheral nerve blocks, it provides a sense of well-being and is considered to have a good quality of recovery and early discharge in patients from anaesthesia. Controversial role of dexamethasone in causing post-operative surgical site infections have been solved and overall adverse effects of dexamethasone are rare and its benefits out-weighs the risks involved. The author did a literature search in Google scholar and PubMed databases (latest articles related to the role of dexamethasone in perioperative period over a period of two years 2015-17)¹¹

McKeown et al., (2017) conducted a study to summarise the evidence for use of intravenous magnesium for analgesic effect in caesarean section patients. *Background.* Post caesarean pain requires effective analgesia. Magnesium, an *N*-methyl-D-aspartate receptor antagonist and calcium-channel blocker, has previously been investigated for its analgesic properties. A systematic search was conducted of *PubMed, Scopus, MEDLINE, Cochrane Library, and Google Scholar* databases for randomised-control trials comparing intravenous magnesium to placebo with analgesic outcomes in caesarean patients. Ten trials met inclusion criteria. Seven were qualitatively compared after exclusion of three for unclear bias risk. Four trials were conducted with general anaesthesia, while three utilised neuraxial anaesthesia. Five of seven trials resulted in decreased analgesic requirement postoperatively and four of seven resulted in lower serial visual analogue scale scores. Adjunct analgesic agents are utilised to improve analgesic outcomes and minimise opioid side effects. Preoperative intravenous magnesium may decrease total post caesarean rescue analgesia consumption with few side effects; however, small sample size and heterogeneity of methodology in included trials restricts the ability to draw strong conclusions. Therefore, given the apparent safety and efficacy of magnesium, its role as an adjunct analgesic in caesarean section patients should be further investigated with the most current anaesthetic techniques.¹²

Kurhekar et al., (2016) conducted Intrathecal opioids like morphine added to local anaesthetic agents have been found to be effective in achieving prolonged post-operative analgesia. Intrathecal dexmedetomidine may be devoid of undesirable side effects related to morphine and hence, this study was designed to evaluate analgesic efficacy, haemodynamic stability and adverse effects of both these adjuvants in patients undergoing gynaecological surgeries. This was a prospective, randomised, double blind study involving 25 patients in each group. Group M received 15 mg of 0.5% hyperbaric bupivacaine with 250 µg of morphine while Group D received 15 mg of 0.5% hyperbaric bupivacaine with 2.5 µg of dexmedetomidine. Characteristics of spinal block, time for first rescue analgesic and total dose of rescue analgesics were noted. Vital parameters and adverse effects were noted perioperatively. Data analysis was done with independent two sample t-test and Mann-Whitney U test. Time for first rescue analgesic ($P = 0.056$) and total analgesic demand were similar in both groups. Duration of sensory ($P = 0.001$) and motor ($P = 0.000$) block was significantly higher in dexmedetomidine group. Itching was noticed in 36% and nausea in 52% of patients in the morphine group, either of which was not seen in dexmedetomidine group. Intrathecal dexmedetomidine produces prolonged

motor and sensory blockade without undesirable side effects but intraoperative hypotension was more frequent in dexmedetomidine group.¹³

Sidharth SrabanRoutray et al., (2016) conducted A Comparative Study of the Effects of Intrathecal Tramadol and Intrathecal Fentanyl as adjuvants with 0.5% Bupivacaine Heavy in Lower Limb Surgeries. Patients of ASA status I and II posted for lower limb surgeries were randomly divided into two groups. Group T was administered Hyperbaric Bupivacaine 15 mg + tramadol 25 mg, group F was administered Hyperbaric Bupivacaine 15 mg + Fentanyl 25mcg. He observed that there was no incidence of shivering in both groups¹⁴.

Rakhi et al., (2015) The purpose of this study was to evaluate the effect of intravenous dexmedetomidine 1µg/kg given over 10 minutes before induction of anaesthesia and 0.4mcg/kg/hour as maintenance during the surgery, on haemodynamic stress response resulting from laryngoscopy and endotracheal intubation and the haemodynamic stability during surgery. Seventy patients scheduled for elective surgery were randomized into two groups each having thirty five patients-dexmedetomidine group (Group 1) and control group (Group 2). Heart rate, systolic blood pressure, and diastolic blood pressure were recorded at just before intubation, immediately after intubation, 1, 2, 3, 4, 5 minutes after intubation followed by every 5 minutes till the first 45 minutes of surgery. Anaesthesia was induced with inj.Propofol 2mg/kg IV followed by succinyl choline 2mg/kg for endotracheal intubation. Anaesthesia was maintained with oxygen, nitrous oxide, isoflurane, atracurium. Any further need for analgesia was supplemented by IV fentanyl. The data was analysed by SPSS 16.0 with independent t-test. Intravenous dexmedetomidine significantly attenuates sympathoadrenal response to laryngoscopy and endotracheal intubation and also cause reduction in intra operative anaesthetic requirement, without affecting intraoperative cardiovascular stability.¹⁵

4. MATERIALS AND METHODS

Materials

Drugs and Equipment

1. Quincke's spinal needle 25 gauge
2. Injection tramadol hydrochloride 50 mg/ml
3. Injection 0.5% hyperbaric bupivacaine
4. Injection atropine 0.6 mg/ml
5. Injection mephentermine 30 mg/ml

Study Location

The study was conducted in the Department of Anaesthesiology, Pacific Institute of Medical Sciences, Umarda, Udaipur.

Study Design

Prospective, comparative double blinded randomized design.

Sample Size

The calculated sample size was 30 subjects for each of three groups at α error 0.5 and power 80%, assuming difference in mean to be detected 0.5 with SD 0.8 as per seed article, so for study a sample size of 30 patients was taken for each group.

Randomization

The patients were randomly assigned into three groups including 30 patients in each group, using "closed envelope method".

Group C (n=30) – Hyperbaric 0.5% Bupivacaine 3.0ml + 0.5ml normal saline.

Group T1 (n=30) – Hyperbaric 0.5% Bupivacaine 3.0ml + tramadol 10 mg (0.2 ml of preservative free injection tramadol hydrochloride 50 mg/ ml).

Group T2 (n = 30) – Hyperbaric 0.5% Bupivacaine 3.0 ml + tramadol 20 mg (0.4 ml)

The total volume was made 3.5 ml by adding appropriate volume of normal saline and given intrathecally.

Inclusion Criteria:

Patients of either sex posted for elective infra umbilical surgeries under spinal anaesthesia
Patients who had given written informed consent
Age group between 20-60 years
ASA grade I and II.

Exclusion Criteria:

Patient's refusal
Emergency surgeries
ASA grade III and IV
Severe anaemia
Coagulopathy and patients on anti coagulant therapy
Patients with previous history of surgeries on spine
Patients with spinal deformity
Patients with history of chronic backache
Patients with active skin lesions over the lumbosacral area .

Modified Crossely and Mahajan scale

Grade 0 - No shivering

Grade 1 - Mild - Muscular activity involving only one muscle group.

Grade 2 - Moderate - Muscular activity involving two or more than two muscle groups but not involving whole body.

Grade 3 - Severe - Shivering involving entire body.

Modified Bromage Scale

Grade I – Free movement of legs and feet

Grade II – Just able to flex knees with free movement of feet

Grade III – Unable to flex knees, but with free movement of feet

Grade IV – Unable to move legs or feet

ASA Physical Status Classification (December 2020)

- ASA 1- Healthy patients.
- ASA 2- Mild to moderate systemic disease caused by the surgical condition or by other pathological processes and medically well controlled.
- ASA 3- Severe disease process which limits activity but is not incapacitating.
- ASA 4- Severe incapacitating disease process that is constant threat to life.
- ASA 5- Moribund patient not expected to survive 24 hours with or without an operation.
- ASA 6- Declared brain-dead patient whose organs are being removed for donor purposes.

Method

One day prior to the surgery, a comprehensive pre-anaesthetic evaluation was carried out, including airway assessment, review of the patient's medical history, general and systemic examination, routine biochemical tests, chest X-ray, and electrocardiography. The patients were informed about the procedure of spinal anaesthesia and written consent was obtained. All patients were kept nil per oral overnight and were pre-medicated with oral alprazolam 0.25 mg the night before surgery.

5. RESULTS

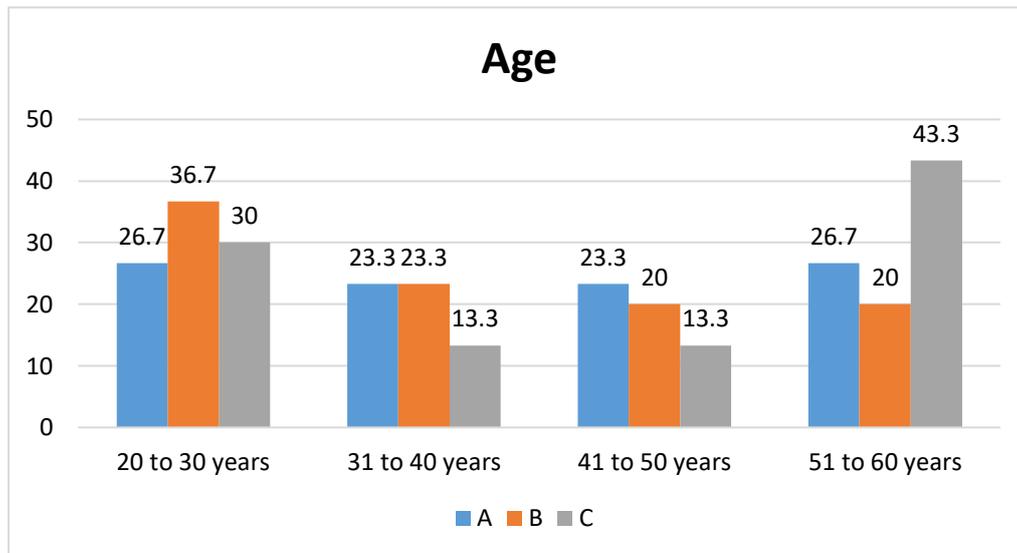


Figure 5.1 Age

From the above graph it was observed that majority of patients of group A and B belongs to 20-30 years age group (26.7% and 36.7%). The study also observed that in group C there was a majority of patients (43.3%) belonging to 51-60 years followed by 30% patients of age group 20-30 years.

From the above graph it was observed that the mean age of patients in group A, B and C was 39.5333 ± 13.68 , 35.6333 ± 13.12 and 42.100 ± 13.99 years respectively.

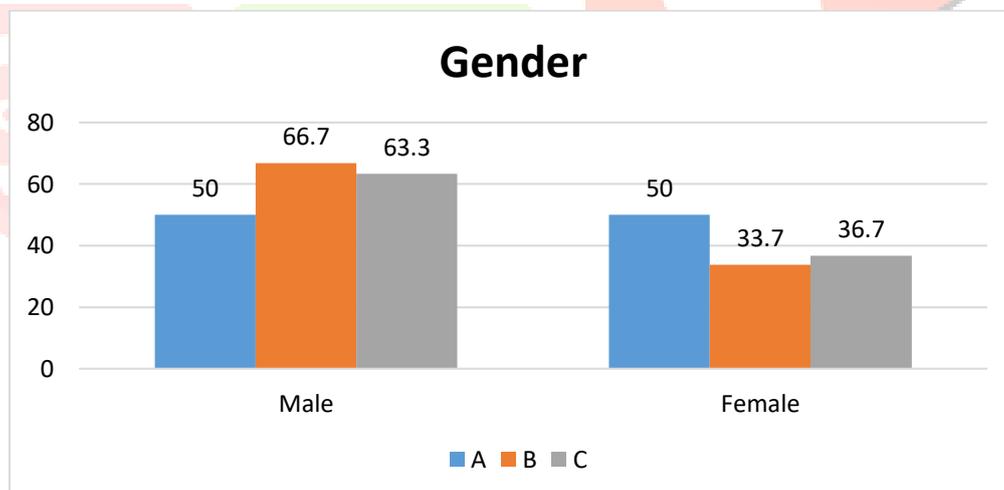


Figure 5.2 Gender

From the above graph it was observed that each group has 30 subjects. There was a majority of male patients in group B (male = 20) and C (male = 19) while there were equal number of male and female patients in group A (each 15).

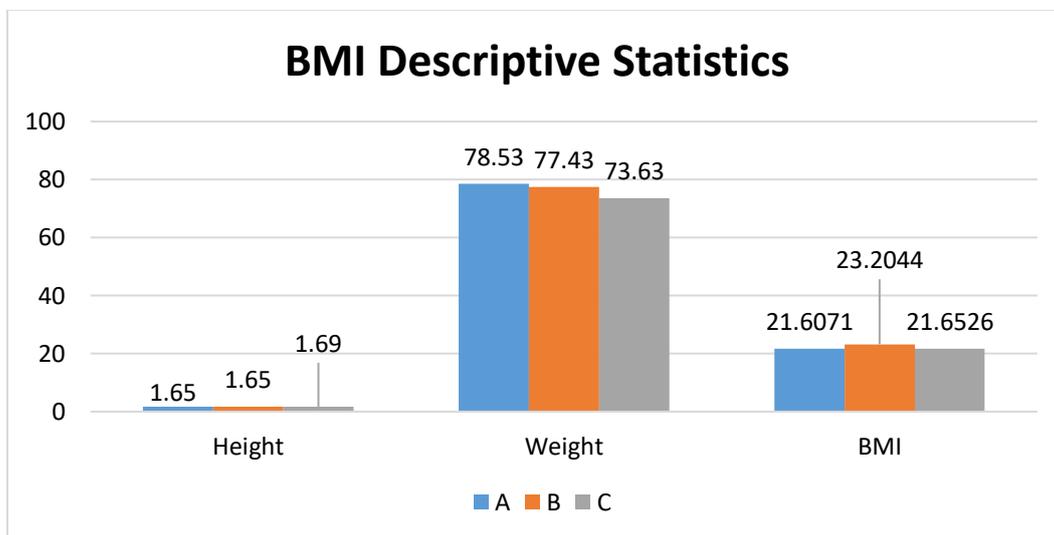


Figure 5.3 BMI Descriptive Statistics

From the above graph it was observed that the mean BMI of patients in group A, B and C was 21.607 ± 3.91 , 23.204 ± 3.53 and 21.652 ± 3.21 Kg/m² respectively.

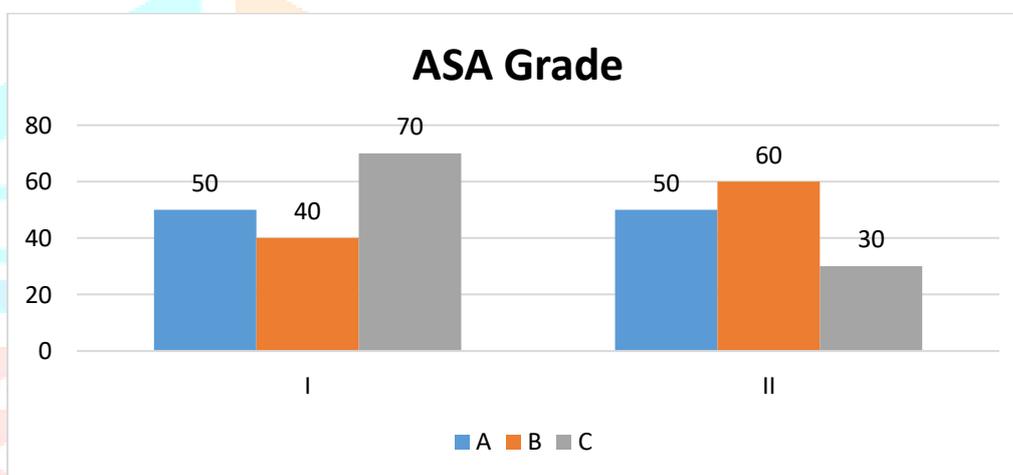


Figure 5.4 ASA Grade

From the above graph it was observed that majority of patients (60%) of group B had ASA grade II while majority of patients (70%) of group C had ASA grade I. There were equal number of patients belonging to ASA grade I and II.

Hemodynamic Parameters

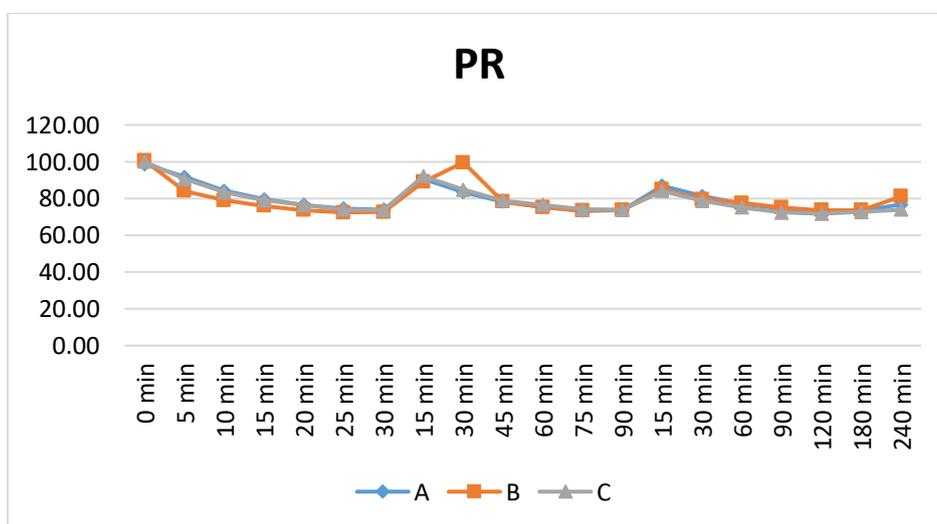


Figure 5.5 PR

The above graph present the monitoring of pulse rate every 5 mins for first 30 mins after giving spinal anaesthesia. From the above table and graph it was observed that the pulse rate was on its peak at the baseline (during first 5 minutes) but after this the pulse rate was kept decreasing with time. The pulse rate at 5 min was 91.67 ± 9.29 , 84.0 ± 7.4 and 90.60 ± 9.63 in group A, B and C respectively. While the pulse rate at 30 min in group A, B and C was 73.87 ± 3.55 , 72.6 ± 2.6 , and 73.63 ± 3.82 respectively.

The above graph present the monitoring of pulse rate at every 15 mins till the end of surgery.

From the above graph it was observed that the PR was on its peak at the baseline (during first 15 minutes) in group A and C patients while PR was on its peak at 30 min in group B patients.

The mean PR of group A patients decreased gradually at every 15 minutes interval up to 75 min and then it increased in next 15 minutes. The study observed that in group B patients the mean PR increased during first 15-30 minutes but then it decreased up to 75 min. While in group C patients the mean PR was decreased at every 15 minutes interval till the end of surgery.

The above graph present the monitoring of PR at every 15 mins postoperatively upto 4 hours.

From the above graph it was observed that the PR at baseline was 86.93 ± 9.25 , 84.9 ± 5.0 , and 84.10 ± 8.91 respectively. The study observed that PR at 240 min was 76.73 ± 7.59 , 81.1 ± 6.3 , and 74.00 ± 4.02 respectively.

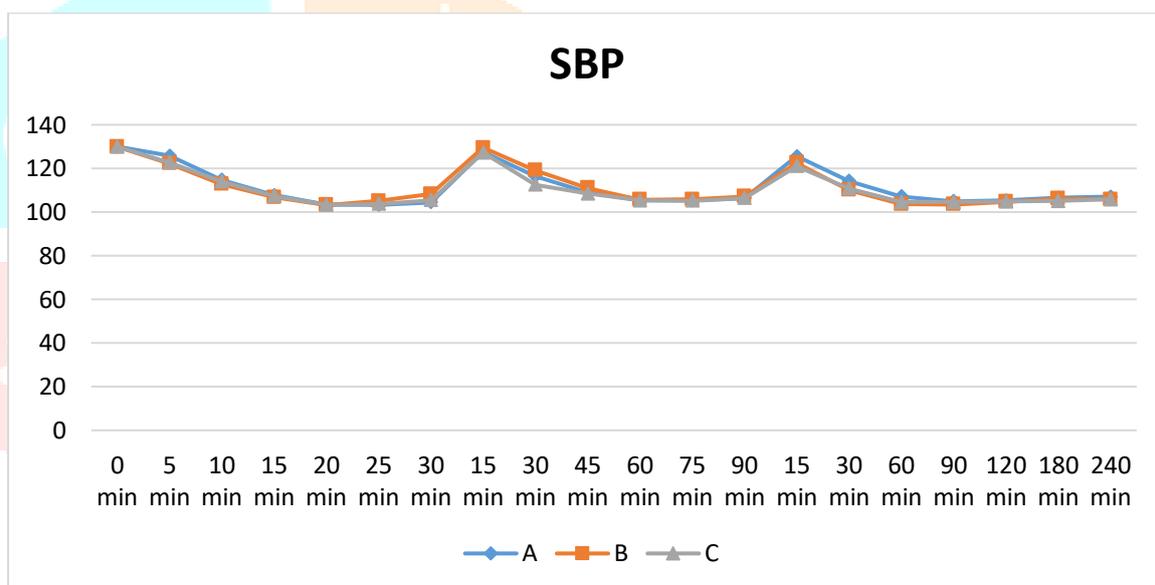


Figure 5.6 SBP

The above graph present the monitoring of SBP at every 5 mins for first 30 mins after giving spinal anaesthesia. From the above table and graph it was observed that the SBP was on its peak at the baseline (during first 5 minutes) but after this it was decreased with time. The mean SBP of group A patients decreased up to 25 min and then it increased at 30min.

The mean SBP of group B and C patients was decreased up to 20 min and then it increased at every 5-minute interval. The SBP at 30 minutes was 104.93 ± 4.91 , 108.3 ± 4.1 and 105.50 ± 2.98 in group A, B and C patients respectively.

The above graph present the monitoring of SBP at every 15 mins till the end of surgery.

From the above graph it was observed that the SBP was on its peak at the baseline (during first 15 minutes) in group A, B and C patients. The mean SBP of group A and C patients decreased gradually up to 75 minutes and then it increased in next 15 minutes. The mean SBP of group B patients was decreased gradually up to 60 minutes and then it increased in next 15 minutes up to 90 minutes.

The above graph present the monitoring of SBP at every 15 mins postoperatively upto 4 hours.

From the above graph it was observed that the SBP at baseline was 125.63 ± 125.48 , 122.5 ± 11.1 , and 121.03 ± 9.63 respectively. The study observed that SBP at 240 min was 107.03 ± 106.93 , 105.8 ± 5.1 and 105.83 ± 2.87 respectively.

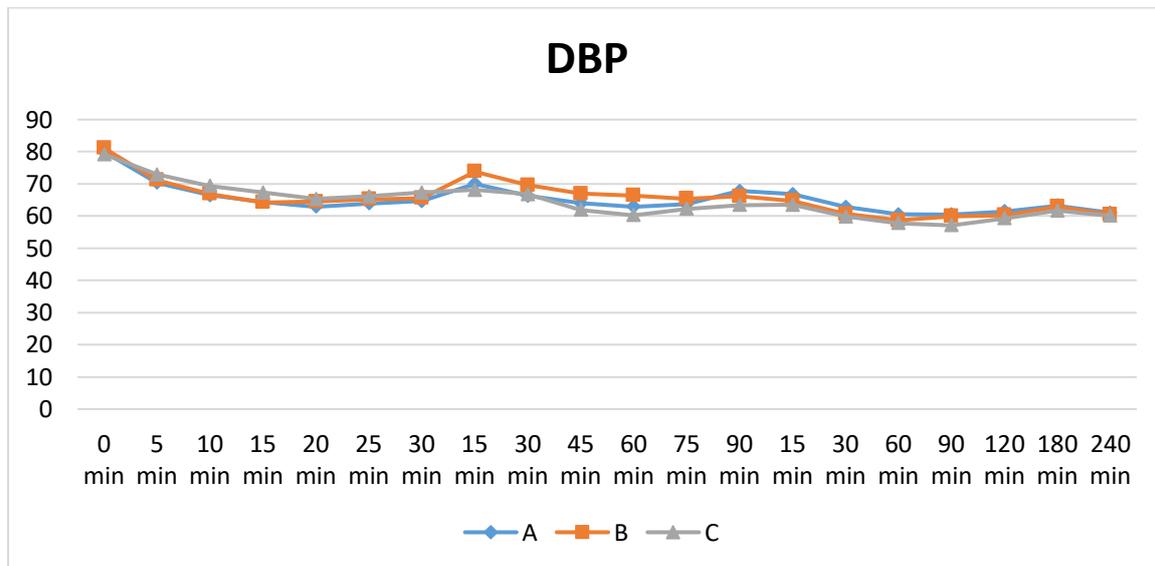


Figure 5.7 DBP

The above graph present the monitoring of DBP at every 5 mins for first 30 mins after giving spinal anaesthesia. From the above table and graph it was observed that the DBP was on its peak at the baseline (during first 5 minutes) but after this it was decreased with time. The mean DBP of group B patients decreased up to 15 min and then it increased gradually at every 5-minute interval. The mean DBP of group A and C patients was decreased up to 20 min and then it increased gradually at every 5-minute interval. The DBP at 30 minutes in group A, B and C patients was 64.67 ± 5.18 , 65.6 ± 4.4 and 67.27 ± 5.15 respectively.

The above graph present the monitoring of DBP at every 15 mins till the end of surgery.

From the above graph it was observed that the DBP was on its peak at the baseline (during first 15 minutes) in group A, B and C patients. The mean DBP of group A and C patients decreased gradually up to 60 minutes and then it increased in next 15 minutes interval up to 90 minutes. The mean DBP of group B patients was decreased gradually up to 75 minutes and then it increased in next 15 minutes.

The above graph present the monitoring of DBP at every 15 mins postoperatively upto 4 hours.

From the above graph it was observed that the DBP at baseline was 66.83 ± 66.72 , 64.7 ± 4.5 , and 63.50 ± 5.99 respectively. The study observed that DBP at 240 min was 61.00 ± 61.14 , 60.5 ± 3.7 , and 60.10 ± 5.16 respectively.

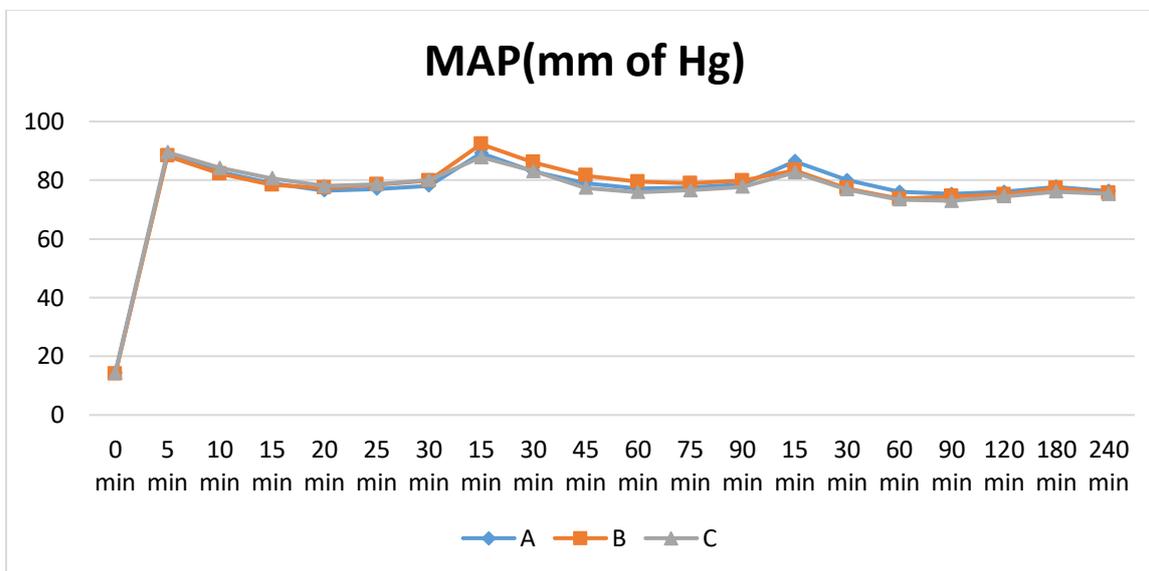


Figure 5.8 MAP

The above graph present the monitoring of MAP at every 5 mins for first 30 mins after giving spinal anaesthesia. From the above table and graph it was observed that the MAP was on its peak at the baseline (during first 5 minutes) but after this it was decreased with time. The mean MAP of group A, B and C patients was decreased up to 20 min and then it increased gradually at every 5-minute interval. The MAP at 30 minutes in group A, B and C patients was 78.09 ± 4.13 , 79.8 ± 3.3 and 80.01 ± 3.14 respectively.

The above graph present the monitoring of MAP at every 15 mins till the end of surgery.

From the above graph it was observed that the MAP was on its peak at the baseline (during first 15 minutes) in group A, B and C patients. The mean MAP of group A and C patients decreased gradually up to 60 minutes and then it increased in next 15 minutes interval up to 90 minutes. The mean MAP of group B patients was decreased gradually up to 75 minutes and then it increased in next 15 minutes.

The above graph present the monitoring of MAP at every 15 mins postoperatively upto 4 hours.

From the above graph it was observed that the MAP at baseline was 86.43 ± 86.31 , 83.9 ± 5.9 , and 82.68 ± 6.47 respectively. The study observed that MAP at 240 min was 76.34 ± 76.40 , 75.6 ± 3.3 , and 75.34 ± 3.72 respectively.

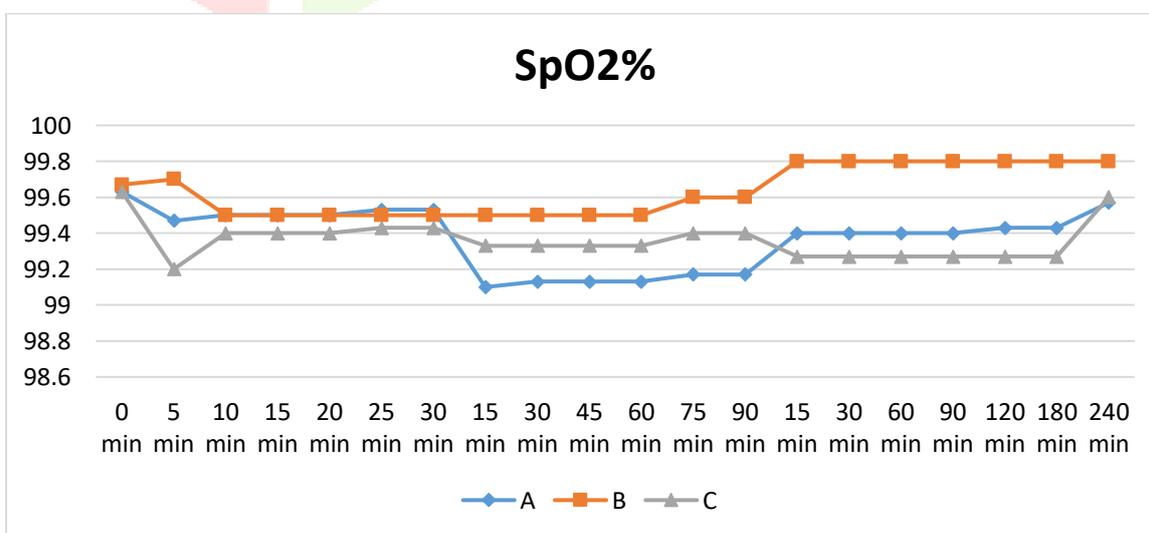


Figure 5.9 SpO2

The above graph present the monitoring of SPO2 at every 5 mins for first 30 mins after giving spinal anaesthesia. From the above table and graph it was observed that the SPO2 was on its peak at the baseline (during first 5 minutes) in group B patients.

The mean SPO₂ of group A patients increased gradually at every 5 minutes interval. The study observed that in group B patients the mean SpO₂ decreased during first 5-10 minutes but then it remains same throughout the time. While in group C patients the mean SpO₂ was increased during first 5-10 minutes and then it remains same up to 20 min and then it increased at 25 minutes.

The above graph present the monitoring of SPO₂ at every 15 mins till the end of surgery.

From the above graph it was observed that the SPO₂ was on its peak at 90 minutes in group A, B and C patients. The mean SPO₂ of group A, B and C patients remains same up to 60 min and then increased in next 15 minutes interval up to 90 minutes.

The above graph present the monitoring of SpO₂ at every 15 mins postoperatively upto 4 hours. From the above table and graph it was observed that the SpO₂ at baseline was 99.40 ± 99.45 , 99.8 ± 0.4 , and 99.27 ± 0.58 respectively. The study observed that SpO₂ at 240 min was 99.57 ± 99.55 , 99.5 ± 0.9 , and 99.60 ± 0.89 respectively.

Incidence of Shivering

Table 5.1 Intra-Operative & Post-Operative Shivering

Shivering						
Shivering	A		B		C	
	Intra-operative	Post-operative	Intra-operative	Post-operative	Intra-operative	Post-operative
Yes	19	9	8	3	4	1
No	11	21	22	27	26	29
Total	30		30		30	

From the above table it was observed that intra-operative and post-operative shivering was reported in 19 and 9 patients of group A respectively.

From the above table it was observed that intra-operative and post-operative shivering was reported in 8 and 3 patients of group B respectively.

From the above table it was observed that intra-operative and post-operative shivering was reported in 4 and 1 patients of group C respectively.

Table 5.2 Number of Patients

Number of Patients							
Shivering	A (30)		B (30)		C (30)		P Value
	Intra-operative	Post-operative	Intra-operative	Post-operative	Intra-operative	Post-operative	
Shivering	19	9	8	3	4	1	<0.001
Total	28		11		5		

From the above table it was observed that there is a significant decrease in the incidences of shivering in group A intra-operatively as compared to group B and C and postoperatively group A in comparison to group B and C ($p < 0.001$).

Table 5.3 Modified Mahajan's Grading Of Shivering

Number of Patients				
Grade of shivering	A	B	C	P Value
0 (no shivering)	2	19	25	0.002
1	14	6	3	
2	8	3	2	
3	5	2	0	
4	1	0	0	
Total	30	30	30	

From the above table it was observed that majority of group A patients had grade 1 shivering followed by 8 patients of grade 2.

The study observed that majority of group B patients had grade 0 shivering followed by 6 patients of grade 1.

The study observed that majority of group C patients had grade 0 shivering followed by 3 patients of grade 1.

Table 5.3 Post-Operative Complications

Number of Patients				
Complications	A	B	C	P Value
Hypotension	5 (16.66)	2 (6.66)	3 (10.0)	0.002
Nausea	1 (3.33)	2 (6.66)	3 (10.0)	
Vomiting	2 (6.66)	1 (3.33)	2 (6.66)	
Pruritus	Nil	Nil	Nil	
Bradycardia	Nil	Nil	Nil	
Sedation	Nil	Nil	Nil	
Respiratory Depression	Nil	Nil	Nil	

From the above table it was observed that hypotension, nausea and vomiting was most reported complications found in study population.

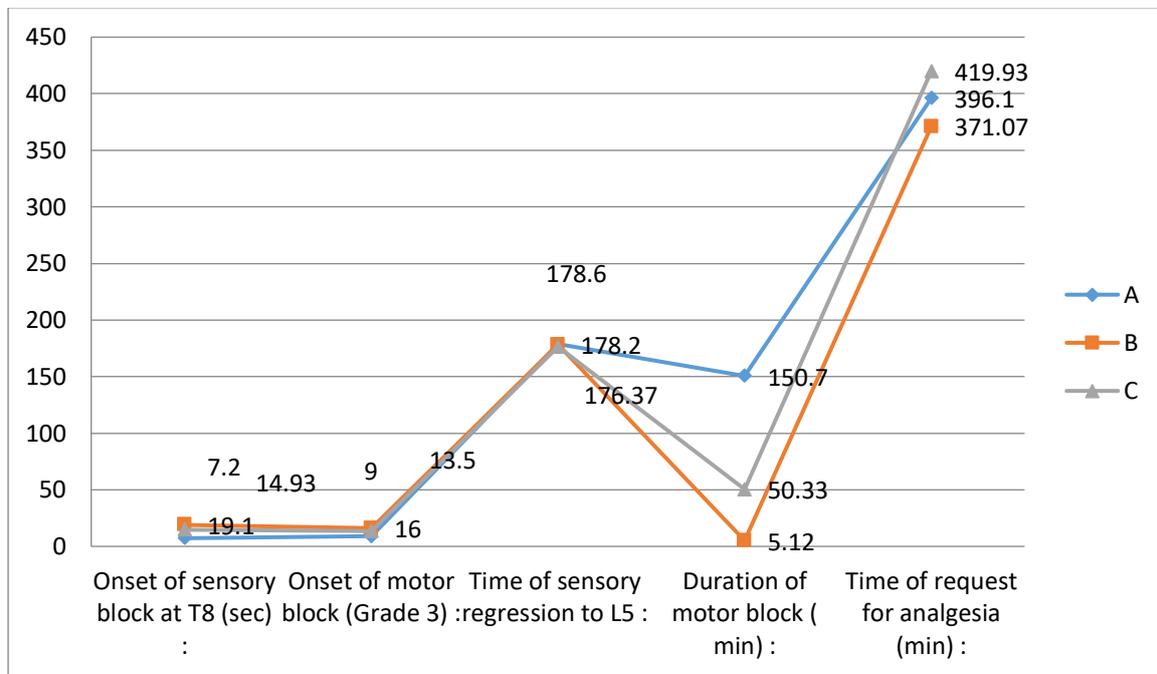


Figure 5.10 Subarachnoid Block Characteristics

From the above graph it was observed that sensory block onset time was reportedly minimum in group C patients (7.2 ± 1.73) while it was maximum in group A patients (19.1 ± 1.75). The study observed that motor block onset time was reportedly minimum in group C patients and maximum in group A patients (9.0 ± 1.73 and 16 respectively).

The study observed that time of sensory regression to L5 was reportedly minimum in group B and maximum in group C patients (176.37 ± 28.82 and 178.6 ± 30.26 respectively).

The reported duration of motor block in group C, A and B was 150.7 ± 32.33 , 105.12 ± 0.50 and 150.33 ± 66.38 min respectively.

The mean time of request for analgesia in group C, A and B was 396.1 ± 109.42 , 371.07 ± 101.82 and 419.93 ± 111.05 min respectively.

6. DISCUSSION AND CONCLUSION

The present study was performed to assess a comparative study of intrathecal tramadol with bupivacaine & intrathecal bupivacaine plain on prevention of peri-operative shivering in infra umbilical surgeries. The present study has included 90 patients and these study subjects was further divided into three groups each of 30 patients.

Spinal anesthesia using a solution of 0.5% hyperbaric bupivacaine is commonly used for surgeries in the lower abdomen and for gynecological procedures. To prolong the effects of the local anesthesia, various adjuvants have been added when administering the anesthesia through the central neuraxial route. The use of intrathecal opioids has been shown to provide effective pain relief after a variety of surgeries, but it also increases the risk of respiratory depression.¹⁶ Tramadol, on the other hand, has minimal effects on respiration and has a much lower affinity for μ receptors compared to morphine, and also has no reported neural toxicity^{17,18}. This makes it a potentially effective option for postoperative pain relief without the risk of respiratory depression¹⁹. However, it has been associated with side effects such as itching, nausea, vomiting, urinary retention, and activation of herpes labialis and unpredictable respiratory depression, which has led to the use of lower doses of tramadol for intrathecal administration to achieve effective and prolonged pain relief without these complications.

Study Groups,

The present study has included 90 patients of ASA grade I or II and these study subjects was further divided into three groups each of 30 patients.

The first group i.e., group A had received Hyperbaric 0.5% Bupivacaine 3.0ml + 0.5ml normal saline

Group B had received Hyperbaric 0.5% Bupivacaine 3.0ml + tramadol 10 mg (0.2 ml of preservative free injection tramadol hydrochloride 50 mg/ ml) while the third group i.e.,

Group C had received Hyperbaric 0.5% Bupivacaine 3.0 ml + tramadol 20 mg (0.4 ml). This chapter has discussed the major findings with reference studies.

The present study was performed to assess a comparative study of intrathecal tramadol with bupivacaine & intrathecal bupivacaine plain on prevention of peri-operative shivering in infra umbilical surgeries. Spinal anaesthesia using a solution of 0.5% hyperbaric bupivacaine is commonly used for surgeries in the lower abdomen and for gynaecological procedures. To prolong the effects of the local anaesthesia, various adjuvants have been added when administering the anaesthesia through the central neuraxial route. The use of intrathecal opioids has been shown to provide effective pain relief after a variety of surgeries, but it also increases the risk of respiratory depression¹⁶. Tramadol, on the other hand, has minimal effects on respiration and has a much lower affinity for μ receptors compared to morphine, and also has no reported neural toxicity^{17,18}. This makes it a potentially effective option for postoperative pain relief without the risk of respiratory depression¹⁹. However, it has been associated with side effects such as itching, nausea, vomiting, urinary retention, and activation of herpes labialis and unpredictable respiratory depression, which has led to the use of lower doses of tramadol for intrathecal administration to achieve effective and prolonged pain relief without these complications^{20,21}.

Demographics

In the present study it was found that there was a majority of patients belonging to age group 20-30 years. The age wise distribution of the patients signified that 26.7% and 36.7% patients of group A and B belongs to 20-30 years age group while majority of the group C patients (43.3%) belongs to 51-60 years age group followed by 30% patients of age group 20-30 years. The gender wise distribution of the patients signified that there was a majority of male patients (60%) in study population. The study found out that in group B and C there was a majority of male patients (66.7% and 63.3% respectively) while in group A there were equal number of male and female patients (each 50%). Vijayan et al., (2019)²² conducted a comparative study between intrathecal tramadol with bupivacaine and intrathecal bupivacaine on incidence of perioperative shivering. The study reported that the mean age of patients received bupivacaine alone was 48.98 ± 6.99 years while the mean age of patients who had received combination of tramadol and bupivacaine was 48.84 ± 6.02 years. In another study it was noted that majority of the patients in the groups were males with mean age of 38 years²³. These findings were consistent with the findings of our study.

Block Parameters

The present study found out that there was significant difference in the onset of sensory block between the three groups ($p=0.008$). The study found out that onset of sensory block was longest in the group A in which patients had received combination of Hyperbaric 0.5% Bupivacaine 3.0ml and 0.5ml normal saline. The onset of sensory block in the three groups were 19.1 ± 1.75 , 9.93 ± 6.13 , and 7.2 ± 1.73 minutes for the groups A, B and C respectively.

The study found out that Group A (16 ± 0.00) showed a statistically significant onset in motor block as compared to group B (13.50 ± 3.70) and C (9.0 ± 1.73) ($p=0.000$). These findings suggest that the onset in motor block was longest in group A while it was shortest in group C patients who had received a combination of Hyperbaric 0.5% Bupivacaine 3.0 ml and tramadol 20 mg (0.4 ml).

In the present study it was found that group B and C had showed a statistically significant duration of motor block as compared to group A ($p<0.05$). The study found out that the duration of motor block was shortest in group A patients (105.12 ± 0.50 min) who had received combination of Hyperbaric 0.5% Bupivacaine 3.0ml and 0.5ml normal saline.

Our findings were consistent with the findings of a study by Agrawal et al., (2019)²⁴. Agrawal et al., reported that there was a significant difference in the time for onset of sensory block and, onset of motor block ($p<0.006$) between the groups B and T. Group B (n=15) received inj. bupivacaine 0.5% heavy 2 ml + 0.2 ml

0.9% normal saline and Group T (n=15) received inj. bupivacaine 0.5% heavy 2 ml + inj. tramadol 0.2 ml (10 mg) preservative free intrathecally. Group T showed a statistically significant onset in the sensory block (8.33 ± 0.90 minutes) as compared to group B (9.20 ± 0.68 minutes). Also, Group T showed a statistically significant onset in motor block that was 11.13 ± 0.834 minutes versus 12.00 ± 0.756 minutes in group B.

Fahad Zahid et al., (2017)²⁵ in their study reported that duration of anaesthesia was effectively prolonged in group tramadol bupivacaine (TB) 181.56 ± 12.42 mins as compared to group bupivacaine alone (SB) 120.93 ± 15.54 mins. Higher peak sensory block levels (T6) were achieved in group TB as compared to group SB. However, time to reach the peak sensory block levels were significantly longer in group TB. (4.5 ± 0.47 mins vs 3.09 ± 0.54 mins).

Also, there was significant difference in the time to first analgesic request between the three groups ($p=0.036$). The study found out that the time to first analgesic requests was longest in the group B that had combination of Hyperbaric 0.5% Bupivacaine 3.0ml and tramadol 10 mg. Time to first analgesic request was 371.07 ± 101.82 , 419.93 ± 111.05 and 396.1 ± 109.42 minutes for the groups A, B and C respectively.

This is in agreement with a study by Verma et al., (2013)²⁶ who also studied post operative analgesic efficacy of intrathecal tramadol added to bupivacaine in spinal anaesthesia for surgery. They recorded duration of analgesia of 260 minutes, though with intrathecal tramadol 50mg. The result is also in agreement with that of Afolayan et al., (2014)²⁷ who recorded time to first analgesic with intrathecal tramadol 25mg as 238.39 ± 61.28 minutes in their comparison of intrathecal tramadol and intrathecal fentanyl for pain control during bupivacaine subarachnoid block for open appendicectomy. In another study Ahashemiet al., (2003)²⁸ using intrathecal tramadol 25mg noted time to first analgesic request as 6.3 hours. The result in this study is however not in consonance with Akhoon et al., (2010)²⁹ who recorded exceptionally long duration of analgesia, up to 14, 18 and 19 hours for those that had intrathecal tramadol 30, 40 and 50mg respectively. Perhaps, environmental factors, type of surgery and methodology contributed.

Hemodynamic Parameters and Shivering

The present study found out that pre-operative and post-operative mean pulse rate, systolic blood pressure and diastolic blood pressure, MAP, and SpO₂% showed statistically significant difference between the groups ($p < 0.05$).

The result of our study evaluated that there was a significant decrease in the incidences of shivering in group B and C both intra-operatively and post operatively as compared to group A. The present study found out that intra-operative and post-operative shivering was reported in 19 and 9 patients of group A while intra-operative and post-operative shivering was reported in 8 and 3 patients of group B respectively with increased incidences of grade 2 and 3 shivering in group A. The shivering was less reported in group C patients both intra-operatively and postoperatively. The results signified that intra-operative and post-operative shivering was reported in 4 and 1 patients of group C respectively. These findings suggest that shivering was reported in a smaller number of patients administered with combination of bupivacaine and tramadol groups as compared to patients received bupivacaine alone.

These findings were consistent with findings of a study by Subedi et al, (2013)³⁰. This study reported reduced incidence of shivering in the tramadol group. They therefore concluded that compared to intrathecal fentanyl 10ug, tramadol 10mg as an adjunct to bupivacaine for subarachnoid block Caesarean section, shows a longer duration of analgesia with reduced incidence of shivering³⁰. In another study shivering (6.25%) was observed only in the group that had bupivacaine alone²³. Our study has also reported higher incidence of shivering in patients receiving bupivacaine alone. This is in agreement with a previous study by Afolayan et al., (2014)²⁷ who recorded 4.8% shivering in the bupivacaine group. This could be explained by the anti-shivering action of tramadol mediated by its opioid or serotonergic and adrenergic activity or both³¹. Other agents which can reduce shivering include opioids (pethidine, fentanyl, alfentanil, butorphanol nalbuphine), ketanserine, clonidine, and doxapram.³² Among the opioids, pethidine has the longest standing history as a medical treatment of post anaesthetic shivering. However, most studies, whether randomized controlled trials or systemic review found tramadol as effective as, if not superior to pethidine^{32,33}.

Gupta et al., (2018)¹¹ in their study reported that the addition of tramadol 10 or 20 mg IT to 0.5% hyperbaric bupivacaine for SAB is associated with significant reduction in the incidence and intensity of post anaesthesia shivering and prolongation of the duration of postoperative analgesia. Tramadol 20 mg IT

compared to 10 mg IT significantly prolonged the duration of postoperative analgesia but failed to demonstrate any significant attenuation of post-anaesthesia shivering.

In another study Vijayan et al., (2019)²² reported that shivering is a common problem faced during the intraoperative and postoperative period. They conducted a study designed to compare the efficacy and safety of intrathecal tramadol 0.25mg/kg-group 1 with bupivacaine 0.5% 3ml-group2 and intrathecal bupivacaine 0.5% 3ml on prevention of perioperative shivering in patients undergoing surgery under spinal anaesthesia. There was a statistically significant decrease in the incidence of shivering in group1. There was a statistically significant difference in temperature between Group1 and Group 2 at 30min, 60 min and 90 min respectively. Group 2 had a lower mean temperature than Group 1.

Adverse Effects

In our study, incidences of adverse effects in the study were minimal and tolerated by the patients. The incidences of hypotension were reported in 16.6% patients of group A, 6.66% of group B and 10% of group C patients. The study found out that nausea was reported in 3.33%, 6.66% and 10% patients of group A, B and C respectively. The study reported vomiting in 6.66%, 3.33% and 6.66% patients of group A, B and C respectively. The study has found that significantly higher number of complications were reported in group A patients as compared to counterparts in other groups ($p=0.002$).

In a study Agu et al., (2016)²³ reported that hypotension, bradycardia, nausea and vomiting was the most common complication reported in patients. Vomiting (6.25%) was recorded only in the group that had tramadol 40mg. Hypotension was noted in 5(10.42%) patients in groups BT40 and B, and 6(12.50%) patients in group BT25. Bradycardia was recorded in 3(6.25%) patients each in groups BT40 and B while two (4.17%) patients in group BT25 had bradycardia. Pruritus, respiratory depression, and sedation were not recorded in any of the groups.

The incidence of nausea and vomiting in our study was comparable with previous studies^{34,35}. Some studies however, recorded slightly higher incidence of vomiting. Akhoun et al., (2010)²⁹ reported incidence of vomiting in those that had intrathecal tramadol 30mg, 40mg and 50mg as 13.8%, 17.2% and 34.5 % respectively in patients undergoing TURP probably due to the type of surgery. Afolayan et al., (2014)²⁷ also recorded significant post operative vomiting (16.1%) in patients who had intrathecal tramadol 25 mg for open appendectomy. The absence of respiratory depression in this study could be attributed to the potential advantage of tramadol by its action through different receptors. Pruritus was not recorded in any of the groups in this study. This is in agreement with previous studies^{27,28}.

Conclusion

In conclusion, the study found that the longest onset of sensory block was in the group that received Hyperbaric 0.5% Bupivacaine 3.0ml and 0.5ml normal saline, while the shortest onset of motor block was in the group that received Hyperbaric 0.5% Bupivacaine 3.0 ml and tramadol 20 mg (0.4 ml). The shortest duration of motor block was found in the group that received Hyperbaric 0.5% Bupivacaine 3.0ml and 0.5ml normal saline. The study suggests that adding tramadol to bupivacaine in spinal anaesthesia leads to a shorter onset of motor block and longer duration of motor block, with fewer cases of shivering ($p<0.005$) compared to bupivacaine alone. Intrathecal tramadol 20 mg provided longer duration of analgesia than intrathecal tramadol 10 mg, with similar side effects. Further research is needed to confirm these findings and evaluate the potential side effects associated with tramadol as an adjuvant in spinal anaesthesia

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