International Journal of Science and Research (IJSR)
ISSN: 2319-7064
SJIF (2022): 7.942

Comparative Study of Effect of Intrathecal Tramadol 20 Mg Use as Adjuvant with Hyperbaric Bupivacaine and Hyperbaric Bupivacaine for Postoperative Analgesia in Infraumblical Surgeries

Dr. Jitendra Sharma[1], Dr. Rajan Nanda[2]

[1]Rajasthan University of Health Sciences, Jaipur, Rajasthan, India

[2]HOD and Senior Professor in Jhalawar medical college, Rajasthan, India

Abstract: ***Background and aim: To assess and compare the analgesic effect of intrathecal 20mg tramadol as anadjuvant to intrathecal 0.5% hyperbaric bupivacaine and 0.5% hyperbaric bupivacaine alone in infraumbilical surgeries, with the following objectives. Difference in mean time duration for need of first rescue analgesia. Methodology: The present study was conducted on 60 patients divided into two group 30 each Group A received 3.0 ml of 0.5% hyperbaric bupivacaine + 0.4 ml of tramadol (20mg) intrathecally. Group B received 3.0 ml of 0.5% hyperbaric bupivacaine + 0.4 ml of normal saline intrathecally. Patients were observed for vital parameters and sensory & motor block onset & duration intra operatively & post operatively. Result: The mean time for onset of sensory block was 2.24 ± 0.388min. in Group A as compared to 3.51 ± 0.612 min. in Group B. The difference in the mean time for onset of sensory block was statistically significant (P<0.05). The mean duration of effective analgesia was 364.58 ± 11.146min. in Group A as compared to 203.47 ± 7.995 min. in Group B. The difference in the mean total duration of effective analgesia was statistically significant (P<0.05). Conclusion: From this study we concluded that tramadol can be safely used for adjuvant with hyperbaric bupivacaine for intrathecal use for better sensory and motor block characteristics and post operative pain management.***

Keywords: Tramadol, Bupivacaine, Analgesia, Sensory Block, Motor Block.

1. Introduction

Post-operative pain management remains a challenge despite recent advances in our understanding of the physiology of acute pain[(1)]. Spinal anesthesia is a safe, reliable, and inexpensive technique with the advantage of providing surgical anesthesia and postoperative pain relief for lower abdominal, lower limb surgeries and urological procedures[(2,3)]. Neuraxial adjuvants are used to improve or prolong analgesia and to decrease the adverse effects associated with the usual or high doses of a single local anaesthetic agents alone[(4-6)]. The intrathecal administration of a combination of opioids and local anaesthetics produces a well-documented synergistic effect without prolonged motor nerve block or delayed hospital discharge[(7,8)]. In view of this we planned this present study to evaluate effect of tramadol as adjuvant with bupivacaine intrathecally on postop duration of analgesia and requirement of first rescue analgesia in various infraumbilical surgeries.

1.1 Aim

To assess and compare the analgesic effect of intrathecal 20mg tramadol as anadjuvant to intrathecal 0.5% hyperbaric bupivacaine and 0.5% hyperbaric bupivacaine alone in infraumbilical surgeries, with the following objectives.

1.2 Objectives:

Primary Objectives:
Difference in mean time duration for need of first rescue analgesia.

Secondary Objectives:
Onset and duration of sensory and motor block.
Effect on Haemodynamic variable at different time interval.
VAS score
Sedation score

2. Review of Literature

Bandreddy S et al (2019)[(9)] evaluated dose of low dose bupivacaine with tramadol as an alternative to conventional dose of bupivacaine. 64 patients scheduled for TURP surgeries, aged-7years with ASA-PSI and II were recruitedand randomly divided into2groups.GroupI-injection bupivacaine 0.5 ml (2.5 mg) preservative free tramadol 1ml (50mg) diluted with 0.5 ml NS intrathecally. Group II-injection bupivacaine 2ml(10mg) intrathecally. Attainment of sensory blockade in group I was slow ie.,8.44+2.3 min compared to that in group II ie.,6.53+1.6min and the two segments regression is faster in group I ie.,65.38+20.2 min compared that of group II ie.,86.78+36.88 min which were statistically significant. The time for rescue analgesia was significantly higher in group I ie.,312.6+137.42 min compared to group II ie.,26.97+130.46 min. The degree of motor blockade was less in group I. There were no significant changes in heart rate and SpO2, but the fall in MAP in group II was significant compared to that in group I. They concluded that 50 mg preservative free tramadol added to intrathecal bupivacaine 2.5 mg offers adequate anaesthesia, stable hemodynamics, early ambulation and prolongs analgesia.

Amin OAI et al (2020)[(10)]found a significant rapid onset of sensory and motor block (1.95±.44 and 3.50±0.43 min) with

slower regression of sensory block and time to bromage 1 (211.6±13.2 and 219.8±20.2 min) in group N compared to groups M, C ($p < 0.001$), with statistically significant rapid onset and long duration of both blocks in group M compared to C ($p<0.001$). The effective analgesic time was significantly prolonged in group N (263.7±16.3) compared to groups M and C (224.2 ± 18.6, 185.5±17.45), respectively, ($p<0.001$) and prolonged in group M compared to C ($p<0.001$), with increase in analgesic requirement in group C compared to groups N and M ($p<0.001$) and no significant difference between groups N and M. There was higher sedation score in groups N, M (1.78±0.63, 2.75±0.54), respectively, compared to group C (0.61±0.12) ($p<0.001$) with lower Apgar score in group M (6.9±0.73) at one minute than in groups N, C (7.1±0.91, 7.7±0.84) ($p<0.001$). There was no significant difference between groups regarding the adverse effects. Adding 1 mg nalbuphine to 12.5 mg hyperbaric bupivacaine provided more effective postoperative analgesia than adding 2.5 mg midazolam, with less non-significant adverse effects in midazolam group in patients undergoing elective caesarean section.

Garg K et al (2020)[11] conducted a study to assess the effectiveness of adding intrathecalnalbuphine or fentanyl as an adjuvant to bupivacaine in spinal anaesthesia for patients undergoing the transurethral resection of the prostate (TURP). This is a single-center, prospective, double-blind, randomized study. Materials and Methods: Sixty men (40– 80 years) undergoing TURP received an intrathecal injection with 2.5mL of 0.5% hyperbaric bupivacaine with fentanyl 25 µg (Group 1) or nalbuphine hydrochloride 0.8mg (Group 2) in this prospective, randomized, double-blind study. They found that patients in the nalbuphine group reported significantly prolonged sensory block (198.60 ± 16.8min) compared to patients in the fentanyl group (185.40 ± 22.2min), ($P < 0.001$). Similarly, patients in the nalbuphine group had a longer motor block (210.60 ± 19.8min) in comparison to those in the fentanyl group (194.40 ± 21min; $P < 0.001$). Intraoperative hemodynamic variability was comparable in both the groups. Postoperative pain was significantly higher in the fentanyl they concluded that intrathecalnalbuphine is a safe and valuable alternative to intrathecal fentanyl for spinal anaesthesia.

3. Methodology

Study Center
The study will be conducted in the Department of Anaesthesia in Jhalawar Medical College and SRG Hospital Jhalawar with due permission from the institutional ethics committee and review board.

Study Universe: Cases undergoing infra-umbilical surgery

Study Design:
This was a hospital based prospective randomized double blind comparative study.

Statistical Analysis:
The sample size was calculated to be 56 patients with a power 95 percent and confidence interval 95 percent and type – 1 error of 0.05 but for compensating the loss to drop outs and attrition sample size was kept 60.

Standard qualitative and quantitative tests were used to compare the data (e.g. unpaired student– t- test, Chi-Square). Statistical analyses were performed by the help of SPSS software. p-value of < 0.05 was considered to be statistically significant.

Randomization: Simple random technique through sealed envelope method

Double Blinding: This study is so planned that neither the Anaesthesiologist nor the patient will be aware of the groups and the drug used.

The study will be conducted in following two groups of patients.

- **Group A** (n=30): Patients will receive 3.0 ml of 0.5% hyperbaric bupivacaine + 0.4 ml of tramadol (20mg) intrathecally. (Total volume 3.4 ml)
- **Group B** (n=30): Patients will receive 3.0 ml of 0.5% hyperbaric bupivacaine + 0.4 ml of normal saline intrathecally. (Total volume3.4ml)

Eligibility Criteria

Inclusion Criteria:
- Age group between 20 and 60 years.
- ASA grade I & II.
- Body weight 45 to 70 kg.
- Undergoing infra-umbilical surgery

Exclusion Criteria:
- Patients not willing to participate in the study.
- Cases with sepsis, bacteremia or skin infection of local site.
- History of severe hypovolemia, anemia and compromised renal, cardiac or respiratory status.
- Cases with raised intracranial tension.
- History of blood coagulopathies.
- Patient allergic to drugs used for study.
- Failure of spinal anesthesia, cases in which general anaesthesia will be required.

Pre-Anaesthetic Checkup
All patients in this study will be subjected to detailed pre anaesthetic evaluation which includes:

Complete medical and surgical history of past and present including any known drug allergy or any other complaint.

Previous history of operation and complication occurred.

Complete general physical examination of
Airway from the point of difficult airway.
Back examination.
Pallor for anaemia.
Vital parameters like BP, pulse, temperature and respiratory rate, weight of the patient, height of the patient.
Systemic examination:
Cardiovascular system

Respiratory system
Central nervous system.
Abdominal examination.

Investigations
Hematological – Hb%, TLC, DLC, BT, CT.
Blood urea, serum creatinine.
Liver function test (S. Bilirubin, SGOT, SGPT)
Serum electrolytes.
Fasting/random blood sugar.
Chest X-ray, ECG.
Covid-19 test (RT-PCR).
Informed written consent will be obtained after complete explanation about the study protocol and the procedure.

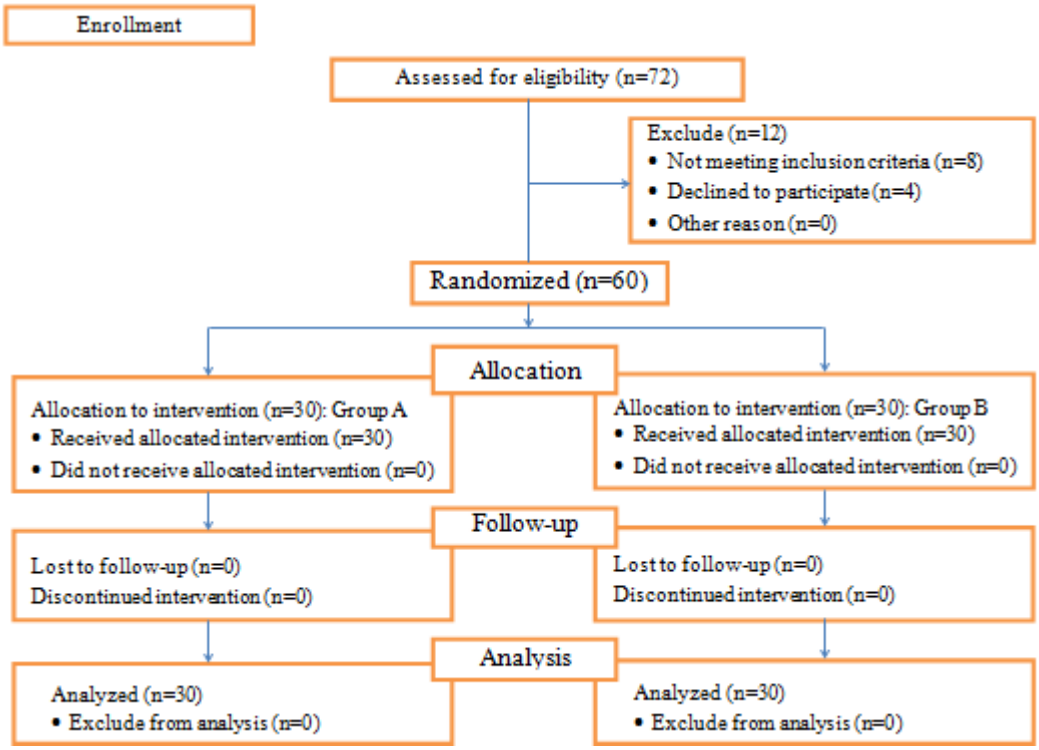

Figure: Consort flow diagram

4. Procedure

After taking informed written consent and confirming overnight fasting, patient was taken on the operation table, and connected to monitors and baseline vitals like BP, pulse rate, respiratory rate was recorded. After an 18-gauge intravenous (IV) cannula have been inserted at the forearm level, lactated Ringers solution was administered as a bolus of 10 ml/kg before subarachnoid block to all patients.

Vitals was noted just before lumbar puncture. Spinal anaesthesia was performed at L3-L4 interspace with the patient in sitting position by using a 25 Gauge Quincke needle under strict aseptic conditions. Free flow of cerebrospinal fluid was verified before injection of the anaesthetic solution 3.4 ml volume, which was administered over 30 seconds. The direction of the needle aperture was cranial during the injection. All patients were immediately placed in a supine position following the injection with a head down tilt to achieve level of block of T5-T6. Monitoring was done using continuous electrocardiography (lead II & V), heart rate, non-invasive blood pressure and continuous pulse oximetry and patients were given 4.0 L/min of oxygen by venti-mask.

Vitals were checked every 5 minutes for first 30 minutes then every 10 minutes till surgery and then every 30 minutes for 4 hours postoperatively.

When adequate spinal block was achieved, the time from the end of intrathecal injection to readiness for surgery was recorded. Then the patient was positioned for planned surgery. Patient were observed for vital parameters and sensory & motor block onset & duration intra operatively & post operatively.

5. Observation

Hypotension was defined as a systolic arterial blood pressure (SABP) < 90 mm of Hg or a decrease in SABP by 30% or more from baseline values and will be treated by incremental doses of mephentermine 6 mg IV and IV fluid as required.

Bradycardia was defined as fall in heart rate below 60 beats per minute and will be treated with incremental doses of atropine 0.3 0.6 mg IV.

Respiratory depression was defined as a respiratory rate less than 8 breaths per minute and/or oxygen saturation less than 90% in room air.

Sensory blockade: the onset of sensory block was defined as the time from the intrathecal injection of the study drug to the time taken to start of loss of sensation of pin prick. This will be assessed every 2 minutes by pinprick test bilaterally in the midclavicular line by using 25 G needle. The highest level of the block and the time to achieve the same was also

noted. Regression of sensory block was defined as the time taken for the sensory block to regress up to 2 segments of dermatome from the highest level and it will be considered as duration of sensory block.

Motor Blockade: Onset of motor block was defined as the time from intrathecal injection of the study drug to the time taken to start of motor block (grade-1) by using Bromage scale. Duration of motor block was assessed by recording the time elapsed from the onset of motor block to able to lift the leg (grade-0).

6. Result

The mean time for onset of sensory block was 2.24 ± 0.388min. in Group A as compared to 3.51 ± 0.612 min. in Group B. The difference in the mean time for onset of sensory block was statistically significant **(P<0.05)**.

Table 1: Comparison of mean time (min.) of onset of sensory block after SAB

Group	N	Mean	Std. Deviation
Group A	30	2.24	0.388
Group B	30	3.51	0.612
t= 7.801; at 58 degree of freedom; p= <0.0001 (S)			

The mean time for onset of motor block was 3.55 ± 0.462min. in Group A as compared to 4.24 ± 0.559 min. in Group B. The difference in the mean time for onset of sensory block was statistically significant **(P<0.05)**.

Table 2: Comparison of mean time (min.) of onset of motor block after SAB

Group	N	Mean	Std. Deviation
Group A	30	3.55	0.462
Group B	30	4.24	0.559
t= 5.223; at 58 degree of freedom; p< 0.0001 (S)			

The mean duration of effective analgesia was 364.58 ± 11.146min. in Group A as compared to 203.47 ± 7.995 min. in Group B. The difference in the mean total duration of effective analgesia was statistically significant **(*P*<0.05)**.

Table 3: Comparison of mean duration of effective analgesia in min

Group	N	Mean	Std. Deviation
Group A	30	364.58	11.146
Group B	30	203.47	7.995
t= 22.570; at 58 degree of freedom; *P*< 0.001 (S)			

7. Discussion

In our study, the mean duration of analgesia in Group A was 364.58 ± 11.146 min. and in Group B was 203.47 ± 7.995 min. which was statistically significant **(p<0.001)**. Thus, we observed that intrathecal tramadol with bupivacaine led to prolongation of sensory blockade and duration of analgesia as compared to bupivacaine alone.

In our study, the mean time for onset of sensory block was 2.24 ± 0.388 min. in Group A as compared to 3.51 ± 0.612 min. in Group B. The difference in the mean time for onset of sensory block was statistically significant (P<0.0001). Thus, we observed that the addition of tramadol to bupivacaine significantly increases the onset of sensory block.

In our study, the mean time for onset of motor block was 3.55 ± 0.462min. in Group A as compared to 4.24 ± 0.559 min. in Group B. The difference in the mean time for onset of motor block was statistically significant (p <0.001). Thus, we observed that the onset was faster in tramadol group as compared to bupivacaine alone group.

8. Conclusion

From our study we found that tramadol (20mg) used as an adjuvant with bupivacaine for intrathecal route significantly hasten onset and prolonging duration of sensory and motor blockade, provide effective postoperative analgesia and prolongs the duration for first rescue analgesia without any significant difference in side effects and haemodynamic parameter .Tramadol (20mg) with hyperbaric bupivacaine 0.5% (15mg) intrathecally good for intra and postoperative pain and discomfort peritoneal and intestinal manipulation in various infraumbilical surgeries.

So, we concluded that tramadol can be safely used for adjuvant with hyperbaric bupivacaine for intrathecal use for better sensory and motor block characteristics and post operative pain management.

9. Future Scope

Tramadol use with spinal anesthesia to faster the onset of action prolong the duration of surgery and less requirement of post op analegia can be found out.

References

[1] White PF Pain management after ambulatory surgery: where is the disconnect? Can J Anaesth 2008; 55:201– 207.
[2] Andres J, Valia JC, Gill A, Bolinches R. Predictor of patient satisfaction with regional anesthesia. RegAnesth 1995;20:198-505.
[3] Roussel JR, Heindel L. Effect of intrathecal fentanyl on duration of bupivacaine spinal blockade for outpatient knee arthroscopy. AANA J 1999; 67(4):337-43.
[4] Axelsson K, Gupta A. Local anaesthetic adjuvants: neuraxial versus peripheral nerve block. Current Opinion in Anesthesiology. 2009 Oct 1;22(5):649-54.
[5] Roelants F. The use of neuraxial adjuvant drugs (neostigmine, clonidine) in obstetrics.Current Opinion in Anesthesiology. 2006 Jun 1;19(3):233-7.
[6] Emelife PI, Eng MR, Menard BL, Myers AS, Cornett EM, Urman RD, Kaye AD. Adjunct medications for peripheral and neuraxialanesthesia. Best Practice & Research Clinical Anaesthesiology. 2018 Jun 1;32(2):83-99.
[7] Maves TJ, Gebhart GF: Antinociceptivesynergybetweenintrathecal morphine and lidocaineduring visceral and somatic nociception in therat. *Anesthesiology* 1992; **76:** 91 – 99.

[8] Wang C, Chakrabarti MK, WhitwamJG:Specific enhancement by fentanyl of the effectsofintrathecal bupivacaine on nociceptiveafferent but not on sympathetic efferentpathways in dogs. *Anesthesiology* 1993; **79:** 766– 773.
[9] Bandreddy S, Madhusudhana R. Evaluation of low dose Bupivacaine with Tramadol as an Alternative to Conventional dose of Bupivacaine in Spinal Anaesthesia for TURP. *Ind J AnesthAnalg*. 2019;6(3):852-868.
[10] Amin OAI, Ibrahem MA, Salem DAE. Nalbuphine versus Midazolam as an Adjuvant to Intrathecal Bupivacaine for Postoperative Analgesia in Patients Undergoing Caesarean Section.J Pain Res. 2020; 13:1369-1376.
[11] Garg K, Garg P, Katyal S. Comparative analysis of intrathecalnalbuphinevs fentanyl as an adjuvant to bupivacaine for urological procedures. MGM Journal of Medical Sciences. 2020 Oct 1;7(4):203.

Author Profile

Dr. Jitendra Sharma is 34 years old from Rajasthan. He is doing third year residentship in the department of Anaesthesiology, Jhalawar Medical College, Rajasthan. Author has passion for critical care and want to handle a trauma centre.
E mail ID: *jitendrasharma729@gmail.com*

Dr. Rajan Nanda, is 57 years old from Rajasthan. He is currently working as HOD and Senior Professor in Jhalawar Medical College, Rajasthan.
E mail ID:drrajnandajmc@gmail.com

Dr. Rakesh Kumar Choudhary, He is 44 years old from Rajasthan. He is currently working as Assistant professor in Jhalawar medical college, Rajasthan.
E mail ID:drrakeshjpr@gmail.com